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

March 8, 2024, 1:00 – 2:00 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through December 31, 2023

- Report on performance goals for 1st Quarter FY 2024
- TPLC Advisor Program (TAP)

Guidance Development

Registration and Listing

Qualitative Update on Finances – 1st Quarter FY 2024

- User fee receipts through the 1st Quarter FY 2024

Annual Hiring Goals Update

Quality Management Update

- Performance Goal Deficiency Audit

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 31 December 2023

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

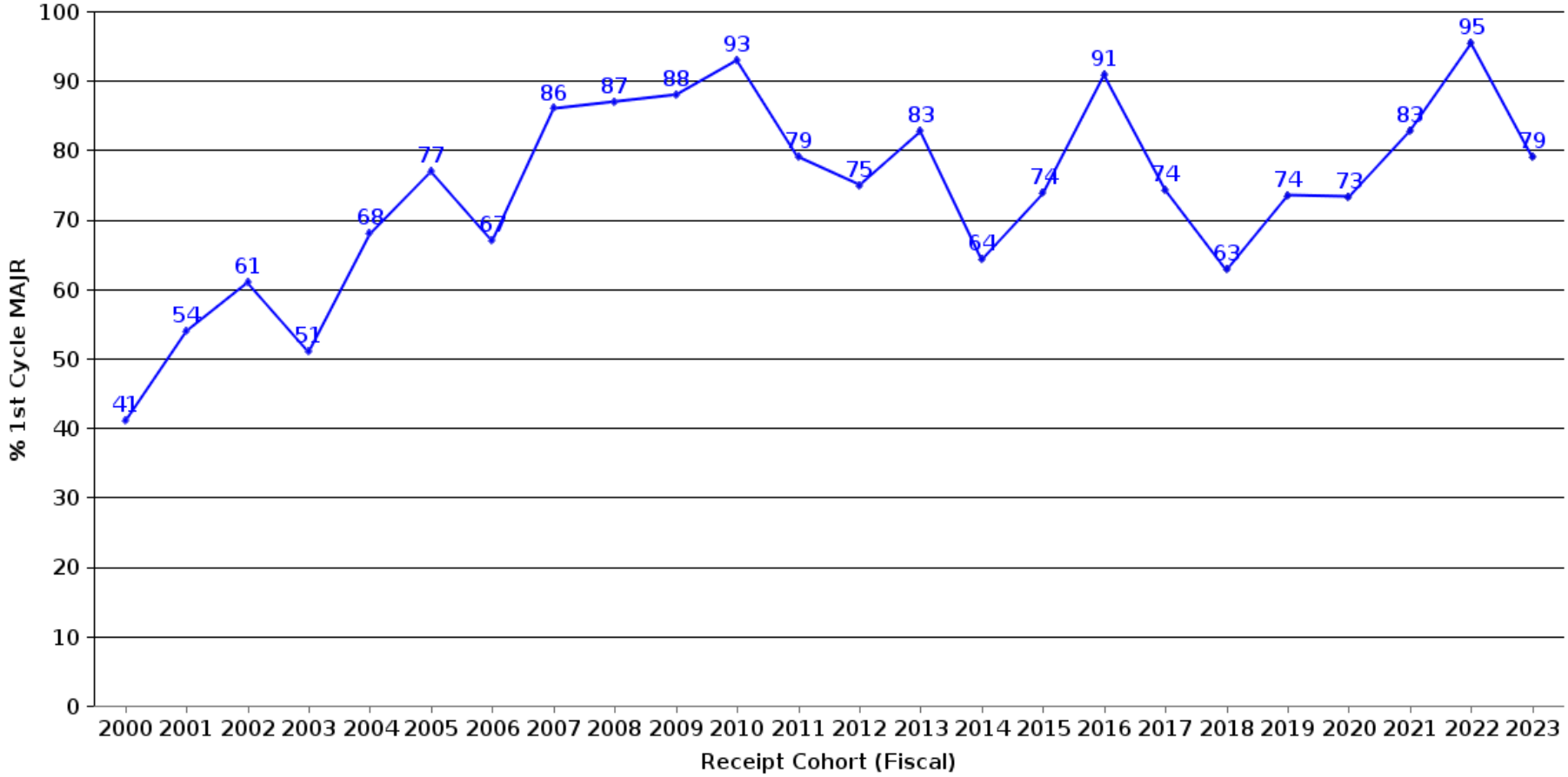
OHT8: Office of Radiological Health

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

PMAs

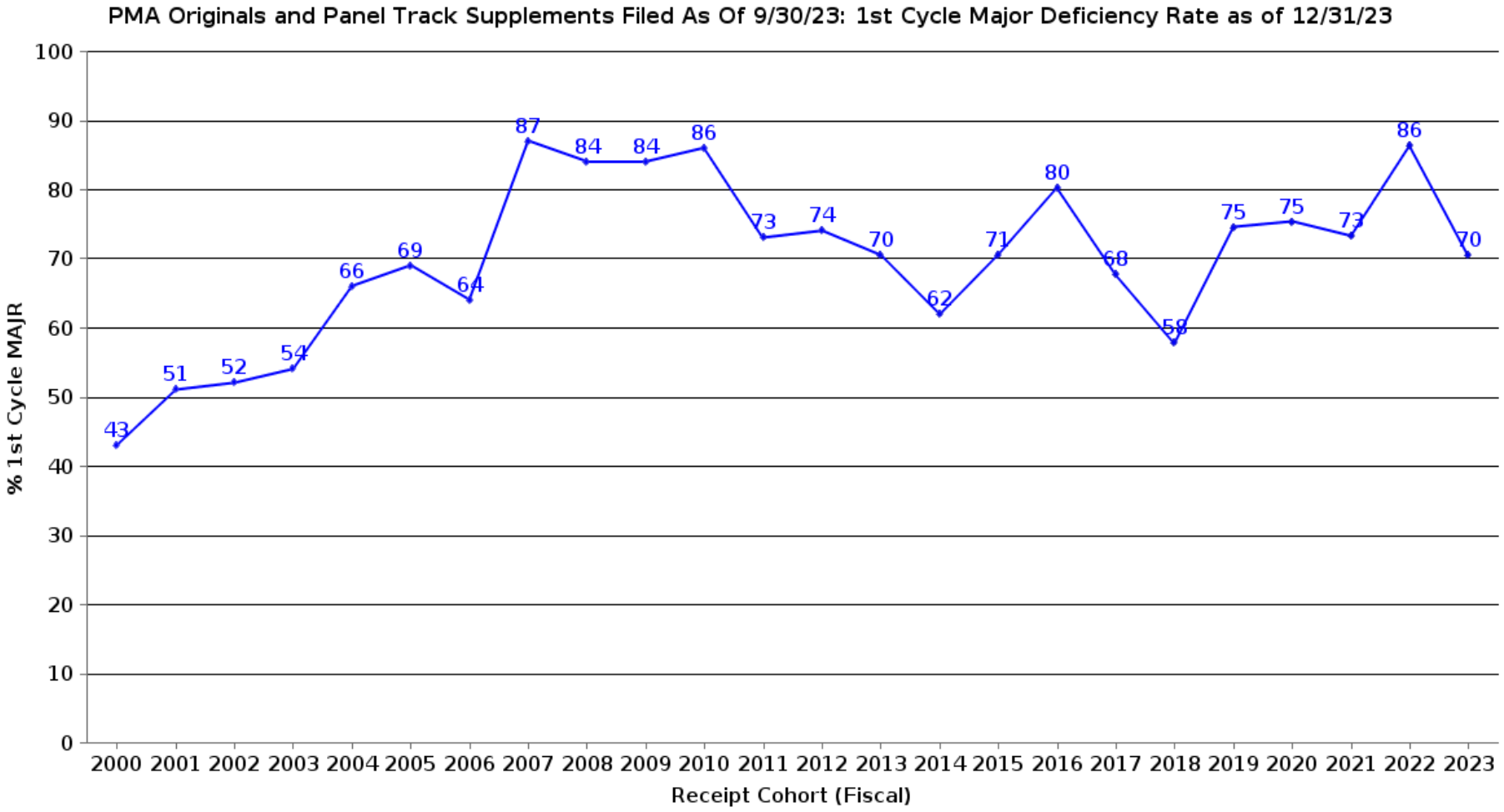
Q1 FY2024

PMA Originals Filed As Of 9/30/23: 1st Cycle Major Deficiency Rate as of 12/31/23



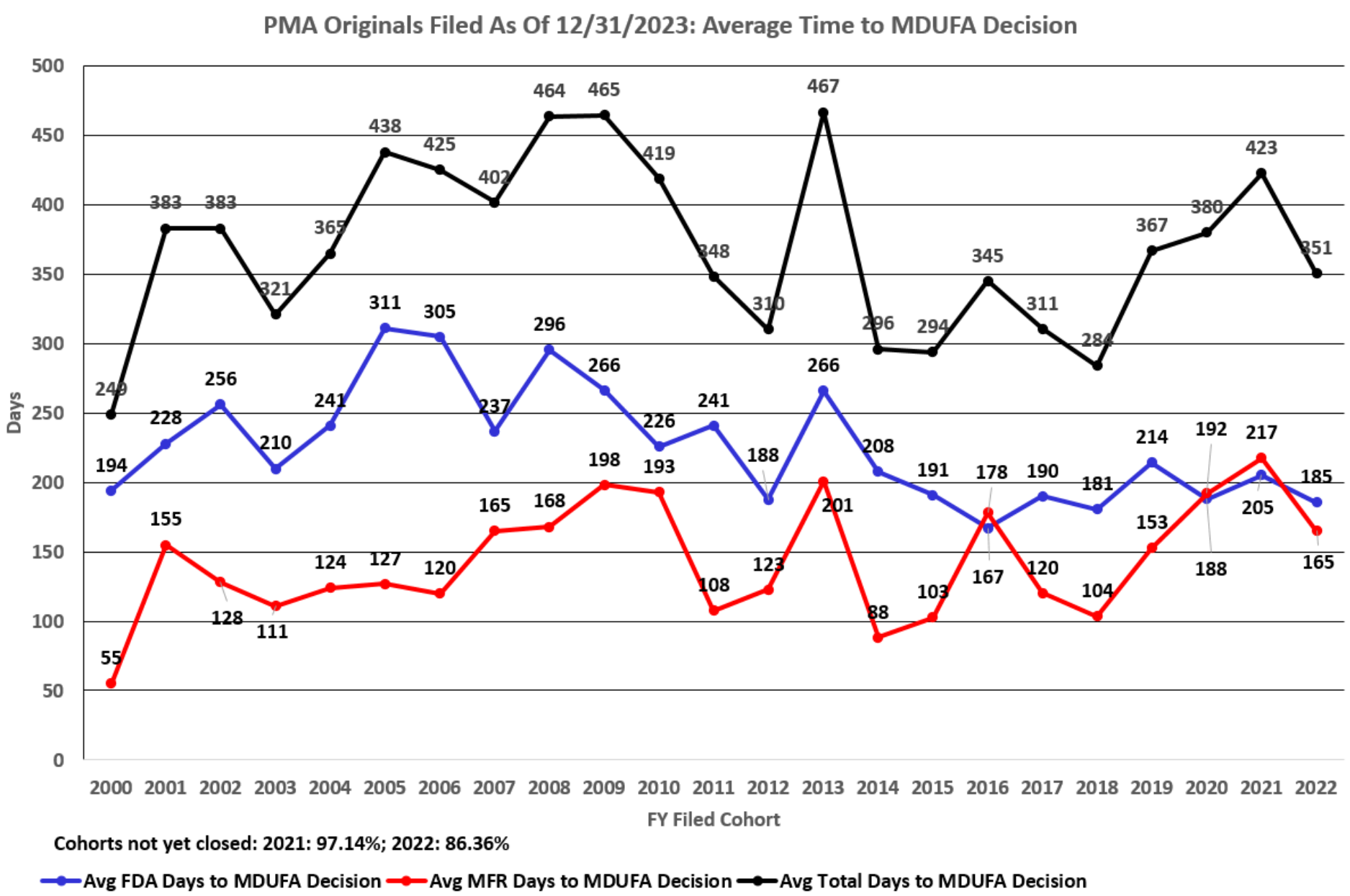
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 9/30/23.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

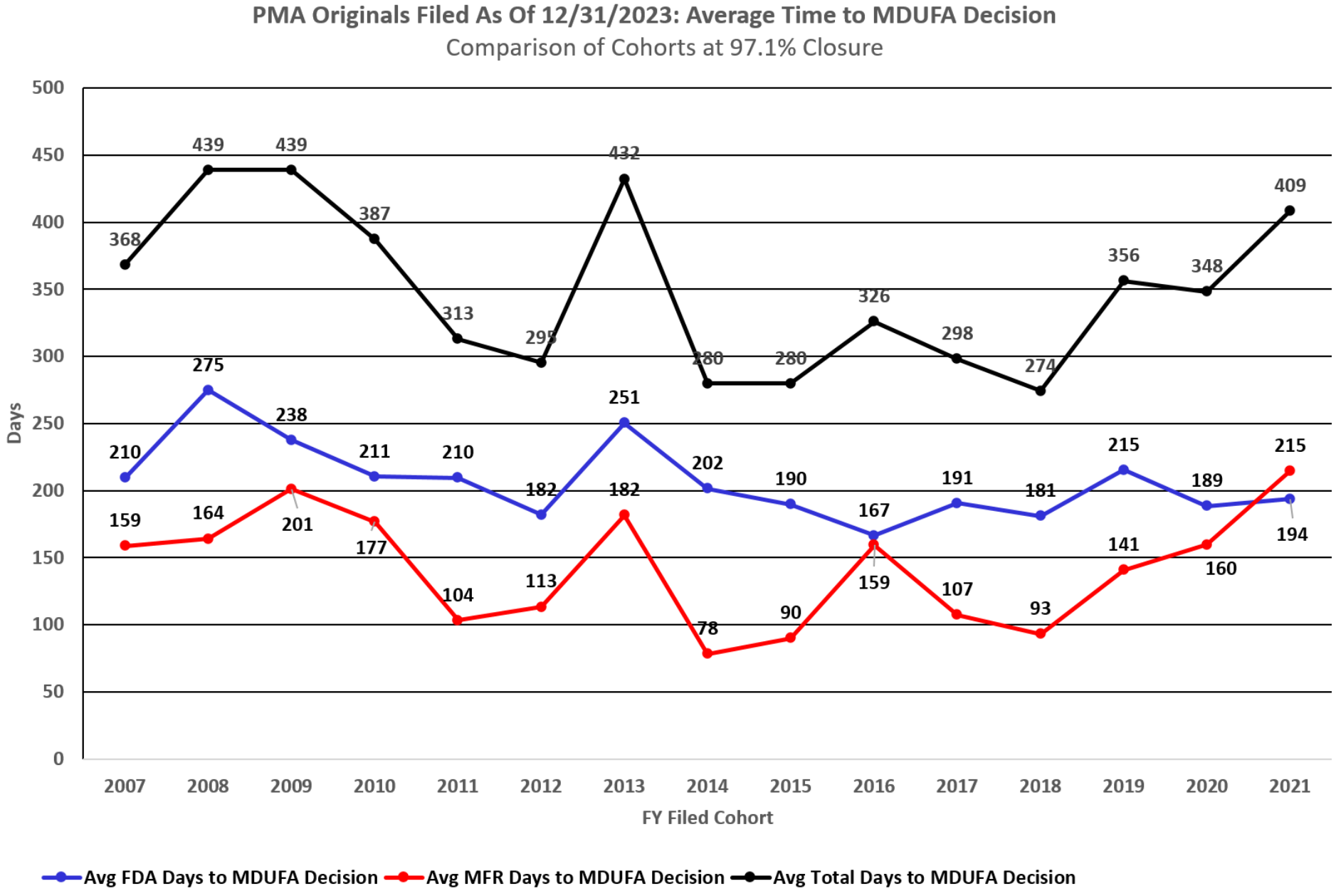
◆ % 1st Cycle MAJR PMAO

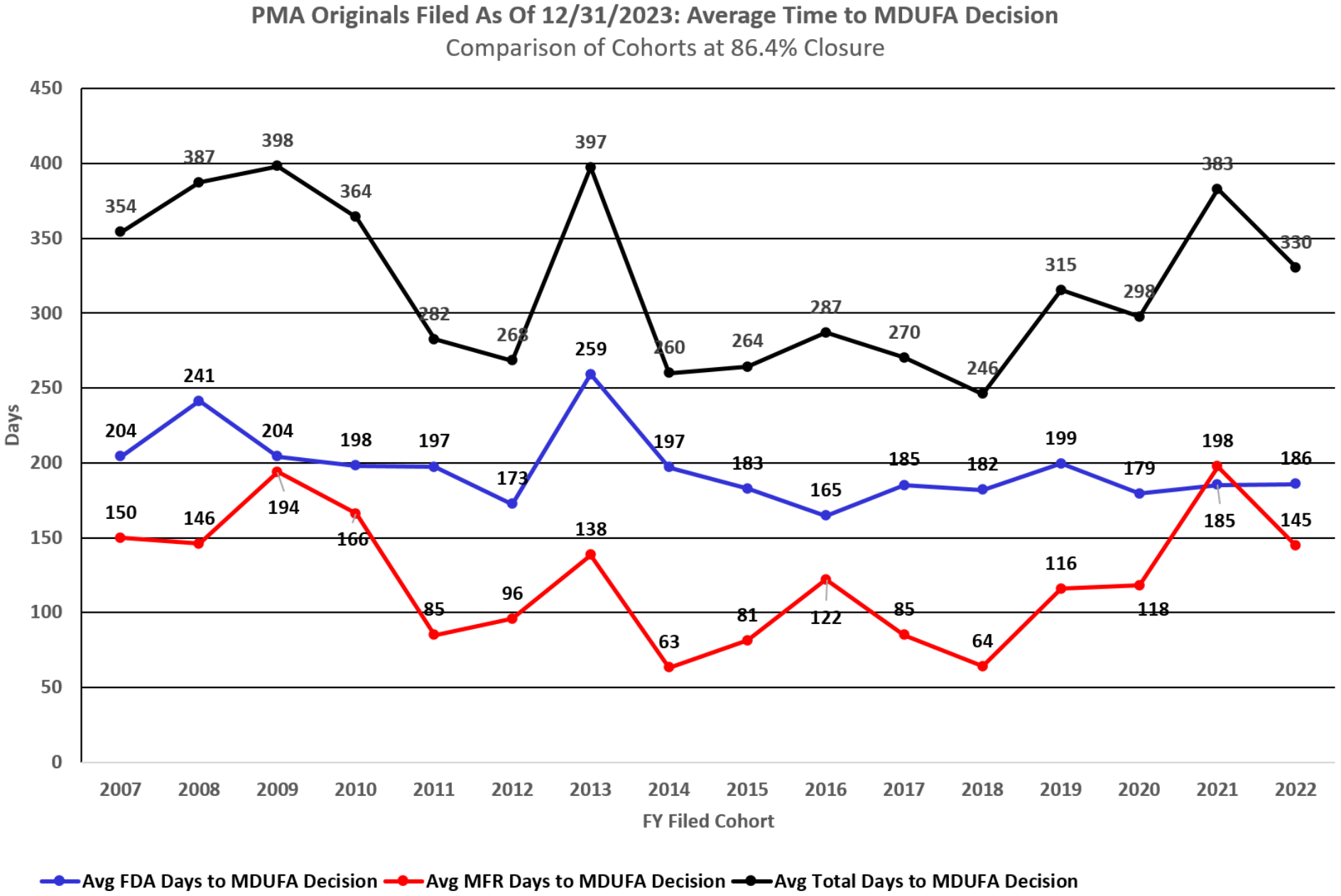


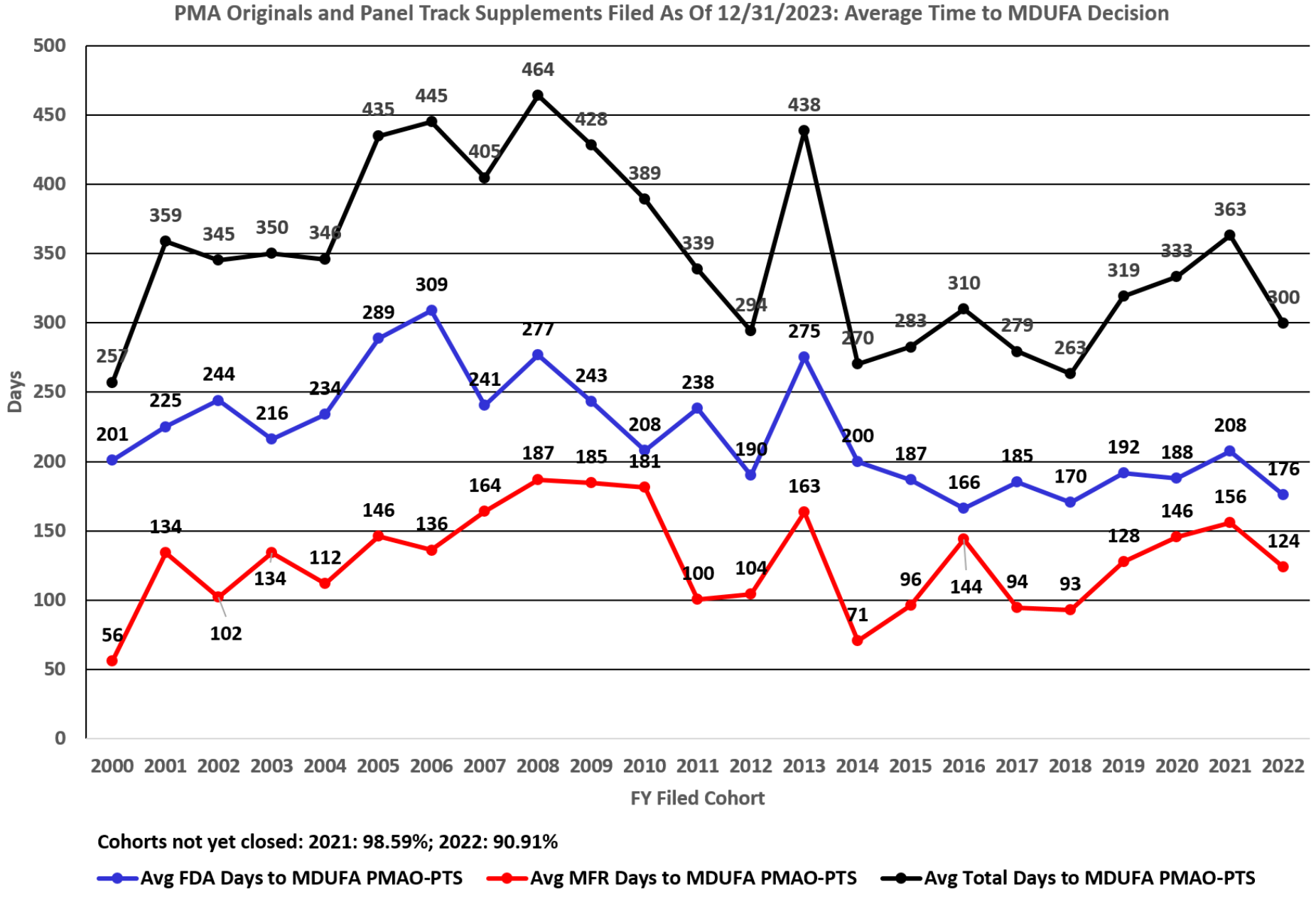
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 9/30/23. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

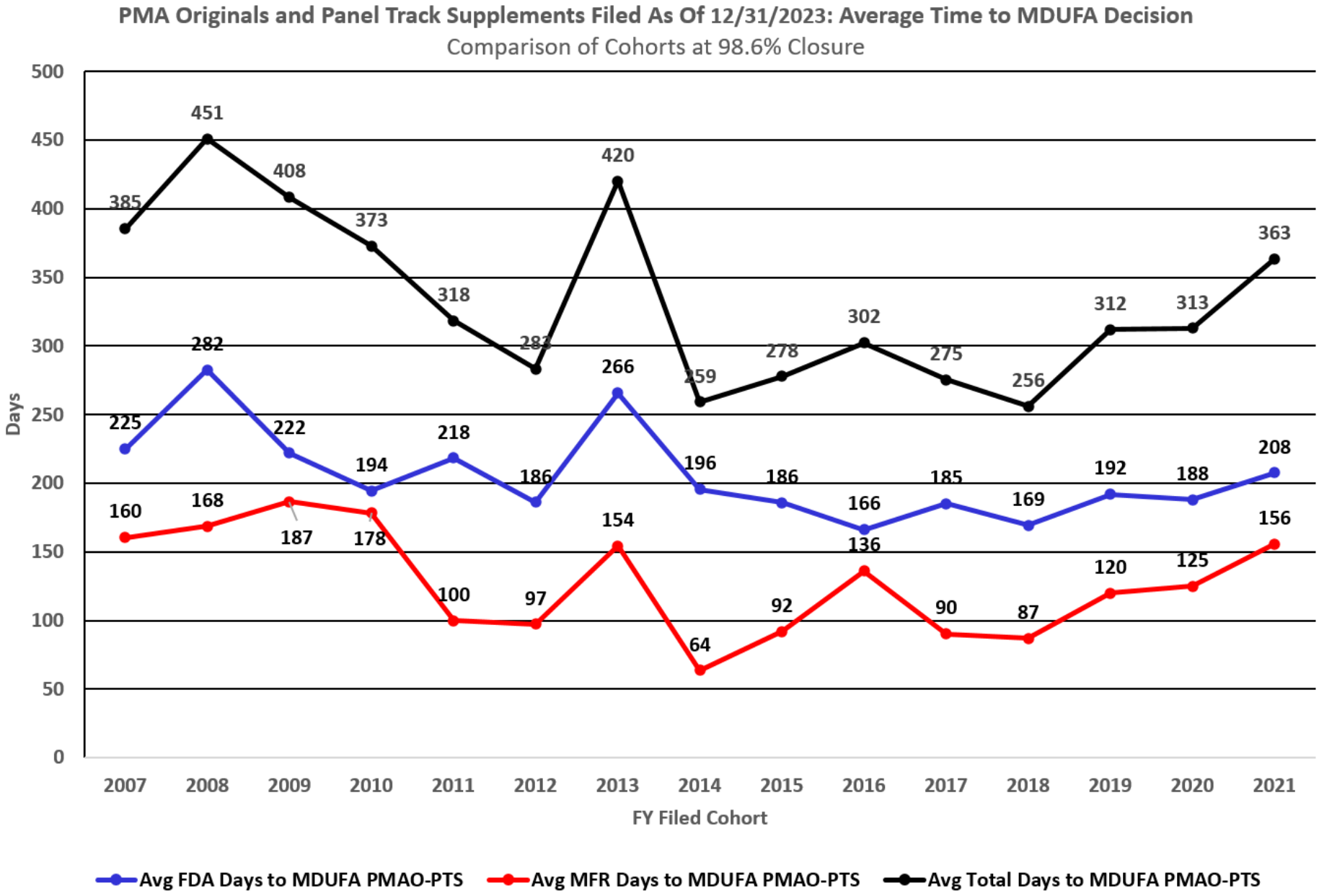
◆ % 1st Cycle MAJR PMAO/PTS


PMA Originals Filed As Of 12/31/2023: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2021: 97.14%; 2022: 86.36%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 12/31/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 97.1% Closure
Days
500
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
FY Filed Cohort
368
439
439
387
313
298
432
280
280
326
298
274
356
348
409
210
275
238
211
210
182
251
202
190
167
191
181
215
189
194
159
164
201
177
104
113
182
78
90
159
107
93
141
160
215
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 12/31/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 86.4% 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
354
387
398
364
282
268
397
260
264
287
270
246
315
298
383
330
204
241
204
198
197
173
259
197
183
165
185
182
199
179
198
186
150
146
194
166
85
96
138
63
81
122
85
64
116
118
185
145
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 12/31/2023: 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
FY Filed Cohort
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 263 319 333 363 300
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 188 208 176
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 93 128 146 156 124
Cohorts not yet closed: 2021: 98.59%; 2022: 90.91%
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 12/31/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 98.6% Closure
Days
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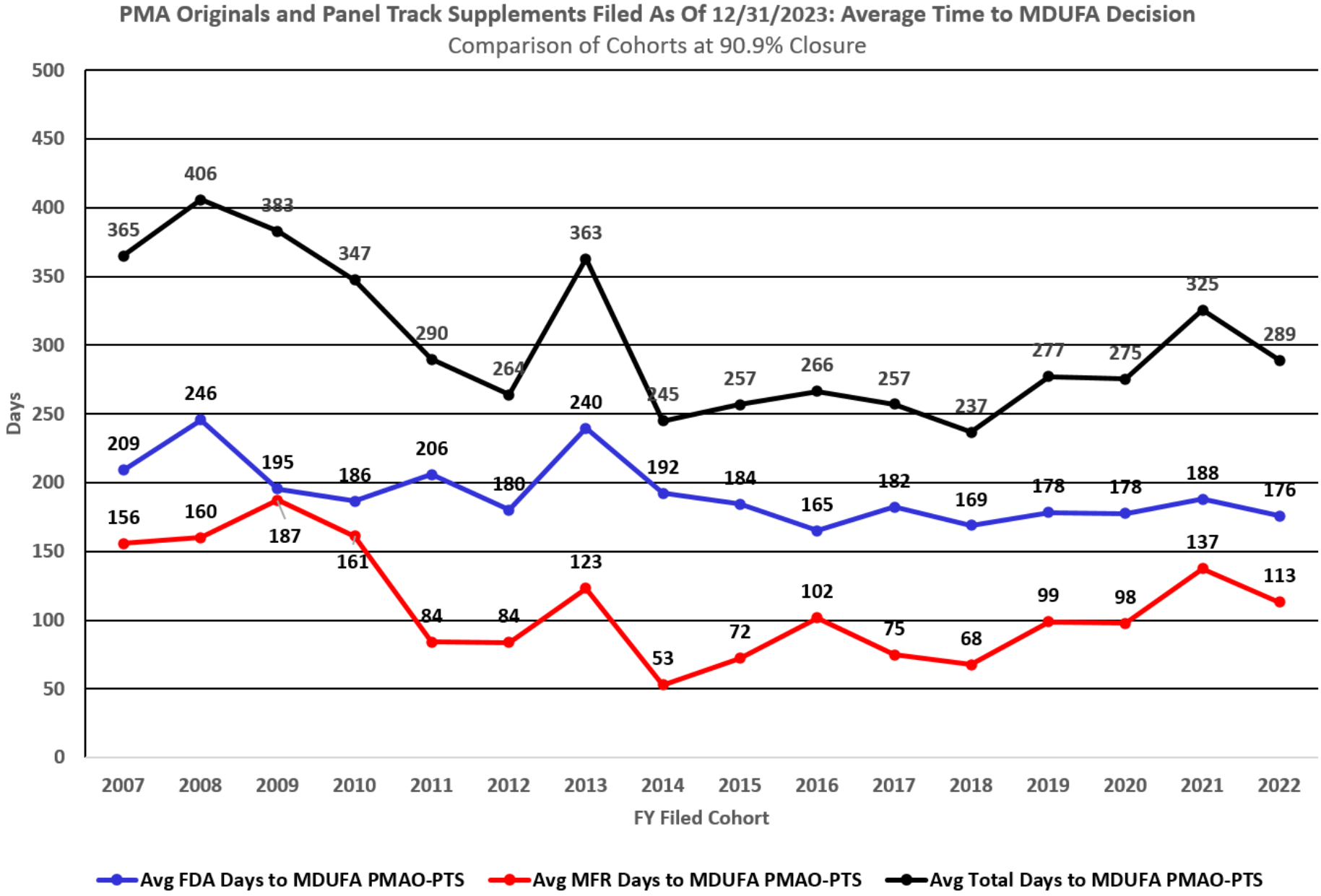
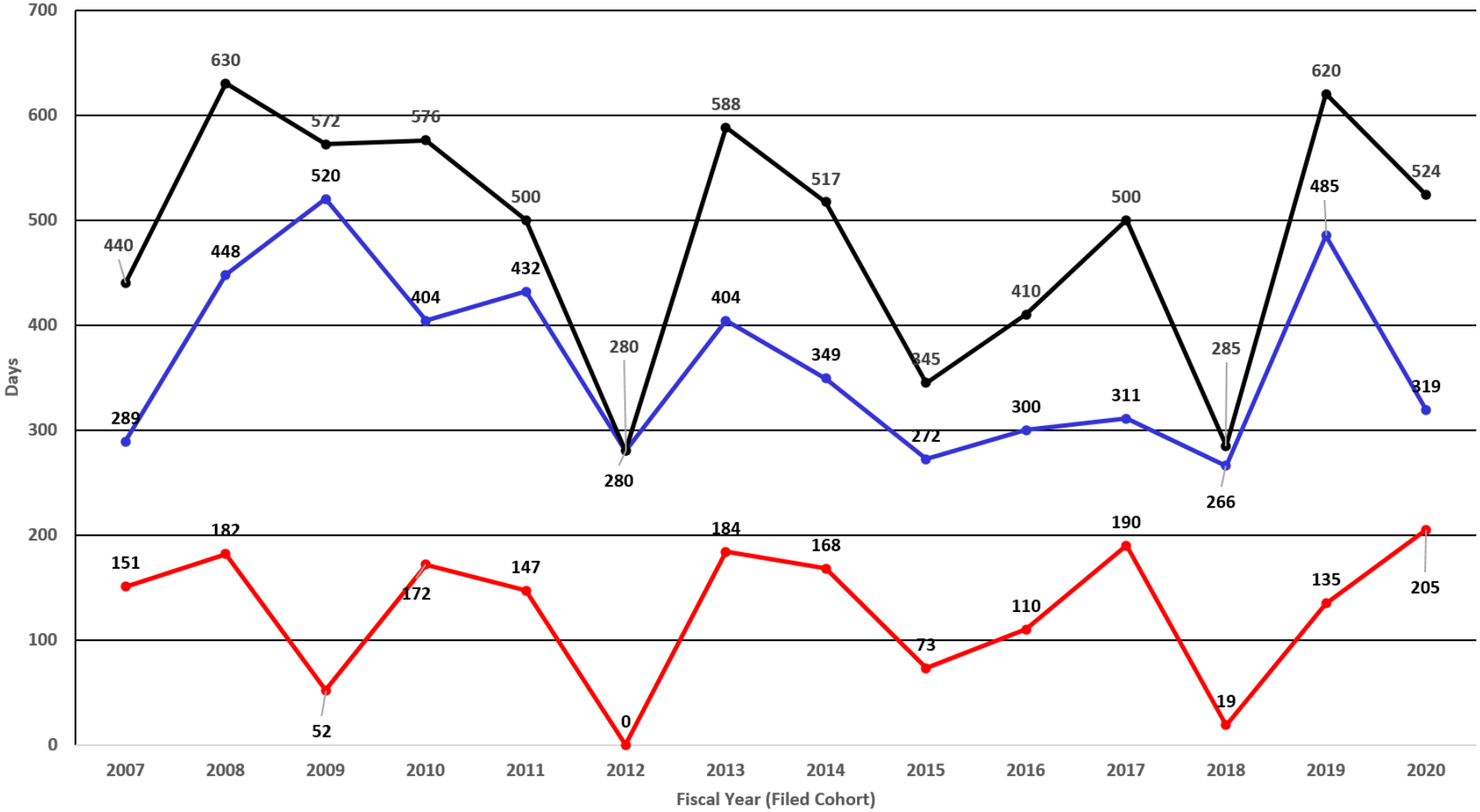
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY Filed Cohort
385
451
408
373
318
283
420
259
278
302
275
256
312
313
363
225
282
222
194
218
186
266
196
186
166
185
169
192
188
208
160
168
187
178
100
97
154
64
92
136
90
87
120
125
156
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 12/31/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 90.9% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
365
406
383
347
290
264
363
245
257
266
257
237
277
275
325
289
209
246
195
186
206
180
240
192
184
165
182
169
178
178
188
176
156
160
187
161
84
84
123
53
72
102
75
68
99
98
137
113
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

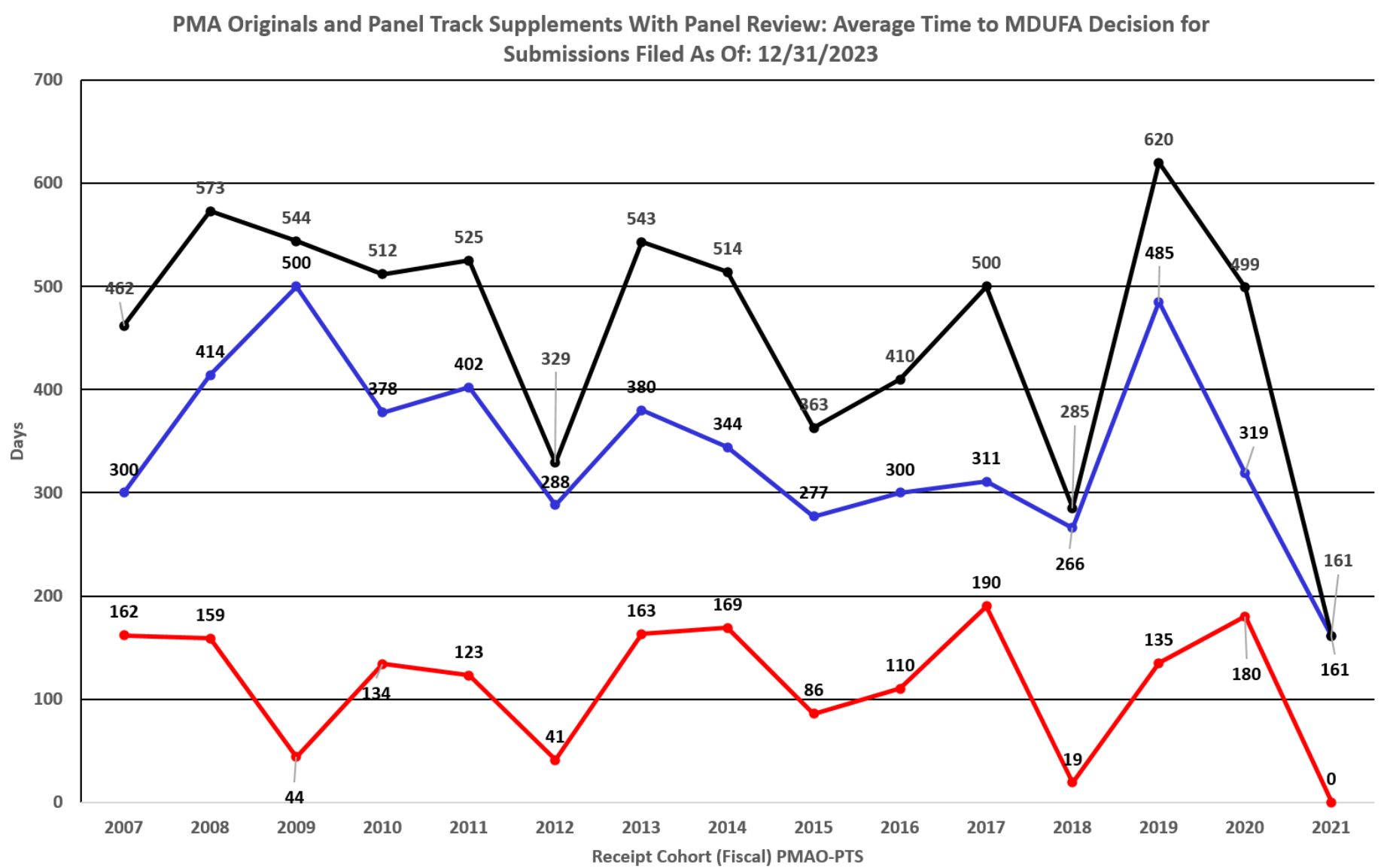
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 12/31/2023



Numbers Filed/Closed: 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

***Note: For FY21 and 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**

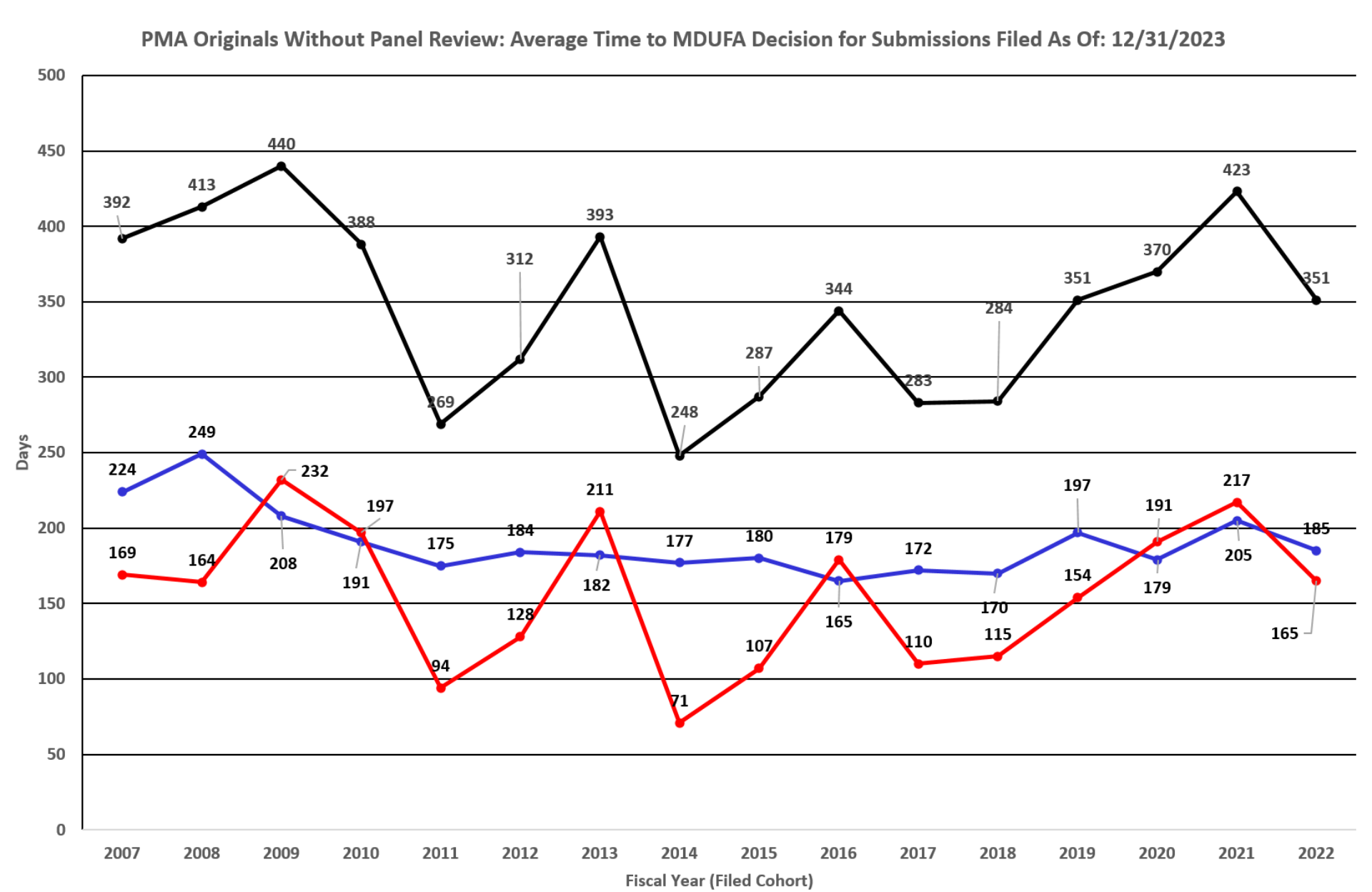


Numbers Filed/Closed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013: 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/1

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

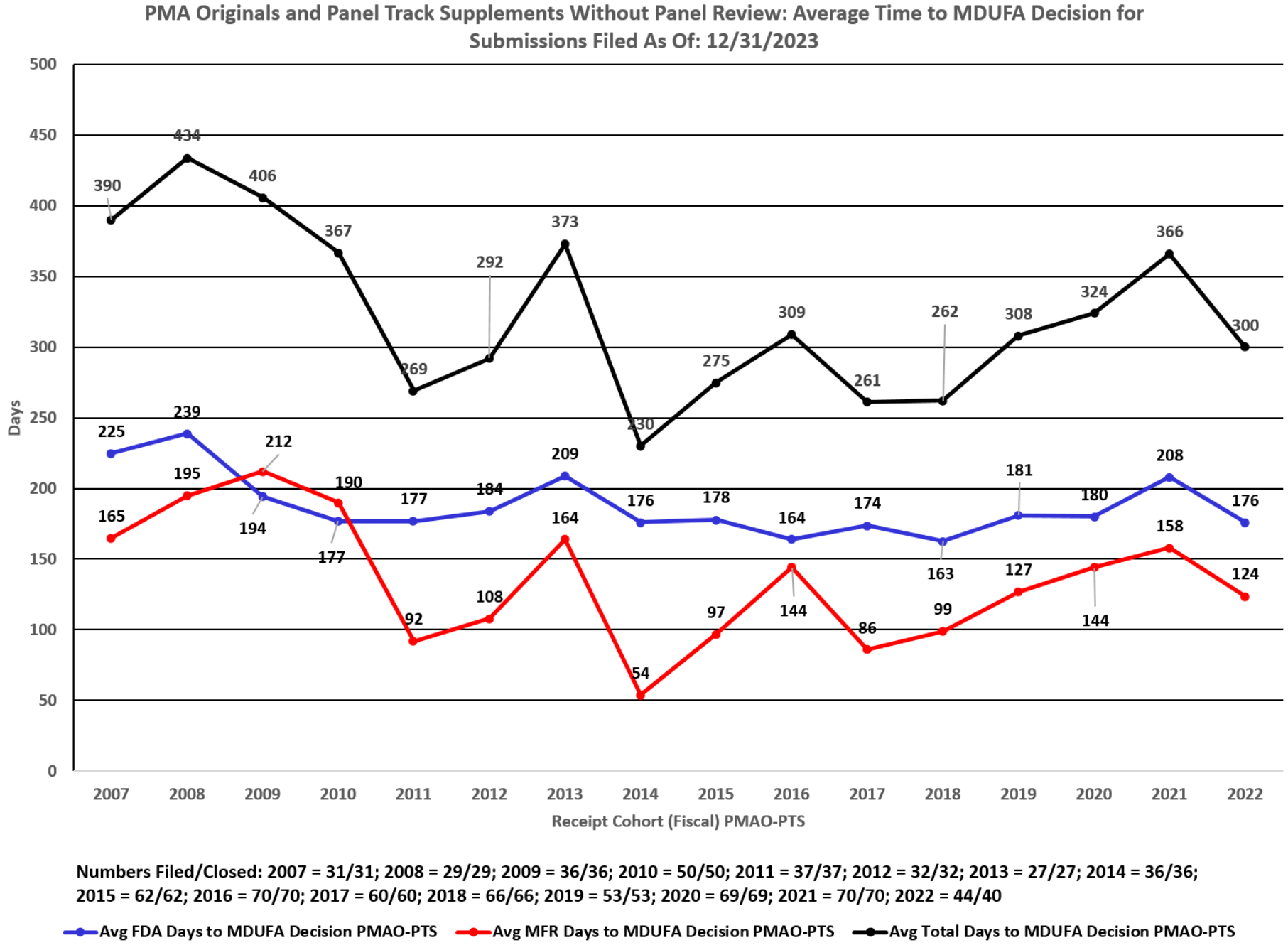
Avg FDA Days to MDUFA Decision PMAO-PTS **Avg MFR Days to MDUFA Decision PMAO-PTS** **Avg Total Days to MDUFA Decision PMAO-PTS**

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



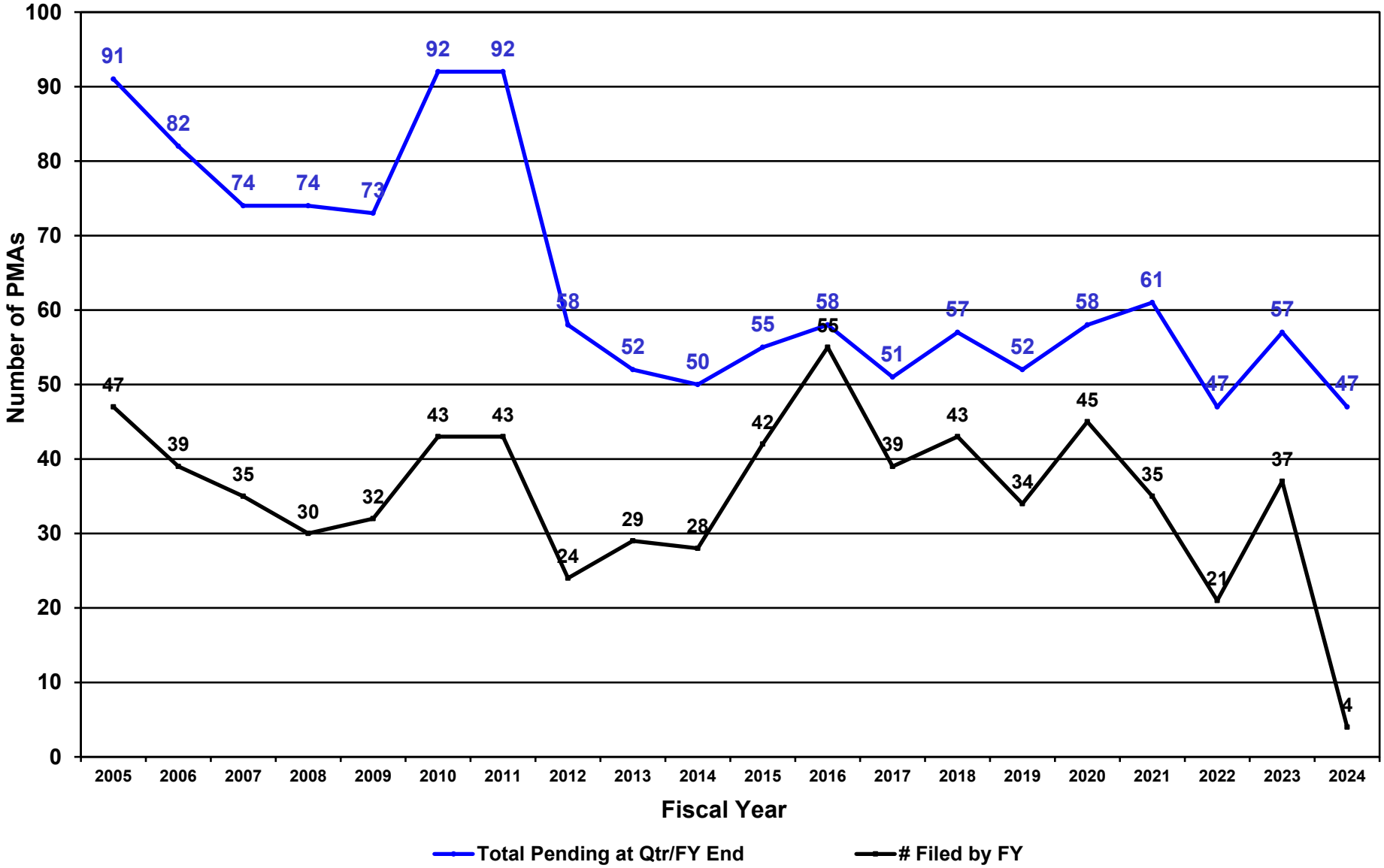
Numbers Filed/Closed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 22/19

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



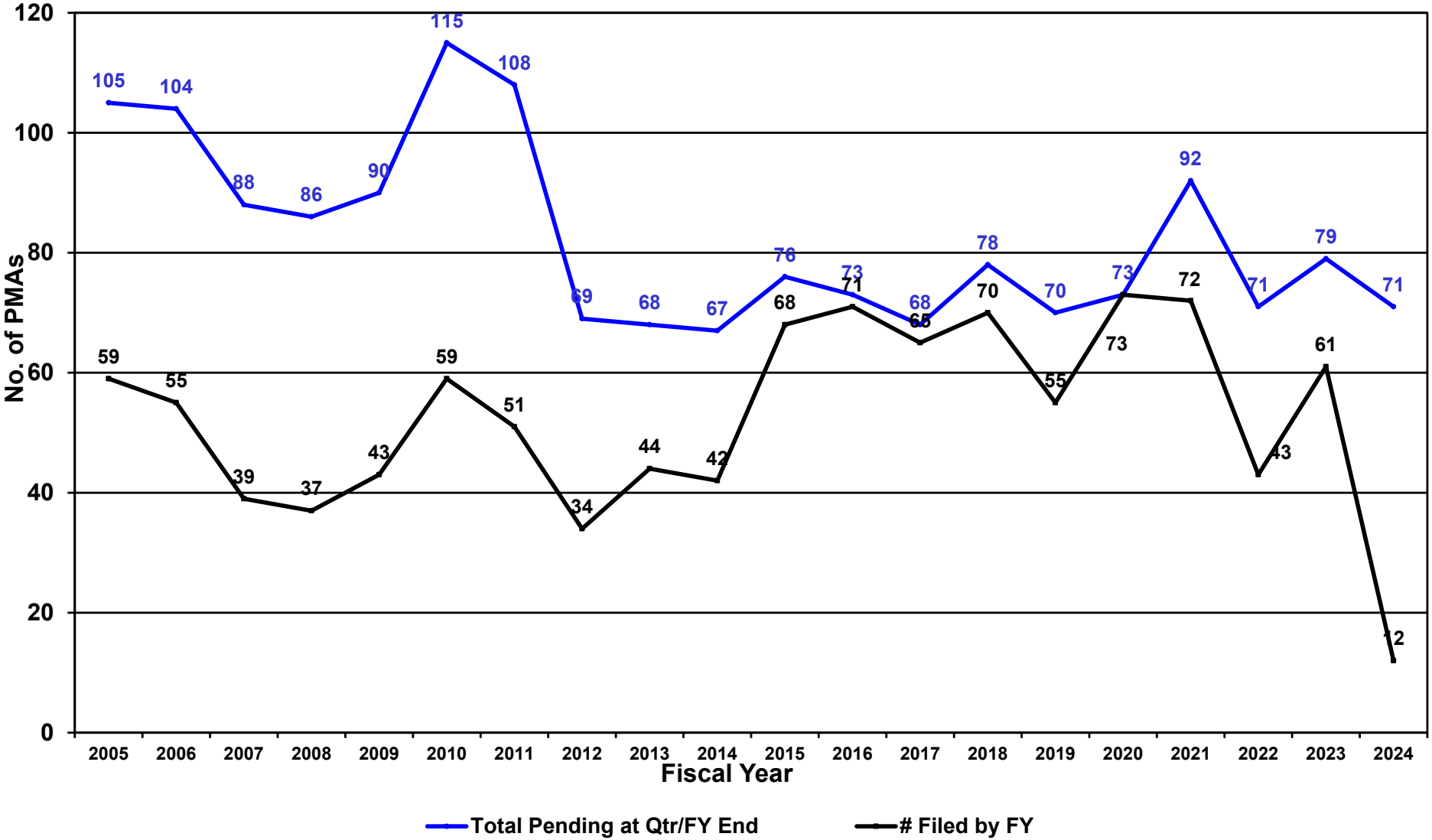
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

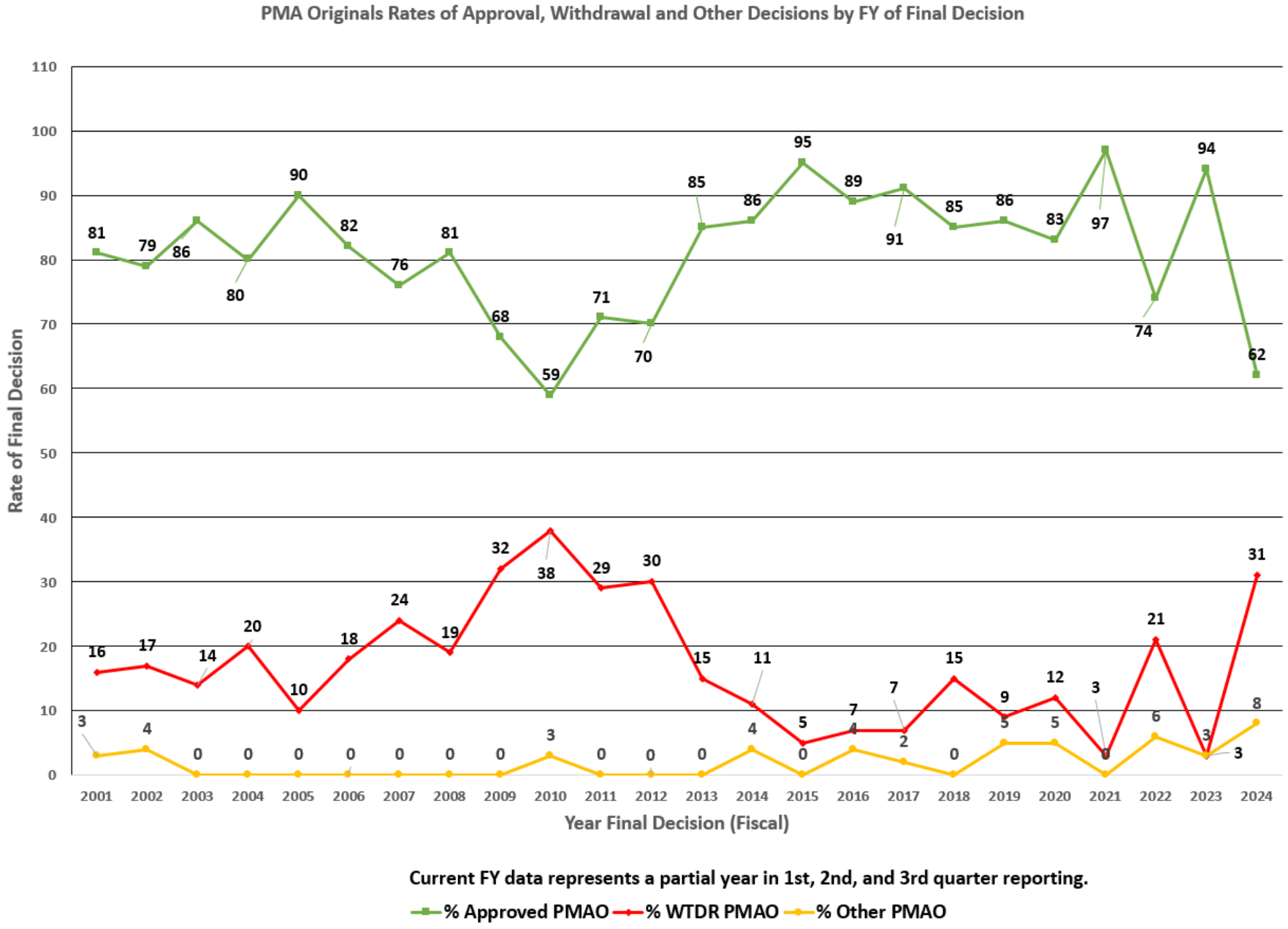


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

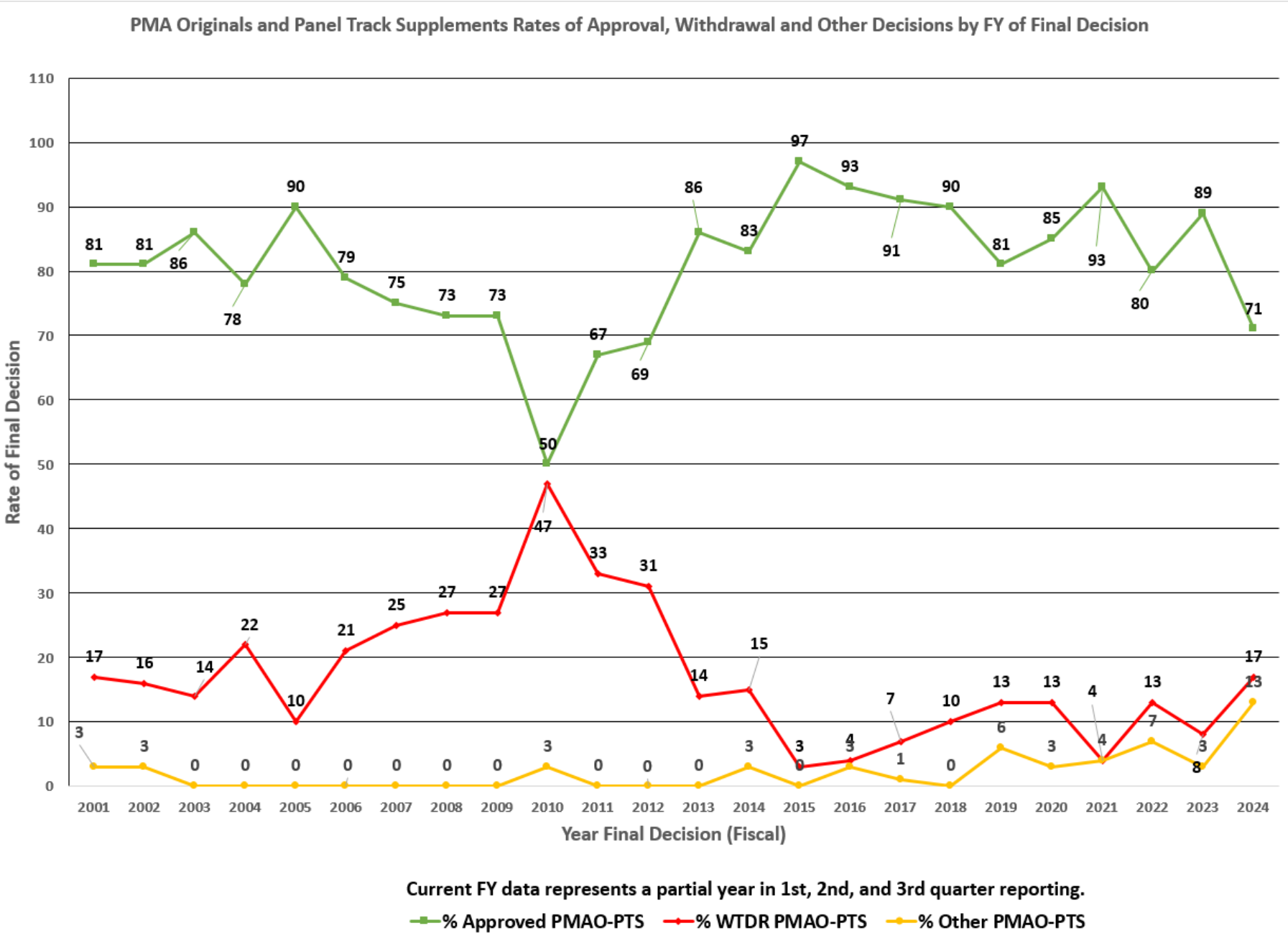
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



*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.

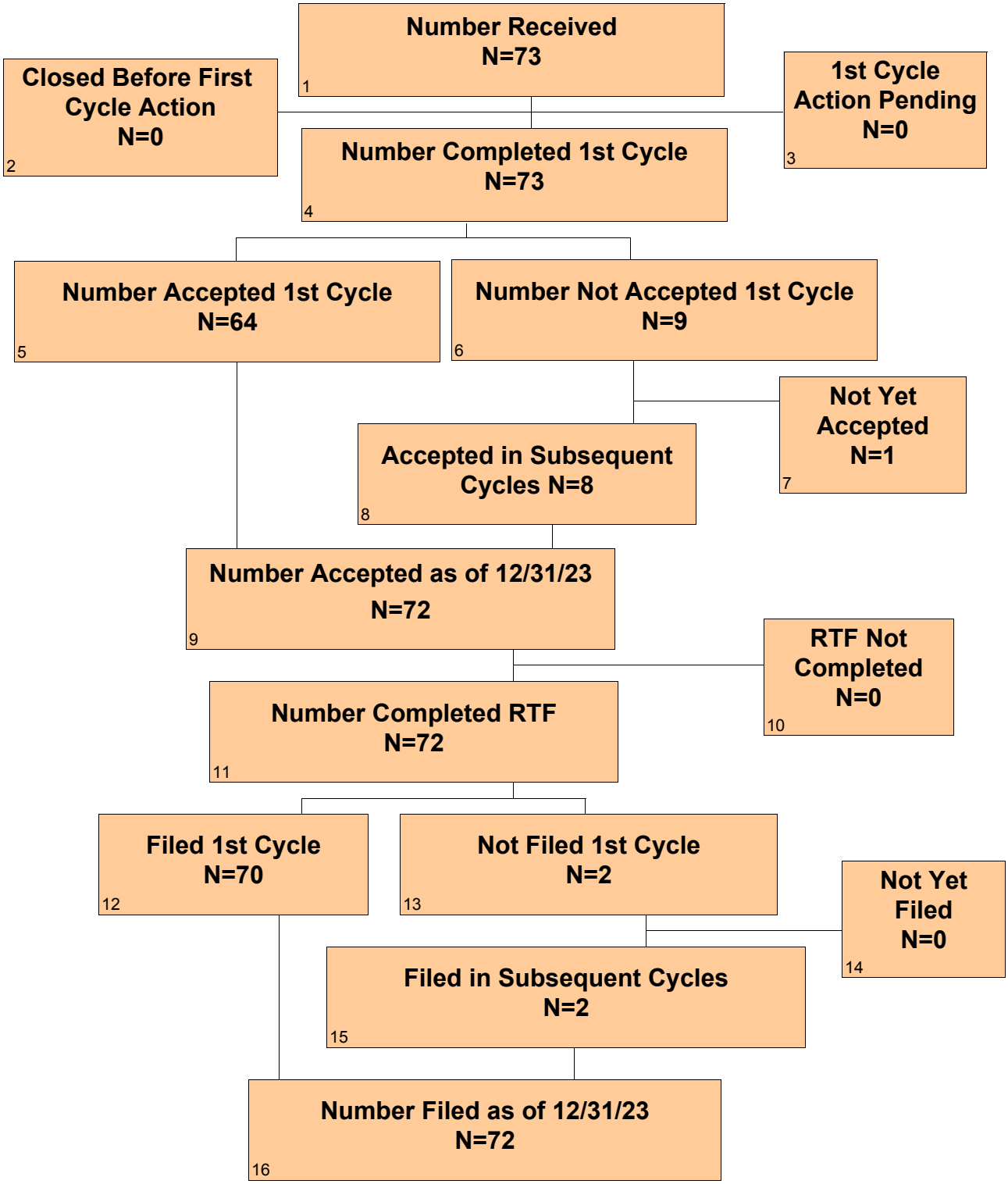


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

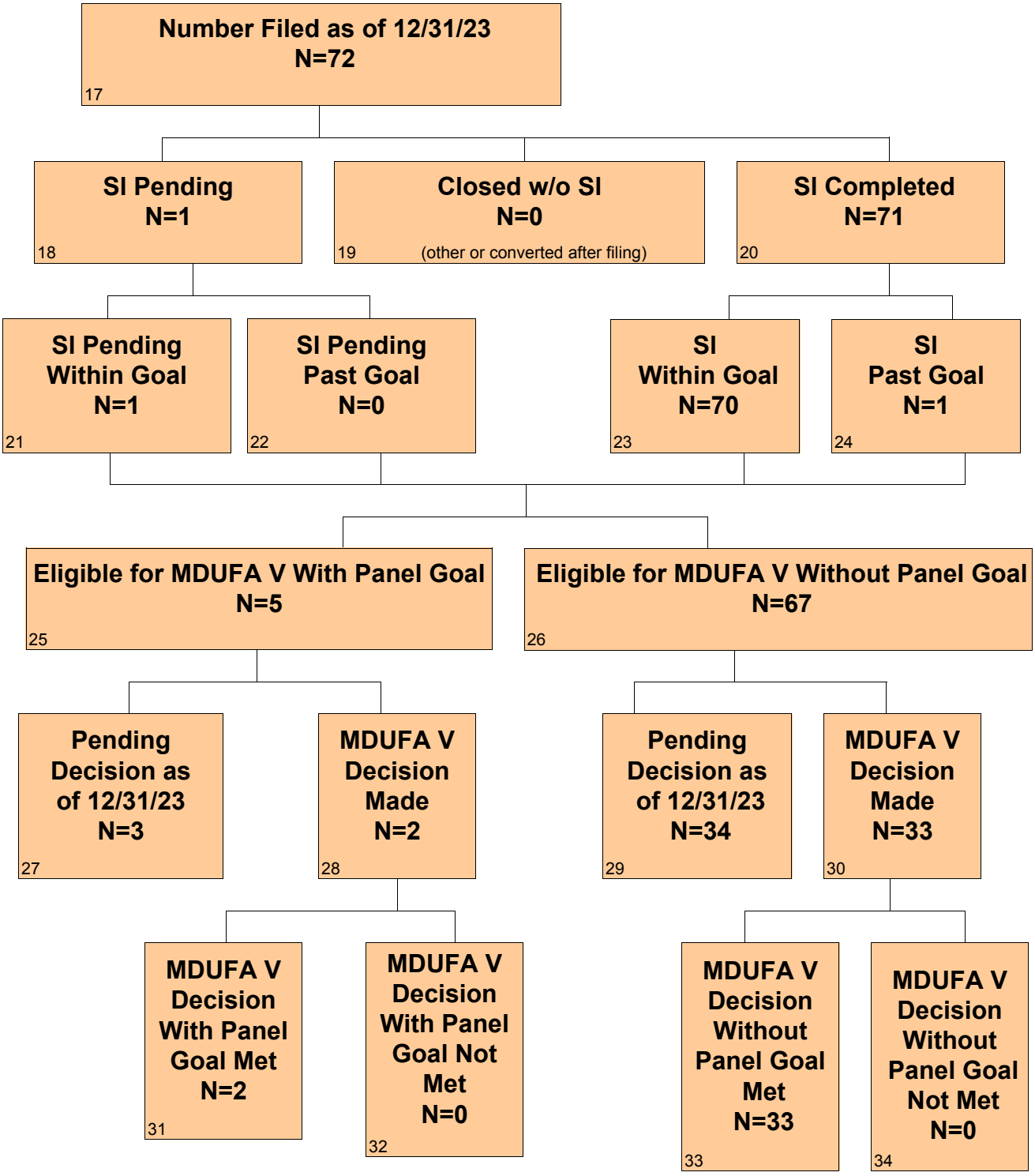


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

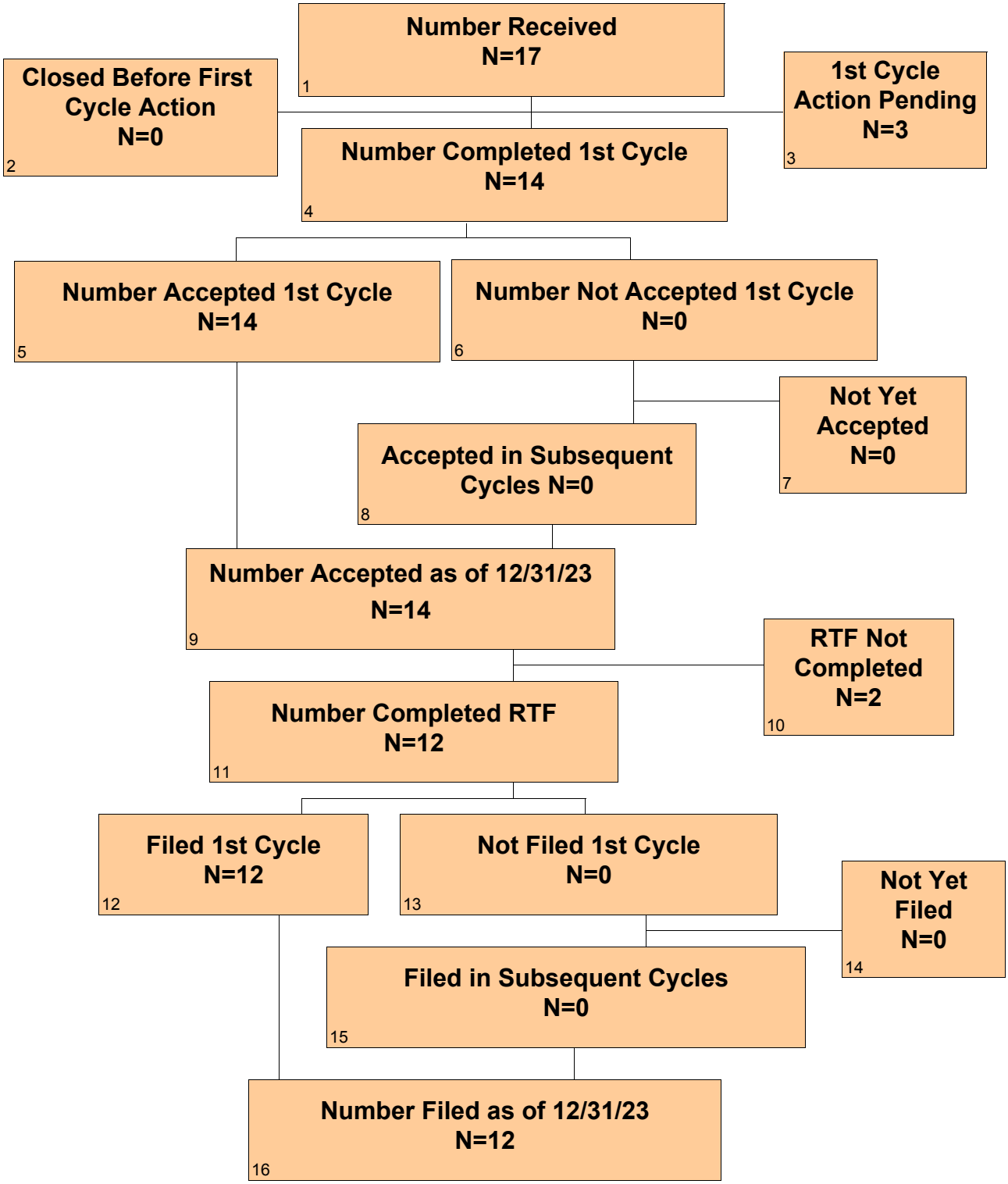
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/23



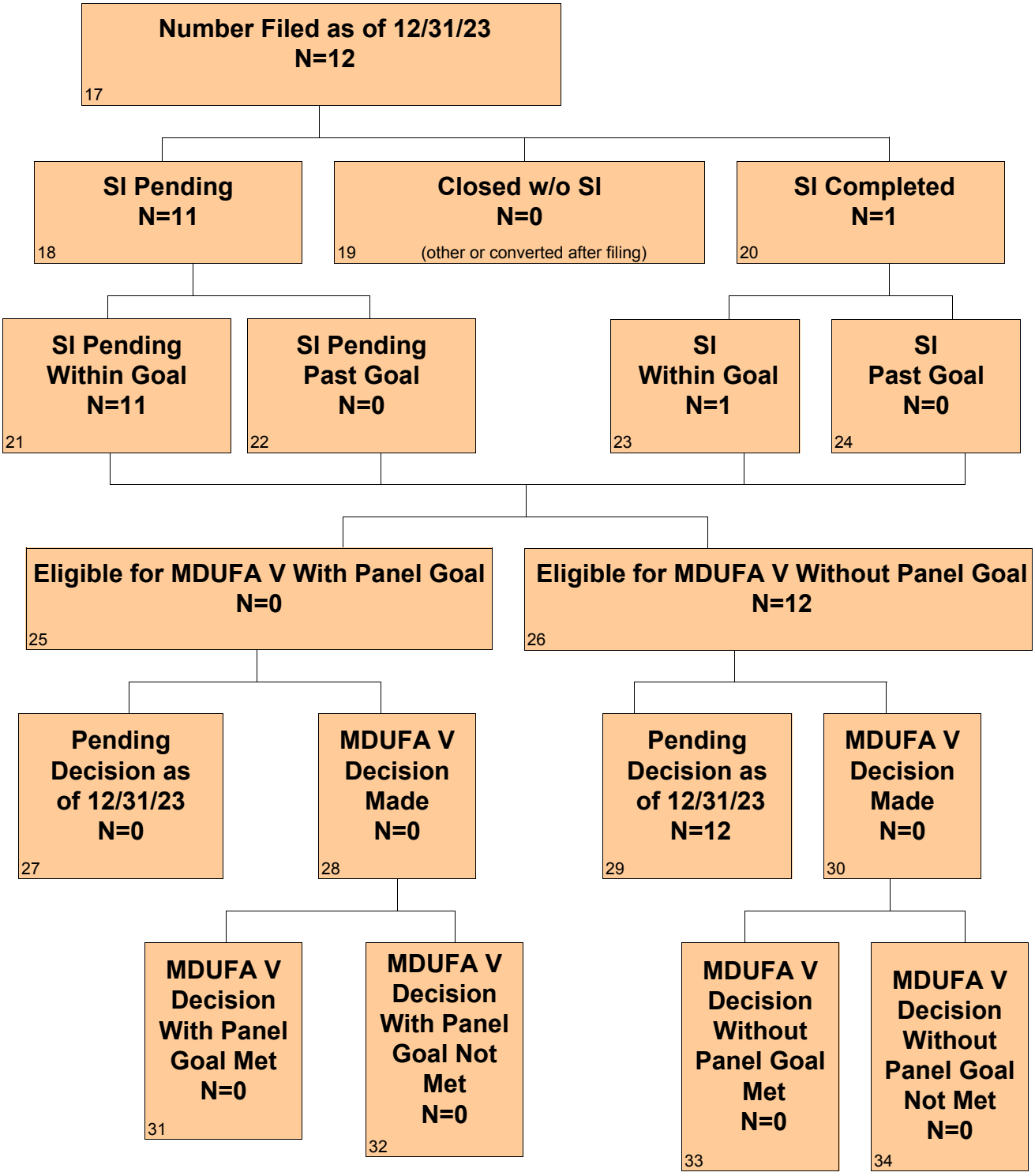
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/23 Continued



CDRH PMA Original and Panel Track Supplements - FY 2024 as of 12/31/23



CDRH PMA Original and Panel Track Supplements - FY 2024 as of 12/31/23 Continued



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	17			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	64	14			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	3			
Number Not Accepted for Filing Review on First Cycle	9	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	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 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	17			
Number Accepted	64	14			
Completed RTF	72	12			
Number Not Filed	2	0			
Rate of Submissions Not Filed	2.78%	0.00%			

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	12			
SI Goal Met	70	1			
SI Goal Not Met	1	0			
SI Pending Within Goal	1	11			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.59%	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	71	1			
Average Number of FDA Days to Substantive Interaction	87.38	82.00			
20th Percentile FDA Days to Substantive Interaction	86	82			
40th Percentile FDA Days to Substantive Interaction	88	82			
60th Percentile FDA Days to Substantive Interaction	90	82			
80th Percentile FDA Days to Substantive Interaction	90	82			
Maximum FDA Days to Substantive Interaction	91	82			

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	12			
Non-MDUFA Decision	0	0			
MDUFA Decision	33	0			
MDUFA Decision Goal Met	33	0			
PMAs Pending MDUFA Decision	34	12			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	2	0			
MDUFA Decision Goal Met	2	0			
PMAs Pending MDUFA Decision	3	0			
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	33	0			
Average FDA Days to MDUFA Decision	163.79	N/A			
20th Percentile FDA Days to MDUFA Decision	171	0			
40th Percentile FDA Days to MDUFA Decision	178	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	58.73	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	11	0			
60th Percentile Industry Days to MDUFA Decision	51	0			
80th Percentile Industry Days to MDUFA Decision	86	0			
Maximum Industry Days to MDUFA Decision	287	0			
Average Total Days to MDUFA Decision	222.52	N/A			
20th Percentile Total Days to MDUFA Decision	179	0			
40th Percentile Total Days to MDUFA Decision	190	0			
60th Percentile Total Days to MDUFA Decision	231	0			
80th Percentile Total Days to MDUFA Decision	265	0			
Maximum Total Days to MDUFA Decision	442	0			

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	2	0			
Average FDA Days to MDUFA Decision	319.00	N/A			
20th Percentile FDA Days to MDUFA Decision	318	0			
40th Percentile FDA Days to MDUFA Decision	319	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	49.00	N/A			
20th Percentile Industry Days to MDUFA Decision	44	0			
40th Percentile Industry Days to MDUFA Decision	47	0			
60th Percentile Industry Days to MDUFA Decision	51	0			
80th Percentile Industry Days to MDUFA Decision	54	0			
Maximum Industry Days to MDUFA Decision	57	0			
Average Total Days to MDUFA Decision	368.00	N/A			
20th Percentile Total Days to MDUFA Decision	363	0			
40th Percentile Total Days to MDUFA Decision	366	0			
60th Percentile Total Days to MDUFA Decision	370	0			
80th Percentile Total Days to MDUFA Decision	373	0			
Maximum Total Days to MDUFA Decision	377	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	12			
Number with MDUFA Decision	33	0			
Number of Withdrawal	3	0			
Number of Not Approvable	4	0			
Number of Deleted	0	0			
Rate of Withdrawal	9.09%	N/A			
Rate of Not Approvable	12.12%	N/A			

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	0			
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 1.11 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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
PMAs Pending MDUFA Decision	2	0			
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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Goal Met	5	0			
PMAs Pending MDUFA Decision	10	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

***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	4			
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	0			
Number Not Accepted for Filing Review on First Cycle	6	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	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 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	4			
Number Accepted	3	4			
Completed RTF	8	3			
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	3			
SI Goal Met	7	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	1	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	N/A			

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	7	0			
Average Number of FDA Days to Substantive Interaction	80.86	N/A			
20th Percentile FDA Days to Substantive Interaction	87	0			
40th Percentile FDA Days to Substantive Interaction	89	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
PMAs Pending MDUFA Decision	4	3			
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	100.00%			

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	4	0			
Average FDA Days to MDUFA Decision	120.00	N/A			
20th Percentile FDA Days to MDUFA Decision	66	0			
40th Percentile FDA Days to MDUFA Decision	108	0			
60th Percentile FDA Days to MDUFA Decision	161	0			
80th Percentile FDA Days to MDUFA Decision	179	0			
Maximum FDA Days to MDUFA Decision	180	0			
Average Industry Days to MDUFA Decision	106.00	N/A			
20th Percentile Industry Days to MDUFA Decision	31	0			
40th Percentile Industry Days to MDUFA Decision	59	0			
60th Percentile Industry Days to MDUFA Decision	78	0			
80th Percentile Industry Days to MDUFA Decision	166	0			
Maximum Industry Days to MDUFA Decision	287	0			
Average Total Days to MDUFA Decision	226.00	N/A			
20th Percentile Total Days to MDUFA Decision	152	0			
40th Percentile Total Days to MDUFA Decision	238	0			
60th Percentile Total Days to MDUFA Decision	258	0			
80th Percentile Total Days to MDUFA Decision	309	0			
Maximum Total Days to MDUFA Decision	377	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	3			
Number with MDUFA Decision	4	0			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	25.00%	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	6			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	19	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	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	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 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	6			
Number Accepted	19	6			
Completed RTF	20	5			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	0.00%			

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	5			
SI Goal Met	20	1			
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	1			
Average Number of FDA Days to Substantive Interaction	88.25	82.00			
20th Percentile FDA Days to Substantive Interaction	86	82			
40th Percentile FDA Days to Substantive Interaction	90	82			
60th Percentile FDA Days to Substantive Interaction	90	82			
80th Percentile FDA Days to Substantive Interaction	90	82			
Maximum FDA Days to Substantive Interaction	90	82			

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	5			
Non-MDUFA Decision	0	0			
MDUFA Decision	9	0			
MDUFA Decision Goal Met	9	0			
PMAs Pending MDUFA Decision	8	5			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	2	0			
MDUFA Decision Goal Met	2	0			
PMAs Pending MDUFA Decision	1	0			
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	9	0			
Average FDA Days to MDUFA Decision	176.44	N/A			
20th Percentile FDA Days to MDUFA Decision	174	0			
40th Percentile FDA Days to MDUFA Decision	178	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	66.78	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	20	0			
60th Percentile Industry Days to MDUFA Decision	49	0			
80th Percentile Industry Days to MDUFA Decision	101	0			
Maximum Industry Days to MDUFA Decision	271	0			
Average Total Days to MDUFA Decision	243.22	N/A			
20th Percentile Total Days to MDUFA Decision	178	0			
40th Percentile Total Days to MDUFA Decision	198	0			
60th Percentile Total Days to MDUFA Decision	229	0			
80th Percentile Total Days to MDUFA Decision	281	0			
Maximum Total Days to MDUFA Decision	442	0			

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	2	0			
Average FDA Days to MDUFA Decision	319.00	N/A			
20th Percentile FDA Days to MDUFA Decision	318	0			
40th Percentile FDA Days to MDUFA Decision	319	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	49.00	N/A			
20th Percentile Industry Days to MDUFA Decision	44	0			
40th Percentile Industry Days to MDUFA Decision	47	0			
60th Percentile Industry Days to MDUFA Decision	51	0			
80th Percentile Industry Days to MDUFA Decision	54	0			
Maximum Industry Days to MDUFA Decision	57	0			
Average Total Days to MDUFA Decision	368.00	N/A			
20th Percentile Total Days to MDUFA Decision	363	0			
40th Percentile Total Days to MDUFA Decision	366	0			
60th Percentile Total Days to MDUFA Decision	370	0			
80th Percentile Total Days to MDUFA Decision	373	0			
Maximum Total Days to MDUFA Decision	377	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	5			
Number with MDUFA Decision	9	0			
Number of Withdrawal	1	0			
Number of Not Approvable	2	0			
Number of Deleted	0	0			
Rate of Withdrawal	11.11%	N/A			
Rate of Not Approvable	22.22%	N/A			

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	0			
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 1.11 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	1			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	3	0			
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	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	N/A			

***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	1			
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 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	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 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	0			
Average Number of FDA Days to Substantive Interaction	88.33	N/A			
20th Percentile FDA Days to Substantive Interaction	87	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	88	0			
80th Percentile FDA Days to Substantive Interaction	89	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	2	0			
MDUFA Decision Goal Met	2	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 1.6 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	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	1	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	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 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	0			
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	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 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	1			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	9	0			
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	0			
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	N/A			

***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	1			
Number Accepted	9	0			
Completed RTF	9	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	N/A			

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	0			
SI Goal Met	9	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 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	0			
Average Number of FDA Days to Substantive Interaction	88.78	N/A			
20th Percentile FDA Days to Substantive Interaction	88	0			
40th Percentile FDA Days to Substantive Interaction	90	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	0			
MDUFA Decision Goal Met	7	0			
PMAs Pending MDUFA Decision	2	0			
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	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 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	7	0			
Average FDA Days to MDUFA Decision	178.86	N/A			
20th Percentile FDA Days to MDUFA Decision	178	0			
40th Percentile FDA Days to MDUFA Decision	178	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	31.29	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	16	0			
60th Percentile Industry Days to MDUFA Decision	47	0			
80th Percentile Industry Days to MDUFA Decision	60	0			
Maximum Industry Days to MDUFA Decision	66	0			
Average Total Days to MDUFA Decision	210.14	N/A			
20th Percentile Total Days to MDUFA Decision	179	0			
40th Percentile Total Days to MDUFA Decision	195	0			
60th Percentile Total Days to MDUFA Decision	226	0			
80th Percentile Total Days to MDUFA Decision	238	0			
Maximum Total Days to MDUFA Decision	246	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	0			
Number with MDUFA Decision	7	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	14.29%	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	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 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	2			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	5	2			
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	16.67%	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 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	2			
Number Accepted	5	2			
Completed RTF	6	2			
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	2			
SI Goal Met	5	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	83.33%	N/A			

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	0			
Average Number of FDA Days to Substantive Interaction	88.50	N/A			
20th Percentile FDA Days to Substantive Interaction	88	0			
40th Percentile FDA Days to Substantive Interaction	90	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	91	0			

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	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Goal Met	1	0			
PMAs Pending MDUFA Decision	5	2			
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	1	0			
Average FDA Days to MDUFA Decision	180.00	N/A			
20th Percentile FDA Days to MDUFA Decision	180	0			
40th Percentile FDA Days to MDUFA Decision	180	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	101.00	N/A			
20th Percentile Industry Days to MDUFA Decision	101	0			
40th Percentile Industry Days to MDUFA Decision	101	0			
60th Percentile Industry Days to MDUFA Decision	101	0			
80th Percentile Industry Days to MDUFA Decision	101	0			
Maximum Industry Days to MDUFA Decision	101	0			
Average Total Days to MDUFA Decision	281.00	N/A			
20th Percentile Total Days to MDUFA Decision	281	0			
40th Percentile Total Days to MDUFA Decision	281	0			
60th Percentile Total Days to MDUFA Decision	281	0			
80th Percentile Total Days to MDUFA Decision	281	0			
Maximum Total Days to MDUFA Decision	281	0			

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	2			
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%	0.00%			
Rate of Not Approvable	0.00%	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	1			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	4	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	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	1			
Number Accepted	4	1			
Completed RTF	5	1			
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	1			
SI Goal Met	5	0			
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%	N/A			

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	0			
Average Number of FDA Days to Substantive Interaction	85.40	N/A			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	86	0			
60th Percentile FDA Days to Substantive Interaction	87	0			
80th Percentile FDA Days to Substantive Interaction	88	0			
Maximum FDA Days to Substantive Interaction	88	0			

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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Goal Met	1	0			
PMAs Pending MDUFA Decision	4	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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	1	0			
Average FDA Days to MDUFA Decision	171.00	N/A			
20th Percentile FDA Days to MDUFA Decision	171	0			
40th Percentile FDA Days to MDUFA Decision	171	0			
60th Percentile FDA Days to MDUFA Decision	171	0			
80th Percentile FDA Days to MDUFA Decision	171	0			
Maximum FDA Days to MDUFA Decision	171	0			
Average Industry Days to MDUFA Decision	172.00	N/A			
20th Percentile Industry Days to MDUFA Decision	172	0			
40th Percentile Industry Days to MDUFA Decision	172	0			
60th Percentile Industry Days to MDUFA Decision	172	0			
80th Percentile Industry Days to MDUFA Decision	172	0			
Maximum Industry Days to MDUFA Decision	172	0			
Average Total Days to MDUFA Decision	343.00	N/A			
20th Percentile Total Days to MDUFA Decision	343	0			
40th Percentile Total Days to MDUFA Decision	343	0			
60th Percentile Total Days to MDUFA Decision	343	0			
80th Percentile Total Days to MDUFA Decision	343	0			
Maximum Total Days to MDUFA Decision	343	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	1			
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%	11.11%			
Rate of Not Approvable	100.00%	0.00%			

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	2			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	21	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	1			
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 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	2			
Number Accepted	21	1			
Completed RTF	21	1			
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	1			
SI Goal Met	21	0			
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%	N/A			

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	0			
Average Number of FDA Days to Substantive Interaction	88.14	N/A			
20th Percentile FDA Days to Substantive Interaction	87	0			
40th Percentile FDA Days to Substantive Interaction	87	0			
60th Percentile FDA Days to Substantive Interaction	89	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	9	0			
MDUFA Decision Goal Met	9	0			
PMAs Pending MDUFA Decision	11	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	0	0			
MDUFA Decision Goal Met	0	0			
PMAs Pending MDUFA Decision	1	0			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	9	0			
Average FDA Days to MDUFA Decision	153.67	N/A			
20th Percentile FDA Days to MDUFA Decision	116	0			
40th Percentile FDA Days to MDUFA Decision	177	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	43.67	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	14	0			
80th Percentile Industry Days to MDUFA Decision	59	0			
Maximum Industry Days to MDUFA Decision	248	0			
Average Total Days to MDUFA Decision	197.33	N/A			
20th Percentile Total Days to MDUFA Decision	162	0			
40th Percentile Total Days to MDUFA Decision	179	0			
60th Percentile Total Days to MDUFA Decision	194	0			
80th Percentile Total Days to MDUFA Decision	237	0			
Maximum Total Days to MDUFA Decision	335	0			

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	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 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	1			
Number with MDUFA Decision	9	0			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	11.11%	N/A			
Rate of Not Approvable	0.00%	N/A			

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	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 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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
PMAs Pending MDUFA Decision	2	0			
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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Goal Met	5	0			
PMAs Pending MDUFA Decision	10	1			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

***Includes submission that went to panel**

Table 1.1 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	0			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	0	0			
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	N/A	N/A			

***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	0			
Number Accepted	0	0			
Completed RTF	0	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	N/A	N/A			

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	0			
SI Goal Met	0	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	N/A	N/A			

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	0			
Average Number of FDA Days to Substantive Interaction	N/A	N/A			
20th Percentile FDA Days to Substantive Interaction	0	0			
40th Percentile FDA Days to Substantive Interaction	0	0			
60th Percentile FDA Days to Substantive Interaction	0	0			
80th Percentile FDA Days to Substantive Interaction	0	0			
Maximum FDA Days to Substantive Interaction	0	0			

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	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 1.6 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	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 1.10 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			

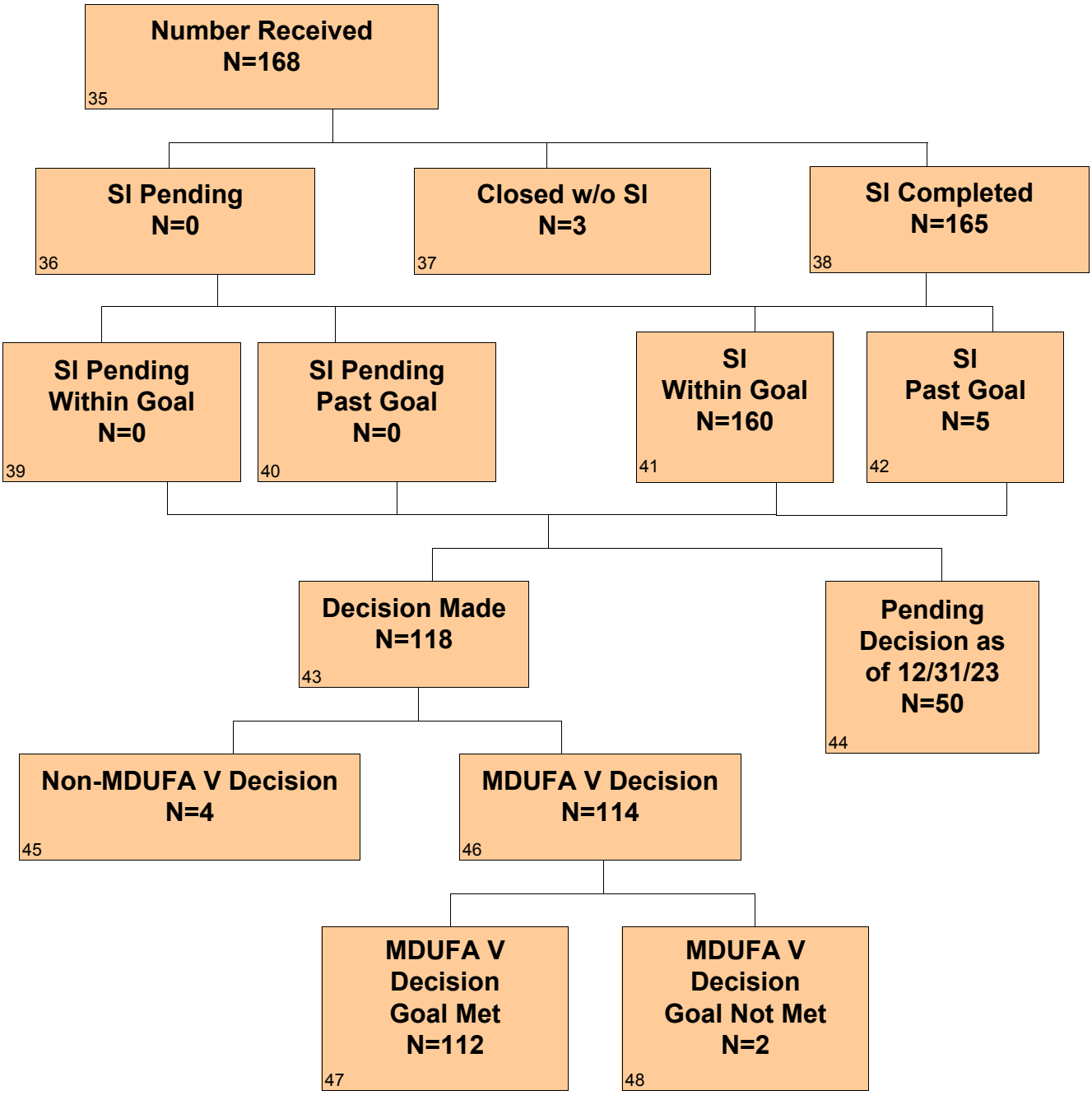
***Includes submission that went to panel**

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

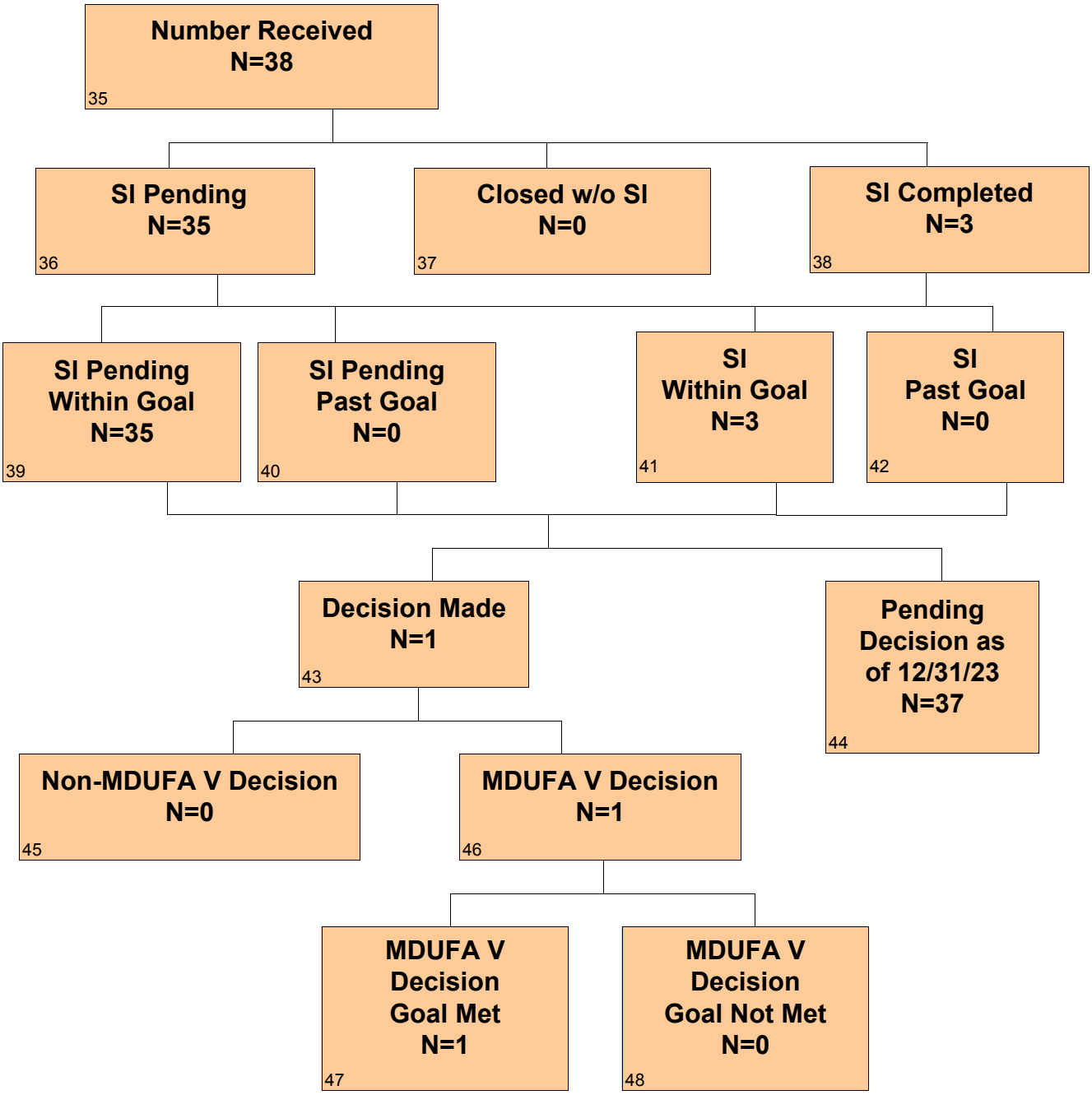
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A			
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 12/31/23



CDRH PMA 180 Day Supplements - FY 2024 as of 12/31/23



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	38			
SI Goal Met	160	3			
SI Goal Not Met	5	0			
SI Pending Within Goal	0	35			
SI Pending Past Goal	0	0			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	96.97%	100.00%			

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	38			
Non-MDUFA Decision	4	0			
MDUFA Decision	114	1			
MDUFA Decision Goal Met	112	1			
Supplements Pending MDUFA Decision	50	37			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	98.25%	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	38			
Number with MDUFA Decision	114	1			
Number of Not Approvable	3	0			
Rate of Not Approvable	2.63%	0.00%			

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	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			

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	1			
SI Goal Met	16	0			
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%	N/A			

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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	9	0			
MDUFA Decision Goal Met	9	0			
Supplements Pending MDUFA Decision	7	1			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	1			
Number with MDUFA Decision	9	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

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	15			
SI Goal Met	55	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	14			
SI Pending Past Goal	0	0			
Closed Without SI	1	0			
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	15			
Non-MDUFA Decision	1	0			
MDUFA Decision	44	0			
MDUFA Decision Goal Met	44	0			
Supplements Pending MDUFA Decision	11	15			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	15			
Number with MDUFA Decision	44	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	2.27%	N/A			

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	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 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	6			
SI Goal Met	20	1			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	5			
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	6			
Non-MDUFA Decision	0	0			
MDUFA Decision	19	1			
MDUFA Decision Goal Met	19	1			
Supplements Pending MDUFA Decision	2	5			
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	6			
Number with MDUFA Decision	19	1			
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	0			
SI Goal Met	8	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 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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
Supplements Pending MDUFA Decision	8	0			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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	0			
Number with MDUFA Decision	0	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	N/A	N/A			

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	3			
SI Goal Met	20	1			
SI Goal Not Met	3	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	86.96%	100.00%			

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	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	13	0			
MDUFA Decision Goal Met	11	0			
Supplements Pending MDUFA Decision	10	3			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	84.62%	N/A			

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	3			
Number with MDUFA Decision	13	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	15.38%	N/A			

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	0			
SI Goal Met	7	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 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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Goal Met	5	0			
Supplements Pending MDUFA Decision	2	0			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	0			
Number with MDUFA Decision	5	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

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	13			
SI Goal Met	33	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	13			
SI Pending Past Goal	0	0			
Closed Without SI	2	0			
Current SI Performance Percent Goal Met	97.06%	N/A			

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	13			
Non-MDUFA Decision	3	0			
MDUFA Decision	24	0			
MDUFA Decision Goal Met	24	0			
Supplements Pending MDUFA Decision	9	13			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	13			
Number with MDUFA Decision	24	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

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	0			
SI Goal Met	1	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 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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Goal Met	0	0			
Supplements Pending MDUFA Decision	1	0			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

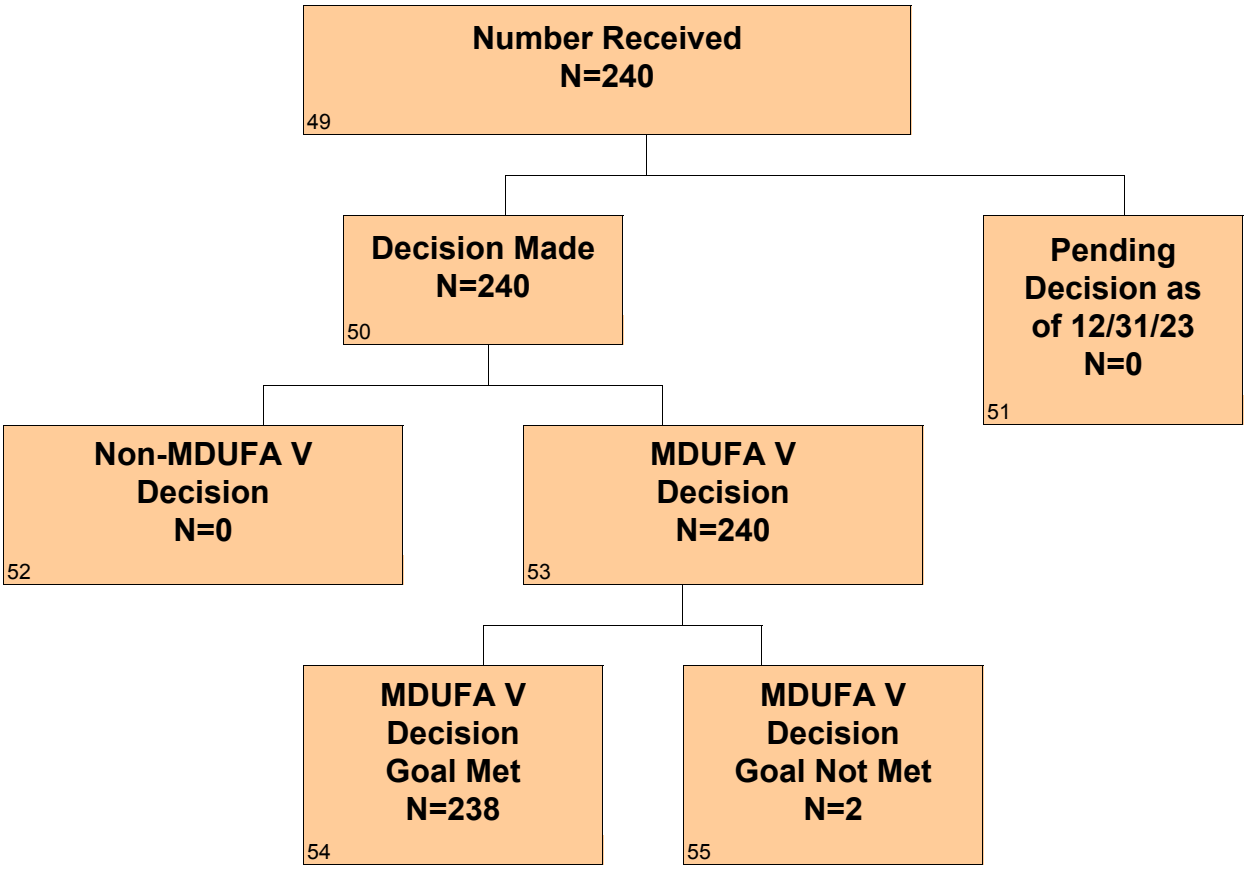
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

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

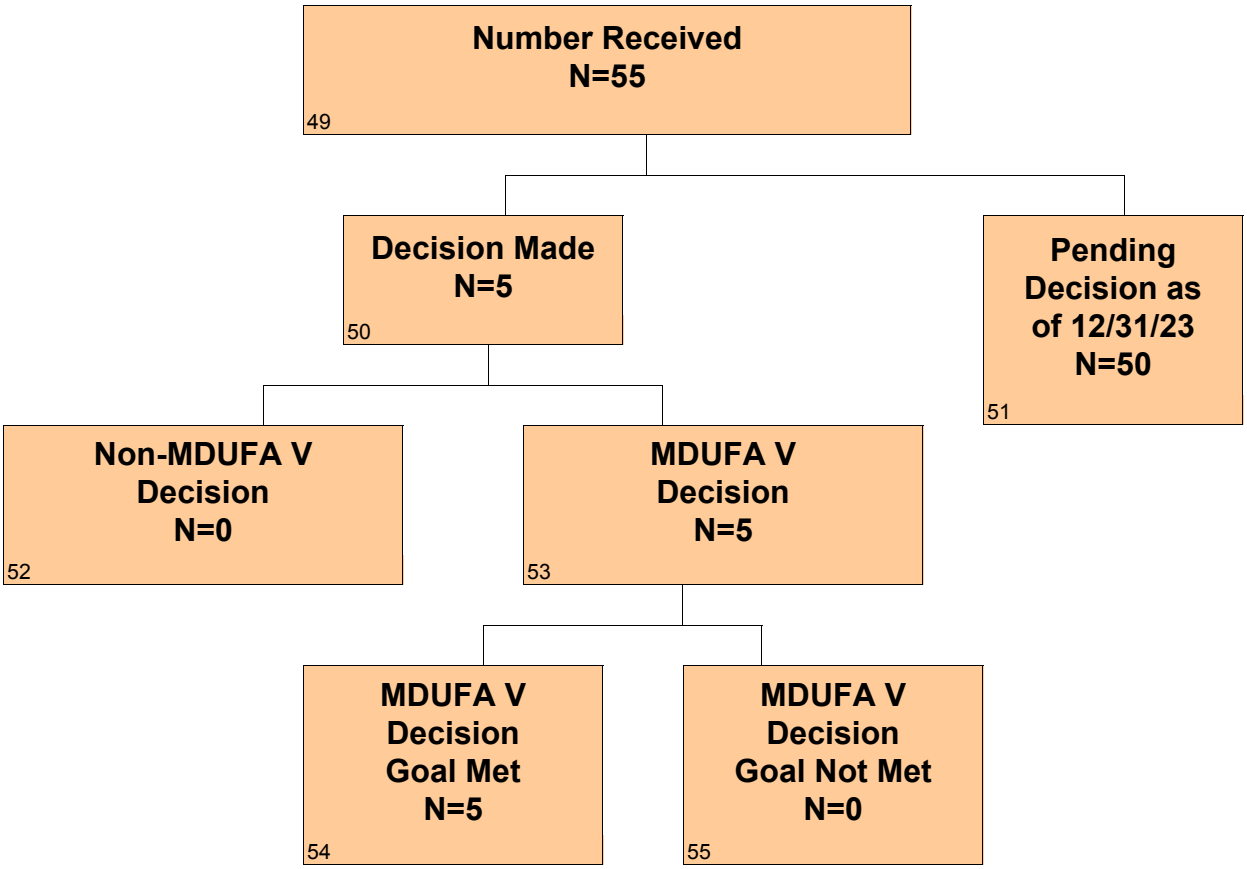
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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 12/31/23



CDRH PMA Real Time Supplements - FY 2024 as of 12/31/23



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	55			
Non-MDUFA Decision	0	0			
MDUFA Decision	240	5			
MDUFA Decision Goal Met	238	5			
Supplements Pending MDUFA Decision	0	50			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	99.17%	100.00%			

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	55			
Number With MDUFA Decision	240	5			
Number of Not Approvable	11	0			
Rate of Not Approvable	4.58%	0.00%			

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	0			
Mean FDA Days for Submissions that Missed the Goal	109.50	N/A			
Mean Industry Days for Submissions that Missed the Goal	0.00	N/A			

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	9			
Non-MDUFA Decision	0	0			
MDUFA Decision	24	0			
MDUFA Decision Goal Met	24	0			
Supplements Pending MDUFA Decision	0	9			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	9			
Number With MDUFA Decision	24	0			
Number of Not Approvable	3	0			
Rate of Not Approvable	12.50%	N/A			

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	18			
Non-MDUFA Decision	0	0			
MDUFA Decision	136	4			
MDUFA Decision Goal Met	136	4			
Supplements Pending MDUFA Decision	0	14			
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	18			
Number With MDUFA Decision	136	4			
Number of Not Approvable	4	0			
Rate of Not Approvable	2.94%	0.00%			

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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	19	0			
MDUFA Decision Goal Met	18	0			
Supplements Pending MDUFA Decision	0	1			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	94.74%	N/A			

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	1			
Number With MDUFA Decision	19	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	10.53%	N/A			

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	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	0			
MDUFA Decision Goal Met	7	0			
Supplements Pending MDUFA Decision	0	3			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	3			
Number With MDUFA Decision	7	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	28.57%	N/A			

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	5			
Non-MDUFA Decision	0	0			
MDUFA Decision	16	1			
MDUFA Decision Goal Met	15	1			
Supplements Pending MDUFA Decision	0	4			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	93.75%	100.00%			

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	5			
Number With MDUFA Decision	16	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

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	0			
Mean FDA Days for Submissions that Missed the Goal	127.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	0.00	N/A			

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	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
Supplements Pending MDUFA Decision	0	2			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	2			
Number With MDUFA Decision	4	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

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	16			
Non-MDUFA Decision	0	0			
MDUFA Decision	32	0			
MDUFA Decision Goal Met	32	0			
Supplements Pending MDUFA Decision	0	16			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	16			
Number With MDUFA Decision	32	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

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	0			
MDUFA Decision Goal Met	2	0			
Supplements Pending MDUFA Decision	0	1			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

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 December 31, 2023.

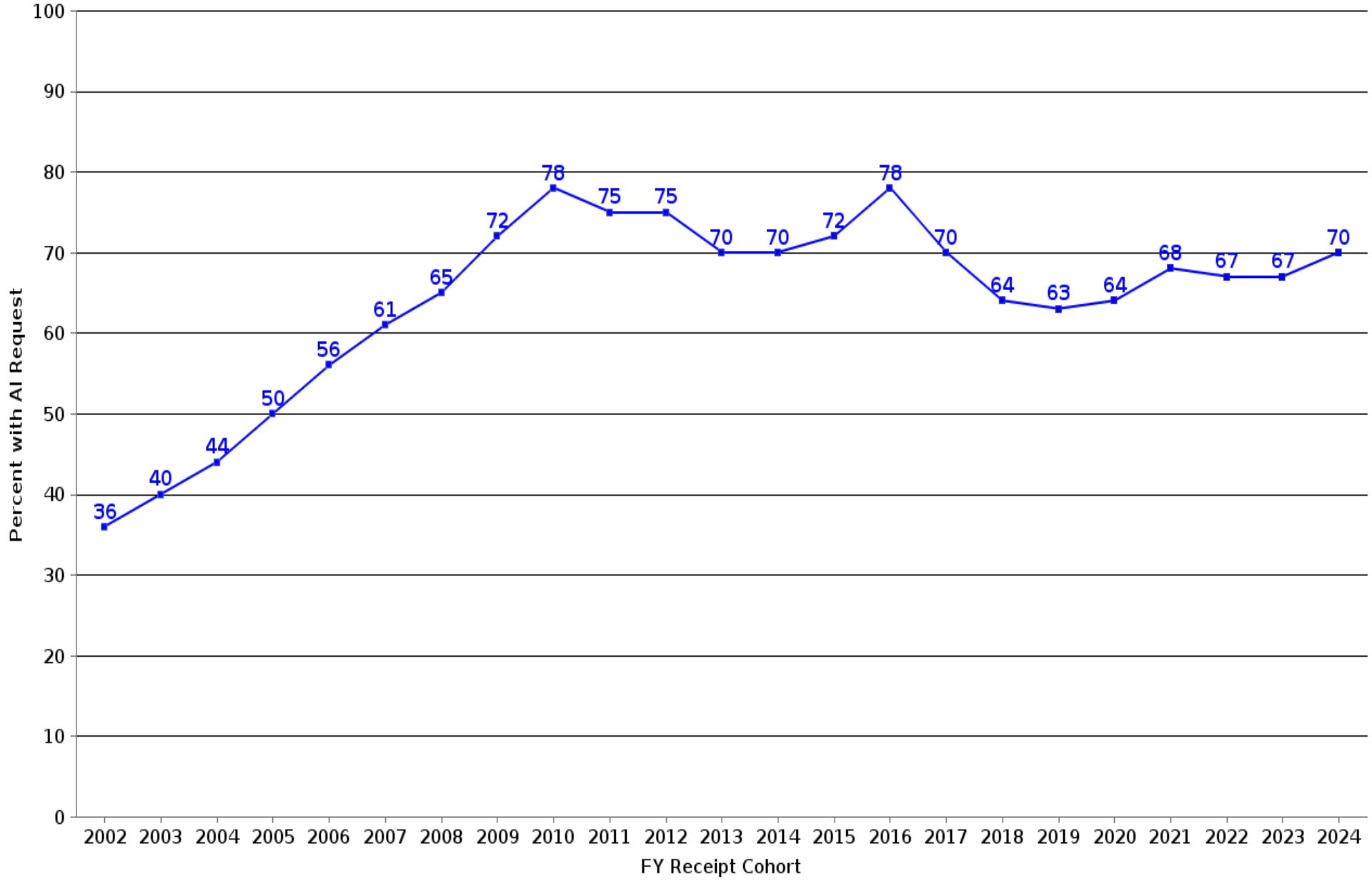
Section 5 PMA Annual Metrics and Goals

PMA Annual Metrics and Goals will be reported in the Annual Report.

510(k)s

Q1 FY2024

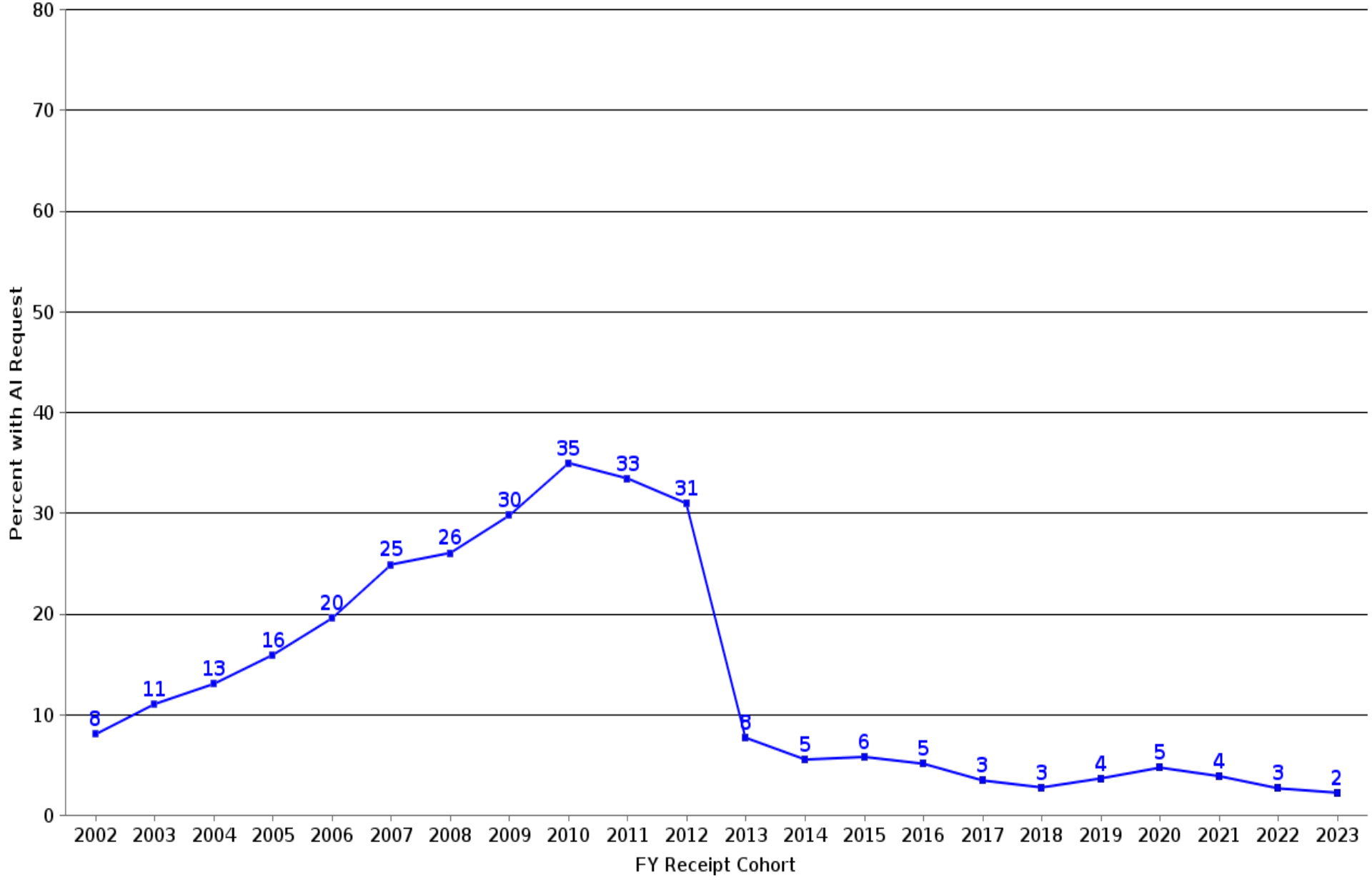
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 10/31/23

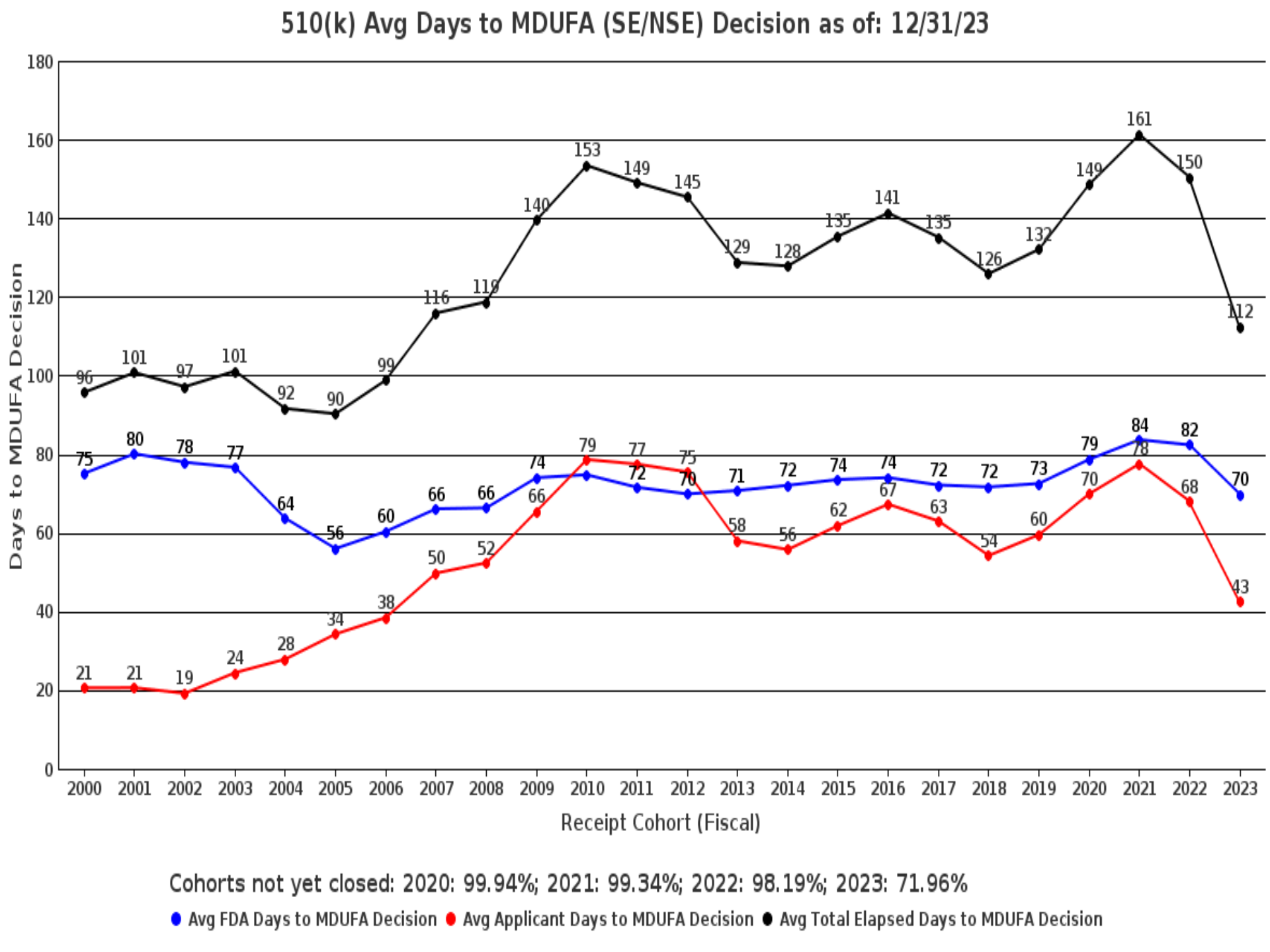
■ % with 1st Cycle AI Request

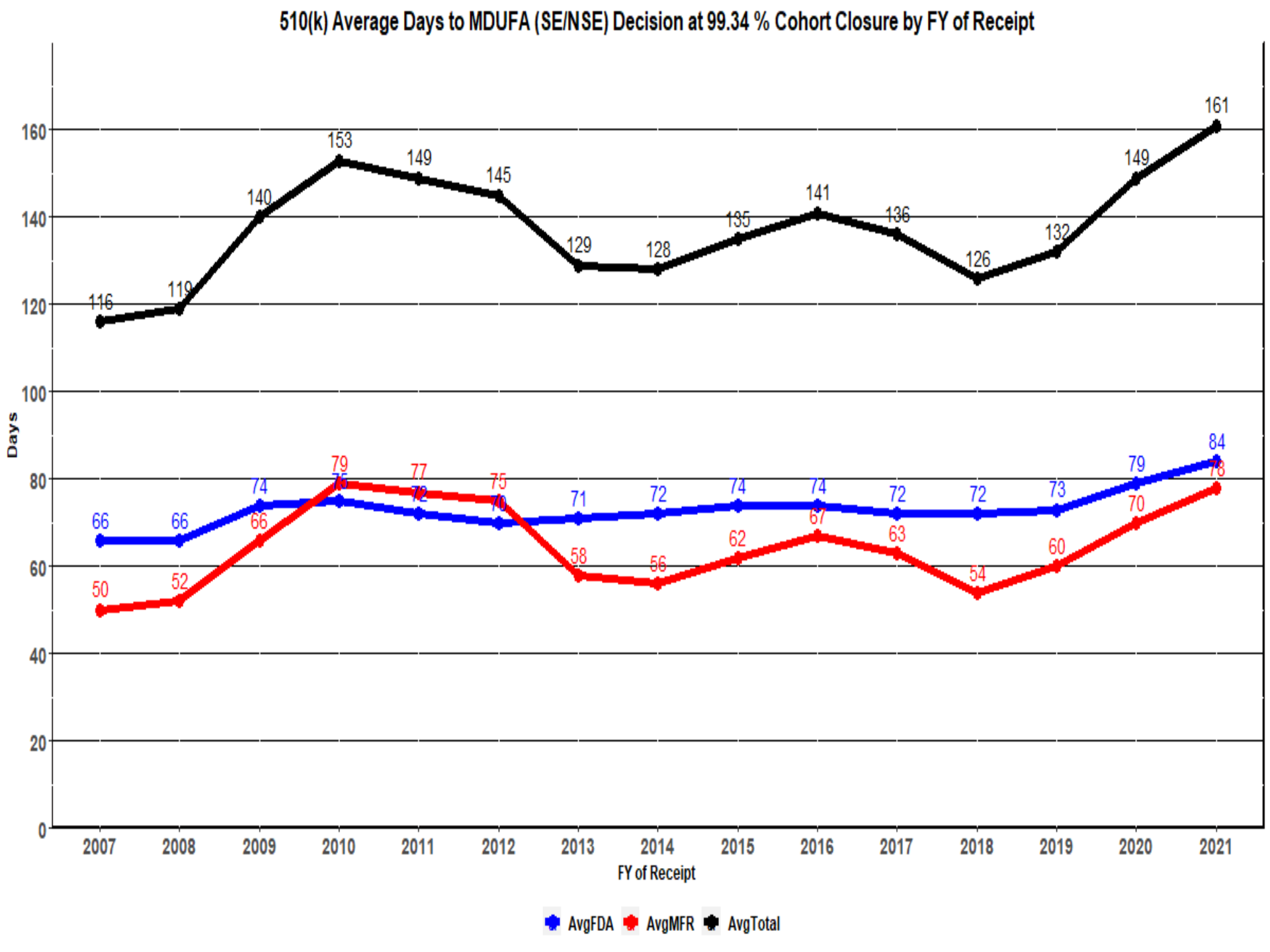
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

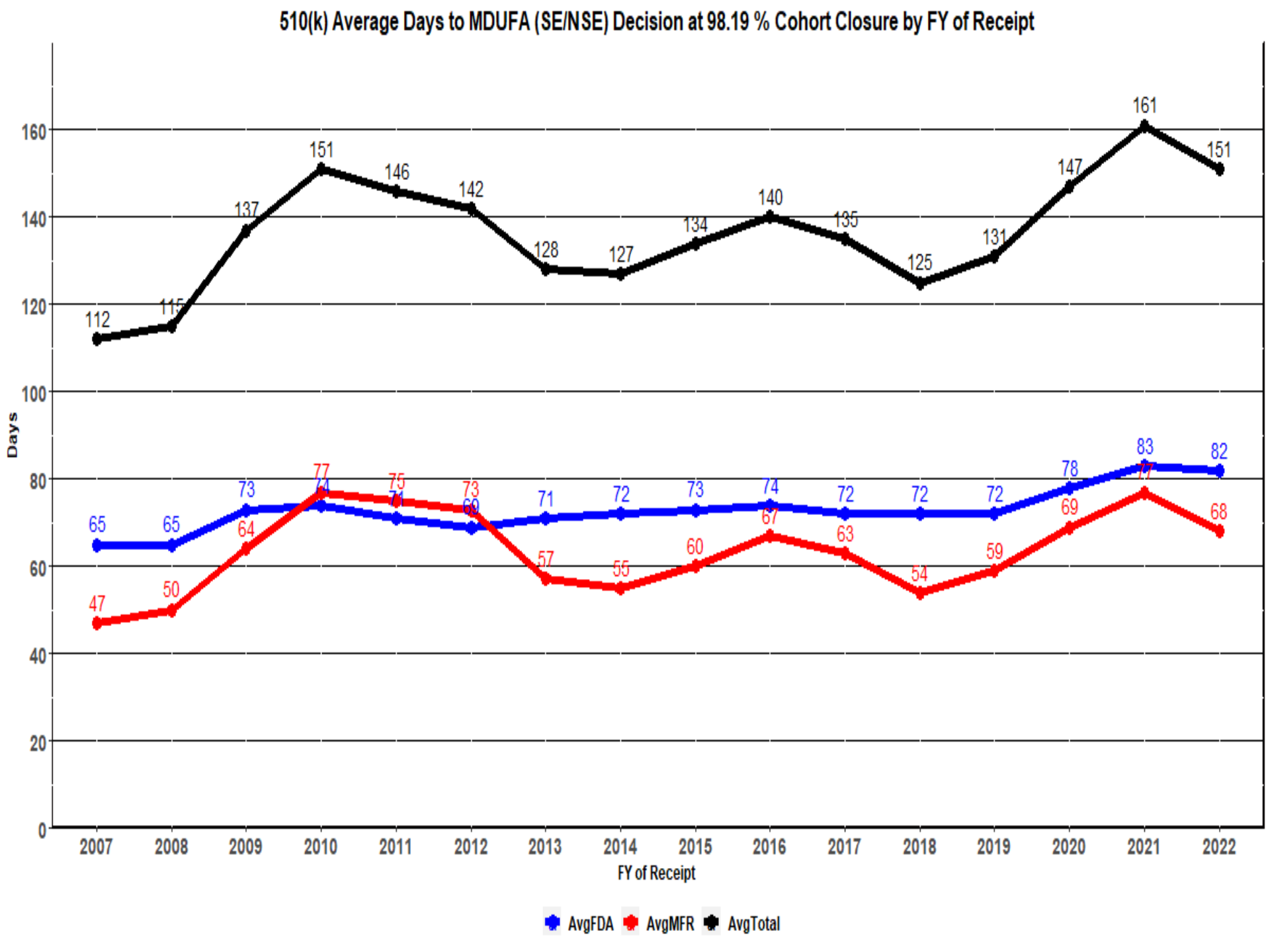


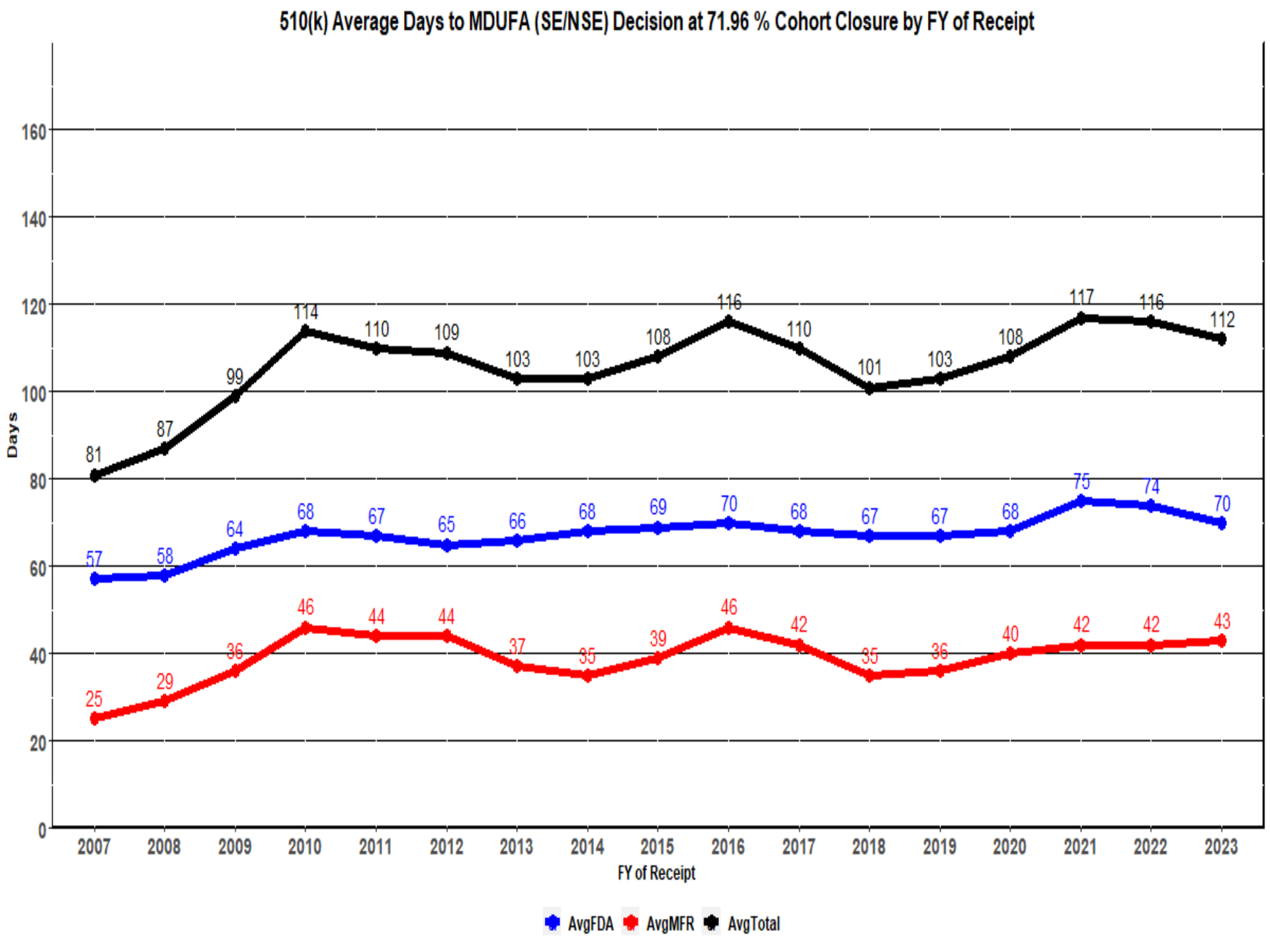
AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 5/31/23

■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 12/31/23
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2020: 99.94%; 2021: 99.34%; 2022: 98.19%; 2023: 71.96%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision

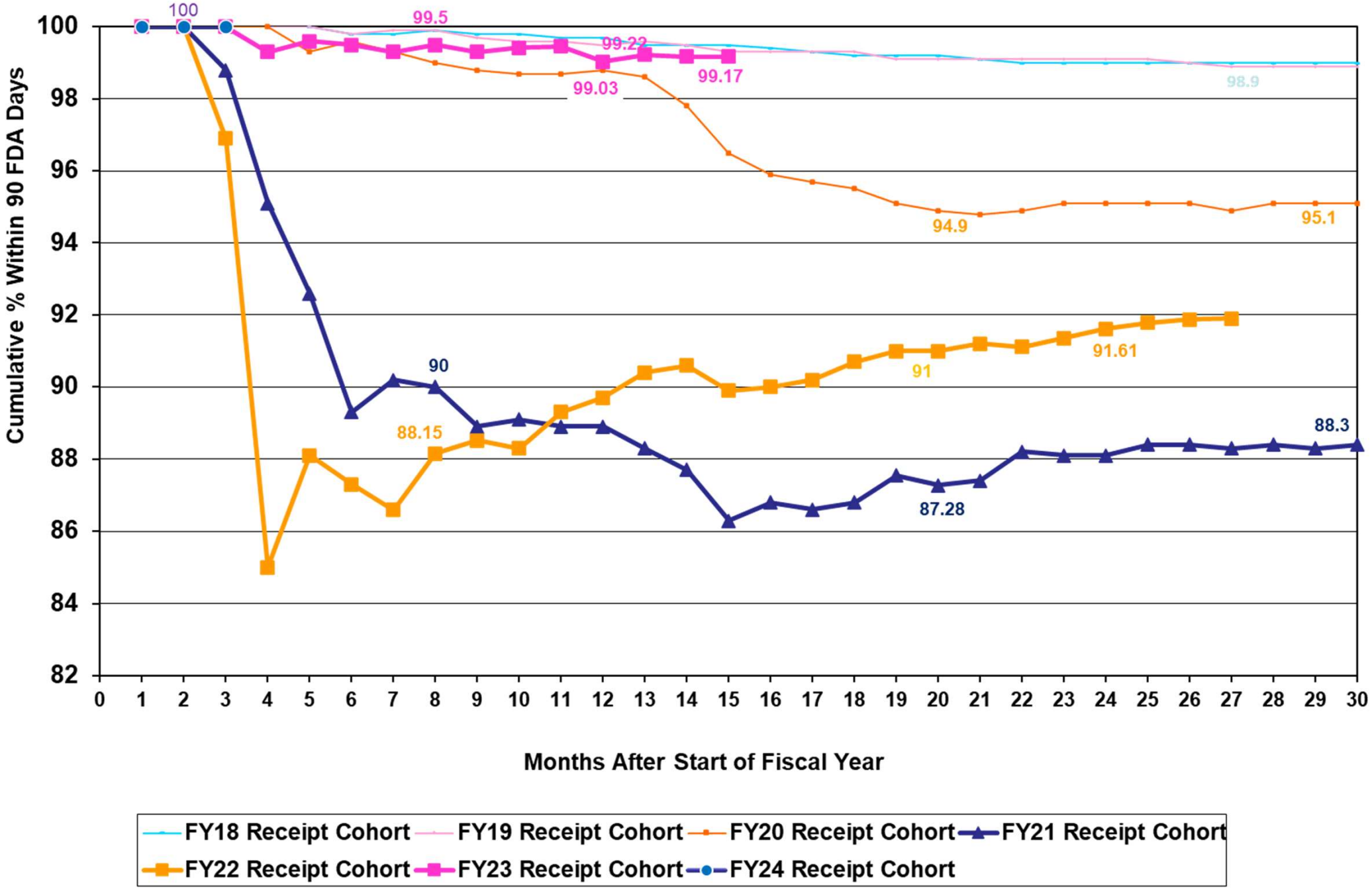

510(k) Average Days to MDUFA (SE/NSE) Decision at 99.34 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
AvgFDA
AvgMFR
AvgTotal
116
119
140
153
149
145
129
128
135
141
136
126
132
149
161
66
66
74
75
72
70
71
72
74
74
72
72
73
79
84
50
52
66
79
77
75
58
56
62
67
63
54
60
70
78


510(k) Average Days to MDUFA (SE/NSE) Decision at 98.19 % 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
AvgFDA
AvgMFR
AvgTotal
112
115
137
151
146
142
128
127
134
140
135
125
131
147
161
151
65
65
73
74
71
69
71
72
73
74
72
72
72
78
83
82
47
50
64
77
75
73
57
55
60
67
63
54
59
69
77
68

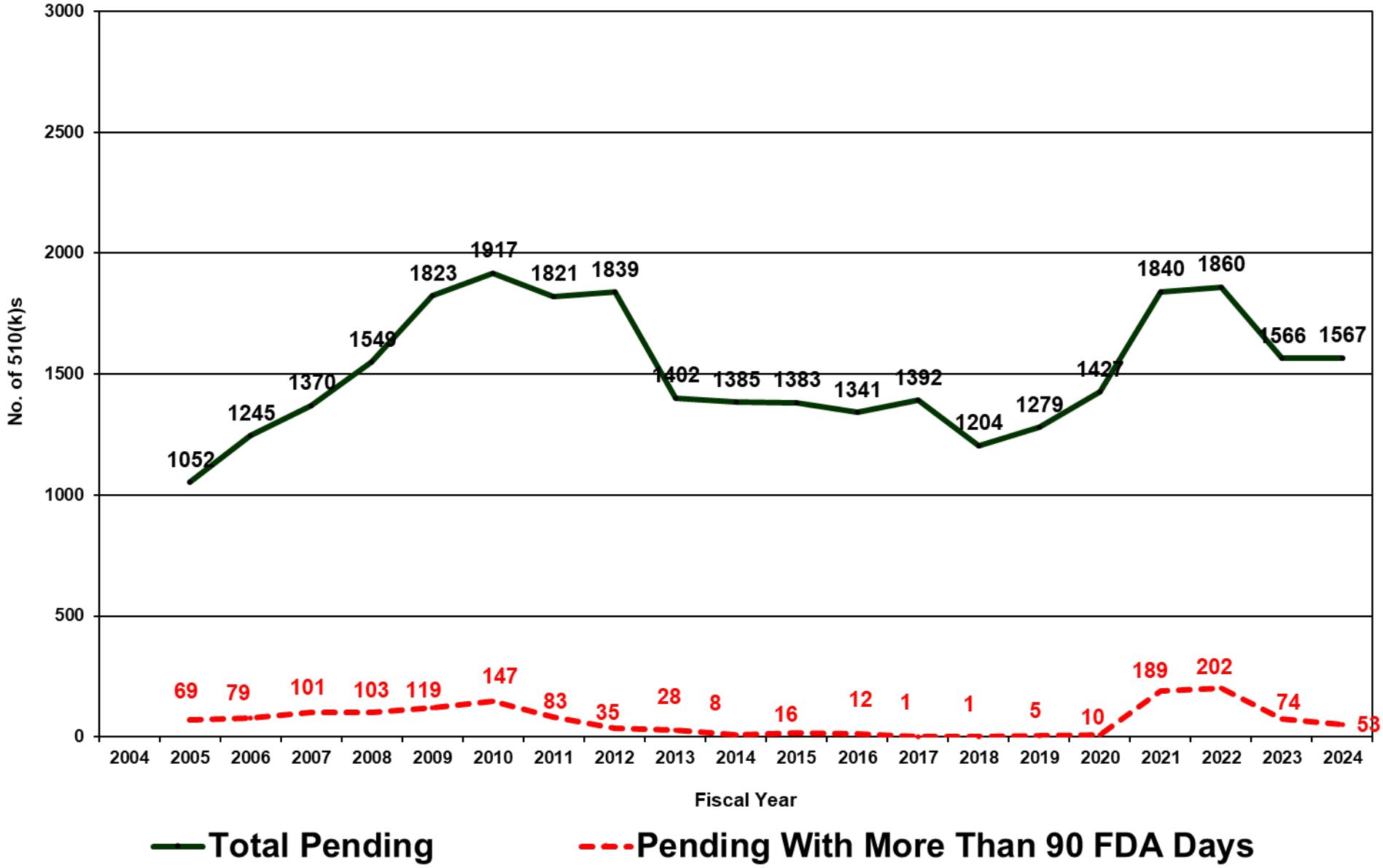

510(k) Average Days to MDUFA (SE/NSE) Decision at 71.96 % Cohort Closure by FY of Receipt
Days
FY of Receipt
AvgFDA
AvgMFR
AvgTotal
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
81
87
99
114
110
109
103
103
108
116
110
101
103
108
117
116
112
57
58
64
68
67
65
66
68
69
70
68
67
67
68
75
74
70
25
29
36
46
44
44
37
35
39
46
42
35
36
40
42
42
43

Trend in 510(k) MDUFA Decision Goal Performance

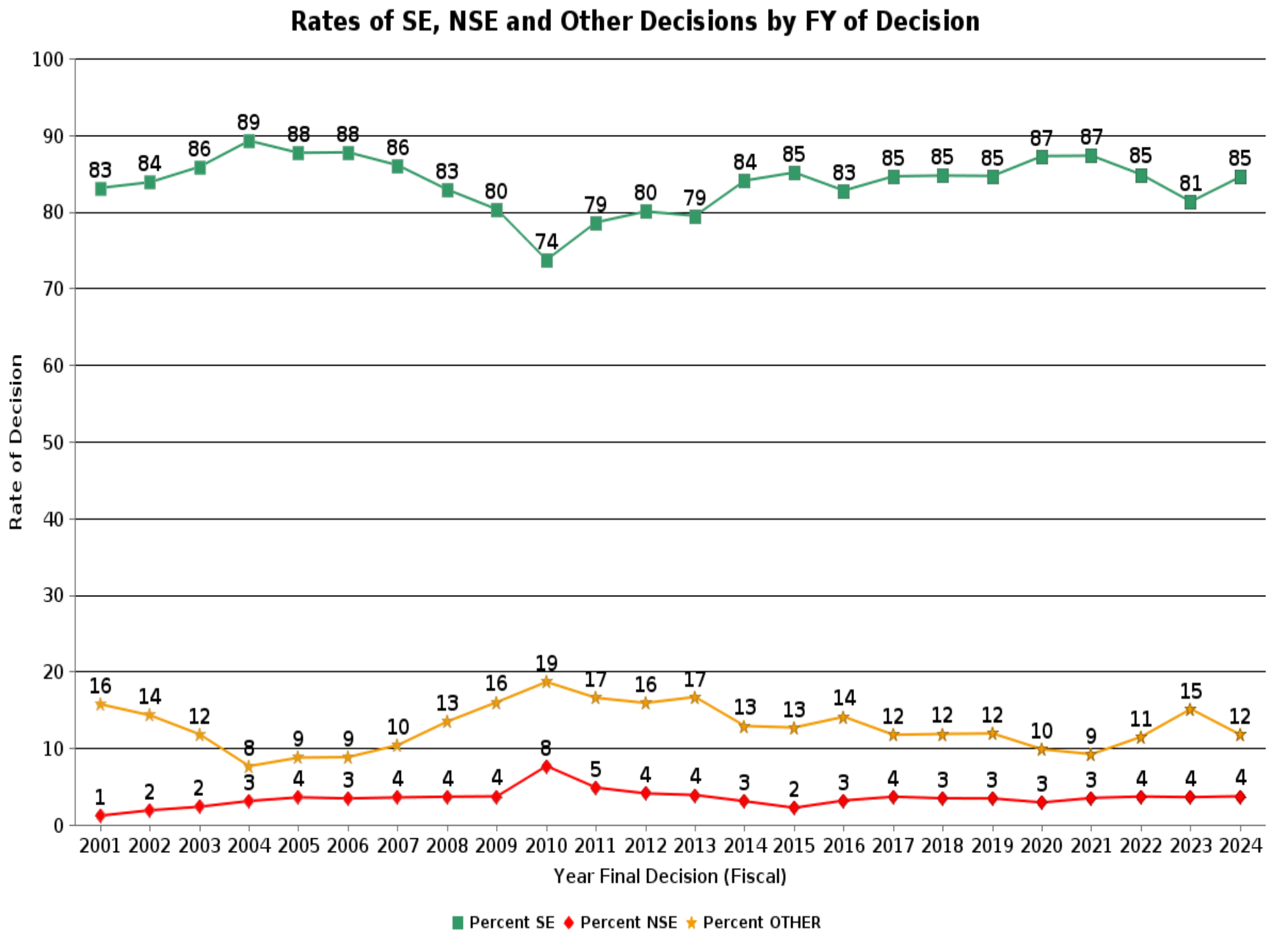
Comparison of FY18 – FY24 Receipt Cohorts



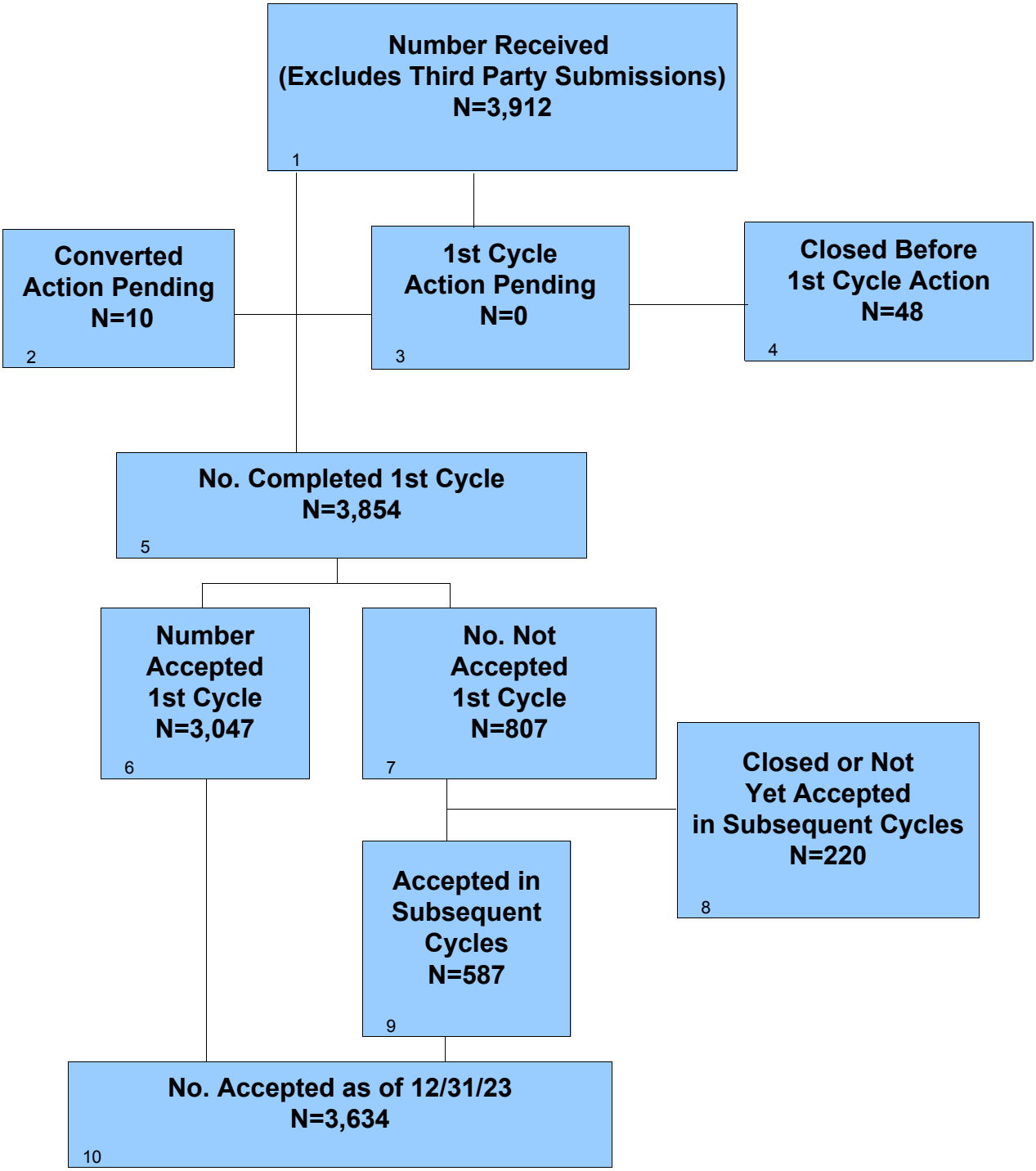
510(k)s Pending at End of Quarter/Year



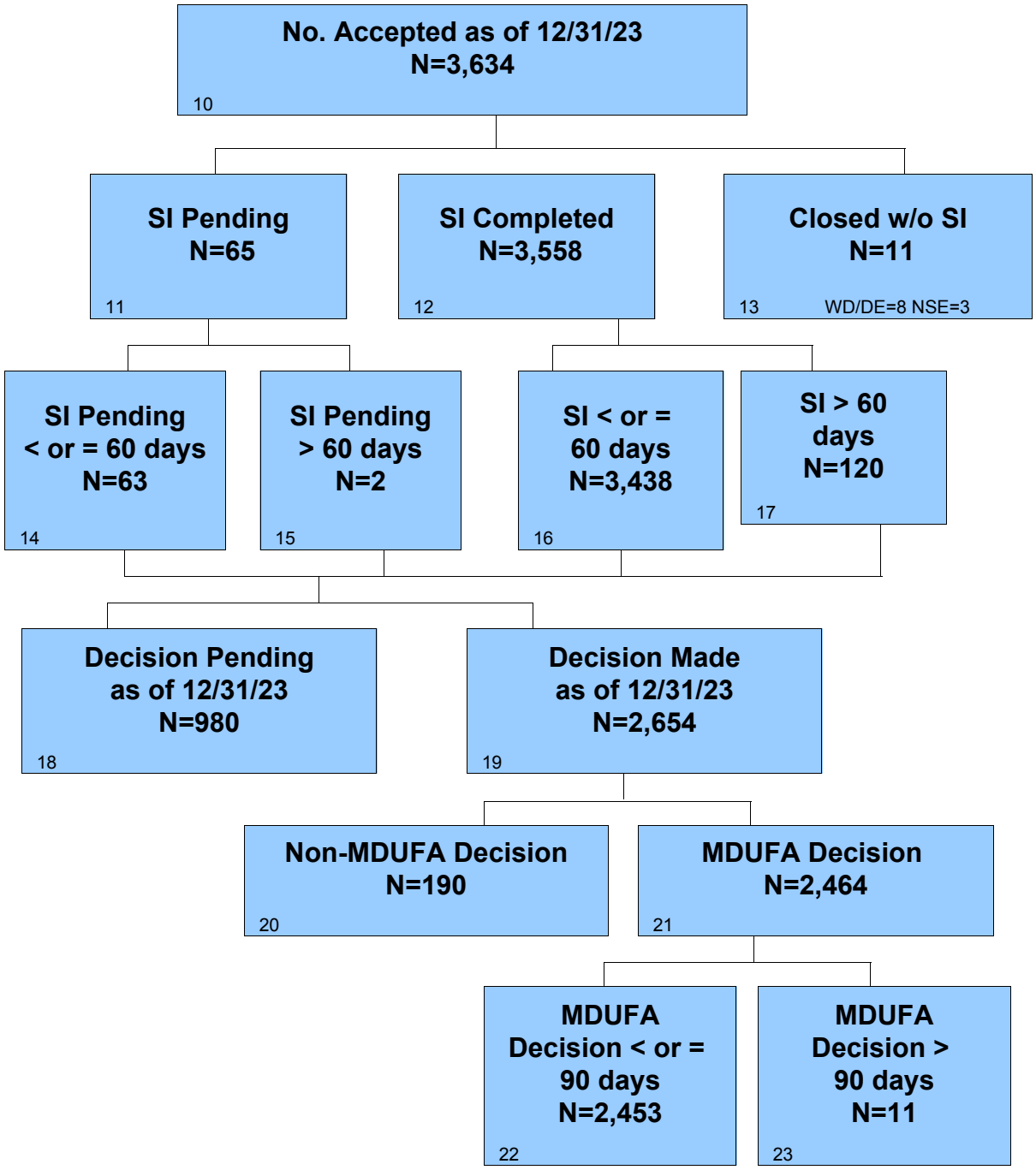
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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 85
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15 12
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4 4 4
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

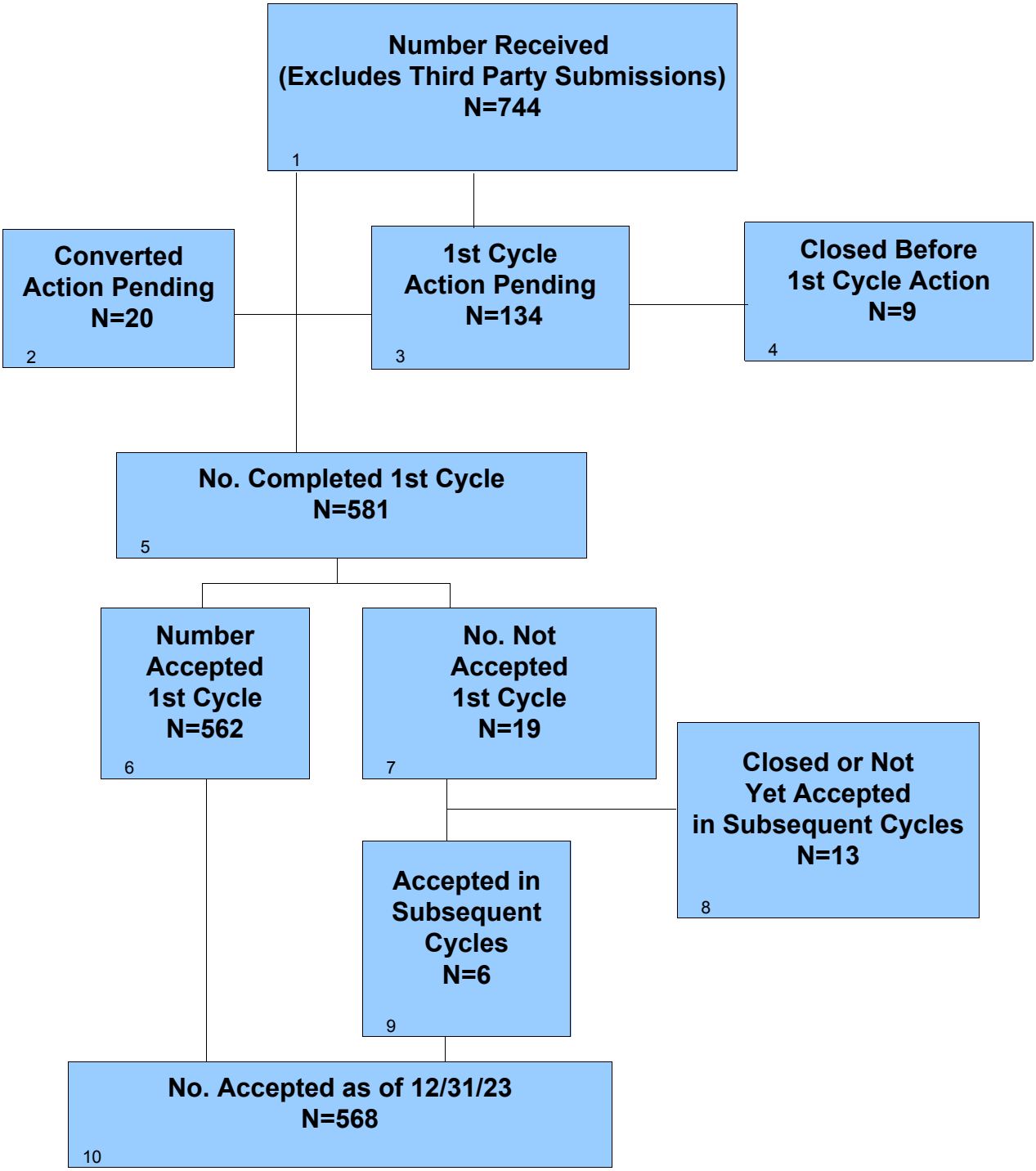
CDRH 510(k)s - FY 2023
as of 12/31/23



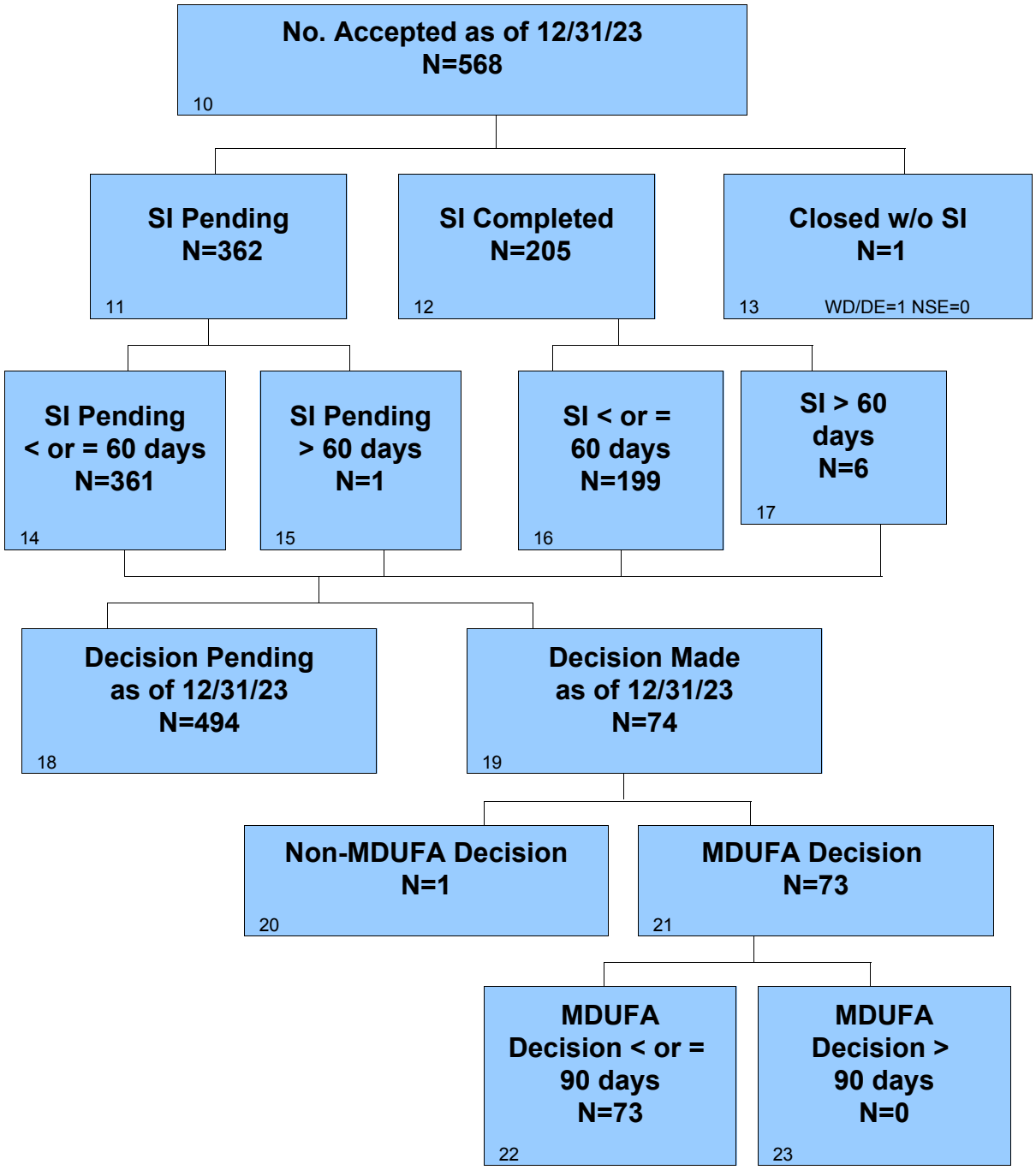
CDRH 510(k)s - FY 2023
as of 12/31/23 Continued



CDRH 510(k)s - FY 2024
as of 12/31/23



CDRH 510(k)s - FY 2024
as of 12/31/23 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	3,912	744			
Closed Before First RTA or TS Action [1]	48	9			
Number Accepted or Passed TS on First Cycle [2]	3,028	561			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	19	1			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	10	154			
Number Not Accepted or Failed TS on First Cycle [2]	807	19			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.94%	3.27%			

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	3,634	568			
Deleted or Withdrawn Prior to SI	8	1			
SI Within 60 FDA Days	3,438	199			
SI Over 60 FDA Days	120	6			
SI Pending Within 60 FDA Days	63	361			
SI Pending Over 60 FDA Days	2	1			
510(k)s NSE Without SI	3	0			
Current SI Performance Percent Within 60 FDA Days	96.49%	96.60%			

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	3,558	205			
Average Number of FDA Days to Substantive Interaction	52.56	44.56			
20th Percentile FDA Days to Substantive Interaction	48	28			
40th Percentile FDA Days to Substantive Interaction	57	43			
60th Percentile FDA Days to Substantive Interaction	59	55			
80th Percentile FDA Days to Substantive Interaction	60	58			
Maximum FDA Days to Substantive Interaction	212	67			

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	3,634	568			
Non-MDUFA V Decision	190	1			
MDUFA V Decision (SE/NSE)	2,464	73			
MDUFA V Decision Within 90 FDA Days	2,453	73			
510(k)s Pending MDUFA V Decision	980	494			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	6	0			
Current Performance Percent Within 90 FDA Days	99.31%	100.00%			

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	1.55	1.04			
Number With MDUFA V Decision	2464	73			
Average Number of FDA Days to MDUFA V Decision	71.01	35.36			
20th Percentile FDA Days to MDUFA V Decision	53	25			
40th Percentile FDA Days to MDUFA V Decision	77	28			
60th Percentile FDA Days to MDUFA V Decision	87	30			
80th Percentile FDA Days to MDUFA V Decision	89	51			
Maximum FDA Days to MDUFA V Decision	276	80			
Average Number of Industry Days to MDUFA V Decision	43.65	0.32			
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	33	0			
80th Percentile Industry Days to MDUFA V Decision	94	0			
Maximum Industry Days to MDUFA V Decision	237	14			
Average Number of Total Days to MDUFA V Decision	114.40	35.67			
20th Percentile Total Days to MDUFA V Decision	55	25			
40th Percentile Total Days to MDUFA V Decision	86	28			
60th Percentile Total Days to MDUFA V Decision	118	30			
80th Percentile Total Days to MDUFA V Decision	180	51			
Maximum Total Days to MDUFA V Decision	332	80			

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	3,634	568			
Number With MDUFA V Decision	2,464	73			
Number of SE Decision	2,398	73			
Number of NSE Decision	66	0			
Number of Withdrawal	113	1			
Number of Deleted	69	0			
Rate of SE Decision	97.32%	100.00%			
Rate of NSE Decision	2.68%	0.00%			
Rate of Withdrawal	3.11%	0.18%			
Rate of Deleted	1.90%	0.00%			

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	11	0			
Mean FDA Days for Submissions that Missed the Goal	115.27	N/A			
Mean Industry Days for Submissions that Missed the Goal	104.91	N/A			

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	1			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	2	0			
MDUFA V Decision Within 90 FDA Days	2	0			
510(k)s Pending MDUFA V Decision	0	1			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	N/A			

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	263	36			
Non-MDUFA V Decision	28	0			
MDUFA V Decision (SE/NSE)	152	4			
MDUFA V Decision Within 90 FDA Days	152	4			
510(k)s Pending MDUFA V Decision	83	32			
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	595	109			
Closed Before First RTA or TS Action [1]	8	1			
Number Accepted or Passed TS on First Cycle [2]	319	77			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	1			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	1	24			
Number Not Accepted or Failed TS on First Cycle [2]	264	6			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	45.05%	7.14%			

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	508	78			
Deleted or Withdrawn Prior to SI	2	0			
SI Within 60 FDA Days	392	16			
SI Over 60 FDA Days	87	5			
SI Pending Within 60 FDA Days	26	57			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	81.67%	76.19%			

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	479	21			
Average Number of FDA Days to Substantive Interaction	56.57	49.38			
20th Percentile FDA Days to Substantive Interaction	54	36			
40th Percentile FDA Days to Substantive Interaction	58	49			
60th Percentile FDA Days to Substantive Interaction	60	56			
80th Percentile FDA Days to Substantive Interaction	60	61			
Maximum FDA Days to Substantive Interaction	212	67			

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	508	78			
Non-MDUFA V Decision	27	0			
MDUFA V Decision (SE/NSE)	302	2			
MDUFA V Decision Within 90 FDA Days	297	2			
510(k)s Pending MDUFA V Decision	179	76			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0			
Current Performance Percent Within 90 FDA Days	98.02%	100.00%			

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	1.67	1.00			
Number With MDUFA V Decision	302	2			
Average Number of FDA Days to MDUFA V Decision	80.31	26.50			
20th Percentile FDA Days to MDUFA V Decision	61	25			
40th Percentile FDA Days to MDUFA V Decision	87	26			
60th Percentile FDA Days to MDUFA V Decision	89	27			
80th Percentile FDA Days to MDUFA V Decision	90	28			
Maximum FDA Days to MDUFA V Decision	276	29			
Average Number of Industry Days to MDUFA V Decision	52.94	N/A			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	15	0			
60th Percentile Industry Days to MDUFA V Decision	49	0			
80th Percentile Industry Days to MDUFA V Decision	113	0			
Maximum Industry Days to MDUFA V Decision	222	0			
Average Number of Total Days to MDUFA V Decision	132.85	26.50			
20th Percentile Total Days to MDUFA V Decision	77	25			
40th Percentile Total Days to MDUFA V Decision	99	26			
60th Percentile Total Days to MDUFA V Decision	137	27			
80th Percentile Total Days to MDUFA V Decision	203	28			
Maximum Total Days to MDUFA V Decision	332	29			

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	508	78			
Number With MDUFA V Decision	302	2			
Number of SE Decision	282	2			
Number of NSE Decision	20	0			
Number of Withdrawal	16	0			
Number of Deleted	10	0			
Rate of SE Decision	93.38%	100.00%			
Rate of NSE Decision	6.62%	0.00%			
Rate of Withdrawal	3.15%	0.00%			
Rate of Deleted	1.97%	0.00%			

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	5	0			
Mean FDA Days for Submissions that Missed the Goal	142.40	N/A			
Mean Industry Days for Submissions that Missed the Goal	116.60	N/A			

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	386	89			
Closed Before First RTA or TS Action [1]	7	1			
Number Accepted or Passed TS on First Cycle [2]	335	67			
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]	3	17			
Number Not Accepted or Failed TS on First Cycle [2]	39	4			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.37%	5.63%			

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	368	69			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	354	22			
SI Over 60 FDA Days	10	0			
SI Pending Within 60 FDA Days	2	47			
SI Pending Over 60 FDA Days	2	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.72%	100.00%			

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	364	22			
Average Number of FDA Days to Substantive Interaction	51.51	41.73			
20th Percentile FDA Days to Substantive Interaction	44	28			
40th Percentile FDA Days to Substantive Interaction	55	30			
60th Percentile FDA Days to Substantive Interaction	59	53			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	122	60			

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	368	69			
Non-MDUFA V Decision	13	0			
MDUFA V Decision (SE/NSE)	263	13			
MDUFA V Decision Within 90 FDA Days	259	13			
510(k)s Pending MDUFA V Decision	92	56			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	4	0			
Current Performance Percent Within 90 FDA Days	97.00%	100.00%			

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	1.60	1.00			
Number With MDUFA V Decision	263	13			
Average Number of FDA Days to MDUFA V Decision	69.89	37.38			
20th Percentile FDA Days to MDUFA V Decision	50	28			
40th Percentile FDA Days to MDUFA V Decision	74	30			
60th Percentile FDA Days to MDUFA V Decision	87	30			
80th Percentile FDA Days to MDUFA V Decision	89	53			
Maximum FDA Days to MDUFA V Decision	95	80			
Average Number of Industry Days to MDUFA V Decision	51.58	N/A			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	3	0			
60th Percentile Industry Days to MDUFA V Decision	53	0			
80th Percentile Industry Days to MDUFA V Decision	105	0			
Maximum Industry Days to MDUFA V Decision	185	0			
Average Number of Total Days to MDUFA V Decision	121.13	37.38			
20th Percentile Total Days to MDUFA V Decision	51	28			
40th Percentile Total Days to MDUFA V Decision	90	30			
60th Percentile Total Days to MDUFA V Decision	135	30			
80th Percentile Total Days to MDUFA V Decision	191	53			
Maximum Total Days to MDUFA V Decision	280	80			

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	368	69			
Number With MDUFA V Decision	263	13			
Number of SE Decision	252	13			
Number of NSE Decision	11	0			
Number of Withdrawal	8	0			
Number of Deleted	5	0			
Rate of SE Decision	95.82%	100.00%			
Rate of NSE Decision	4.18%	0.00%			
Rate of Withdrawal	2.17%	0.00%			
Rate of Deleted	1.36%	0.00%			

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	0			
Mean FDA Days for Submissions that Missed the Goal	92.75	N/A			
Mean Industry Days for Submissions that Missed the Goal	82.50	N/A			

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	490	80			
Closed Before First RTA or TS Action [1]	4	2			
Number Accepted or Passed TS on First Cycle [2]	395	58			
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]	1	18			
Number Not Accepted or Failed TS on First Cycle [2]	88	2			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	18.14%	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 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	465	58			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	446	26			
SI Over 60 FDA Days	10	0			
SI Pending Within 60 FDA Days	8	32			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.81%	100.00%			

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	456	26			
Average Number of FDA Days to Substantive Interaction	54.88	48.15			
20th Percentile FDA Days to Substantive Interaction	55	30			
40th Percentile FDA Days to Substantive Interaction	58	52			
60th Percentile FDA Days to Substantive Interaction	59	57			
80th Percentile FDA Days to Substantive Interaction	60	59			
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	465	58			
Non-MDUFA V Decision	24	0			
MDUFA V Decision (SE/NSE)	272	7			
MDUFA V Decision Within 90 FDA Days	271	7			
510(k)s Pending MDUFA V Decision	169	51			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.63%	100.00%			

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	1.65	1.00			
Number With MDUFA V Decision	272	7			
Average Number of FDA Days to MDUFA V Decision	76.26	28.14			
20th Percentile FDA Days to MDUFA V Decision	59	19			
40th Percentile FDA Days to MDUFA V Decision	87	24			
60th Percentile FDA Days to MDUFA V Decision	88	29			
80th Percentile FDA Days to MDUFA V Decision	90	30			
Maximum FDA Days to MDUFA V Decision	93	55			
Average Number of Industry Days to MDUFA V Decision	54.76	N/A			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	10	0			
60th Percentile Industry Days to MDUFA V Decision	57	0			
80th Percentile Industry Days to MDUFA V Decision	109	0			
Maximum Industry Days to MDUFA V Decision	237	0			
Average Number of Total Days to MDUFA V Decision	130.87	28.14			
20th Percentile Total Days to MDUFA V Decision	65	19			
40th Percentile Total Days to MDUFA V Decision	92	24			
60th Percentile Total Days to MDUFA V Decision	140	29			
80th Percentile Total Days to MDUFA V Decision	199	30			
Maximum Total Days to MDUFA V Decision	325	55			

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	465	58			
Number With MDUFA V Decision	272	7			
Number of SE Decision	266	7			
Number of NSE Decision	6	0			
Number of Withdrawal	11	0			
Number of Deleted	12	0			
Rate of SE Decision	97.79%	100.00%			
Rate of NSE Decision	2.21%	0.00%			
Rate of Withdrawal	2.37%	0.00%			
Rate of Deleted	2.58%	0.00%			

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	0			
Mean FDA Days for Submissions that Missed the Goal	93.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	192.00	N/A			

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	671	122			
Closed Before First RTA or TS Action [1]	9	0			
Number Accepted or Passed TS on First Cycle [2]	528	93			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	1	28			
Number Not Accepted or Failed TS on First Cycle [2]	132	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	19.97%	1.06%			

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	629	94			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	616	34			
SI Over 60 FDA Days	4	0			
SI Pending Within 60 FDA Days	8	60			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	99.35%	100.00%			

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	620	34			
Average Number of FDA Days to Substantive Interaction	52.47	45.85			
20th Percentile FDA Days to Substantive Interaction	49	28			
40th Percentile FDA Days to Substantive Interaction	56	48			
60th Percentile FDA Days to Substantive Interaction	58	57			
80th Percentile FDA Days to Substantive Interaction	60	58			
Maximum FDA Days to Substantive Interaction	71	60			

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	629	94			
Non-MDUFA V Decision	34	0			
MDUFA V Decision (SE/NSE)	431	11			
MDUFA V Decision Within 90 FDA Days	430	11			
510(k)s Pending MDUFA V Decision	164	83			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.77%	100.00%			

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	1.49	1.09			
Number With MDUFA V Decision	431	11			
Average Number of FDA Days to MDUFA V Decision	71.82	32.73			
20th Percentile FDA Days to MDUFA V Decision	56	23			
40th Percentile FDA Days to MDUFA V Decision	78	27			
60th Percentile FDA Days to MDUFA V Decision	86	29			
80th Percentile FDA Days to MDUFA V Decision	89	38			
Maximum FDA Days to MDUFA V Decision	92	76			
Average Number of Industry Days to MDUFA V Decision	32.58	0.09			
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	17	0			
80th Percentile Industry Days to MDUFA V Decision	66	0			
Maximum Industry Days to MDUFA V Decision	181	1			
Average Number of Total Days to MDUFA V Decision	104.22	32.82			
20th Percentile Total Days to MDUFA V Decision	57	23			
40th Percentile Total Days to MDUFA V Decision	84	27			
60th Percentile Total Days to MDUFA V Decision	95	29			
80th Percentile Total Days to MDUFA V Decision	148	39			
Maximum Total Days to MDUFA V Decision	324	76			

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	629	94			
Number With MDUFA V Decision	431	11			
Number of SE Decision	421	11			
Number of NSE Decision	10	0			
Number of Withdrawal	21	0			
Number of Deleted	13	0			
Rate of SE Decision	97.68%	100.00%			
Rate of NSE Decision	2.32%	0.00%			
Rate of Withdrawal	3.34%	0.00%			
Rate of Deleted	2.07%	0.00%			

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	1	0			
Mean FDA Days for Submissions that Missed the Goal	92.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	49.00	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	318	66			
Closed Before First RTA or TS Action [1]	3	0			
Number Accepted or Passed TS on First Cycle [2]	216	49			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	13			
Number Not Accepted or Failed TS on First Cycle [2]	98	4			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	31.11%	7.55%			

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	279	51			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	262	19			
SI Over 60 FDA Days	9	1			
SI Pending Within 60 FDA Days	8	30			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.68%	90.48%			

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	271	20			
Average Number of FDA Days to Substantive Interaction	54.27	47.15			
20th Percentile FDA Days to Substantive Interaction	54	30			
40th Percentile FDA Days to Substantive Interaction	58	48			
60th Percentile FDA Days to Substantive Interaction	60	57			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	80	63			

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	279	51			
Non-MDUFA V Decision	11	0			
MDUFA V Decision (SE/NSE)	183	8			
MDUFA V Decision Within 90 FDA Days	183	8			
510(k)s Pending MDUFA V Decision	85	43			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0			
Current Performance Percent Within 90 FDA Days	99.46%	100.00%			

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	1.62	1.00			
Number With MDUFA V Decision	183	8			
Average Number of FDA Days to MDUFA V Decision	73.27	40.75			
20th Percentile FDA Days to MDUFA V Decision	56	29			
40th Percentile FDA Days to MDUFA V Decision	85	30			
60th Percentile FDA Days to MDUFA V Decision	88	45			
80th Percentile FDA Days to MDUFA V Decision	90	53			
Maximum FDA Days to MDUFA V Decision	90	60			
Average Number of Industry Days to MDUFA V Decision	55.75	N/A			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	6	0			
60th Percentile Industry Days to MDUFA V Decision	54	0			
80th Percentile Industry Days to MDUFA V Decision	116	0			
Maximum Industry Days to MDUFA V Decision	231	0			
Average Number of Total Days to MDUFA V Decision	128.37	40.75			
20th Percentile Total Days to MDUFA V Decision	58	29			
40th Percentile Total Days to MDUFA V Decision	90	30			
60th Percentile Total Days to MDUFA V Decision	138	45			
80th Percentile Total Days to MDUFA V Decision	205	53			
Maximum Total Days to MDUFA V Decision	281	60			

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	279	51			
Number With MDUFA V Decision	183	8			
Number of SE Decision	176	8			
Number of NSE Decision	7	0			
Number of Withdrawal	3	0			
Number of Deleted	5	0			
Rate of SE Decision	96.17%	100.00%			
Rate of NSE Decision	3.83%	0.00%			
Rate of Withdrawal	1.08%	0.00%			
Rate of Deleted	1.79%	0.00%			

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	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 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	670	112			
Closed Before First RTA or TS Action [1]	7	1			
Number Accepted or Passed TS on First Cycle [2]	553	88			
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]	1	21			
Number Not Accepted or Failed TS on First Cycle [2]	106	2			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	16.01%	2.22%			

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 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	644	89			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	637	37			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	6	52			
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	637	37			
Average Number of FDA Days to Substantive Interaction	50.16	41.59			
20th Percentile FDA Days to Substantive Interaction	30	28			
40th Percentile FDA Days to Substantive Interaction	56	32			
60th Percentile FDA Days to Substantive Interaction	58	49			
80th Percentile FDA Days to Substantive Interaction	60	56			
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	644	89			
Non-MDUFA V Decision	36	0			
MDUFA V Decision (SE/NSE)	501	21			
MDUFA V Decision Within 90 FDA Days	501	21			
510(k)s Pending MDUFA V Decision	107	68			
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	1.40	1.05			
Number With MDUFA V Decision	501	21			
Average Number of FDA Days to MDUFA V Decision	63.37	37.00			
20th Percentile FDA Days to MDUFA V Decision	30	27			
40th Percentile FDA Days to MDUFA V Decision	58	29			
60th Percentile FDA Days to MDUFA V Decision	83	33			
80th Percentile FDA Days to MDUFA V Decision	89	49			
Maximum FDA Days to MDUFA V Decision	90	77			
Average Number of Industry Days to MDUFA V Decision	28.57	0.38			
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	62	0			
Maximum Industry Days to MDUFA V Decision	206	8			
Average Number of Total Days to MDUFA V Decision	91.78	37.38			
20th Percentile Total Days to MDUFA V Decision	30	27			
40th Percentile Total Days to MDUFA V Decision	58	29			
60th Percentile Total Days to MDUFA V Decision	89	35			
80th Percentile Total Days to MDUFA V Decision	138	49			
Maximum Total Days to MDUFA V Decision	296	77			

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	644	89			
Number With MDUFA V Decision	501	21			
Number of SE Decision	498	21			
Number of NSE Decision	3	0			
Number of Withdrawal	28	0			
Number of Deleted	6	0			
Rate of SE Decision	99.40%	100.00%			
Rate of NSE Decision	0.60%	0.00%			
Rate of Withdrawal	4.35%	0.00%			
Rate of Deleted	0.93%	0.00%			

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	294	59			
Closed Before First RTA or TS Action [1]	7	4			
Number Accepted or Passed TS on First Cycle [2]	241	37			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	5	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	1	18			
Number Not Accepted or Failed TS on First Cycle [2]	40	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.99%	0.00%			

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 (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	265	37			
Deleted or Withdrawn Prior to SI	3	0			
SI Within 60 FDA Days	257	19			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	3	18			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	2	0			
Current SI Performance Percent Within 60 FDA Days	99.23%	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	257	19			
Average Number of FDA Days to Substantive Interaction	52.54	41.42			
20th Percentile FDA Days to Substantive Interaction	46	26			
40th Percentile FDA Days to Substantive Interaction	56	39			
60th Percentile FDA Days to Substantive Interaction	58	50			
80th Percentile FDA Days to Substantive Interaction	60	54			
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	265	37			
Non-MDUFA V Decision	28	0			
MDUFA V Decision (SE/NSE)	154	4			
MDUFA V Decision Within 90 FDA Days	154	4			
510(k)s Pending MDUFA V Decision	83	33			
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	1.39	1.00			
Number With MDUFA V Decision	154	4			
Average Number of FDA Days to MDUFA V Decision	71.75	23.75			
20th Percentile FDA Days to MDUFA V Decision	50	20			
40th Percentile FDA Days to MDUFA V Decision	84	24			
60th Percentile FDA Days to MDUFA V Decision	88	26			
80th Percentile FDA Days to MDUFA V Decision	90	28			
Maximum FDA Days to MDUFA V Decision	90	29			
Average Number of Industry Days to MDUFA V Decision	47.64	N/A			
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	134	0			
Maximum Industry Days to MDUFA V Decision	236	0			
Average Number of Total Days to MDUFA V Decision	119.10	23.75			
20th Percentile Total Days to MDUFA V Decision	50	20			
40th Percentile Total Days to MDUFA V Decision	87	24			
60th Percentile Total Days to MDUFA V Decision	90	26			
80th Percentile Total Days to MDUFA V Decision	223	28			
Maximum Total Days to MDUFA V Decision	325	29			

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	265	37			
Number With MDUFA V Decision	154	4			
Number of SE Decision	148	4			
Number of NSE Decision	6	0			
Number of Withdrawal	16	0			
Number of Deleted	12	0			
Rate of SE Decision	96.10%	100.00%			
Rate of NSE Decision	3.90%	0.00%			
Rate of Withdrawal	6.04%	0.00%			
Rate of Deleted	4.53%	0.00%			

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	1			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	2	0			
MDUFA V Decision Within 90 FDA Days	2	0			
510(k)s Pending MDUFA V Decision	0	1			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	N/A			

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	263	36			
Non-MDUFA V Decision	28	0			
MDUFA V Decision (SE/NSE)	152	4			
MDUFA V Decision Within 90 FDA Days	152	4			
510(k)s Pending MDUFA V Decision	83	32			
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	107			
Closed Before First RTA or TS Action [1]	3	0			
Number Accepted or Passed TS on First Cycle [2]	441	92			
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]	2	15			
Number Not Accepted or Failed TS on First Cycle [2]	40	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.28%	0.00%			

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 (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	92			
Deleted or Withdrawn Prior to SI	0	1			
SI Within 60 FDA Days	474	26			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	2	65			
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 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	474	26			
Average Number of FDA Days to Substantive Interaction	49.46	42.27			
20th Percentile FDA Days to Substantive Interaction	35	28			
40th Percentile FDA Days to Substantive Interaction	53	30			
60th Percentile FDA Days to Substantive Interaction	57	51			
80th Percentile FDA Days to Substantive Interaction	59	58			
Maximum FDA Days to Substantive Interaction	60	60			

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	92			
Non-MDUFA V Decision	17	1			
MDUFA V Decision (SE/NSE)	358	7			
MDUFA V Decision Within 90 FDA Days	358	7			
510(k)s Pending MDUFA V Decision	101	84			
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	1.65	1.14			
Number With MDUFA V Decision	358	7			
Average Number of FDA Days to MDUFA V Decision	68.28	41.00			
20th Percentile FDA Days to MDUFA V Decision	43	27			
40th Percentile FDA Days to MDUFA V Decision	73	28			
60th Percentile FDA Days to MDUFA V Decision	85	42			
80th Percentile FDA Days to MDUFA V Decision	88	57			
Maximum FDA Days to MDUFA V Decision	90	70			
Average Number of Industry Days to MDUFA V Decision	48.05	2.00			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	13	0			
60th Percentile Industry Days to MDUFA V Decision	43	0			
80th Percentile Industry Days to MDUFA V Decision	98	0			
Maximum Industry Days to MDUFA V Decision	204	14			
Average Number of Total Days to MDUFA V Decision	116.15	43.00			
20th Percentile Total Days to MDUFA V Decision	49	27			
40th Percentile Total Days to MDUFA V Decision	89	28			
60th Percentile Total Days to MDUFA V Decision	128	46			
80th Percentile Total Days to MDUFA V Decision	181	64			
Maximum Total Days to MDUFA V Decision	272	70			

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	92			
Number With MDUFA V Decision	358	7			
Number of SE Decision	355	7			
Number of NSE Decision	3	0			
Number of Withdrawal	10	1			
Number of Deleted	6	0			
Rate of SE Decision	99.16%	100.00%			
Rate of NSE Decision	0.84%	0.00%			
Rate of Withdrawal	2.10%	1.09%			
Rate of Deleted	1.26%	0.00%			

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

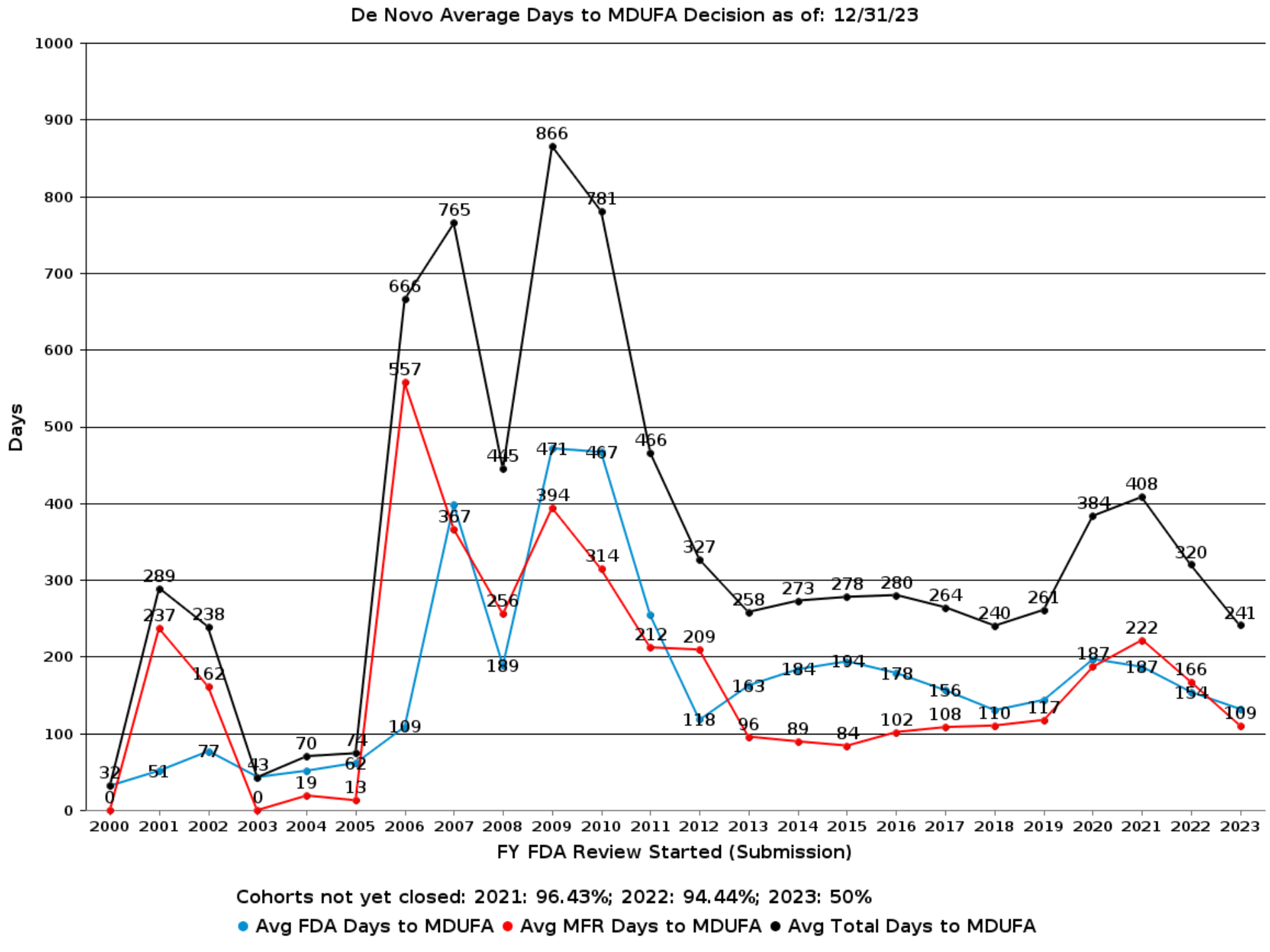
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A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

Section 7 510(k) Annual General Metrics

510(k) Annual Metrics and Goals will be reported in the Annual Report.

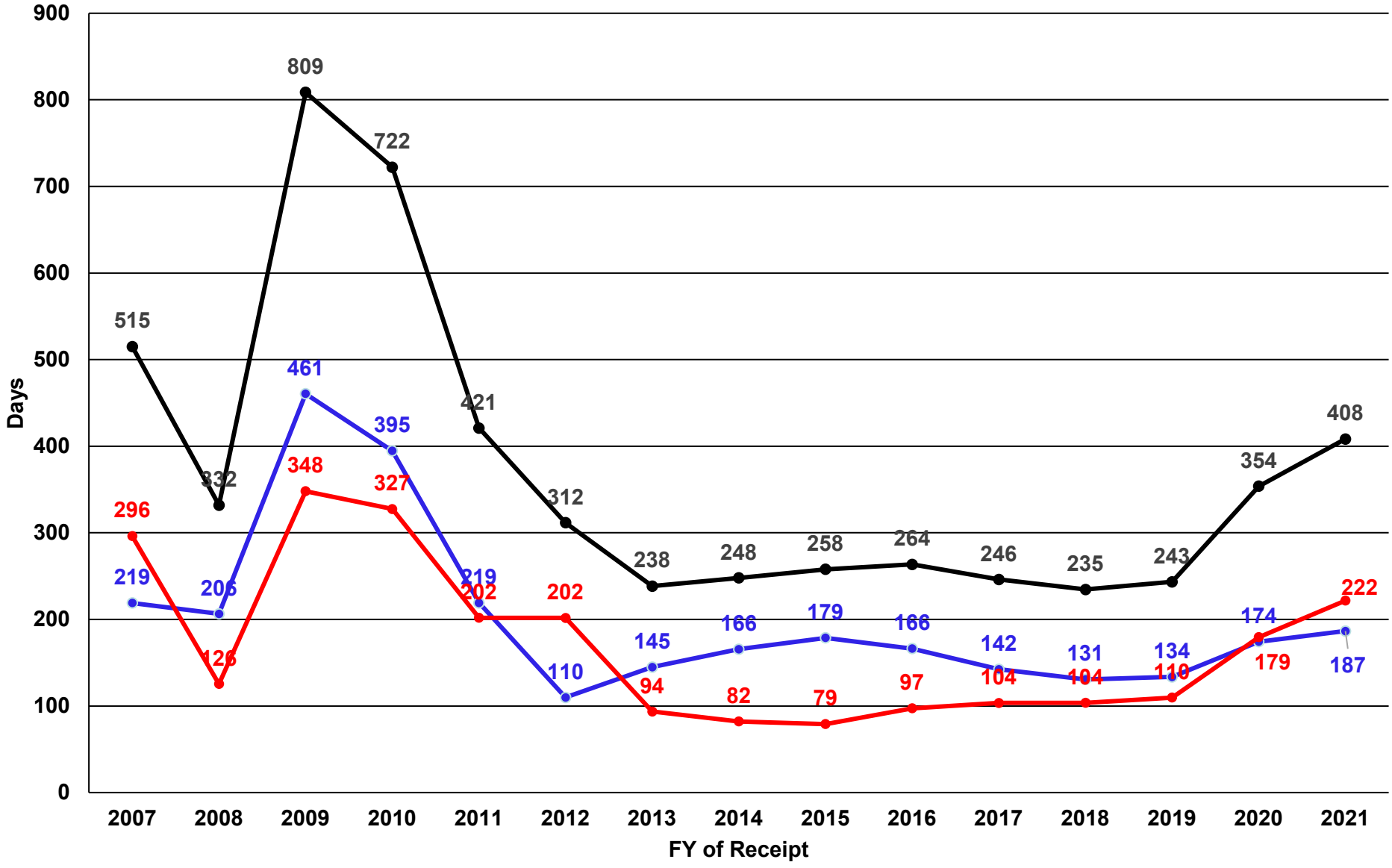
De Novos

Q1FY2024


De Novo Average Days to MDUFA Decision as of: 12/31/23
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2021: 96.43%; 2022: 94.44%; 2023: 50%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

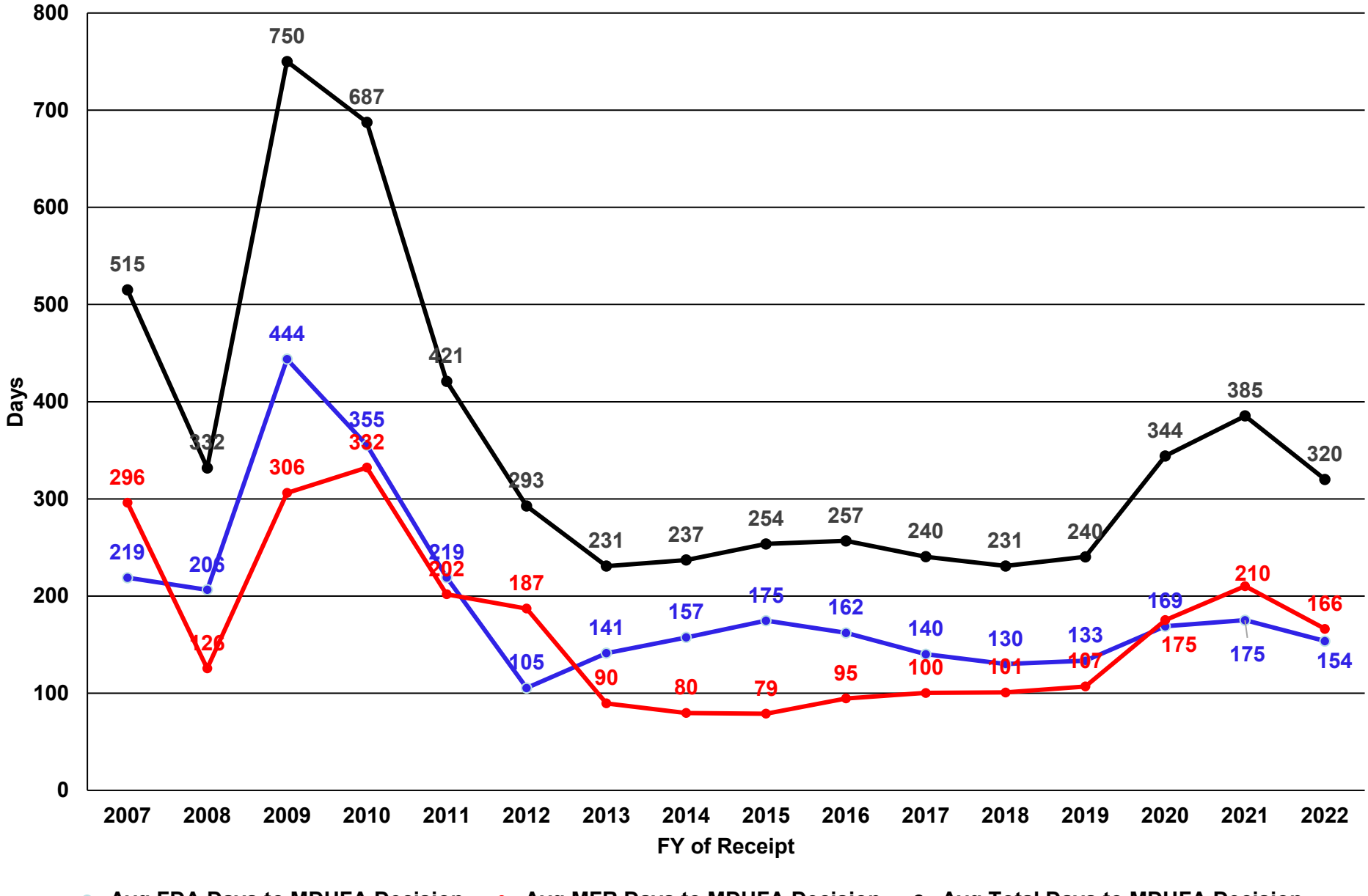
Average Time to MDUFA Decision: De Novos

(96.43% closure comparison)



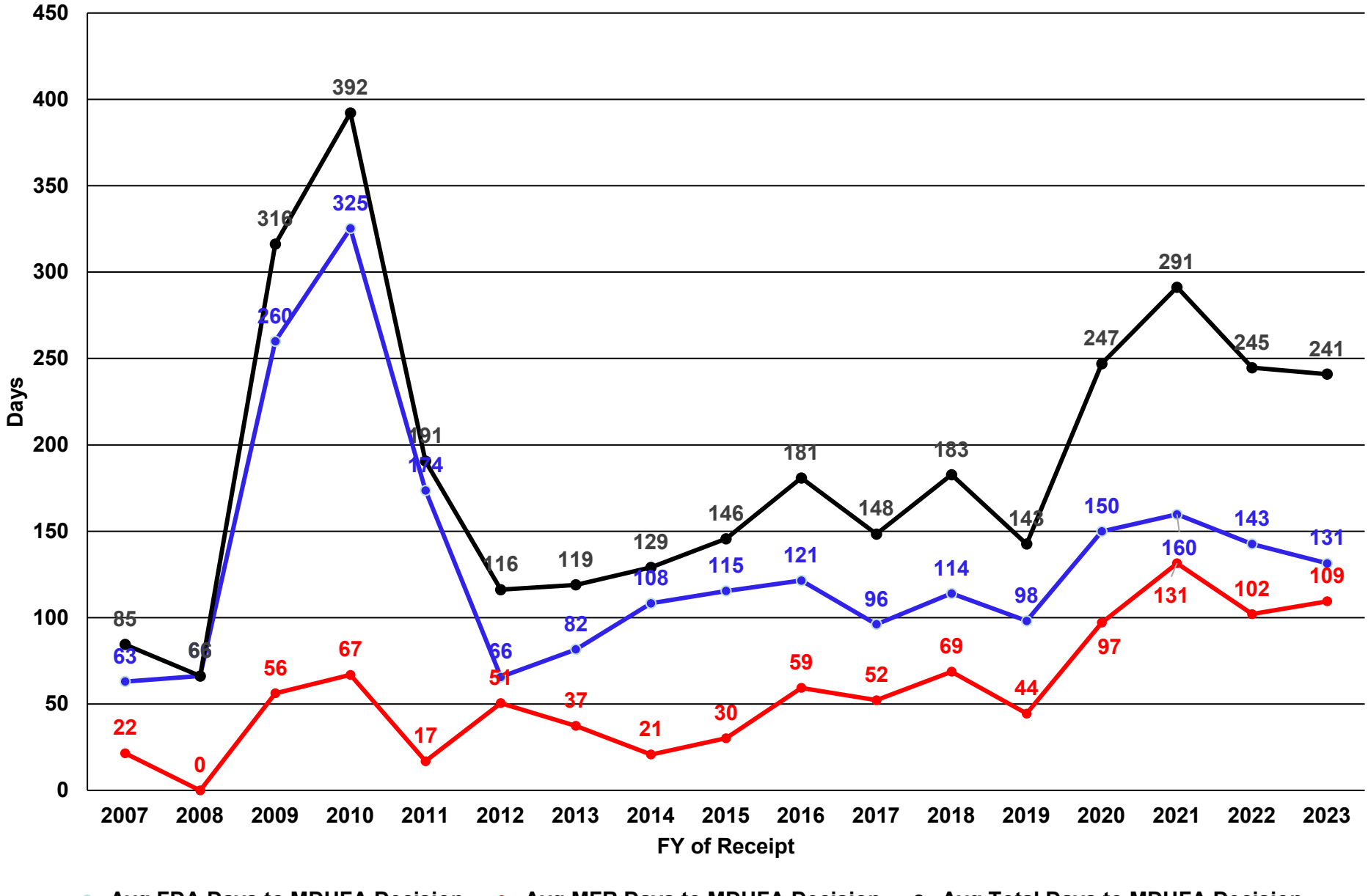
Average Time to MDUFA Decision: De Novos

(94.44% closure comparison)

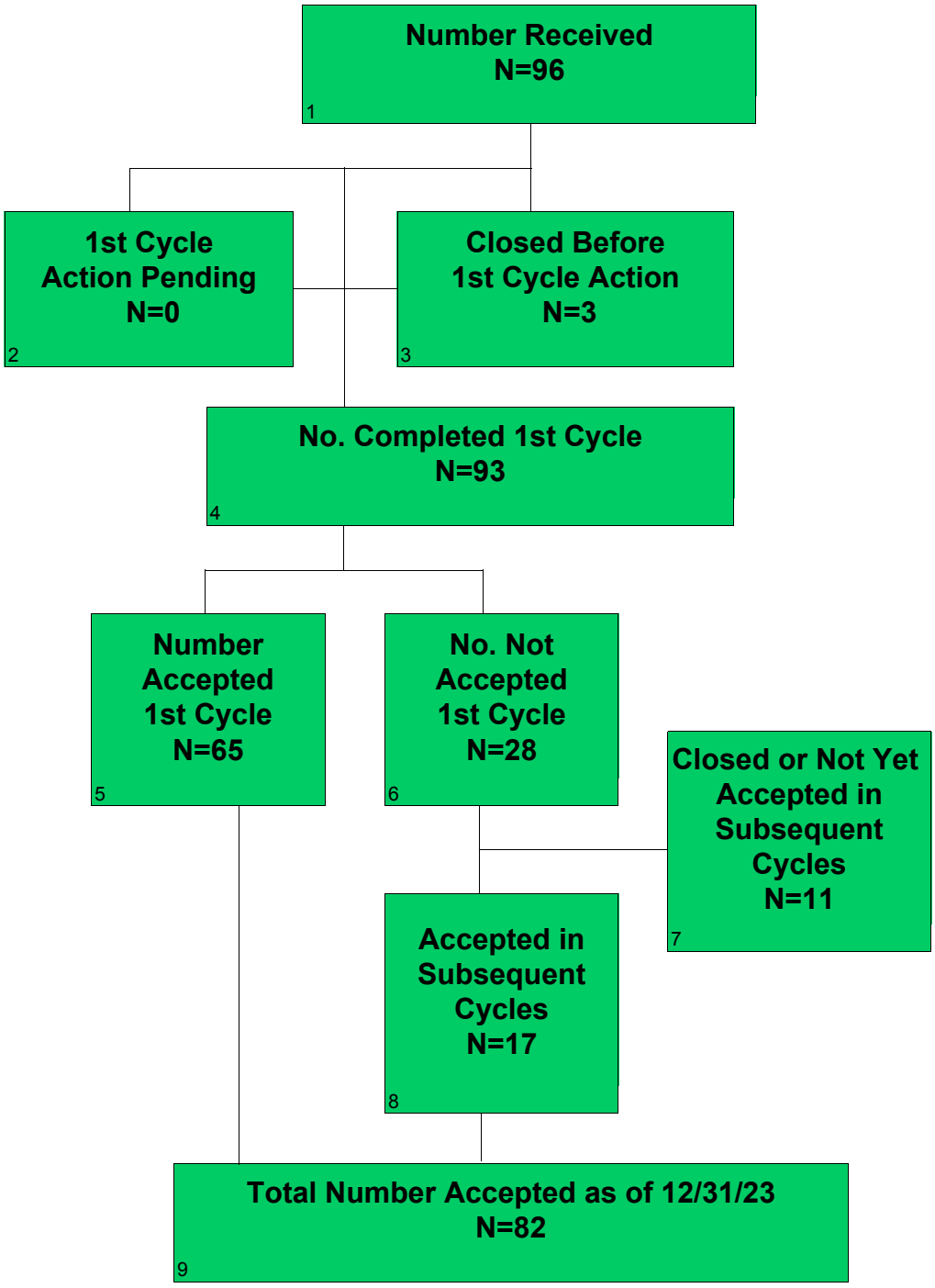


Average Time to MDUFA Decision: De Novos

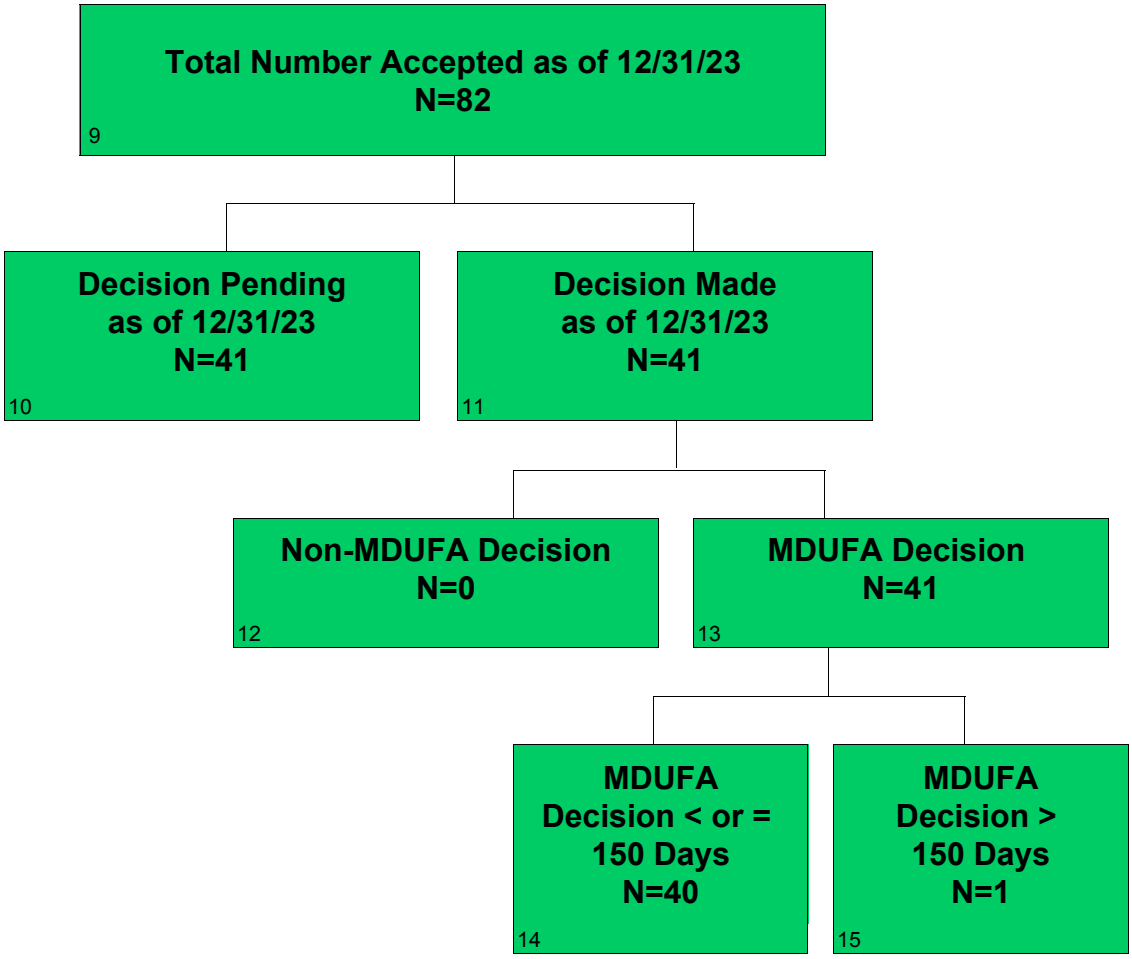
(50.00% closure comparison)



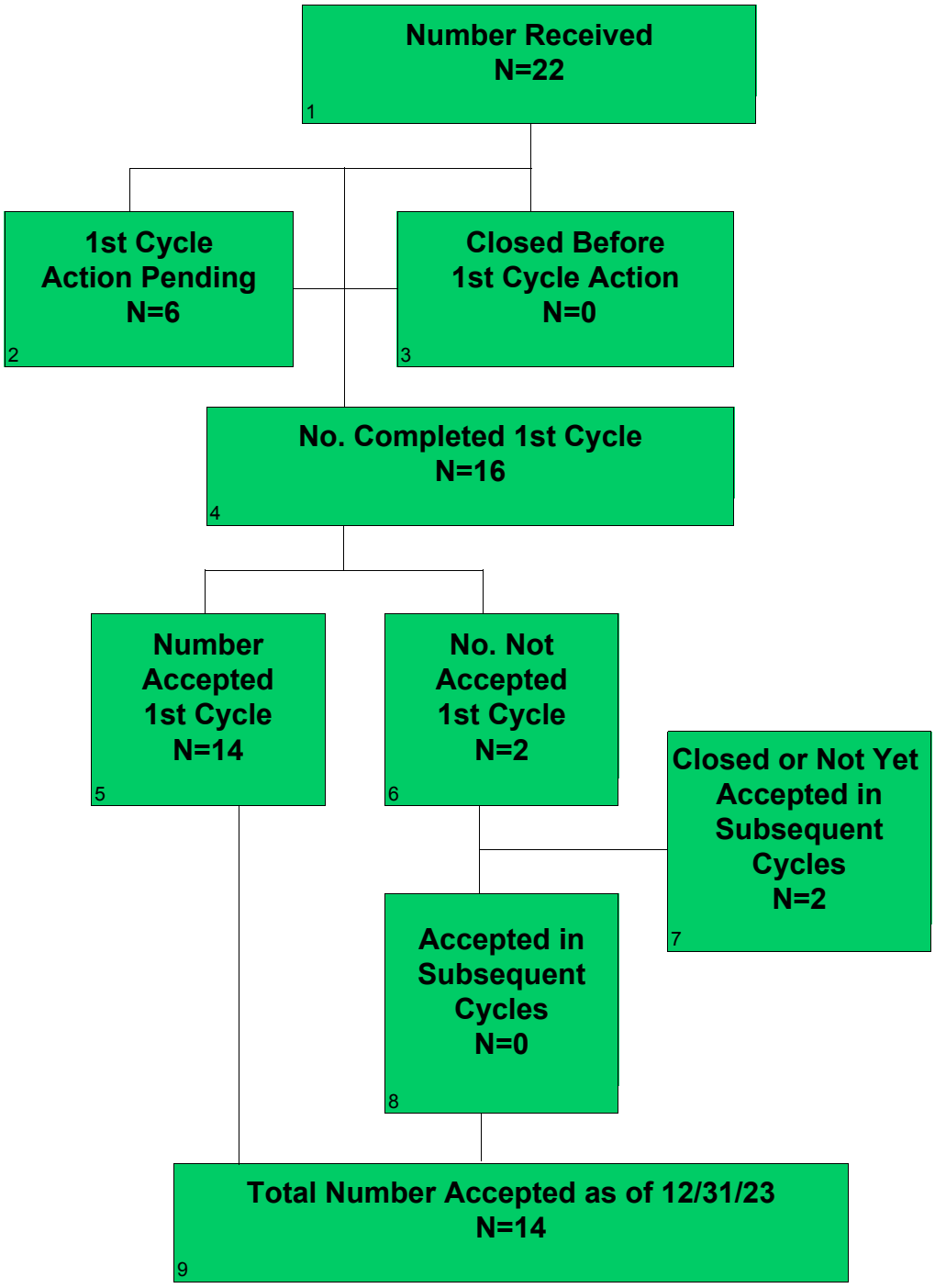
CDRH De Novo - FY 2023
as of 12/31/23



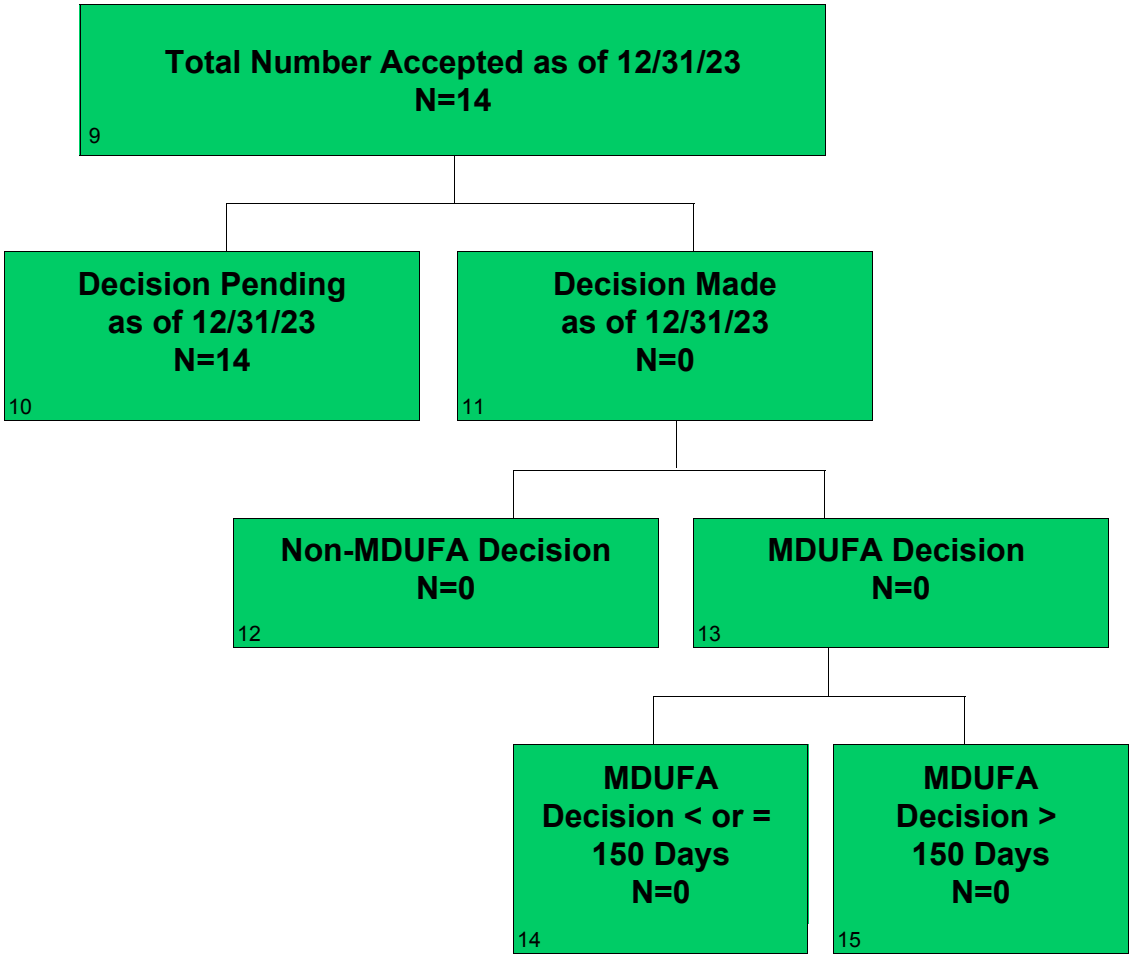
CDRH De Novo - FY 2023 as of 12/31/23 Continued



CDRH De Novo - FY 2024
as of 12/31/23



CDRH De Novo - FY 2024 as of 12/31/23 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	22			
Closed Before First RTA or TS Action	3	0			
Number Accepted or Passed TS on First Cycle	65	14			
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	6			
Number Not Accepted or Failed TS on First Cycle	28	2			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	12.50%			

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	82	14			
Non-MDUFA Decision	0	0			
MDUFA Decision	41	0			
MDUFA Decision Within 150 FDA Days	40	0			
De Novos Pending MDUFA Decision	41	14			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	97.56%	N/A			

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	1.63	N/A			
Number With MDUFA Decision	41	0			
Average FDA Days to MDUFA Decision	131.41	N/A			
20th Percentile FDA Days to MDUFA Decision	75	0			
40th Percentile FDA Days to MDUFA Decision	148	0			
60th Percentile FDA Days to MDUFA Decision	150	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	203	0			
Average Industry Days to MDUFA Decision	109.49	N/A			
20th Percentile Industry Days to MDUFA Decision	19	0			
40th Percentile Industry Days to MDUFA Decision	89	0			
60th Percentile Industry Days to MDUFA Decision	163	0			
80th Percentile Industry Days to MDUFA Decision	180	0			
Maximum Industry Days to MDUFA Decision	183	0			
Average Total Days to MDUFA Decision	240.90	N/A			
20th Percentile Total Days to MDUFA Decision	167	0			
40th Percentile Total Days to MDUFA Decision	231	0			
60th Percentile Total Days to MDUFA Decision	267	0			
80th Percentile Total Days to MDUFA Decision	314	0			
Maximum Total Days to MDUFA Decision	331	0			

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	82	14			
Number With MDUFA Decision	41	0			
Number With Granted Decision	18	0			
Number With Declined Decision	11	0			
Number of Withdrawal	6	0			
Number of Deleted	6	0			
Rate of Granted Decision	43.90%	N/A			
Rate of Declined Decision	26.83%	N/A			
Rate of Withdrawal	14.63%	N/A			
Rate of Deleted	14.63%	N/A			

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	1	0			
Mean FDA Days for Submissions that Missed the Goal	203.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	105.00	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	2	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Within 150 FDA Days	0	0			
De Novos Pending MDUFA Decision	2	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 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	18	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	0			
MDUFA Decision Within 150 FDA Days	8	0			
De Novos Pending MDUFA Decision	10	1			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	5			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	6	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	6	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	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 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	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Within 150 FDA Days	5	0			
De Novos Pending MDUFA Decision	6	3			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	1.20	N/A			
Number With MDUFA Decision	5	0			
Average FDA Days to MDUFA Decision	89.20	N/A			
20th Percentile FDA Days to MDUFA Decision	73	0			
40th Percentile FDA Days to MDUFA Decision	74	0			
60th Percentile FDA Days to MDUFA Decision	75	0			
80th Percentile FDA Days to MDUFA Decision	90	0			
Maximum FDA Days to MDUFA Decision	150	0			
Average Industry Days to MDUFA Decision	139.40	N/A			
20th Percentile Industry Days to MDUFA Decision	109	0			
40th Percentile Industry Days to MDUFA Decision	161	0			
60th Percentile Industry Days to MDUFA Decision	181	0			
80th Percentile Industry Days to MDUFA Decision	182	0			
Maximum Industry Days to MDUFA Decision	182	0			
Average Total Days to MDUFA Decision	228.60	N/A			
20th Percentile Total Days to MDUFA Decision	199	0			
40th Percentile Total Days to MDUFA Decision	235	0			
60th Percentile Total Days to MDUFA Decision	254	0			
80th Percentile Total Days to MDUFA Decision	255	0			
Maximum Total Days to MDUFA Decision	257	0			

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	3			
Number With MDUFA Decision	5	0			
Number With Granted Decision	1	0			
Number With Declined Decision	0	0			
Number of Withdrawal	1	0			
Number of Deleted	3	0			
Rate of Granted Decision	20.00%	N/A			
Rate of Declined Decision	0.00%	N/A			
Rate of Withdrawal	20.00%	N/A			
Rate of Deleted	60.00%	N/A			

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	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 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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	1			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	10	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	0			
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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	0			
MDUFA Decision Within 150 FDA Days	8	0			
De Novos Pending MDUFA Decision	2	1			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	1.88	N/A			
Number With MDUFA Decision	8	0			
Average FDA Days to MDUFA Decision	134.00	N/A			
20th Percentile FDA Days to MDUFA Decision	121	0			
40th Percentile FDA Days to MDUFA Decision	150	0			
60th Percentile FDA Days to MDUFA Decision	150	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	150	0			
Average Industry Days to MDUFA Decision	129.75	N/A			
20th Percentile Industry Days to MDUFA Decision	59	0			
40th Percentile Industry Days to MDUFA Decision	156	0			
60th Percentile Industry Days to MDUFA Decision	179	0			
80th Percentile Industry Days to MDUFA Decision	180	0			
Maximum Industry Days to MDUFA Decision	183	0			
Average Total Days to MDUFA Decision	263.75	N/A			
20th Percentile Total Days to MDUFA Decision	209	0			
40th Percentile Total Days to MDUFA Decision	246	0			
60th Percentile Total Days to MDUFA Decision	292	0			
80th Percentile Total Days to MDUFA Decision	329	0			
Maximum Total Days to MDUFA Decision	329	0			

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	1			
Number With MDUFA Decision	8	0			
Number With Granted Decision	4	0			
Number With Declined Decision	3	0			
Number of Withdrawal	0	0			
Number of Deleted	1	0			
Rate of Granted Decision	50.00%	N/A			
Rate of Declined Decision	37.50%	N/A			
Rate of Withdrawal	0.00%	N/A			
Rate of Deleted	12.50%	N/A			

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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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	3			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	9	2			
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	18.18%	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 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	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	0			
MDUFA Decision Within 150 FDA Days	7	0			
De Novos Pending MDUFA Decision	4	2			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	1.57	N/A			
Number With MDUFA Decision	7	0			
Average FDA Days to MDUFA Decision	138.00	N/A			
20th Percentile FDA Days to MDUFA Decision	145	0			
40th Percentile FDA Days to MDUFA Decision	149	0			
60th Percentile FDA Days to MDUFA Decision	150	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	150	0			
Average Industry Days to MDUFA Decision	91.43	N/A			
20th Percentile Industry Days to MDUFA Decision	17	0			
40th Percentile Industry Days to MDUFA Decision	85	0			
60th Percentile Industry Days to MDUFA Decision	110	0			
80th Percentile Industry Days to MDUFA Decision	155	0			
Maximum Industry Days to MDUFA Decision	181	0			
Average Total Days to MDUFA Decision	229.43	N/A			
20th Percentile Total Days to MDUFA Decision	166	0			
40th Percentile Total Days to MDUFA Decision	234	0			
60th Percentile Total Days to MDUFA Decision	249	0			
80th Percentile Total Days to MDUFA Decision	270	0			
Maximum Total Days to MDUFA Decision	313	0			

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	2			
Number With MDUFA Decision	7	0			
Number With Granted Decision	6	0			
Number With Declined Decision	0	0			
Number of Withdrawal	0	0			
Number of Deleted	1	0			
Rate of Granted Decision	85.71%	N/A			
Rate of Declined Decision	0.00%	N/A			
Rate of Withdrawal	0.00%	N/A			
Rate of Deleted	14.29%	N/A			

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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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	4			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	11	4			
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	9	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	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 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	4			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	0			
MDUFA Decision Within 150 FDA Days	6	0			
De Novos Pending MDUFA Decision	8	4			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	85.71%	N/A			

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	1.57	N/A			
Number With MDUFA Decision	7	0			
Average FDA Days to MDUFA Decision	133.29	N/A			
20th Percentile FDA Days to MDUFA Decision	88	0			
40th Percentile FDA Days to MDUFA Decision	149	0			
60th Percentile FDA Days to MDUFA Decision	150	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	203	0			
Average Industry Days to MDUFA Decision	101.71	N/A			
20th Percentile Industry Days to MDUFA Decision	13	0			
40th Percentile Industry Days to MDUFA Decision	80	0			
60th Percentile Industry Days to MDUFA Decision	150	0			
80th Percentile Industry Days to MDUFA Decision	181	0			
Maximum Industry Days to MDUFA Decision	182	0			
Average Total Days to MDUFA Decision	235.00	N/A			
20th Percentile Total Days to MDUFA Decision	162	0			
40th Percentile Total Days to MDUFA Decision	229	0			
60th Percentile Total Days to MDUFA Decision	287	0			
80th Percentile Total Days to MDUFA Decision	326	0			
Maximum Total Days to MDUFA Decision	331	0			

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	4			
Number With MDUFA Decision	7	0			
Number With Granted Decision	3	0			
Number With Declined Decision	2	0			
Number of Withdrawal	1	0			
Number of Deleted	1	0			
Rate of Granted Decision	42.86%	N/A			
Rate of Declined Decision	28.57%	N/A			
Rate of Withdrawal	14.29%	N/A			
Rate of Deleted	14.29%	N/A			

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	1	0			
Mean FDA Days for Submissions That Missed the Goal	203.00	N/A			
Mean Industry Days for Submissions That Missed the Goal	105.00	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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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	3			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	5	2			
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	4	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	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 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	8	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	3	0			
MDUFA Decision Within 150 FDA Days	3	0			
De Novos Pending MDUFA Decision	5	2			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	N/A			
Number With MDUFA Decision	3	0			
Average FDA Days to MDUFA Decision	149.67	N/A			
20th Percentile FDA Days to MDUFA Decision	149	0			
40th Percentile FDA Days to MDUFA Decision	150	0			
60th Percentile FDA Days to MDUFA Decision	150	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	150	0			
Average Industry Days to MDUFA Decision	75.00	N/A			
20th Percentile Industry Days to MDUFA Decision	34	0			
40th Percentile Industry Days to MDUFA Decision	49	0			
60th Percentile Industry Days to MDUFA Decision	75	0			
80th Percentile Industry Days to MDUFA Decision	112	0			
Maximum Industry Days to MDUFA Decision	150	0			
Average Total Days to MDUFA Decision	224.67	N/A			
20th Percentile Total Days to MDUFA Decision	183	0			
40th Percentile Total Days to MDUFA Decision	198	0			
60th Percentile Total Days to MDUFA Decision	224	0			
80th Percentile Total Days to MDUFA Decision	262	0			
Maximum Total Days to MDUFA Decision	300	0			

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	8	2			
Number With MDUFA Decision	3	0			
Number With Granted Decision	1	0			
Number With Declined Decision	2	0			
Number of Withdrawal	0	0			
Number of Deleted	0	0			
Rate of Granted Decision	33.33%	N/A			
Rate of Declined Decision	66.67%	N/A			
Rate of Withdrawal	0.00%	N/A			
Rate of Deleted	0.00%	N/A			

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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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	0			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	3	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	0	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	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 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	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	1	0			
MDUFA Decision Within 150 FDA Days	1	0			
De Novos Pending MDUFA Decision	2	0			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

Table 8.3 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	1.00	N/A			
Number With MDUFA Decision	1	0			
Average FDA Days to MDUFA Decision	148.00	N/A			
20th Percentile FDA Days to MDUFA Decision	148	0			
40th Percentile FDA Days to MDUFA Decision	148	0			
60th Percentile FDA Days to MDUFA Decision	148	0			
80th Percentile FDA Days to MDUFA Decision	148	0			
Maximum FDA Days to MDUFA Decision	148	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	148.00	N/A			
20th Percentile Total Days to MDUFA Decision	148	0			
40th Percentile Total Days to MDUFA Decision	148	0			
60th Percentile Total Days to MDUFA Decision	148	0			
80th Percentile Total Days to MDUFA Decision	148	0			
Maximum Total Days to MDUFA Decision	148	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	0			
Number With MDUFA Decision	1	0			
Number With Granted Decision	1	0			
Number With Declined Decision	0	0			
Number of Withdrawal	0	0			
Number of Deleted	0	0			
Rate of Granted Decision	100.00%	N/A			
Rate of Declined Decision	0.00%	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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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	5			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	17	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	3			
Number Not Accepted or Failed TS on First Cycle	5	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	50.00%			

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 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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	0			
MDUFA Decision Within 150 FDA Days	8	0			
De Novos Pending MDUFA Decision	12	1			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	1.75	N/A			
Number With MDUFA Decision	8	0			
Average FDA Days to MDUFA Decision	145.38	N/A			
20th Percentile FDA Days to MDUFA Decision	142	0			
40th Percentile FDA Days to MDUFA Decision	147	0			
60th Percentile FDA Days to MDUFA Decision	150	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	150	0			
Average Industry Days to MDUFA Decision	128.75	N/A			
20th Percentile Industry Days to MDUFA Decision	62	0			
40th Percentile Industry Days to MDUFA Decision	160	0			
60th Percentile Industry Days to MDUFA Decision	177	0			
80th Percentile Industry Days to MDUFA Decision	179	0			
Maximum Industry Days to MDUFA Decision	180	0			
Average Total Days to MDUFA Decision	274.13	N/A			
20th Percentile Total Days to MDUFA Decision	209	0			
40th Percentile Total Days to MDUFA Decision	309	0			
60th Percentile Total Days to MDUFA Decision	317	0			
80th Percentile Total Days to MDUFA Decision	329	0			
Maximum Total Days to MDUFA Decision	330	0			

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	1			
Number With MDUFA Decision	8	0			
Number With Granted Decision	1	0			
Number With Declined Decision	4	0			
Number of Withdrawal	3	0			
Number of Deleted	0	0			
Rate of Granted Decision	12.50%	N/A			
Rate of Declined Decision	50.00%	N/A			
Rate of Withdrawal	37.50%	N/A			
Rate of Deleted	0.00%	N/A			

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	2	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	0	0			
MDUFA Decision Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	2	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	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	18	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	0			
MDUFA Decision Within 150 FDA Days	8	0			
De Novos Pending MDUFA IV Decision	10	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	1			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	4	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	0			
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 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	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	2	0			
MDUFA Decision Within 150 FDA Days	2	0			
De Novos Pending MDUFA Decision	2	1			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	N/A			

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	1.50	N/A			
Number With MDUFA Decision	2	0			
Average FDA Days to MDUFA Decision	105.50	N/A			
20th Percentile FDA Days to MDUFA Decision	80	0			
40th Percentile FDA Days to MDUFA Decision	97	0			
60th Percentile FDA Days to MDUFA Decision	114	0			
80th Percentile FDA Days to MDUFA Decision	131	0			
Maximum FDA Days to MDUFA Decision	148	0			
Average Industry Days to MDUFA Decision	73.50	N/A			
20th Percentile Industry Days to MDUFA Decision	46	0			
40th Percentile Industry Days to MDUFA Decision	64	0			
60th Percentile Industry Days to MDUFA Decision	83	0			
80th Percentile Industry Days to MDUFA Decision	101	0			
Maximum Industry Days to MDUFA Decision	119	0			
Average Total Days to MDUFA Decision	179.00	N/A			
20th Percentile Total Days to MDUFA Decision	126	0			
40th Percentile Total Days to MDUFA Decision	161	0			
60th Percentile Total Days to MDUFA Decision	197	0			
80th Percentile Total Days to MDUFA Decision	232	0			
Maximum Total Days to MDUFA Decision	267	0			

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	1			
Number With MDUFA Decision	2	0			
Number With Granted Decision	1	0			
Number With Declined Decision	0	0			
Number of Withdrawal	1	0			
Number of Deleted	0	0			
Rate of Granted Decision	50.00%	N/A			
Rate of Declined Decision	0.00%	N/A			
Rate of Withdrawal	50.00%	N/A			
Rate of Deleted	0.00%	N/A			

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			

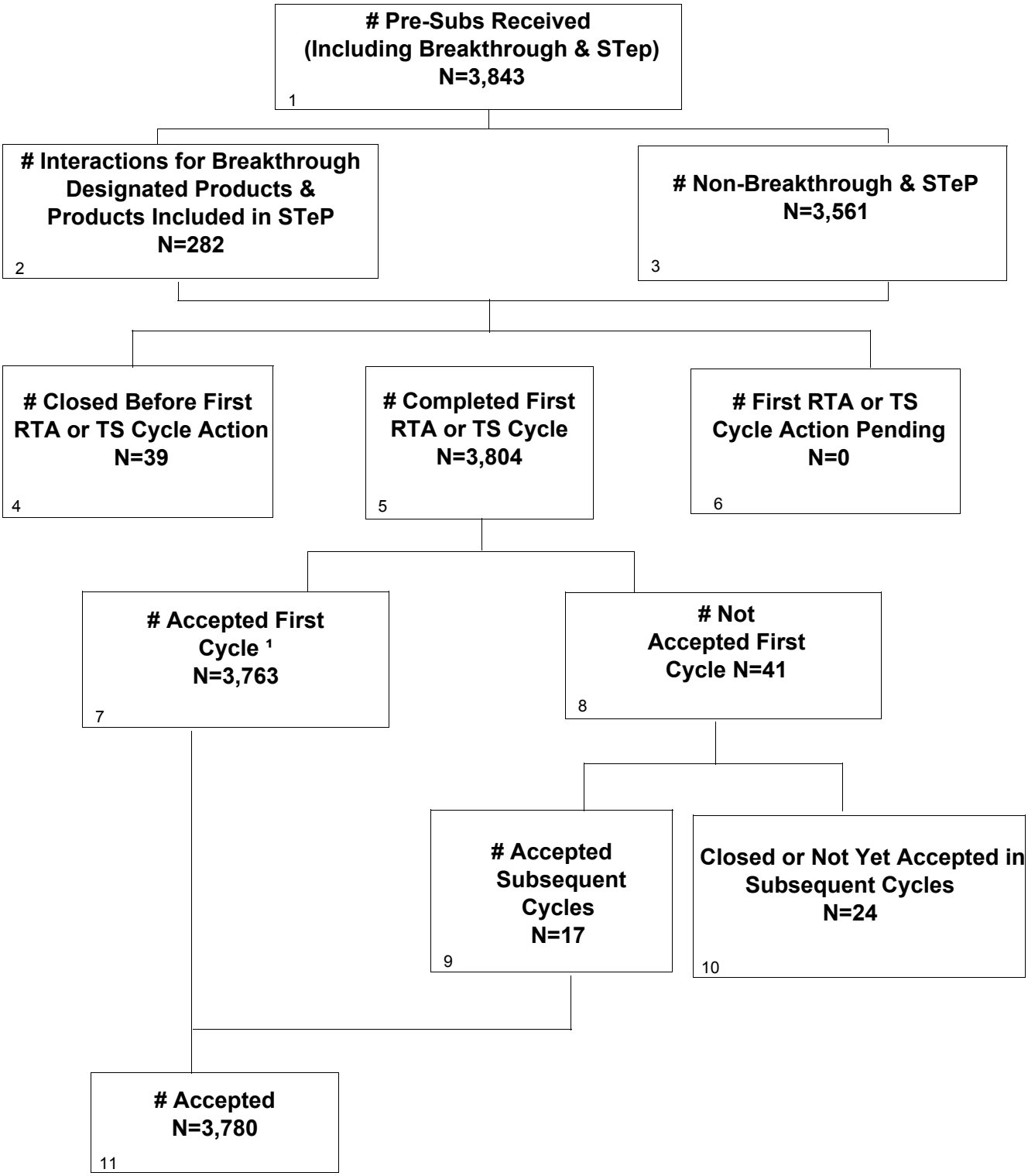
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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 IV Decision	N/A	N/A			
De Novos Pending MDUFA IV 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

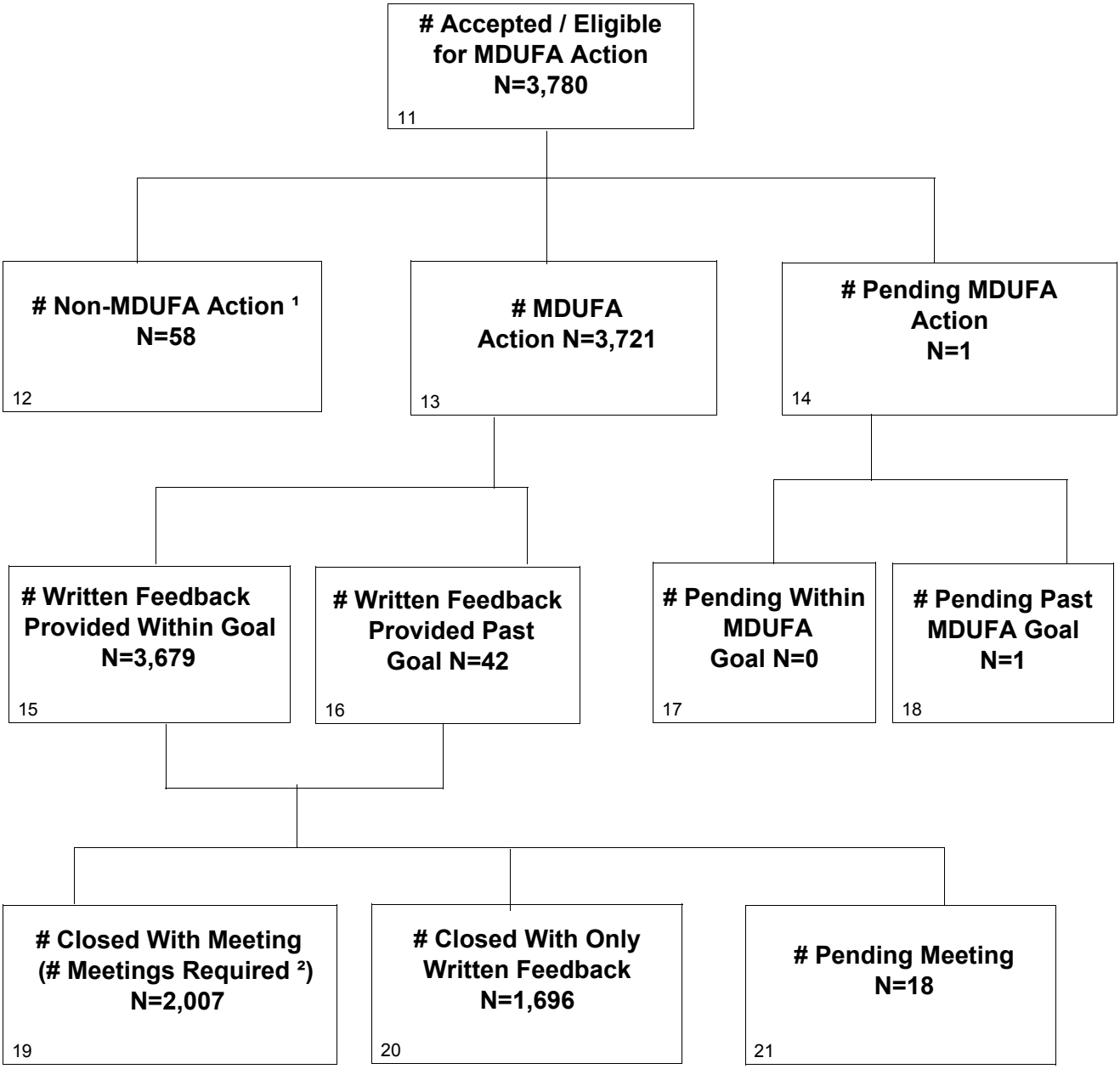
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA IV Decision	N/A	N/A			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A			
Current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

CDRH Pre-Sub - FY 2023
as of 12/31/23



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.

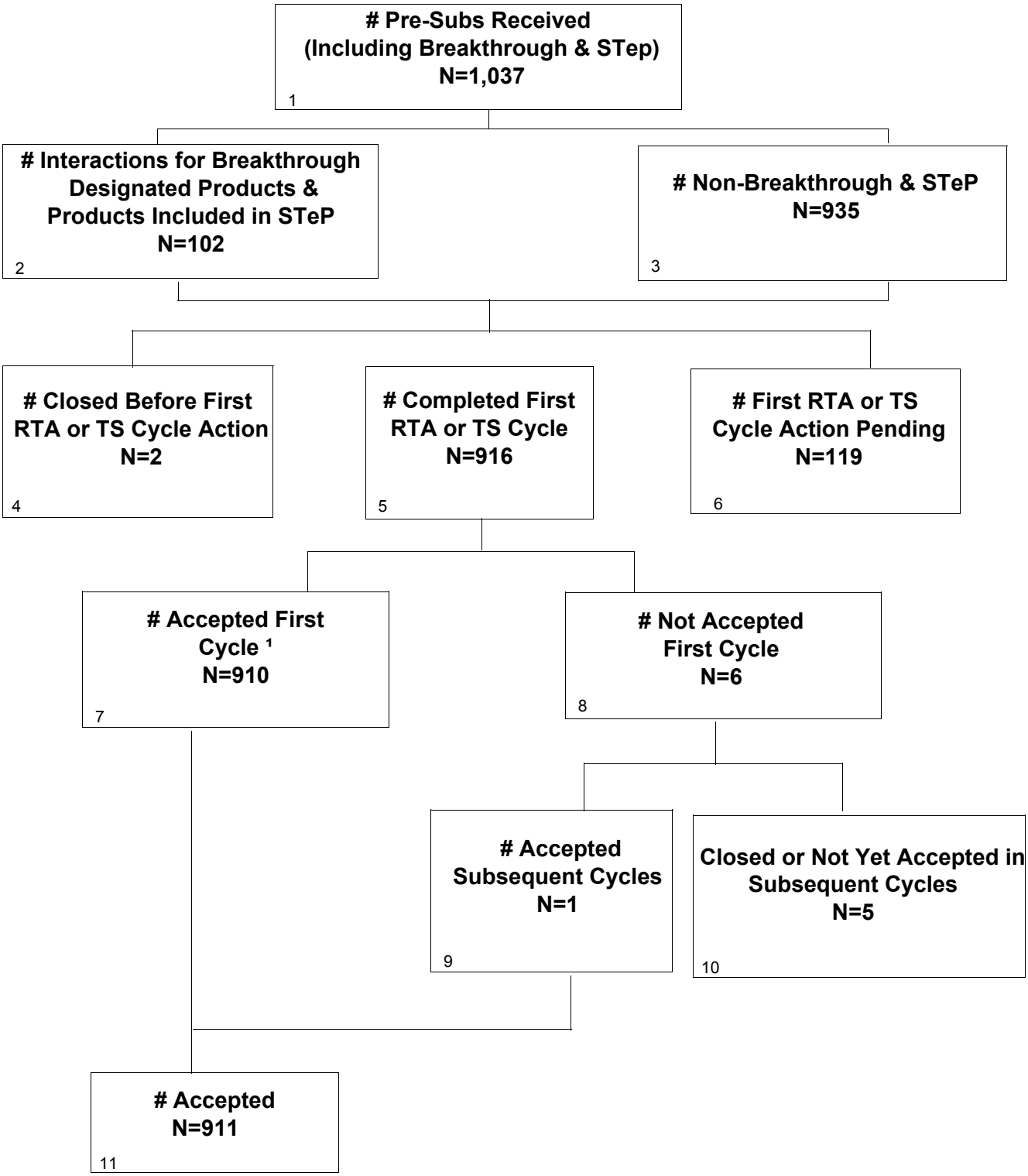
CDRH Pre-Sub - FY 2023 as of 12/31/23 Continued



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.

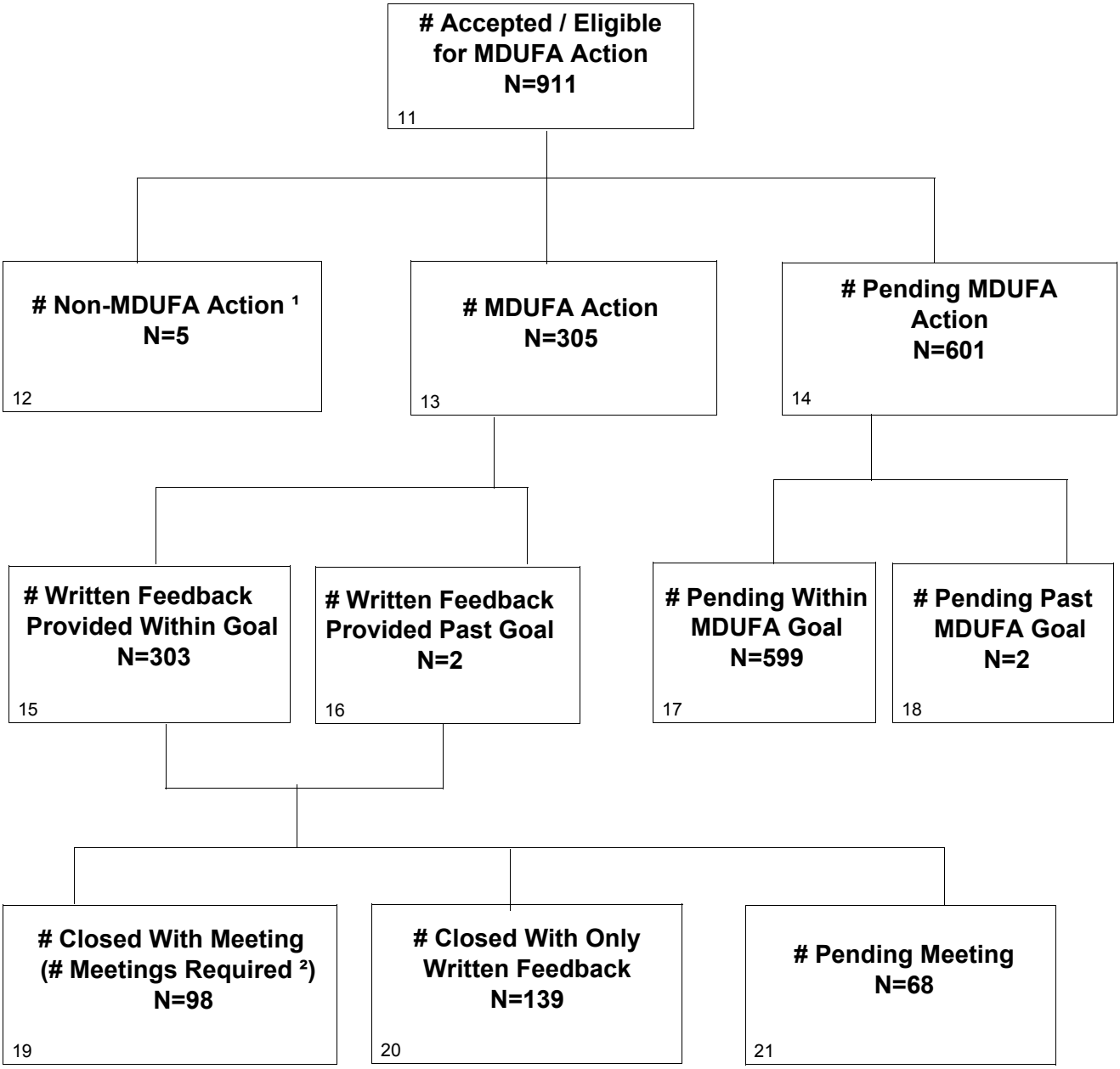
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 12/31/23



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 12/31/23 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	1,037			
Interactions for Breakthrough Designated Products & Products Included in STeP	282	102			
Number Closed Before First RTA Action	39	2			
Number Accepted First RTA Cycle [1]	3,642	893			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	17			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	119			
Number Not Accepted First RTA Cycle	41	6			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.66%			

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	911			
Number with Non-MDUFA Action [3]	58	5			
Number with MDUFA Action	3,721	305			
Written Feedback Provided Within Goal	3,679	303			
Number Pending MDUFA Action	1	601			
Pending MDUFA Action Past Goal	1	2			
Number in MDUFA Cohort (up to max 4300)[4]	3,722	906			
Current Performance Percent Within Goal	98.84%	98.70%			

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 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	305			
Average FDA Days to Written Feedback	62	56			
20th Percentile FDA Days to Written Feedback	56	45			
40th Percentile FDA Days to Written Feedback	64	56			
60th Percentile FDA Days to Written Feedback	68	62			
80th Percentile FDA Days to Written Feedback	70	67			
Maximum FDA Days to Written Feedback	141	70			

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	10			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	37.80			

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]	2,006	98			
Meeting Minutes Submitted Within 15 Days of Meeting	1,526	71			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	17			
Meeting Minutes Past 15 Days of Meeting	423	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	57	9			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.07%	87.65%			

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	445	136			
Interactions for Breakthrough Designated Products & Products Included in STeP	20	7			
Number Closed Before First RTA Action	4	0			
Number Accepted First RTA Cycle [1]	412	107			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	3			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	24			
Number Not Accepted First RTA Cycle	9	2			
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.04%	1.79%			

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	436	111			
Number with Non-MDUFA Action [3]	12	0			
Number with MDUFA Action	424	43			
Written Feedback Provided Within Goal	411	43			
Number Pending MDUFA Action	0	68			
Pending MDUFA Action Past Goal	0	2			
Number in MDUFA Cohort (up to max 4300)[4]	424	111			
Current Performance Percent Within Goal	96.93%	95.56%			

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	424	43			
Average FDA Days to Written Feedback	65.27	61.28			
20th Percentile FDA Days to Written Feedback	62	56			
40th Percentile FDA Days to Written Feedback	66	60			
60th Percentile FDA Days to Written Feedback	69	66			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	141	70			

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	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	41.00			

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	13			
Meeting Minutes Submitted Within 15 Days of Meeting	179	8			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	59	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	100.00%			

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	724	156			
Interactions for Breakthrough Designated Products & Products Included in STeP	72	17			
Number Closed Before First RTA Action	6	0			
Number Accepted First RTA Cycle [1]	700	140			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	2			
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	5	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.70%	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 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	717	142			
Number with Non-MDUFA Action [3]	4	2			
Number with MDUFA Action	712	56			
Written Feedback Provided Within Goal	697	55			
Number Pending MDUFA Action	1	84			
Pending MDUFA Action Past Goal	1	0			
Number in MDUFA Cohort (up to max 4300)[4]	713	140			
Current Performance Percent Within Goal	97.76%	98.21%			

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	712	56			
Average FDA Days to Written Feedback	59.34	55.66			
20th Percentile FDA Days to Written Feedback	50	45			
40th Percentile FDA Days to Written Feedback	60	56			
60th Percentile FDA Days to Written Feedback	66	61			
80th Percentile FDA Days to Written Feedback	70	65			
Maximum FDA Days to Written Feedback	103	70			

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	33	2			
Average Days to Scheduling for Meetings Scheduled After Day 30	38.09	39.50			

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]	404	21			
Meeting Minutes Submitted Within 15 Days of Meeting	308	13			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	86	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	10	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.24%	81.25%			

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	463	129			
Interactions for Breakthrough Designated Products & Products Included in STeP	41	16			
Number Closed Before First RTA Action	5	1			
Number Accepted First RTA Cycle [1]	440	108			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	5			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	13			
Number Not Accepted First RTA Cycle	6	2			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.31%	1.74%			

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	455	113			
Number with Non-MDUFA Action [3]	10	1			
Number with MDUFA Action	445	34			
Written Feedback Provided Within Goal	441	34			
Number Pending MDUFA Action	0	78			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	445	112			
Current Performance Percent Within Goal	99.10%	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 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	445	34			
Average FDA Days to Written Feedback	62.09	53.35			
20th Percentile FDA Days to Written Feedback	56	43			
40th Percentile FDA Days to Written Feedback	64	56			
60th Percentile FDA Days to Written Feedback	67	60			
80th Percentile FDA Days to Written Feedback	70	66			
Maximum FDA Days to Written Feedback	78	70			

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	3			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	36.67			

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]	256	10			
Meeting Minutes Submitted Within 15 Days of Meeting	201	10			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	49	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.52%	100.00%			

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	361	115			
Interactions for Breakthrough Designated Products & Products Included in STeP	21	9			
Number Closed Before First RTA Action	4	0			
Number Accepted First RTA Cycle [1]	343	97			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	3			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	15			
Number Not Accepted First RTA Cycle	5	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.40%	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 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	354	100			
Number with Non-MDUFA Action [3]	9	0			
Number with MDUFA Action	345	38			
Written Feedback Provided Within Goal	345	38			
Number Pending MDUFA Action	0	62			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	345	100			
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 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	345	38			
Average FDA Days to Written Feedback	60.53	55.05			
20th Percentile FDA Days to Written Feedback	54	45			
40th Percentile FDA Days to Written Feedback	62	55			
60th Percentile FDA Days to Written Feedback	65	59			
80th Percentile FDA Days to Written Feedback	69	66			
Maximum FDA Days to Written Feedback	70	70			

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	14	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	37.71	0.00			

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]	196	10			
Meeting Minutes Submitted Within 15 Days of Meeting	152	10			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	35	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	9	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.55%	100.00%			

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	397	107			
Interactions for Breakthrough Designated Products & Products Included in STeP	42	11			
Number Closed Before First RTA Action	5	0			
Number Accepted First RTA Cycle [1]	371	92			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	1			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	12			
Number Not Accepted First RTA Cycle	4	2			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.11%			

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 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	390	93			
Number with Non-MDUFA Action [3]	5	0			
Number with MDUFA Action	385	22			
Written Feedback Provided Within Goal	383	22			
Number Pending MDUFA Action	0	71			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	385	93			
Current Performance Percent Within Goal	99.48%	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 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	385	22			
Average FDA Days to Written Feedback	66.13	63.14			
20th Percentile FDA Days to Written Feedback	64	58			
40th Percentile FDA Days to Written Feedback	68	66			
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	70			

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	3			
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	37.67			

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	5			
Meeting Minutes Submitted Within 15 Days of Meeting	176	1			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	64	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	70.97%	50.00%			

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	300	78			
Interactions for Breakthrough Designated Products & Products Included in STeP	52	21			
Number Closed Before First RTA Action	5	0			
Number Accepted First RTA Cycle [1]	280	72			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	2			
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	5	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.69%	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	292	74			
Number with Non-MDUFA Action [3]	8	0			
Number with MDUFA Action	284	25			
Written Feedback Provided Within Goal	280	24			
Number Pending MDUFA Action	0	49			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	284	74			
Current Performance Percent Within Goal	98.59%	96.00%			

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 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	284	25			
Average FDA Days to Written Feedback	58.56	48.96			
20th Percentile FDA Days to Written Feedback	45	39			
40th Percentile FDA Days to Written Feedback	58	44			
60th Percentile FDA Days to Written Feedback	65	57			
80th Percentile FDA Days to Written Feedback	69	62			
Maximum FDA Days to Written Feedback	97	65			

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	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	0.00			

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]	128	8			
Meeting Minutes Submitted Within 15 Days of Meeting	94	5			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	29	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	2			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.44%	62.50%			

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	882	252			
Interactions for Breakthrough Designated Products & Products Included in STeP	29	19			
Number Closed Before First RTA Action	9	1			
Number Accepted First RTA Cycle [1]	835	221			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	1			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	29			
Number Not Accepted First RTA Cycle	3	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	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 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	870	222			
Number with Non-MDUFA Action [3]	7	2			
Number with MDUFA Action	863	66			
Written Feedback Provided Within Goal	859	66			
Number Pending MDUFA Action	0	154			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	863	220			
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	863	66			
Average FDA Days to Written Feedback	63.71	56.30			
20th Percentile FDA Days to Written Feedback	60	45			
40th Percentile FDA Days to Written Feedback	66	56			
60th Percentile FDA Days to Written Feedback	69	64			
80th Percentile FDA Days to Written Feedback	70	66			
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	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	35.00			

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]	318	18			
Meeting Minutes Submitted Within 15 Days of Meeting	256	14			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	57	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.50%	93.33%			

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	271	64			
Interactions for Breakthrough Designated Products & Products Included in STeP	5	2			
Number Closed Before First RTA Action	1	0			
Number Accepted First RTA Cycle [1]	261	56			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	0			
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	1.48%	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	266	56			
Number with Non-MDUFA Action [3]	3	0			
Number with MDUFA Action	263	21			
Written Feedback Provided Within Goal	263	21			
Number Pending MDUFA Action	0	35			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	263	56			
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	263	21			
Average FDA Days to Written Feedback	60.53	54.90			
20th Percentile FDA Days to Written Feedback	55	49			
40th Percentile FDA Days to Written Feedback	60	53			
60th Percentile FDA Days to Written Feedback	64	60			
80th Percentile FDA Days to Written Feedback	67	64			
Maximum FDA Days to Written Feedback	70	69			

Table 9.4 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

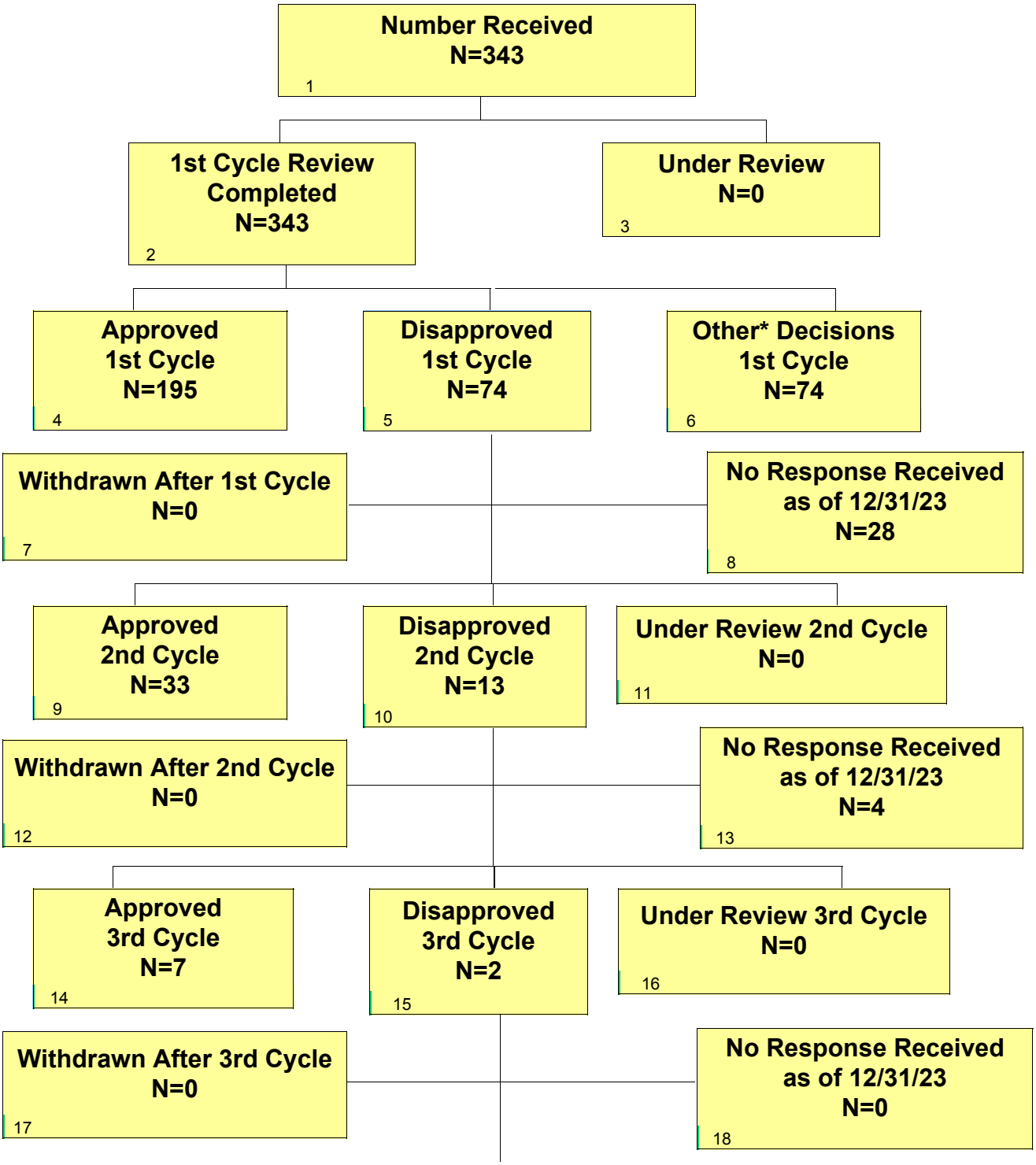
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	0.00			

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]	207	13			
Meeting Minutes Submitted Within 15 Days of Meeting	160	10			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	1			
Meeting Minutes Past 15 Days of Meeting	44	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	2			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.29%	83.33%			

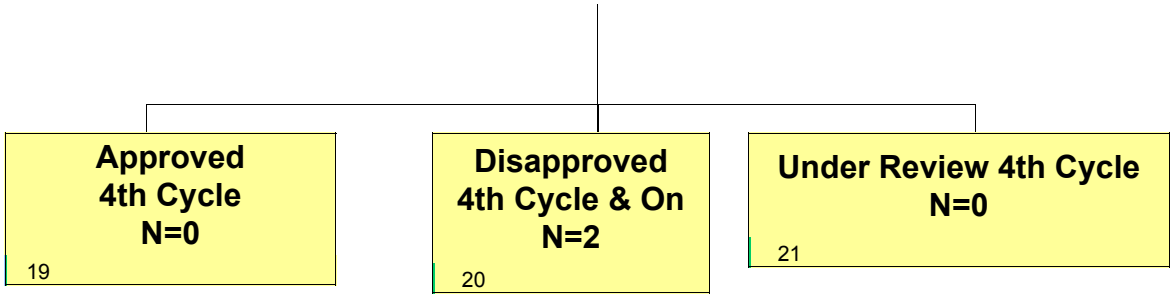
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 12/31/23

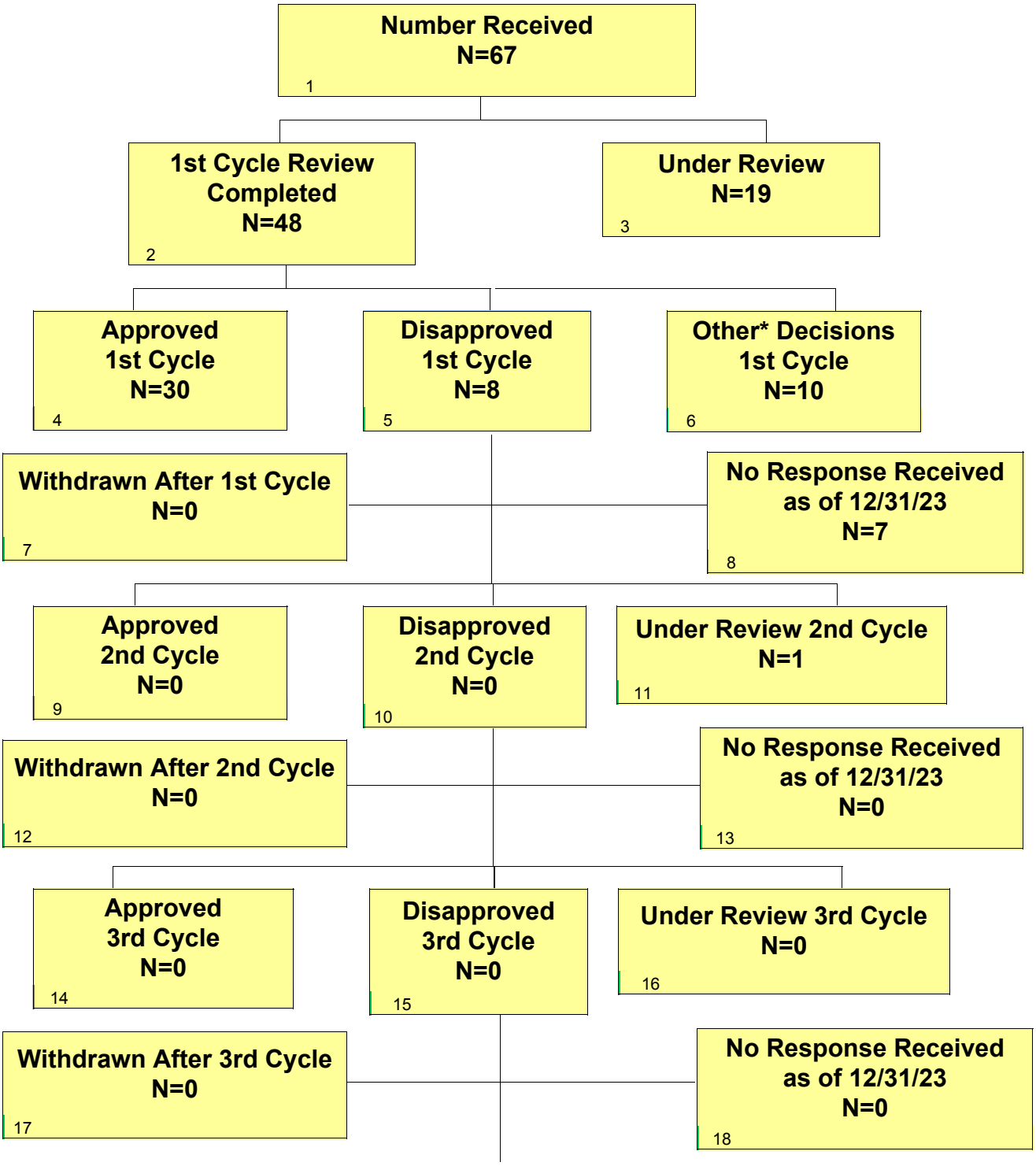


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 12/31/23

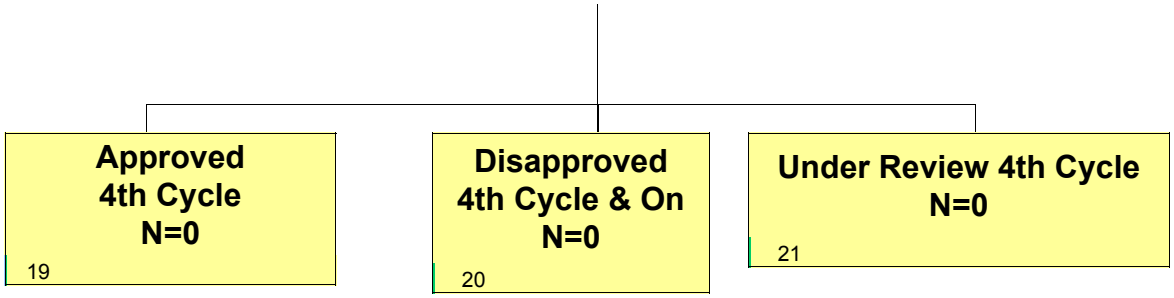


CDRH IDEs - FY 2024
as of 12/31/23



*** Other decisions include withdrawn (N=0), withdrawn and converted (N=7), RTA (N=0), nonsignificant risk device (N=3), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=0), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 12/31/23



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	67			
Average Number of Cycles to IDE Approval or Conditional Approval	1.23	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.23	0.00			

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	42	5			
Average Number of Cycles to IDE Approval or Conditional Approval	1.37	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.37	0.00			

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	18			
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			

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	36	9			
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.00			

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	33	4			
Average Number of Cycles to IDE Approval or Conditional Approval	1.11	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.11	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	74	18			
Average Number of Cycles to IDE Approval or Conditional Approval	1.14	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.14	0.00			

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	29	5			
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.00			

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	8			
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	9	0			
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	N/A			

Section 11 CLIA Waiver Annual Metrics

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

Section 12 Dual (510(k) and CLIA Waiver) Annual Metrics

Dual (510(k) and CLIA Waiver) Annual Metrics and Goals will be reported in the Annual Report.

Section 13 TAP Center Level Metrics

Table 13.1 CDRH - TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested	3			
Closed before Teleconference	0			
Teleconferences Held	3			
Teleconferences Held Within 14 Days	3			
Teleconferences Pending	0			
Teleconferences Pending Over 14 Days	0			
Current Performance Percent Within 14 Days	100.00%			

Table 13.2 CDRH - TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	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 CDRH - TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested	8			
Closed before Written Feedback	0			
Written Feedback Provided	5			
Written Feedback Provided Within 40 Days	5			
Written Feedback Pending	3			
Written Feedback Pending Over 40 Days	0			
Current Performance Percent Within 40 Days	100.00%			

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 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 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 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 13.1 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested	3			
Closed before Teleconference	0			
Teleconferences Held	3			
Teleconferences Held Within 14 Days	3			
Teleconferences Pending	0			
Teleconferences Pending Over 14 Days	0			
Current Performance Percent Within 14 Days	100.00%			

Table 13.2 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 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 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested	8			
Closed before Written Feedback	0			
Written Feedback Provided	5			
Written Feedback Provided Within 40 Days	5			
Written Feedback Pending	3			
Written Feedback Pending Over 40 Days	0			
Current Performance Percent Within 40 Days	100.00%			

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 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 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 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 13.1 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	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 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 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 13.1 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	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 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	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 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 13.1 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	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 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 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 13.1 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	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 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 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 13.1 OHT8 - Office of Radiological Health
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	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 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 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			

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 (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th 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 (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th 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 Produce 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)

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 31 December 2023

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	1			
SI Goal Met	2	0			
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%	N/A			

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	1			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	3	0			
MDUFA V Decision Goal Met	2	0			
Supplements Pending MDUFA V Decision	1	1			
Supplements Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	66.67%	N/A			

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	1			
Number with MDUFA V Decision	3	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	33.33%	N/A			

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	1			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	3	0			
MDUFA V Decision Goal Met	3	0			
Supplements Pending MDUFA V Decision	0	1			
Supplements Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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	1			
Number With MDUFA V Decision	3	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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	3			
Closed Before First RTA or TS Action [1]	0	0			
Number Accepted or Passed TS on First Cycle [2]	30	3			
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	0			
Number Not Accepted or Failed TS on First Cycle [2]	11	0			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	0.00%			

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	37	3			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	35	0			
SI Over 60 FDA Days	2	0			
SI Pending Within 60 FDA Days	0	3			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	94.59%	N/A			

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	37	0			
Average Number of FDA Days to Substantive Interaction	53.43	0.00			
20th Percentile FDA Days to Substantive Interaction	50	0			
40th Percentile FDA Days to Substantive Interaction	56	0			
60th Percentile FDA Days to Substantive Interaction	58	0			
80th Percentile FDA Days to Substantive Interaction	60	0			
Maximum FDA Days to Substantive Interaction	60	0			

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	37	3			
Non-MDUFA V Decision	2	0			
MDUFA V Decision (SE/NSE)	27	0			
MDUFA V Decision Within 90 FDA Days	27	0			
510(k)s Pending MDUFA V Decision	8	3			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	N/A			

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	1.15	0.00			
Number With MDUFA V Decision	27	0			
Average Number of FDA Days to MDUFA V Decision	76.67	0.00			
20th Percentile FDA Days to MDUFA V Decision	75	0			
40th Percentile FDA Days to MDUFA V Decision	82	0			
60th Percentile FDA Days to MDUFA V Decision	88	0			
80th Percentile FDA Days to MDUFA V Decision	90	0			
Maximum FDA Days to MDUFA V Decision	90	0			
Average Number of Industry Days to MDUFA V Decision	11.07	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	115	0			
Average Number of Total Days to MDUFA V Decision	87.74	0.00			
20th Percentile Total Days to MDUFA V Decision	79	0			
40th Percentile Total Days to MDUFA V Decision	85	0			
60th Percentile Total Days to MDUFA V Decision	89	0			
80th Percentile Total Days to MDUFA V Decision	90	0			
Maximum Total Days to MDUFA V Decision	196	0			

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	37	3			
Number With MDUFA V Decision	27	0			
Number of SE Decision	27	0			
Number of NSE Decision	0	0			
Number of Withdrawal	1	0			
Number of Deleted	1	0			
Rate of SE Decision	100.00%	N/A			
Rate of NSE Decision	0.00%	N/A			
Rate of Withdrawal	2.70%	0.00%			
Rate of Deleted	2.70%	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	0			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	7	0			
MDUFA V Decision Within 90 FDA Days	7	0			
510(k)s Pending MDUFA V Decision	1	0			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0			
Current Performance Percent Within 90 FDA Days	87.50%	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			

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	67	15			
Interactions for Breakthrough Designated Products & Products Included in STeP	2	0			
Number Closed Before First RTA Action	7	0			
Number Accepted First RTA Cycle [1]	56	14			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	4	1			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted First RTA Cycle	0	0			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	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 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	60	14			
Number with Non-MDUFA Action [3]	2	0			
Number with MDUFA Action	57	5			
Written Feedback Provided Within Goal	54	5			
Number Pending MDUFA Action	1	9			
Pending MDUFA Action Past Goal	1	0			
Number in MDUFA Cohort (up to max 4300)[4]	58	14			
Current Performance Percent Within Goal	93.10%	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	57	5			
Average FDA Days to Written Feedback	59.38	54.20			
20th Percentile FDA Days to Written Feedback	54	45			
40th Percentile FDA Days to Written Feedback	60	54			
60th Percentile FDA Days to Written Feedback	64	61			
80th Percentile FDA Days to Written Feedback	69	64			
Maximum FDA Days to Written Feedback	72	65			

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	1			
Meeting Minutes Submitted Within 15 Days of Meeting	21	1			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	3	0			
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%	100.00%			

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	0			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	NA			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	NA			

BLA

CBER – Annual General Metric Report for BLAs
****Annual Metrics and Goals will be reported in the Annual Report****

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
10	Q1	Select Updates for the 506J Guidance: 506J Device List and Additional Notifications	11/17/2023	No	Yes	Section 2514 of the Prepare for	A-List

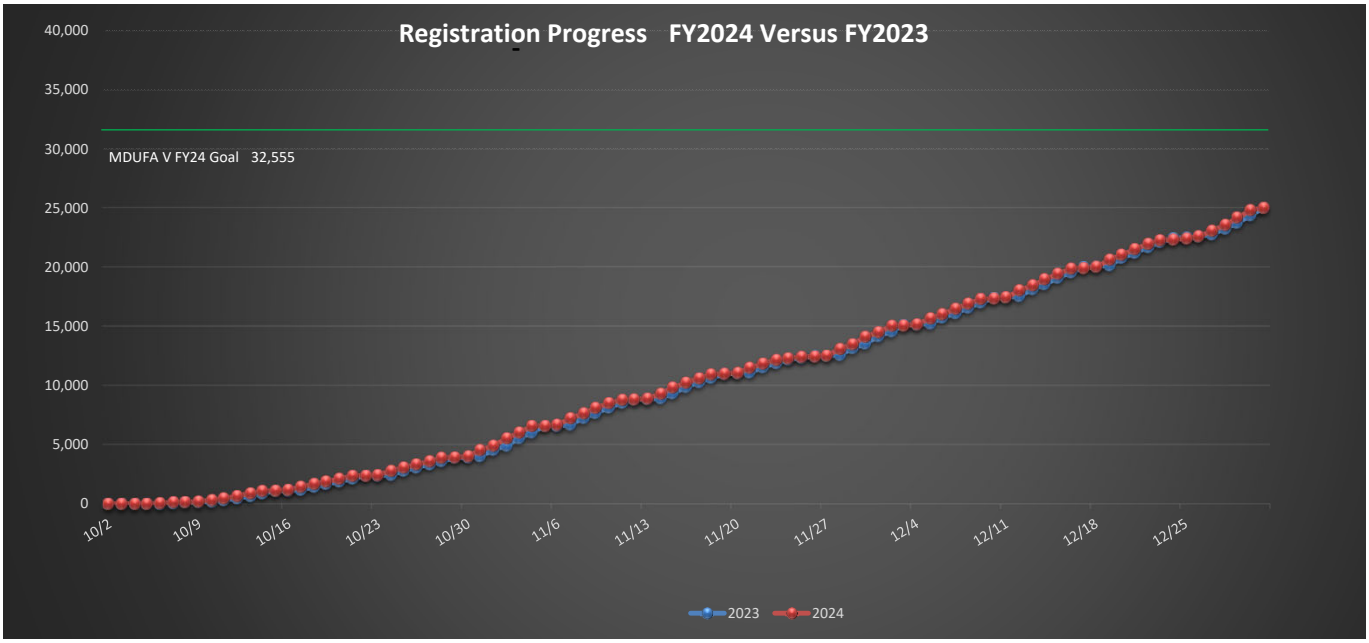
[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

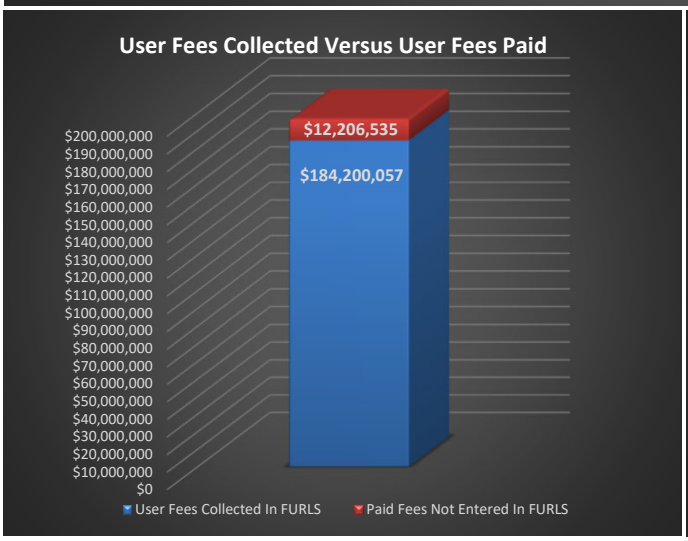
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
		www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-506j-guidance-506j-device-list-and-additional-notifications				and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	
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

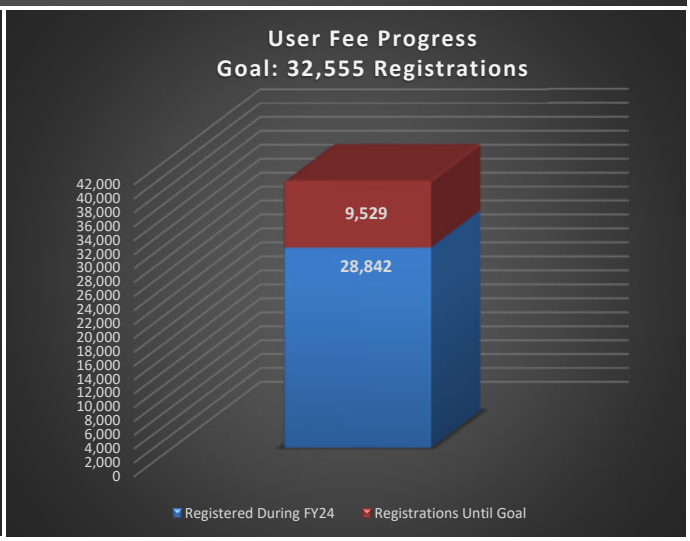
MDUFA V Registrations - 1st Quarter Summary FY2024*

Current Active Registrations by Type	FY24 Q1			FY23 Year End Active Totals			FY24 vs End FY23
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,492	9,954	15,446	6,677	12,332	19,009	81.26%
Contract Manufacturer	1,019	1,614	2,633	1,243	1,893	3,136	83.96%
Contract Sterilizer	72	144	216	76	169	245	88.16%
Specification Developer	1,235	495	1,730	1,668	557	2,225	77.75%
Reprocessor of Single Use Devices	22	2	24	34	3	37	64.86%
U.S. Manufacturer of Export Only Devices	95	0	95	127	0	127	74.80%
Repackager/Relabeler	839	147	986	1,116	221	1,337	73.75%
Remanufacturer	10	9	19	14	9	23	82.61%
Foreign Exporter/Private Label Distributor		901	901		1,132	1,132	79.59%
Initial Importer	2,517		2,517	3,357		3,357	74.98%
Unknown	2	8	10	6	11	17	58.82%
Total:	**11,303**	**13,274**	**24,577**	**14,318**	**16,327**	**30,645**	**80.20%**

*Note: This data is current as of 12/29/2023







FY 2024 Medical Device User Fee Collections as of December 31, 2023 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$188,851,478	-$84,183	$188,767,295		
Application Fees	$23,709,690	-$139,870	$23,569,820		
Total	**$212,561,168**	**-$224,053**	**$212,337,115**	**$362,381,000**	**59%**

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	$208,692,185	$215,669,093	$275,338,627	$269,260,125
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$324,300,992	$212,337,115			

MDUFA V Commitment Letter - VI. Performance Reports
2.12. Number of discretionary fee waivers or reductions granted by type of submission[1/]

CDRH Data 1st Quarter FY 2024 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	2	0
PMA	2	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	1
De Novo Classification	2	9
180-Day Supplements	1	1
Real-Time Supplements	0	3
510(k)s	12	283
30-day Notices /135 day supplements*	3	13
513(g)s	0	11
PMA Annual Report	0	0
Total	**20**	**321**

[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.

***135-day supplements were initially received and paid as 30-day notices; totals are combinations of both cohorts**