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Agenda for Quarterly Meeting on
MDUFA V (FY 2023-2027) Performance

November 22, 2024, 2:30 – 4:00 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through September 30, 2024

- Report on decision goals for 4th Quarter FY 2024

Guidance Development

Registration and Listing

Qualitative Update on Finances – 4th Quarter FY 2024

- User fee receipts through the 4th Quarter FY 2024
- Carry over balance

Annual Hiring Goals Update – Will be covered in the ROI presentation

Reviewer to Manager Ratio

Quality Management Update

- Quality Management Annual Report
- Planning for FY 2025 audits
- Summary of FY 2024 deficiency audits conducted

Independent Assessment of MDUFA Workforce Metrics – Will be covered in the ROI presentation

Summary of Training Courses

Return on Investment

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 30 September 2024

Table of Contents

Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
IDE	Investigational Device Exemption
IVD	In Vitro Diagnostic
LDT	Laboratory Developed Test
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

Office Organizations

OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device

OHT2: Office of Cardiovascular Devices

OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

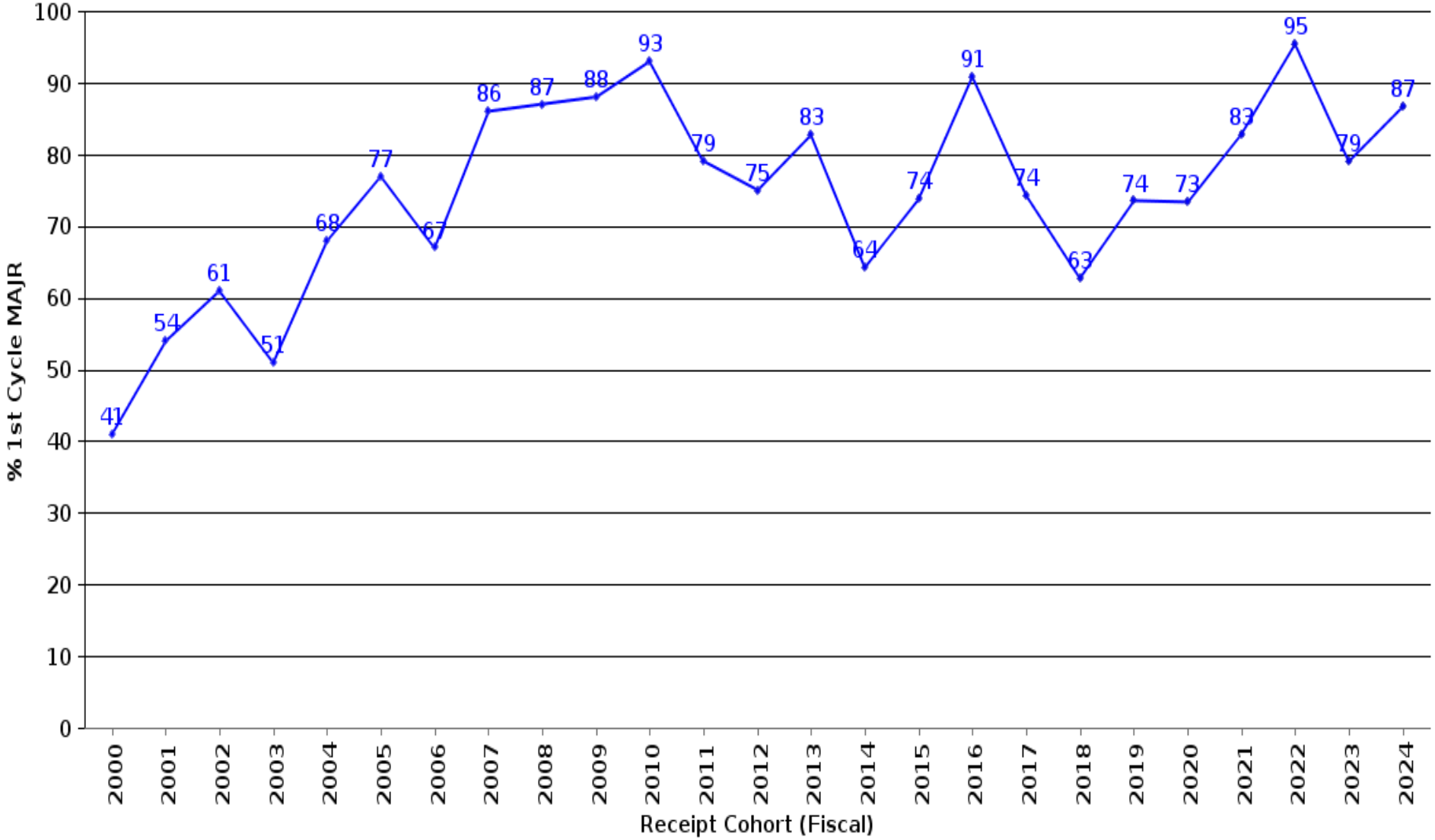
OHT8: Office of Radiological Health

Note: Data may change in subsequent quarterly and annual reports.

PMAs

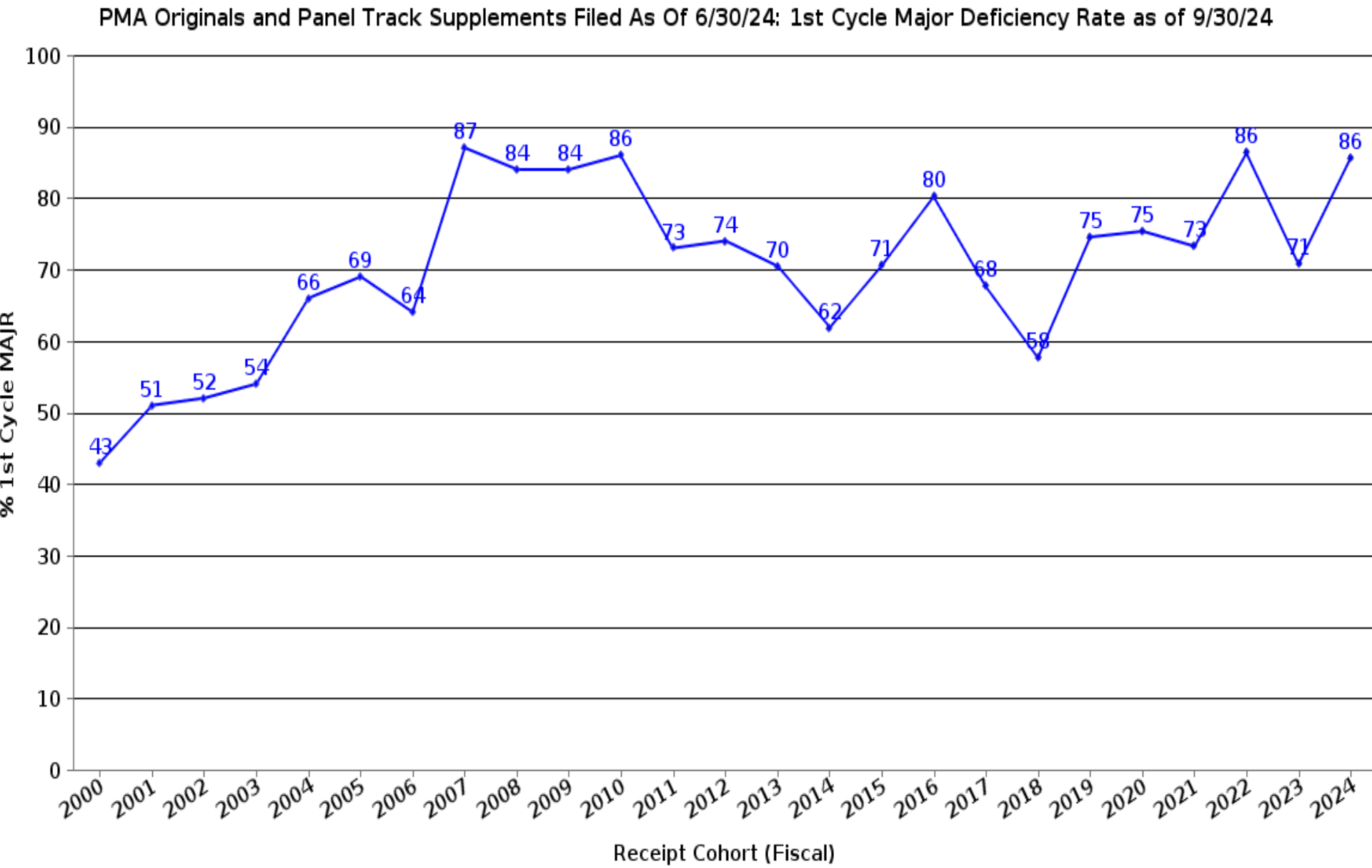
Q4FY2024

PMA Originals Filed As Of 6/30/24: 1st Cycle Major Deficiency Rate as of 9/30/24



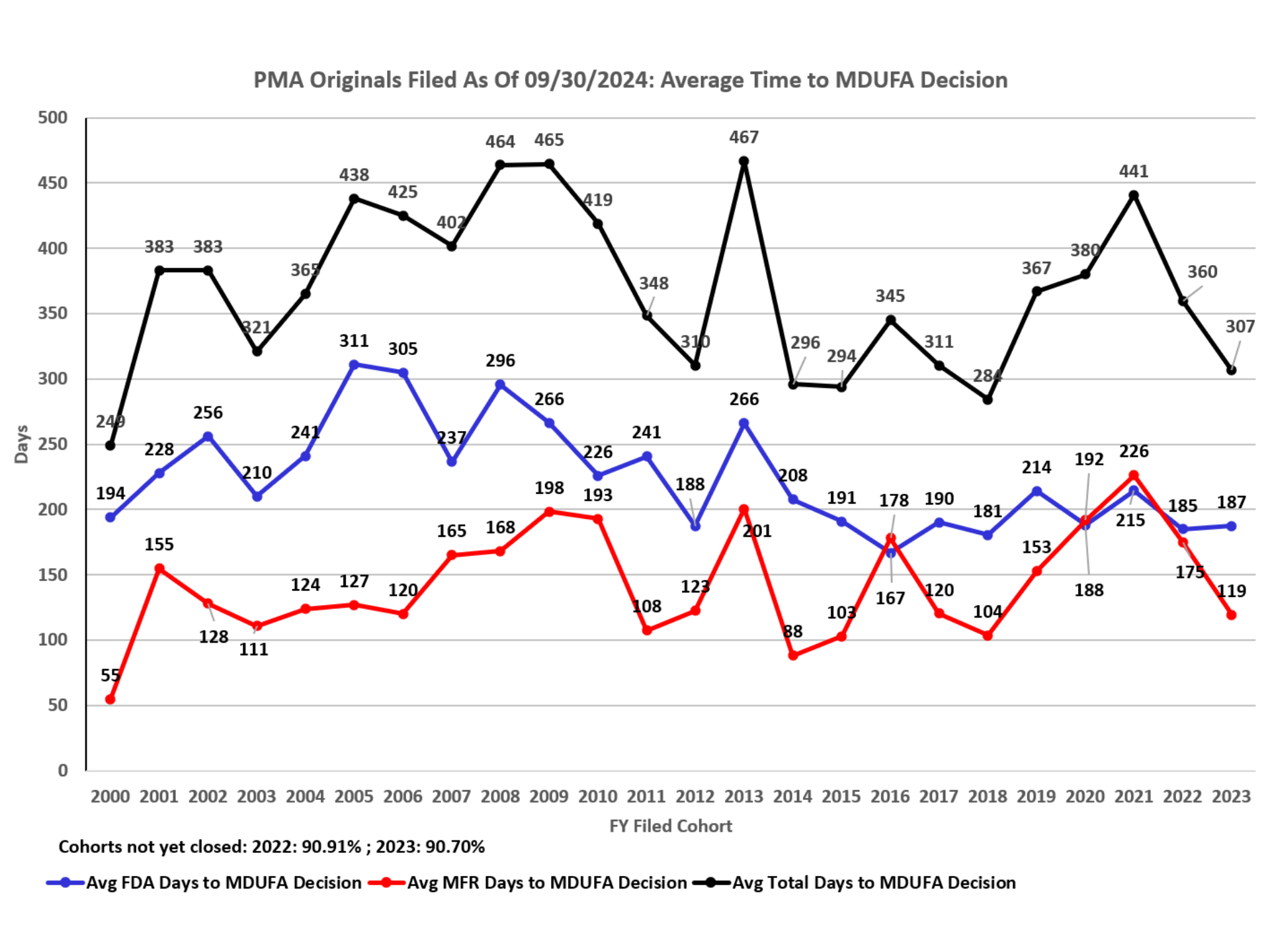
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/24.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

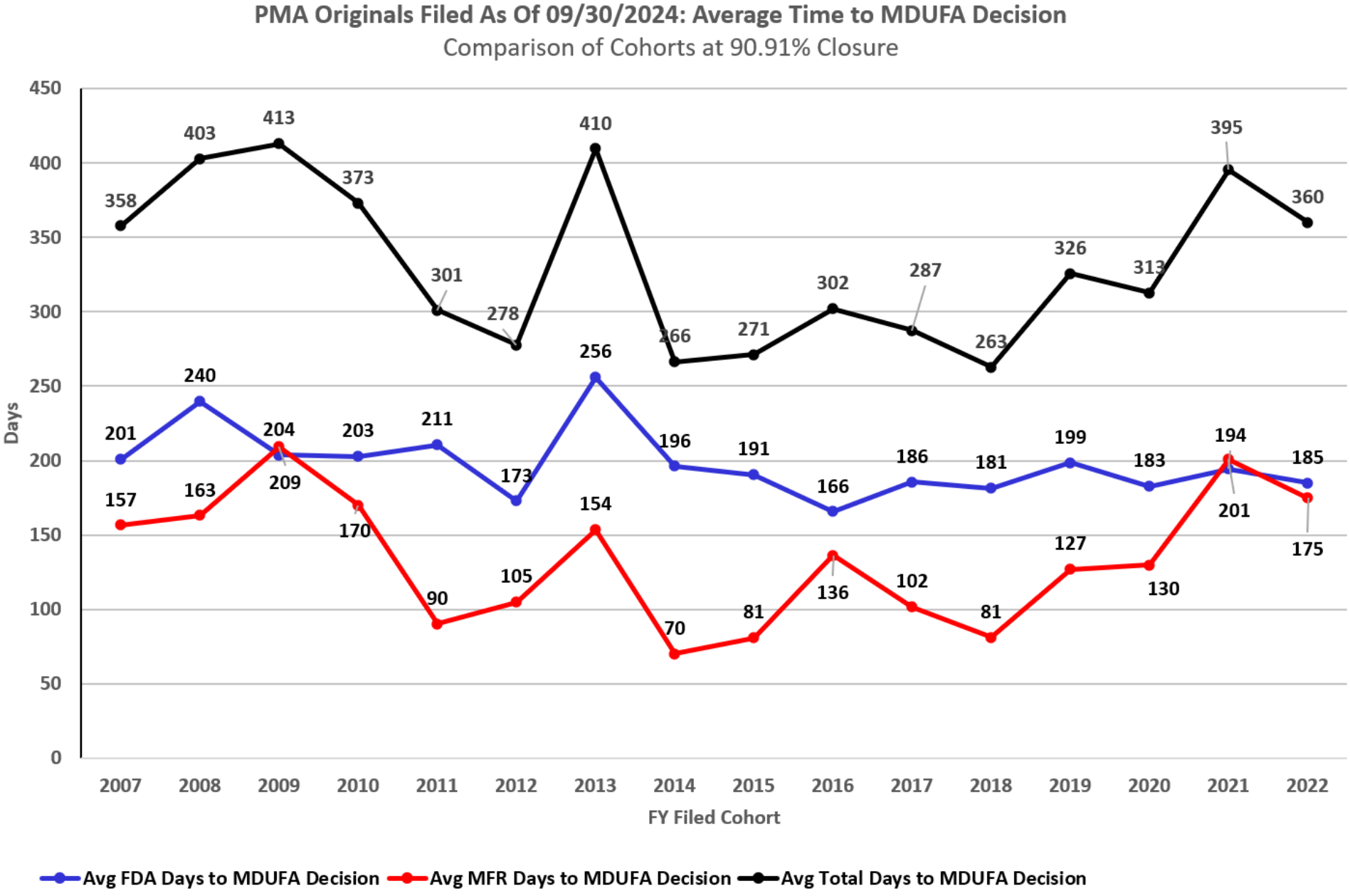
◆ % 1st Cycle MAJR PMAO

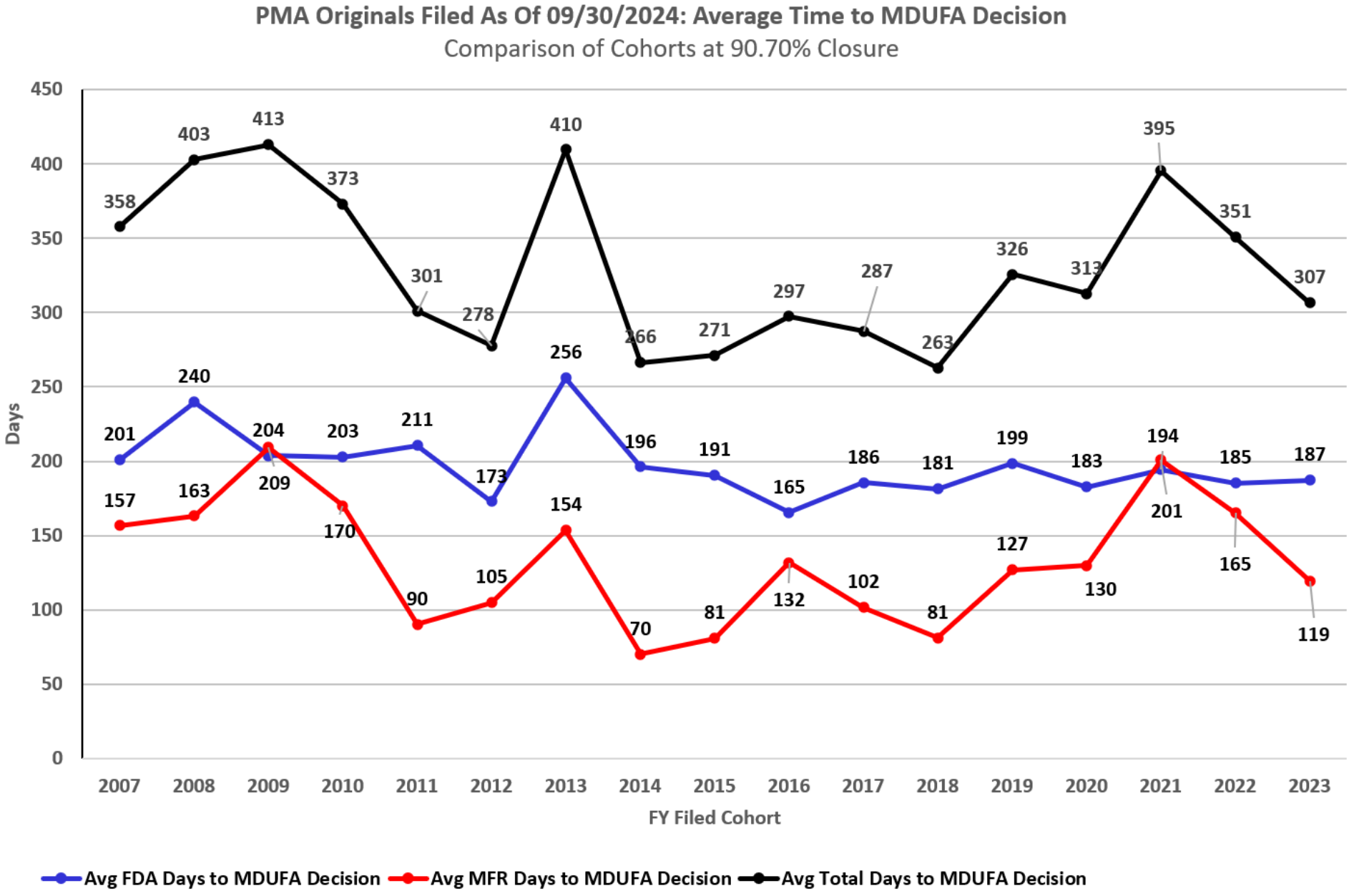


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/24. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO/PTS


PMA Originals Filed As Of 09/30/2024: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
FY Filed Cohort
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 380 441 360 307
194 228 256 210 241 311 305 237 296 266 226 241 188 266 208 191 178 190 181 214 192 226 185 187
55 155 128 111 124 127 120 165 168 198 193 108 123 201 88 103 167 120 104 153 188 215 175 119
Cohorts not yet closed: 2022: 90.91% ; 2023: 90.70%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 09/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 90.91% Closure
Days
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
358
403
413
373
301
278
410
266
271
302
287
263
326
313
395
360
201
240
204
203
211
173
256
196
191
166
186
181
199
183
194
185
157
163
209
170
90
105
154
70
81
136
102
81
127
130
201
175
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 09/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 90.70% Closure
Days
450
400
350
300
250
200
150
100
50
0
358
403
413
373
301
278
410
266
271
297
287
263
326
313
395
351
307
201
240
204
203
211
173
256
196
191
165
186
181
199
183
194
185
187
157
163
209
170
90
105
154
70
81
132
102
81
127
130
201
165
119
2007
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2016
2017
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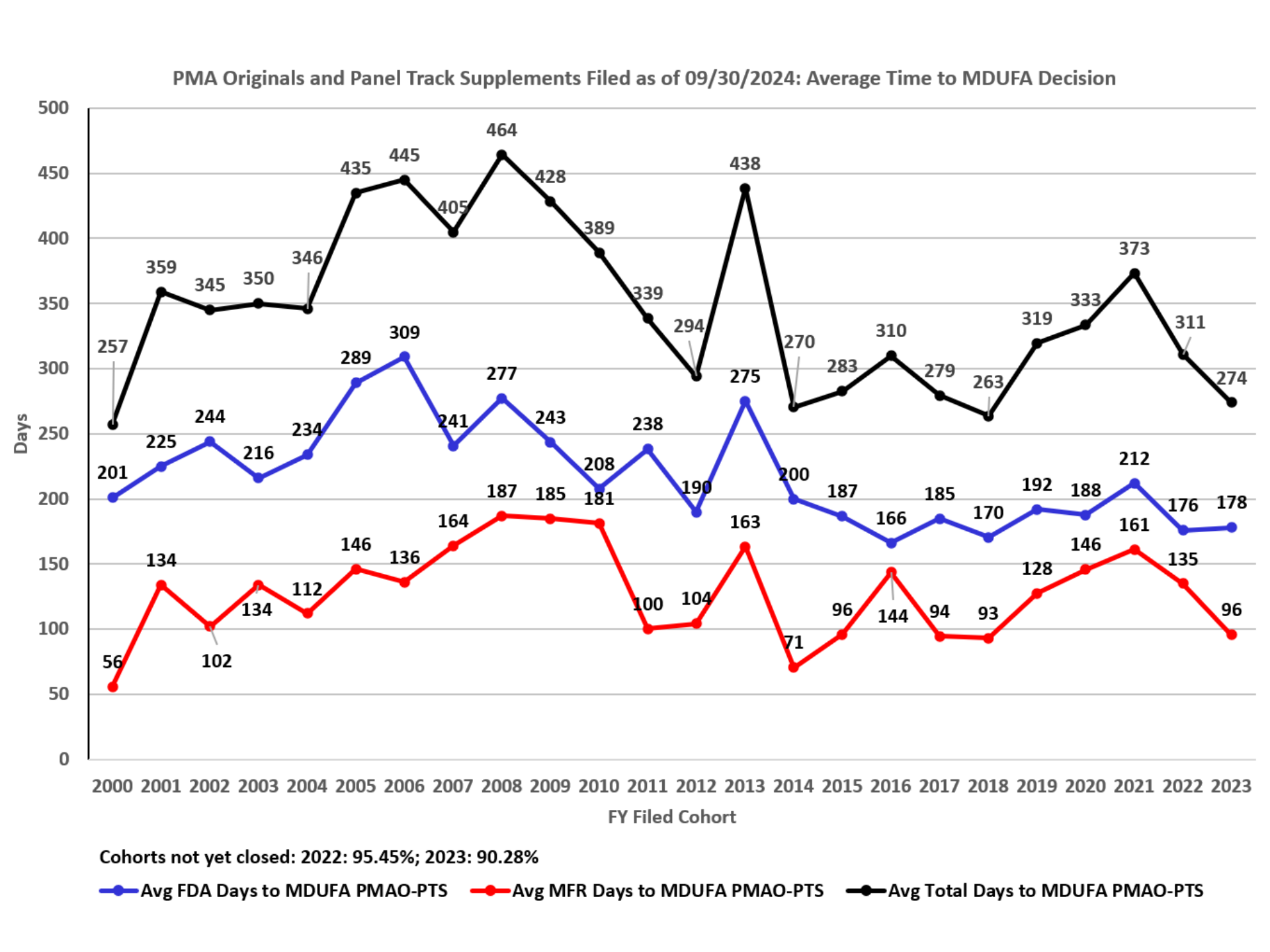
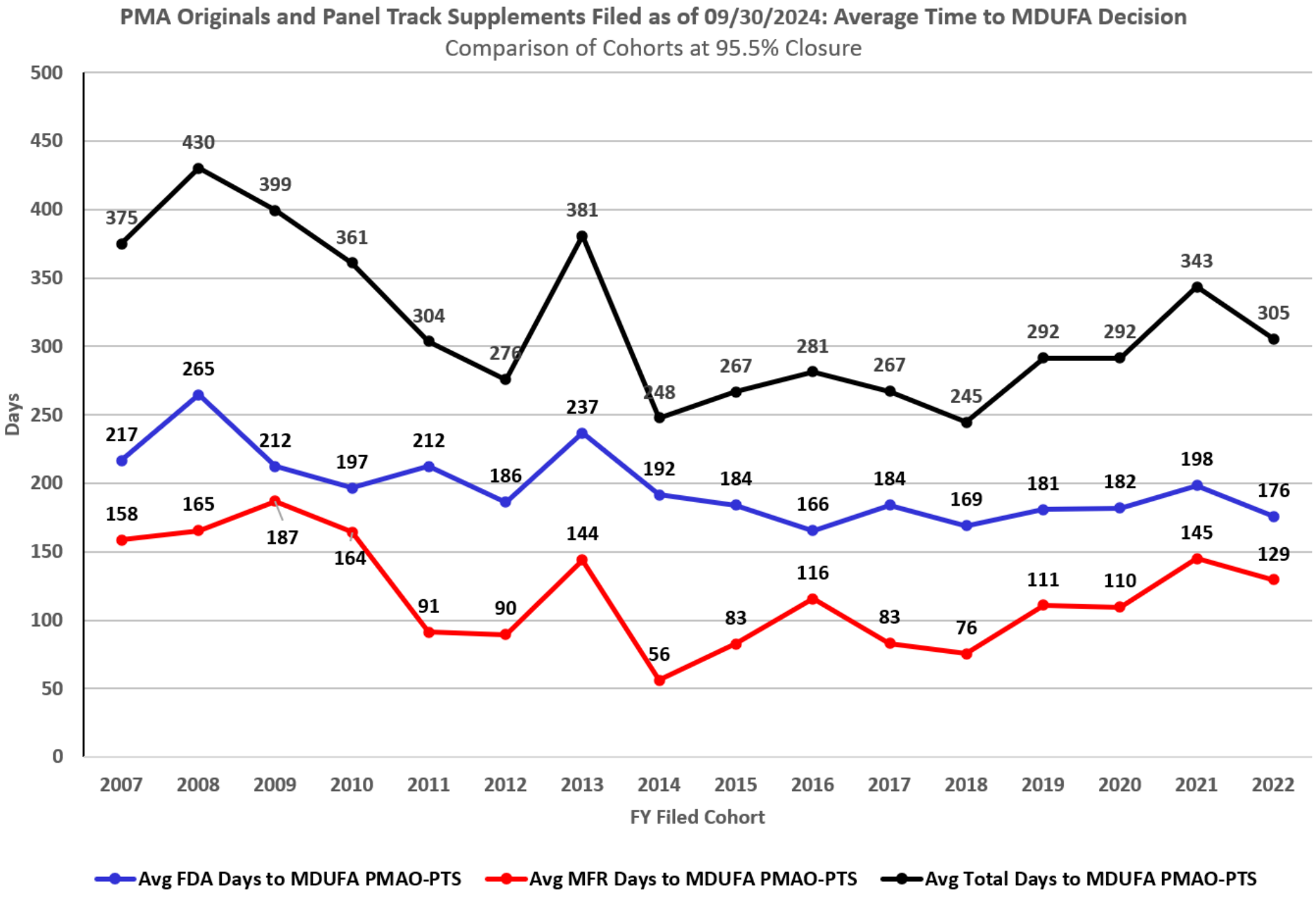
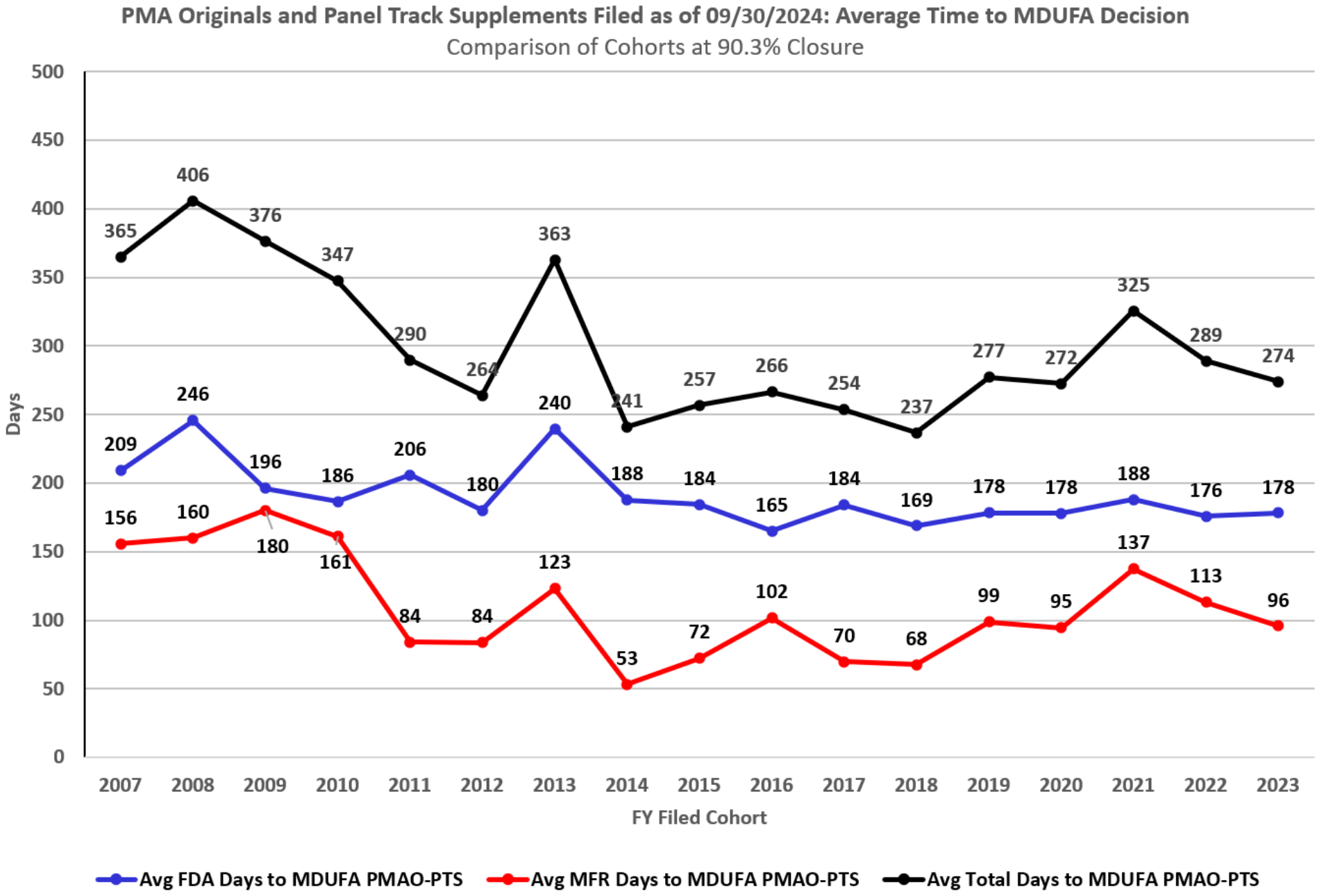
2019
2020
2021
2022
2023
FY Filed Cohort
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed as of 09/30/2024: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
257
359
345
350
346
435
445
405
464
428
389
339
294
438
270
283
310
279
263
319
333
373
311
274
201
225
244
216
234
289
309
241
277
243
208
238
190
275
200
187
166
185
170
192
188
212
176
178
56
134
102
134
112
146
136
164
187
185
181
100
104
163
71
96
144
94
93
128
146
161
135
96
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
FY Filed Cohort
Cohorts not yet closed: 2022: 95.45%; 2023: 90.28%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS


PMA Originals and Panel Track Supplements Filed as of 09/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 95.5% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
375
430
399
361
304
276
381
248
267
281
267
245
292
292
343
305
217
265
212
197
212
186
237
192
184
166
184
169
181
182
198
176
158
165
187
164
91
90
144
56
83
116
83
76
111
110
145
129
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS


PMA Originals and Panel Track Supplements Filed as of 09/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 90.3% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
365
406
376
347
290
264
363
241
257
266
254
237
277
272
325
289
274
209
246
196
186
206
180
240
188
184
165
184
169
178
178
188
176
178
156
160
180
161
84
84
123
53
72
102
70
68
99
95
137
113
96
2007
2008
2009
2010
2011
2012
2013
2014
2015
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2017
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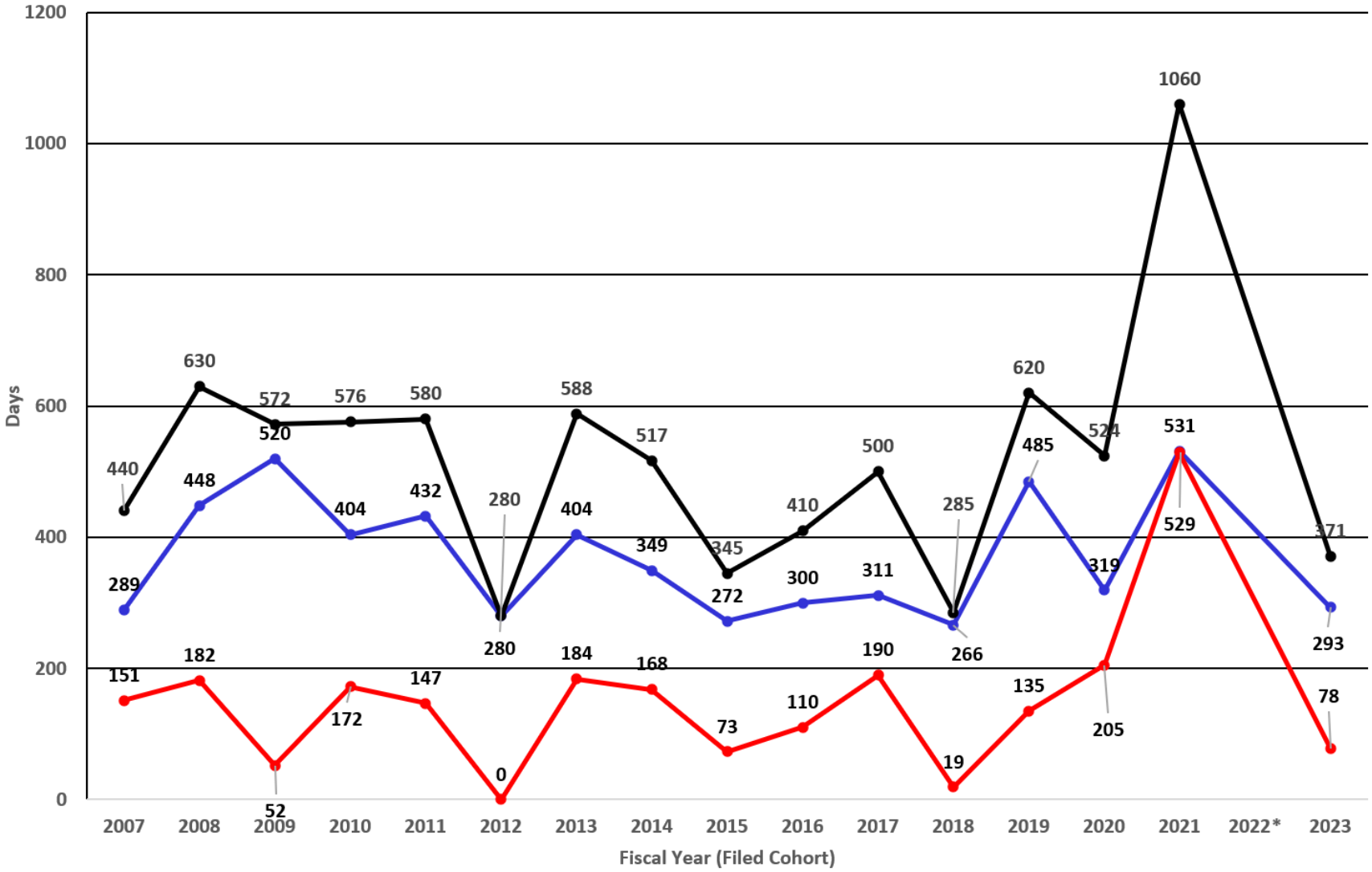
2019
2020
2021
2022
2023
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

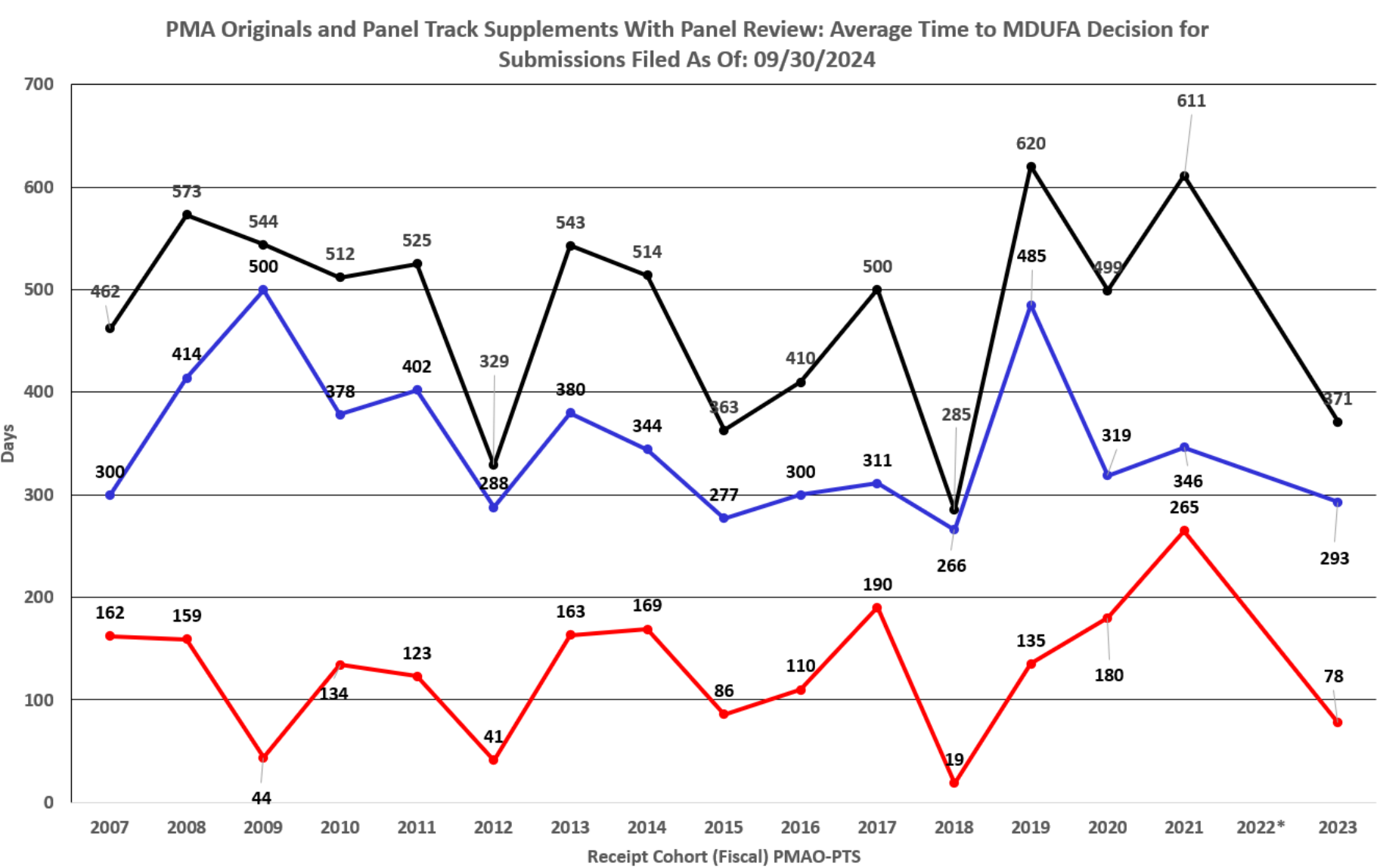
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 09/30/2024



Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2021 = 1/1; 2023 = 5/5

***Note: For FY22, there were no applicable MDUFA decisions for PMA Originals with Panel Review**

Avg FDA Days to MDUFA Decision PMAO **Avg MFR Days to MDUFA Decision PMAO** **Avg Total Days to MDUFA Decision PMAO**

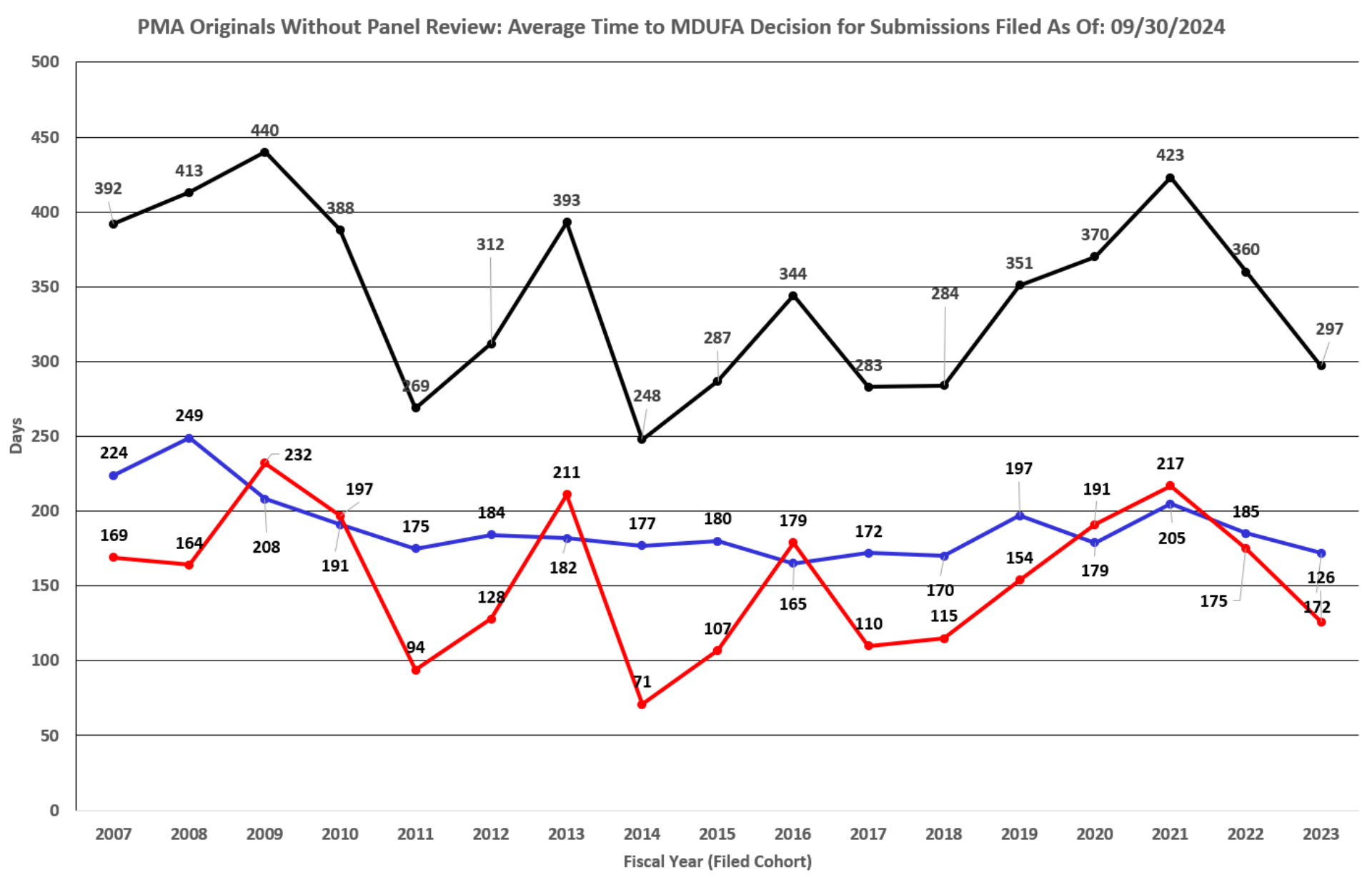


Numbers Closed/Filed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013 = 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/2; 2023 = 5/5

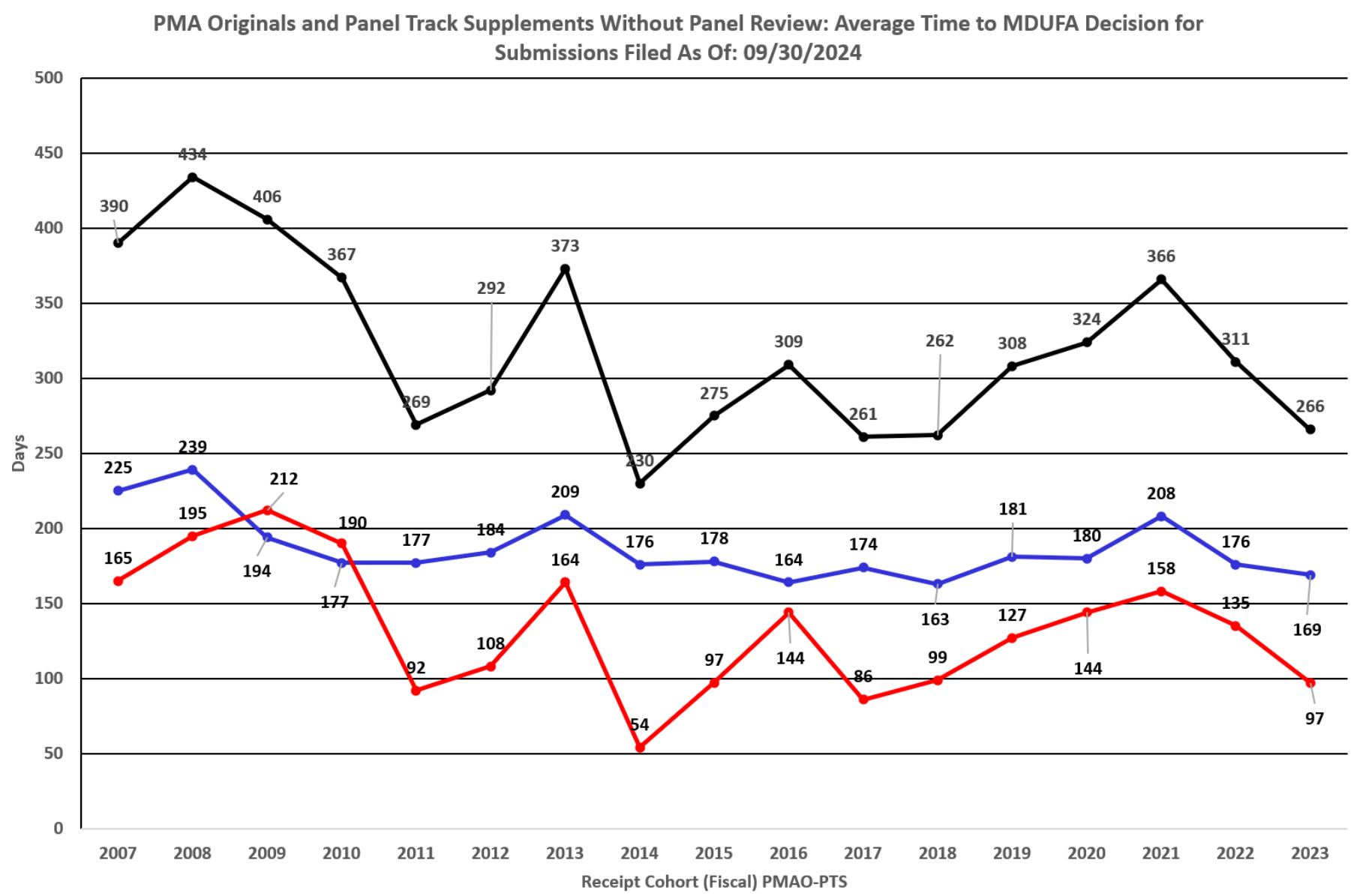
***Note: For FY22, there were no applicable MDUFA decisions for PMA Originals and Panel Track Supplements with Panel Review**

Avg FDA Days to MDUFA Decision PMAO-PTS **Avg MFR Days to MDUFA Decision PMAO-PTS** **Avg Total Days to MDUFA Decision PMAO-PTS**

Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.

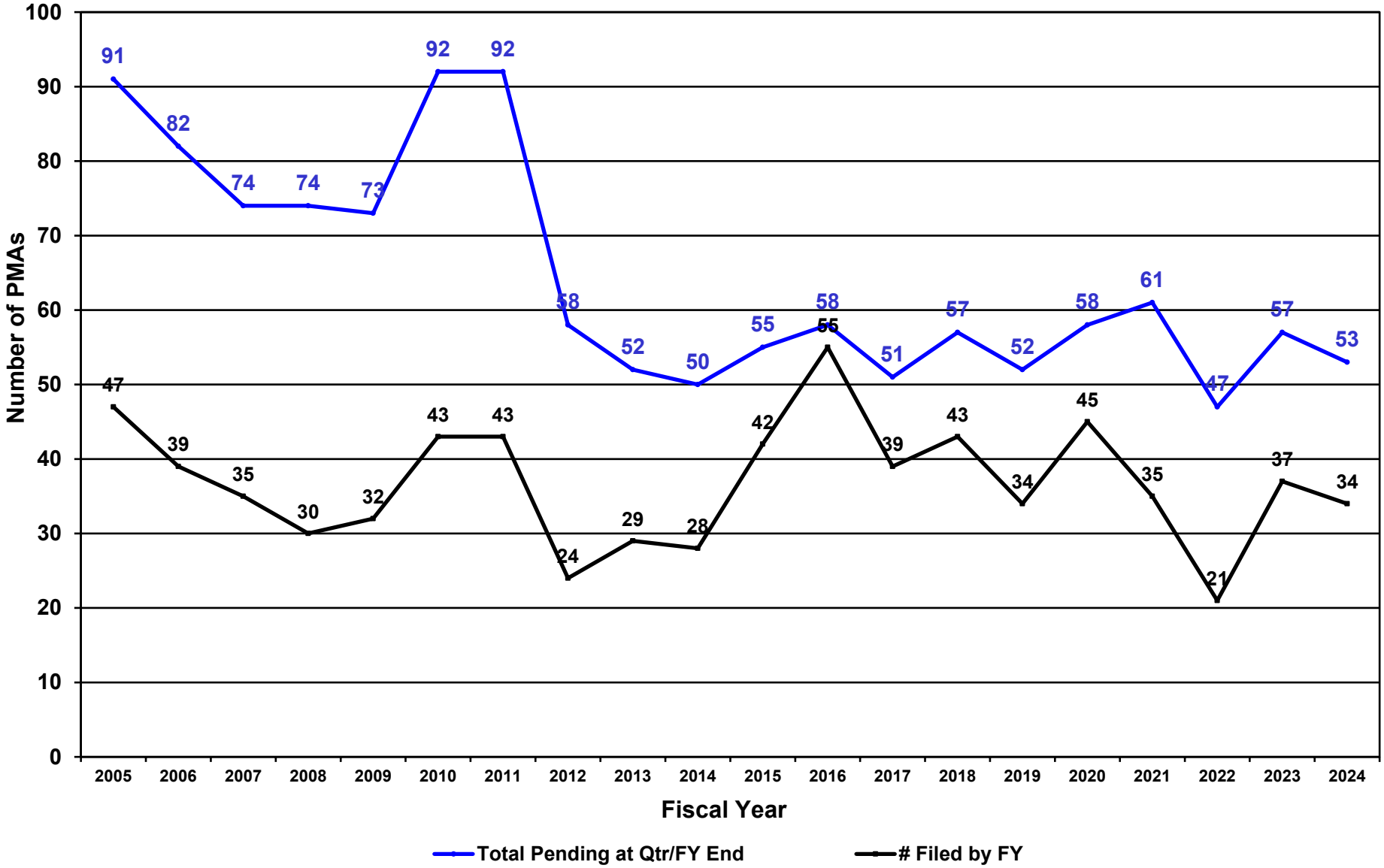


Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 20/22; 2023 = 34/38



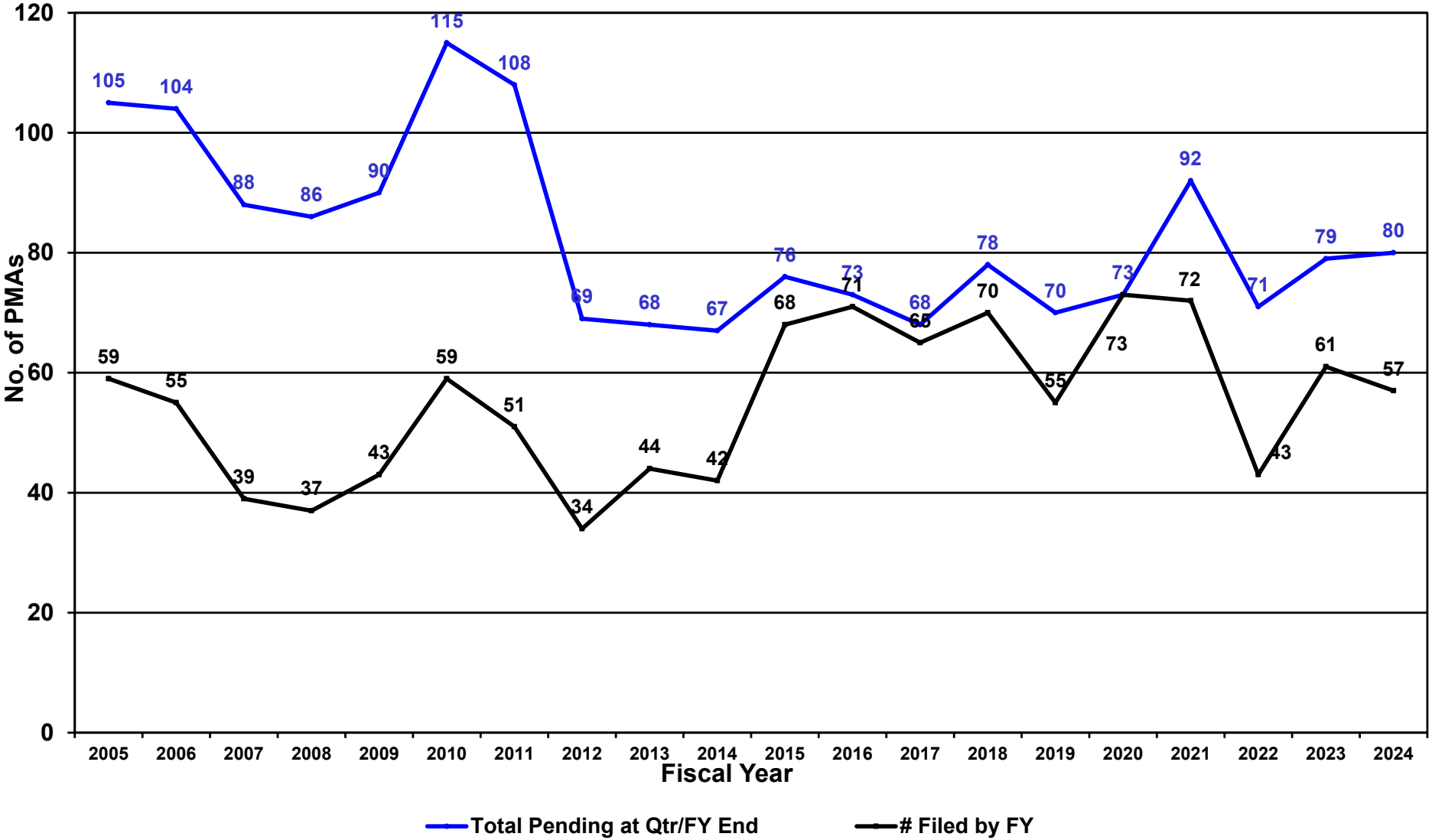
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

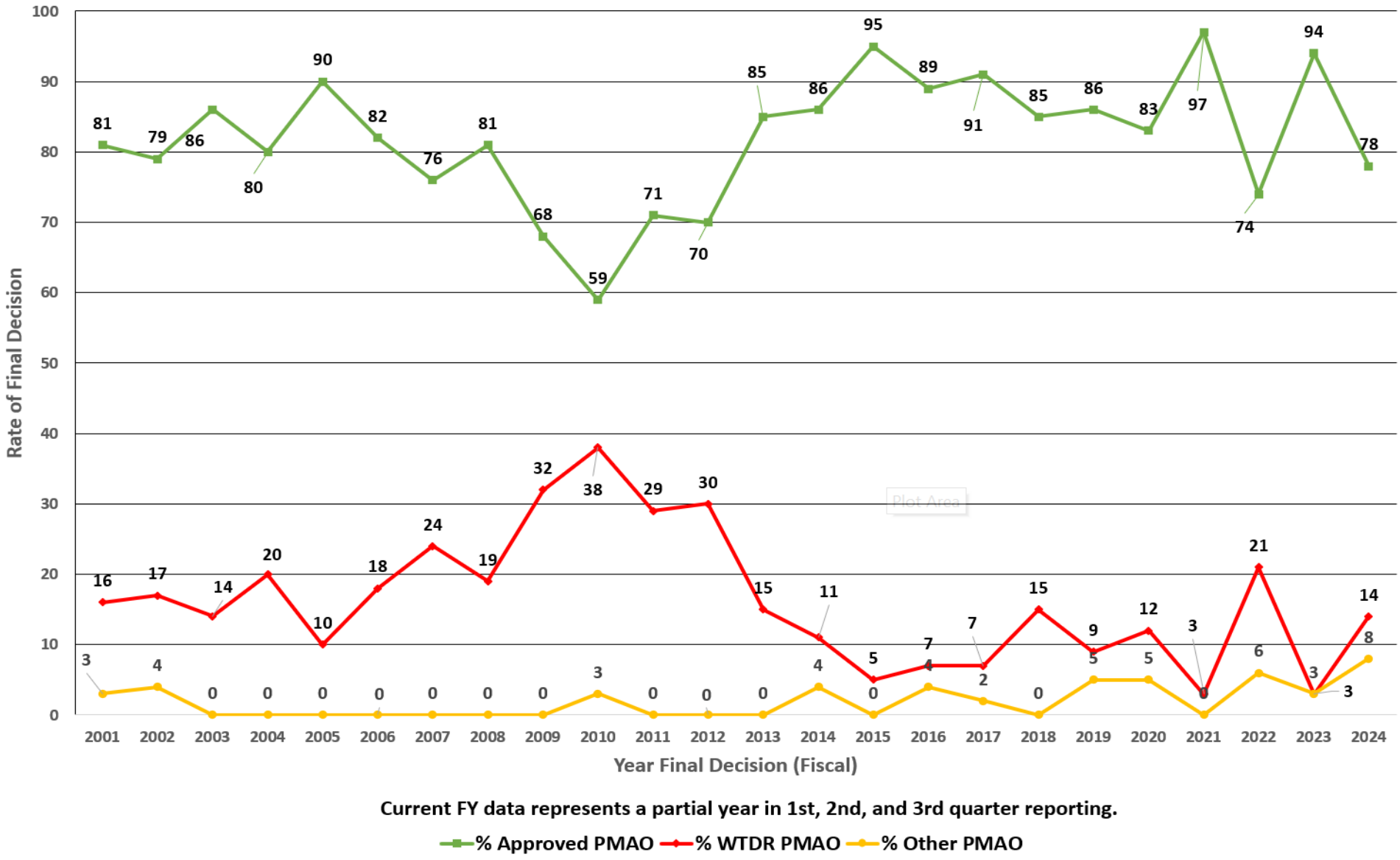


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

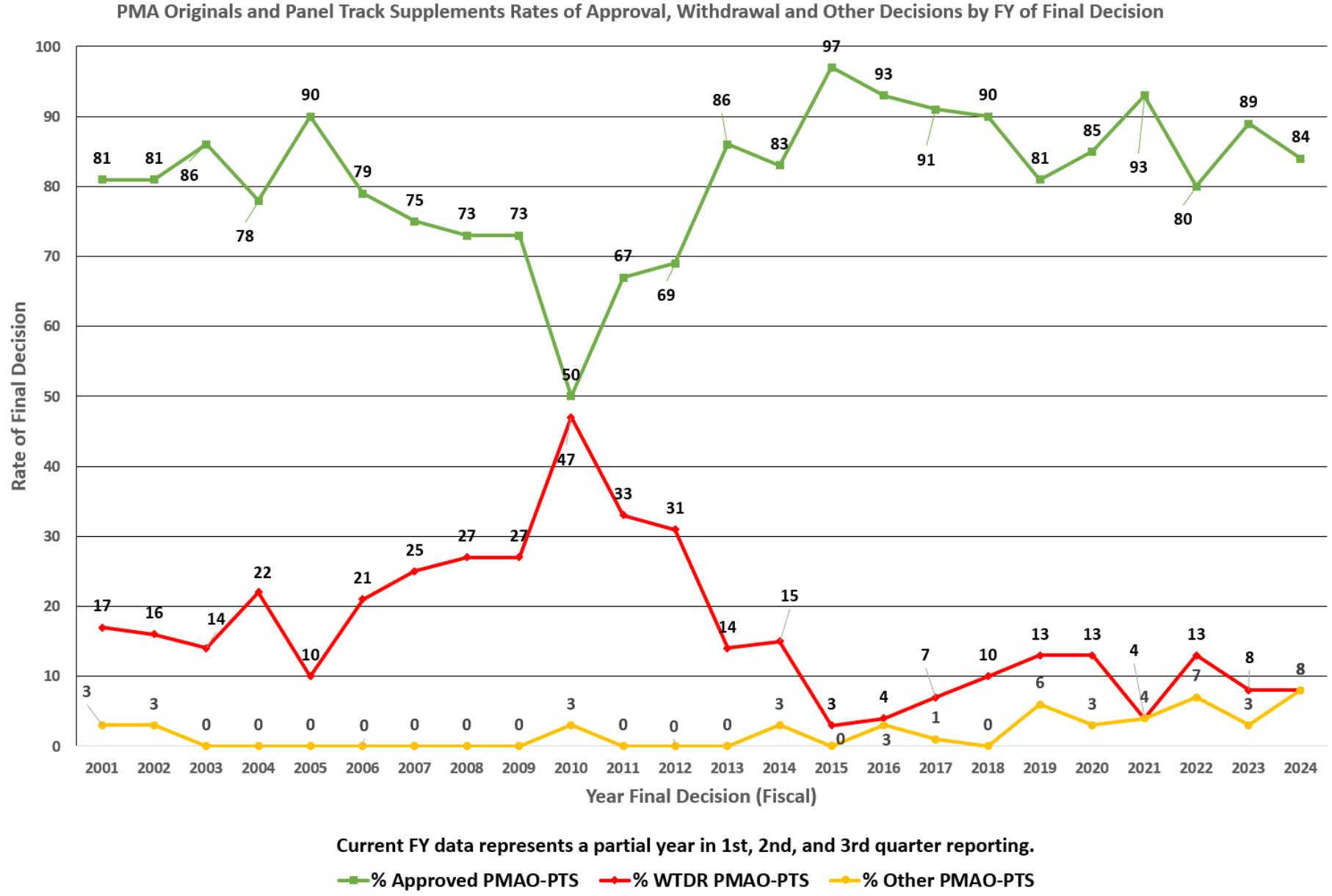
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



*Original PMAs/PTS awaiting filing, MDUFA or final decision, under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

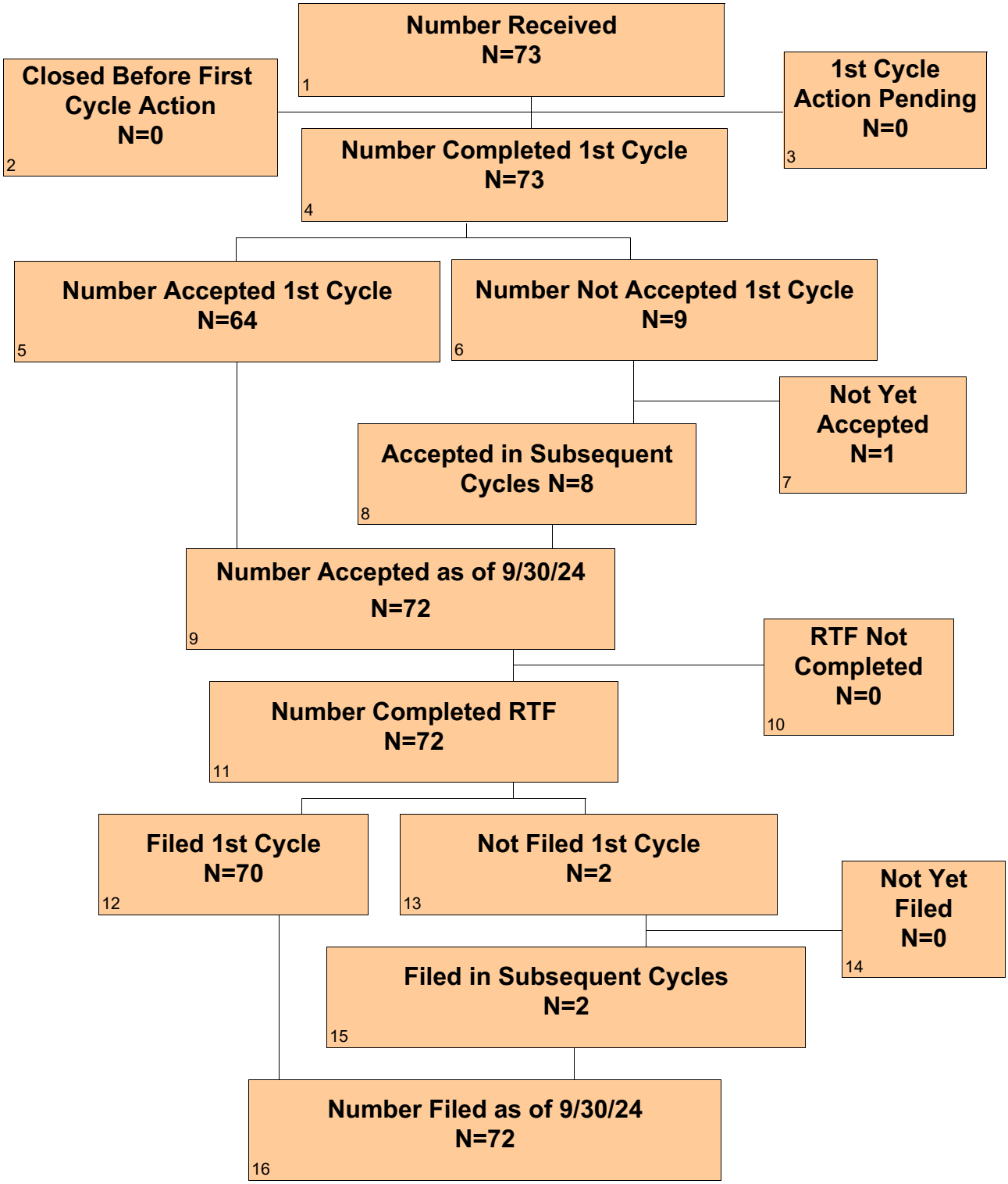


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions from FY16 onward

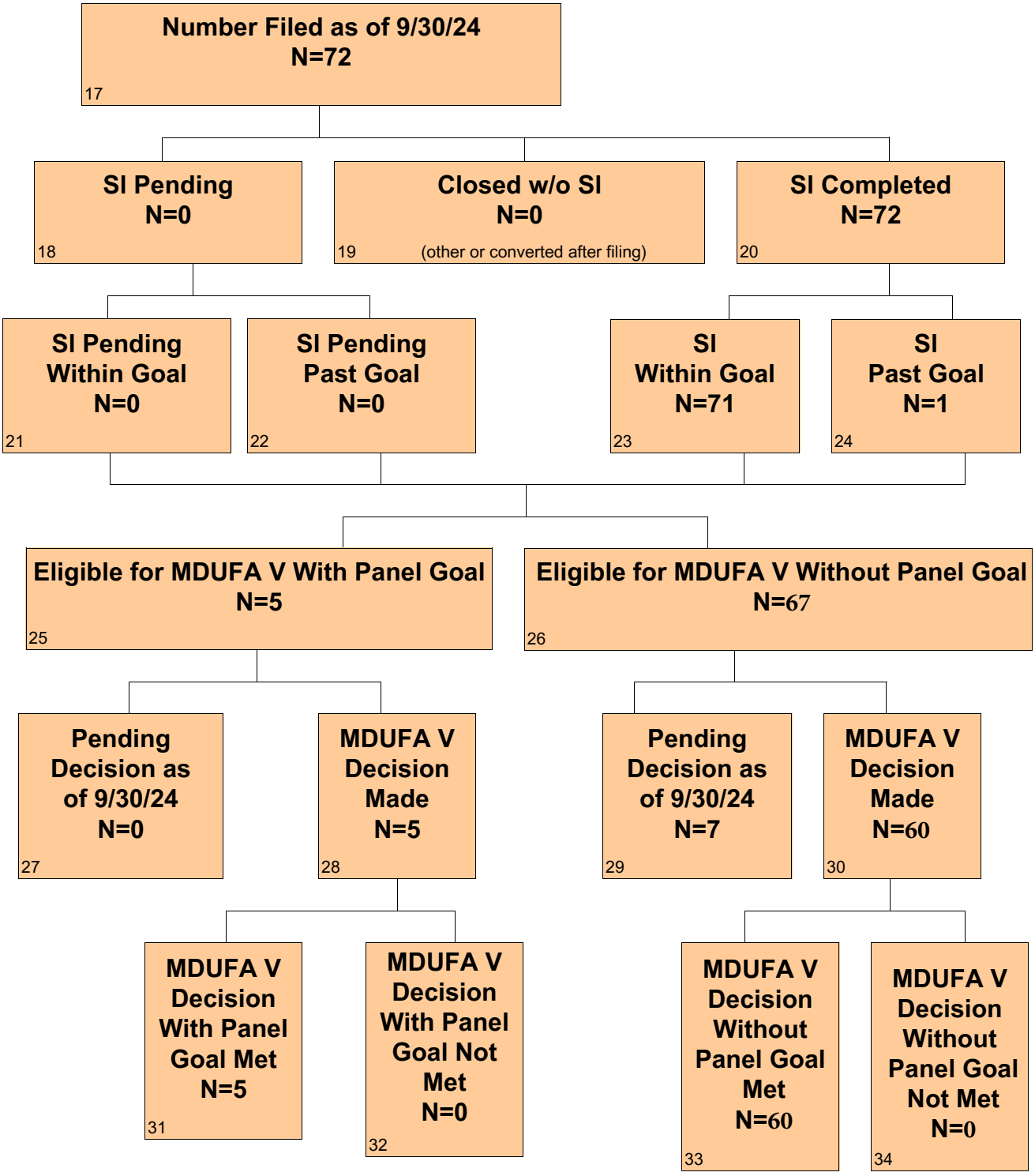


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions from FY16 onward

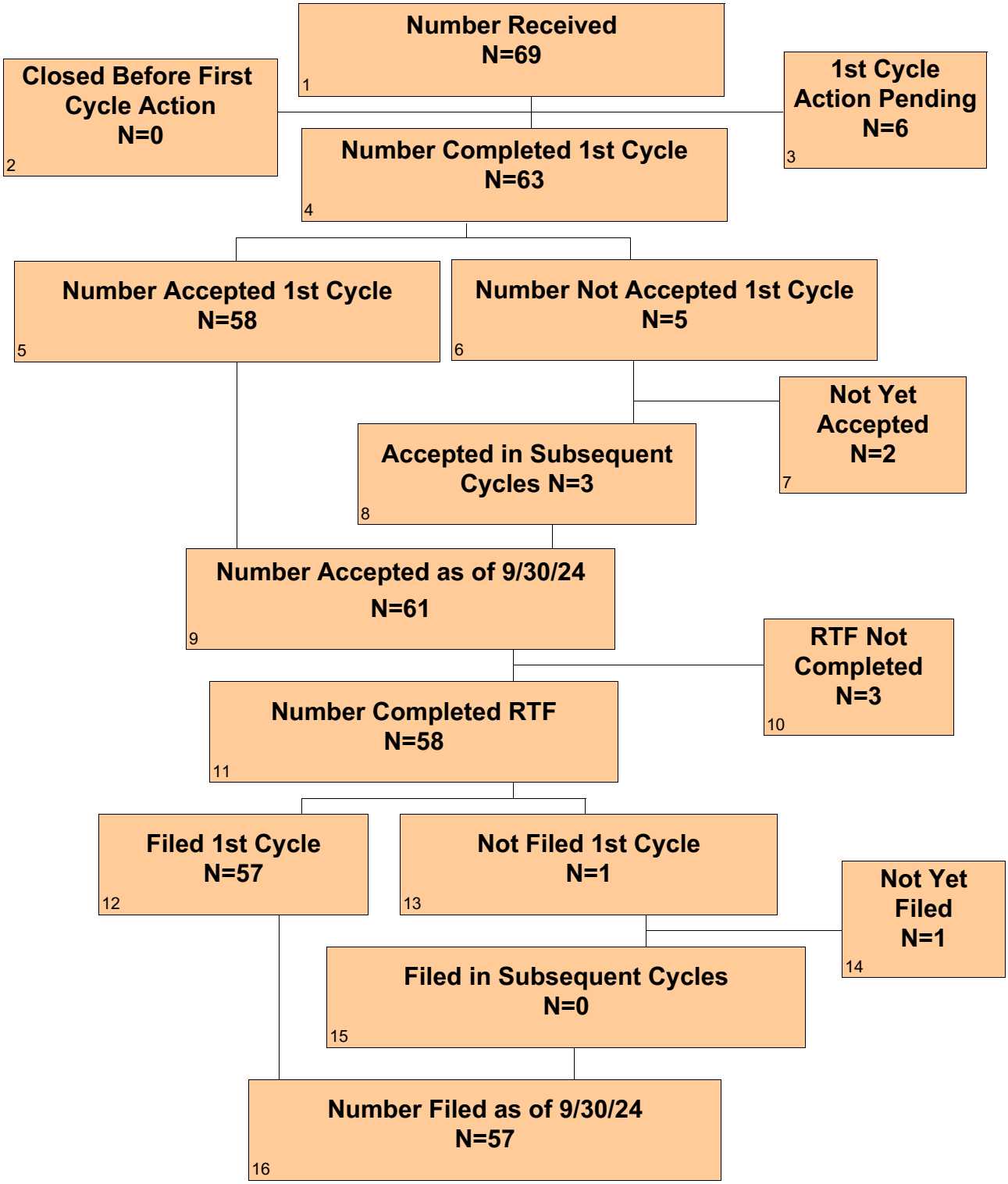
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 9/30/24



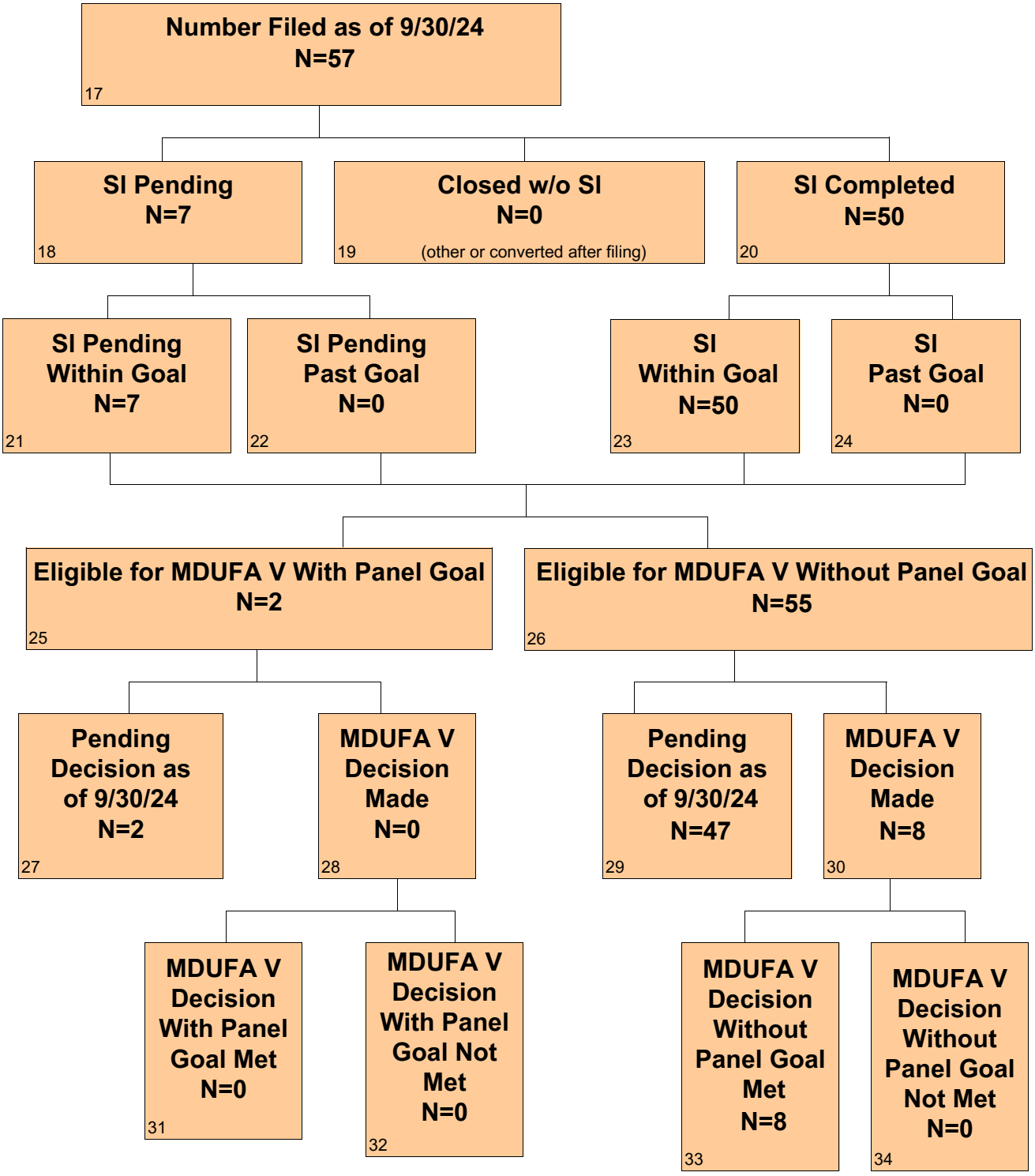
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 9/30/24 Con't



CDRH PMA Original and Panel Track Supplements - FY 2024 as of 9/30/24



CDRH PMA Original and Panel Track Supplements - FY 2024 as of 9/30/24 Con't



Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

Table 1.1 CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	64	56			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2			
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	6			
Number Not Accepted for Filing Review on First Cycle	9	5			
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	7.94%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69			
Number Accepted	64	58			
Completed RTF	72	58			
Number Not Filed	2	1			
Rate of Submissions Not Filed	2.78%	1.72%			

Table 1.3 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	72	57			
SI Goal Met	71	50			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	7			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.61%	100.00%			

Table 1.4 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	72	50			
Average Number of FDA Days to Substantive Interaction	87.42	88.00			
20th Percentile FDA Days to Substantive Interaction	86	88			
40th Percentile FDA Days to Substantive Interaction	88	89			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	91	90			

Table 1.5 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	67	55			
Non-MDUFA Decision	0	0			
MDUFA Decision	60	8			
MDUFA Decision Goal Met	60	8			
PMAs Pending MDUFA Decision	7	47			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 1.6 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	5	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Goal Met	5	0			
PMAs Pending MDUFA Decision	0	2			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)
Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	60	8			
Average FDA Days to MDUFA Decision	168.52	174.88			
20th Percentile FDA Days to MDUFA Decision	169	177			
40th Percentile FDA Days to MDUFA Decision	178	178			
60th Percentile FDA Days to MDUFA Decision	180	180			
80th Percentile FDA Days to MDUFA Decision	180	180			
Maximum FDA Days to MDUFA Decision	271	180			
Average Industry Days to MDUFA Decision	97.25	18.00			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	37	0			
60th Percentile Industry Days to MDUFA Decision	77	2			
80th Percentile Industry Days to MDUFA Decision	207	22			
Maximum Industry Days to MDUFA Decision	356	104			
Average Total Days to MDUFA Decision	265.77	192.88			
20th Percentile Total Days to MDUFA Decision	179	178			
40th Percentile Total Days to MDUFA Decision	216	180			
60th Percentile Total Days to MDUFA Decision	260	182			
80th Percentile Total Days to MDUFA Decision	351	202			
Maximum Total Days to MDUFA Decision	536	280			

Table 1.8 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	5	0			
Average FDA Days to MDUFA Decision	293.40	N/A			
20th Percentile FDA Days to MDUFA Decision	293	0			
40th Percentile FDA Days to MDUFA Decision	318	0			
60th Percentile FDA Days to MDUFA Decision	319	0			
80th Percentile FDA Days to MDUFA Decision	320	0			
Maximum FDA Days to MDUFA Decision	320	0			
Average Industry Days to MDUFA Decision	77.60	N/A			
20th Percentile Industry Days to MDUFA Decision	38	0			
40th Percentile Industry Days to MDUFA Decision	51	0			
60th Percentile Industry Days to MDUFA Decision	65	0			
80th Percentile Industry Days to MDUFA Decision	98	0			
Maximum Industry Days to MDUFA Decision	186	0			
Average Total Days to MDUFA Decision	371.00	N/A			
20th Percentile Total Days to MDUFA Decision	331	0			
40th Percentile Total Days to MDUFA Decision	370	0			
60th Percentile Total Days to MDUFA Decision	385	0			
80th Percentile Total Days to MDUFA Decision	418	0			
Maximum Total Days to MDUFA Decision	504	0			

Table 1.9 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	67	55			
Number with MDUFA Decision	60	8			
Number of Withdrawal	3	0			
Number of Not Approvable	8	1			
Number of Deleted	0	0			
Rate of Withdrawal	5.00%	0.00%			
Rate of Not Approvable	13.33%	12.50%			

Table 1.10 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	5	2			
Number With MDUFA Decision	5	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	20.00%	N/A			

Table 1.11 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 CDRH - LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	6	0			
MDUFA Decision Goal Met	6	0			
PMAs Pending MDUFA Decision	0	3			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

***Includes submission that went to panel**

Table 1.14 CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	15	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	12	1			
MDUFA Decision Goal Met	12	1			
PMAs Pending MDUFA Decision	3	10			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

***Includes submission that went to panel**

Section 1 PMA Original and Panel-Track Supplements - Office Level Metric

Table 1.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	3	6			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted for Filing Review on First Cycle	6	1			
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7			
Number Accepted	3	6			
Completed RTF	8	7			
Number Not Filed	1	0			
Rate of Submissions Not Filed	12.50%	0.00%			

Table 1.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	7			
SI Goal Met	8	7			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 1.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	8	7			
Average Number of FDA Days to Substantive Interaction	82.00	89.43			
20th Percentile FDA Days to Substantive Interaction	87	88			
40th Percentile FDA Days to Substantive Interaction	90	90			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

Table 1.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	8	7			
Non-MDUFA Decision	0	0			
MDUFA Decision	6	0			
MDUFA Decision Goal Met	6	0			
PMAs Pending MDUFA Decision	2	7			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	0	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	6	0			
Average FDA Days to MDUFA Decision	139.00	N/A			
20th Percentile FDA Days to MDUFA Decision	90	0			
40th Percentile FDA Days to MDUFA Decision	174	0			
60th Percentile FDA Days to MDUFA Decision	179	0			
80th Percentile FDA Days to MDUFA Decision	180	0			
Maximum FDA Days to MDUFA Decision	180	0			
Average Industry Days to MDUFA Decision	181.50	N/A			
20th Percentile Industry Days to MDUFA Decision	52	0			
40th Percentile Industry Days to MDUFA Decision	85	0			
60th Percentile Industry Days to MDUFA Decision	287	0			
80th Percentile Industry Days to MDUFA Decision	309	0			
Maximum Industry Days to MDUFA Decision	356	0			
Average Total Days to MDUFA Decision	320.50	N/A			
20th Percentile Total Days to MDUFA Decision	232	0			
40th Percentile Total Days to MDUFA Decision	264	0			
60th Percentile Total Days to MDUFA Decision	377	0			
80th Percentile Total Days to MDUFA Decision	483	0			
Maximum Total Days to MDUFA Decision	536	0			

Table 1.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	N/A	N/A			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	N/A	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	N/A	N/A			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 1.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	8	7			
Number with MDUFA Decision	6	0			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	16.67%	N/A			
Rate of Not Approvable	0.00%	N/A			

Table 1.10 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0			
Number With MDUFA Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.11 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.1 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	19	17			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted for Filing Review on First Cycle	1	1			
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20			
Number Accepted	19	19			
Completed RTF	20	18			
Number Not Filed	0	1			
Rate of Submissions Not Filed	0.00%	5.56%			

Table 1.3 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	20	17			
SI Goal Met	20	13			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 1.4 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	20	13			
Average Number of FDA Days to Substantive Interaction	88.25	87.92			
20th Percentile FDA Days to Substantive Interaction	86	85			
40th Percentile FDA Days to Substantive Interaction	90	90			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

Table 1.5 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	17	16			
Non-MDUFA Decision	0	0			
MDUFA Decision	17	6			
MDUFA Decision Goal Met	17	6			
PMAs Pending MDUFA Decision	0	10			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 1.6 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	3	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	3	0			
MDUFA Decision Goal Met	3	0			
PMAs Pending MDUFA Decision	0	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.7 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	6			
Average FDA Days to MDUFA Decision	177.65	173.83			
20th Percentile FDA Days to MDUFA Decision	172	178			
40th Percentile FDA Days to MDUFA Decision	177	178			
60th Percentile FDA Days to MDUFA Decision	180	180			
80th Percentile FDA Days to MDUFA Decision	180	180			
Maximum FDA Days to MDUFA Decision	271	180			
Average Industry Days to MDUFA Decision	64.29	6.67			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	23	0			
60th Percentile Industry Days to MDUFA Decision	47	0			
80th Percentile Industry Days to MDUFA Decision	113	10			
Maximum Industry Days to MDUFA Decision	271	30			
Average Total Days to MDUFA Decision	241.94	180.50			
20th Percentile Total Days to MDUFA Decision	176	178			
40th Percentile Total Days to MDUFA Decision	201	178			
60th Percentile Total Days to MDUFA Decision	236	180			
80th Percentile Total Days to MDUFA Decision	305	190			
Maximum Total Days to MDUFA Decision	442	210			

Table 1.8 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	0			
Average FDA Days to MDUFA Decision	319.33	N/A			
20th Percentile FDA Days to MDUFA Decision	319	0			
40th Percentile FDA Days to MDUFA Decision	320	0			
60th Percentile FDA Days to MDUFA Decision	320	0			
80th Percentile FDA Days to MDUFA Decision	320	0			
Maximum FDA Days to MDUFA Decision	320	0			
Average Industry Days to MDUFA Decision	58.00	N/A			
20th Percentile Industry Days to MDUFA Decision	47	0			
40th Percentile Industry Days to MDUFA Decision	54	0			
60th Percentile Industry Days to MDUFA Decision	61	0			
80th Percentile Industry Days to MDUFA Decision	68	0			
Maximum Industry Days to MDUFA Decision	76	0			
Average Total Days to MDUFA Decision	377.33	N/A			
20th Percentile Total Days to MDUFA Decision	366	0			
40th Percentile Total Days to MDUFA Decision	373	0			
60th Percentile Total Days to MDUFA Decision	381	0			
80th Percentile Total Days to MDUFA Decision	388	0			
Maximum Total Days to MDUFA Decision	396	0			

Table 1.9 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	17	16			
Number with MDUFA Decision	17	6			
Number of Withdrawal	1	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	5.88%	0.00%			
Rate of Not Approvable	17.65%	0.00%			

Table 1.10 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	1			
Number With MDUFA Decision	3	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	0.00%	N/A			

Table 1.11 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT2 - Office of Cardiovascular Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 OHT2 - Office of Cardiovascular Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	3	4			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	3			
Number Not Accepted for Filing Review on First Cycle	0	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7			
Number Accepted	3	4			
Completed RTF	3	3			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	0.00%			

Table 1.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	3			
SI Goal Met	3	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 1.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	3			
Average Number of FDA Days to Substantive Interaction	88.33	83.00			
20th Percentile FDA Days to Substantive Interaction	87	78			
40th Percentile FDA Days to Substantive Interaction	88	85			
60th Percentile FDA Days to Substantive Interaction	88	88			
80th Percentile FDA Days to Substantive Interaction	89	89			
Maximum FDA Days to Substantive Interaction	90	90			

Table 1.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	2	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	2	0			
MDUFA Decision Goal Met	2	0			
PMAs Pending MDUFA Decision	0	3			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	1	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Goal Met	1	0			
PMAs Pending MDUFA Decision	0	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	2	0			
Average FDA Days to MDUFA Decision	175.50	N/A			
20th Percentile FDA Days to MDUFA Decision	173	0			
40th Percentile FDA Days to MDUFA Decision	175	0			
60th Percentile FDA Days to MDUFA Decision	176	0			
80th Percentile FDA Days to MDUFA Decision	178	0			
Maximum FDA Days to MDUFA Decision	179	0			
Average Industry Days to MDUFA Decision	14.00	N/A			
20th Percentile Industry Days to MDUFA Decision	6	0			
40th Percentile Industry Days to MDUFA Decision	11	0			
60th Percentile Industry Days to MDUFA Decision	17	0			
80th Percentile Industry Days to MDUFA Decision	22	0			
Maximum Industry Days to MDUFA Decision	28	0			
Average Total Days to MDUFA Decision	189.50	N/A			
20th Percentile Total Days to MDUFA Decision	183	0			
40th Percentile Total Days to MDUFA Decision	187	0			
60th Percentile Total Days to MDUFA Decision	192	0			
80th Percentile Total Days to MDUFA Decision	196	0			
Maximum Total Days to MDUFA Decision	200	0			

Table 1.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	1	0			
Average FDA Days to MDUFA Decision	191.00	N/A			
20th Percentile FDA Days to MDUFA Decision	191	0			
40th Percentile FDA Days to MDUFA Decision	191	0			
60th Percentile FDA Days to MDUFA Decision	191	0			
80th Percentile FDA Days to MDUFA Decision	191	0			
Maximum FDA Days to MDUFA Decision	191	0			
Average Industry Days to MDUFA Decision	28.00	N/A			
20th Percentile Industry Days to MDUFA Decision	28	0			
40th Percentile Industry Days to MDUFA Decision	28	0			
60th Percentile Industry Days to MDUFA Decision	28	0			
80th Percentile Industry Days to MDUFA Decision	28	0			
Maximum Industry Days to MDUFA Decision	28	0			
Average Total Days to MDUFA Decision	219.00	N/A			
20th Percentile Total Days to MDUFA Decision	219	0			
40th Percentile Total Days to MDUFA Decision	219	0			
60th Percentile Total Days to MDUFA Decision	219	0			
80th Percentile Total Days to MDUFA Decision	219	0			
Maximum Total Days to MDUFA Decision	219	0			

Table 1.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	2	3			
Number with MDUFA Decision	2	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	0.00%	N/A			

Table 1.10 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0			
Number With MDUFA Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	100.00%	N/A			

Table 1.11 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.1 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	9	6			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted for Filing Review on First Cycle	0	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6			
Number Accepted	9	6			
Completed RTF	9	6			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	0.00%			

Table 1.3 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	9	6			
SI Goal Met	9	6			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 1.4 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	9	6			
Average Number of FDA Days to Substantive Interaction	88.78	89.33			
20th Percentile FDA Days to Substantive Interaction	88	89			
40th Percentile FDA Days to Substantive Interaction	90	89			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

Table 1.5 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	9	5			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	0			
MDUFA Decision Goal Met	8	0			
PMAs Pending MDUFA Decision	1	5			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.6 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	0	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.7 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	8	0			
Average FDA Days to MDUFA Decision	179.00	N/A			
20th Percentile FDA Days to MDUFA Decision	178	0			
40th Percentile FDA Days to MDUFA Decision	179	0			
60th Percentile FDA Days to MDUFA Decision	180	0			
80th Percentile FDA Days to MDUFA Decision	180	0			
Maximum FDA Days to MDUFA Decision	180	0			
Average Industry Days to MDUFA Decision	60.38	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	32	0			
60th Percentile Industry Days to MDUFA Decision	53	0			
80th Percentile Industry Days to MDUFA Decision	64	0			
Maximum Industry Days to MDUFA Decision	264	0			
Average Total Days to MDUFA Decision	239.38	N/A			
20th Percentile Total Days to MDUFA Decision	179	0			
40th Percentile Total Days to MDUFA Decision	210	0			
60th Percentile Total Days to MDUFA Decision	233	0			
80th Percentile Total Days to MDUFA Decision	244	0			
Maximum Total Days to MDUFA Decision	444	0			

Table 1.8 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	N/A	N/A			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	N/A	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	N/A	N/A			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 1.9 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	5			
Number with MDUFA Decision	8	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	12.50%	N/A			

Table 1.10 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	1			
Number With MDUFA Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.11 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT4 - Office of Surgical and Infection Control Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 OHT4 - Office of Surgical and Infection Control Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	5	6			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted for Filing Review on First Cycle	1	1			
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	14.29%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7			
Number Accepted	5	6			
Completed RTF	6	6			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	0.00%			

Table 1.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	6	6			
SI Goal Met	5	5			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	83.33%	100.00%			

Table 1.4 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	6	5			
Average Number of FDA Days to Substantive Interaction	88.50	85.00			
20th Percentile FDA Days to Substantive Interaction	88	83			
40th Percentile FDA Days to Substantive Interaction	90	87			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	91	90			

Table 1.5 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	6			
Non-MDUFA Decision	0	0			
MDUFA Decision	6	1			
MDUFA Decision Goal Met	6	1			
PMAs Pending MDUFA Decision	0	5			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 1.6 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	0	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.7 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	6	1			
Average FDA Days to MDUFA Decision	175.33	176.00			
20th Percentile FDA Days to MDUFA Decision	179	176			
40th Percentile FDA Days to MDUFA Decision	180	176			
60th Percentile FDA Days to MDUFA Decision	180	176			
80th Percentile FDA Days to MDUFA Decision	180	176			
Maximum FDA Days to MDUFA Decision	180	176			
Average Industry Days to MDUFA Decision	55.17	104.00			
20th Percentile Industry Days to MDUFA Decision	0	104			
40th Percentile Industry Days to MDUFA Decision	37	104			
60th Percentile Industry Days to MDUFA Decision	71	104			
80th Percentile Industry Days to MDUFA Decision	101	104			
Maximum Industry Days to MDUFA Decision	122	104			
Average Total Days to MDUFA Decision	230.50	280.00			
20th Percentile Total Days to MDUFA Decision	180	280			
40th Percentile Total Days to MDUFA Decision	217	280			
60th Percentile Total Days to MDUFA Decision	251	280			
80th Percentile Total Days to MDUFA Decision	281	280			
Maximum Total Days to MDUFA Decision	301	280			

Table 1.8 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	N/A	N/A			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	N/A	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	N/A	N/A			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 1.9 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	6	6			
Number with MDUFA Decision	6	1			
Number of Withdrawal	0	0			
Number of Not Approvable	1	1			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	0.00%			
Rate of Not Approvable	16.67%	100.00%			

Table 1.10 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0			
Number With MDUFA Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.11 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT5 - Office of Neurological and Physical Medicine Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.1 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	4	3			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted for Filing Review on First Cycle	1	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	20.00%	0.00%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3			
Number Accepted	4	3			
Completed RTF	5	3			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	0.00%			

Table 1.3 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	5	3			
SI Goal Met	5	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 1.4 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	5	3			
Average Number of FDA Days to Substantive Interaction	85.40	88.00			
20th Percentile FDA Days to Substantive Interaction	84	87			
40th Percentile FDA Days to Substantive Interaction	86	87			
60th Percentile FDA Days to Substantive Interaction	87	88			
80th Percentile FDA Days to Substantive Interaction	88	89			
Maximum FDA Days to Substantive Interaction	88	90			

Table 1.5 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	5	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
PMAs Pending MDUFA Decision	1	3			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.6 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	0	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.7 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	4	0			
Average FDA Days to MDUFA Decision	172.50	N/A			
20th Percentile FDA Days to MDUFA Decision	167	0			
40th Percentile FDA Days to MDUFA Decision	172	0			
60th Percentile FDA Days to MDUFA Decision	177	0			
80th Percentile FDA Days to MDUFA Decision	179	0			
Maximum FDA Days to MDUFA Decision	180	0			
Average Industry Days to MDUFA Decision	156.00	N/A			
20th Percentile Industry Days to MDUFA Decision	58	0			
40th Percentile Industry Days to MDUFA Decision	111	0			
60th Percentile Industry Days to MDUFA Decision	157	0			
80th Percentile Industry Days to MDUFA Decision	246	0			
Maximum Industry Days to MDUFA Decision	356	0			
Average Total Days to MDUFA Decision	328.50	N/A			
20th Percentile Total Days to MDUFA Decision	225	0			
40th Percentile Total Days to MDUFA Decision	274	0			
60th Percentile Total Days to MDUFA Decision	326	0			
80th Percentile Total Days to MDUFA Decision	420	0			
Maximum Total Days to MDUFA Decision	536	0			

Table 1.8 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	N/A	N/A			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	N/A	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	N/A	N/A			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 1.9 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	5	3			
Number with MDUFA Decision	4	0			
Number of Withdrawal	0	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	75.00%	N/A			

Table 1.10 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0			
Number With MDUFA Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.11 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT6 - Office of Orthopedic Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 OHT6 - Office of Orthopedic Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.1 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	21	13			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	1			
Number Not Accepted for Filing Review on First Cycle	0	2			
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	13.33%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16			
Number Accepted	21	13			
Completed RTF	21	14			
Number Not Filed	1	0			
Rate of Submissions Not Filed	4.76%	0.00%			

Table 1.3 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	14			
SI Goal Met	21	12			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 1.4 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	21	12			
Average Number of FDA Days to Substantive Interaction	88.14	88.92			
20th Percentile FDA Days to Substantive Interaction	87	88			
40th Percentile FDA Days to Substantive Interaction	87	89			
60th Percentile FDA Days to Substantive Interaction	89	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

Table 1.5 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	20	14			
Non-MDUFA Decision	0	0			
MDUFA Decision	17	1			
MDUFA Decision Goal Met	17	1			
PMAs Pending MDUFA Decision	3	13			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 1.6 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	1	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Goal Met	1	0			
PMAs Pending MDUFA Decision	0	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.7 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	1			
Average FDA Days to MDUFA Decision	160.71	180.00			
20th Percentile FDA Days to MDUFA Decision	136	180			
40th Percentile FDA Days to MDUFA Decision	178	180			
60th Percentile FDA Days to MDUFA Decision	180	180			
80th Percentile FDA Days to MDUFA Decision	180	180			
Maximum FDA Days to MDUFA Decision	180	180			
Average Industry Days to MDUFA Decision	128.65	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	27	0			
60th Percentile Industry Days to MDUFA Decision	170	0			
80th Percentile Industry Days to MDUFA Decision	273	0			
Maximum Industry Days to MDUFA Decision	340	0			
Average Total Days to MDUFA Decision	289.35	180.00			
20th Percentile Total Days to MDUFA Decision	179	180			
40th Percentile Total Days to MDUFA Decision	206	180			
60th Percentile Total Days to MDUFA Decision	306	180			
80th Percentile Total Days to MDUFA Decision	448	180			
Maximum Total Days to MDUFA Decision	520	180			

Table 1.8 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	1	0			
Average FDA Days to MDUFA Decision	318.00	N/A			
20th Percentile FDA Days to MDUFA Decision	318	0			
40th Percentile FDA Days to MDUFA Decision	318	0			
60th Percentile FDA Days to MDUFA Decision	318	0			
80th Percentile FDA Days to MDUFA Decision	318	0			
Maximum FDA Days to MDUFA Decision	318	0			
Average Industry Days to MDUFA Decision	186.00	N/A			
20th Percentile Industry Days to MDUFA Decision	186	0			
40th Percentile Industry Days to MDUFA Decision	186	0			
60th Percentile Industry Days to MDUFA Decision	186	0			
80th Percentile Industry Days to MDUFA Decision	186	0			
Maximum Industry Days to MDUFA Decision	186	0			
Average Total Days to MDUFA Decision	504.00	N/A			
20th Percentile Total Days to MDUFA Decision	504	0			
40th Percentile Total Days to MDUFA Decision	504	0			
60th Percentile Total Days to MDUFA Decision	504	0			
80th Percentile Total Days to MDUFA Decision	504	0			
Maximum Total Days to MDUFA Decision	504	0			

Table 1.9 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	20	14			
Number with MDUFA Decision	17	1			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	5.88%	0.00%			
Rate of Not Approvable	0.00%	0.00%			

Table 1.10 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0			
Number With MDUFA Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	0.00%	N/A			

Table 1.11 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT7 - Office of In Vitro Diagnostics
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	6	0			
MDUFA Decision Goal Met	6	0			
PMAs Pending MDUFA Decision	0	3			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

***Includes submission that went to panel**

Table 1.14 OHT7 - Office of In Vitro Diagnostics
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	15	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	12	1			
MDUFA Decision Goal Met	12	1			
PMAs Pending MDUFA Decision	3	10			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

***Includes submission that went to panel**

Table 1.1 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0	3			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	0	1			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	2			
Number Not Accepted for Filing Review on First Cycle	0	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	N/A	0.00%			

***The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).**

Table 1.2 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0	3			
Number Accepted	0	1			
Completed RTF	0	1			
Number Not Filed	0	0			
Rate of Submissions Not Filed	N/A	0.00%			

Table 1.3 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	0	1			
SI Goal Met	0	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	N/A	100.00%			

Table 1.4 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	0	1			
Average Number of FDA Days to Substantive Interaction	N/A	90.00			
20th Percentile FDA Days to Substantive Interaction	0	90			
40th Percentile FDA Days to Substantive Interaction	0	90			
60th Percentile FDA Days to Substantive Interaction	0	90			
80th Percentile FDA Days to Substantive Interaction	0	90			
Maximum FDA Days to Substantive Interaction	0	90			

Table 1.5 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	0	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.6 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	0	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.7 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	N/A	N/A			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	N/A	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	N/A	N/A			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 1.8 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	N/A	N/A			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	N/A	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	N/A	N/A			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 1.9 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	1			
Number with MDUFA Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.10 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0			
Number With MDUFA Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.11 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.12 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 1.13 OHT8 - Office of Radiological Health
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

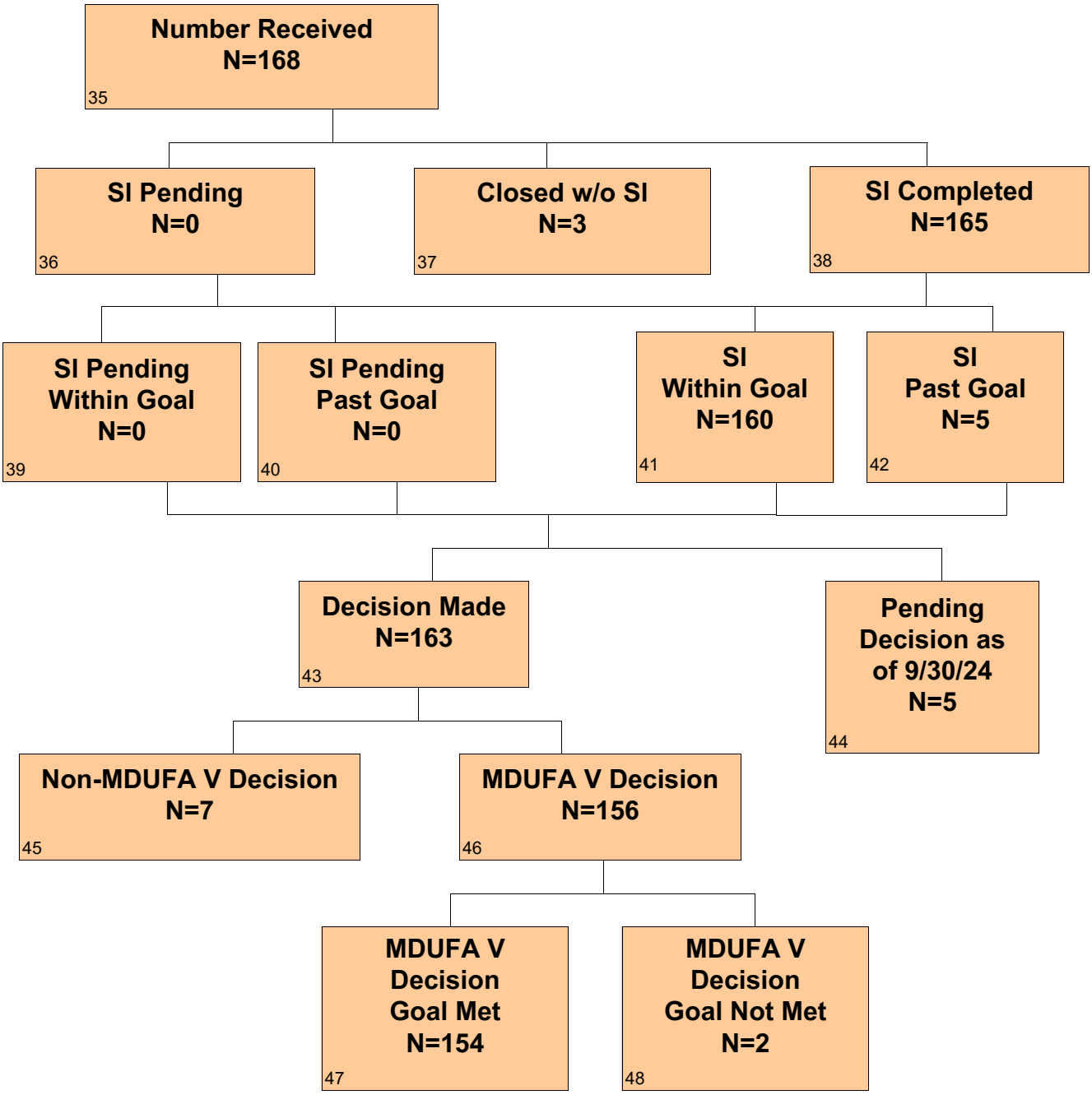
***Includes submission that went to panel**

Table 1.14 OHT8 - Office of Radiological Health
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric*

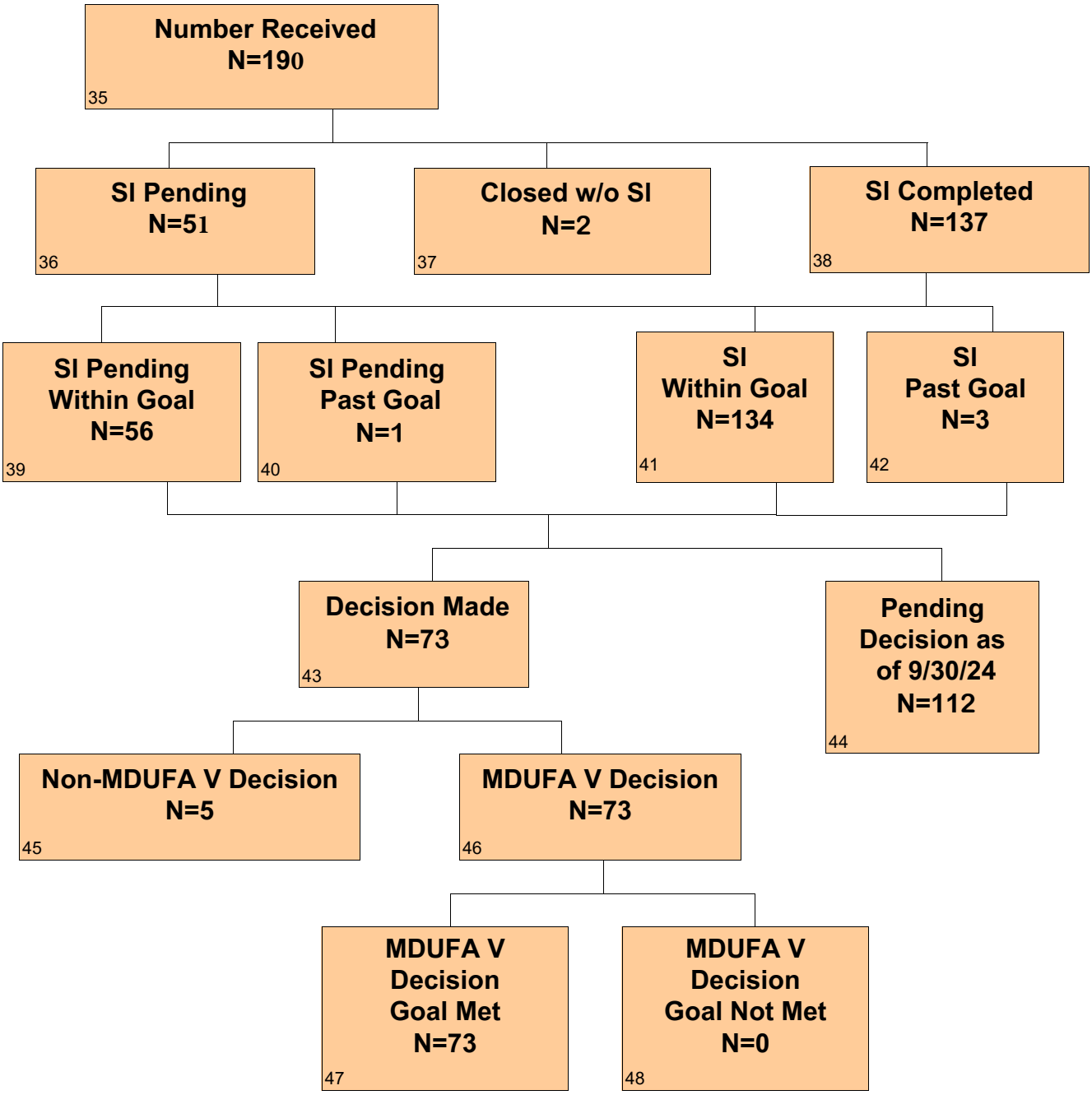
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA Decision	N/A	N/A			
PMAs Pending MDUFA Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

CDRH PMA 180 Day Supplements - FY 2023 as of 9/30/24



CDRH PMA 180 Day Supplements - FY 2024 as of 9/30/24



Section 2 PMA 180-Day Supplements - Center Level Metric

Table 2.1 CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	168	190			
SI Goal Met	160	134			
SI Goal Not Met	5	3			
SI Pending Within Goal	0	51			
SI Pending Past Goal	0	0			
Closed Without SI	3	2			
Current SI Performance Percent Goal Met	96.97%	97.81%			

Table 2.2 CDRH - PMA 180-Day Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	168	190			
Non-MDUFA Decision	7	5			
MDUFA Decision	156	73			
MDUFA Decision Goal Met	154	73			
Supplements Pending MDUFA Decision	5	112			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	98.72%	100.00%			

Table 2.3 CDRH - PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	168	190			
Number with MDUFA Decision	156	73			
Number of Not Approvable	7	10			
Rate of Not Approvable	4.49%	13.70%			

Table 2.4 CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	3			
Mean FDA Days for Submissions that Missed the Goal	197.00	186.00			
Mean Industry Days for Submissions that Missed the Goal	77.00	0.00			

Section 2 PMA 180-Day Supplements - Office Level Metric

Table 2.1 OHT1 - - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	16	15			
SI Goal Met	16	14			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 2.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	16	15			
Non-MDUFA Decision	1	0			
MDUFA Decision	15	4			
MDUFA Decision Goal Met	15	4			
Supplements Pending MDUFA Decision	0	11			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 2.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	15			
Number with MDUFA Decision	15	4			
Number of Not Approvable	1	1			
Rate of Not Approvable	6.67%	25.00%			

Table 2.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 2.1 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	56	82			
SI Goal Met	55	55			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	26			
SI Pending Past Goal	0	0			
Closed Without SI	1	1			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 2.2 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	56	82			
Non-MDUFA Decision	3	4			
MDUFA Decision	53	35			
MDUFA Decision Goal Met	53	35			
Supplements Pending MDUFA Decision	0	43			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 2.3 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	56	82			
Number with MDUFA Decision	53	35			
Number of Not Approvable	1	9			
Rate of Not Approvable	1.89%	25.71%			

Table 2.4 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	3			
Mean FDA Days for Submissions that Missed the Goal	N/A	186.00			
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00			

Table 2.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	17			
SI Goal Met	20	14			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	95.24%	100.00%			

Table 2.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	21	17			
Non-MDUFA Decision	0	0			
MDUFA Decision	20	9			
MDUFA Decision Goal Met	20	9			
Supplements Pending MDUFA Decision	1	8			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 2.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	17			
Number with MDUFA Decision	20	9			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

Table 2.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 2.1 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	12			
SI Goal Met	8	5			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	7			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 2.2 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	8	12			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	2			
MDUFA Decision Goal Met	7	2			
Supplements Pending MDUFA Decision	1	10			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 2.3 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8	12			
Number with MDUFA Decision	7	2			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

Table 2.4 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 2.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	23	20			
SI Goal Met	20	13			
SI Goal Not Met	3	3			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	86.96%	81.25%			

Table 2.2 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	23	20			
Non-MDUFA Decision	0	0			
MDUFA Decision	21	8			
MDUFA Decision Goal Met	19	8			
Supplements Pending MDUFA Decision	2	12			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	90.48%	100.00%			

Table 2.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20			
Number with MDUFA Decision	21	8			
Number of Not Approvable	2	0			
Rate of Not Approvable	9.52%	0.00%			

Table 2.4 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions that Missed the Goal	197.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	77.00	N/A			

Table 2.1 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	7	5			
SI Goal Met	7	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 2.2 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	7	5			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	3			
MDUFA Decision Goal Met	7	3			
Supplements Pending MDUFA Decision	0	2			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 2.3 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	5			
Number with MDUFA Decision	7	3			
Number of Not Approvable	1	0			
Rate of Not Approvable	14.29%	0.00%			

Table 2.4 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 2.1 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	36	37			
SI Goal Met	33	29			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	7			
SI Pending Past Goal	0	0			
Closed Without SI	2	1			
Current SI Performance Percent Goal Met	97.06%	100.00%			

Table 2.2 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	36	37			
Non-MDUFA Decision	3	1			
MDUFA Decision	32	11			
MDUFA Decision Goal Met	32	11			
Supplements Pending MDUFA Decision	1	25			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 2.3 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	36	37			
Number with MDUFA Decision	32	11			
Number of Not Approvable	2	0			
Rate of Not Approvable	6.25%	0.00%			

Table 2.4 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 2.1 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	1	2			
SI Goal Met	1	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 2.2 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Supplements Received	1	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	1			
MDUFA Decision Goal Met	1	1			
Supplements Pending MDUFA Decision	0	1			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

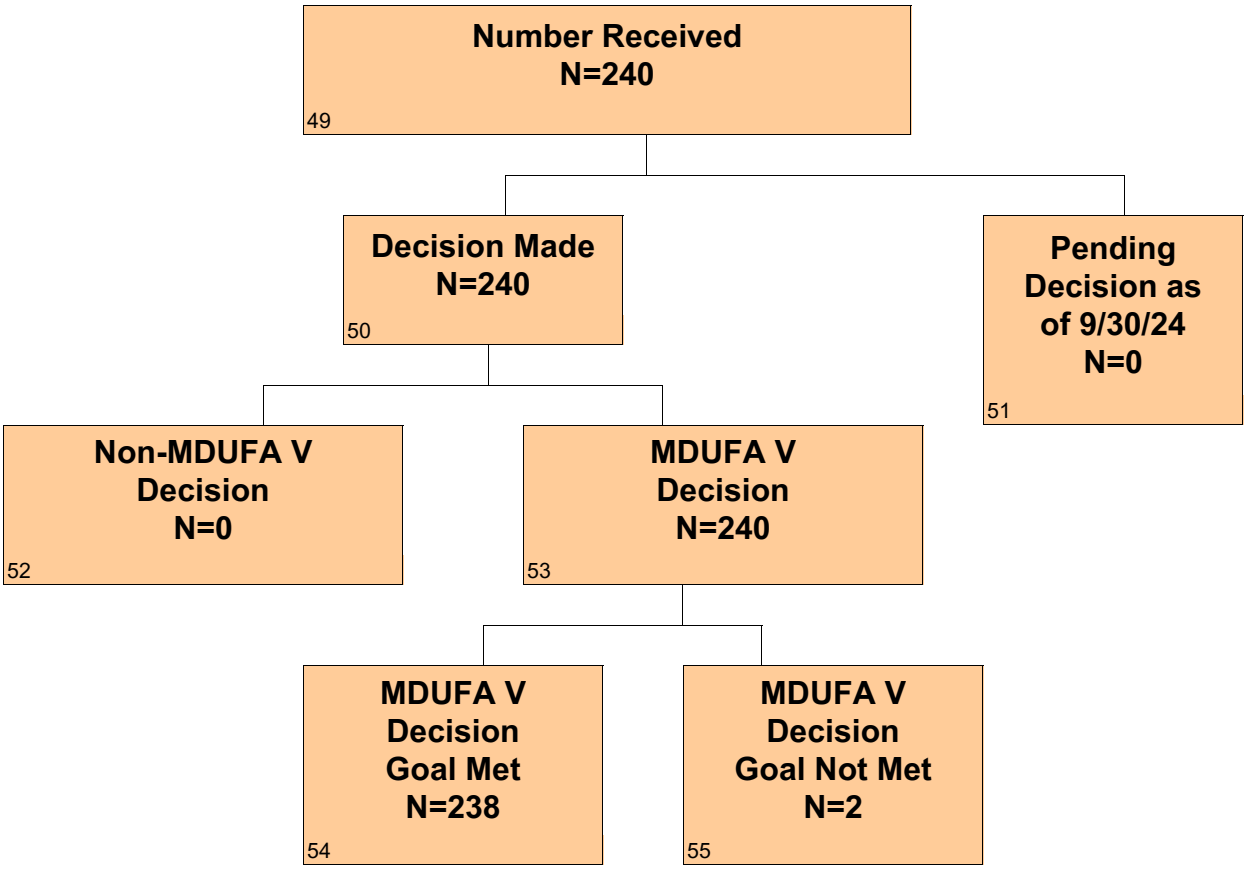
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1	2			
Number with MDUFA Decision	1	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

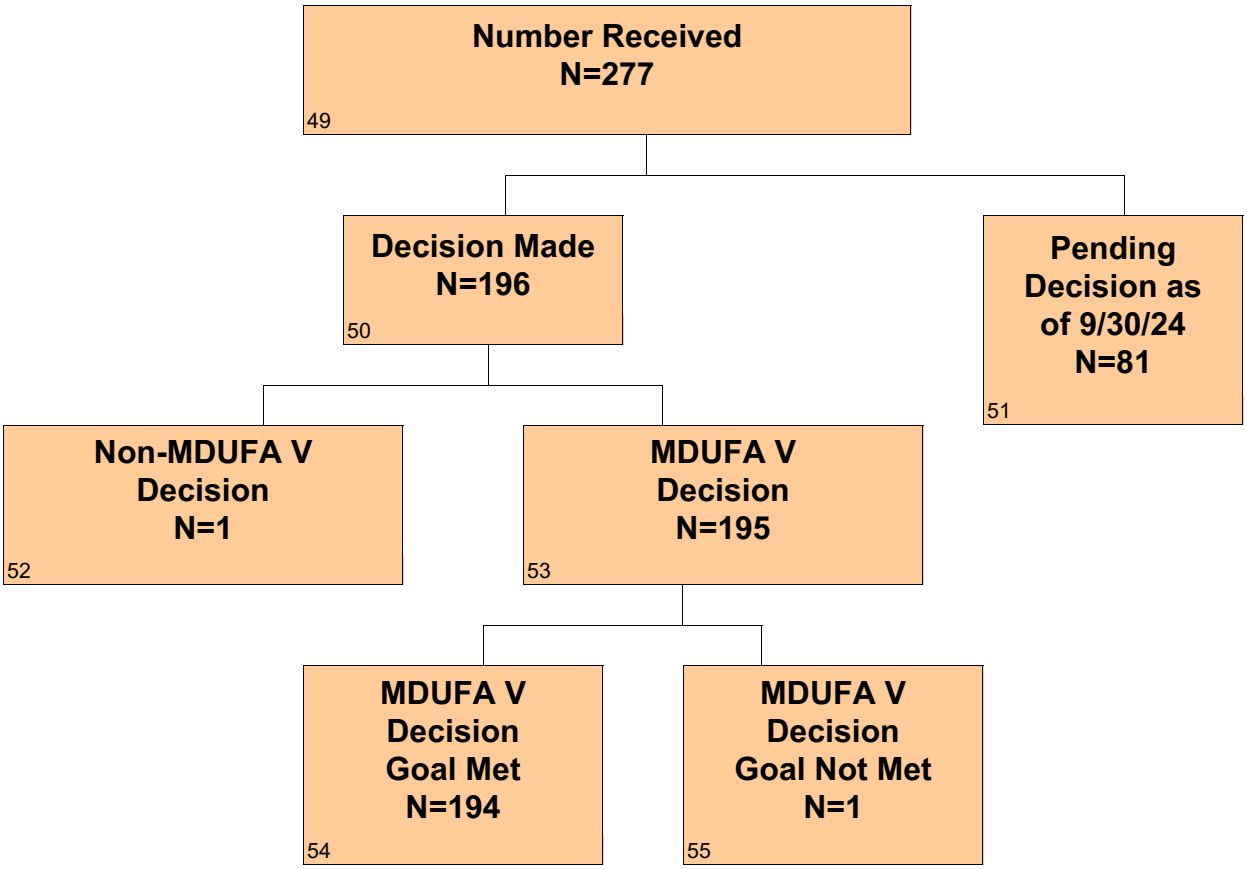
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

CDRH PMA Real Time Supplements - FY 2023 as of 9/30/24



CDRH PMA Real Time Supplements - FY 2024 as of 9/30/24



Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CDRH - PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	240	277			
Non-MDUFA Decision	0	1			
MDUFA Decision	240	195			
MDUFA Decision Goal Met	238	194			
Supplements Pending MDUFA Decision	0	81			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	99.17%	99.49%			

Table 3.2 CDRH - PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	240	277			
Number With MDUFA Decision	240	195			
Number of Not Approvable	11	6			
Rate of Not Approvable	4.58%	3.08%			

Table 3.3 CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	1			
Mean FDA Days for Submissions that Missed the Goal	109.50	148.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 3 PMA Real-Time Supplements - Office Level Metric

Table 3.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	24	19			
Non-MDUFA Decision	0	0			
MDUFA Decision	24	13			
MDUFA Decision Goal Met	24	13			
Supplements Pending MDUFA Decision	0	6			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	24	19			
Number With MDUFA Decision	24	13			
Number of Not Approvable	3	2			
Rate of Not Approvable	12.50%	15.38%			

Table 3.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 3.1 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	136	142			
Non-MDUFA Decision	0	0			
MDUFA Decision	136	96			
MDUFA Decision Goal Met	136	96			
Supplements Pending MDUFA Decision	0	46			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	136	142			
Number With MDUFA Decision	136	96			
Number of Not Approvable	4	1			
Rate of Not Approvable	2.94%	1.04%			

Table 3.3 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 3.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	19	23			
Non-MDUFA Decision	0	1			
MDUFA Decision	19	15			
MDUFA Decision Goal Met	18	15			
Supplements Pending MDUFA Decision	0	7			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	94.74%	100.00%			

Table 3.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	19	23			
Number With MDUFA Decision	19	15			
Number of Not Approvable	2	1			
Rate of Not Approvable	10.53%	6.67%			

Table 3.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	92.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	0.00	N/A			

Table 3.1 OHT4 - Office of Surgical and Infection Control Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	7	10			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	6			
MDUFA Decision Goal Met	7	6			
Supplements Pending MDUFA Decision	0	4			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 OHT4 - Office of Surgical and Infection Control Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	10			
Number With MDUFA Decision	7	6			
Number of Not Approvable	2	0			
Rate of Not Approvable	28.57%	0.00%			

Table 3.3 OHT4 - Office of Surgical and Infection Control Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 3.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	16	37			
Non-MDUFA Decision	0	0			
MDUFA Decision	16	30			
MDUFA Decision Goal Met	15	29			
Supplements Pending MDUFA Decision	0	7			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	93.75%	96.67%			

Table 3.2 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	37			
Number With MDUFA Decision	16	30			
Number of Not Approvable	0	1			
Rate of Not Approvable	0.00%	3.33%			

Table 3.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1			
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 3.1 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	4	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	5			
MDUFA Decision Goal Met	4	5			
Supplements Pending MDUFA Decision	0	6			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	11			
Number With MDUFA Decision	4	5			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

Table 3.3 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 3.1 OHT7 - Office of In Vitro Diagnostics
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	32	34			
Non-MDUFA Decision	0	0			
MDUFA Decision	32	29			
MDUFA Decision Goal Met	32	29			
Supplements Pending MDUFA Decision	0	5			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 OHT7 - Office of In Vitro Diagnostics
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	32	34			
Number With MDUFA Decision	32	29			
Number of Not Approvable	0	1			
Rate of Not Approvable	0.00%	3.45%			

Table 3.3 OHT7 - Office of In Vitro Diagnostics
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 3.1 OHT8 - Office of Radiological Health
PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	2	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	2	1			
MDUFA Decision Goal Met	2	1			
Supplements Pending MDUFA Decision	0	0			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 OHT8 - Office of Radiological Health
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	2	1			
Number With MDUFA Decision	2	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

Table 3.3 OHT8 - Office of Radiological Health
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2023 and September 30, 2024.

Section 5 PMA Annual General Metrics

Table 5.1 CDRH - PMAs (All Review Tracks) Annual General Metrics - PMAs Received by Type

PMA Submissions Received	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Premarket Report Submissions	0	0			
Original PMAs (Panel) - Breakthrough Device	4	0			
Original PMAs (No Panel) - Breakthrough Device	13	9			
Original PMAs (Panel) - Non-Breakthrough Device	1	1			
Original PMAs (No Panel) - Non-Breakthrough Device	26	32			
Panel-Tracked Supplements (Panel) - Breakthrough Device	0	0			
Panel-Tracked Supplements (No Panel) - Breakthrough Device	1	1			
Panel-Tracked Supplements (Panel) - Non-Breakthrough Device	0	1			
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	28	25			
PMA Modules	79	90			
180-Day Supplements	168	190			
Real-Time Supplements	240	277			

Table 5.2 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Percent Cohorts Closed

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	72	57			
Number With a Decision (MDUFA or Non-MDUFA)	65	8			
% of FY Closed	90.28%	14.04%			

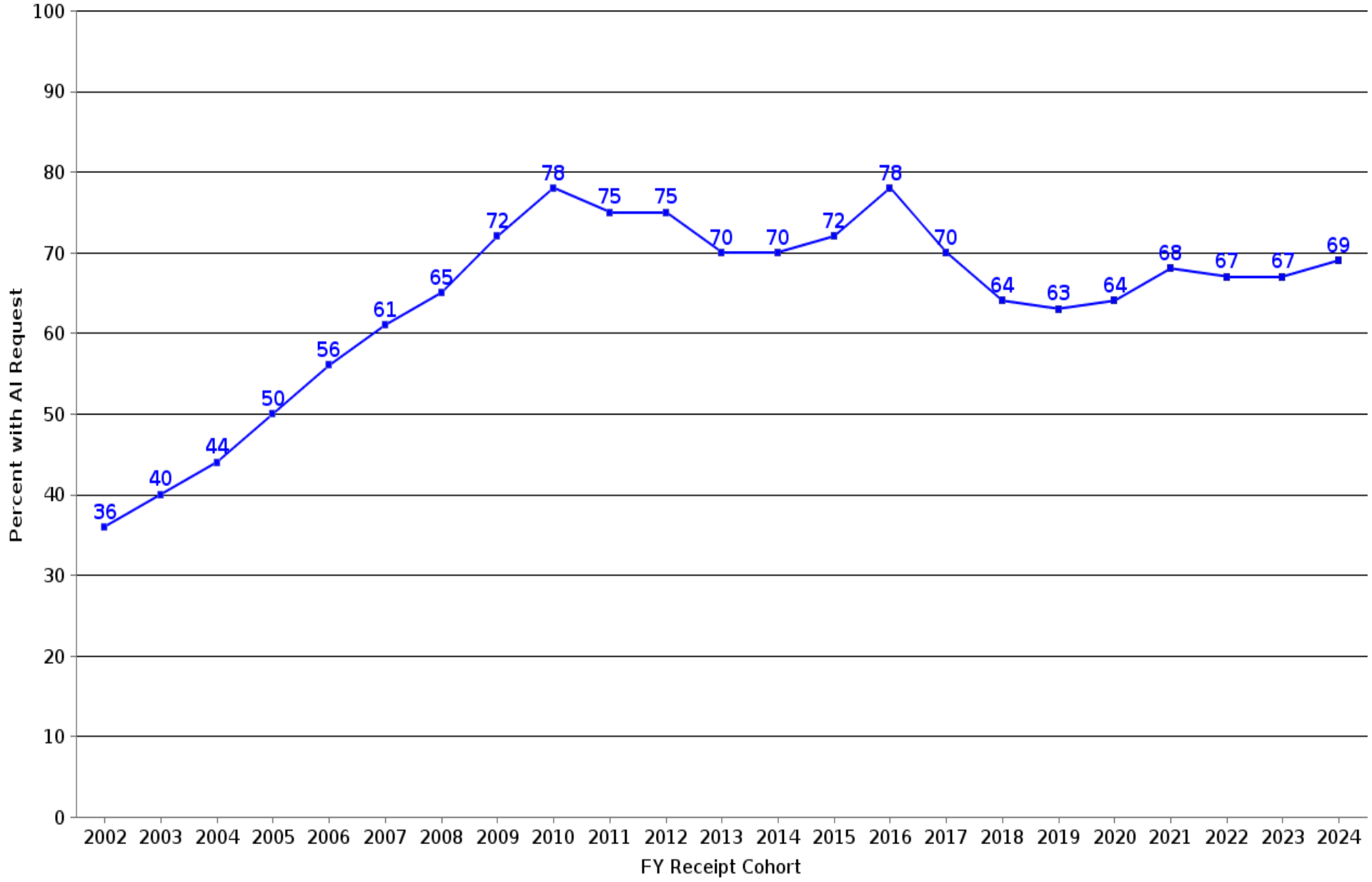
Table 5.3 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Three-Year Rolling Average Time to MDUFA V Decision

Performance Metric	FY 2023 3 Year Cohort 290 FDA Days	FY 2024 3 Year Cohort 290 FDA Days	FY 2025 3 Year Cohort 285 FDA Days	FY 2026 3 Year Cohort 285 FDA Days	FY 2027 3 Year Cohort 285 FDA Days
Number With a MDUFA Decision	178	115			
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	162	105			
Three-year Rolling Average Total Time to MDUFA Decision	N/A	N/A			

510(k)s

Q4FY2024

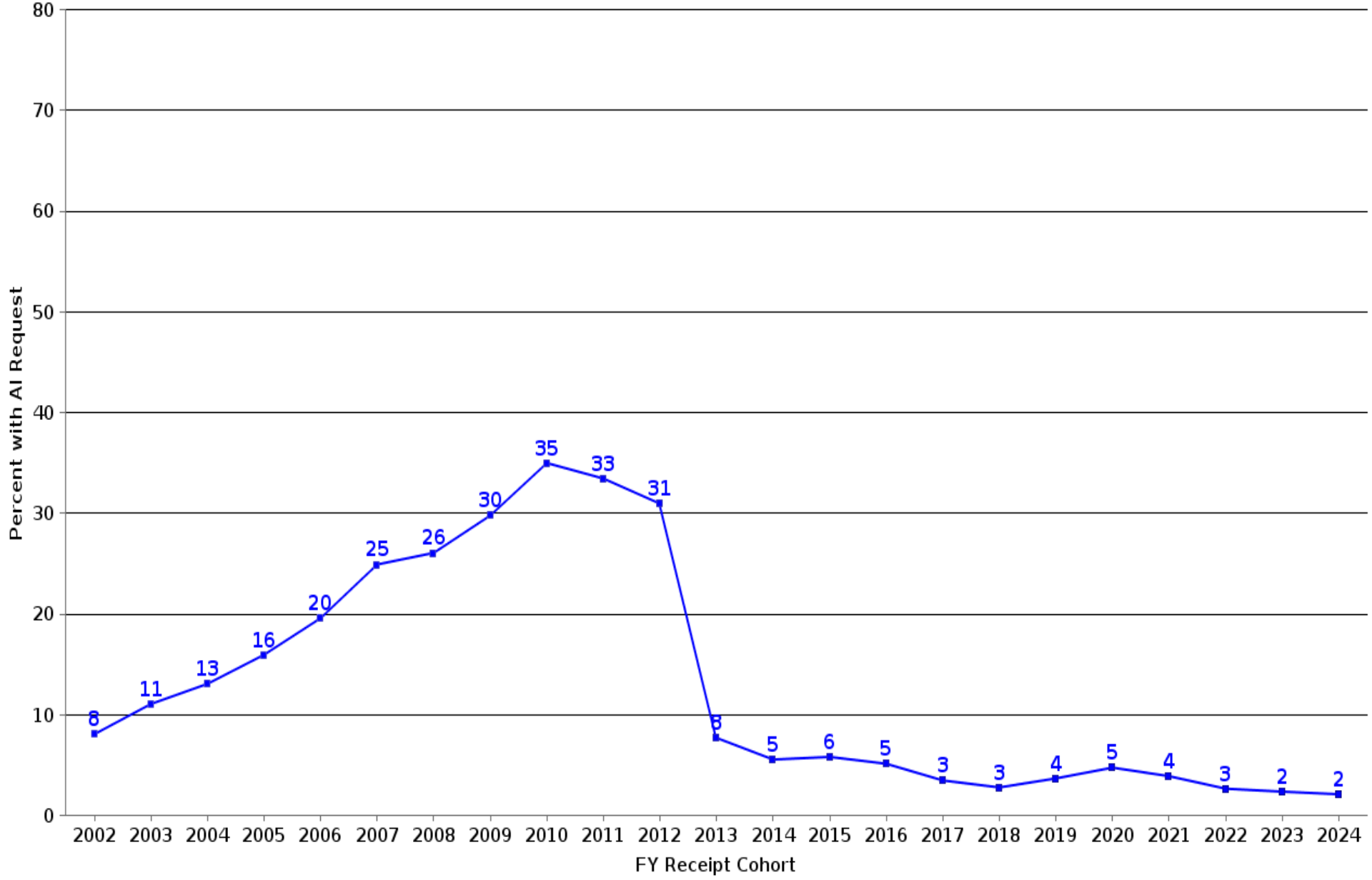
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/24

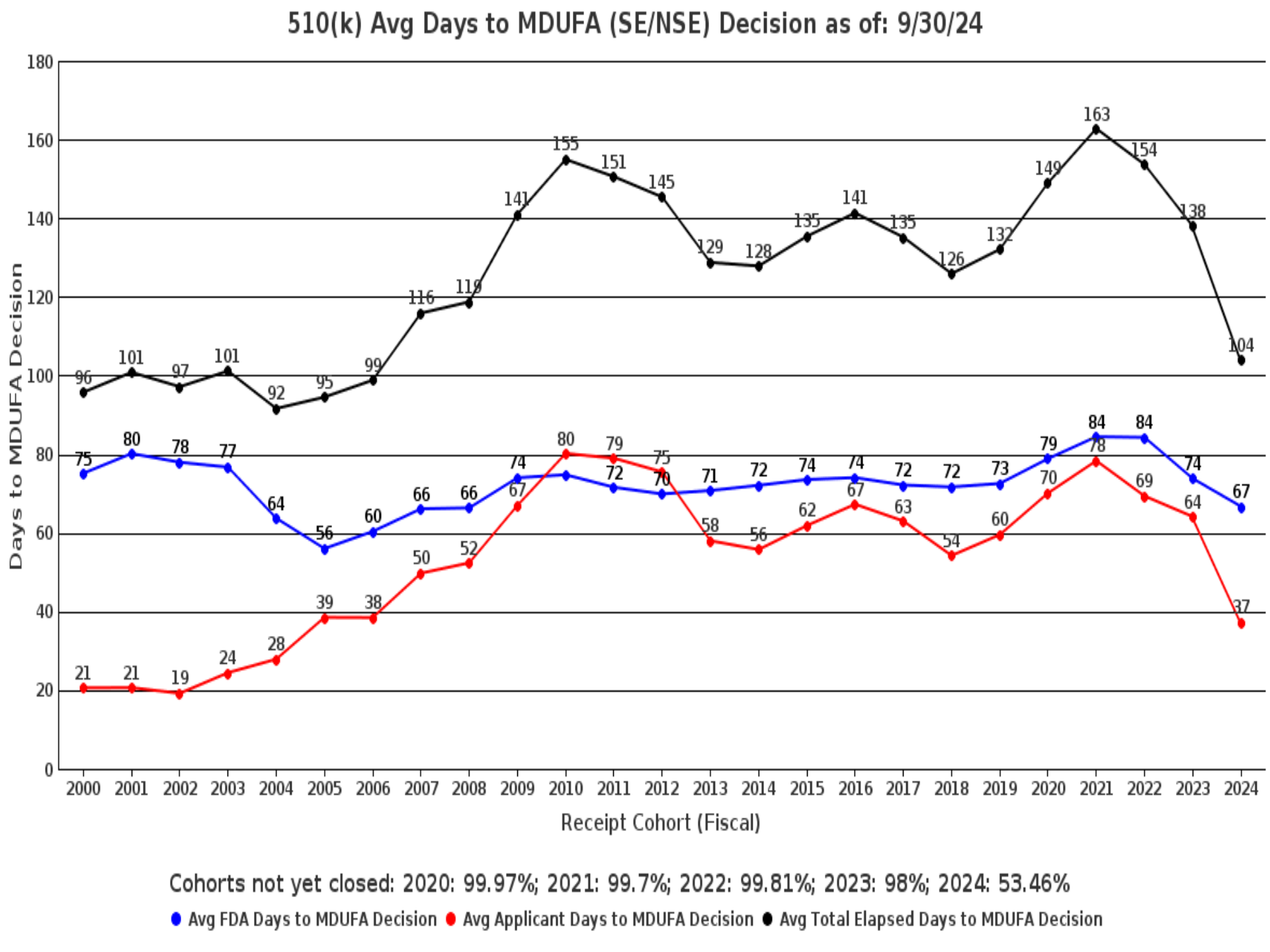
■ % with 1st Cycle AI Request

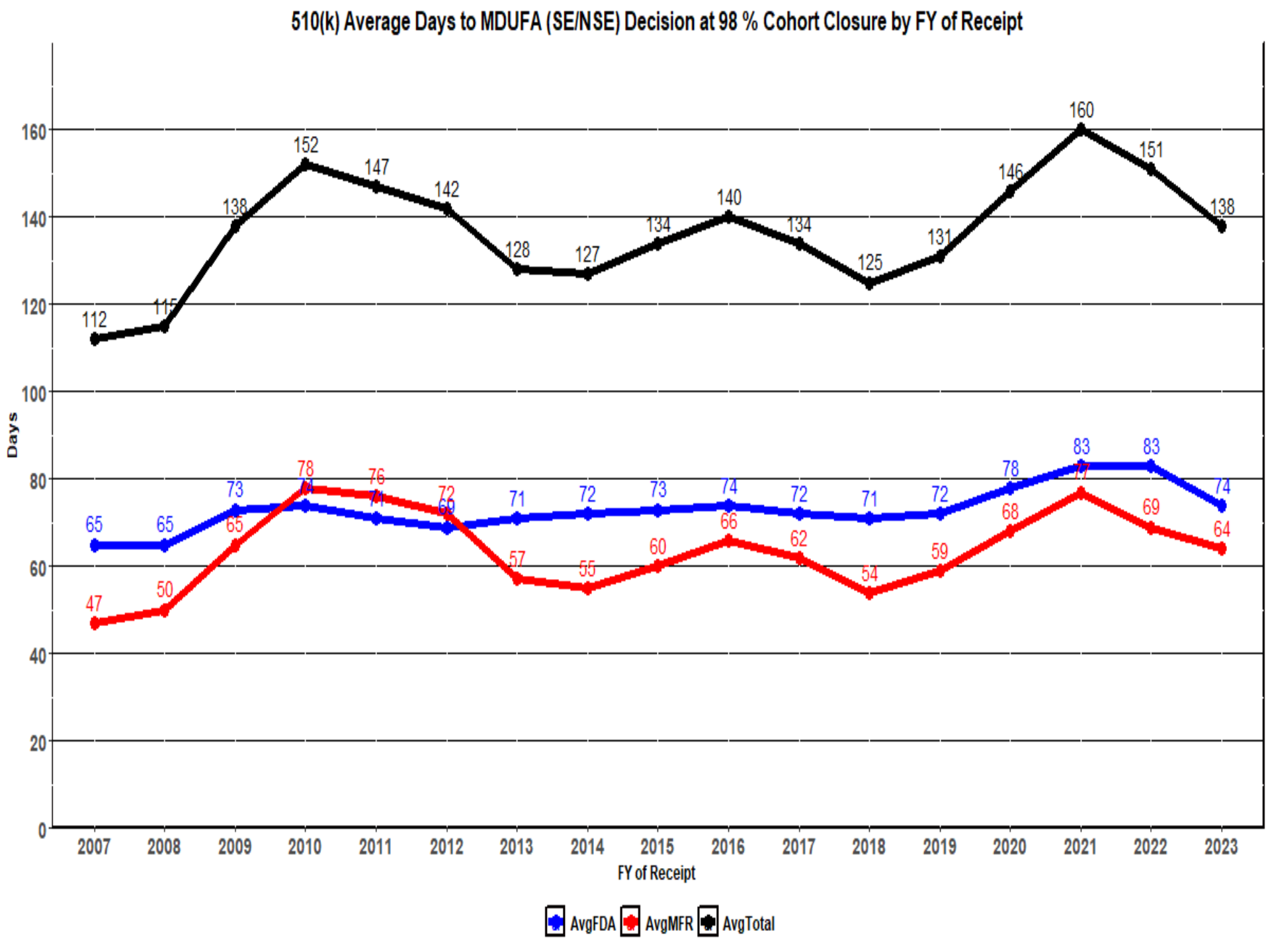
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

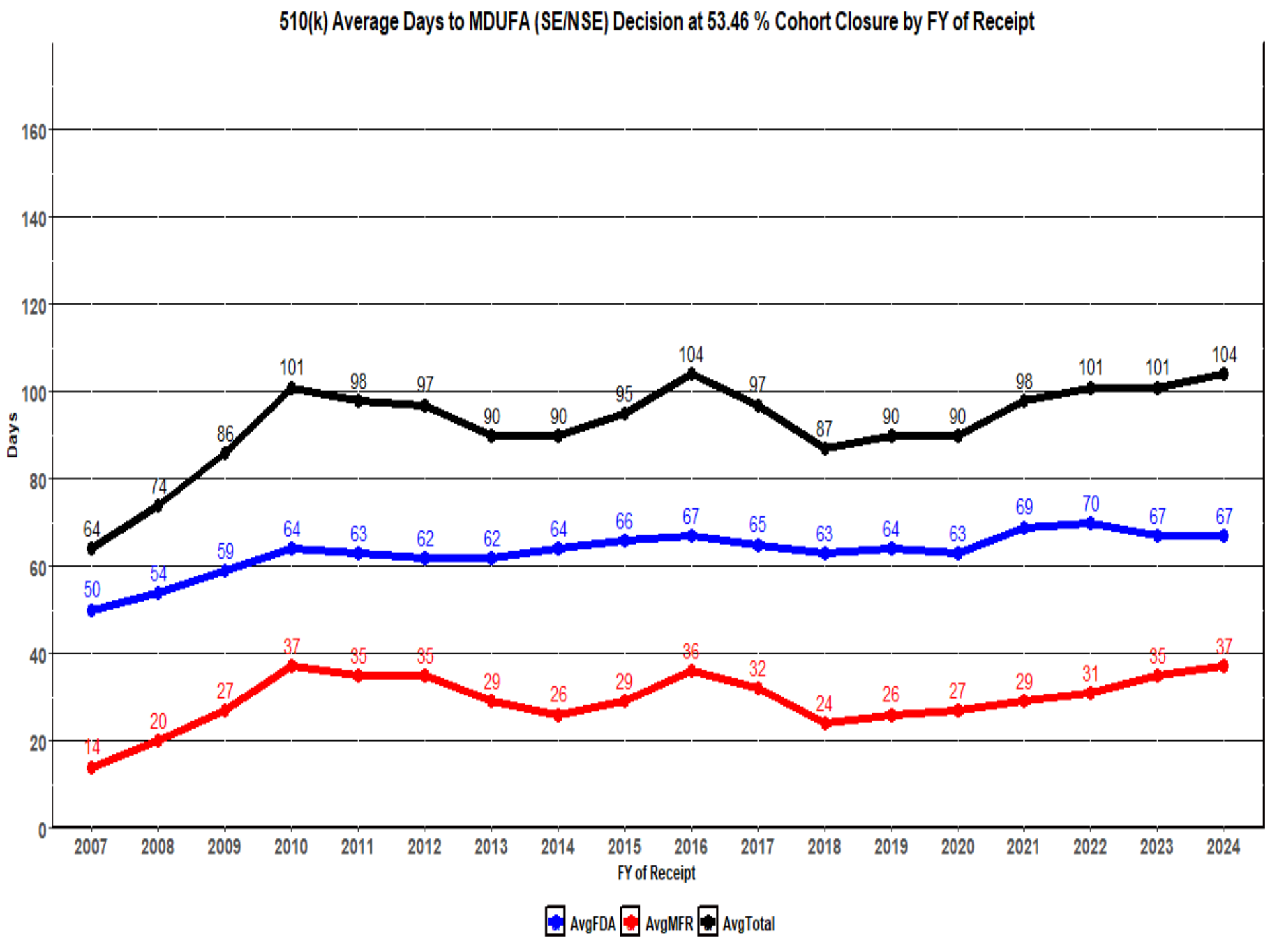


AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 2/29/24

■ % with 2nd Cycle AI Request

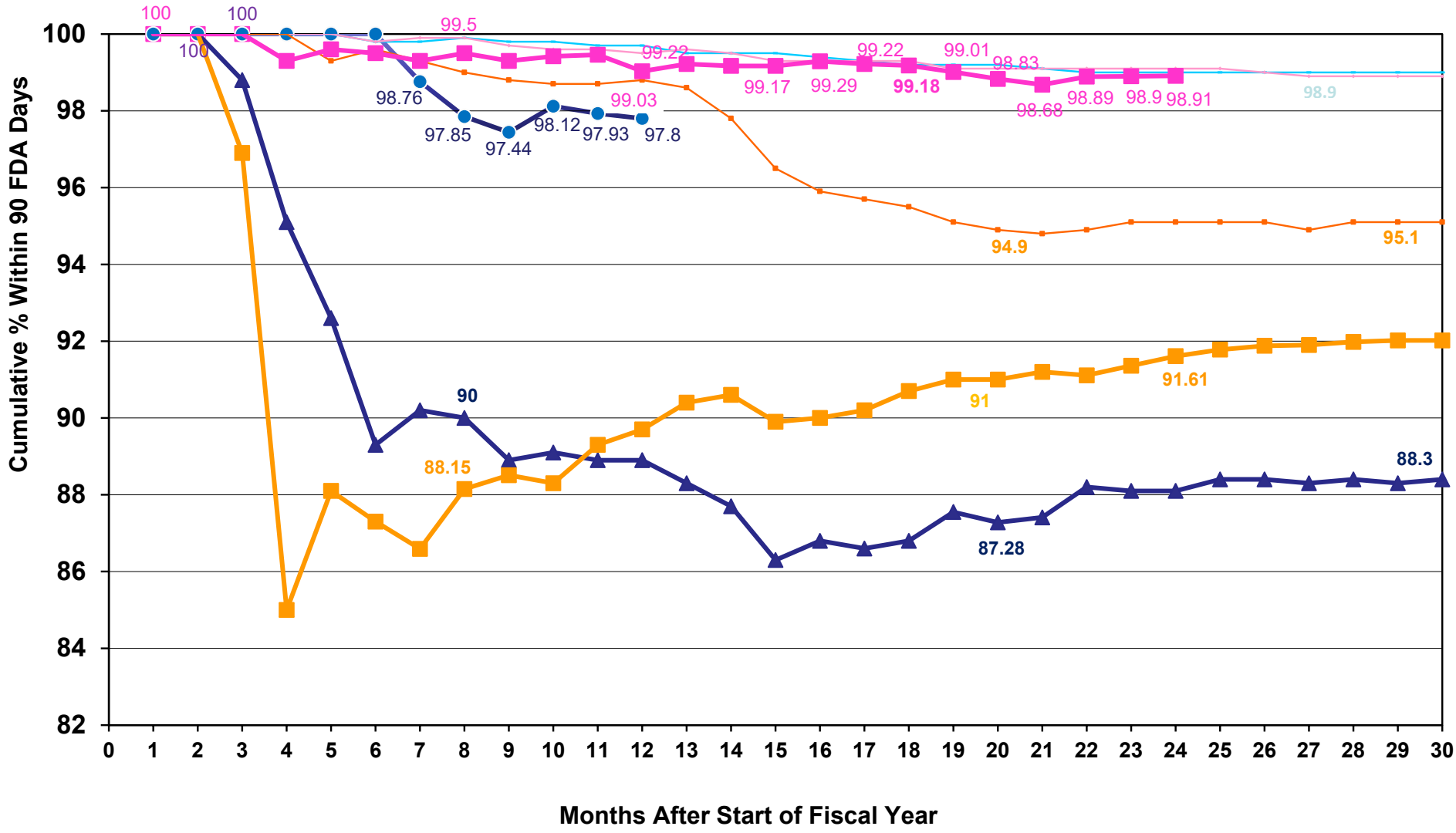

510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 9/30/24
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2020: 99.97%; 2021: 99.7%; 2022: 99.81%; 2023: 98%; 2024: 53.46%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision


510(k) Average Days to MDUFA (SE/NSE) Decision at 98 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
AvgFDA
AvgMFR
AvgTotal
112
115
138
152
147
142
128
127
134
140
134
125
131
146
160
151
138
65
65
73
74
71
69
71
72
73
74
72
71
72
78
83
83
74
47
50
65
78
76
72
57
55
60
66
62
54
59
68
77
69
64

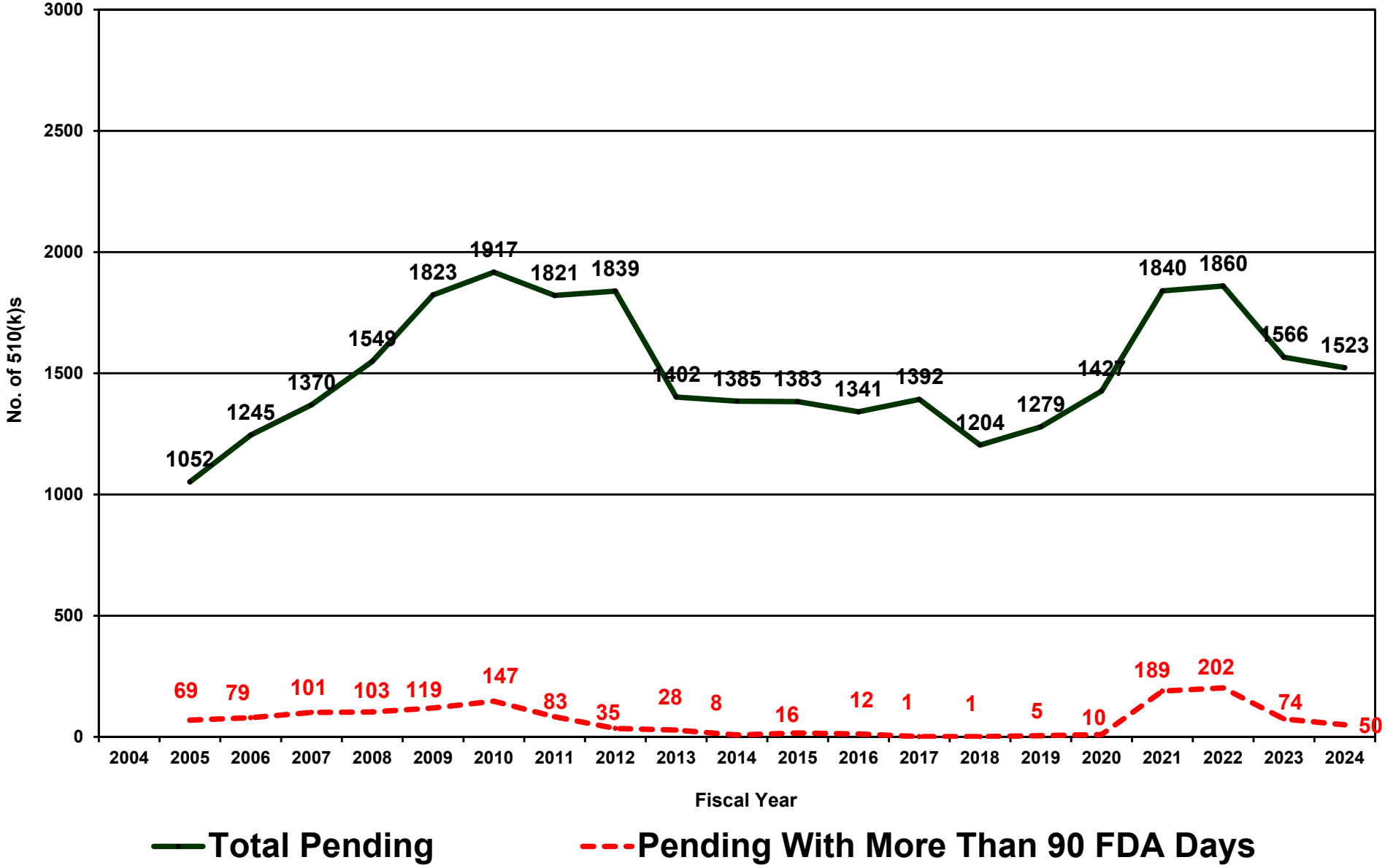

510(k) Average Days to MDUFA (SE/NSE) Decision at 53.46 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
FY of Receipt
64
74
86
101
98
97
90
90
95
104
97
87
90
90
98
101
101
104
50
54
59
64
63
62
62
64
66
67
65
63
64
63
69
70
67
67
14
20
27
37
35
35
29
26
29
36
32
24
26
27
29
31
35
37
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

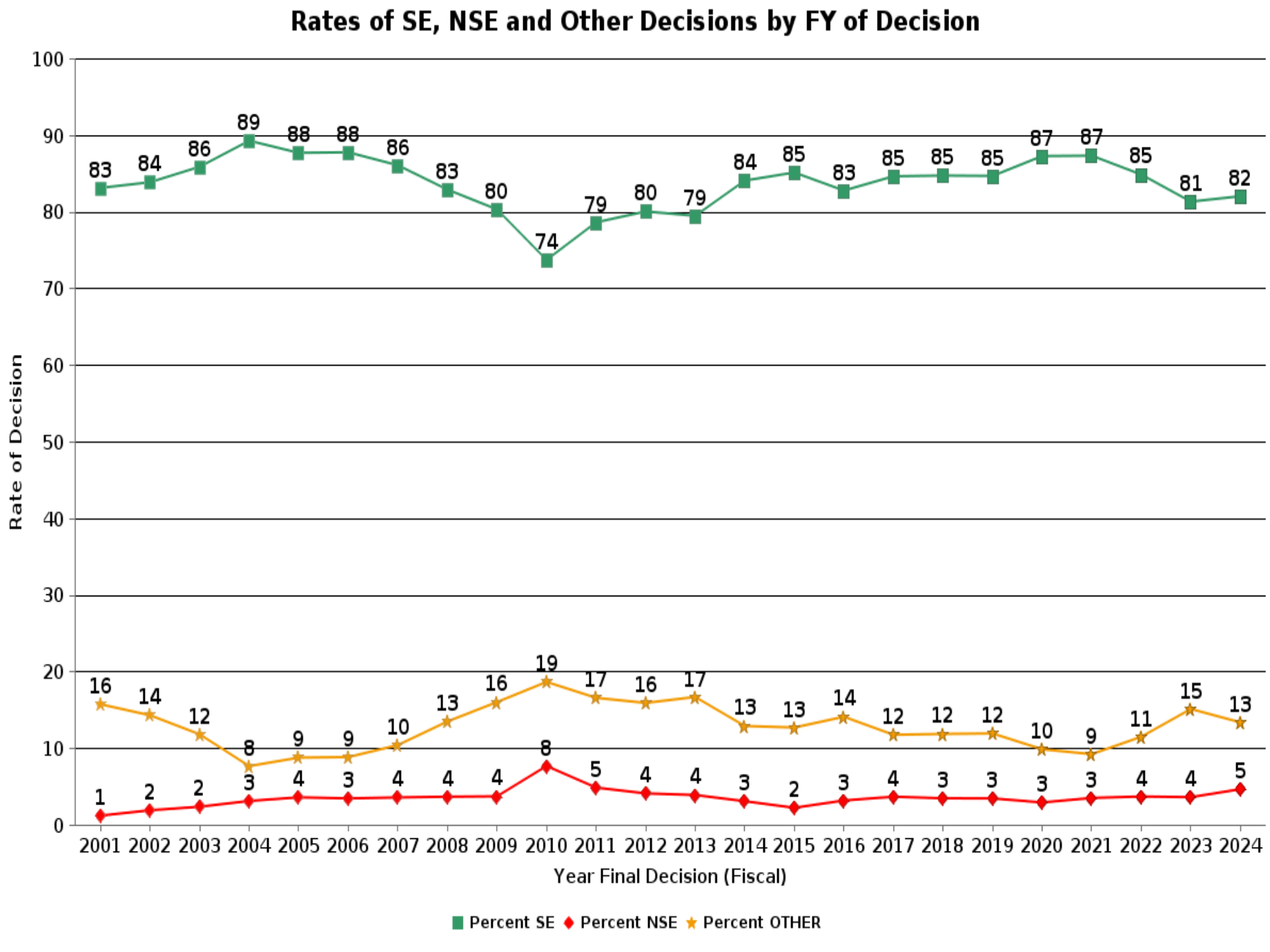
Comparison of FY18 – FY24 Receipt Cohorts



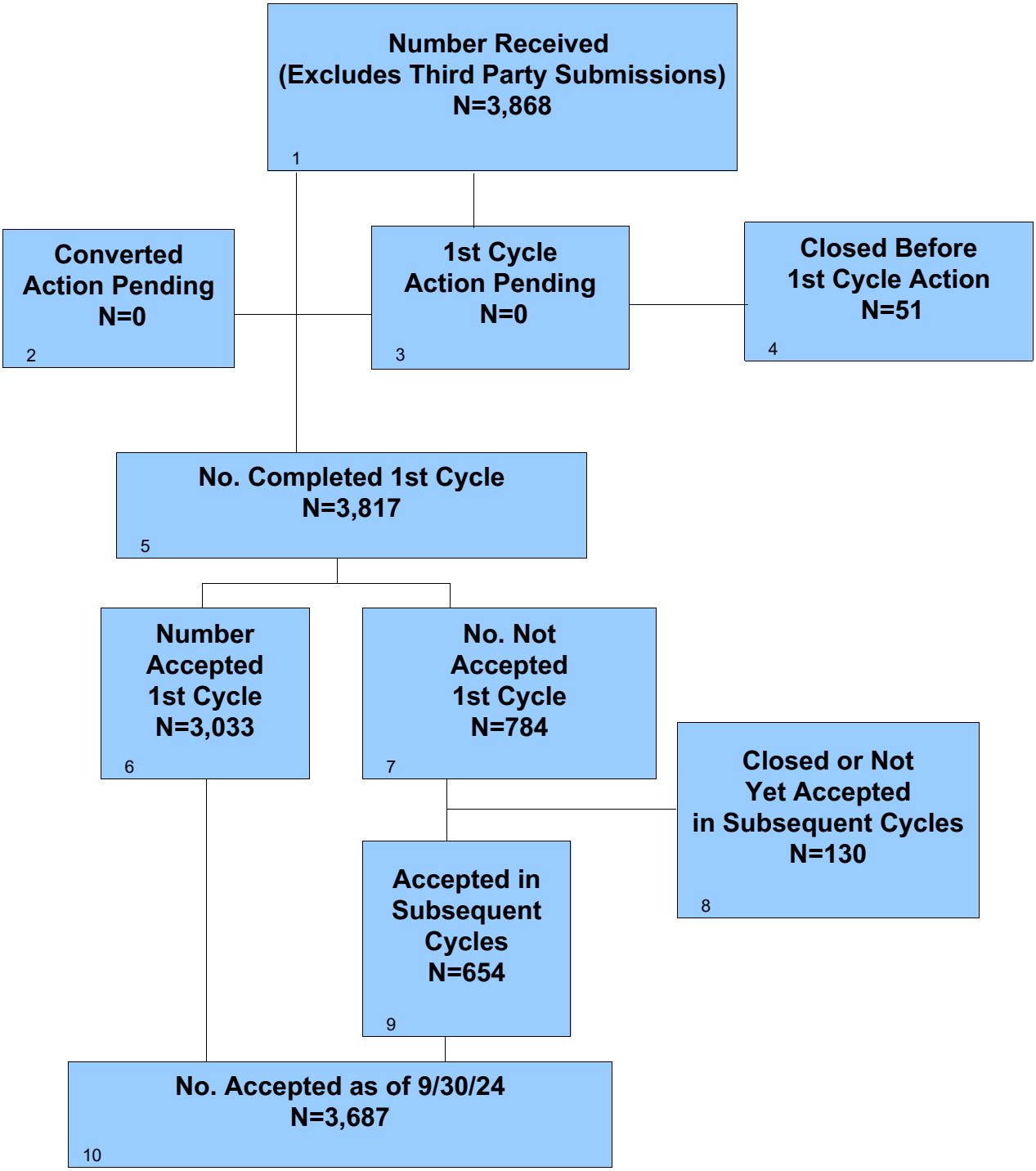
510(k)s Pending at End of Quarter/Year



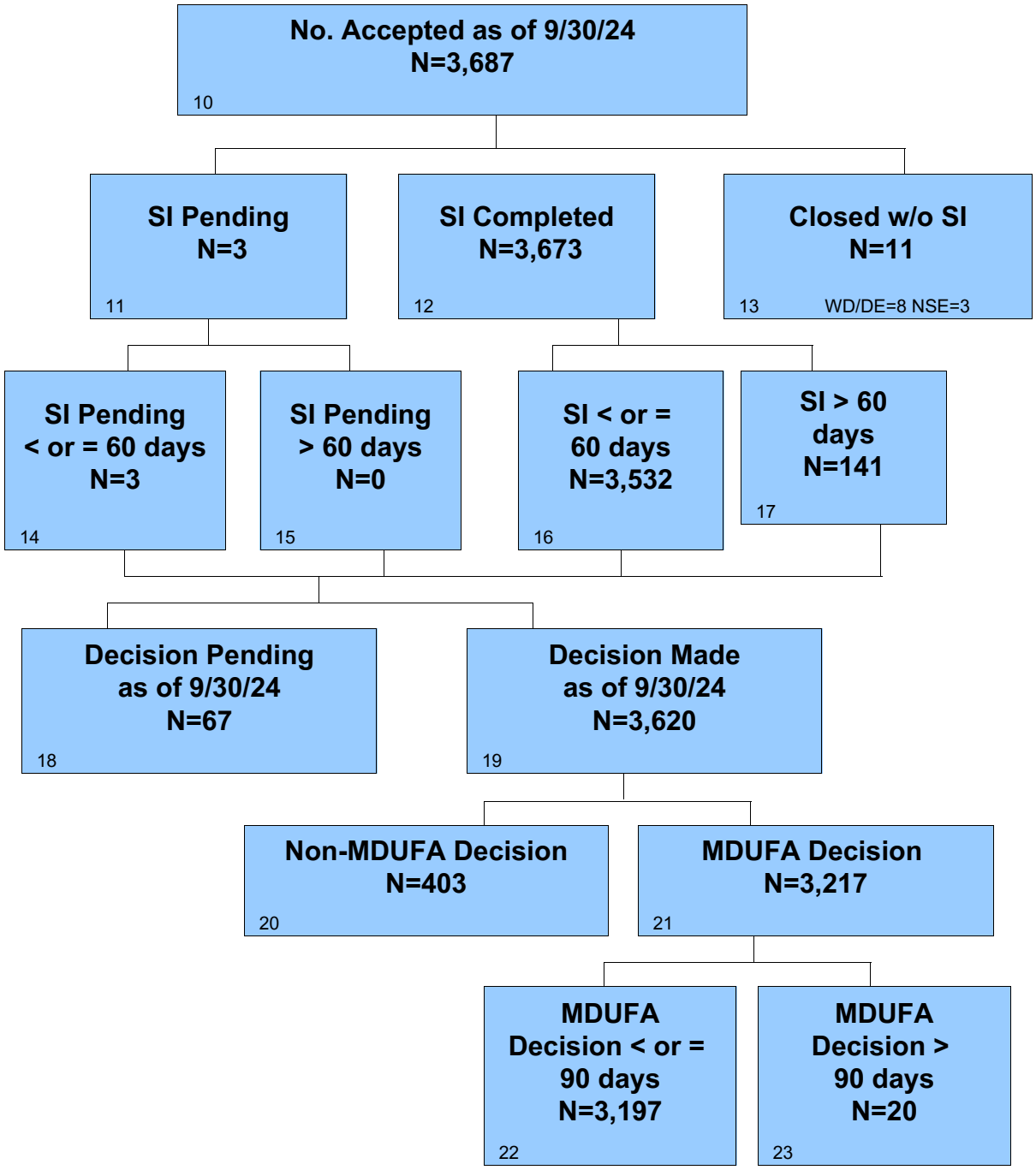
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


Rates of SE, NSE and Other Decisions by FY of Decision
Rate of Decision
100
90
80
70
60
50
40
30
20
10
0
83 84 86 89 88 88 86 83 80 74 79 80 79 84 85 83 85 85 85 87 87 85 81 82
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15 13
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4 4 5
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

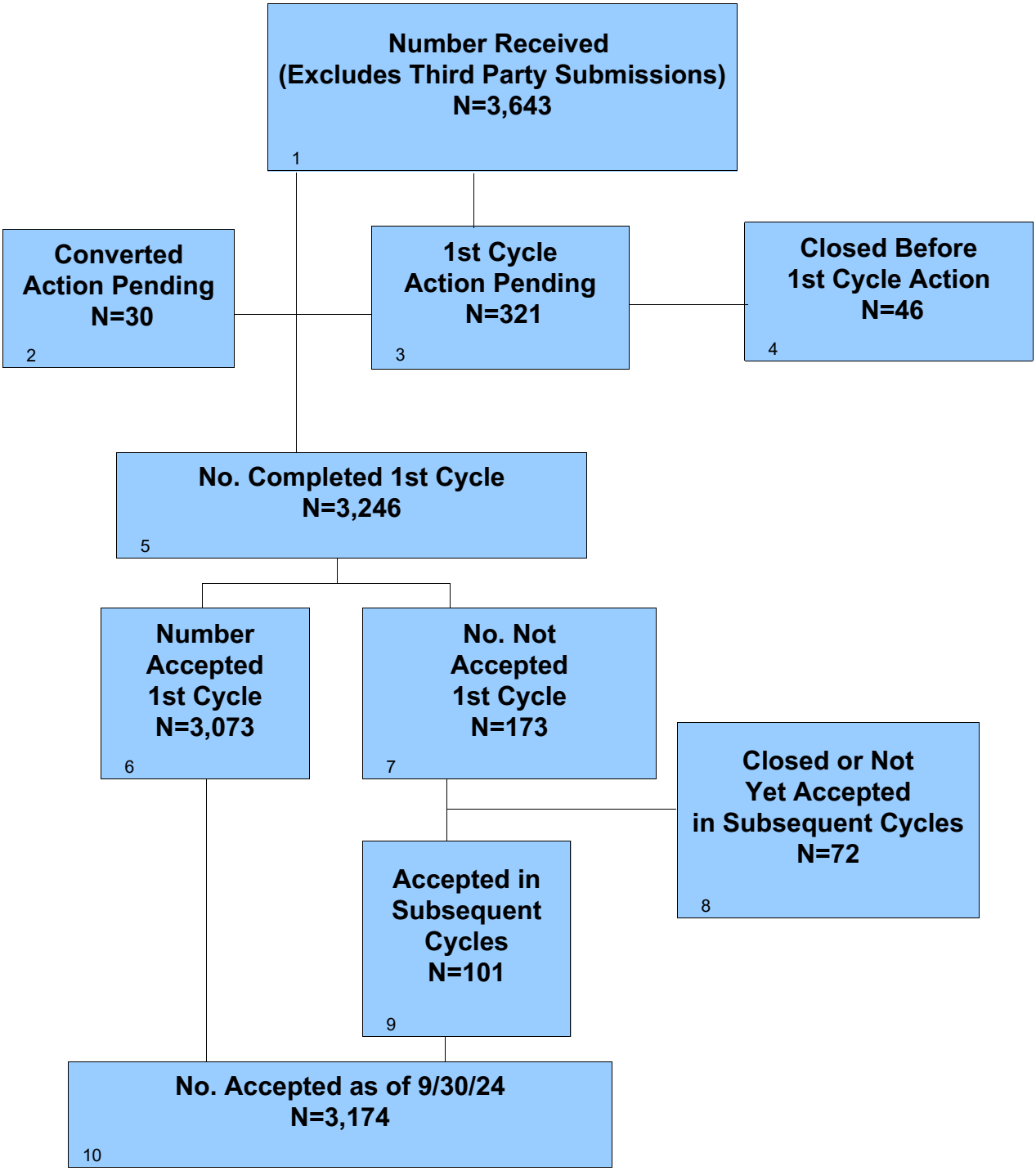
CDRH 510(k)s - FY 2023
as of 9/30/24



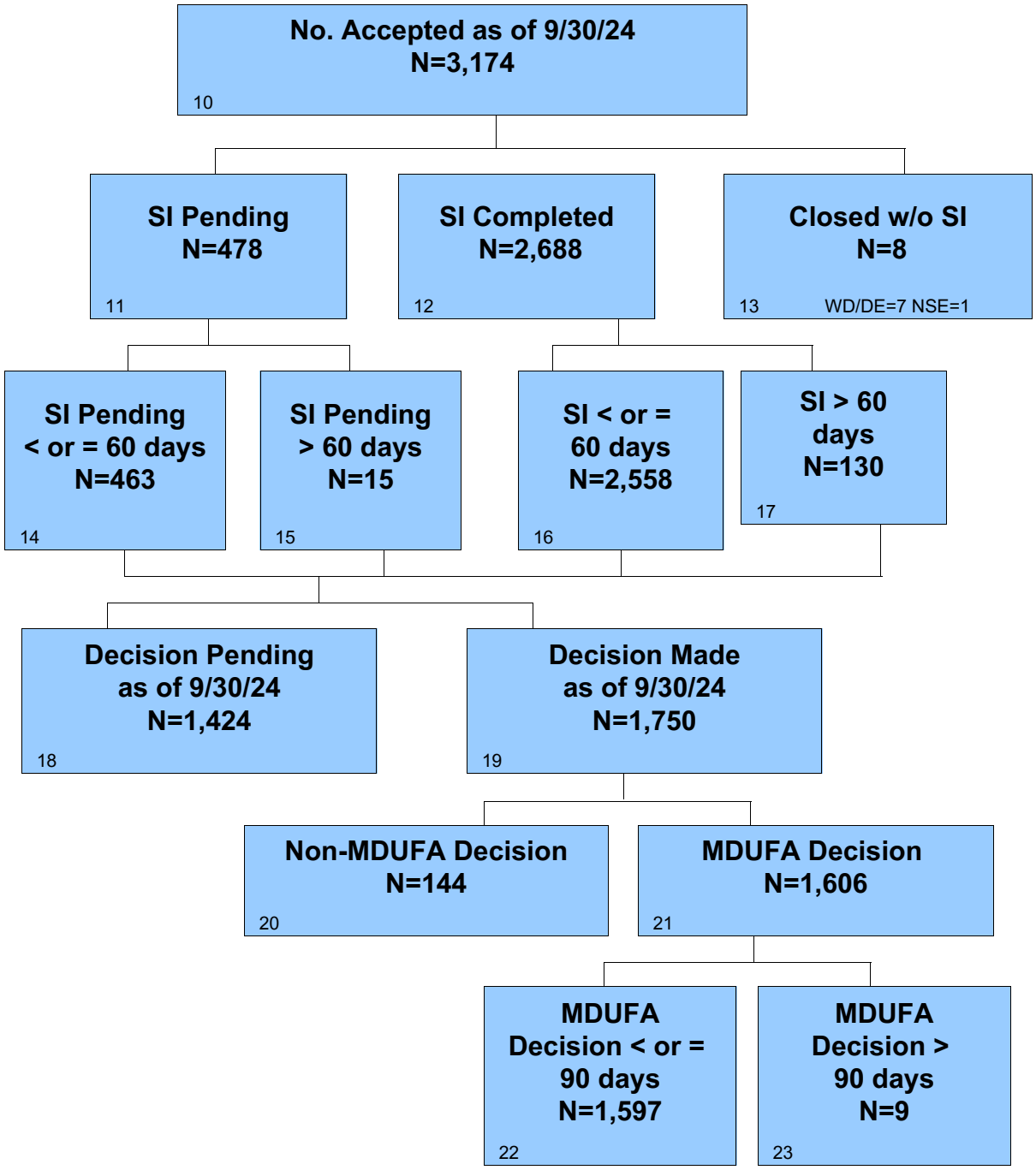
CDRH 510(k)s - FY 2023
as of 9/30/24 Continued



CDRH 510(k)s - FY 2024
as of 9/30/24



CDRH 510(k)s - FY 2024
as of 9/30/24 Continued



Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,868	3,643			
Closed Before First RTA or TS Action [1]	51	46			
Number Accepted or Passed TS on First Cycle [2]	3,015	3,051			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	18	22			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	351			
Number Not Accepted or Failed TS on First Cycle [2]	784	173			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.54%	5.33%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible for SI	3,687	3,174			
Deleted or Withdrawn Prior to SI	8	7			
SI Within 60 FDA Days	3,532	2,558			
SI Over 60 FDA Days	141	130			
SI Pending Within 60 FDA Days	3	463			
SI Pending Over 60 FDA Days	0	15			
510(k)s NSE Without SI	3	1			
Current SI Performance Percent Within 60 FDA Days	96.08%	94.60%			

Table 6.3 CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	3,673	2,688			
Average Number of FDA Days to Substantive Interaction	52.71	52.04			
20th Percentile FDA Days to Substantive Interaction	48	45			
40th Percentile FDA Days to Substantive Interaction	57	56			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	212	95			

Table 6.4 CDRH - 510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	3,687	3,174			
Non-MDUFA V Decision	403	144			
MDUFA V Decision (SE/NSE)	3,217	1,606			
MDUFA V Decision Within 90 FDA Days	3,197	1,597			
510(k)s Pending MDUFA V Decision	67	1,424			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	9	26			
Current Performance Percent Within 90 FDA Days	99.10%	97.86%			

Table 6.5 CDRH - 510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.66	1.51			
Number With MDUFA V Decision	3,217	1,606			
Average Number of FDA Days to MDUFA V Decision	74.73	68.05			
20th Percentile FDA Days to MDUFA V Decision	57	30			
40th Percentile FDA Days to MDUFA V Decision	84	66			
60th Percentile FDA Days to MDUFA V Decision	88	87			
80th Percentile FDA Days to MDUFA V Decision	90	89			
Maximum FDA Days to MDUFA V Decision	276	120			
Average Number of Industry Days to MDUFA V Decision	65.15	38.15			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	14	0			
60th Percentile Industry Days to MDUFA V Decision	67	23			
80th Percentile Industry Days to MDUFA V Decision	149	81			
Maximum Industry Days to MDUFA V Decision	367	210			
Average Number of Total Days to MDUFA V Decision	139.71	106.24			
20th Percentile Total Days to MDUFA V Decision	59	32			
40th Percentile Total Days to MDUFA V Decision	96	80			
60th Percentile Total Days to MDUFA V Decision	153	107			
80th Percentile Total Days to MDUFA V Decision	234	167			
Maximum Total Days to MDUFA V Decision	517	300			

Table 6.6 CDRH - 510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	3,687	3,174			
Number With MDUFA V Decision	3,217	1,606			
Number of SE Decision	3,078	1,554			
Number of NSE Decision	139	52			
Number of Withdrawal	216	84			
Number of Deleted	179	54			
Rate of SE Decision	95.68%	96.76%			
Rate of NSE Decision	4.32%	3.24%			
Rate of Withdrawal	5.86%	2.65%			
Rate of Deleted	4.85%	1.70%			

Table 6.7 CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	20	9			
Mean FDA Days for Submissions that Missed the Goal	124.45	98.67			
Mean Industry Days for Submissions that Missed the Goal	129.15	88.33			

Table 6.8 CDRH - LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	2	2			
MDUFA V Decision Within 90 FDA Days	2	2			
510(k)s Pending MDUFA V Decision	0	2			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.9 CDRH - Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	218			
Non-MDUFA V Decision	50	18			
MDUFA V Decision (SE/NSE)	215	99			
MDUFA V Decision Within 90 FDA Days	215	99			
510(k)s Pending MDUFA V Decision	4	101			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Section 6 510(k) Office Level Metric (Excludes Third Party Review)

Table 6.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	580	546			
Closed Before First RTA or TS Action [1]	8	8			
Number Accepted or Passed TS on First Cycle [2]	315	429			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	3			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	55			
Number Not Accepted or Failed TS on First Cycle [2]	254	51			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.41%	10.56%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	531	462			
Deleted or Withdrawn Prior to SI	2	1			
SI Within 60 FDA Days	421	301			
SI Over 60 FDA Days	105	81			
SI Pending Within 60 FDA Days	2	78			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	79.89%	78.59%			

Table 6.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	526	382			
Average Number of FDA Days to Substantive Interaction	56.94	55.85			
20th Percentile FDA Days to Substantive Interaction	55	52			
40th Percentile FDA Days to Substantive Interaction	58	58			
60th Percentile FDA Days to Substantive Interaction	60	60			
80th Percentile FDA Days to Substantive Interaction	60	61			
Maximum FDA Days to Substantive Interaction	212	80			

Table 6.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	531	462			
Non-MDUFA V Decision	75	19			
MDUFA V Decision (SE/NSE)	435	200			
MDUFA V Decision Within 90 FDA Days	426	197			
510(k)s Pending MDUFA V Decision	21	243			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2	4			
Current Performance Percent Within 90 FDA Days	97.48%	96.57%			

Table 6.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.76	1.64			
Number With MDUFA V Decision	435	200			
Average Number of FDA Days to MDUFA V Decision	82.91	78.13			
20th Percentile FDA Days to MDUFA V Decision	82	60			
40th Percentile FDA Days to MDUFA V Decision	88	87			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	90			
Maximum FDA Days to MDUFA V Decision	276	120			
Average Number of Industry Days to MDUFA V Decision	74.96	52.22			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	37	11			
60th Percentile Industry Days to MDUFA V Decision	84	47			
80th Percentile Industry Days to MDUFA V Decision	158	106			
Maximum Industry Days to MDUFA V Decision	353	181			
Average Number of Total Days to MDUFA V Decision	157.67	130.34			
20th Percentile Total Days to MDUFA V Decision	87	69			
40th Percentile Total Days to MDUFA V Decision	125	98			
60th Percentile Total Days to MDUFA V Decision	174	134			
80th Percentile Total Days to MDUFA V Decision	246	195			
Maximum Total Days to MDUFA V Decision	443	271			

Table 6.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	531	462			
Number With MDUFA V Decision	435	200			
Number of SE Decision	400	192			
Number of NSE Decision	35	8			
Number of Withdrawal	38	10			
Number of Deleted	36	8			
Rate of SE Decision	91.95%	96.00%			
Rate of NSE Decision	8.05%	4.00%			
Rate of Withdrawal	7.16%	2.16%			
Rate of Deleted	6.78%	1.73%			

Table 6.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	9	3			
Mean FDA Days for Submissions that Missed the Goal	148.78	103.33			
Mean Industry Days for Submissions that Missed the Goal	120.78	99.00			

Table 6.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.1 OHT2 - Office of Cardiovascular Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	380	387			
Closed Before First RTA or TS Action [1]	8	4			
Number Accepted or Passed TS on First Cycle [2]	333	329			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	6			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	40			
Number Not Accepted or Failed TS on First Cycle [2]	38	8			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.22%	2.33%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT2 - Office of Cardiovascular Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	366	342			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	356	279			
SI Over 60 FDA Days	10	21			
SI Pending Within 60 FDA Days	0	38			
SI Pending Over 60 FDA Days	0	4			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.27%	91.78%			

Table 6.3 OHT2 - Office of Cardiovascular Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	366	300			
Average Number of FDA Days to Substantive Interaction	51.42	50.96			
20th Percentile FDA Days to Substantive Interaction	44	30			
40th Percentile FDA Days to Substantive Interaction	56	56			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	85			

Table 6.4 OHT2 - Office of Cardiovascular Devices
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	366	342			
Non-MDUFA V Decision	33	17			
MDUFA V Decision (SE/NSE)	330	183			
MDUFA V Decision Within 90 FDA Days	326	181			
510(k)s Pending MDUFA V Decision	3	142			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	2			
Current Performance Percent Within 90 FDA Days	98.49%	97.84%			

Table 6.5 OHT2 - Office of Cardiovascular Devices
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.71	1.57			
Number With MDUFA V Decision	330	183			
Average Number of FDA Days to MDUFA V Decision	73.34	65.52			
20th Percentile FDA Days to MDUFA V Decision	55	30			
40th Percentile FDA Days to MDUFA V Decision	84	58			
60th Percentile FDA Days to MDUFA V Decision	88	88			
80th Percentile FDA Days to MDUFA V Decision	90	89			
Maximum FDA Days to MDUFA V Decision	95	103			
Average Number of Industry Days to MDUFA V Decision	71.13	46.31			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	27	0			
60th Percentile Industry Days to MDUFA V Decision	78	41			
80th Percentile Industry Days to MDUFA V Decision	155	99			
Maximum Industry Days to MDUFA V Decision	360	210			
Average Number of Total Days to MDUFA V Decision	144.34	111.84			
20th Percentile Total Days to MDUFA V Decision	57	30			
40th Percentile Total Days to MDUFA V Decision	107	69			
60th Percentile Total Days to MDUFA V Decision	162	121			
80th Percentile Total Days to MDUFA V Decision	238	184			
Maximum Total Days to MDUFA V Decision	448	300			

Table 6.6 OHT2 - Office of Cardiovascular Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	366	342			
Number With MDUFA V Decision	330	183			
Number of SE Decision	307	174			
Number of NSE Decision	23	9			
Number of Withdrawal	16	12			
Number of Deleted	17	3			
Rate of SE Decision	93.03%	95.08%			
Rate of NSE Decision	6.97%	4.92%			
Rate of Withdrawal	4.37%	3.51%			
Rate of Deleted	4.64%	0.88%			

Table 6.7 OHT2 - Office of Cardiovascular Devices
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	2			
Mean FDA Days for Submissions that Missed the Goal	92.75	101.50			
Mean Industry Days for Submissions that Missed the Goal	82.50	87.50			

Table 6.8 OHT2 - Office of Cardiovascular Devices
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT2 - Office of Cardiovascular Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	480	469			
Closed Before First RTA or TS Action [1]	5	10			
Number Accepted or Passed TS on First Cycle [2]	391	391			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	2			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	50			
Number Not Accepted or Failed TS on First Cycle [2]	82	16			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	17.26%	3.91%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	462	401			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	451	343			
SI Over 60 FDA Days	10	0			
SI Pending Within 60 FDA Days	0	56			
SI Pending Over 60 FDA Days	0	2			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.83%	99.42%			

Table 6.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	461	343			
Average Number of FDA Days to Substantive Interaction	54.95	52.19			
20th Percentile FDA Days to Substantive Interaction	55	45			
40th Percentile FDA Days to Substantive Interaction	58	57			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	77	60			

Table 6.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	462	401			
Non-MDUFA V Decision	51	21			
MDUFA V Decision (SE/NSE)	403	174			
MDUFA V Decision Within 90 FDA Days	402	173			
510(k)s Pending MDUFA V Decision	8	206			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	8			
Current Performance Percent Within 90 FDA Days	99.01%	95.05%			

Table 6.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.78	1.60			
Number With MDUFA V Decision	403	174			
Average Number of FDA Days to MDUFA V Decision	79.89	68.87			
20th Percentile FDA Days to MDUFA V Decision	79	30			
40th Percentile FDA Days to MDUFA V Decision	88	76			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	90			
Maximum FDA Days to MDUFA V Decision	93	91			
Average Number of Industry Days to MDUFA V Decision	85.22	44.60			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	47	1			
60th Percentile Industry Days to MDUFA V Decision	106	41			
80th Percentile Industry Days to MDUFA V Decision	172	102			
Maximum Industry Days to MDUFA V Decision	354	180			
Average Number of Total Days to MDUFA V Decision	164.74	113.48			
20th Percentile Total Days to MDUFA V Decision	87	30			
40th Percentile Total Days to MDUFA V Decision	132	89			
60th Percentile Total Days to MDUFA V Decision	192	122			
80th Percentile Total Days to MDUFA V Decision	259	191			
Maximum Total Days to MDUFA V Decision	443	267			

Table 6.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	462	401			
Number With MDUFA V Decision	403	174			
Number of SE Decision	379	165			
Number of NSE Decision	24	9			
Number of Withdrawal	23	11			
Number of Deleted	27	8			
Rate of SE Decision	94.04%	94.83%			
Rate of NSE Decision	5.96%	5.17%			
Rate of Withdrawal	4.98%	2.74%			
Rate of Deleted	5.84%	2.00%			

Table 6.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1			
Mean FDA Days for Submissions that Missed the Goal	93.00	91.00			
Mean Industry Days for Submissions that Missed the Goal	192.00	42.00			

Table 6.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.1 OHT4 - Office of Surgical and Infection Control Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	712	641			
Closed Before First RTA or TS Action [1]	10	5			
Number Accepted or Passed TS on First Cycle [2]	561	525			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	7			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	71			
Number Not Accepted or Failed TS on First Cycle [2]	140	33			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	19.94%	5.84%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT4 - Office of Surgical and Infection Control Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	679	548			
Deleted or Withdrawn Prior to SI	1	1			
SI Within 60 FDA Days	672	458			
SI Over 60 FDA Days	5	9			
SI Pending Within 60 FDA Days	1	72			
SI Pending Over 60 FDA Days	0	7			
510(k)s NSE Without SI	0	1			
Current SI Performance Percent Within 60 FDA Days	99.26%	96.42%			

Table 6.3 OHT4 - Office of Surgical and Infection Control Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	677	467			
Average Number of FDA Days to Substantive Interaction	52.62	52.15			
20th Percentile FDA Days to Substantive Interaction	49	47			
40th Percentile FDA Days to Substantive Interaction	56	57			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	122	63			

Table 6.4 OHT4 - Office of Surgical and Infection Control Devices
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	679	548			
Non-MDUFA V Decision	86	26			
MDUFA V Decision (SE/NSE)	579	303			
MDUFA V Decision Within 90 FDA Days	577	303			
510(k)s Pending MDUFA V Decision	14	219			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	8			
Current Performance Percent Within 90 FDA Days	99.14%	97.43%			

Table 6.5 OHT4 - Office of Surgical and Infection Control Devices
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.61	1.44			
Number With MDUFA V Decision	579	303			
Average Number of FDA Days to MDUFA V Decision	75.02	68.07			
20th Percentile FDA Days to MDUFA V Decision	58	38			
40th Percentile FDA Days to MDUFA V Decision	83	63			
60th Percentile FDA Days to MDUFA V Decision	87	87			
80th Percentile FDA Days to MDUFA V Decision	89	89			
Maximum FDA Days to MDUFA V Decision	101	90			
Average Number of Industry Days to MDUFA V Decision	53.82	28.72			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	44	8			
80th Percentile Industry Days to MDUFA V Decision	115	50			
Maximum Industry Days to MDUFA V Decision	359	180			
Average Number of Total Days to MDUFA V Decision	128.94	96.79			
20th Percentile Total Days to MDUFA V Decision	59	42			
40th Percentile Total Days to MDUFA V Decision	88	74			
60th Percentile Total Days to MDUFA V Decision	126	91			
80th Percentile Total Days to MDUFA V Decision	198	138			
Maximum Total Days to MDUFA V Decision	449	270			

Table 6.6 OHT4 - Office of Surgical and Infection Control Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	679	548			
Number With MDUFA V Decision	579	303			
Number of SE Decision	563	300			
Number of NSE Decision	16	3			
Number of Withdrawal	50	13			
Number of Deleted	36	12			
Rate of SE Decision	97.24%	99.01%			
Rate of NSE Decision	2.76%	0.99%			
Rate of Withdrawal	7.36%	2.37%			
Rate of Deleted	5.30%	2.19%			

Table 6.7 OHT4 - Office of Surgical and Infection Control Devices
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions that Missed the Goal	96.50	N/A			
Mean Industry Days for Submissions that Missed the Goal	59.50	N/A			

Table 6.8 OHT4 - Office of Surgical and Infection Control Devices
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT4 - Office of Surgical and Infection Control Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.1 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	314	308			
Closed Before First RTA or TS Action [1]	3	3			
Number Accepted or Passed TS on First Cycle [2]	214	255			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	1			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	23			
Number Not Accepted or Failed TS on First Cycle [2]	96	26			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	30.87%	9.22%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	297	276			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	286	205			
SI Over 60 FDA Days	11	18			
SI Pending Within 60 FDA Days	0	52			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.30%	91.52%			

Table 6.3 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	297	223			
Average Number of FDA Days to Substantive Interaction	54.65	54.83			
20th Percentile FDA Days to Substantive Interaction	56	52			
40th Percentile FDA Days to Substantive Interaction	58	58			
60th Percentile FDA Days to Substantive Interaction	60	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	80	95			

Table 6.4 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	297	276			
Non-MDUFA V Decision	27	10			
MDUFA V Decision (SE/NSE)	256	124			
MDUFA V Decision Within 90 FDA Days	252	121			
510(k)s Pending MDUFA V Decision	14	142			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	4			
Current Performance Percent Within 90 FDA Days	98.44%	94.53%			

Table 6.5 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.73	1.60			
Number With MDUFA V Decision	256	124			
Average Number of FDA Days to MDUFA V Decision	77.67	72.38			
20th Percentile FDA Days to MDUFA V Decision	59	54			
40th Percentile FDA Days to MDUFA V Decision	87	76			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	90			
Maximum FDA Days to MDUFA V Decision	150	101			
Average Number of Industry Days to MDUFA V Decision	74.08	46.19			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	32	1			
60th Percentile Industry Days to MDUFA V Decision	81	35			
80th Percentile Industry Days to MDUFA V Decision	163	96			
Maximum Industry Days to MDUFA V Decision	367	190			
Average Number of Total Days to MDUFA V Decision	151.13	118.56			
20th Percentile Total Days to MDUFA V Decision	60	55			
40th Percentile Total Days to MDUFA V Decision	114	89			
60th Percentile Total Days to MDUFA V Decision	165	123			
80th Percentile Total Days to MDUFA V Decision	248	185			
Maximum Total Days to MDUFA V Decision	517	280			

Table 6.6 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	297	276			
Number With MDUFA V Decision	256	124			
Number of SE Decision	240	113			
Number of NSE Decision	16	11			
Number of Withdrawal	9	3			
Number of Deleted	15	7			
Rate of SE Decision	93.75%	91.13%			
Rate of NSE Decision	6.25%	8.87%			
Rate of Withdrawal	3.03%	1.09%			
Rate of Deleted	5.05%	2.54%			

Table 6.7 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	3			
Mean FDA Days for Submissions that Missed the Goal	123.25	94.67			
Mean Industry Days for Submissions that Missed the Goal	213.75	93.67			

Table 6.8 OHT5 - Office of Neurological and Physical Medicine Devices
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.1 OHT6 - Office of Orthopedic Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	619	569			
Closed Before First RTA or TS Action [1]	6	3			
Number Accepted or Passed TS on First Cycle [2]	517	493			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	56			
Number Not Accepted or Failed TS on First Cycle [2]	93	17			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.17%	3.33%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT6 - Office of Orthopedic Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	605	503			
Deleted or Withdrawn Prior to SI	1	2			
SI Within 60 FDA Days	604	429			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	72			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%			

Table 6.3 OHT6 - Office of Orthopedic Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	604	429			
Average Number of FDA Days to Substantive Interaction	49.84	49.46			
20th Percentile FDA Days to Substantive Interaction	30	30			
40th Percentile FDA Days to Substantive Interaction	56	55			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	60	60			

Table 6.4 OHT6 - Office of Orthopedic Devices
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	605	503			
Non-MDUFA V Decision	50	15			
MDUFA V Decision (SE/NSE)	552	309			
MDUFA V Decision Within 90 FDA Days	552	309			
510(k)s Pending MDUFA V Decision	3	179			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.5 OHT6 - Office of Orthopedic Devices
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48	1.32			
Number With MDUFA V Decision	552	309			
Average Number of FDA Days to MDUFA V Decision	65.74	59.70			
20th Percentile FDA Days to MDUFA V Decision	30	29			
40th Percentile FDA Days to MDUFA V Decision	59	55			
60th Percentile FDA Days to MDUFA V Decision	85	77			
80th Percentile FDA Days to MDUFA V Decision	89	88			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	42.42	20.43			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	16	0			
80th Percentile Industry Days to MDUFA V Decision	92	22			
Maximum Industry Days to MDUFA V Decision	354	188			
Average Number of Total Days to MDUFA V Decision	108.07	80.31			
20th Percentile Total Days to MDUFA V Decision	30	29			
40th Percentile Total Days to MDUFA V Decision	60	56			
60th Percentile Total Days to MDUFA V Decision	98	84			
80th Percentile Total Days to MDUFA V Decision	177	111			
Maximum Total Days to MDUFA V Decision	443	287			

Table 6.6 OHT6 - Office of Orthopedic Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	605	503			
Number With MDUFA V Decision	552	309			
Number of SE Decision	542	307			
Number of NSE Decision	10	2			
Number of Withdrawal	37	12			
Number of Deleted	11	3			
Rate of SE Decision	98.19%	99.35%			
Rate of NSE Decision	1.81%	0.65%			
Rate of Withdrawal	6.12%	2.39%			
Rate of Deleted	1.82%	0.60%			

Table 6.7 OHT6 - Office of Orthopedic Devices
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 6.8 OHT6 - Office of Orthopedic Devices
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT6 - Office of Orthopedic Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.1 OHT7 - Office of In Vitro Diagnostics
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	295	260			
Closed Before First RTA or TS Action [1]	7	12			
Number Accepted or Passed TS on First Cycle [2]	243	214			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	5	3			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	19			
Number Not Accepted or Failed TS on First Cycle [2]	40	12			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.89%	5.24%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT7 - Office of In Vitro Diagnostics
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	271	222			
Deleted or Withdrawn Prior to SI	3	0			
SI Within 60 FDA Days	266	195			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	27			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	2	0			
Current SI Performance Percent Within 60 FDA Days	99.25%	100.00%			

Table 6.3 OHT7 - Office of In Vitro Diagnostics
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	266	195			
Average Number of FDA Days to Substantive Interaction	52.54	50.45			
20th Percentile FDA Days to Substantive Interaction	47	40			
40th Percentile FDA Days to Substantive Interaction	56	55			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	60	60			

Table 6.4 OHT7 - Office of In Vitro Diagnostics
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	271	222			
Non-MDUFA V Decision	50	18			
MDUFA V Decision (SE/NSE)	217	101			
MDUFA V Decision Within 90 FDA Days	217	101			
510(k)s Pending MDUFA V Decision	4	103			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.5 OHT7 - Office of In Vitro Diagnostics
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.58	1.43			
Number With MDUFA V Decision	217	101			
Average Number of FDA Days to MDUFA V Decision	76.10	67.20			
20th Percentile FDA Days to MDUFA V Decision	58	32			
40th Percentile FDA Days to MDUFA V Decision	87	74			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	90			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	79.66	41.02			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	112	4			
80th Percentile Industry Days to MDUFA V Decision	177	94			
Maximum Industry Days to MDUFA V Decision	361	184			
Average Number of Total Days to MDUFA V Decision	155.57	108.22			
20th Percentile Total Days to MDUFA V Decision	59	32			
40th Percentile Total Days to MDUFA V Decision	90	82			
60th Percentile Total Days to MDUFA V Decision	201	90			
80th Percentile Total Days to MDUFA V Decision	265	179			
Maximum Total Days to MDUFA V Decision	451	272			

Table 6.6 OHT7 - Office of In Vitro Diagnostics
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	271	222			
Number With MDUFA V Decision	217	101			
Number of SE Decision	209	98			
Number of NSE Decision	8	3			
Number of Withdrawal	27	9			
Number of Deleted	23	9			
Rate of SE Decision	96.31%	97.03%			
Rate of NSE Decision	3.69%	2.97%			
Rate of Withdrawal	9.96%	4.05%			
Rate of Deleted	8.49%	4.05%			

Table 6.7 OHT7 - Office of In Vitro Diagnostics
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 6.8 OHT7 - Office of In Vitro Diagnostics
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	2	2			
MDUFA V Decision Within 90 FDA Days	2	2			
510(k)s Pending MDUFA V Decision	0	2			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.9 OHT7 - Office of In Vitro Diagnostics
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	218			
Non-MDUFA V Decision	50	18			
MDUFA V Decision (SE/NSE)	215	99			
MDUFA V Decision Within 90 FDA Days	215	99			
510(k)s Pending MDUFA V Decision	4	101			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.1 OHT8 - Office of Radiological Health
510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	488	463			
Closed Before First RTA or TS Action [1]	4	1			
Number Accepted or Passed TS on First Cycle [2]	441	415			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	37			
Number Not Accepted or Failed TS on First Cycle [2]	41	10			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.47%	2.35%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

Table 6.2 OHT8 - Office of Radiological Health
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	476	420			
Deleted or Withdrawn Prior to SI	0	3			
SI Within 60 FDA Days	476	348			
SI Over 60 FDA Days	0	1			
SI Pending Within 60 FDA Days	0	68			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100.00%	99.71%			

Table 6.3 OHT8 - Office of Radiological Health
510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	476	349			
Average Number of FDA Days to Substantive Interaction	49.51	50.78			
20th Percentile FDA Days to Substantive Interaction	35	46			
40th Percentile FDA Days to Substantive Interaction	53	55			
60th Percentile FDA Days to Substantive Interaction	57	58			
80th Percentile FDA Days to Substantive Interaction	59	59			
Maximum FDA Days to Substantive Interaction	60	61			

Table 6.4 OHT8 - Office of Radiological Health
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	476	420			
Non-MDUFA V Decision	31	18			
MDUFA V Decision (SE/NSE)	445	212			
MDUFA V Decision Within 90 FDA Days	445	212			
510(k)s Pending MDUFA V Decision	0	190			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.5 OHT8 - Office of Radiological Health
510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.66			
Number With MDUFA V Decision	445	212			
Average Number of FDA Days to MDUFA V Decision	71.52	70.07			
20th Percentile FDA Days to MDUFA V Decision	52	44			
40th Percentile FDA Days to MDUFA V Decision	79	77			
60th Percentile FDA Days to MDUFA V Decision	86	87			
80th Percentile FDA Days to MDUFA V Decision	89	89			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	63.68	45.79			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	24	12			
60th Percentile Industry Days to MDUFA V Decision	62	38			
80th Percentile Industry Days to MDUFA V Decision	138	88			
Maximum Industry Days to MDUFA V Decision	210	180			
Average Number of Total Days to MDUFA V Decision	135.03	115.86			
20th Percentile Total Days to MDUFA V Decision	56	54			
40th Percentile Total Days to MDUFA V Decision	107	90			
60th Percentile Total Days to MDUFA V Decision	146	122			
80th Percentile Total Days to MDUFA V Decision	222	171			
Maximum Total Days to MDUFA V Decision	272	269			

Table 6.6 OHT8 - Office of Radiological Health
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	476	420			
Number With MDUFA V Decision	445	212			
Number of SE Decision	438	205			
Number of NSE Decision	7	7			
Number of Withdrawal	16	14			
Number of Deleted	14	4			
Rate of SE Decision	98.43%	96.70%			
Rate of NSE Decision	1.57%	3.30%			
Rate of Withdrawal	3.36%	3.33%			
Rate of Deleted	2.94%	0.95%			

Table 6.7 OHT8 - Office of Radiological Health
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 6.8 OHT8 - Office of Radiological Health
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 OHT8 - Office of Radiological Health
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Section 7 510(k) Annual General Metrics

Table 7.1 CDRH - 510(k) Annual General Metrics - 510(k)s Received by Type

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted	3,764	3,241			
Number of Traditional Submissions	3,111	2,699			
Number of Special Submissions	525	436			
Number of Abbreviated Submissions	51	38			
Average Number of Days to Accept/Refuse to Accept	11.48	10.73			
Number of Third Party Submissions	77	68			

Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal

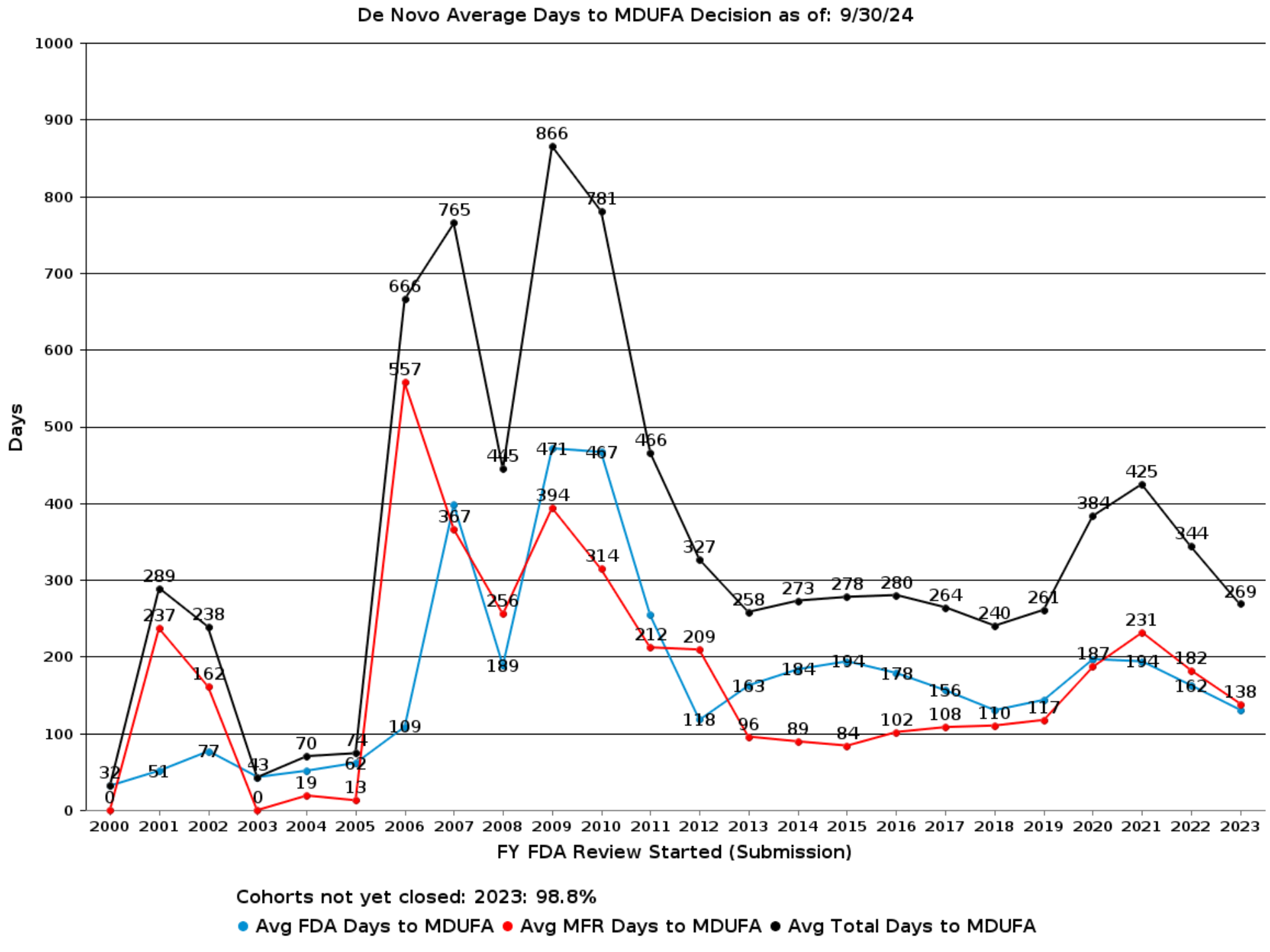
Performance Metrics	FY 2023 128 Days	FY 2024 124 Days	FY 2025 112 Days	FY 2026 112 Days	FY 2027 112 Days
Number Accepted	3,764	3,241			
Currently Under Review	67	1,438			
Number With Non-MDUFA V Decision	412	150			
Number With MDUFA V Decision	3,285	1,653			
Percent of Cohort Closed	98.00%	53.48%			
Number With MDUFA V Decision After Trimming the Upper and Lower 2%	3,164	1,837			
Average Total Time to MDUFA V Decision	137.98	104.08			

Table 7.3 CDRH - 510(k) Third Party Performance

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Third Party Submissions	77	68			
90th Percentile FDA Days to MDUFA V Decision	60.00	30.00			

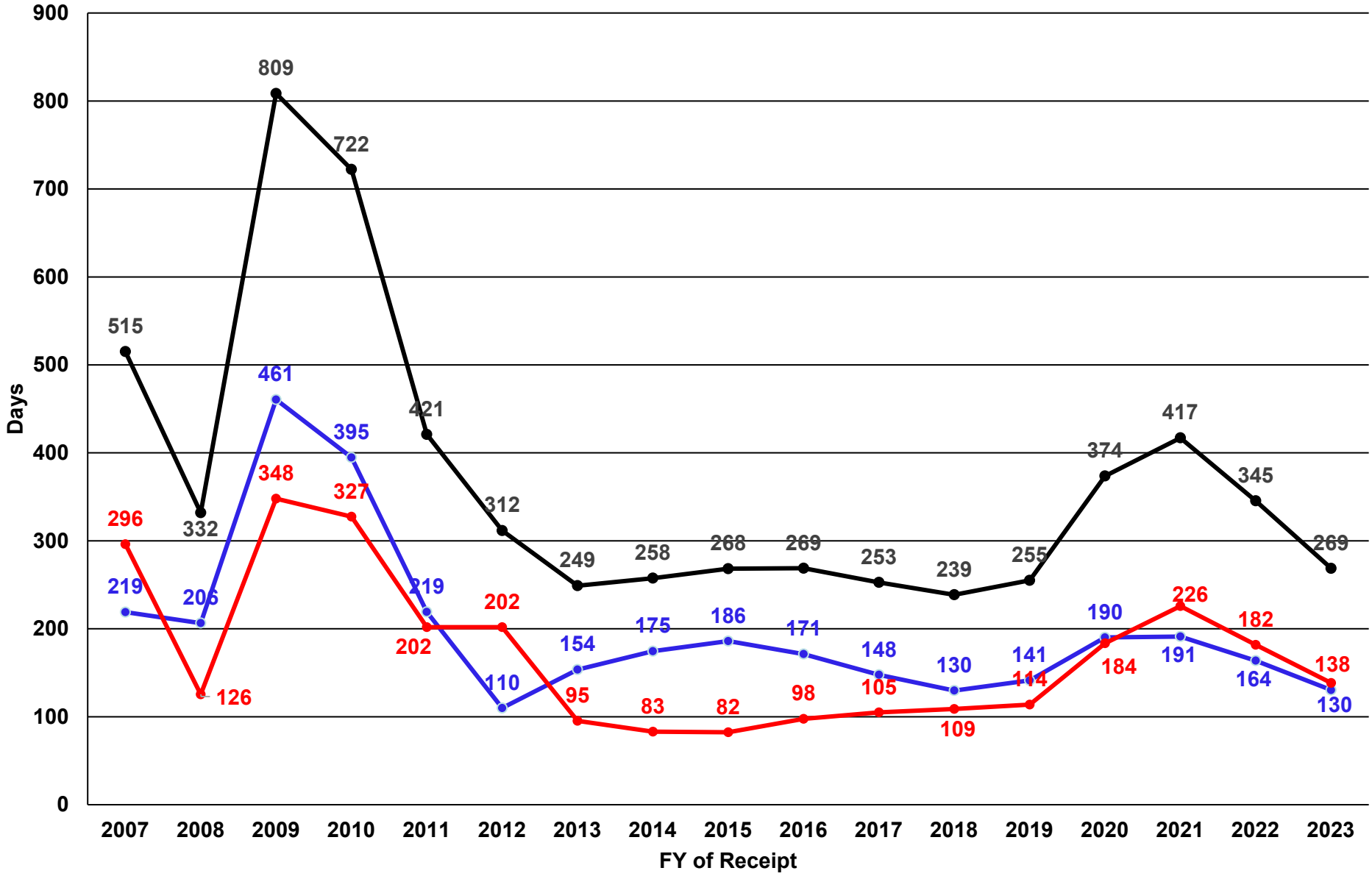
De Novos

Q4FY2024

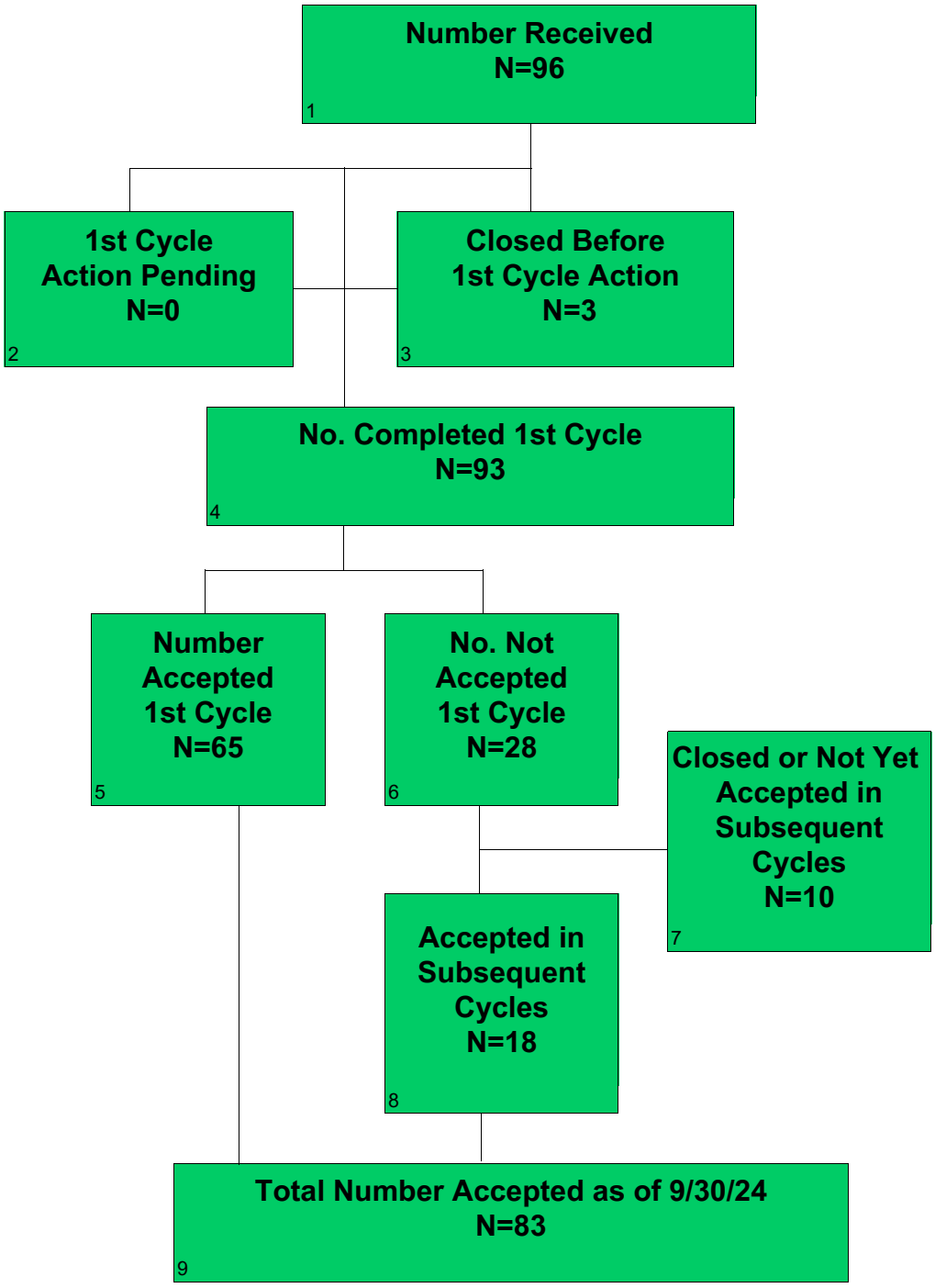

De Novo Average Days to MDUFA Decision as of: 9/30/24
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2023: 98.8%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos

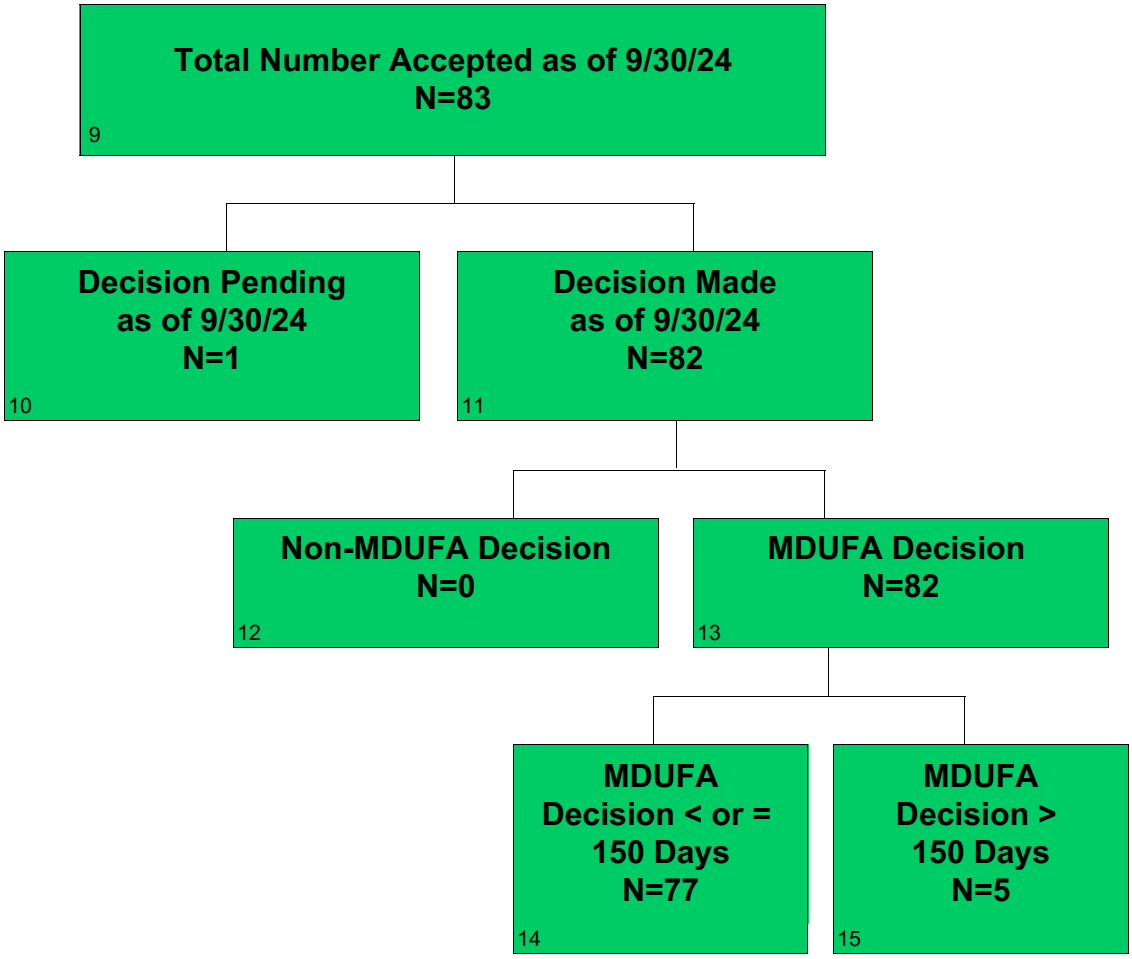
(98.8% closure comparison)



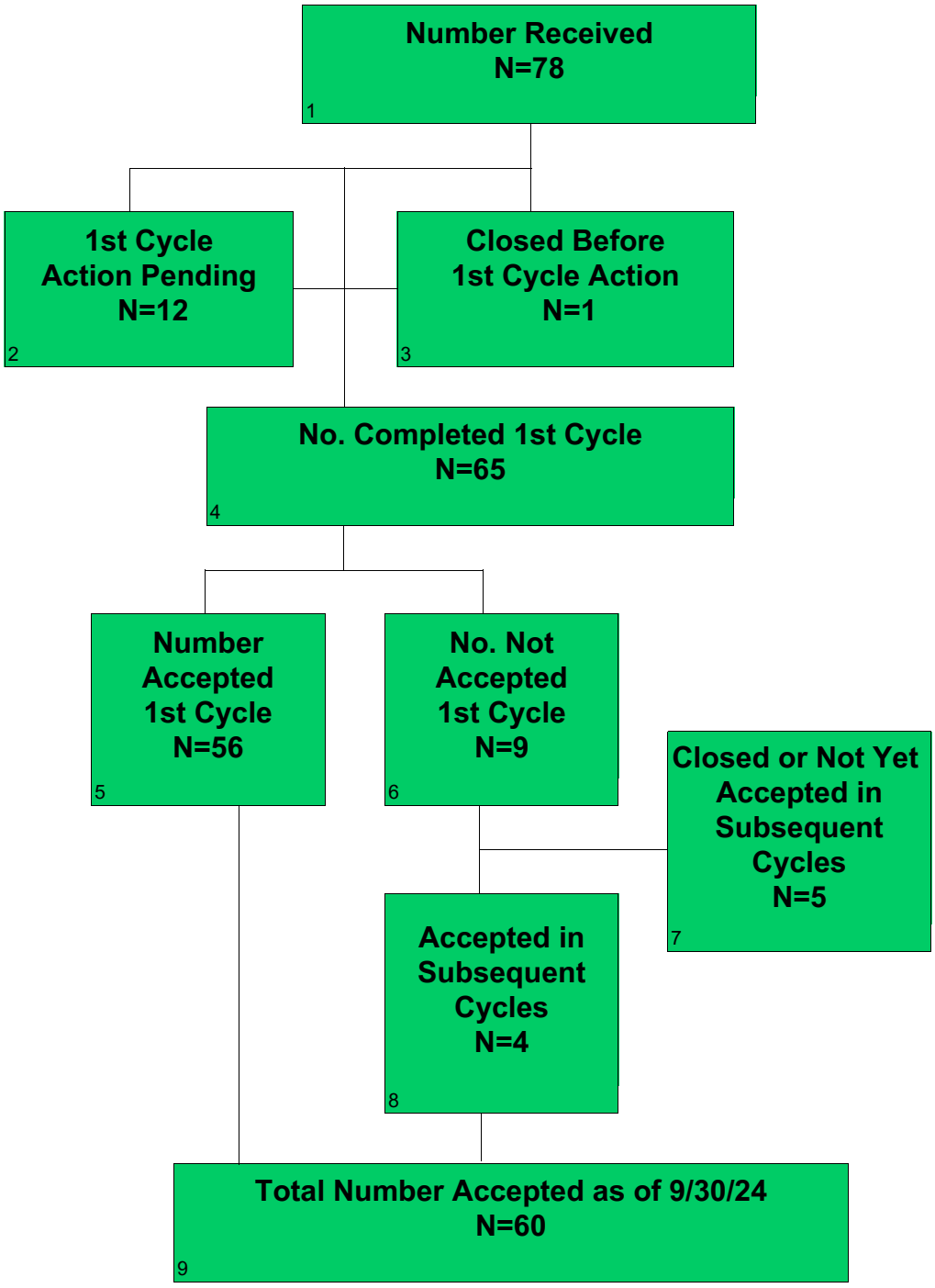
CDRH De Novo - FY 2023
as of 9/30/24



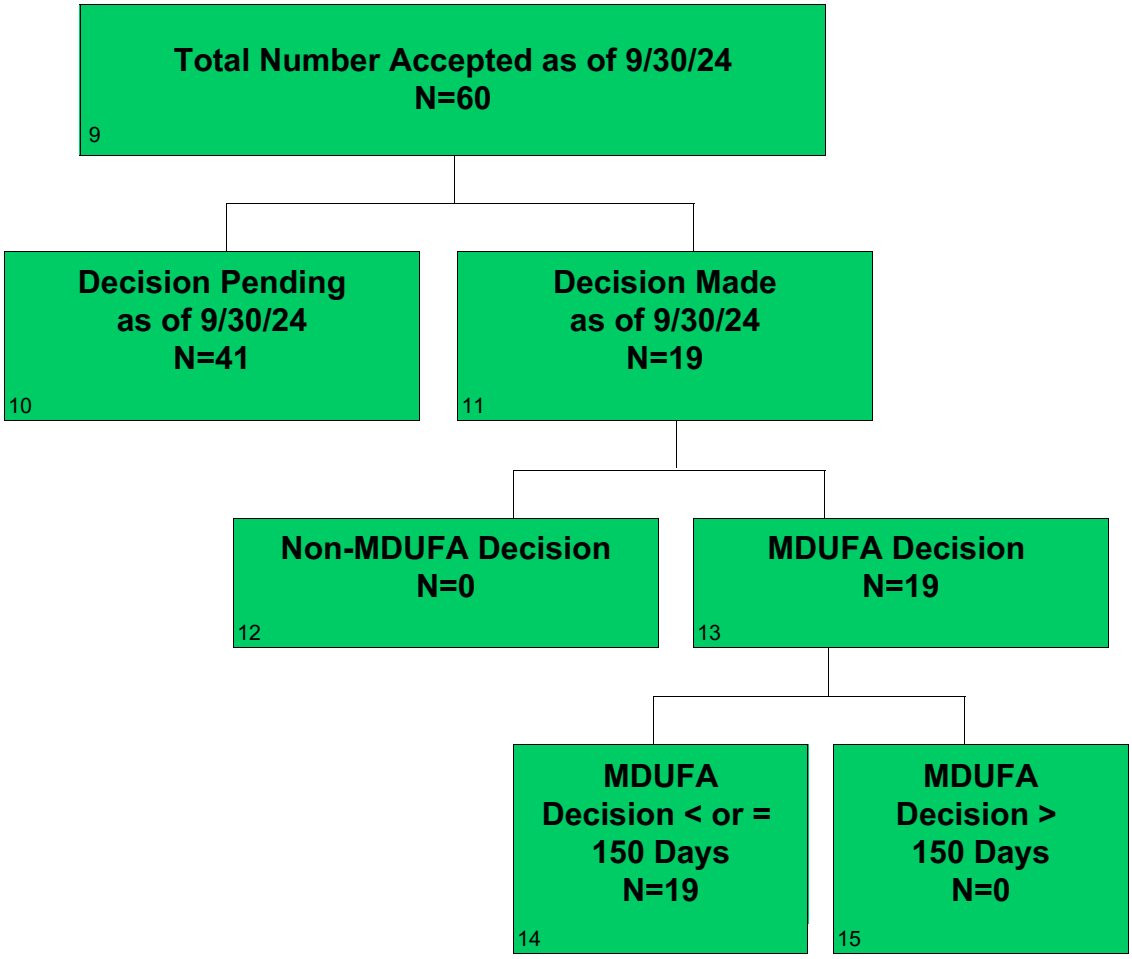
CDRH De Novo - FY 2023
as of 9/30/24 Continued



CDRH De Novo - FY 2024
as of 9/30/24



CDRH De Novo - FY 2024
as of 9/30/24 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96	78			
Closed Before First RTA or TS Action	3	1			
Number Accepted or Passed TS on First Cycle	65	56			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	12			
Number Not Accepted or Failed TS on First Cycle	28	9			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	13.85%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	83	60			
Non-MDUFA Decision	0	0			
MDUFA Decision	82	19			
MDUFA Decision Within 150 FDA Days	77	19			
De Novos Pending MDUFA Decision	1	41			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	93.90%	100.00%			

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.32			
Number With MDUFA Decision	82	19			
Average FDA Days to MDUFA Decision	130.37	112.84			
20th Percentile FDA Days to MDUFA Decision	75	75			
40th Percentile FDA Days to MDUFA Decision	148	89			
60th Percentile FDA Days to MDUFA Decision	150	144			
80th Percentile FDA Days to MDUFA Decision	150	149			
Maximum FDA Days to MDUFA Decision	251	150			
Average Industry Days to MDUFA Decision	138.35	83.95			
20th Percentile Industry Days to MDUFA Decision	69	0			
40th Percentile Industry Days to MDUFA Decision	151	10			
60th Percentile Industry Days to MDUFA Decision	178	130			
80th Percentile Industry Days to MDUFA Decision	181	180			
Maximum Industry Days to MDUFA Decision	350	185			
Average Total Days to MDUFA Decision	268.72	196.79			
20th Percentile Total Days to MDUFA Decision	213	104			
40th Percentile Total Days to MDUFA Decision	256	160			
60th Percentile Total Days to MDUFA Decision	302	239			
80th Percentile Total Days to MDUFA Decision	329	259			
Maximum Total Days to MDUFA Decision	437	330			

Table 8.4 CDRH - De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	83	60			
Number With MDUFA Decision	82	19			
Number With Granted Decision	36	8			
Number With Declined Decision	18	4			
Number of Withdrawal	17	4			
Number of Deleted	11	3			
Rate of Granted Decision	43.90%	42.11%			
Rate of Declined Decision	21.95%	21.05%			
Rate of Withdrawal	20.73%	21.05%			
Rate of Deleted	13.41%	15.79%			

Table 8.5 CDRH - De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	5	0			
Mean FDA Days for Submissions that Missed the Goal	194.80	N/A			
Mean Industry Days for Submissions that Missed the Goal	111.20	N/A			

Table 8.6 CDRH - LDT De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Within 150 FDA Days	1	0			
De Novos Pending MDUFA Decision	0	0			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

Table 8.7 CDRH - Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	16			
Non-MDUFA Decision	0	0			
MDUFA Decision	19	5			
MDUFA Decision Within 150 FDA Days	19	5			
De Novos Pending MDUFA Decision	0	11			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.8 CDRH - De Novo Annual General Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	83	60			
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.23	11.45			

Section 8 - De Novo Office Level Metrics

Table 8.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	13			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	6	8			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted or Failed TS on First Cycle	6	3			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	27.27%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11	9			
Non-MDUFA Decision	0	0			
MDUFA Decision	11	3			
MDUFA Decision Within 150 FDA Days	8	3			
De Novos Pending MDUFA Decision	0	6			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	72.73%	100.00%			

Table 8.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.33			
Number With MDUFA Decision	11	3			
Average FDA Days to MDUFA Decision	130.82	102.00			
20th Percentile FDA Days to MDUFA Decision	73	79			
40th Percentile FDA Days to MDUFA Decision	75	82			
60th Percentile FDA Days to MDUFA Decision	150	97			
80th Percentile FDA Days to MDUFA Decision	178	122			
Maximum FDA Days to MDUFA Decision	251	147			
Average Industry Days to MDUFA Decision	137.45	91.67			
20th Percentile Industry Days to MDUFA Decision	81	54			
40th Percentile Industry Days to MDUFA Decision	152	109			
60th Percentile Industry Days to MDUFA Decision	178	137			
80th Percentile Industry Days to MDUFA Decision	182	138			
Maximum Industry Days to MDUFA Decision	189	139			
Average Total Days to MDUFA Decision	268.27	193.67			
20th Percentile Total Days to MDUFA Decision	231	136			
40th Percentile Total Days to MDUFA Decision	255	188			
60th Percentile Total Days to MDUFA Decision	262	228			
80th Percentile Total Days to MDUFA Decision	328	255			
Maximum Total Days to MDUFA Decision	343	283			

Table 8.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	9			
Number With MDUFA Decision	11	3			
Number With Granted Decision	5	1			
Number With Declined Decision	1	0			
Number of Withdrawal	1	2			
Number of Deleted	4	0			
Rate of Granted Decision	45.45%	33.33%			
Rate of Declined Decision	9.09%	0.00%			
Rate of Withdrawal	9.09%	66.67%			
Rate of Deleted	36.36%	0.00%			

Table 8.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	3	0			
Mean FDA Days for Submissions That Missed the Goal	206.67	N/A			
Mean Industry Days for Submissions That Missed the Goal	122.33	N/A			

Table 8.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.1 OHT2 - Office of Cardiovascular Devices
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	4			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	10	3			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted or Failed TS on First Cycle	2	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	16.67%	0.00%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	10	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	10	1			
MDUFA Decision Within 150 FDA Days	10	1			
De Novos Pending MDUFA Decision	0	2			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.3 OHT2 - Office of Cardiovascular Devices
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.00			
Number With MDUFA Decision	10	1			
Average FDA Days to MDUFA Decision	137.10	149.00			
20th Percentile FDA Days to MDUFA Decision	140	149			
40th Percentile FDA Days to MDUFA Decision	150	149			
60th Percentile FDA Days to MDUFA Decision	150	149			
80th Percentile FDA Days to MDUFA Decision	150	149			
Maximum FDA Days to MDUFA Decision	150	149			
Average Industry Days to MDUFA Decision	114.40	N/A			
20th Percentile Industry Days to MDUFA Decision	47	0			
40th Percentile Industry Days to MDUFA Decision	90	0			
60th Percentile Industry Days to MDUFA Decision	178	0			
80th Percentile Industry Days to MDUFA Decision	180	0			
Maximum Industry Days to MDUFA Decision	183	0			
Average Total Days to MDUFA Decision	251.50	149.00			
20th Percentile Total Days to MDUFA Decision	197	149			
40th Percentile Total Days to MDUFA Decision	238	149			
60th Percentile Total Days to MDUFA Decision	267	149			
80th Percentile Total Days to MDUFA Decision	328	149			
Maximum Total Days to MDUFA Decision	329	149			

Table 8.4 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	10	3			
Number With MDUFA Decision	10	1			
Number With Granted Decision	6	1			
Number With Declined Decision	3	0			
Number of Withdrawal	0	0			
Number of Deleted	1	0			
Rate of Granted Decision	60.00%	100.00%			
Rate of Declined Decision	30.00%	0.00%			
Rate of Withdrawal	0.00%	0.00%			
Rate of Deleted	10.00%	0.00%			

Table 8.5 OHT2 - Office of Cardiovascular Devices
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A			

Table 8.6 OHT2 - Office of Cardiovascular Devices
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT2 - Office of Cardiovascular Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	11	8			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	9	6			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted or Failed TS on First Cycle	2	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	14.29%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11	6			
Non-MDUFA Decision	0	0			
MDUFA Decision	11	1			
MDUFA Decision Within 150 FDA Days	11	1			
De Novos Pending MDUFA Decision	0	5			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	2.00			
Number With MDUFA Decision	11	1			
Average FDA Days to MDUFA Decision	128.45	149.00			
20th Percentile FDA Days to MDUFA Decision	74	149			
40th Percentile FDA Days to MDUFA Decision	148	149			
60th Percentile FDA Days to MDUFA Decision	150	149			
80th Percentile FDA Days to MDUFA Decision	150	149			
Maximum FDA Days to MDUFA Decision	150	149			
Average Industry Days to MDUFA Decision	122.73	180.00			
20th Percentile Industry Days to MDUFA Decision	83	180			
40th Percentile Industry Days to MDUFA Decision	124	180			
60th Percentile Industry Days to MDUFA Decision	163	180			
80th Percentile Industry Days to MDUFA Decision	180	180			
Maximum Industry Days to MDUFA Decision	214	180			
Average Total Days to MDUFA Decision	251.18	329.00			
20th Percentile Total Days to MDUFA Decision	231	329			
40th Percentile Total Days to MDUFA Decision	247	329			
60th Percentile Total Days to MDUFA Decision	274	329			
80th Percentile Total Days to MDUFA Decision	293	329			
Maximum Total Days to MDUFA Decision	330	329			

Table 8.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	6			
Number With MDUFA Decision	11	1			
Number With Granted Decision	7	0			
Number With Declined Decision	1	1			
Number of Withdrawal	1	0			
Number of Deleted	2	0			
Rate of Granted Decision	63.64%	0.00%			
Rate of Declined Decision	9.09%	100.00%			
Rate of Withdrawal	9.09%	0.00%			
Rate of Deleted	18.18%	0.00%			

Table 8.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A			

Table 8.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.1 OHT4 - Office of Surgical and Infection Control Devices
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	14			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	11	11			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted or Failed TS on First Cycle	9	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	8.33%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT4 - Office of Surgical and Infection Control Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	15	12			
Non-MDUFA Decision	0	0			
MDUFA Decision	15	5			
MDUFA Decision Within 150 FDA Days	13	5			
De Novos Pending MDUFA Decision	0	7			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	86.67%	100.00%			

Table 8.3 OHT4 - Office of Surgical and Infection Control Devices
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.20			
Number With MDUFA Decision	15	5			
Average FDA Days to MDUFA Decision	126.87	108.80			
20th Percentile FDA Days to MDUFA Decision	75	75			
40th Percentile FDA Days to MDUFA Decision	143	88			
60th Percentile FDA Days to MDUFA Decision	148	118			
80th Percentile FDA Days to MDUFA Decision	150	150			
Maximum FDA Days to MDUFA Decision	203	150			
Average Industry Days to MDUFA Decision	134.87	106.00			
20th Percentile Industry Days to MDUFA Decision	80	0			
40th Percentile Industry Days to MDUFA Decision	156	99			
60th Percentile Industry Days to MDUFA Decision	180	171			
80th Percentile Industry Days to MDUFA Decision	181	181			
Maximum Industry Days to MDUFA Decision	198	185			
Average Total Days to MDUFA Decision	261.73	214.80			
20th Percentile Total Days to MDUFA Decision	228	139			
40th Percentile Total Days to MDUFA Decision	254	204			
60th Percentile Total Days to MDUFA Decision	302	247			
80th Percentile Total Days to MDUFA Decision	329	272			
Maximum Total Days to MDUFA Decision	346	330			

Table 8.4 OHT4 - Office of Surgical and Infection Control Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	15	12			
Number With MDUFA Decision	15	5			
Number With Granted Decision	7	3			
Number With Declined Decision	2	0			
Number of Withdrawal	5	1			
Number of Deleted	1	1			
Rate of Granted Decision	46.67%	60.00%			
Rate of Declined Decision	13.33%	0.00%			
Rate of Withdrawal	33.33%	20.00%			
Rate of Deleted	6.67%	20.00%			

Table 8.5 OHT4 - Office of Surgical and Infection Control Devices
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A			
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A			

Table 8.6 OHT4 - Office of Surgical and Infection Control Devices
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT4 - Office of Surgical and Infection Control Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.1 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	10	12			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	5	9			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted or Failed TS on First Cycle	4	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	10.00%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	9	10			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	3			
MDUFA Decision Within 150 FDA Days	8	3			
De Novos Pending MDUFA Decision	1	7			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.3 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00	1.33			
Number With MDUFA Decision	8	3			
Average FDA Days to MDUFA Decision	140.38	103.67			
20th Percentile FDA Days to MDUFA Decision	149	80			
40th Percentile FDA Days to MDUFA Decision	150	85			
60th Percentile FDA Days to MDUFA Decision	150	99			
80th Percentile FDA Days to MDUFA Decision	150	124			
Maximum FDA Days to MDUFA Decision	150	149			
Average Industry Days to MDUFA Decision	134.88	96.67			
20th Percentile Industry Days to MDUFA Decision	94	43			
40th Percentile Industry Days to MDUFA Decision	151	86			
60th Percentile Industry Days to MDUFA Decision	167	122			
80th Percentile Industry Days to MDUFA Decision	178	153			
Maximum Industry Days to MDUFA Decision	183	183			
Average Total Days to MDUFA Decision	275.25	200.33			
20th Percentile Total Days to MDUFA Decision	226	155			
40th Percentile Total Days to MDUFA Decision	292	222			
60th Percentile Total Days to MDUFA Decision	304	256			
80th Percentile Total Days to MDUFA Decision	320	257			
Maximum Total Days to MDUFA Decision	330	258			

Table 8.4 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	10			
Number With MDUFA Decision	8	3			
Number With Granted Decision	2	0			
Number With Declined Decision	5	2			
Number of Withdrawal	0	0			
Number of Deleted	1	1			
Rate of Granted Decision	25.00%	0.00%			
Rate of Declined Decision	62.50%	66.67%			
Rate of Withdrawal	0.00%	0.00%			
Rate of Deleted	12.50%	33.33%			

Table 8.5 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A			

Table 8.6 OHT5 - Office of Neurological and Physical Medicine Devices
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.1 OHT6 - Office of Orthopedic Devices
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	3	1			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted or Failed TS on First Cycle	0	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	0.00%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT6 - Office of Orthopedic Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	3	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	3	0			
MDUFA Decision Within 150 FDA Days	3	0			
De Novos Pending MDUFA Decision	0	1			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	#DIV/0!			

Table 8.3 OHT6 - Office of Orthopedic Devices
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	N/A			
Number With MDUFA Decision	3	0			
Average FDA Days to MDUFA Decision	149.00	N/A			
20th Percentile FDA Days to MDUFA Decision	148	0			
40th Percentile FDA Days to MDUFA Decision	149	0			
60th Percentile FDA Days to MDUFA Decision	149	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	150	0			
Average Industry Days to MDUFA Decision	119.33	N/A			
20th Percentile Industry Days to MDUFA Decision	71	0			
40th Percentile Industry Days to MDUFA Decision	142	0			
60th Percentile Industry Days to MDUFA Decision	178	0			
80th Percentile Industry Days to MDUFA Decision	179	0			
Maximum Industry Days to MDUFA Decision	180	0			
Average Total Days to MDUFA Decision	268.33	N/A			
20th Percentile Total Days to MDUFA Decision	220	0			
40th Percentile Total Days to MDUFA Decision	292	0			
60th Percentile Total Days to MDUFA Decision	328	0			
80th Percentile Total Days to MDUFA Decision	329	0			
Maximum Total Days to MDUFA Decision	329	0			

Table 8.4 OHT6 - Office of Orthopedic Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	3	1			
Number With MDUFA Decision	3	0			
Number With Granted Decision	2	0			
Number With Declined Decision	1	0			
Number of Withdrawal	0	0			
Number of Deleted	0	0			
Rate of Granted Decision	66.67%	N/A			
Rate of Declined Decision	33.33%	N/A			
Rate of Withdrawal	0.00%	N/A			
Rate of Deleted	0.00%	N/A			

Table 8.5 OHT6 - Office of Orthopedic Devices
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A			

Table 8.6 OHT6 - Office of Orthopedic Devices
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT6 - Office of Orthopedic Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.1 OHT7 - Office of In Vitro Diagnostics
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20			
Closed Before First RTA or TS Action	1	1			
Number Accepted or Passed TS on First Cycle	17	15			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted or Failed TS on First Cycle	5	2			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	11.76%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	20	16			
Non-MDUFA Decision	0	0			
MDUFA Decision	20	5			
MDUFA Decision Within 150 FDA Days	20	5			
De Novos Pending MDUFA Decision	0	11			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.3 OHT7 - Office of In Vitro Diagnostics
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.60	1.40			
Number With MDUFA Decision	20	5			
Average FDA Days to MDUFA Decision	127.95	115.20			
20th Percentile FDA Days to MDUFA Decision	85	74			
40th Percentile FDA Days to MDUFA Decision	140	109			
60th Percentile FDA Days to MDUFA Decision	149	138			
80th Percentile FDA Days to MDUFA Decision	150	148			
Maximum FDA Days to MDUFA Decision	150	150			
Average Industry Days to MDUFA Decision	167.85	64.00			
20th Percentile Industry Days to MDUFA Decision	139	0			
40th Percentile Industry Days to MDUFA Decision	175	30			
60th Percentile Industry Days to MDUFA Decision	179	64			
80th Percentile Industry Days to MDUFA Decision	182	105			
Maximum Industry Days to MDUFA Decision	350	185			
Average Total Days to MDUFA Decision	295.80	179.20			
20th Percentile Total Days to MDUFA Decision	252	119			
40th Percentile Total Days to MDUFA Decision	299	172			
60th Percentile Total Days to MDUFA Decision	328	213			
80th Percentile Total Days to MDUFA Decision	330	238			
Maximum Total Days to MDUFA Decision	437	260			

Table 8.4 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	20	16			
Number With MDUFA Decision	20	5			
Number With Granted Decision	5	3			
Number With Declined Decision	5	0			
Number of Withdrawal	9	1			
Number of Deleted	1	1			
Rate of Granted Decision	25.00%	60.00%			
Rate of Declined Decision	25.00%	0.00%			
Rate of Withdrawal	45.00%	20.00%			
Rate of Deleted	5.00%	20.00%			

Table 8.5 OHT7 - Office of In Vitro Diagnostics
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A			

Table 8.6 OHT7 - Office of In Vitro Diagnostics
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Within 150 FDA Days	1	0			
De Novos Pending MDUFA Decision	0	0			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

Table 8.7 OHT7 - Office of In Vitro Diagnostics
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	16			
Non-MDUFA Decision	0	0			
MDUFA Decision	19	5			
MDUFA Decision Within 150 FDA Days	19	5			
De Novos Pending MDUFA Decision	0	11			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.1 OHT8 - Office of Radiological Health
De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	4	3			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted or Failed TS on First Cycle	0	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	25.00%			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 OHT8 - Office of Radiological Health
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	4	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	1			
MDUFA Decision Within 150 FDA Days	4	1			
De Novos Pending MDUFA Decision	0	2			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

Table 8.3 OHT8 - Office of Radiological Health
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.25	1.00			
Number With MDUFA Decision	4	1			
Average FDA Days to MDUFA Decision	108.75	109.00			
20th Percentile FDA Days to MDUFA Decision	70	109			
40th Percentile FDA Days to MDUFA Decision	89	109			
60th Percentile FDA Days to MDUFA Decision	133	109			
80th Percentile FDA Days to MDUFA Decision	149	109			
Maximum FDA Days to MDUFA Decision	150	109			
Average Industry Days to MDUFA Decision	130.50	N/A			
20th Percentile Industry Days to MDUFA Decision	83	0			
40th Percentile Industry Days to MDUFA Decision	132	0			
60th Percentile Industry Days to MDUFA Decision	169	0			
80th Percentile Industry Days to MDUFA Decision	186	0			
Maximum Industry Days to MDUFA Decision	193	0			
Average Total Days to MDUFA Decision	239.25	109.00			
20th Percentile Total Days to MDUFA Decision	190	109			
40th Percentile Total Days to MDUFA Decision	258	109			
60th Percentile Total Days to MDUFA Decision	265	109			
80th Percentile Total Days to MDUFA Decision	297	109			
Maximum Total Days to MDUFA Decision	343	109			

Table 8.4 OHT8 - Office of Radiological Health
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	4	3			
Number With MDUFA Decision	4	1			
Number With Granted Decision	2	0			
Number With Declined Decision	0	1			
Number of Withdrawal	1	0			
Number of Deleted	1	0			
Rate of Granted Decision	50.00%	0.00%			
Rate of Declined Decision	0.00%	100.00%			
Rate of Withdrawal	25.00%	0.00%			
Rate of Deleted	25.00%	0.00%			

Table 8.5 OHT8 - Office of Radiological Health
De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A			

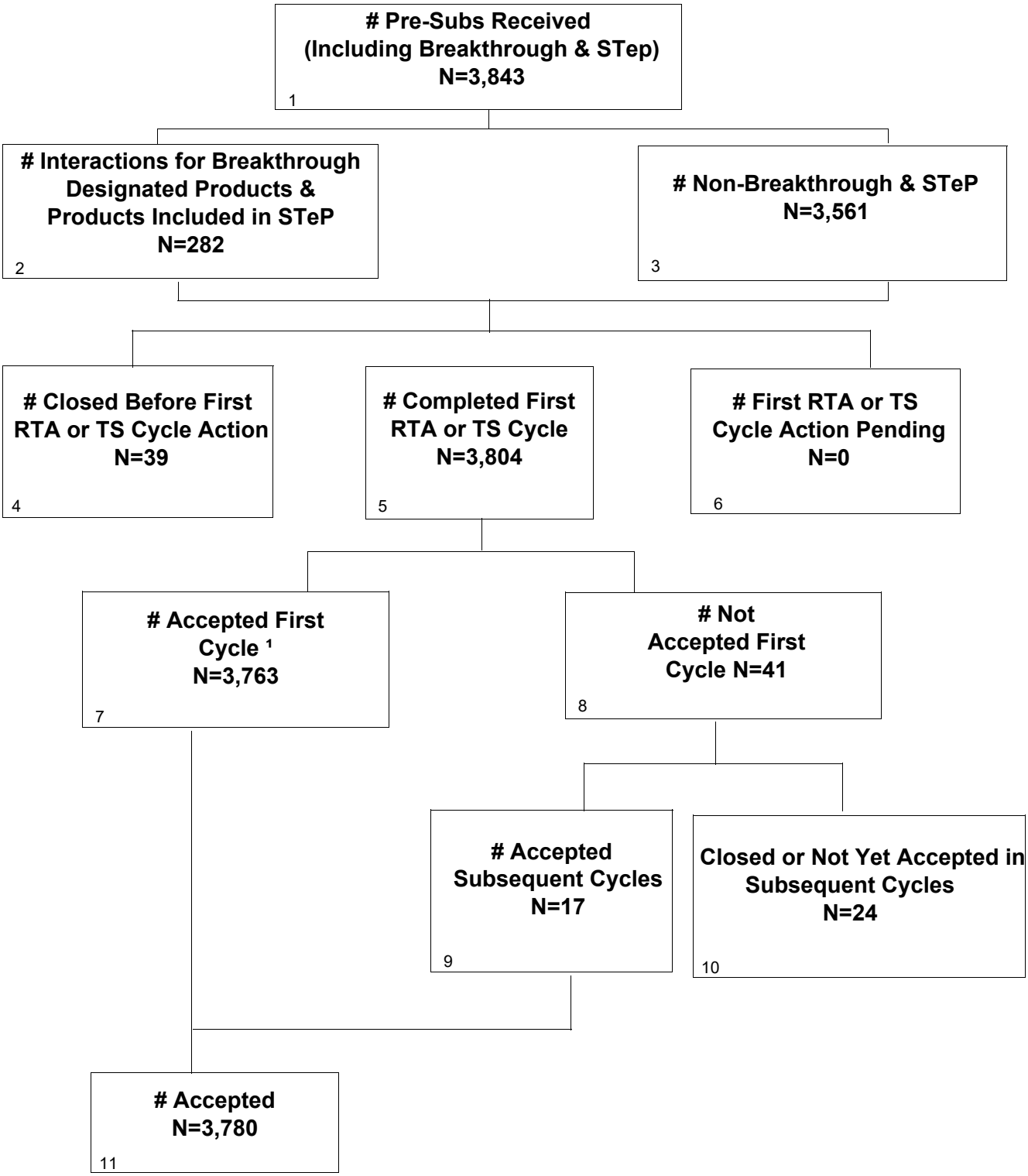
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 OHT8 - Office of Radiological Health
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

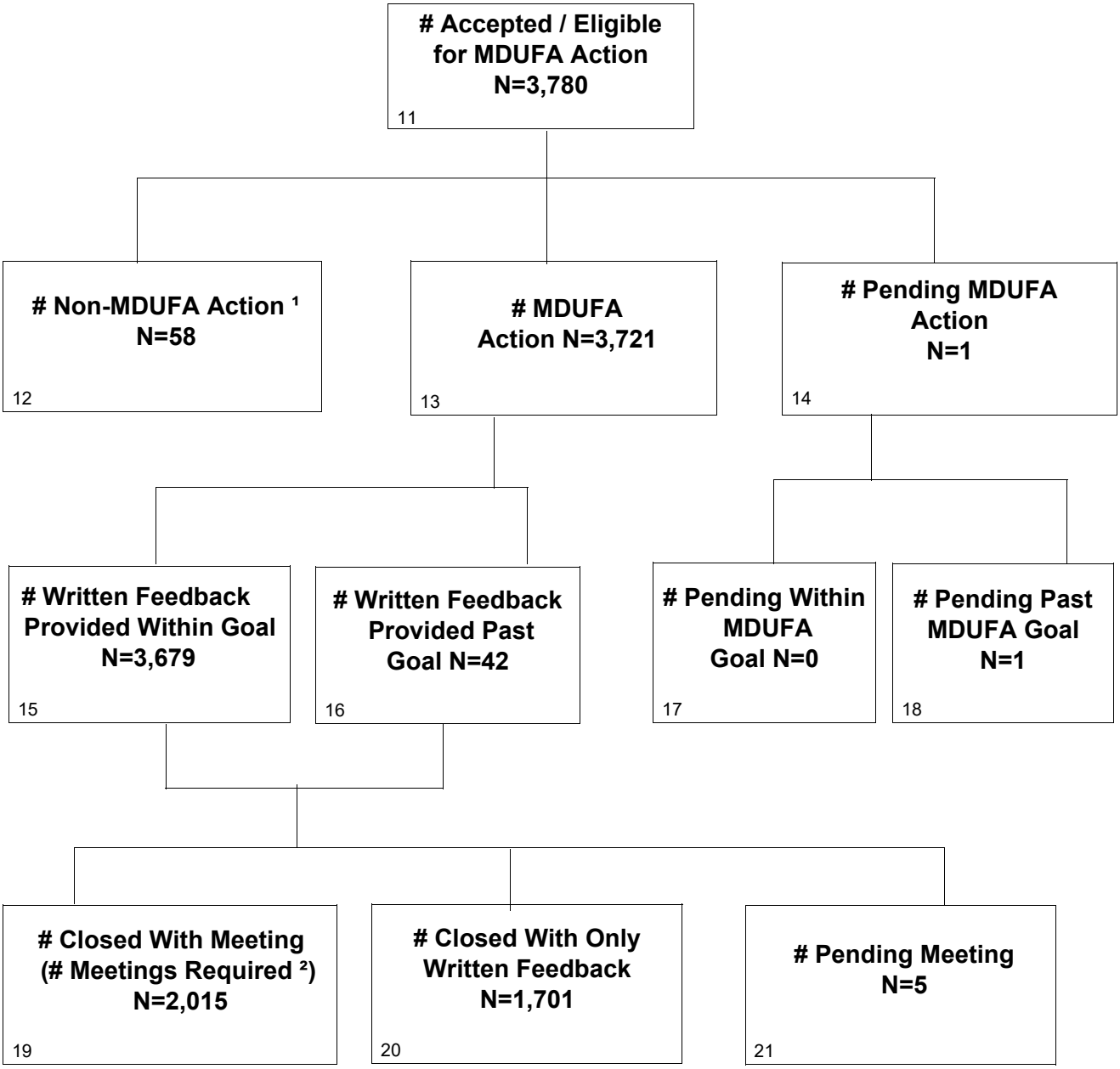
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

CDRH Pre-Sub - FY 2023
as of 9/30/24



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.

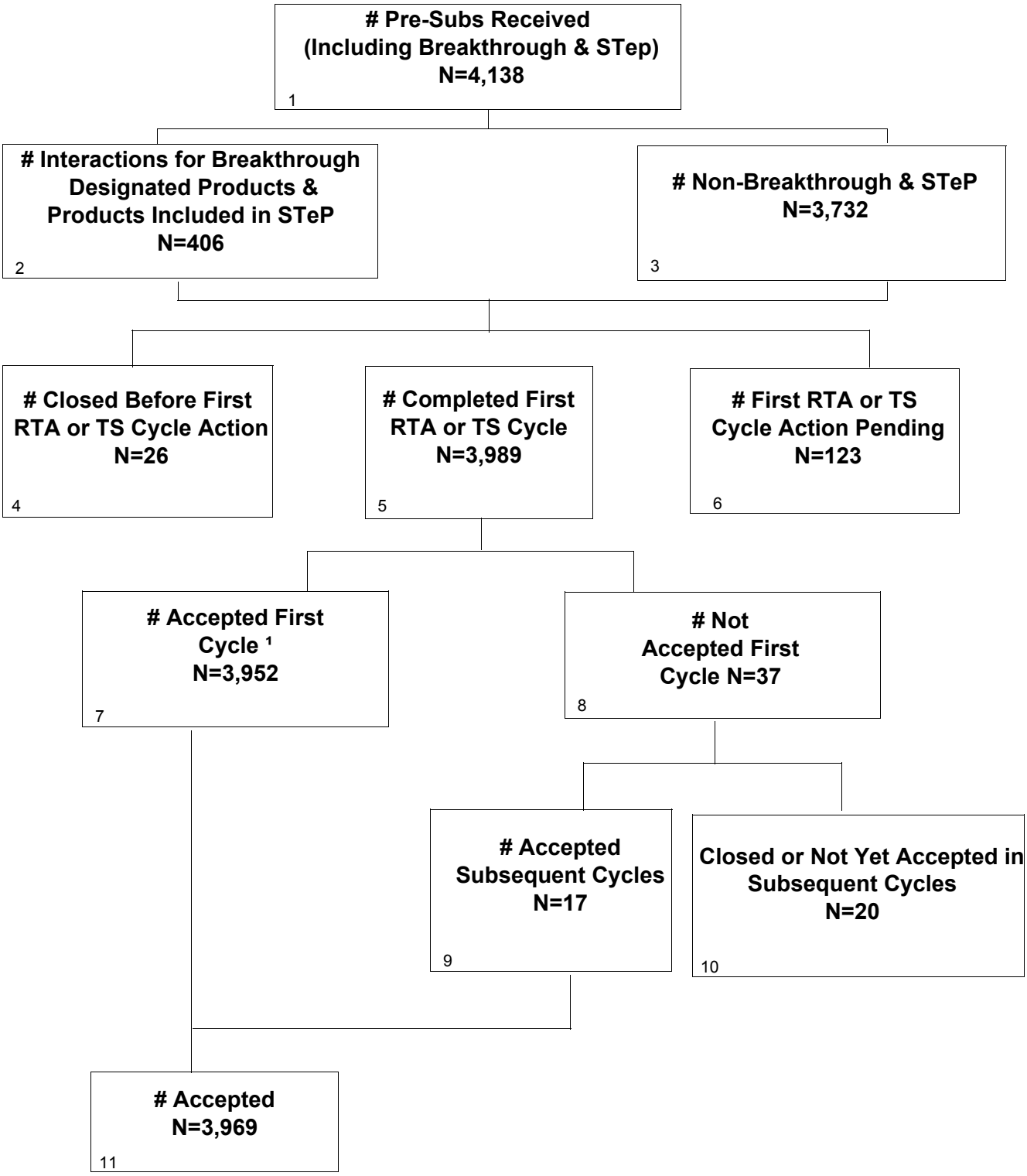
CDRH Pre-Sub - FY 2023
as of 9/30/24 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

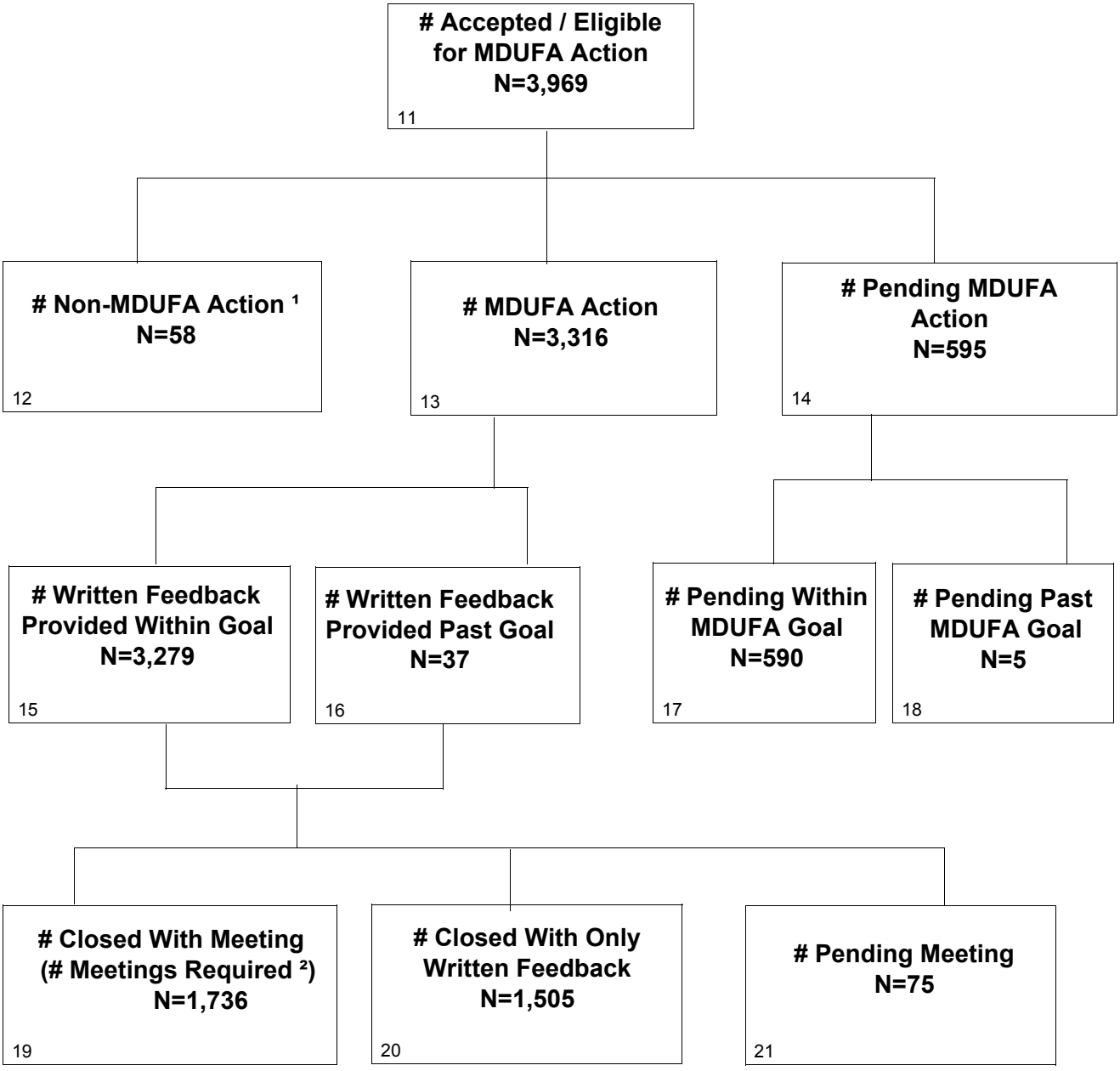
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 9/30/24



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.

CDRH Pre-Sub - FY 2024
as of 9/30/24 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

2. Number of meetings requested and then held after written feedback is provided.

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,843	4,138			
Interactions for Breakthrough Designated Products & Products Included in STeP	282	406			
Number Closed Before First RTA Action	39	26			
Number Accepted First RTA Cycle [1]	3,642	3,860			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	92			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	123			
Number Not Accepted First RTA Cycle	41	37			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.93%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 CDRH - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	3,780	3,969			
Number with Non-MDUFA Action [3]	58	58			
Number with MDUFA Action	3,721	3,316			
Written Feedback Provided Within Goal	3,679	3,279			
Number Pending MDUFA Action	1	595			
Pending MDUFA Action Past Goal	1	5			
Number in MDUFA Cohort (up to max 4300)[4]	3,722	3,911			
Current Performance Percent Within Goal	98.84%	98.74%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 CDRH – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	3,721	3,316			
Average FDA Days to Written Feedback	62.20	61.85			
20th Percentile FDA Days to Written Feedback	56	56			
40th Percentile FDA Days to Written Feedback	64	64			
60th Percentile FDA Days to Written Feedback	68	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	141	113			

Table 9.4 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	136	116			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.55			

Table 9.5 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	2,014	1,736			
Meeting Minutes Submitted Within 15 Days of Meeting	1,530	1,347			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	73			
Meeting Minutes Past 15 Days of Meeting	434	266			
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	50			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.97%	81.00%			

1. Number of meetings requested and then held after written feedback is provided.

Section 9 Pre-Sub Office Level Metrics

Table 9.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	444	492			
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27			
Number Closed Before First RTA Action	4	6			
Number Accepted First RTA Cycle [1]	411	448			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	19			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	14			
Number Not Accepted First RTA Cycle	9	5			
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.06%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT1 -Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	435	471			
Number with Non-MDUFA Action [3]	12	12			
Number with MDUFA Action	423	380			
Written Feedback Provided Within Goal	410	370			
Number Pending MDUFA Action	0	79			
Pending MDUFA Action Past Goal	0	1			
Number in MDUFA Cohort (up to max 4300)[4]	423	459			
Current Performance Percent Within Goal	96.93%	97.11%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	423	380			
Average FDA Days to Written Feedback	65.34	65.18			
20th Percentile FDA Days to Written Feedback	62	62			
40th Percentile FDA Days to Written Feedback	66	66			
60th Percentile FDA Days to Written Feedback	69	69			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	141	101			

Table 9.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	30	20			
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.90			

Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	249	207			
Meeting Minutes Submitted Within 15 Days of Meeting	179	161			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	9			
Meeting Minutes Past 15 Days of Meeting	59	30			
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	7			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	81.31%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT2 - Office of Cardiovascular Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	721	746			
Interactions for Breakthrough Designated Products & Products Included in STeP	73	85			
Number Closed Before First RTA Action	6	2			
Number Accepted First RTA Cycle [1]	698	706			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	13			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	22			
Number Not Accepted First RTA Cycle	4	3			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.42%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	714	720			
Number with Non-MDUFA Action [3]	4	3			
Number with MDUFA Action	709	606			
Written Feedback Provided Within Goal	694	594			
Number Pending MDUFA Action	1	111			
Pending MDUFA Action Past Goal	1	2			
Number in MDUFA Cohort (up to max 4300)[4]	710	717			
Current Performance Percent Within Goal	97.75%	97.70%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	709	606			
Average FDA Days to Written Feedback	59.29	59.13			
20th Percentile FDA Days to Written Feedback	50	49			
40th Percentile FDA Days to Written Feedback	60	60			
60th Percentile FDA Days to Written Feedback	66	65			
80th Percentile FDA Days to Written Feedback	69	69			
Maximum FDA Days to Written Feedback	103	113			

Table 9.4 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	32	17			
Average Days to Scheduling for Meetings Scheduled After Day 30	38.19	36.50			

Table 9.5 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	403	339			
Meeting Minutes Submitted Within 15 Days of Meeting	306	238			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	21			
Meeting Minutes Past 15 Days of Meeting	90	68			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	12			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.93%	74.84%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	459	503			
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63			
Number Closed Before First RTA Action	5	4			
Number Accepted First RTA Cycle [1]	436	464			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	10			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	14			
Number Not Accepted First RTA Cycle	6	11			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.27%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	451	477			
Number with Non-MDUFA Action [3]	10	10			
Number with MDUFA Action	441	393			
Written Feedback Provided Within Goal	437	391			
Number Pending MDUFA Action	0	74			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	441	467			
Current Performance Percent Within Goal	99.09%	99.49%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	441	393			
Average FDA Days to Written Feedback	62.14	61.30			
20th Percentile FDA Days to Written Feedback	56	55			
40th Percentile FDA Days to Written Feedback	64	63			
60th Percentile FDA Days to Written Feedback	67	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	78	78			

Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	13	11			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	44.45			

Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	253	205			
Meeting Minutes Submitted Within 15 Days of Meeting	198	166			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	9			
Meeting Minutes Past 15 Days of Meeting	49	25			
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.26%	84.69%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT4 - Office of Surgical and Infection Control Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	388	468			
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35			
Number Closed Before First RTA Action	4	4			
Number Accepted First RTA Cycle [1]	368	423			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	14			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	19			
Number Not Accepted First RTA Cycle	7	8			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.82%	1.80%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	380	441			
Number with Non-MDUFA Action [3]	11	14			
Number with MDUFA Action	369	346			
Written Feedback Provided Within Goal	369	344			
Number Pending MDUFA Action	0	81			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	369	427			
Current Performance Percent Within Goal	100.00%	99.42%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	369	346			
Average FDA Days to Written Feedback	60.57	61.82			
20th Percentile FDA Days to Written Feedback	55	56			
40th Percentile FDA Days to Written Feedback	62	63			
60th Percentile FDA Days to Written Feedback	65	68			
80th Percentile FDA Days to Written Feedback	69	70			
Maximum FDA Days to Written Feedback	70	71			

Table 9.4 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	15	14			
Average Days to Scheduling for Meetings Scheduled After Day 30	37.53	37.29			

Table 9.5 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	213	172			
Meeting Minutes Submitted Within 15 Days of Meeting	164	135			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	41	29			
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.00%	80.84%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT5 - Office of Neurological and Physical Medicine Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	396	425			
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42			
Number Closed Before First RTA Action	5	3			
Number Accepted First RTA Cycle [1]	370	388			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	9			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	16			
Number Not Accepted First RTA Cycle	4	9			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.22%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	389	402			
Number with Non-MDUFA Action [3]	5	4			
Number with MDUFA Action	384	340			
Written Feedback Provided Within Goal	382	334			
Number Pending MDUFA Action	0	58			
Pending MDUFA Action Past Goal	0	2			
Number in MDUFA Cohort (up to max 4300)[4]	384	398			
Current Performance Percent Within Goal	99.48%	97.66%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	384	340			
Average FDA Days to Written Feedback	66.14	66.44			
20th Percentile FDA Days to Written Feedback	64	65			
40th Percentile FDA Days to Written Feedback	68	69			
60th Percentile FDA Days to Written Feedback	70	70			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	108	81			

Table 9.4 CDRH- OHT5 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	25	35			
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	39.86			

Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	248	202			
Meeting Minutes Submitted Within 15 Days of Meeting	177	158			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	64	32			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	7			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.37%	80.20%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT6 - Office of Orthopedic Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	287	292			
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79			
Number Closed Before First RTA Action	5	1			
Number Accepted First RTA Cycle [1]	268	277			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	6			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	8			
Number Not Accepted First RTA Cycle	4	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.42%	0.00%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	280	283			
Number with Non-MDUFA Action [3]	6	6			
Number with MDUFA Action	274	245			
Written Feedback Provided Within Goal	270	240			
Number Pending MDUFA Action	0	32			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	274	277			
Current Performance Percent Within Goal	98.54%	97.96%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	274	245			
Average FDA Days to Written Feedback	58.45	55.97			
20th Percentile FDA Days to Written Feedback	45	42			
40th Percentile FDA Days to Written Feedback	58	56			
60th Percentile FDA Days to Written Feedback	65	63			
80th Percentile FDA Days to Written Feedback	69	68			
Maximum FDA Days to Written Feedback	97	92			

Table 9.4 CDRH- OHT6 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	4	2			
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50			

Table 9.5 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	123	105			
Meeting Minutes Submitted Within 15 Days of Meeting	91	82			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	4			
Meeting Minutes Past 15 Days of Meeting	28	13			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.98%	81.19%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT7 - Office of In Vitro Diagnostics
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	880	925			
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60			
Number Closed Before First RTA Action	9	5			
Number Accepted First RTA Cycle [1]	833	883			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	15			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	21			
Number Not Accepted First RTA Cycle	3	1			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	868	898			
Number with Non-MDUFA Action [3]	7	9			
Number with MDUFA Action	861	773			
Written Feedback Provided Within Goal	857	773			
Number Pending MDUFA Action	0	116			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	861	889			
Current Performance Percent Within Goal	99.54%	100.00%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	861	773			
Average FDA Days to Written Feedback	63.70	62.88			
20th Percentile FDA Days to Written Feedback	60	59			
40th Percentile FDA Days to Written Feedback	66	64			
60th Percentile FDA Days to Written Feedback	69	68			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	75	70			

Table 9.4 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	13			
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00			

Table 9.5 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	320	332			
Meeting Minutes Submitted Within 15 Days of Meeting	257	269			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	13			
Meeting Minutes Past 15 Days of Meeting	59	43			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	7			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	84.33%			

1. Number of meetings requested and then held after written feedback is provided.

Table 9.1 OHT8 - Office of Radiological Health
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	268	287			
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15			
Number Closed Before First RTA Action	1	1			
Number Accepted First RTA Cycle [1]	258	271			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	6			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	9			
Number Not Accepted First RTA Cycle	4	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.50%	0.00%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	263	277			
Number with Non-MDUFA Action [3]	3	0			
Number with MDUFA Action	260	233			
Written Feedback Provided Within Goal	260	233			
Number Pending MDUFA Action	0	44			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	260	277			
Current Performance Percent Within Goal	100.00%	100.00%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	260	233			
Average FDA Days to Written Feedback	60.55	60.47			
20th Percentile FDA Days to Written Feedback	55	54			
40th Percentile FDA Days to Written Feedback	60	62			
60th Percentile FDA Days to Written Feedback	64	65			
80th Percentile FDA Days to Written Feedback	67	69			
Maximum FDA Days to Written Feedback	70	70			

Table 9.4 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

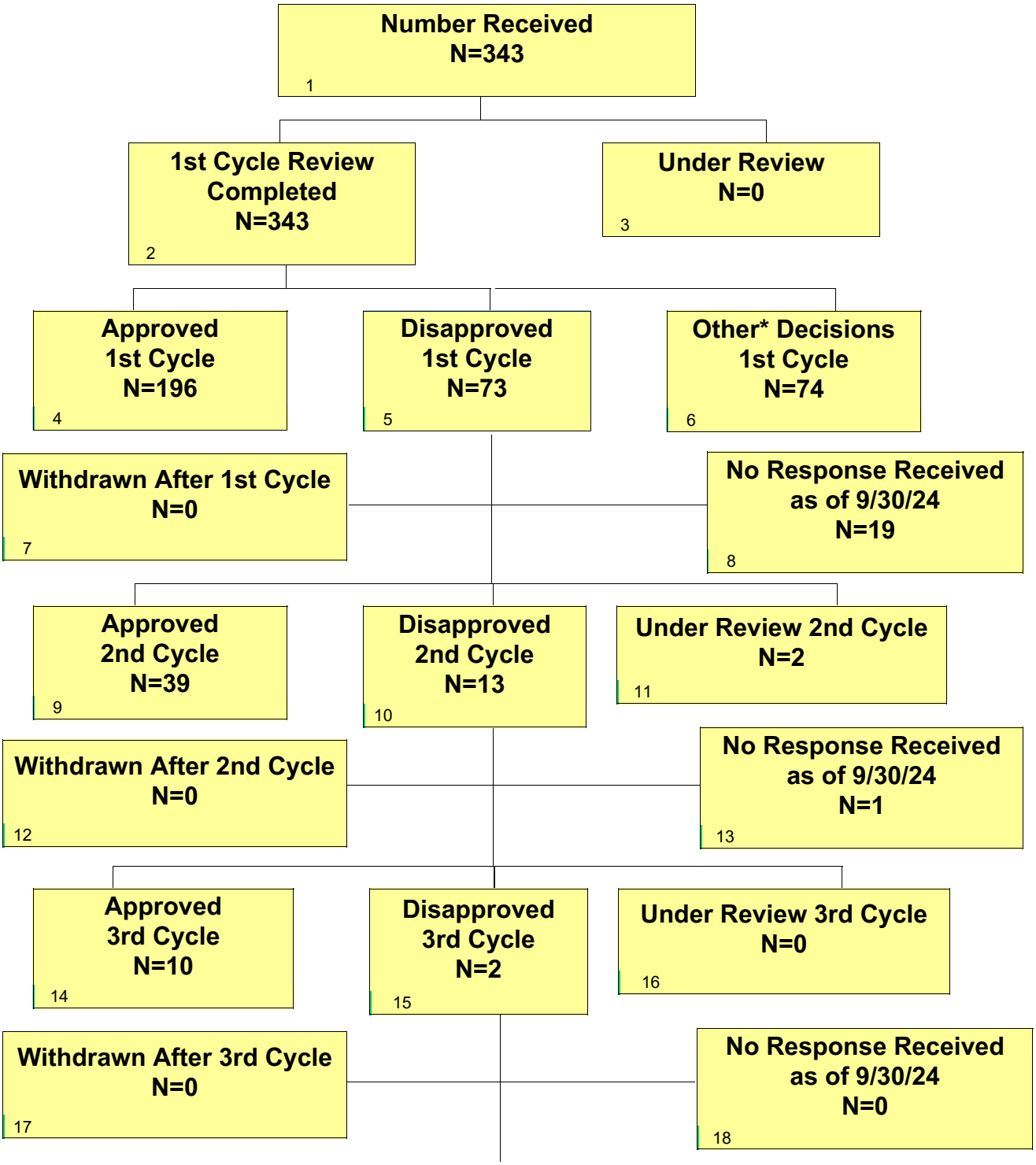
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4			
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25			

Table 9.5 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	205	174			
Meeting Minutes Submitted Within 15 Days of Meeting	158	138			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	7			
Meeting Minutes Past 15 Days of Meeting	44	26			
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.07%	82.63%			

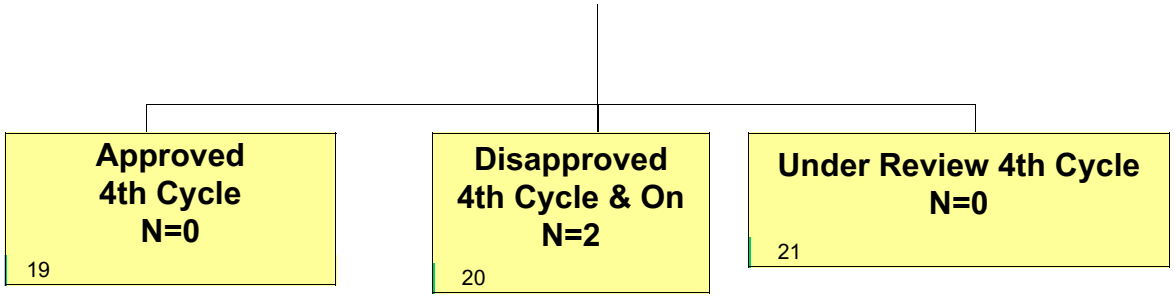
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 9/30/24

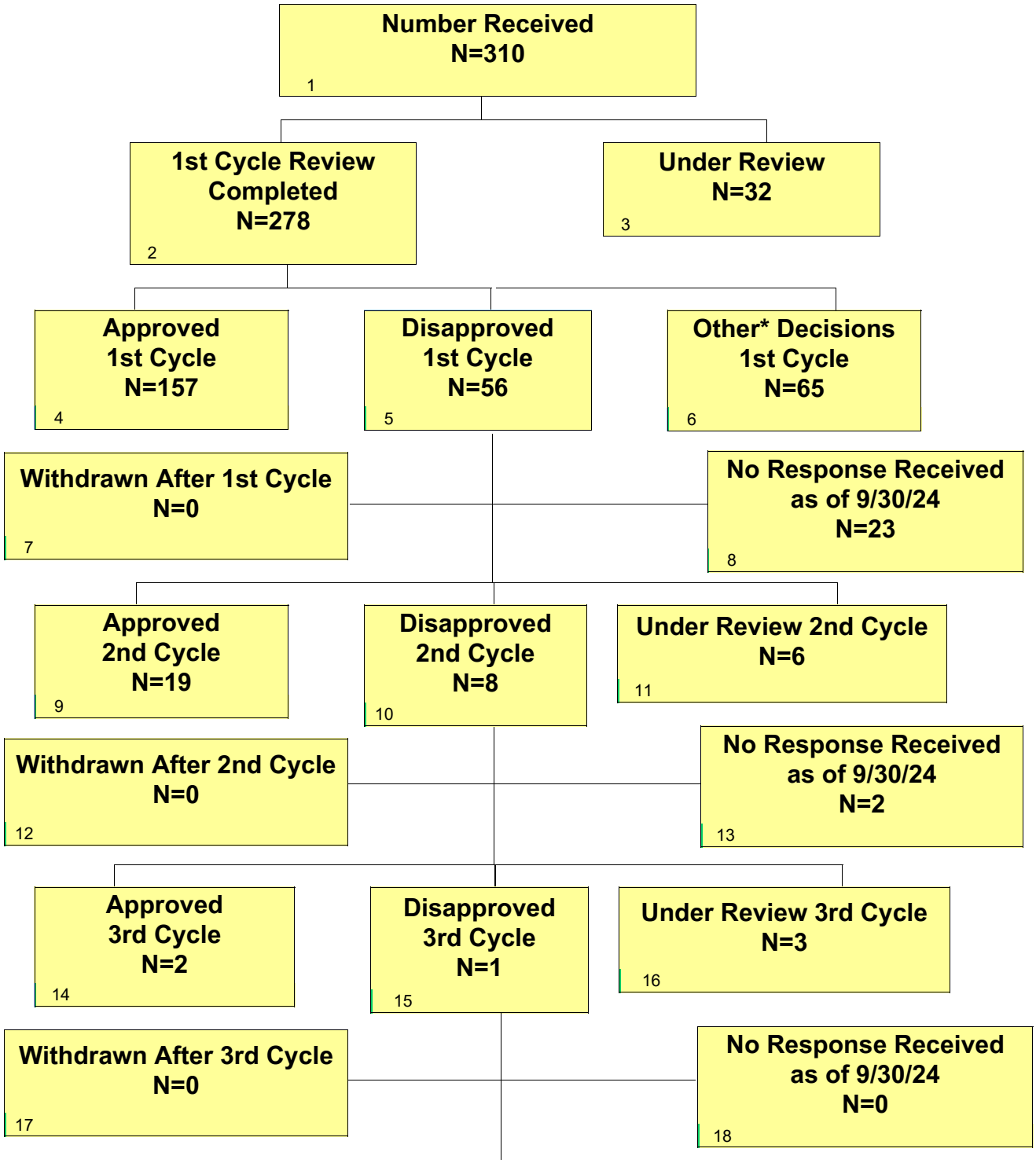


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 9/30/24

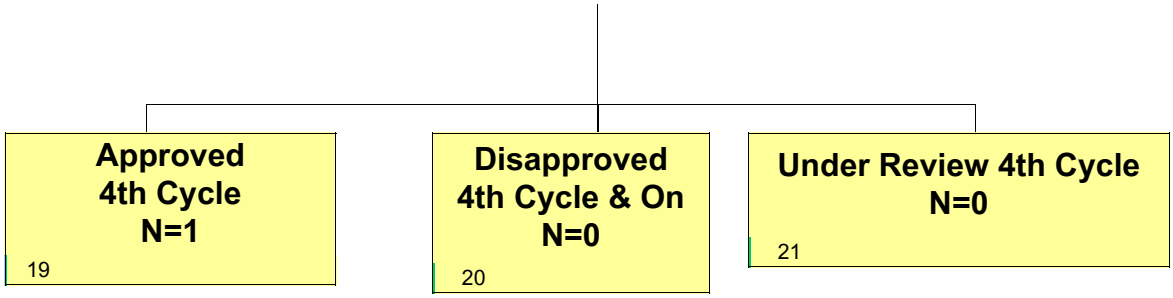


CDRH IDEs - FY 2024
as of 9/30/24



*** Other decisions include withdrawn (N=7), withdrawn and converted (N=33), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 9/30/24



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343	310			
Average Number of Cycles to IDE Approval or Conditional Approval	1.27	1.15			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.27	0.15			

Section 10 IDE - Office Level Metric

Table 10.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	41	32			
Average Number of Cycles to IDE Approval or Conditional Approval	1.38	1.05			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.38	0.05			

Table 10.1 OHT2 - Office of Cardiovascular Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	81			
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.26			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.26			

Table 10.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	35	41			
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.20			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.20			

Table 10.1 OHT4 - Office of Surgical and Infection Control Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	38	17			
Average Number of Cycles to IDE Approval or Conditional Approval	1.10	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10	0.00			

Table 10.1 OHT5 - Office of Neurological and Physical Medicine Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	76	63			
Average Number of Cycles to IDE Approval or Conditional Approval	1.22	1.19			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.22	0.19			

Table 10.1 OHT6 - Office of Orthopedic Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	25	22			
Average Number of Cycles to IDE Approval or Conditional Approval	1.36	1.08			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.36	0.08			

Table 10.1 OHT7 - Office of In Vitro Diagnostics
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	46	43			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

Table 10.1 OHT8 - Office of Radiological Health
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	8	11			
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.00			

Section 11 CLIA Waiver Annual Metrics

Table 11.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	3	9 (12)			
Withdrawn prior to SI	1	0 (1)			
SI within 90 FDA days	1	8 (9)			
SI over 90 FDA days	1	0 (1)			
SI pending within 90 FDA days	0	1 (1)			
SI pending over 90 FDA days	0	0 (0)			
Denial without SI	0	0 (0)			
Current SI Performance Percent within 90 FDA days	N/A*	90.00%			

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.2.CDRH – CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	2	8			
Average number of FDA days to Substantive Interaction	60.50	62.25			
20th Percentile FDA days to Substantive Interaction	37	29			
40th Percentile FDA days to Substantive Interaction	53	76			
60th Percentile FDA days to Substantive Interaction	68	86			
80th Percentile FDA days to Substantive Interaction	84	88			
Maximum FDA days to Substantive Interaction	99	90			

Table 11.3.CDRH – CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	3	9 (12)			
Non-MDUFA IV Decisions	0	0 (0)			
MDUFA IV Decisions	3	6 (9)			
MDUFA IV Decisions within 150 FDA Days	3	6 (9)			
CLIA Waiver Applications pending MDUFA IV Decision	0	3 (3)			
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0	0 (0)			
Current Performance Percent within 150 FDA Days	N/A*	100.00%			

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.4.CDRH – CLIA Waiver with Panel Review MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decisions	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions within 320 FDA Days	0	0			
CLIA Waiver Applications pending MDUFA IV Decision	0	0			
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A*	N/A*			

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.5.CDRH – CLIA Waiver (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA decision	3	6			
Average FDA days to MDUFA IV decision	59.67	67.00			
20th Percentile FDA days to MDUFA IV decision	18	24			
40th Percentile FDA days to MDUFA IV decision	21	36			
60th Percentile FDA days to MDUFA IV decision	46	86			
80th Percentile FDA days to MDUFA IV decision	94	110			
Maximum FDA days to MDUFA IV decision	142	146			
Average Industry days to MDUFA IV decision	0.00	6.33			
20th Percentile Industry days to MDUFA IV decision	0	0			
40th Percentile Industry days to MDUFA IV decision	0	0			
60th Percentile Industry days to MDUFA IV decision	0	0			
80th Percentile Industry days to MDUFA IV decision	0	0			
Maximum Industry days to MDUFA IV decision	0	38			
Average Total days to MDUFA IV decision	59.67	73.33			
20th Percentile Total days to MDUFA IV decision	18	24			
40th Percentile Total days to MDUFA IV decision	21	36			
60th Percentile Total days to MDUFA IV decision	46	86			
80th Percentile Total days to MDUFA IV decision	94	110			
Maximum Total days to MDUFA IV decision	142	184			

Table 11.6.CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA decision	0	0			
Average FDA days to MDUFA IV decision	0.00	0.00			
20th Percentile FDA days to MDUFA IV decision	0	0			
40th Percentile FDA days to MDUFA IV decision	0	0			
60th Percentile FDA days to MDUFA IV decision	0	0			
80th Percentile FDA days to MDUFA IV decision	0	0			
Maximum FDA days to MDUFA IV decision	0	0			
Average Industry days to MDUFA IV decision	0.00	0.00			
20th Percentile Industry days to MDUFA IV decision	0	0			
40th Percentile Industry days to MDUFA IV decision	0	0			
60th Percentile Industry days to MDUFA IV decision	0	0			
80th Percentile Industry days to MDUFA IV decision	0	0			
Maximum Industry days to MDUFA IV decision	0	0			
Average Total days to MDUFA IV decision	0.00	0.00			
20th Percentile Total days to MDUFA IV decision	0	0			
40th Percentile Total days to MDUFA IV decision	0	0			
60th Percentile Total days to MDUFA IV decision	0	0			
80th Percentile Total days to MDUFA IV decision	0	0			
Maximum Total days to MDUFA IV decision	0	0			

Section 12 DUAL (510(k) and CLIA Waiver) Annual Metrics

Table 12.1 CDRH – DUAL (510(k) and CLIA Waiver) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	15	11			
Withdrawn prior to SI	0	0			
SI within 90 FDA days	15	8			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	3			
SI pending over 90 FDA days	0	0			
Denial without SI	0	0			
Current SI Performance Percent within 90 FDA days*	100.00%	100.00%			

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.2.CDRH –DUAL (510(k) and CLIA Waiver)Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	15	8			
Average number of FDA days to Substantive Interaction	82.87	88.63			
20th Percentile FDA days to Substantive Interaction	76	88			
40th Percentile FDA days to Substantive Interaction	86	89			
60th Percentile FDA days to Substantive Interaction	90	90			
80th Percentile FDA days to Substantive Interaction	90	90			
Maximum FDA days to Substantive Interaction	90	90			

Table 12.3.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Eligible for MDUFA V Decision	15	11			
Non-MDUFA V Decisions	0	1			
MDUFA V Decisions	15	2			
MDUFA V Decisions within 180 FDA Days	15	2			
CLIA Waiver Applications pending MDUFA V Decision	0	9			
CLIA Waiver Applications pending MDUFA V Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days*	100.00%	100.00%			

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.4.CDRH – DUAL (510(k) and CLIA Waiver) (with panel review) MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA V Decision	0	0			
Non-MDUFA V Decisions	0	0			
MDUFA V Decisions	0	0			
MDUFA V Decisions with in 320 FDA Days	0	0			
CLIA Waiver Applications pending MDUFA V Decision	0	0			
CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A*	N/A*			

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.5.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V decision	15	2			
Average FDA days to MDUFA V decision	146.13	155.50			
20th Percentile FDA days to MDUFA V decision	90	141			
40th Percentile FDA days to MDUFA V decision	163	151			
60th Percentile FDA days to MDUFA V decision	177	160			
80th Percentile FDA days to MDUFA V decision	179	170			
Maximum FDA days to MDUFA V decision	180	180			
Average Industry days to MDUFA V decision	137.33	78.50			
20th Percentile Industry days to MDUFA V decision	83	31			
40th Percentile Industry days to MDUFA V decision	155	63			
60th Percentile Industry days to MDUFA V decision	176	94			
80th Percentile Industry days to MDUFA V decision	179	126			
Maximum Industry days to MDUFA V decision	202	157			
Average Total days to MDUFA V decision	283.47	234.00			
20th Percentile Total days to MDUFA V decision	221	202			
40th Percentile Total days to MDUFA V decision	258	223			
60th Percentile Total days to MDUFA V decision	335	245			
80th Percentile Total days to MDUFA V decision	355	266			
Maximum Total days to MDUFA V decision	360	288			

Table 12.6.CDRH – DUAL (510(k) and CLIA Waiver) (with Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V decision	0	0			
Average FDA days to MDUFA V decision	0.00	0.00			
20th Percentile FDA days to MDUFA V decision	0	0			
40th Percentile FDA days to MDUFA V decision	0	0			
60th Percentile FDA days to MDUFA V decision	0	0			
80th Percentile FDA days to MDUFA V decision	0	0			
Maximum FDA days to MDUFA V decision	0	0			
Average Industry days to MDUFA V decision	0.00	0.00			
20th Percentile Industry days to MDUFA V decision	0	0			
40th Percentile Industry days to MDUFA V decision	0	0			
60th Percentile Industry days to MDUFA V decision	0	0			
80th Percentile Industry days to MDUFA V decision	0	0			
Maximum Industry days to MDUFA V decision	0	0			
Average Total days to MDUFA V decision	0.00	0.00			
20th Percentile Total days to MDUFA V decision	0	0			
40th Percentile Total days to MDUFA V decision	0	0			
60th Percentile Total days to MDUFA V decision	0	0			
80th Percentile Total days to MDUFA V decision	0	0			
Maximum Total days to MDUFA V decision	0	0			

Section 13 TAP Center Level Metrics

Table 13.1 CDRH - TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		31			
Closed before Teleconference		0			
Teleconferences Held		29			
Teleconferences Held Within 14 Days		28			
Teleconferences Pending		2			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		96.55%			

Table 13.2 CDRH - TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3			
Closed before Written Feedback		0			
Written Feedback Provided		3			
Written Feedback Provided Within 21 Days		3			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		100.00%			

Table 13.3 CDRH - TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		44			
Closed before Written Feedback		0			
Written Feedback Provided		39			
Written Feedback Provided Within 40 Days		39			
Written Feedback Pending		5			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		100.00%			

TAP Pilot Enrollment Data

Table 13.4 - TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	47			
Enrollment Requests Accepted	12	40			
Enrollment Requests Not Accepted	7	7			
Enrollment Requests Pending	0	0			

Section 13 TAP Documents - Office Level Metric

Table 13.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0			
Closed before Teleconference		0			
Teleconferences Held		0			
Teleconferences Held Within 14 Days		0			
Teleconferences Pending		0			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		N/A			

Table 13.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 40 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		N/A			

Table 13.4 - OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0			
Enrollment Requests Accepted	0	0			
Enrollment Requests Not Accepted	0	0			
Enrollment Requests Pending	0	0			

Table 13.1 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		21			
Closed before Teleconference		0			
Teleconferences Held		20			
Teleconferences Held Within 14 Days		19			
Teleconferences Pending		1			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		95.00%			

Table 13.2 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3			
Closed before Written Feedback		0			
Written Feedback Provided		3			
Written Feedback Provided Within 21 Days		3			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		100.00%			

Table 13.3 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		34			
Closed before Written Feedback		0			
Written Feedback Provided		30			
Written Feedback Provided Within 40 Days		30			
Written Feedback Pending		4			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		100.00%			

Table 13.4 - OHT2 - Office of Cardiovascular Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	21			
Enrollment Requests Accepted	12	16			
Enrollment Requests Not Accepted	7	5			
Enrollment Requests Pending	0	0			

Table 13.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0			
Closed before Teleconference		0			
Teleconferences Held		0			
Teleconferences Held Within 14 Days		0			
Teleconferences Pending		0			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		N/A			

Table 13.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 40 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		N/A			

Table 13.4 - OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	1			
Enrollment Requests Accepted	0	0			
Enrollment Requests Not Accepted	0	1			
Enrollment Requests Pending	0	0			

Table 13.1 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0			
Closed before Teleconference		0			
Teleconferences Held		0			
Teleconferences Held Within 14 Days		0			
Teleconferences Pending		0			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		N/A			

Table 13.2 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 40 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		N/A			

Table 13.4 - OHT4 - Office of Surgical and Infection Control Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0			
Enrollment Requests Accepted	0	0			
Enrollment Requests Not Accepted	0	0			
Enrollment Requests Pending	0	0			

Table 13.1 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		10			
Closed before Teleconference		0			
Teleconferences Held		9			
Teleconferences Held Within 14 Days		9			
Teleconferences Pending		1			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		100.00%			

Table 13.2 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		10			
Closed before Written Feedback		0			
Written Feedback Provided		9			
Written Feedback Provided Within 40 Days		9			
Written Feedback Pending		1			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		100.00%			

Table 13.4 - OHT5 - Office of Neurological and Physical Medicine Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	25			
Enrollment Requests Accepted	0	24			
Enrollment Requests Not Accepted	0	1			
Enrollment Requests Pending	0	0			

Table 13.1 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0			
Closed before Teleconference		0			
Teleconferences Held		0			
Teleconferences Held Within 14 Days		0			
Teleconferences Pending		0			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		N/A			

Table 13.2 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 40 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		N/A			

Table 13.4 - OHT6 - Office of Orthopedic Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0			
Enrollment Requests Accepted	0	0			
Enrollment Requests Not Accepted	0	0			
Enrollment Requests Pending	0	0			

Table 13.1 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0			
Closed before Teleconference		0			
Teleconferences Held		0			
Teleconferences Held Within 14 Days		0			
Teleconferences Pending		0			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		N/A			

Table 13.2 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 40 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		N/A			

Table 13.4 - OHT7 - Office of In Vitro Diagnostics
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0			
Enrollment Requests Accepted	0	0			
Enrollment Requests Not Accepted	0	0			
Enrollment Requests Pending	0	0			

Table 13.1 OHT8 - Office of Radiological Health
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0			
Closed before Teleconference		0			
Teleconferences Held		0			
Teleconferences Held Within 14 Days		0			
Teleconferences Pending		0			
Teleconferences Pending Over 14 Days		0			
Current Performance Percent Within 14 Days		N/A			

Table 13.2 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 21 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 21 Days		0			
Current Performance Percent Within 21 Days		N/A			

Table 13.3 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0			
Closed before Written Feedback		0			
Written Feedback Provided		0			
Written Feedback Provided Within 40 Days		0			
Written Feedback Pending		0			
Written Feedback Pending Over 40 Days		0			
Current Performance Percent Within 40 Days		N/A			

Table 13.4 - OHT8 - Office of Radiological Health
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0			
Enrollment Requests Accepted	0	0			
Enrollment Requests Not Accepted	0	0			
Enrollment Requests Pending	0	0			

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

Table 1.1 and Tables 1.1.x **PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Closed Before First RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Filing Review on First Cycle	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

Table 1.2 and Tables 1.2.x **PMA Originals and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of Submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

Table 1.3 and Tables 1.3.x **PMA Originals and Panel Track Supplements Substantive Interaction Performance Goal - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 1.4 and Tables 1.4.x **PMA Originals and Panel Track Supplements Substantive Interaction Metric – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average Number of FDA Days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20th Percentile FDA Days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA Days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA Days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA Days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA Days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 1.5 and Tables 1.5.x PMA Originals and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.6 and Tables 1.6.x PMA Originals and Panel Track Supplements (With Panel Review) MDUFA V Decision Performance Goal - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.7 and Tables 1.7.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.8 and Tables 1.8.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (Without Panel Review) MDUFA V Performance Metric – Rates of Withdrawal, Not Approvable and Deleted - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number With MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.10 and Tables 1.10.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Rate of Withdrawal, Not Approvable and Deleted - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number With MDUFA Decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.11 and Tables 1.11.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Table 1.12 and Tables 1.12.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Tables 1.13 and Tables 1.13.x LDT PMA Originals and Panel-Track Supplements MDUFA V Metric* - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decision	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decision	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements MDUFA V Metric* - Definitions

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goal – Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA (other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA Decision	Supplements received (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements Pending MDUFA Decision	Number of supplements received (line 1) that do not have a MDUFA decision or a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 2.3 and Tables 2.3.x PMA 180 Day Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

Table 2.4 and Tables 2.4.x PMA 180 Day Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA V decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x PMA Real Time Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) within goal.
5	Supplements Pending MDUFA Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA decision and are not closed with a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x PMA Real Time Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

Table 3.3 and Tables 3.3.x **PMA Real Time PMA Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements(No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

Table 5.2 **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number With a Decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY Closed	Number with a decision (line 2) divided by Number Filed (line 1).

Table 5.3 **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-Year Rolling Average Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number With a MDUFA Decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number With a MDUFA Decision After Trimming the Upper and Lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA V decision and 5% of submissions with the highest number of Total Days to MDUFA V decision.
3	Three-Year Rolling Average Total Time to MDUFA Decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA V Performance (Quarterly Data Exclude Third Party Review)

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1st 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).

Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goal – Definitions

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent 510k definitions.
2	Deleted or Withdrawn Prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made as of the quarter end date and before any SI action: WTDR, DELE.
3	SI Within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI Over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI Pending within 60 FDA days	Submissions that are awaiting SI and where 60 days have not yet elapsed.
6	SI Pending over 60 FDA days	Submissions that are awaiting SI and where 60 days have elapsed.
7	510(k)s NSE Without SI	Number of 510(k) submissions that are closed with an NSE decision and did not have an SI.
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) expressed as a percentage of the sum of the number of submissions that received an SI (line 3 and line 4), the number of submissions that missed the SI goal or are awaiting SI after 60 days as of quarter end (line 6), and the number of submissions that were found NSE without receiving an SI (line 7).

Table 6.3 and Tables 6.3.x **510(k) Substantive Interaction Metric – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interaction	Number of 510(k) submissions RTA accepted or passed TS in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 6.4 and Tables 6.4.x 510(k) MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA Decision	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA Decisions (line 3) and pending submissions that have missed the MDUFA goal (line 6).

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA V Decision– Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days to MDUFA V decision.

Table 6.6 and Tables 6.6.x 510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision– Definitions

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

Table 6.7 and Tables 6.7.x 510(k) Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA V Decision Metric– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of LDT submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA Decision over 90 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA decision within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA Decision (line 3) and pending LDT submissions that already missed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA V decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA Decision within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA Decision (line 3) and pending non-LDT IVD submissions that already missed the MDUFA goal (line 6).

Section 7 510(k) Annual General Metrics (Annual data includes Third Party reviews)

Table 7.1 CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type – Definitions

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA/TS review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal – Definitions

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Currently Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA V decision and the 2% of submissions with the highest number of Total Days to MDUFA decision.
7	Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

Table 7.3 CDRH - 510(k) Third Party Performance – Definitions

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90th Percentile FDA Days to MDUFA Decision	The 90th percentile of FDA days to MDUFA decision on 3rd Party 510(k) submissions received in this fiscal year

Section 8 De Novo MDUFA V Performance

Table 8.1 and Tables 8.1.x De Novo Acceptance Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1st 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).

Tables 8.2 and Tables 8.2.x De Novo MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent De Novo definitions.
2	Non-MDUFA Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA V Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already have missed the MDUFA goal (line 6).

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA decision (line 2).
2	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days to MDUFA decision.

Table 8.4 and Tables 8.4.x De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA V Decisions	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA decision (line 2).

Table 8.5 and Tables 8.5.x De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions

#	Measure	Description
1	Number of Submissions that Mssed the Goal	Number of submissions with MDUFA decision made beyond 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Tables 8.6 and Tables 8.6.x LDT De Novo MDUFA V Decision Metrics – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA V Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA V Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA V Decision over 150 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA V review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA Decisions (line 3) and pending LDT submissions that have missed the MDUFA goal (line 6).

Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA Decisions (line 3) and pending non-LDT IVD submissions that have missed the MDUFA goal (line 6).

Section 8 Annual Metrics for De Novo Requests

Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions

#	Measure	Description
1	Number Accepted	Number of De Novo submissions accepted in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept/Technical Screening	Average number of days in the first RTA/TS review cycle

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of Pre-Subs received in this fiscal year (includes Q-Sub types tracked as Pre-Sub Meeting, Pre-Sub Written Feedback, Breakthrough Interaction, and STeP Interaction).
2	Interactions for Breakthrough Designated Products & Products Included in STeP	Number of Breakthrough Interactions and STeP Interactions received in this fiscal year (excludes submissions tracked as Pre-Sub Meeting and Pre-Sub Written Feedback).
3	Number Closed Before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
4	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer and submissions considered accepted upon receipt
5	Number Without First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that had a "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.
6	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
7	Number Not Accepted First RTA Cycle	Number of submissions received in this fiscal year (line 1) that had a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
8	Rate of Submissions Not Accepted for Review on First RTA Cycle	Number Not Accepted First RTA Cycle (line7) expressed as a percentage of the sum of the Number Accepted First RTA Cycle (line 4), Number Without First Cycle RTA Review and > 15 Days Since Date Received (line 5), and Number Not Accepted First RTA Cycle (line 7).

Table 9.2 and Tables 9.2.x MDUFA V Pre-Sub Performance Goals – Definitions

#	Measure	Description
1	Number Accepted / Eligible for MDUFA Action	Number of submissions that passed via the RTA process as of quarter end date and Breakthrough/STeP Interactions
2	Number with Non-MDUFA Action	Number of submissions accepted (line 1) and closed with a non-MDUFA action (WTDR, JPND, JTRX, CLLR). Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.
3	Number with MDUFA Action	Number of submissions accepted (line 1) with a MDUFA action (EMAL, EMFB).
4	Written Feedback Provided Within Goal	Number of submissions with a MDUFA action (line 3) made by the MDUFA review goal (day 70 or 5 days prior to the meeting, whichever is sooner).
5	Number Pending MDUFA Action	Number of submissions accepted (line 1) still under review and pending feedback.
6	Pending MDUFA Action Past Goal	Number of submissions pending a MDUFA action (line 5) that have already missed the MDUFA review goal.
7	Number in MDUFA Cohort (up to max 4300)	Number of submissions accepted with a MDUFA action (line 3) plus the number of submissions accepted and pending a MDUFA action (line 5). If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.
8	Current Performance Percent Within Goal	Number of submissions with MDUFA actions made by the MDUFA review goal (line 4) expressed as a percentage of the sum of the number of submissions with a MDUFA action (line 3) and the number of submissions pending a MDUFA action and already passed the MDUFA review goal (line 6).

Table 9.3 and Tables 9.3.x MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort) – Definitions

#	Measure	Description
1	Number with Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA V Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB) EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA V Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20th Percentile FDA Days to Written Feedback	20th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
4	40th Percentile FDA Days to Written Feedback	40th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
5	60th Percentile FDA Days to Written Feedback	60th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
6	80th Percentile FDA Days to Written Feedback	80th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100th percentile) to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).

Table 9.4 and Tables 9.4.x MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort) - Definitions

#	Measure	Description
1	Meetings Not Scheduled by Day 30	Number of Pre-Subs for which a Meeting was Requested and a Meeting Date was not confirmed by the reviewer in CTS by day 30.
2	Average Days to Scheduling for Meetings Scheduled After Day 30	Average days to confirming a Meeting Date in CTS for Meetings not scheduled by Day 30 (line 1).

Table 9.5 and Tables 9.5.x MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort) - Definitions

#	Measure	Description
1	Number of Meetings Required	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date. Number of meetings requested and then held after written feedback is provided.
2	Meeting Minutes Submitted Within 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date.
3	Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter).
4	Meeting Minutes Past 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date.
5	Meeting Minutes Not Submitted and >15 Days Since Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter).
6	Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5).

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn within 90 FDA days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all CLIA Waivers with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 11.3 **CLIA Waiver (without Panel Review) MDUFA V Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 150 FDA Days	Number of submissions with MDUFA V decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA V Decision for more than 150 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA V Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.4 CLIA Waiver (with Panel Review) MDUFA V Decision Performance Goals) – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 320 FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Section 12 Dual 510(k) and CLIA Waiver Annual Metrics

Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 12.2 **Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 12.3 **Dual 510(k) and CLIA Waiver (without panel review) MDUFA V Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 180 FDA Days	Number of submissions with MDUFA V decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 180 FDA days	Number of submissions pending MDUFA V Decision for more than 180 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA V Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 320FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for FDA days, Industry days, and Total days.

Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision, and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for FDA days, Industry days, and Total days.

Section 13 Total Product Life Cycle Advisory Program (TAP)

Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions

#	Measure	Description
1	Teleconferences Requested	Number of Teleconferences requested
2	Closed before Teleconference	Number of Teleconferences Requested (line 1) that were closed with a final decision before Teleconference Held (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Teleconferences Held	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON))
4	Teleconferences Held Within 14 Days	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON)) within 14 days
5	Teleconferences Pending	Number of Teleconferences Requested (line 1) that are under review without a final decision
6	Teleconferences Pending Over 14 Days	Number of Teleconferences Requested (line 1) that are under review without a final decision and where 14 days have elapsed.
7	Current Performance Percent Within 14 Days	Number of Teleconferences Held Within 14 Days (line 4) expressed as a percentage of the sum of the Teleconferences Held (line 3) and Teleconferences Pending Over 14 Days (line 6)

Table 13.2 TAP Written Feedback (Biocompatibility/Sterility) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on Biocompatibility and Sterility topics(s)
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 21 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 21 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 21 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 21 days have elapsed.
7	Current Performance Percent Within 21 Days	Number of Written Feedback Provided Within 21 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 21 Days (line 6)

Table 13.3 TAP Written Feedback (Other) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on topics(s) other than Biocompatibility and Sterility
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 40 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 40 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 40 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 40 days have elapsed.
7	Current Performance Percent Within 40 Days	Number of Written Feedback Provided Within 40 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 40 Days (line 6)

Table 13.4 TAP Pilot Enrollment Data– Definitions

#	Measure	Description
1	Enrollment Requests Received	Number of TAP Pilot Enrollment Requests received in the fiscal year.
2	Enrollment Requests Accepted	Number of TAP Pilot Enrollment Requests accepted in the fiscal year.
3	Enrollment Requests Not Accepted	Number of TAP Pilot Enrollment Requests not accepted in the fiscal year.
4	Enrollment Requests Pending	Number of TAP Pilot Enrollment Requests still under review.

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 30 September 2024

Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

Table 1.1 CBER - PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	3	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A			

Table 1.2 CBER - PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0			
Number Accepted	3	0			
Completed RTF	3	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	N/A			

Table 1.3 CBER - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	0			
SI Goal Met	3	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	N/A			

Table 1.4 CBER - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	0			
Average Number of FDA Days to Substantive Interaction	88.33	0.00			
20th Percentile FDA Days to Substantive Interaction	87	0.00			
40th Percentile FDA Days to Substantive Interaction	88	0.00			
60th Percentile FDA Days to Substantive Interaction	88	0.00			
80th Percentile FDA Days to Substantive Interaction	89	0.00			
Maximum FDA Days to Substantive Interaction	90	0.00			

Table 1.5 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	0			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	3	0			
MDUFA V Decision Goal Met	3	0			
PMAs Pending MDUFA V Decision	0	0			
PMAs Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 1.6 CBER - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	0	0			
MDUFA V Decision Goal Met	0	0			
PMAs Pending MDUFA V Decision	0	0			
PMAs Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

Table 1.7 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)
Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	3	0			
Average FDA Days to MDUFA V Decision	177.00	0.00			
20th Percentile FDA Days to MDUFA V Decision	175	0			
40th Percentile FDA Days to MDUFA V Decision	178	0			
60th Percentile FDA Days to MDUFA V Decision	179	0			
80th Percentile FDA Days to MDUFA V Decision	180	0			
Maximum FDA Days to MDUFA V Decision	180	0			
Average Industry Days to MDUFA V Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	0	0			
80th Percentile Industry Days to MDUFA V Decision	0	0			
Maximum Industry Days to MDUFA V Decision	0	0			
Average Total Days to MDUFA V Decision	177.00	0.00			
20th Percentile Total Days to MDUFA V Decision	175	0			
40th Percentile Total Days to MDUFA V Decision	178	0			
60th Percentile Total Days to MDUFA V Decision	179	0			
80th Percentile Total Days to MDUFA V Decision	180	0			
Maximum Total Days to MDUFA V Decision	180	0			

Table 1.8 CBER - PMA Original and Panel-Track Supplements (with Panel Review)
Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	0	0			
Average FDA Days to MDUFA V Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA V Decision	0	0			
40th Percentile FDA Days to MDUFA V Decision	0	0			
60th Percentile FDA Days to MDUFA V Decision	0	0			
80th Percentile FDA Days to MDUFA V Decision	0	0			
Maximum FDA Days to MDUFA V Decision	0	0			
Average Industry Days to MDUFA V Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	0	0			
80th Percentile Industry Days to MDUFA V Decision	0.00	0.00			
Maximum Industry Days to MDUFA V Decision	0	0			
Average Total Days to MDUFA V Decision	0	0			
20th Percentile Total Days to MDUFA V Decision	0	0			
40th Percentile Total Days to MDUFA V Decision	0	0			
60th Percentile Total Days to MDUFA V Decision	0	0			
80th Percentile Total Days to MDUFA V Decision	0	0			
Maximum Total Days to MDUFA V Decision	0	0			

Table 1.9 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)
Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	0			
Number with MDUFA V Decision	3	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	0.00%	N/A			

Table 1.10 CBER - PMA Original and Panel-Track Supplements (with Panel Review)
Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0			
Number With MDUFA V Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

Table 1.11 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)
Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 1.12 CBER - PMA Original and Panel-Track Supplements (with Panel Review)
Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 1.13 CBER - LDT PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	0	0			
MDUFA V Decision Goal Met	0	0			
PMAs Pending MDUFA V Decision	0	0			
PMAs Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Table 1.14 CBER - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	0	0			
MDUFA V Decision Goal Met	0	0			
PMAs Pending MDUFA V Decision	0	0			
PMAs Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

***Includes submission that went to panel**

Section 2 PMA 180-Day Supplements - Center Level Metric

Table 2.1 CBER - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	4	5			
SI Goal Met	2	4			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	50.00%	100.00%			

Table 2.2 CBER - PMA 180-Day Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	4	5			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	4	2			
MDUFA V Decision Goal Met	3	2			
Supplements Pending MDUFA V Decision	0	3			
Supplements Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	75.00%	100.00%			

Table 2.3 CBER - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5			
Number with MDUFA V Decision	4	2			
Number of Not Approvable	1	0			
Rate of Not Approvable	25.00%	0.00%			

Table 2.4 CBER - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	121.00	N/A			

Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CBER - PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	3	2			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	3	1			
MDUFA V Decision Goal Met	3	1			
Supplements Pending MDUFA V Decision	0	1			
Supplements Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 3.2 CBER - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2			
Number With MDUFA V Decision	3	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 3.3 CBER - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	41	30			
Closed Before First RTA or TS Action [1]	0	0			
Number Accepted or Passed TS on First Cycle [2]	30	23			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	5			
Number Not Accepted or Failed TS on First Cycle [2]	11	2			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	8.00%			

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 6.2 CBER - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible for SI	39	30			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	37	23			
SI Over 60 FDA Days	2	0			
SI Pending Within 60 FDA Days	0	7			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	94.87%	100.00%			

Table 6.3 CBER - 510(k) Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	39	23			
Average Number of FDA Days to Substantive Interaction	55.53	56.61			
20th Percentile FDA Days to Substantive Interaction	51	57			
40th Percentile FDA Days to Substantive Interaction	56	58			
60th Percentile FDA Days to Substantive Interaction	59	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	90	60			

Table 6.4 CBER - 510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	39	30			
Non-MDUFA V Decision	3	0			
MDUFA V Decision (SE/NSE)	35	13			
MDUFA V Decision Within 90 FDA Days	35	13			
510(k)s Pending MDUFA V Decision	1	17			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Table 6.5 CBER - 510(k) Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.31	1.23			
Number With MDUFA V Decision	35	13			
Average Number of FDA Days to MDUFA V Decision	77.00	75.31			
20th Percentile FDA Days to MDUFA V Decision	67	63			
40th Percentile FDA Days to MDUFA V Decision	83	78			
60th Percentile FDA Days to MDUFA V Decision	88	86			
80th Percentile FDA Days to MDUFA V Decision	90	89			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	44.86	21.23			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	0	0			
80th Percentile Industry Days to MDUFA V Decision	98	50			
Maximum Industry Days to MDUFA V Decision	315	102			
Average Number of Total Days to MDUFA V Decision	121.86	97.77			
20th Percentile Total Days to MDUFA V Decision	81	70			
40th Percentile Total Days to MDUFA V Decision	88	78			
60th Percentile Total Days to MDUFA V Decision	90	86			
80th Percentile Total Days to MDUFA V Decision	90	140			
Maximum Total Days to MDUFA V Decision	375	188			

Table 6.6 CBER - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	39	30			
Number With MDUFA V Decision	35	13			
Number of SE Decision	34	12			
Number of NSE Decision	1	1			
Number of Withdrawal	2	0			
Number of Deleted	1	0			
Rate of SE Decision	97.14%	92.31%			
Rate of NSE Decision	2.86%	7.69%			
Rate of Withdrawal	5.13%	0.00%			
Rate of Deleted	2.56%	0.00%			

Table 6.7 CBER - 510(k) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A			
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A			

Table 6.8 CBER - LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	0	0			
MDUFA V Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA V Decision	0	0			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	8	3			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	8	1			
MDUFA V Decision Within 90 FDA Days	8	1			
510(k)s Pending MDUFA V Decision	0	2			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

Section 7 510(k) Annual General Metrics

Table 7.1 CBER - 510(k) Annual General Metrics - 510(k)s Received by Type

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted	39	30			
Number of Traditional Submissions	35	29			
Number of Special Submissions	4	1			
Number of Abbreviated Submissions	0	0			
Average Number of Days to Accept/Refuse to Accept	13.27	12.24			
Number of Third Party Submissions	0	0			

Table 7.2 CBER - 510(k) Annual Shared Outcome Goal

Performance Metrics	FY 2023 128 Days	FY 2024 124 Days	FY 2025 112 Days	FY 2026 112 Days	FY 2027 112 Days
Number Accepted	39.00	30.00			
Currently Under Review	1.00	17.00			
Number With Non-MDUFA V Decision	3.00	0.00			
Number With MDUFA V Decision	35.00	13.00			
Percent of Cohort Closed	97.22%	43.33%			
Number With MDUFA V Decision After Trimming the Upper and Lower 2%	35	13			
Average Total Time to MDUFA V Decision	121.86	97.77			

Table 7.3 CBER - 510(k) Third Party Performance

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Third Party Submissions	0.00	0.00			
90th Percentile FDA Days to MDUFA V Decision	N/A	N/A			

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1	0			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	0	0			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted or Failed TS on First Cycle	1	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A			

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 CBER - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	1	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Within 150 FDA Days	0	0			
De Novos Pending MDUFA Decision	1	0			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00	0.00			
Number With MDUFA Decision	0	0			
Average FDA Days to MDUFA Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0			
60th Percentile FDA Days to MDUFA Decision	0	0			
80th Percentile FDA Days to MDUFA Decision	0	0			
Maximum FDA Days to MDUFA Decision	0	0			
Average Industry Days to MDUFA Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	0	0			
60th Percentile Industry Days to MDUFA Decision	0	0			
80th Percentile Industry Days to MDUFA Decision	0	0			
Maximum Industry Days to MDUFA Decision	0	0			
Average Total Days to MDUFA Decision	0.00	0.00			
20th Percentile Total Days to MDUFA Decision	0	0			
40th Percentile Total Days to MDUFA Decision	0	0			
60th Percentile Total Days to MDUFA Decision	0	0			
80th Percentile Total Days to MDUFA Decision	0	0			
Maximum Total Days to MDUFA Decision	0	0			

Table 8.4 CBER - De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0			
Number With MDUFA Decision	0	0			
Number With Granted Decision	0	0			
Number With Declined Decision	0	0			
Number of Withdrawal	0	0			
Number of Deleted	0	0			
Rate of Granted Decision	N/A	N/A			
Rate of Declined Decision	N/A	N/A			
Rate of Withdrawal	N/A	N/A			
Rate of Deleted	N/A	N/A			

Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 8.6 CBER - LDT De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Within 150 FDA Days	0	0			
De Novos Pending MDUFA Decision	0	0			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Within 150 FDA Days	0	0			
De Novos Pending MDUFA Decision	0	0			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.8 CBER - De Novo Annual General Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	0	0			
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	0.00	0.00			

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	68	64			
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1			
Number Closed Before First RTA Action	7	0			
Number Accepted First RTA Cycle [1]	59	55			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2	4			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	4			
Number Not Accepted First RTA Cycle	0	1			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.67%			

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	61	64			
Number with Non-MDUFA Action [3]	3	1			
Number with MDUFA Action	58	49			
Written Feedback Provided Within Goal	55	49			
Number Pending MDUFA Action	0	14			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	58	63			
Current Performance Percent Within Goal	94.83%	100.00%			

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 CBER – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	58	49			
Average FDA Days to Written Feedback	59.38	60.04			
20th Percentile FDA Days to Written Feedback	55	52			
40th Percentile FDA Days to Written Feedback	60	60			
60th Percentile FDA Days to Written Feedback	64	65			
80th Percentile FDA Days to Written Feedback	69	68			
Maximum FDA Days to Written Feedback	72	70			

Table 9.4 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00			

Table 9.5 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	24	22			
Meeting Minutes Submitted Within 15 Days of Meeting	21	18			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	3	4			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	81.82%			

1. Number of meetings requested and then held after written feedback is provided.

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	20	15			
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.00			

BLA

CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard BLAs Filed	6	0			
Number of Standard BLA First Actions less than or equal to 10 months	6	0			
Number of Standard BLA Frist Actions greater than 10 months	0	0			
Number of Standard BLAs Pending	0	0			
Number of Priority BLA Filed	0	0			
Number of Priority BLA First Actions less than or equal to 6 months	0	0			
Number of Priority BLA Frist Actions greater than 6 months	0	0			
Number of Priority BLAs Pending	0	0			

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard Efficacy Supplements Filed	1	0			
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	1	0			
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0	0			
Number of Standard Efficacy Supplements Pending	0	0			
Number of Priority Efficacy Supplements Filed	0	0			
Number of Priority Efficacy Supplements First Actions less than or equal to 6 months	0	0			
Number of Priority Efficacy Supplements Frist Actions greater than 6 months	0	0			
Number of Priority Efficacy Supplements Pending	0	0			

BLA Prior Approval Manufacturing Supplements
CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard PAS Supplements Filed	88	131			
Number of Standard PAS Supplements First Actions less than or equal to 4months	88	69			
Number of Standard PAS Supplements First Actions greater than 4 months	0	0			
Number of Standard PAS Supplements Pending	0	62			

BLA/BLA Resubmissions
CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Class 1 Resubmissions Received	0	0			
Number of Class 1 Resubmission Actions less than or equal to 2 months	0	0			
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0			
Number of Class 1 Resbumssions Pending	0	0			
Number of Class 2 Resubmissions Received	0	2			
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	0			
Number of Class 2 Resubmission Actions greater than 6 months	0	0			
Number of Class 2 Resubmissions Pending	0	2			

Medical Devices

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,[1] the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA V Commitment Letter are indicated as such.[2] The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).[3]

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2024

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	[4]Electronic Submission Template for Medical Device 510(k) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions	10/02/2023	Yes	No	N/A	No
2	Q1	[4]Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment	10/10/2023	Yes	No	N/A	No
3	Q1	[4]Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices	10/10/2023	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.
[3] www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023.
[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
4	Q1	[5]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring	10/19/2023	Yes	No	N/A	No
5	Q1	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses	10/24/2023	No	No	N/A	No
6	Q1	[5]Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-supplements-approved-premarket-approval-pma-or-humanitarian-device	11/02/2023	Yes	No	N/A	No
7	Q1	[4]Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices	11/3/2023	No	No	N/A	No
8	Q1	[5]Enforcement Policy for Clinical Electronic Thermometers www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers	11/3/2023	Yes	No	N/A	No
9	Q1	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	11/17/2023	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List

[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
10	Q1	Select Updates for the 506J Guidance: 506J Device List and Additional Notifications www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-506j-guidance-506j-device-list-and-additional-notifications	11/17/2023	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List
11	Q1	Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions	11/17/2023	Yes	No	N/A	No
12	Q1	[4]Data Standard Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	12/13/2023	Yes	No	N/A	No
13	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/19/2023	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
14	Q1	510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review	12/21/2023	Yes	Yes	Section 2502 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List
15	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations	12/22/2023	Yes	Yes	Section 3607(a) of the Food and Drug Omnibus Reform Act (FDORA)	No
16	Q2	[4]Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled	01/08/2024	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
17	Q2	Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/characterization-metallic-coatings-andor-calcium-phosphate-coatings-orthopedic-devices	01/23/2024	Yes	No	N/A	No
18	Q2	Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical	01/30/2024	Yes	No	N/A	No
19	Q2	Use of Data Monitoring Committees in Clinical Trials www.fda.gov/regulatory-information/search-fda-guidance-documents/use-data-monitoring-committees-clinical-trials	02/13/2024	Yes	No	N/A	No
20	Q2	Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-medical-device-user-fee-small-business-qualification-and-certification-guidance	02/22/2024	Yes	No	N/A	A-List
21	Q2	Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards www.fda.gov/regulatory-information/search-fda-guidance-documents/key-information-and-facilitating-understanding-informed-consent-guidance-sponsors-investigators-and	03/01/2024	No	No	N/A	No
22	Q2	Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-premarket-cybersecurity-guidance-section-524b-fdc-act	03/13/2024	Yes	No	N/A	A-List
23	Q2	Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-thermal-effects-medical-devices-produce-tissue-heating-andor-cooling	03/15/2024	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
24	Q2	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program-draft-guidance	03/15/2024	Yes	Yes	MDUFA V Commitment Letter II.A.	A-List
25	Q2	Animal Studies for Dental Bone Grafting Material Devices - Premarket Notification (510(k)) Submissions: Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions	03/29/2024	Yes	No	N/A	No
26	Q3	[4]Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	04/16/2024	Yes	No	N/A	No
27	Q3	Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564: Draft Guidance for Laboratory Manufacturers and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-in-vitro-diagnostic-devices-immediate-public-health-response-absence	05/06/2024	No	No	N/A	A-List
28	Q3	Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency: Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-tests-during-section-564-declared-emergency	05/06/2024	No	No	N/A	A-List
29	Q3	Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices	05/10/2024	Yes	No	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
30	Q3	Processes and Practices Applicable to Bioresearch Monitoring Inspections: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	06/05/2024	Yes	No	N/A	No
31	Q3	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection: Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection	06/20/2024	No	No	N/A	No
32	Q3	[4]Laboratory Developed Tests: Small Entity Compliance Guide: Guidance for Laboratory Manufacturers and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/laboratory-developed-tests-small-entity-compliance-guide	06/25/2024	No	No	N/A	No
33	Q3	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies	06/26/2024	Yes	Yes	Section 3602 of the Food and Drug Omnibus Reform Act (FDORA)	No
34	Q3	Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/essential-drug-delivery-outputs-devices-intended-deliver-drugs-and-biological-products	06/28/2024	Yes	No	N/A	No
35	Q4	Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/purpose-and-content-use-related-risk-analyses-drugs-biological-products-and-combination-products	07/09/2024	No	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
36	Q4	Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/addressing-misinformation-about-medical-devices-and-prescription-drugs-questions-and-answers	07/09/2024	No	No	N/A	No
37	Q4	Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-considerations-studies-devices-intended-treat-opioid-use-disorder	07/11/2024	Yes	No	N/A	No
38	Q4	Dental Curing Lights - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-curing-lights-premarket-notification-510k-submissions	07/12/2024	Yes	No	N/A	No
39	Q4	Dental Composite Resin Devices - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-composite-resin-devices-premarket-notification-510k-submissions	07/12/2024	Yes	No	N/A	No
40	Q4	[4]Acceptable Media for Electronic Product User Manuals www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptable-media-electronic-product-user-manuals	08/19/2024	No	No	N/A	No
41	Q4	Predetermined Change Control Plans for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices	08/22/2024	Yes	Yes	Section 3308 of the Food and Drug Omnibus Reform Act (FDORA)	A-List
42	Q4	[4]FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic	08/23/2024	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
43	Q4	Electronic Submission Template for Medical Device De Novo Requests: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-de-novo-requests	08/23/2024	Yes	No	N/A	No
44	Q4	[4]Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide www.fda.gov/regulatory-information/search-fda-guidance-documents/mammography-quality-standards-act-and-regulation-amendments-small-entity-compliance-guide	08/26/2024	No	No	N/A	No
45	Q4	Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-malfunction-summary-reporting-vmsr-program-manufacturers	08/29/2024	Yes	No	N/A	B-List
46	Q4	Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle	09/06/2024	Yes	Yes	MDUFA V Commitment Letter V.E.	A-List
47	Q4	[4]Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Referring Provider Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions	09/10/2024	No	No	N/A	No
48	Q4	[4]Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	09/16/2024	Yes	No	N/A	No
49	Q4	Conducting Clinical Trials With Decentralized Elements www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements	09/18/2024	Yes	No	N/A	No

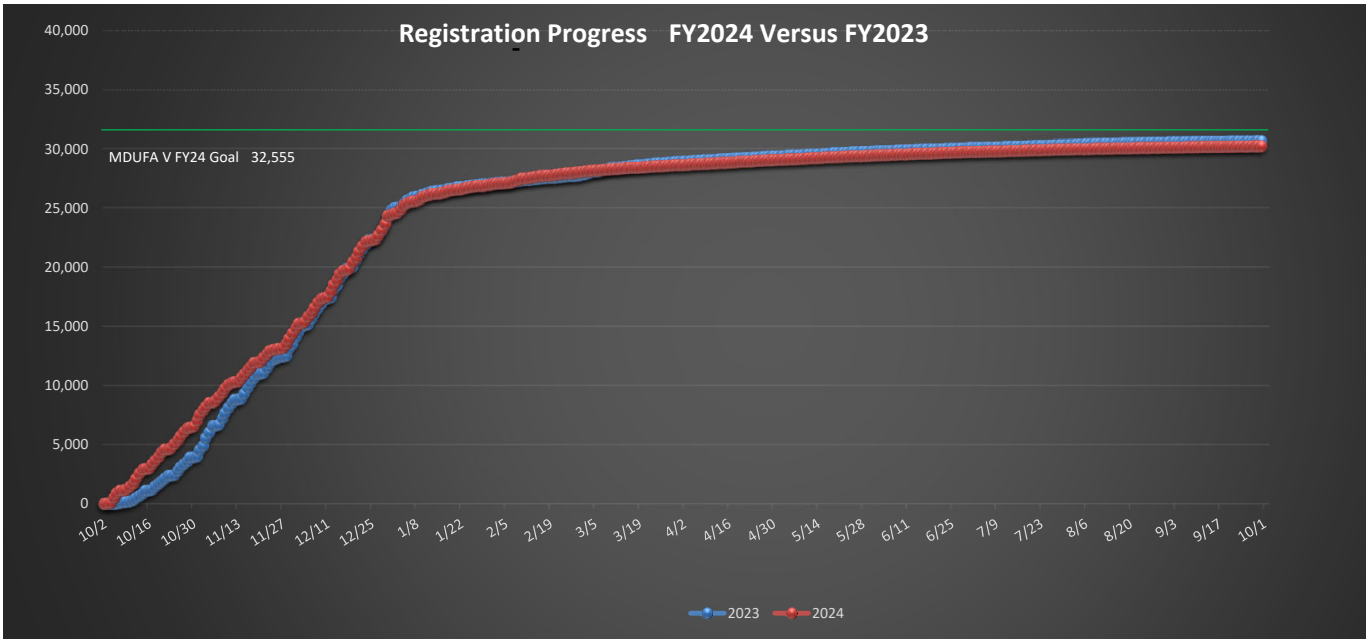
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
50	Q4	Chemical Analysis for Biocompatibility Assessment of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/chemical-analysis-biocompatibility-assessment-medical-devices	09/20/2024	Yes	No	N/A	A-List
51	Q4	The Accreditation Scheme for Conformity Assessment (ASCA) Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-program	09/23/2024	Yes	No	N/A	A-List
52	Q4	Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program : Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme-0	09/23/2024	Yes	No	N/A	A-List
53	Q4	Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and-0	09/23/2024	Yes	No	N/A	A-List
54	Q4	Clarification of Radiation Control Regulations For Manufacturers of Diagnostic X-Ray Equipment: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/clarification-radiation-control-regulations-manufacturers-diagnostic-x-ray-equipment	09/30/2024	No	No	N/A	No

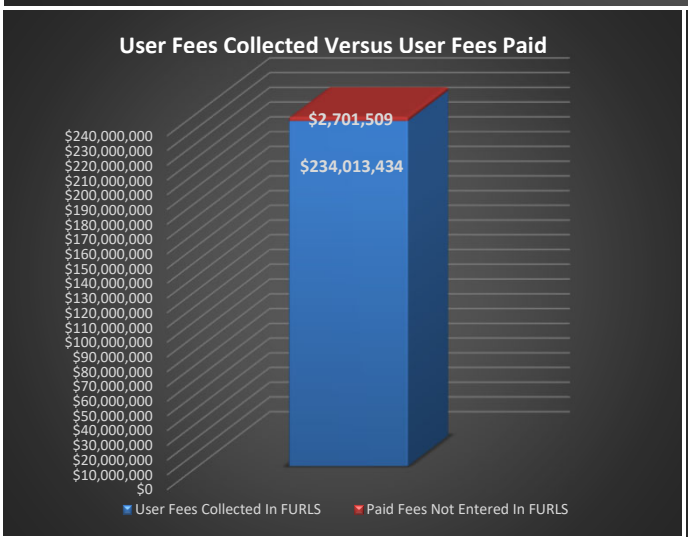
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
55	Q4	Dental Impression Materials - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-impression-materials-performance-criteria-safety-and-performance-based-pathway	09/30/2024	Yes	No	N/A	No
56	Q4	Dental Ceramics - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-ceramics-performance-criteria-safety-and-performance-based-pathway	09/30/2024	Yes	No	N/A	No
57	Q4	Dental Cements - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-cements-performance-criteria-safety-and-performance-based-pathway	09/30/2024	Yes	No	N/A	No
58	Q4	Air Powered Dental Handpieces and Air Motors - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/air-powered-dental-handpieces-and-air-motors-performance-criteria-safety-and-performance-based	09/30/2024	Yes	No	N/A	No

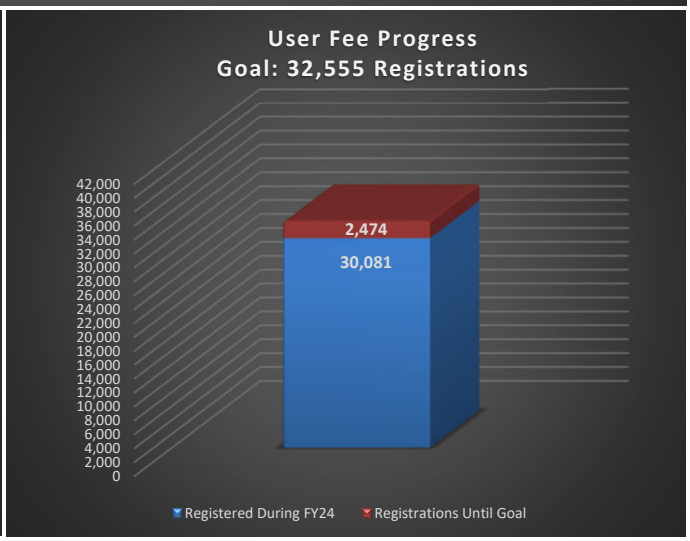
MDUFA V Registrations - 4th Quarter Summary FY2024*

Current Active Registrations by Type	FY24 Q4			FY23 Year End Active Totals			FY24 vs End FY23
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,585	12,235	18,819	6,677	12,332	19,009	99.00%
Contract Manufacturer	1,249	1,967	3,216	1,243	1,893	3,136	102.55%
Contract Sterilizer	79	178	257	76	169	245	104.90%
Specification Developer	1,608	563	2,171	1,668	557	2,225	97.57%
Reprocessor of Single Use Devices	29	3	32	34	3	37	86.49%
U.S. Manufacturer of Export Only Devices	118	0	118	127	0	127	92.91%
Repackager/Relabeler	1,082	189	1,271	1,116	221	1,337	95.06%
Remanufacturer	17	14	31	14	9	23	134.78%
Foreign Exporter/Private Label Distributor		1,097	1,097		1,132	1,132	96.91%
Initial Importer	3,256		3,256	3,357		3,357	96.99%
Unknown	1	10	11	6	11	17	64.71%
Total:	**14,024**	**16,256**	**30,280**	**14,318**	**16,327**	**30,645**	**98.81%**

*Note: This data is current as of 09/27/2024







FY 2024 Medical Device User Fee Collections as of September 30, 2024 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$234,926,289	-$886,589	$234,039,701		
Application Fees	$108,753,641	-$2,583,914	$106,169,726		
Total	**$343,679,930**	**-$3,470,503**	**$340,209,427**	**$362,381,000**	**94%**

Medical Device User Fee Collection History Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,738,775	$34,425,417	$28,031,569
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,794,823	$56,962,602	$63,699,312	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,306,430	$122,346,416	$136,098,825	$147,165,318	$137,782,995
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,896,895	$208,692,116	$215,697,178	$275,338,627	$269,130,850
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$322,347,363	$340,209,427			

MDUFA V Commitment Letter - VII. Performance Reports
2.12. Number of discretionary fee waivers or reductions granted by type of submission[1/]

CDRH and CBER Combined Data 4th Quarter FY 2024 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	12	0
PMA	12	0
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
Panel Track Supplements	0	2
De Novo Classification	5	46
180-Day Supplements	4	13
Real-Time Supplements	0	35
510(k)s	39	2,061
30-day Notices	14	67
513(g)s	0	68
PMA Annual Report	0	55
Total	**74**	**2,347**

[1/] User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter is a small business submitting their first premarket approval application or premarket report. User fees are reduced for small businesses. 510(k)s reviewed through the Third Party Review program are not included because FDA does not collect user fees for 510(k)s reviewed through that program. Counts are cumulative for the Fiscal Year.

[2/] As specified in the MDUFA V Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually. CBER counts are included in PMA's (0 reduced), Panel Track Supplements (0 reduced) DeNovo Classification (0 reduced), 180 Day Supplements (0 reduced), Real-Time Supplements (0 reduced), 510(k)s (13 reduced), 30-day Notices (2 reduced), and PMA Annual Reports (1 reduced).

Section I. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2024 Report meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[1]:

> *"VII. Performance Reports…4. In addition, the Agency will provide the following information on an annual basis… 4.12. Report on QMOE program… 4.13. Summary of QMOE audits, including annual audit of Deficiency Letters…"*

A. Annual Report

A.1. This report fulfils FY 2024 reporting requirements.

Section II. CDRH Quality Management Program

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[2]:

> *"IV.A… The CDRH Quality Management and Organizational Excellence (QMOE) Program is comprised of a team of certified quality management staff who report to the Center Director…"*

A. Quality Management Unit Expertise

A.1. **Quality Management Unit.** The CDRH QMOE Unit resides at the Office of the Center Director. Supporting quality management (QM) staff resides in CDRH Offices, including the Office of Product Evaluation and Quality (OPEQ).

A.2. **ISO and Quality Credentials**. Collectively, CDRH QM staff hold one or more of the following quality-related credentials: ASQ Certified Quality Improvement Associate (CQIA), ASQ Certified Quality Auditor (CQA), ASQ Certified Quality Engineer (CQE), ASQ Certified Software Quality Engineer (CSQE), ASQ Certified Manager of Quality and Operational Excellence (CMQOE), ASQ Certified Lean Six Sigma Yellow Belt (CLSSYB), ASQ Certified Lean Six Sigma Green Belt (CLSSGB), Lean Six Sigma Master Black Belt (LSSMBB), ISO 13485:2013 Lead Auditor, ISO 9001:2015 Lead Auditor, Project Management Professional (PMP), PMI Agile Certified Practitioner (PMI-ACP)®, and Bronze Level Kirkpatrick Evaluation Certification.

[1] MDUFA V Agreement page 28
[2] MDUFA V Agreement page 12

Section III. CDRH Quality Management System (QMS)

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 requirement[3]:

> *"…The QMOE Program establishes and leads the CDRH Quality Management System (QMS) activities, facilitates process improvements, independently audits CDRH processes and activities, and assesses the effectiveness of actions taken to prevent potential (risk management) and resolve existing issues (nonconformity management)…"*

A. ISO 9001:2015 Certification

A.1. ISO 9001:2015 certified since 2018, in November 2023 (FY 2024) CDRH expanded its ISO 9001:2015 Certification to include the Office of the Center Director (OCD) and Office of Science and Engineering Laboratories OSEL).

B. Quality Management Training

B.1. To support the adoption of quality management across CDRH, the following training was provided in FY 2024:

- ISO 9001:2015 Requirements from A-Z
- ASQ Certified Quality Auditor Training
- ASQ Certified Manager of Quality and Organizational Excellence Training
- ASQ Certified Lean Six Sigma Black Belt Training
- How to Write SOPs for Human Error Reduction
- How to Measure Anything: Principles of Applied Information Economics
- NVivo Training
- Agile Ways Fundamentals

B.2. Quality Management System (QMS) training

- In FY 2024, the QMOE program recertification seminar transitioned to the "CDRH Quality Lunch and Learn" series, integrating this quality training with the CDRH Learning Management System and expanding this offering to all CDRH.
- The program routinely introduces CDRH QMS to new CDRH staff during CDRH's New Employee Information Sessions, a required training activity for all new CDRH employees.
- CDRH Offices provide additional training to ensure staff have the skill and capability to deliver CDRH products and services.

[3] MDUFA V Agreement page 12

C. Voice of the Customer (VOC)

C.1. The **CDRH customer satisfaction survey** is available through FDA.gov and is included in all CDRH staff email correspondence. Overall, industry continued to be highly satisfied with CDRH. Industry's customer service satisfaction rate with CDRH was 97 percent (560/580) in FY 2024. Industry respondents continued to comment positively about their satisfaction with the premarket review process.

C.2. **Quality Management email.** As part of the CDRH QMS, CDRH customers can provide feedback about CDRH processes and services using **CDRH_Quality@FDA.HHS.gov**.

C.3. **Feedback✓CDRH** is the internal system used to collect internal staff input. The input is assigned to offices who determine whether actions need to be taken. After feedback is addressed, a summary of actions taken is made available to all CDRH staff. In FY 2024, 53 percent of the feedback received referenced OPEQ processes and procedures, with 52 percent of that feedback related to premarket review. All feedback was examined and addressed within the established CDRH timelines.

D. Document Control

D.1. **CDRH's QMS Documentation.** All documents related to the CDRH QMS are controlled using the CDRH Document Control System (DCS).

D.2. **Conforming Offices Documentation.** All documents related to the management and execution of the premarket review program processes are controlled using the CDRH DCS. The system houses 1013 standard operating procedures, work instructions, forms templates, and governing body charters. At the time of this report, 69 percent (696/1013) of the CDRH controlled documentation pertains to OPEQ core processes. Of those, 48 percent (334/696) are associated with premarket review.

D.3. **FY 2024 Improvements.** The system continues to be CDRH repository for all controlled documents. In FY 2024, CDRH procured Documentum and will be moving the DCS to the new system over the next 2 years. A modern, user-friendly interface was also procured to improve the ability to access documents needed to realize CDRH products and services.

E. Audit Activities

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[4]:

> *"…At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan with the QMOE Program. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's nonconformity management process. FDA will continue to expand the scope of its annual audits as it implements and builds up its auditing capability, as resources permit. At a minimum, FDA audits in the following areas will be completed: Pre-Submissions and Third Party Review Program…"*

[4] MDUFA V Agreement page 12

E.1. **Audit Schedule FY 2025.** The FY 2025 data call for audit topics was submitted in Q3 FY 2024 and the audit schedule will be finalized in Q1 FY 2025.

FY 2025 Audit Schedule (Tentative)*
ISO Required Audits of all QMS Functions
MDUFA V Required Audit of Deficiency Letters
Follow-up audits to assess actions addressing nonconformities associated with the FY 2022 Special 510(k) Conversions, Interactive Review, Withdrawals audits
***Additional programmatic audits under consideration**
Pre-submissions

E.2. **Audit Schedule FY 2024.** The following audits were conducted in FY 2024.

Title	Purpose	Findings
AF-2023-00081	FY 2024 MDUFA V Required audit of Deficiency Letters	CDRH committed to present results at the FY 2025 Q1 meeting. Results are ready and CDRH is releasing FY 2024 results in this report.
AF-2024-00088	QMOE Audit (QMOE Program and QMS Infrastructure)	Internal Audit, No findings
AF-2024-00089	Office of the Center Director Audit (OCD)*	Internal Audit, No findings
AF-2024-00090	Regulatory Science Audit	Internal Audit, No findings

E.3. **AF-2023-00081: FY 2024 Deficiency Letters Audit**

This audit meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[5]:

> *"…FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 2859- 1:1999 ("Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection"). FDA will review each fiscal year's audit results with industry no later than the first quarterly meeting of the following fiscal year…"*

[5] MDUFA V Agreement page 17

- **Purpose:** Determine whether deficiencies include a complete "statement of basis for the deficiency," i.e., a statement of "impact on decision."

- **Sampling:** In FY 2024, FDA issued 2904 letters that met the MDUFA V audit criteria. According to *ISO 2859- 1:1999,* auditors were to a sample size at 125 letters. The FY 2024 MDUFA V Audit sample consisted of 416 letters (~8 letters per week). In total 1854 deficiencies were audited.

- Findings:
  - 87 percent (87%; 1,614 out of 1,854) of the deficiencies examined contained a statement of basis for the deficiency.
  - The FY 2024 goal was 80 percent (80%). CDRH exceed the agreed upon goal.

- Supporting Process Improvement: **In addition,** CDRH auditors examined **799** randomly selected letters in FY 2024 **(**1215 **overall)**. The additional 799 letters were audited to support OPEQ process improvement activities (see G.3 for results).

E.4. CDRH QMS Internal Audits (AF-2024-00088, AF-2024-00089, AF-2024-00090).

- **AF-2024-00088.** Nine QMS core processes were reviewed as part of the internal audit program. The internal audit reported no findings and one best practice related to record organization and accessibility.

- **AF-2024-00089.** Three Office of the Center Director components (international harmonization, strategic communications, and scientific and regulatory programs) were reviewed as part of the internal audit program. The internal audits reported no findings.

- **AF-2024-00090.** An internal audit for Regulatory Science Products was conducted in FY 2024. The internal audit reported no findings while identifying **two** best practices related to project milestone management and internal communication practices.

E.5. Audit Findings/ Next Steps. No nonconformities were found through audits. Best practices were highlighted to the auditee and communicated, where applicable, to the rest of the center.

- **Nonconformities. Audits are one source of nonconformities. Nonconformities identified outside audits are also recorded and addressed, as they are opportunities for improvement.**
  - The FY 2025 audit schedule includes follow-up audits to assess actions taken to address nonconformities associated with the MDUFA IV required Special 510(k) Conversions, Interactive Review, Withdrawals audits[6]

[6] November 16, 2022 MDUFA IV Performance Report pages 360-361

F. Continual Improvement.

F.1. Business Process Improvement (BPI; ongoing).

BPI objectives include:

- Simplifying processes to improve process efficiency, repeatability, and effectiveness,
- Supporting process harmonization to increase standardization, and
- Improving clarity of process and supporting documents (e.g., Standard Operating Procedures, Work Instructions, etc.).

CDRH's Simplicity Strategic Priority initiatives continued through FY 2024. CDRH continues to work on improving its core businesses processes.

F.2. Audit Program Improvements

CDRH continued to expand the Audit Program to support a planned expansion of the CDRH QMS scope and MDUFA V commitments, including the MDUFA V commitment to use audits to assess performance (deficiency letters). QMOE:

- Increased the number of auditors dedicated to premarket review processes and
- Streamlined internal audit processes.

As a result of these actions, QMOE increased the Audit Program's ability to execute audits and assessments and reduced time to deliver results.

F.3. Deficiency Letter Assessments (expanded audit)

As a process improvement project, QMOE auditors conducted additional deficiency letter reviews to support OPEQ's implementation of the FY 2024 MDUFA V deficiency letters performance commitment:

- Auditors examined 799 additional randomly selected deficiency letters, observing that 3,169 out of 3,632 (87%) of the examined deficiencies had a complete "statement of basis for the deficiency."

Overall, auditors examined 1,215 randomly selected deficiency letters in FY 2024, observing that 4,783 out of 5,486 (87%) of the examined deficiencies had a complete "statement of basis for the deficiency":

- OHTs performed above the FY 2024 MDUFA V goal.
- Most divisions performed above the FY 2024 MDUFA V goal.
- When examined by the type of deficiency assessed, auditors observed that there were opportunities for improvement.

F.4. OPEQ ISO 9001:2015 Activities

CDRH continues to demonstrate its commitment to quality across the organization and MDUFA V by supporting the premarket review process through its journey towards inclusion in the

CDRH QMS ISO 9001:2015 certification.

F.5. Innovative Technological Improvements: eSTAR Submission Tool

In 2024, CDRH continued to advance innovative technologies and meet the MDUFA V commitment to develop electronic submission templates to improve the sponsor submission process through the electronic Submission Template and Resource (eSTAR) pilot. eSTAR is a method for industry to submit submissions in an effort to develop resources to aid sponsors in providing structured electronic submissions.

With the publication of the guidance "Electronic Submission Template for Medical Device De Novo Requests" on August 23, 2024, De Novo submissions prepared as eSTARs will be required as of October 1, 2025.

The use of eSTAR by Health Canada (HC) in an International Pilot began on January 10, 2023. As part of the pilot FDA and HC conducted surveys, made changes based on the feedback, and have further changes still in process. Additional improvements identified during through the pilot to be released in early 2025.

So far, all submissions have been authorized in both jurisdictions. All participants had positive feedback regarding their experience. Both HC and FDA agree the eSTAR pilot was a success and are currently considering next steps which may include a more extensive pilot with at least one additional jurisdiction. eSTAR was updated to ensure consistency with the updated IMDRF TOC documents published on June 25, 2024.

CDRH released 513(g) content in the Early Submission Requests eSTAR (PreSTAR) on March 29, 2024, which enables applicants to see the 513(g) workflow and provide what reviewers are expecting.

PMA content was enabled in the nIVD and IVD eSTARs on December 6, 2023. The development of the 30 Day Notice PMA supplement type has concluded and is now going through internal approval for deployment in early 2025.

CDRH previously conveyed that the Center would be developing eSTAR content for IDE Originals. In the process of development, it was decided to include all supplement types in the initial deployment as well. Due to the amount of content that needs to be considered with the inclusion of all supplements, we expect the IDE eSTAR content will be deployed by the end of 2025.

Section IV. Independent Assessment of Review Process

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 requirement[7]:

"*…FDA and the industry will participate in a targeted assessment of the process for the*

[7] MDUFA V Agreement page 27

review of device applications. The assessment will include consultation with both FDA and industry at the start of the assessment and prior to issuance of the final report. The assessment shall be conducted under contract to FDA by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment scope described below within the budget provided under this user fee agreement.

The contractor will:

1. Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V;
2. *Assess the alignment of resource needs with the training and expertise of hires;*
3. *Identify and share best practices across OHTs in OPEQ;*
4. *Assess the effectiveness of program areas targeted for improvement under this agreement, including the following:*
    - *a.* Implementation and impact of changes to the guidance "Developing and Responding to the Deficiencies in Accordance with the Least Burdensome Provisions*,*
    - *b.* Implementation and impact of changes to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The QSubmission Program,"
    - c. Third Party Review program (continued reduction of routine re-review by FDA of Third Party reviews)
    - *d. Digital Health program,*
    - e. *Patient Engagement program,*
    - *f. Real World Evidence program;*
    - *g. I*nternational Harmonization
5. Assess other key areas identified by FDA and industry as resources permit

FDA will award the contract no later than March 31, 2025. However, the contractor would not begin the audit of Pre-Submissions before October 1, 2025. The contractor will publish comprehensive findings and recommendations within 1 year, after reviews with FDA and industry and opportunities to provide feedback for the contractor's consideration prior to finalizing the final report. For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable.

FDA will incorporate findings and recommendations, as appropriate, into its management of the process for the review of device applications. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness."

Reporting Status. The contract for the MDUFA V required assessment is in the process of being awarded. The assessment is on schedule to start on time.

Center for Devices and Radiological Health Internal Training Summary Report

FY24: October 2023 – September 2024

Prepared by: The Division of Employee Training and Development

Table of Contents

Introduction

CDRH is committed to providing high-quality developmental opportunities that ensure Center staff are successful in their roles regulating medical devices and radiation emitting products. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, and leadership training; career development programs; and customized learning experiences. It helps further the Center's mission by facilitating a culture of continuous learning and growth. DETD's approach to developing employees' knowledge and skills incorporates instructor-led, experiential, and self-paced learning, mentoring, self-study initiatives, and specialty programs.

Formal Training

Formal training is structured instruction provided by CDRH's Division of Employee Training and Development (DETD) to ensure review staff have the requisite knowledge and skills to perform their jobs. It is designed to accomplish specific objectives through a set curriculum that includes videos, self-paced modules, instructor-led courses, activities, and assessments. Table 1 summarizes CDRH's formal training in FY24.

Category	Program	# of Events	# of Completions
Regulatory and Law (LAW)	ELP	36	814
	MDUFA V	4	230
	Other LAW	352	17,680
LAW Subtotal:		**392**	**18,724**
Leadership Development (LED)	Leadership for Managers	47	1,132
	Leadership for Non-Managers	8	105
	Other LED	38	575
LED Subtotal:		**93**	**1,812**
Professional Development (PRO)	New Employee Information Sessions	13	336
	Other PRO	145	2,758
PRO Subtotal:		**158**	**3,094**
Science (SCI)	All SCI	172	3,200
SCI Subtotal		**172**	**3,200**
FY24 Training Total		**820**	**27,017**

Table 1: CDRH formal training conducted by DETD in FY24

Reviewer Certification Program (RCP)

The RCP curriculum provides new review staff with the knowledge and skills they need to do their jobs. The program consists of 22 online modules, 14 instructor-led courses, activities, and assessments. After reviewers complete the foundational curriculum, they have a year to take the advanced courses. The curriculum consists of the following:

- Instructor-led courses
- Online modules
- Practical activities and hands-on exercises
- Knowledge assessments

Table 2 provides a summary of participants in the six FY24 RCP cohorts.

Cohort	Participants	Course Completions	Training Hours
2023 Fall 1	63	2195	2838
2023 Fall 2	42	1669	2254
2024 Spring 1	42	1572	2659
2024 Spring 2	17	678	1607
2024 Summer 1	12	289	354
2024 Summer 2	16	543	592
TOTAL:	**192**	**6946**	**10304**

Table 2: FY24 Reviewer Certification Program Metrics by Cohort

Experiential Learning Program (ELP)

ELP provides CDRH review staff with immersive training experiences designed to close the gap between emerging and innovative technology and the review of the resulting medical devices. Program participants learn about medical device development, testing, and manufacturing from the medical device industry, clinical community, and academic stakeholders. By participating in the program, regulatory personnel have the opportunity to gain instights into advancements in industry through exposure to manufacturing facilities, surgical centers, clinical trials, and other sites.

In FY24, CDRH conducted 36 site visits for 814 attendees. Participants received a total of 1633 hours of training in the areas of innovation, digital health, biocompatibility, reprocessing, and sterilization.

CDRH Informal Training

Overview

Informal training is offered by Offices, Divisions, Branches, and Teams to provide specific audiences with specialized knowledge and skills related to their roles, processes, and challenges. It is composed of on-the-job training, all-hands meetings, informational webinars, communities of practice, small group sessions, and instructor-led and self-paced training. Informal training is an integral part of meeting the mission-critical training needs of CDRH staff.

Examples of informal training topics include:

- Monitored practical activities following formal training
- Device-specific processes and procedures
- Best practices for specific product areas
- Overview of policy changes and updates
- Introduction to new technology and recent advancements

In FY24 CDRH offered 64 informal events for a total of 4,131 participants.

U.S. FOOD & DRUG ADMINISTRATION

FY24 Return on MDUFA Investment

Marta Gozzi, Ph.D.
FDA/CDRH/OPEQ
Policy Analyst, Office of Regulatory Programs

Jonathan Sauer, MBA
FDA/CDRH/OM
Director, Management Systems and Analysis

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Outline

- Background Information
  - Language in Commitment Letter
  - Definition of Return on MDUFA Investment (ROMI)
  - Overall Strategic Framework
- FY24 ROMI Highlights
  - Overall Summary for FY24
  - Pre-Submissions
  - Hiring and Retention
- Main ROMI Takeaways

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BACKGROUND INFORMATION

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ROI Reporting Language in MDUFA V Commitment Letter

"The Agency will provide the following information on an annual basis: (…) The return on investment, which may include process improvements, improved performance, and other enhancements, under MDUFA V."
(MDUFA V Commitment Letter, Section VII, Item 4.15)

- During and after MDUFA V negotiations, we received clarification from Industry regarding their vision and expectations for this commitment.
- Last year represented our initial response. This year we continued to develop MDUFA ROI reporting and provided three highlights.

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Return on MDUFA Investment (ROMI)

- *Traditionally*, return on investment (ROI) is a financial performance measure used to evaluate the efficiency or profitability of an investment or to compare the efficiency of different investments. ROI measures the amount of return on a particular investment, relative to the investment's cost.
- *In MDUFA*, some types of returns cannot be easily monetized, so we adopted a broader framework that captures a wide range of returns, including qualitative and quantitative benefits that go beyond the typical financial measures used in business.

$$\text{ROMI} = \frac{\text{Value of Improvements}}{\text{MDUFA Fees Paid}}$$

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Overall Strategic Framework

- We aim at capturing **monetized, quantified, and intangible benefits**. Whenever possible, we are trying to monetize (or at least quantify) returns, using sound and defensible values and procedures. We are also looking beyond quantifiable benefits and capturing other benefits that we may not be able to quantify at this time, but that are important when assessing value.
- We are looking at benefits for a **variety of stakeholders** at macro level (public, patients, providers, industry sector, FDA, medical device ecosystem) and micro level (individual company/product, individual patient).
- We are taking a **multi-year approach.** Each year we will improve the methodology and build upon previous feedback. For this year, we will present benefits, enhancements, and improvements in qualitative and quantitative ways.
- As MDUFA V unfolds, we aspire to add a **variety of ROMI metrics**.

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FY24 ROMI Highlights

OVERALL SUMMARY FOR FY24

PRE-SUBMISSIONS

HIRING AND RETENTION

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FY24 ROMI Highlights

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MDUFA V Review Performance

Submiss on Type	Rev ew Time Goal	FY23 Performance	FY24 Performance
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports			
Substantive Interaction	90 calendar days		
Decision with No Advisory Committee Input	180 FDA days		
Decision with Advisory Committee Input	320 FDA days	#	#
180-Day PMA Supplements			
Substantive Interaction	90 calendar days		
Decision	180 FDA days		
Real-Time PMA Supplements			
Decision	90 FDA days		
De Novo Classification Requests			
Decision	150 FDA days		
510(k) Premarket Notifications			
Substantive Interaction	60 calendar days		
Decision	90 FDA days		
Pre-Submissions			
Provide Written Feedback	70 calendar days or 5 days prior to meeting		

CDRH + CBER data as of 09/30/24; complete list of goals will be available in Annual MDUFA Performance Report to Congress.

= Goal met
= Goal on track to be met
= Insufficient cohort (<10) to calculate performance

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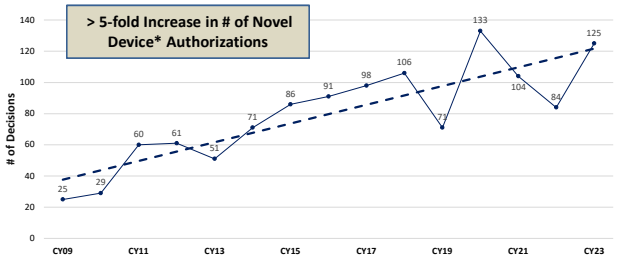
Sustained Increase in Novel Device Authorizations



*Novel devices include original PMAs, panel track supplement PMAs, De Novos, HDEs, breakthrough 510(k)s, and specific EUAs deemed novel.
As of December 31, 2023

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Other MDUFA V Accomplishments Include *(but are not limited to)*

	FY 2023	FY 2024
Submission Review Performance	✓ Published guidance on deficiency letters; provided training to FDA review staff; met FY23 goal ✓ Expanded CDRH Portal to include Pre-Submissions ✓ Required 510(k) submitters to use eSTAR	✓ Met FY24 deficiency goal ✓ Issued draft guidance to clarify use of Pre-Submissions ✓ Expanded CDRH Portal to include PMAs
Program and Process Improvements	✓ Launched TAP pilot ✓ Transitioned ASCA pilot to sustainable program ✓ Published draft guidance on predetermined change control plans for AI/ML-enabled device software functions ✓ Issued draft International Harmonization Strategic Plan	✓ Expanded TAP pilot ✓ Completed assessment of CDRH's implementation of IMDRF technical documents ✓ Issued draft guidance to clarify use of real-world evidence to support regulatory decision-making for medical device
Financial Transparency and Hiring	✓ Published MDUFA V Five-Year Financial Plan ✓ Filled 100% of CDRH's 141 MDUFA V hires for FY23	✓ Published FY24 update to financial plan ✓ Filled 100% of CDRH's 42 MDUFA V hires for FY24

CDRH also conducted audits of internal processes and published detailed performance and financial reports.

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FY24 ROMI Highlights

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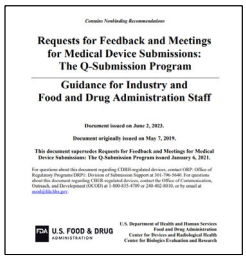
Pre-Submissions are one type of Q-Submission



Contains Nonbinding Recommendations

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 2, 2023.

Document originally issued on May 7, 2019.

This document supersedes Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program issued January 6, 2021.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Center for Biologics Evaluation and Research

- Formal written request for feedback from FDA to help guide product development and/or submission preparation.
- On **March 15, 2024,** we issued draft guidance to better clarify circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission.
- The draft guidance, when final, will supersede the current guidance (shown on the left).

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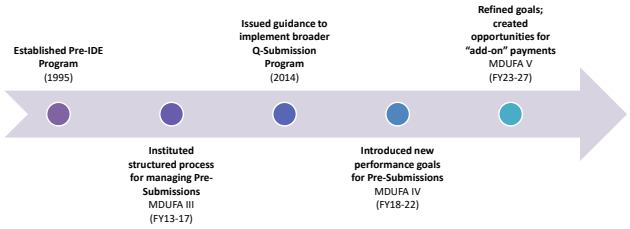
History of Pre-Submission Program



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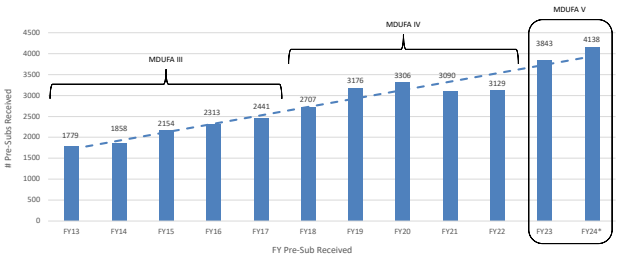
Use of Pre-Submissions has steadily increased and is now over 4000 requests per year



** Data are as of 09/30/24 and may change until cohort is closed.*

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Benefits of Pre-Submissions Include:

- Obtain FDA **advice** to help drive development and regulatory strategy
- Provide FDA **preview** of novel/unique issues
- Get a **head start** on resolving potential issues in advance

TIME SAVINGS

- **Align** on evidentiary expectations
- Improve submission **completeness**
- Avoid **roadblocks**
- Avoid generation of **unnecessary** data

COST SAV NGS

- Gain insights to FDA **expectations**
- Get **clarity** on path forward
- Help reduce **surprises** at time of submission

RISK REDUCTION

- Develop a **human relationship** with the FDA
- Explain and **orient** FDA staff on complex issues
- Help improve **quality** of subsequent submission

IMPROVED EXPERIENCE

Pre-Submissions are intended to have a positive impact on subsequent submissions, driving a smoother and more successful review process.

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Challenges with Quantitative Analyses

- It remains a challenge to **link** Pre-Submissions with subsequent submissions in our current IT systems.
  - We started incorporating automated methods; yet the effort was still partly **manual** and very time consuming.
- We encountered many **confounding factors** (e.g., variety of companies and devices), making it hard to compare "apples to apples."
- We observed **programmatic changes** (e.g., eSTAR, cybersecurity requirements) potentially affecting the results.

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Exploratory Analysis Methodology

- Traditional, eCopy* 510(k)s received in FY23, with final decision as of 09/30/2024
- Divided into two groups, with and without previous Pre Sub** with written feedback ***

General Exploration:

- Started from **2,242** 510(k)s across all OHTs and panels
- Ended with **1,040** 510(k)s when only keeping submissions with the same procodes in both groups
- **133** primary procodes

Specific Exploration:

- Started from subset of general exploration data: **185** 510(k)s in Radiology panel
- Ended with **22** 510(k)s when matching the two groups based on device similarity and submission purpose
- **7** primary procodes

**eSTAR submissions were excluded to avoid potential confounding factors.*
***Breakthrough interactions were excluded to avoid potential confounding factors.*
****Pre-Submissions were identified using the "Related Submissions" field in our center tracking system and automated searches of reviewer documents; limitations in these methods, as well as lack of mention in the cover letter of the subsequent related submission, may lead to an underestimate of the true number of related Pre-Submissions.*

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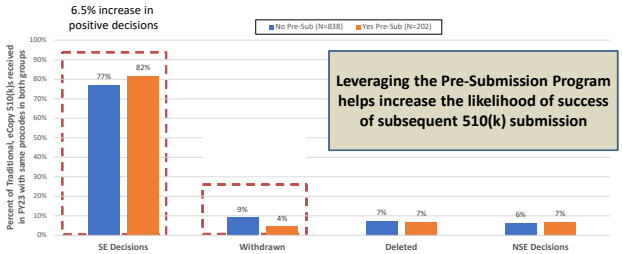
Initial Observations from General-Level Exploration of Traditional, eCopy 510(k)s received in FY23



Leveraging the Pre-Submission Program helps increase the likelihood of success of subsequent 510(k) submission

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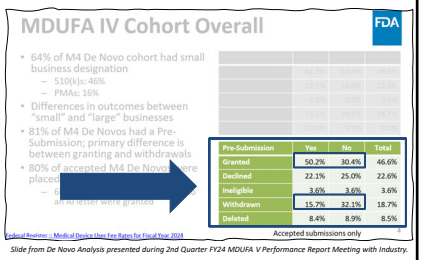
Previous De Novo Analysis

- FDA presented De Novo Analysis during 2nd Quarter FY24 MDUFA V Performance Report Meeting with Industry (May 31st, 2024).
- Like 510(k)s, De Novos seemed to benefit from the Pre-Sub program, with increased rate of **"granted"** and decreased rate of **"withdrawn."**
- **This suggests that Pre-Subs may have a similar, positive impact at least across two different submission types.**



Slide from De Novo Analysis presented during 2nd Quarter FY24 MDUFA V Performance Report Meeting with Industry.

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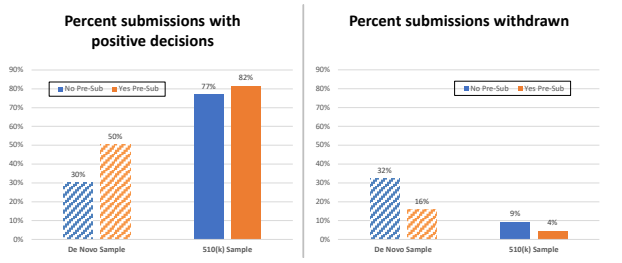
510(k) Trends Consistent with De Novo Trends



More details on De Novos can be found in De Novo Analysis presented during 2nd Quarter FY24 MDUFA V Performance Report Meeting with Industry.

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Initial Specific-Level Exploration

- The general-level exploration involved **>1,000** submissions across **133** procodes, **18** panels and **8** OHTs to gain broad insights.
- Next, we wanted to explore ways to more accurately compare "apples to apples" and control for potential confounders.
  - For example, time to decision may vary with the OHT in which a device is reviewed at the FDA or the panel to which it belongs.
- We developed a potential method to more closely match submissions with and without Pre-Subs and gathered initial exploratory observations.

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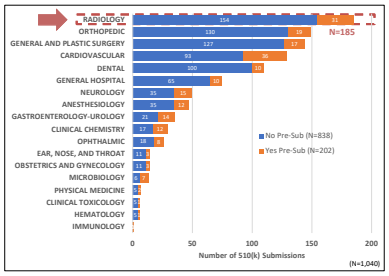
Panel Characterization and Selection



- We looked at the distribution of 510(k)s in our sample by panel.
- We selected the panel with the highest volume of 510(k)s.
- We asked reviewers to identify matches in the two groups based on similarity of device and purpose for the submission.

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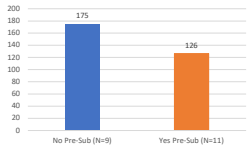
Initial Exploratory Radiology Panel Observations

Preliminary Observations

- Could only match **35%** of 510(k)s with previous Pre-Sub (11 of 31), suggesting that Pre-Subs are frequently used for unique situations.
- Of those that could be matched, 510(k)s with previous Pre-Sub had **more SE decisions** (100% vs. 82%).
- Those SE decisions were associated with **shorter time to decision** (126 vs. 175 days).

**Matches within FY23 sample of Traditional, eCopy 510(k)s.*

Avg. Total Days to Decision (SE Decisions only)



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Summary and Next Steps

- This analysis was **challenging** and required great effort; it represents our first step in trying to assess ROMI for the Pre-Sub program.
- We are seeing signals that Pre-Subs help achieve **improved outcomes**.
  - Our initial general-level exploration in 510(k)s suggests use of Pre-Subs may be associated with **increased rate of positive decisions** as well as **decreased rate of withdrawals**.
  - Our initial exploration of a small number of closely matched 510(k) submissions suggests use of Pre-Subs may be associated with **shorter time to positive decision.**
- There may be **other benefits** of the Pre-Sub Program we did not capture in the current analyses (e.g., fewer deficiencies, improved communication, and better customer experience).
- More work is needed to explore the impact of Pre-Subs on **other submission types** (e.g., PMAs and IDEs).

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FY24 ROMI Highlights

OVERALL SUMMARY FOR FY24

PRE-SUBMISSIONS

HIRING AND RETENTION

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ROMI Framework for Hiring and Retention

- MDUFA V fee investments filled gaps that had eroded base resources during MDUFA IV:
  - Cost-of-living increase absorption.
  - Mandated increases in FDA's retirement and benefit contributions.
- Investment enabled CDRH to retain highly qualified staff acquired during MDUFA IV and on-board additional staff in accordance with MDUFA V hiring goals.
- Benefits of enhanced hiring and retention:
  - Broad improvement in performance.
  - Improved morale and continuity of knowledge from reduced staff turn-over.
  - Ability to hire key subject matter experts using more competitive salaries under 21st Century Cures Act.

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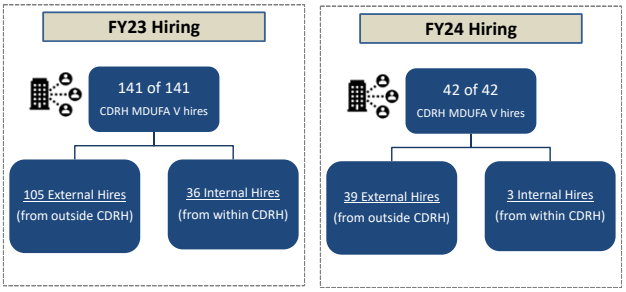
MDUFA V Hiring



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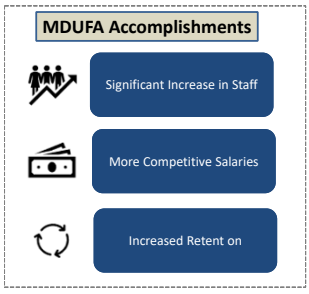
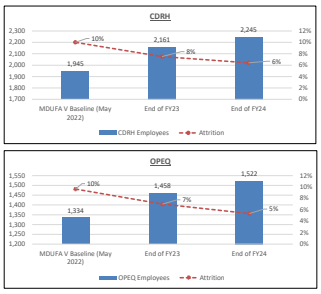
MDUFA V Hiring & Retention ROMI





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Looking Ahead

- Payroll funding remains a priority for CDRH, particularly due to the sizable cost of living adjustment in 2024.
- Upcoming annual update to the MDUFA V Five-Year Financial Plan, which will include payroll cost impact information for 2024.
- Independent Assessment of MDUFA Workforce Metrics is ongoing. The assessment will be published by **March 31, 2025**.

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MAIN ROMI TAKEAWAYS

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Main ROMI Takeaways

- Our initial explorations suggest Pre-Subs have a positive impact on decision outcomes and time to positive decisions.
- Investment enabled CDRH to retain highly qualified staff acquired during MDUFA IV and on-board additional staff.
- We will continue working on making ROMI more quantitative and collaborating with our partners in the medical device ecosystem to maximize the impact of the investments and improve business and public health outcomes.

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