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

September 6, 2024, 11:00 – 12:00 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through June 30, 2024

- Report on performance goals for 3rd Quarter FY 2024

Guidance Development

Registration and Listing

Qualitative Update on Finances – 3rd Quarter FY 2024

- User fee receipts through the 3rd Quarter FY 2024

Annual Hiring Goals Update

ASCA Program Update

De Novo follow up

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----

Actions through 30 June 2024

Table of Contents

Acronyms and Abbreviations

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

Office Organizations

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

OHT2: Office of Cardiovascular Devices

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

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

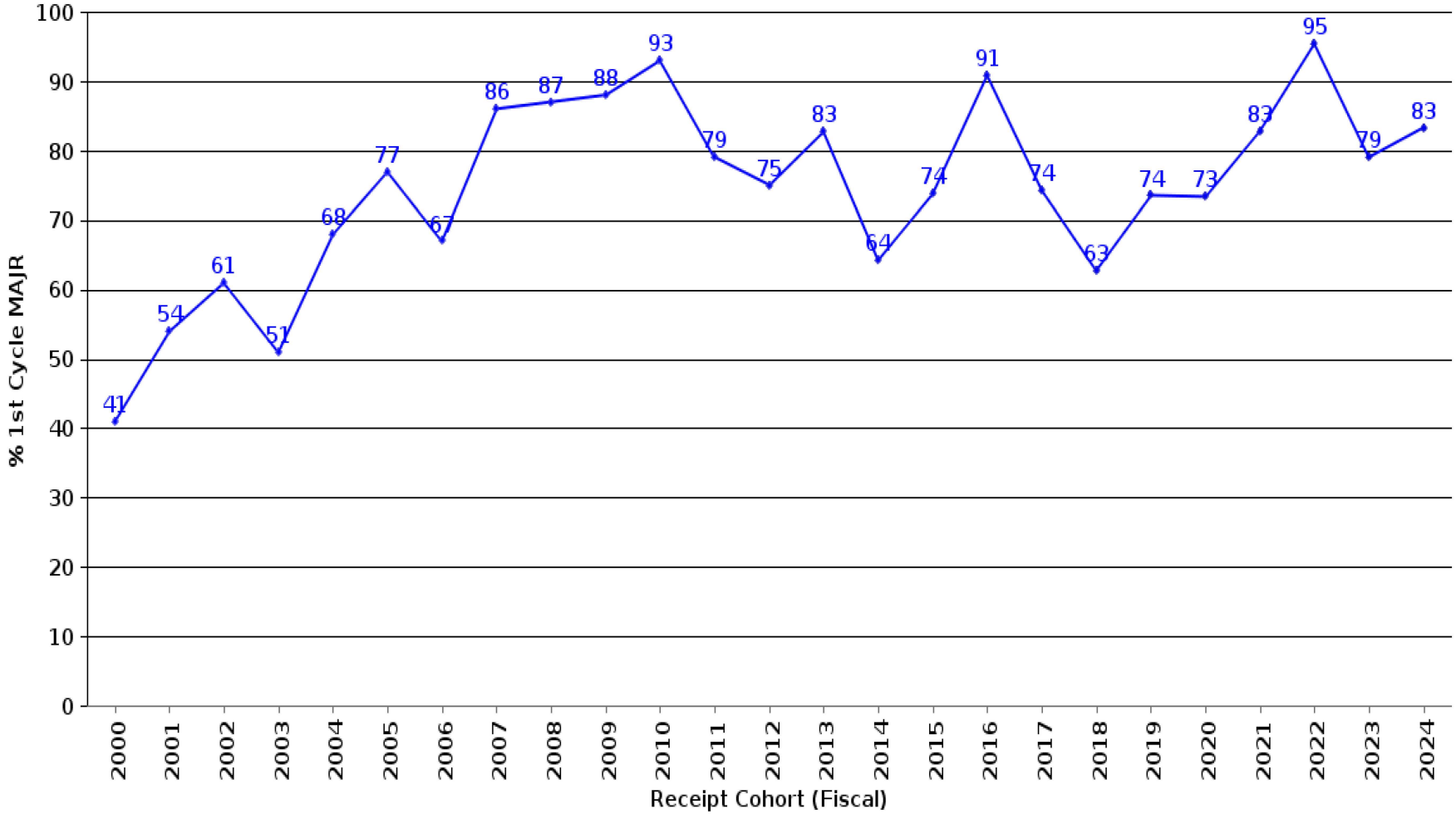
OHT8: Office of Radiological Health

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

PMAs

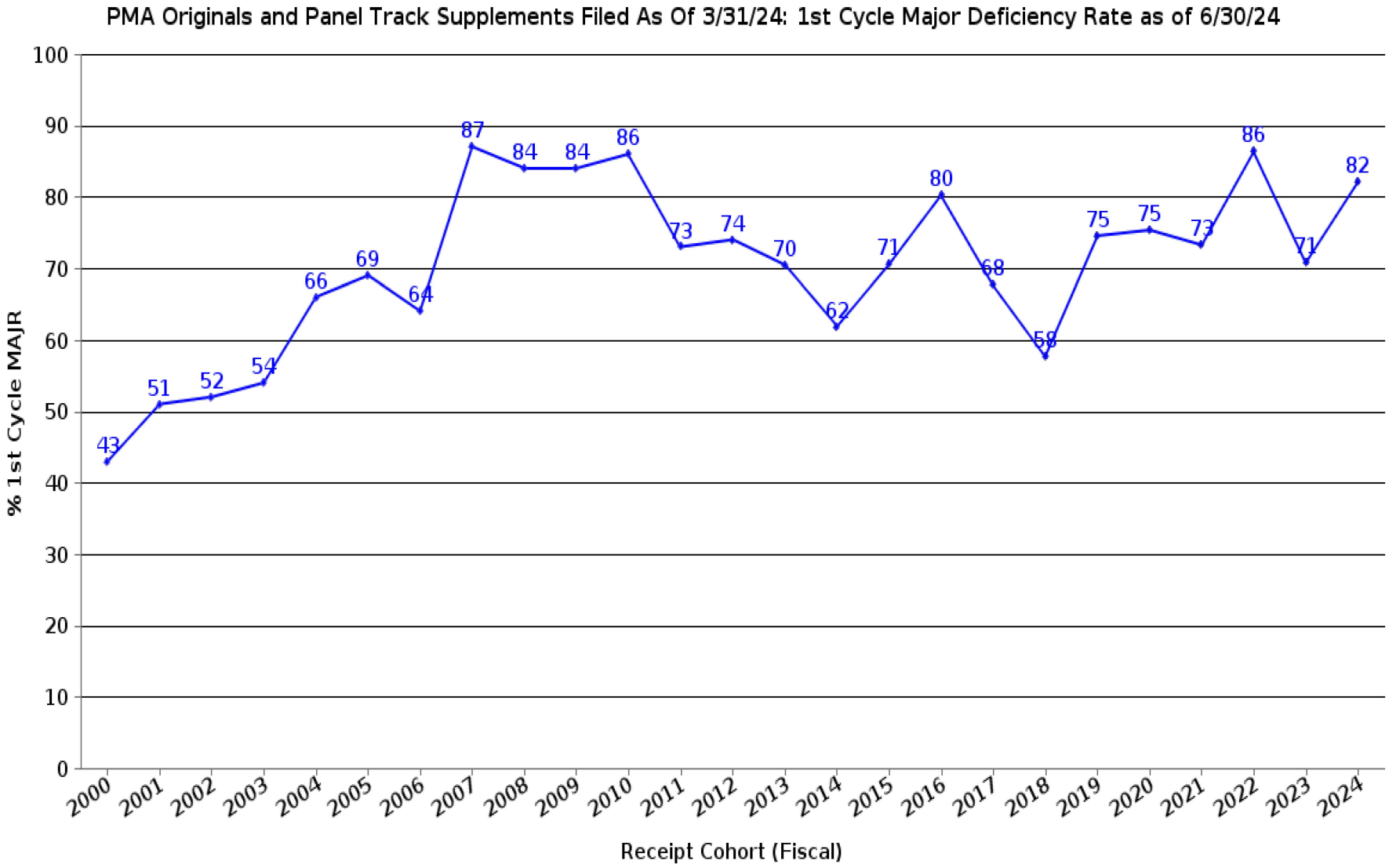
Q3FY2024

PMA Originals Filed As Of 3/31/24: 1st Cycle Major Deficiency Rate as of 6/30/24



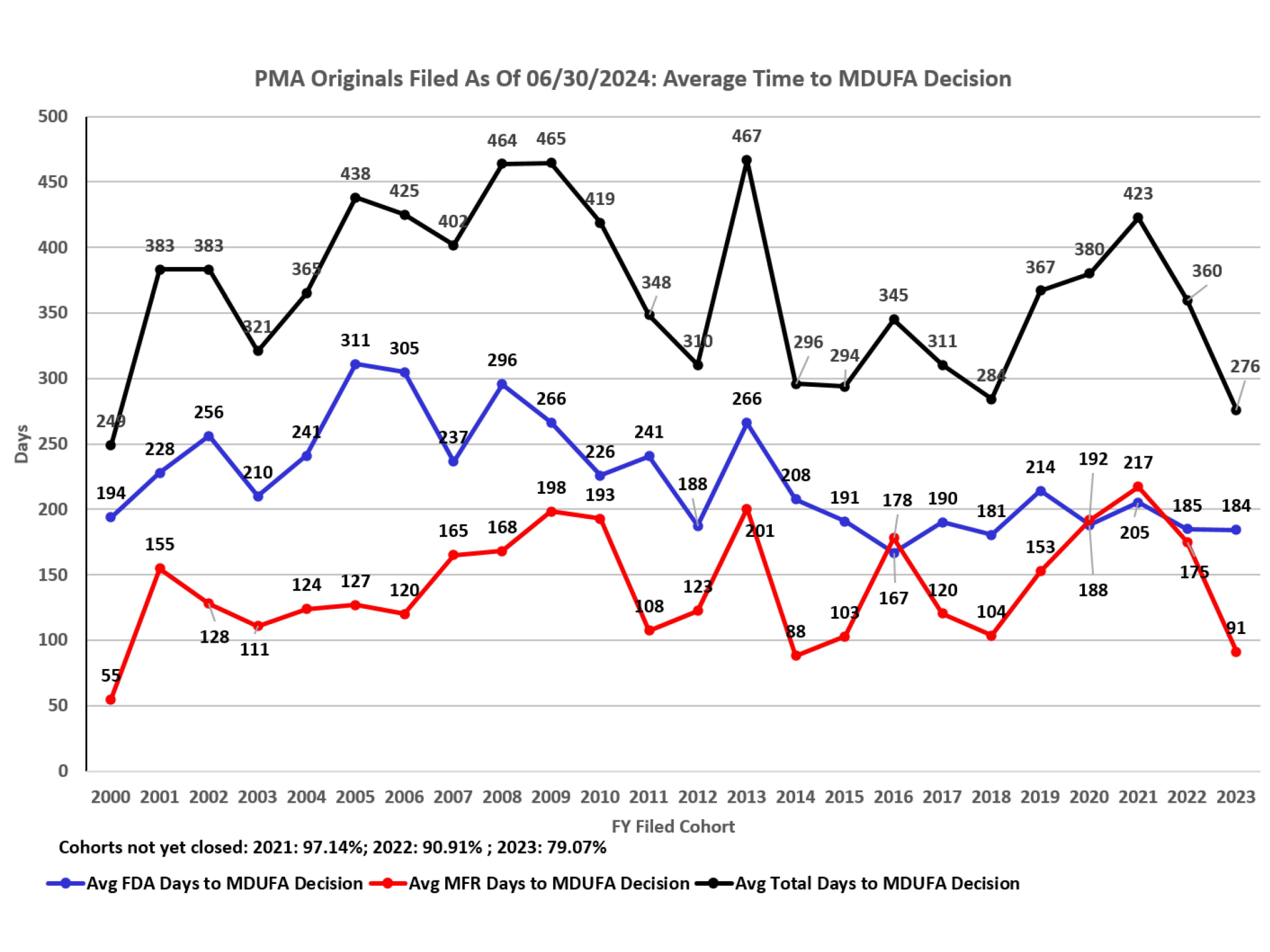
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 3/31/24.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

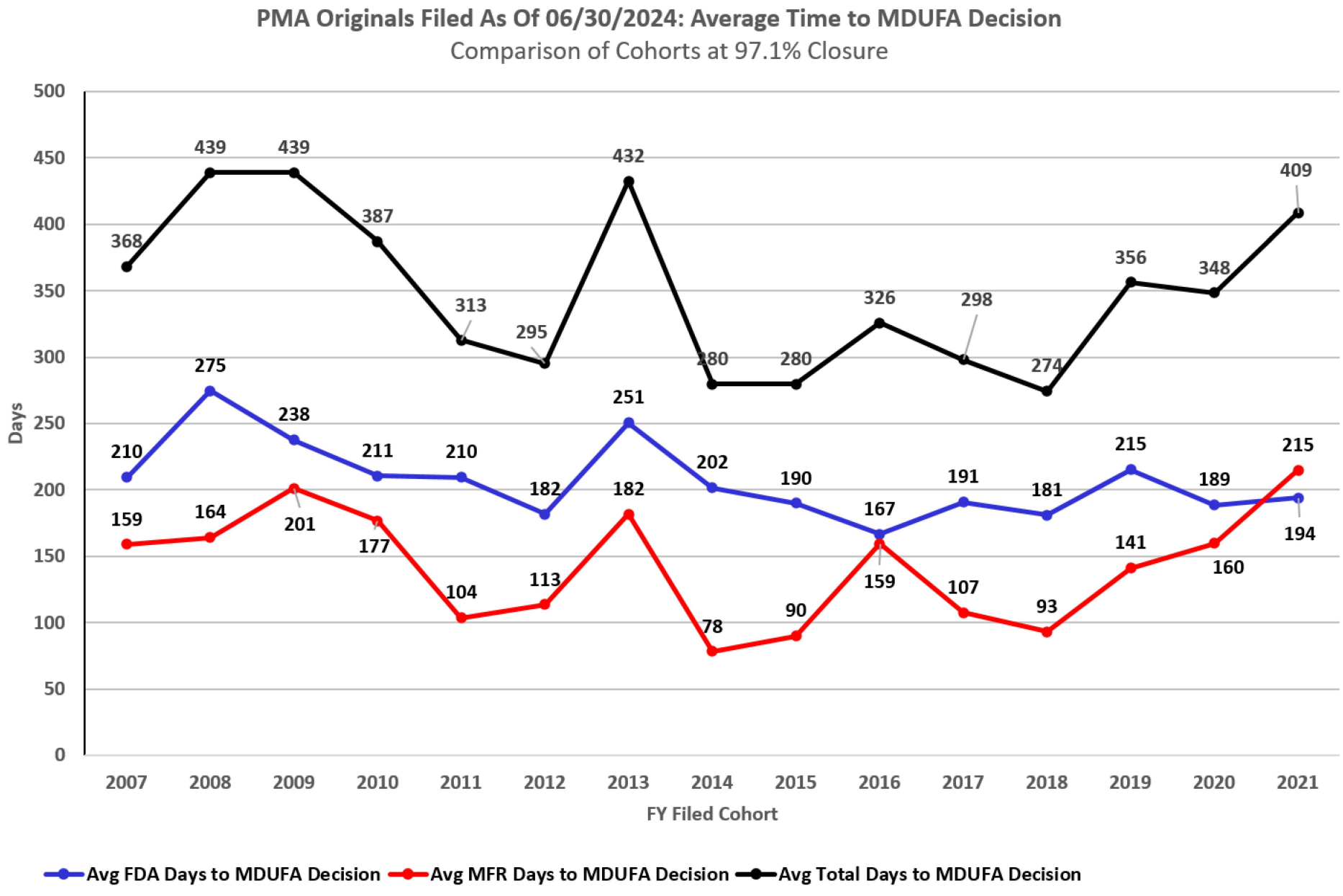
♦ % 1st Cycle MAJR PMAO

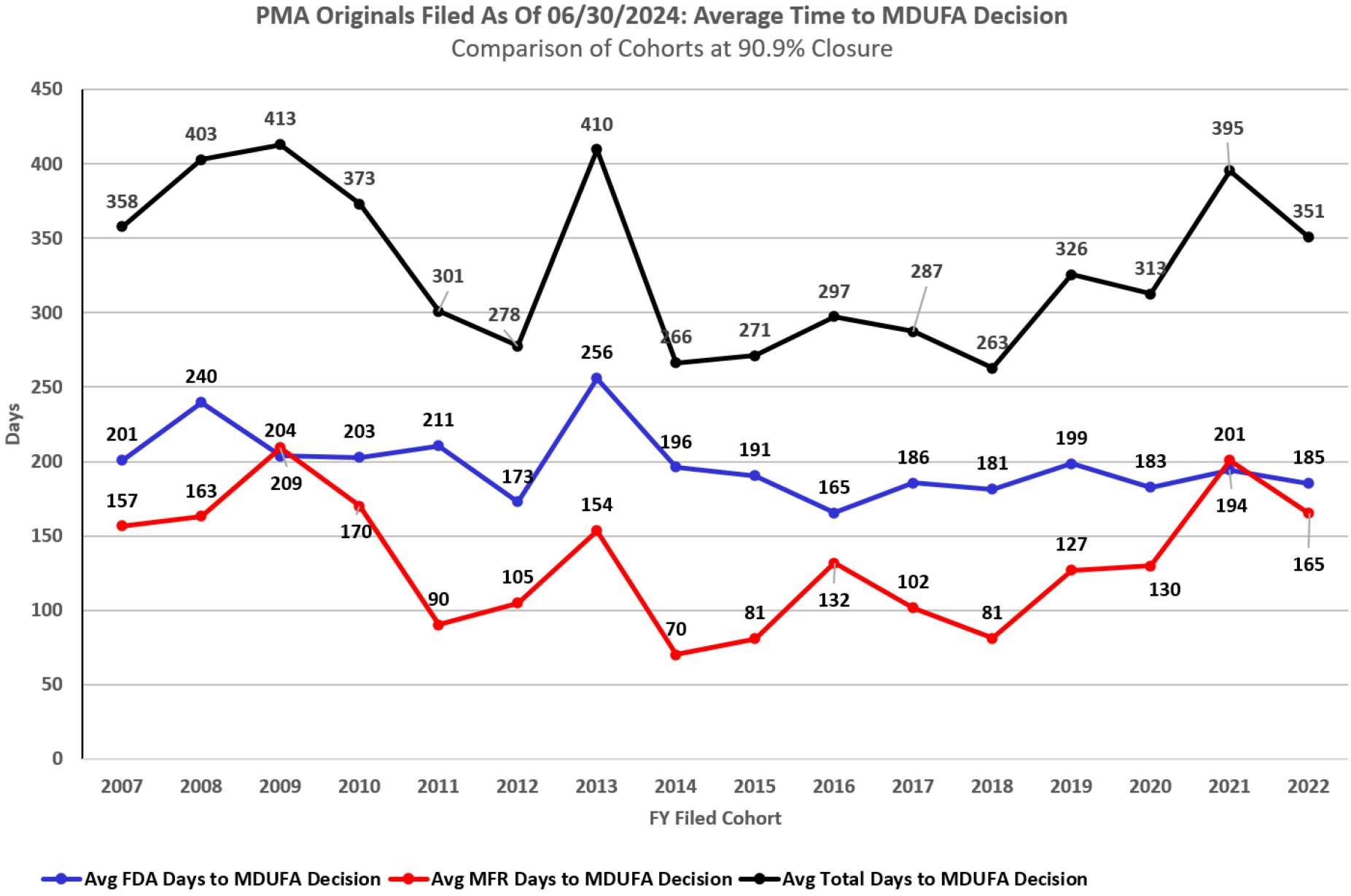


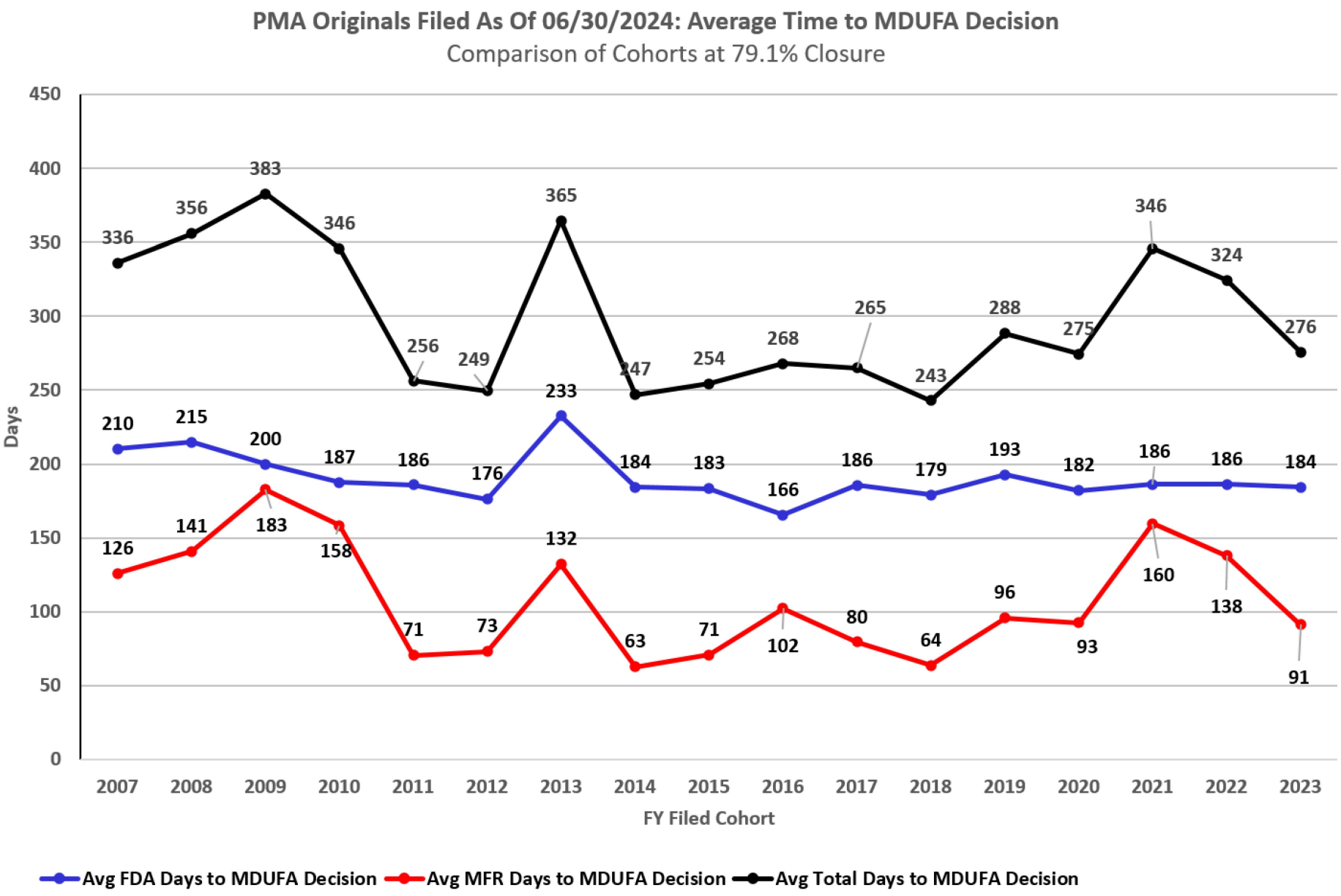
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 3/31/24. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

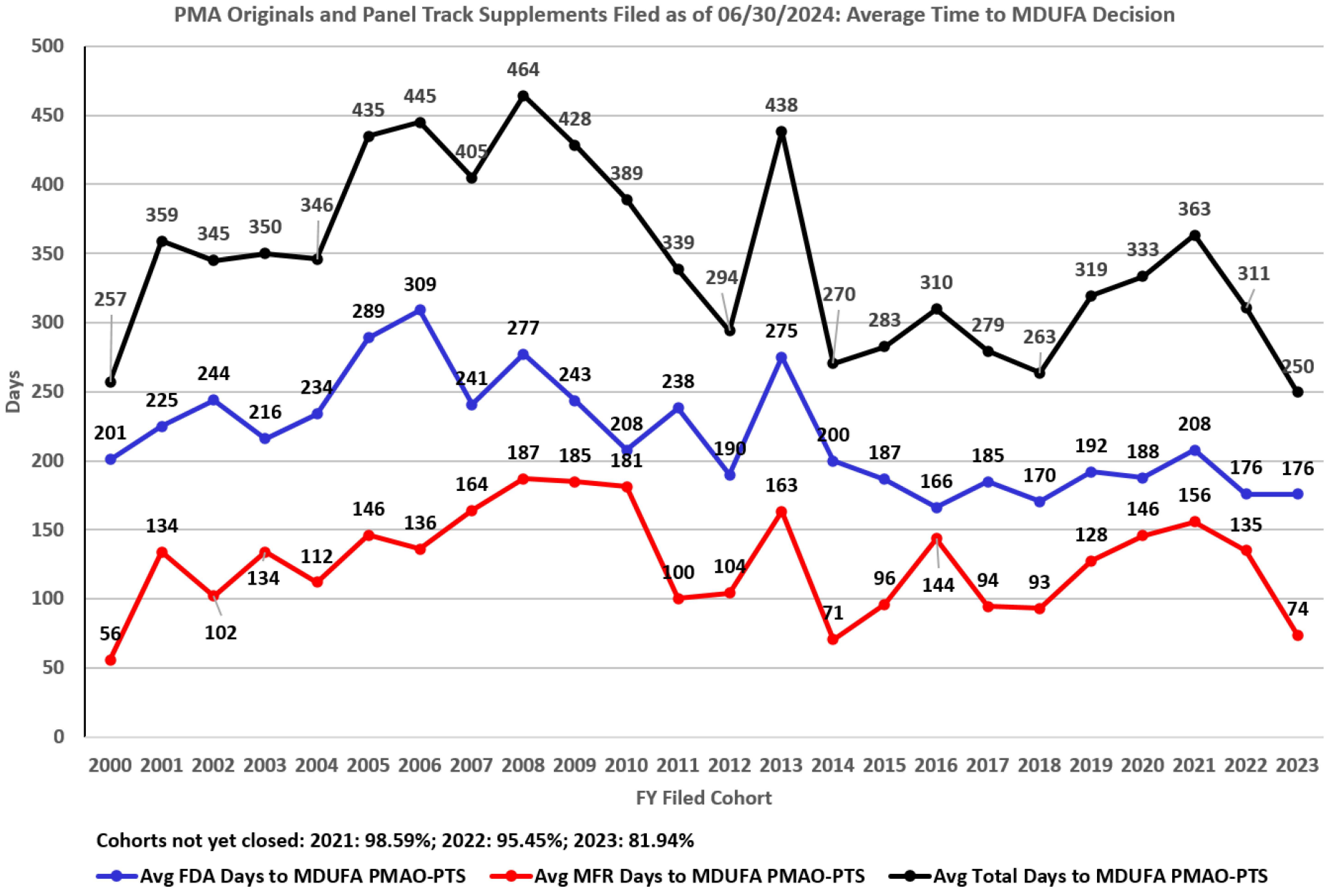
♦ % 1st Cycle MAJR PMAO/PTS

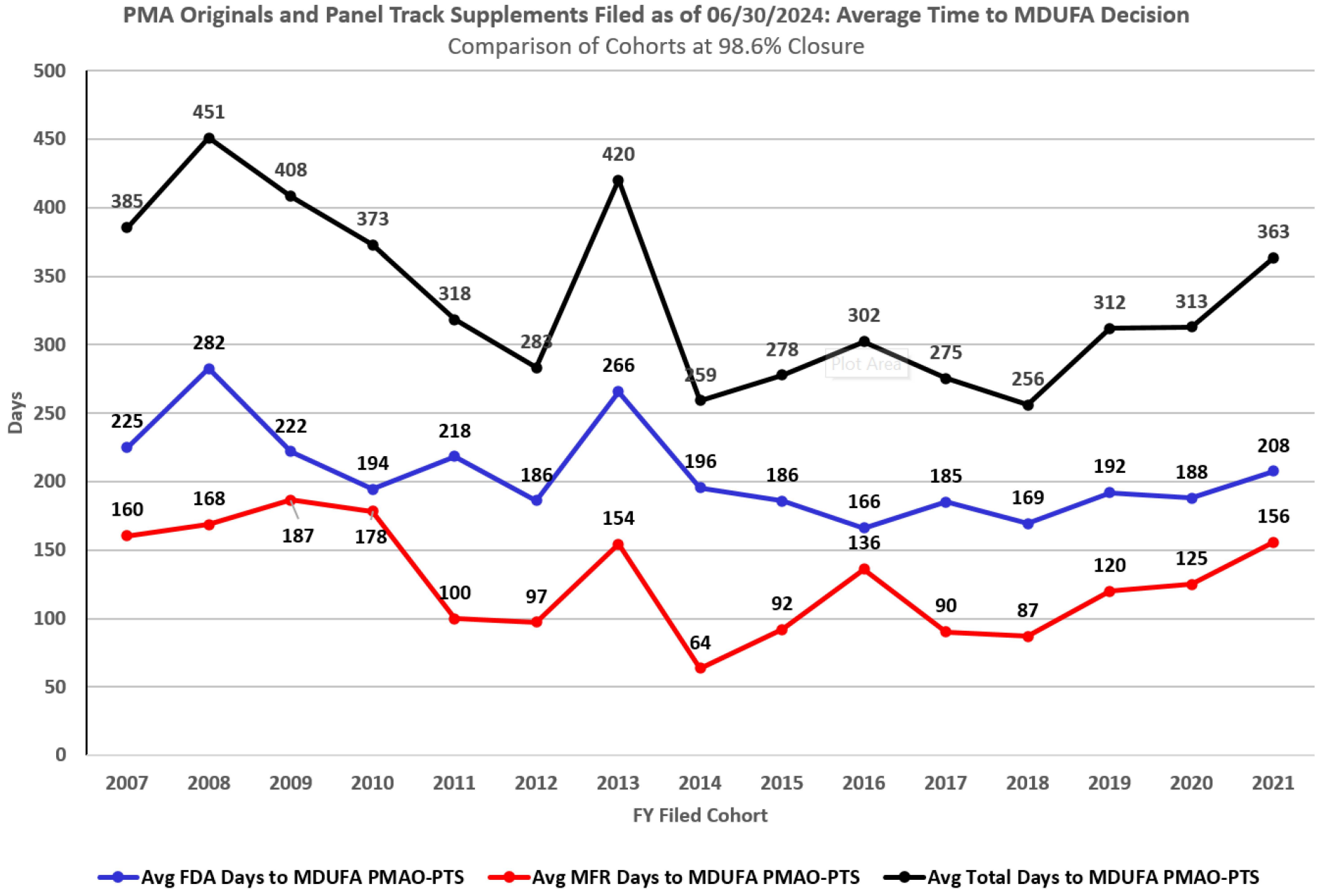

PMA Originals Filed As Of 06/30/2024: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
FY Filed Cohort
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 380 423 360 276
194 228 256 210 241 311 305 237 296 266 226 241 188 266 208 191 178 190 181 214 192 205 185 184
55 155 128 111 124 127 120 165 168 198 193 108 123 201 88 103 167 120 104 153 188 217 175 91
Cohorts not yet closed: 2021: 97.14%; 2022: 90.91% ; 2023: 79.07%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

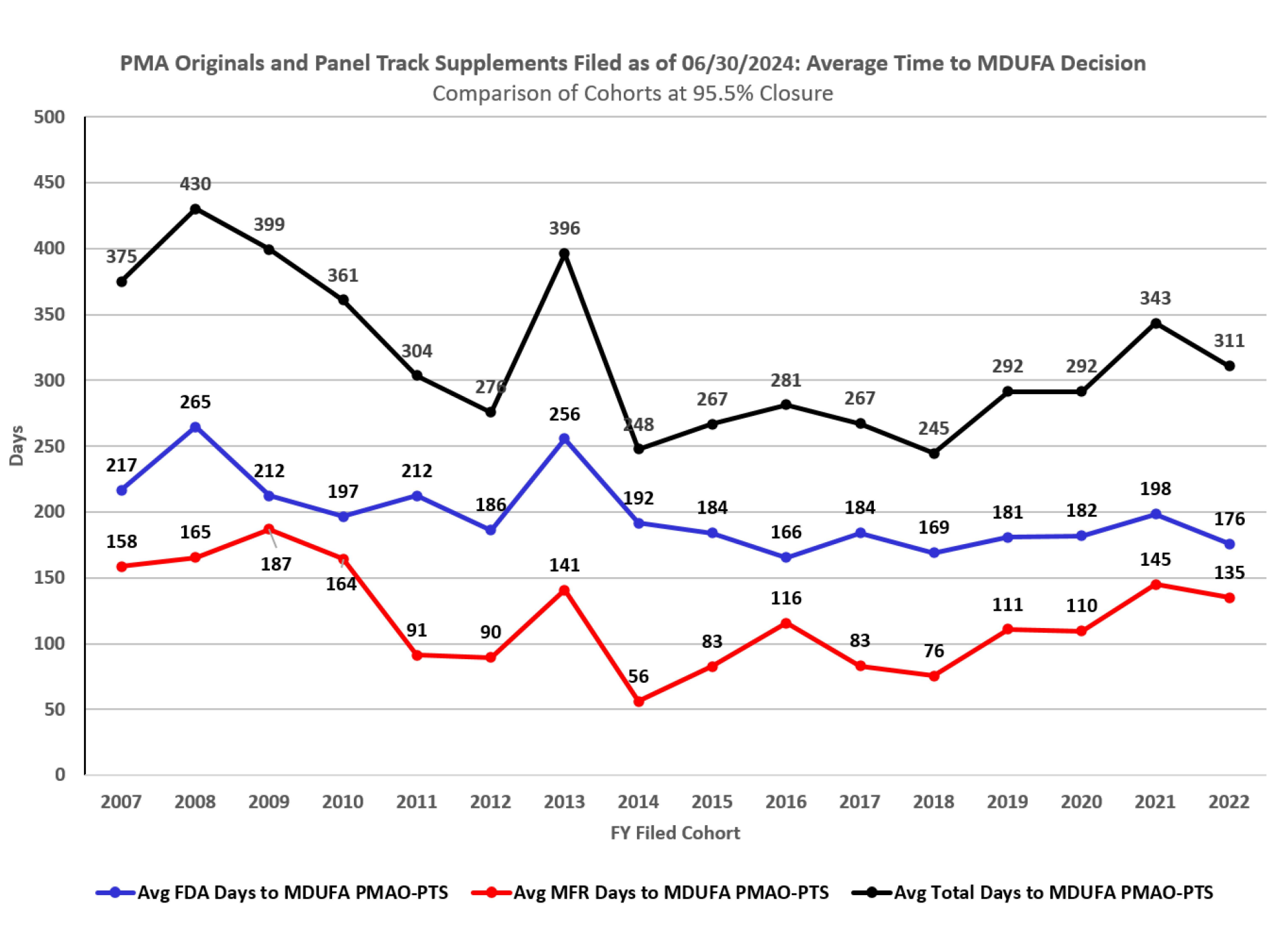

PMA Originals Filed As Of 06/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 97.1% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY Filed Cohort
368
439
439
387
313
295
432
280
280
326
298
274
356
348
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

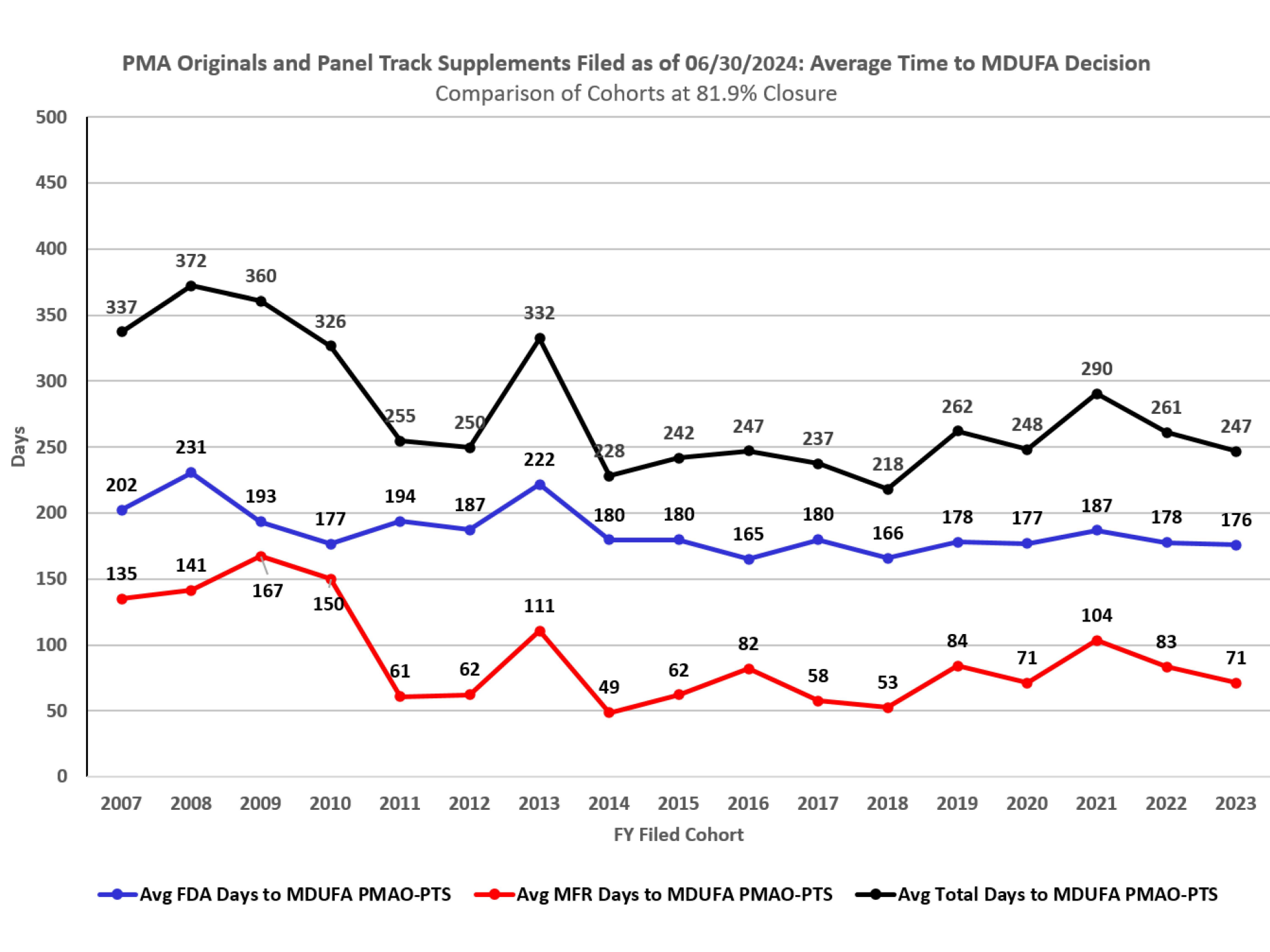

PMA Originals Filed As Of 06/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 90.9% Closure
Days
450
400
350
300
250
200
150
100
50
0
358
403
413
373
301
278
410
266
271
297
287
263
326
313
395
351
201
240
204
203
211
173
256
196
191
165
186
181
199
183
201
185
157
163
209
170
90
105
154
70
81
132
102
81
127
130
194
165
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 06/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 79.1% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
336 356 383 346 256 249 365 247 254 268 265 243 288 275 346 324 276
210 215 200 187 186 176 233 184 183 166 186 179 193 182 186 186 184
126 141 183 158 71 73 132 63 71 102 80 64 96 93 160 138 91
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

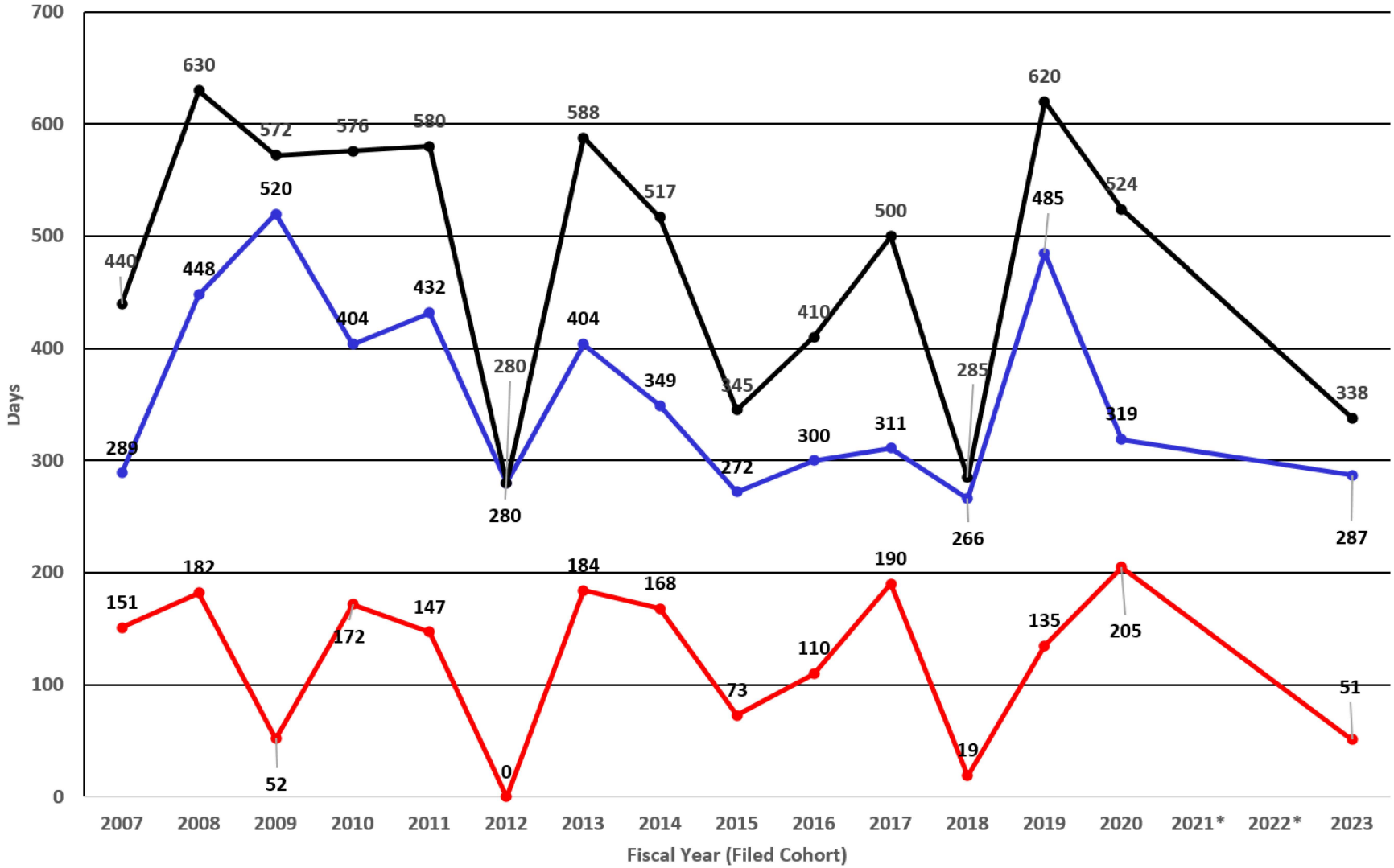

PMA Originals and Panel Track Supplements Filed as of 06/30/2024: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
FY Filed Cohort
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 263 319 333 363 311 250
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 188 208 176 176
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 93 128 146 156 135 74
Cohorts not yet closed: 2021: 98.59%; 2022: 95.45%; 2023: 81.94%
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 06/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 98.6% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
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
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS


PMA Originals and Panel Track Supplements Filed as of 06/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 95.5% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
375
430
399
361
304
270
396
248
267
281
267
245
292
292
343
311
217
265
212
197
212
186
256
192
184
166
184
169
181
182
198
176
158
165
187
164
91
90
141
56
83
116
83
76
111
110
145
135
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 06/30/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 81.9% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
337
372
360
326
255
250
332
228
242
247
237
218
262
248
290
261
247
202
231
193
177
194
187
222
180
180
165
180
166
178
177
187
178
176
135
141
167
150
61
62
111
49
62
82
58
53
84
71
104
83
71
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

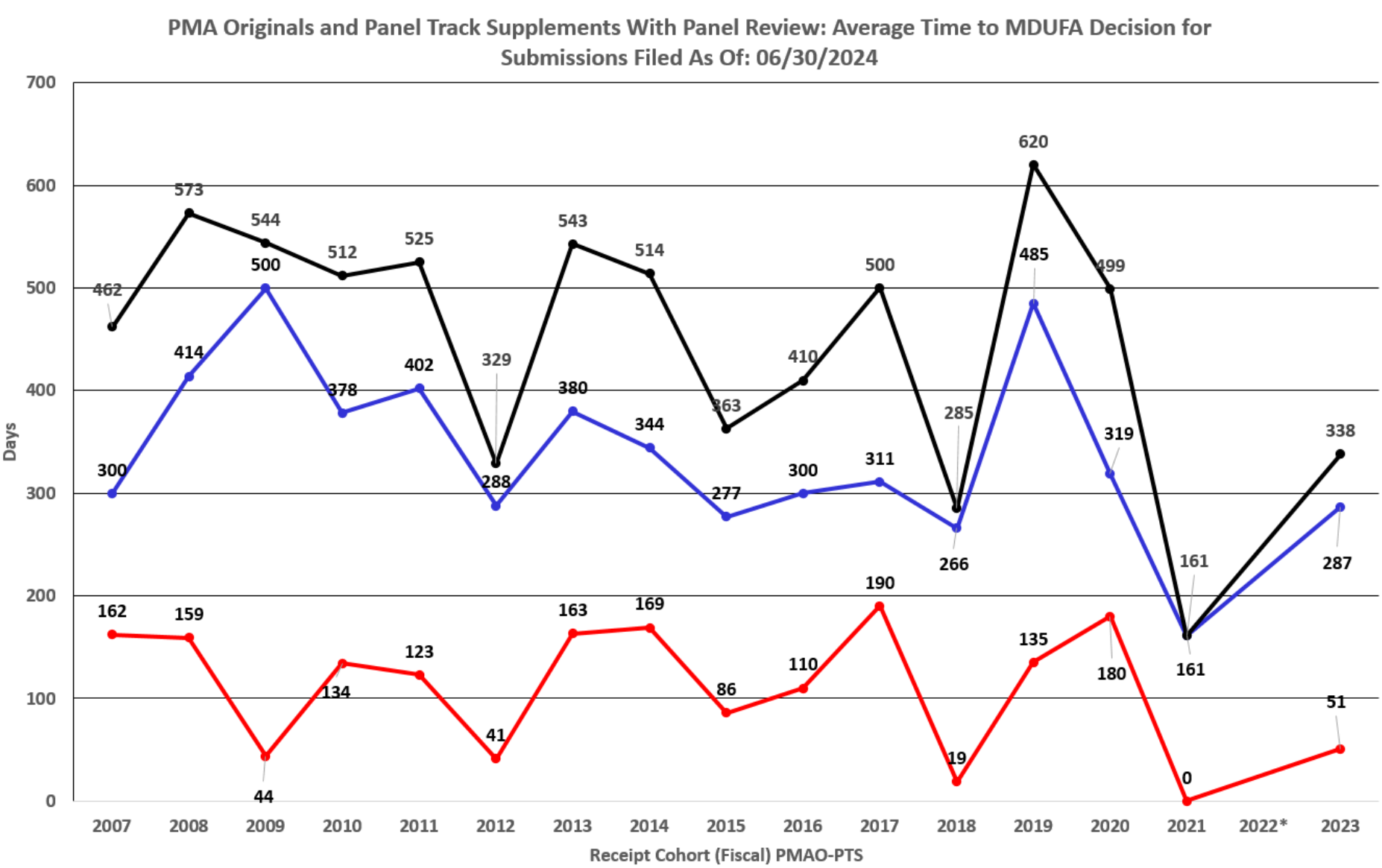
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 06/30/2024



Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2023 = 4/5

***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**

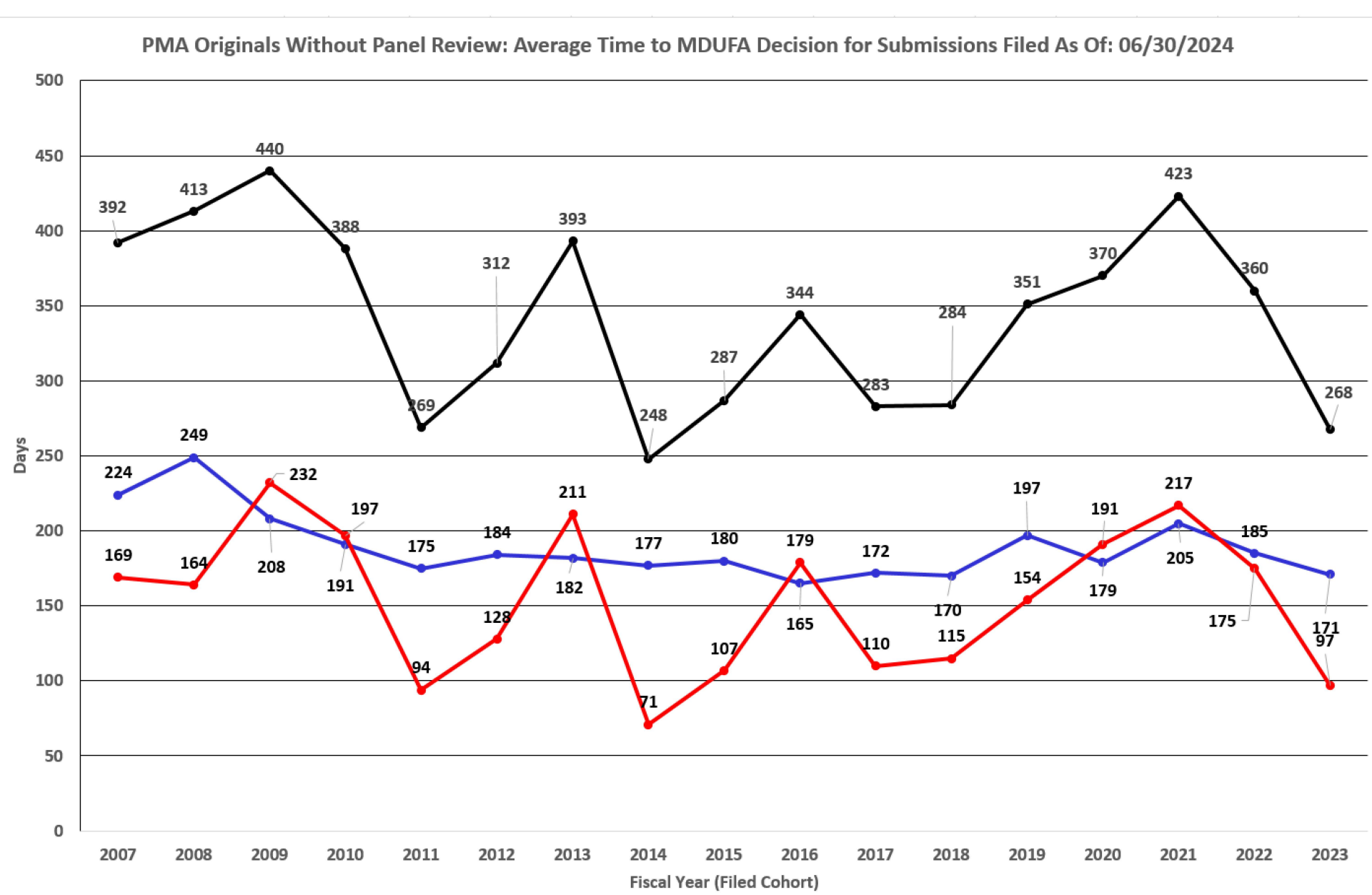


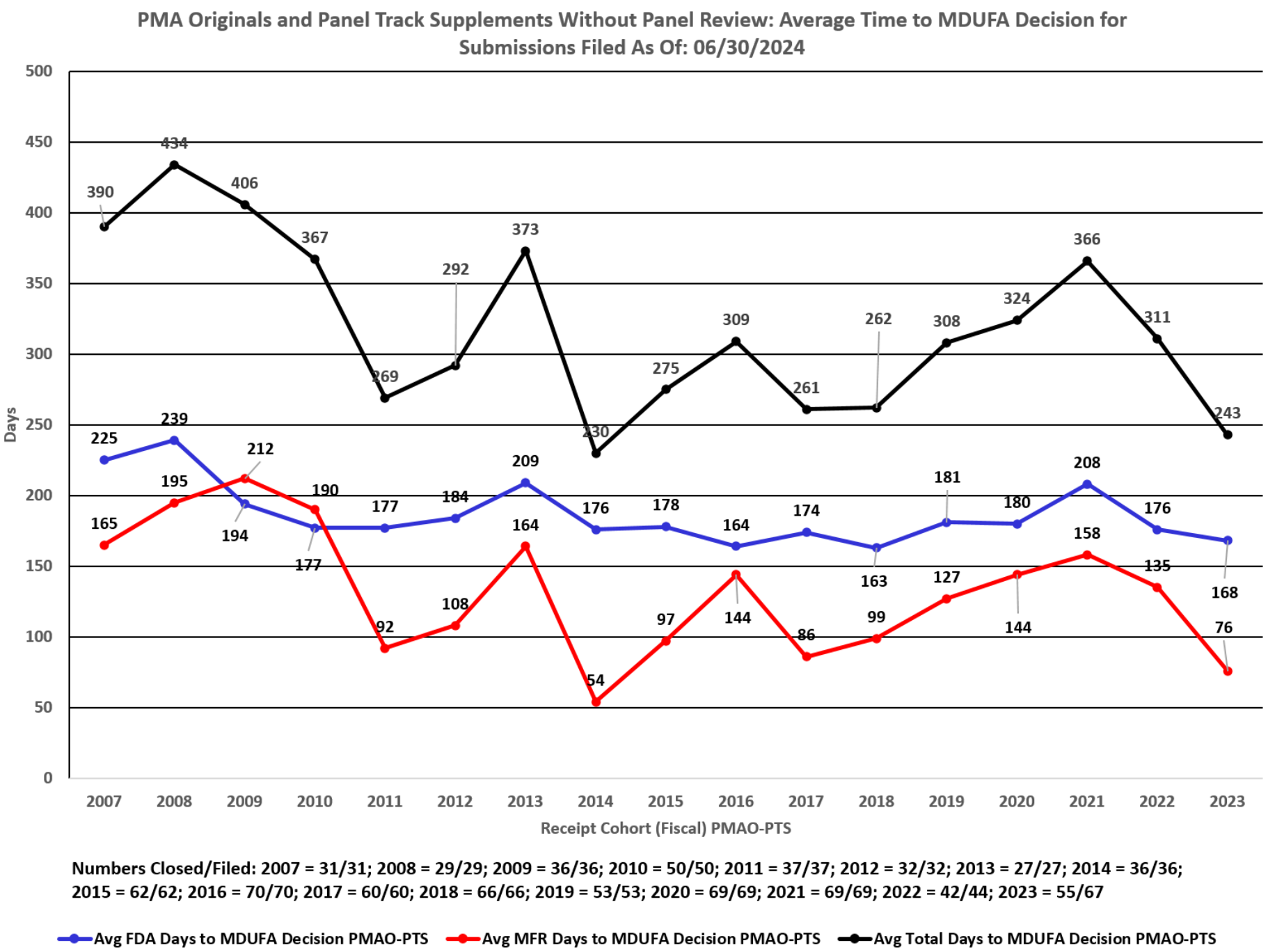
Numbers Closed/Filed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013 = 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 1/2; 2023 = 4/5

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

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

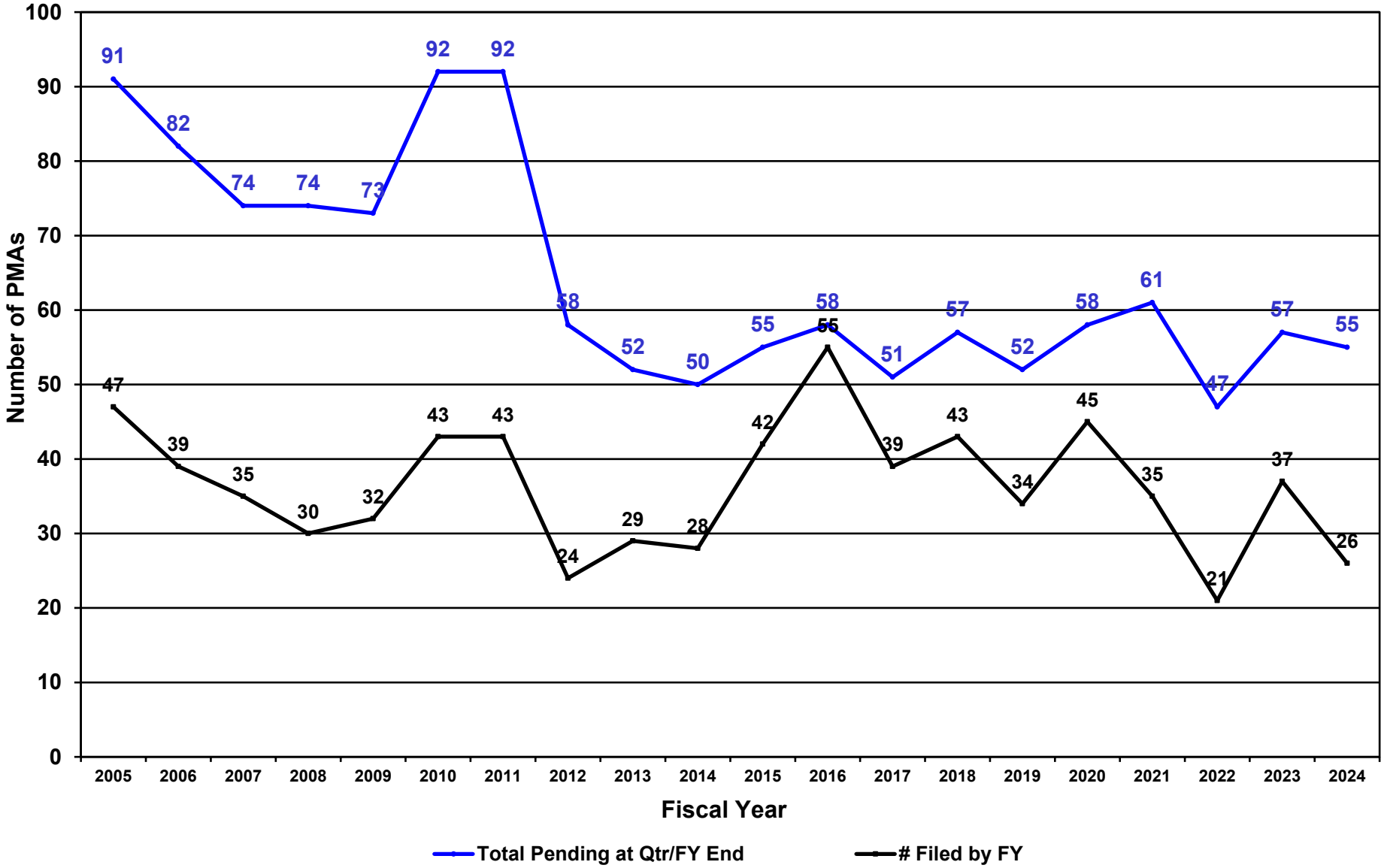
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.


PMA Originals Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 06/30/2024
Days
Fiscal Year (Filed Cohort)
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
0 50 100 150 200 250 300 350 400 450 500
392 413 440 388 269 312 393 248 287 344 283 284 351 370 423 360 268
224 249 208 191 175 184 182 177 180 165 172 170 197 179 205 185 171
169 164 232 191 94 128 211 71 107 179 110 115 154 191 217 175 97
Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 20/22; 2023 = 30/38
Avg FDA Days to MDUFA Decision PMAO
Avg MFR Days to MDUFA Decision PMAO
Avg Total Days to MDUFA Decision PMAO



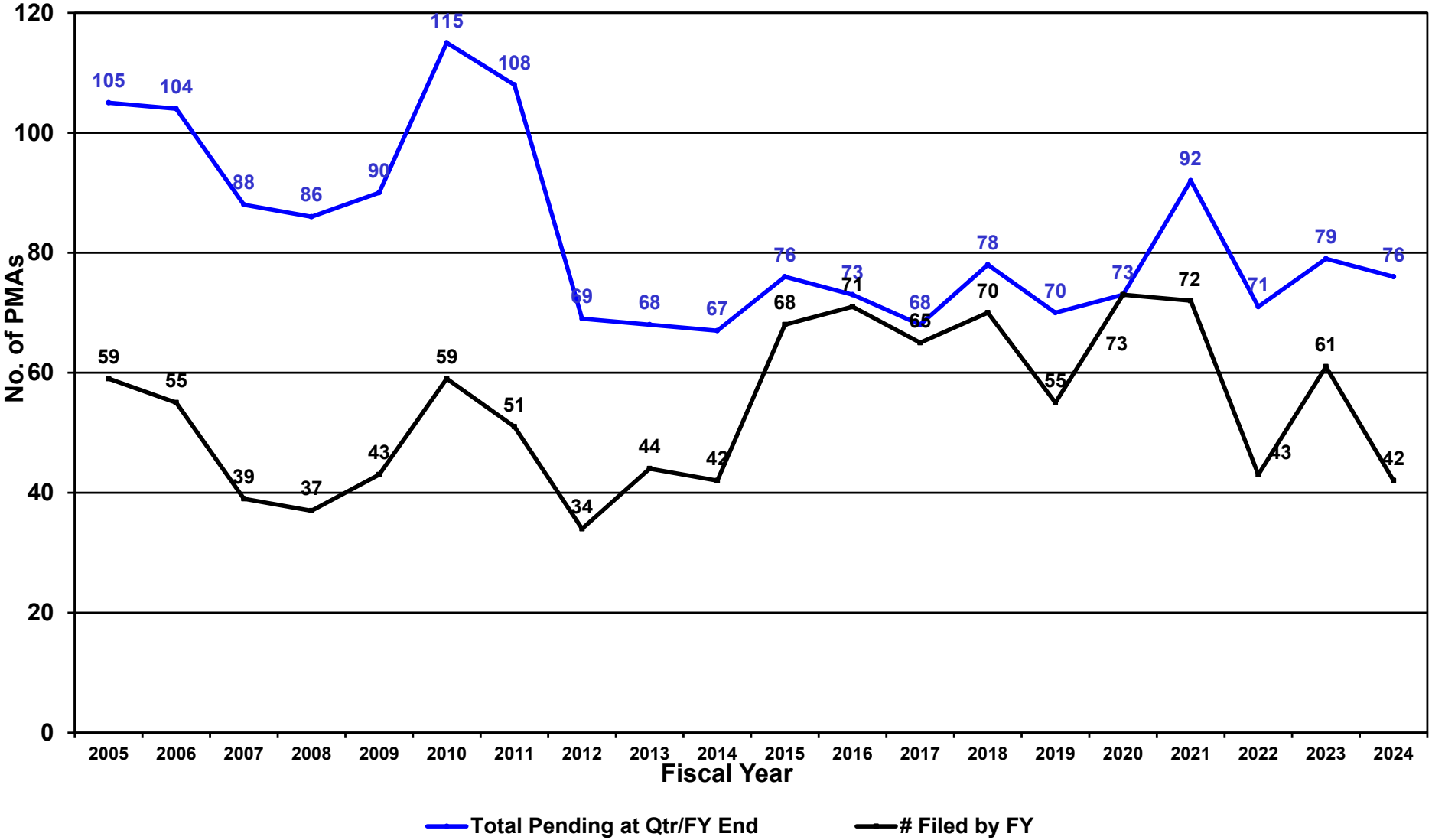
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

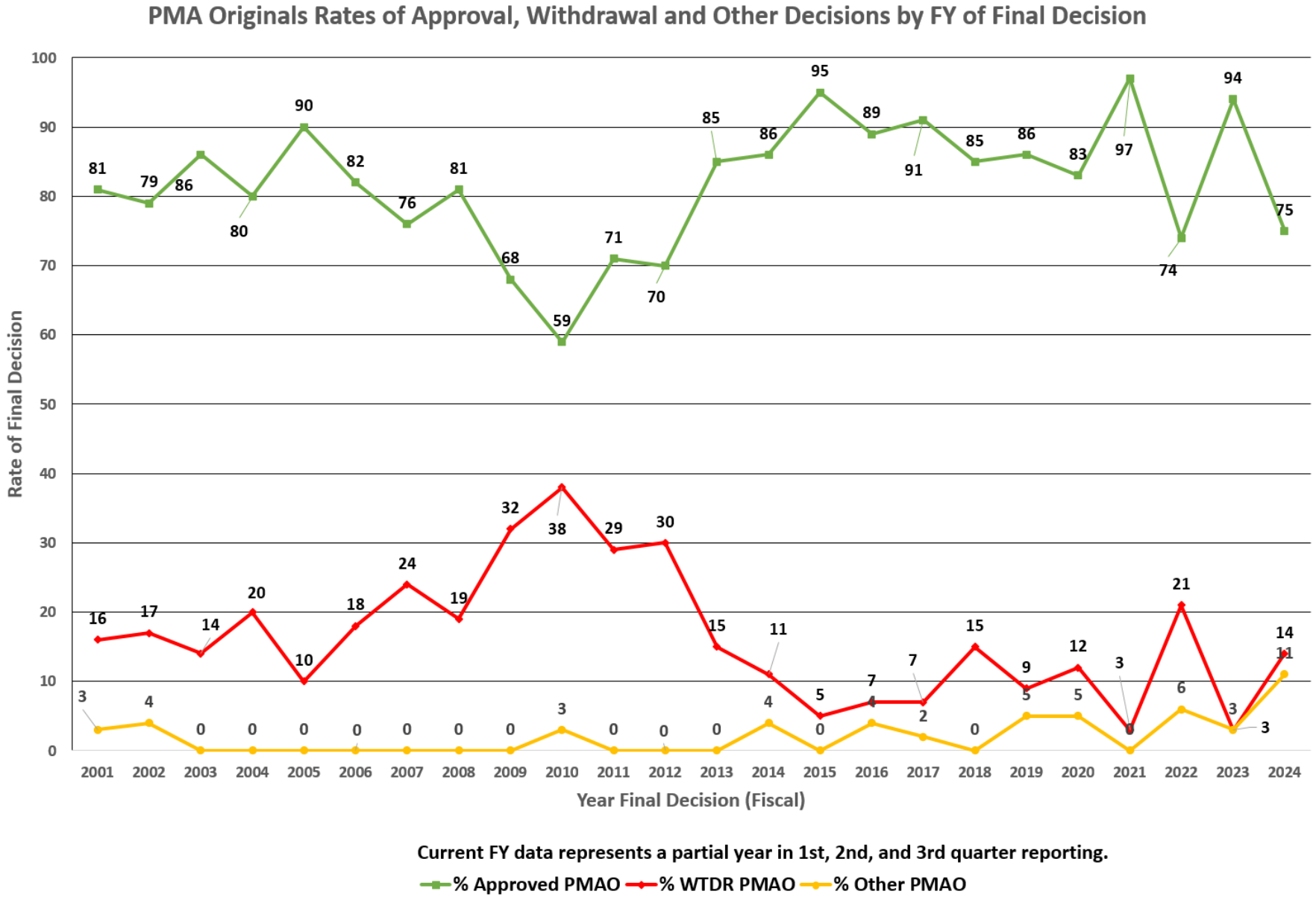


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

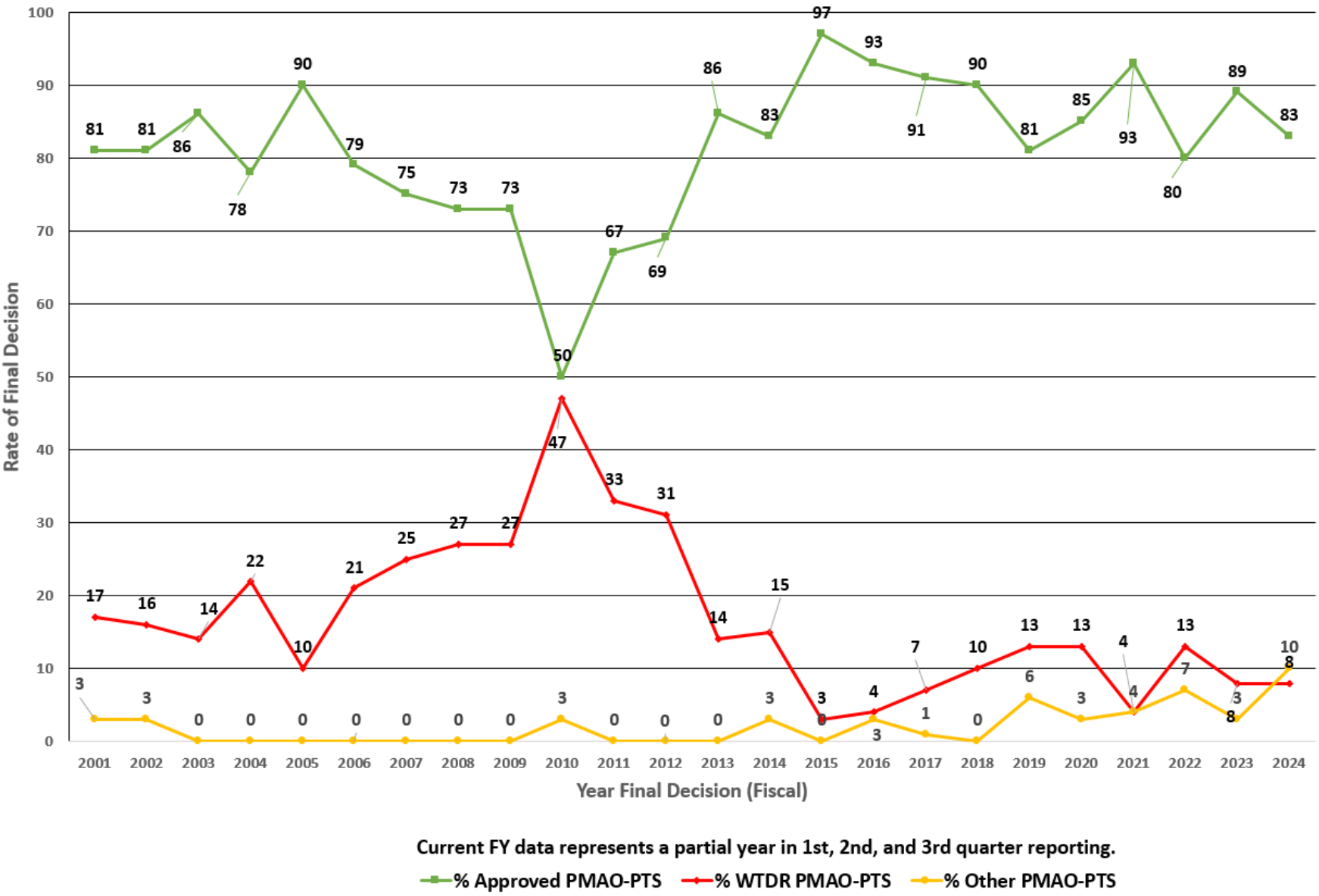
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



*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.

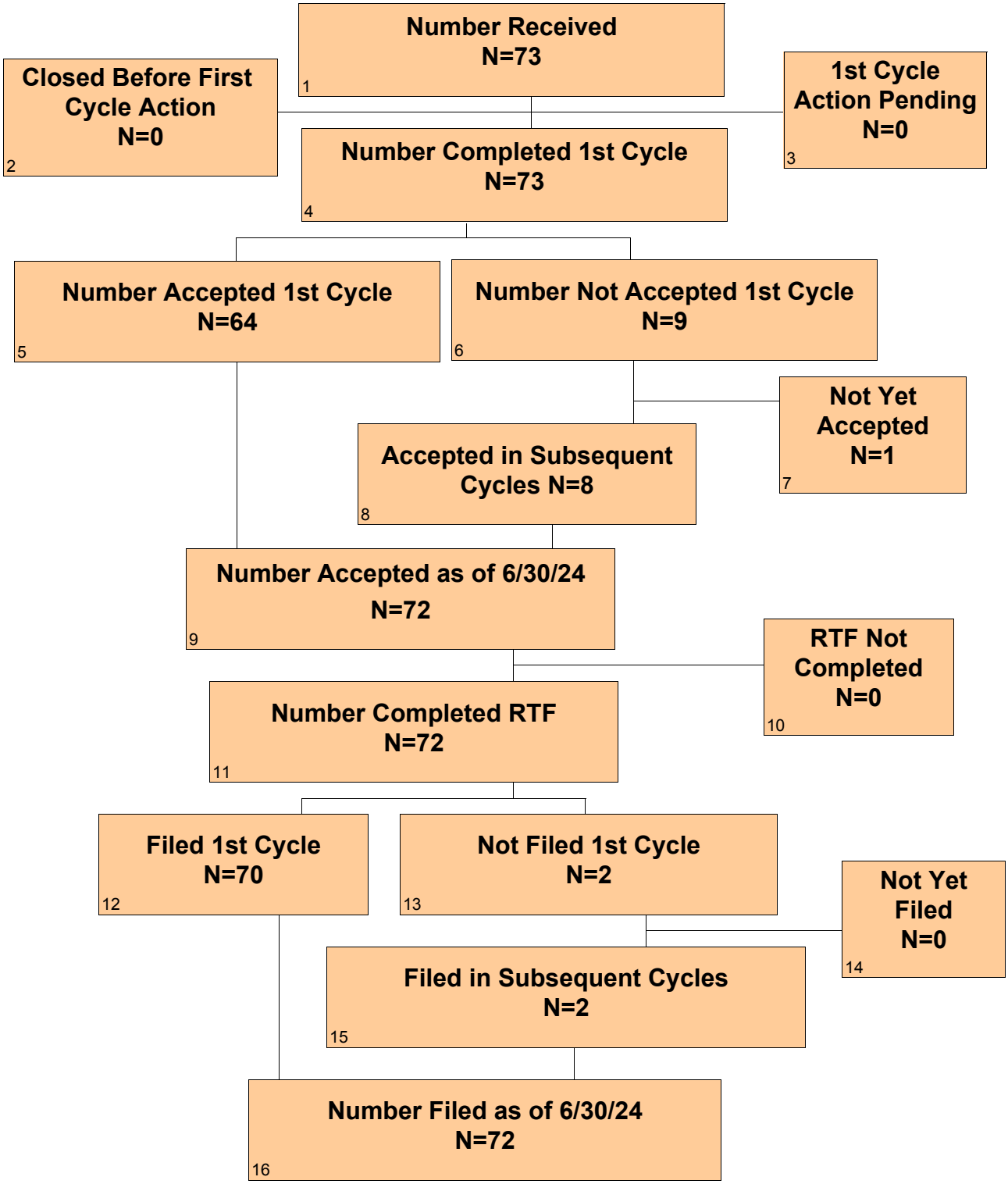


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

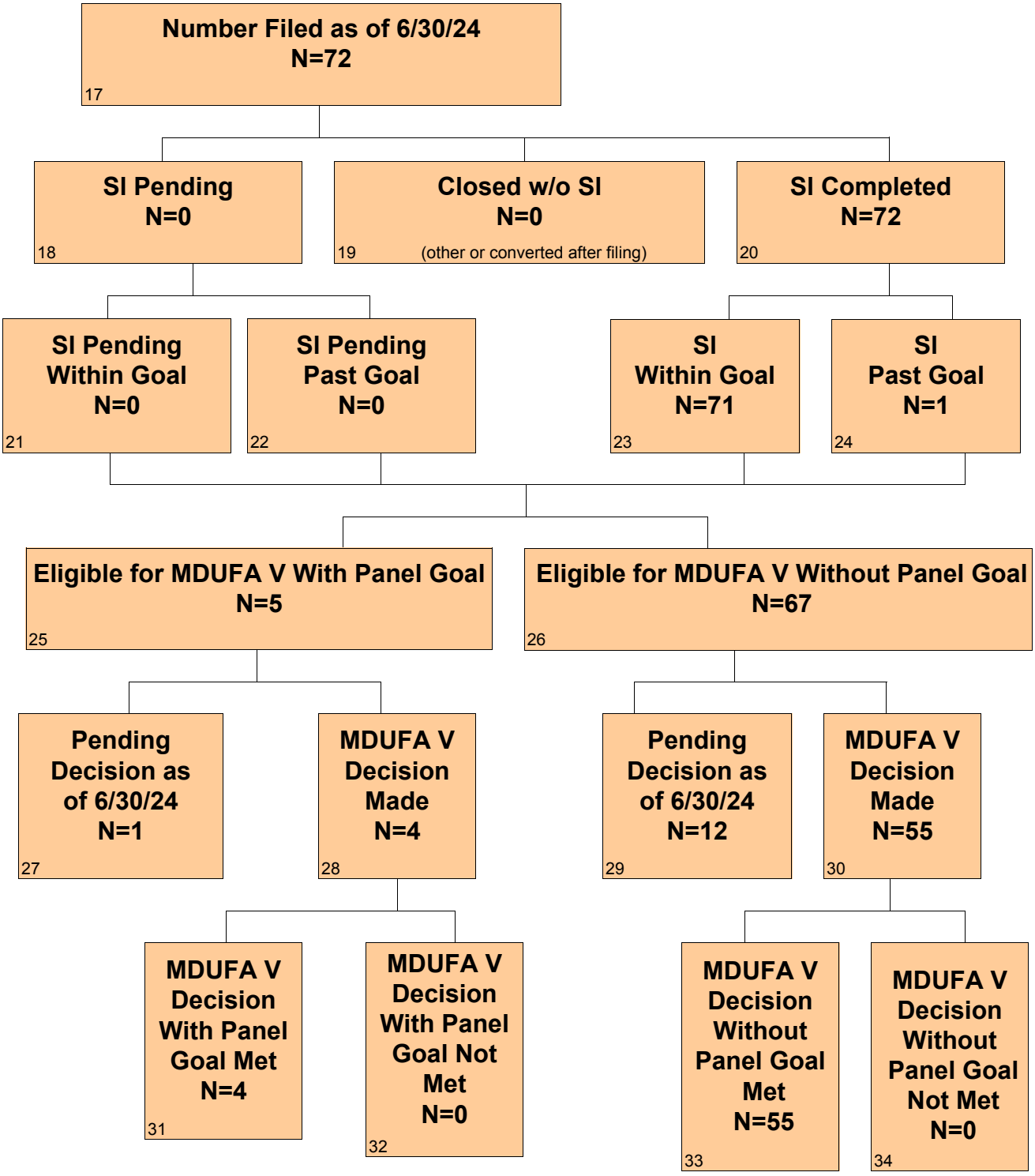


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

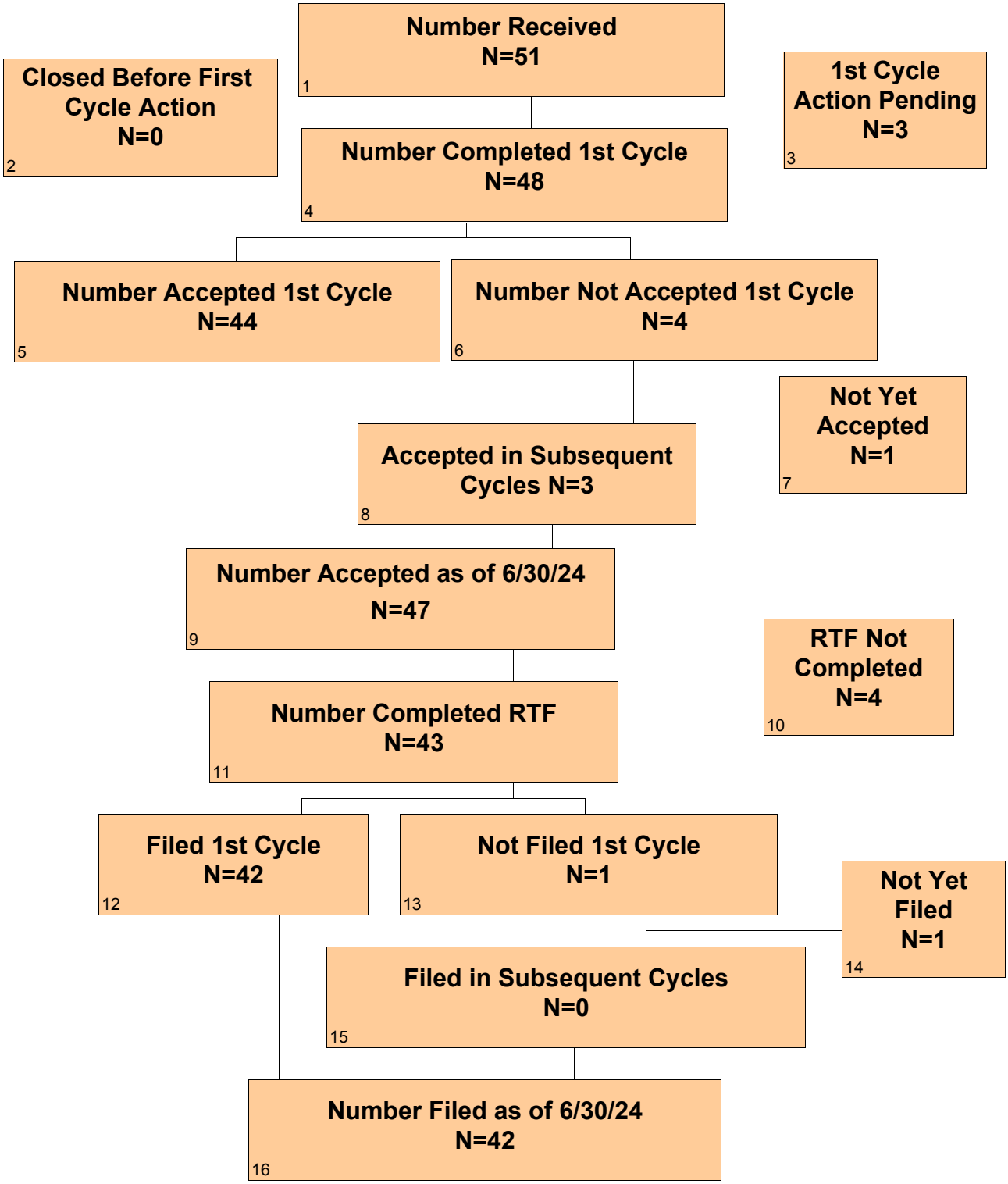
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/24



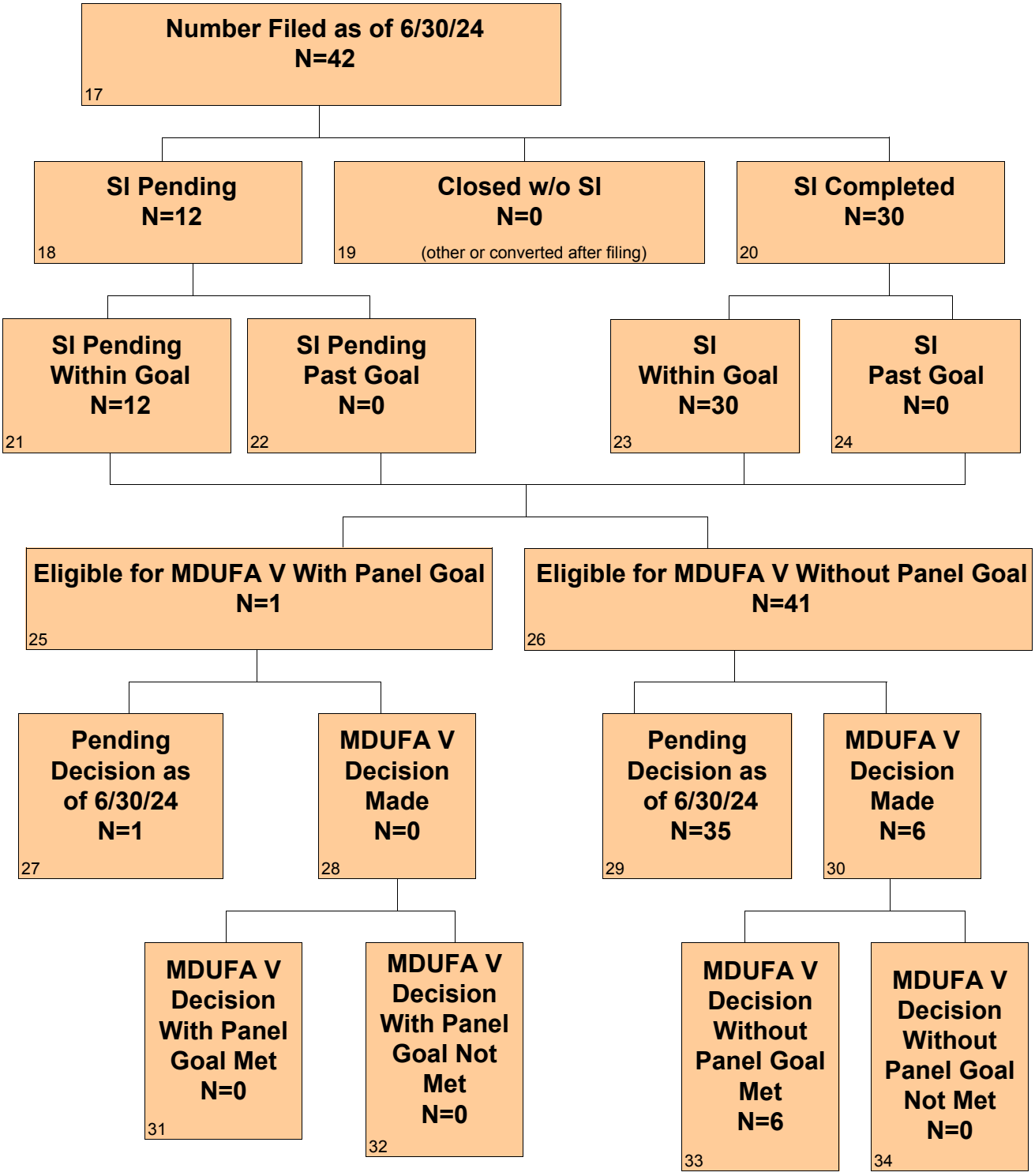
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/24 Continued



CDRH PMA Original and Panel Track Supplements - FY 2024 as of 6/30/24



CDRH PMA Original and Panel Track Supplements - FY 2024 as of 6/30/24 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	51			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	64	43			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	1			
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	4			
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.33%			

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

Table 1.2 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	51			
Number Accepted	64	44			
Completed RTF	72	43			
Number Not Filed	2	1			
Rate of Submissions Not Filed	2.78%	2.33%			

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	42			
SI Goal Met	71	30			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	12			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.61%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	72	30			
Average Number of FDA Days to Substantive Interaction	87.42	88.27			
20th Percentile FDA Days to Substantive Interaction	86	88			
40th Percentile FDA Days to Substantive Interaction	88	90			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	91	90			

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	67	41			
Non-MDUFA Decision	0	0			
MDUFA Decision	55	6			
MDUFA Decision Goal Met	55	6			
PMAs Pending MDUFA Decision	12	35			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	5	1			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
PMAs Pending MDUFA Decision	1	1			
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	55	6			
Average FDA Days to MDUFA Decision	167.58	173.83			
20th Percentile FDA Days to MDUFA Decision	163	178			
40th Percentile FDA Days to MDUFA Decision	178	178			
60th Percentile FDA Days to MDUFA Decision	180	180			
80th Percentile FDA Days to MDUFA Decision	180	180			
Maximum FDA Days to MDUFA Decision	271	180			
Average Industry Days to MDUFA Decision	75.56	6.67			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	24	0			
60th Percentile Industry Days to MDUFA Decision	60	0			
80th Percentile Industry Days to MDUFA Decision	165	10			
Maximum Industry Days to MDUFA Decision	289	30			
Average Total Days to MDUFA Decision	243.15	180.50			
20th Percentile Total Days to MDUFA Decision	178	178			
40th Percentile Total Days to MDUFA Decision	199	178			
60th Percentile Total Days to MDUFA Decision	242	180			
80th Percentile Total Days to MDUFA Decision	306	190			
Maximum Total Days to MDUFA Decision	469	210			

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	4	0			
Average FDA Days to MDUFA Decision	287.25	N/A			
20th Percentile FDA Days to MDUFA Decision	267	0			
40th Percentile FDA Days to MDUFA Decision	318	0			
60th Percentile FDA Days to MDUFA Decision	320	0			
80th Percentile FDA Days to MDUFA Decision	320	0			
Maximum FDA Days to MDUFA Decision	320	0			
Average Industry Days to MDUFA Decision	50.50	N/A			
20th Percentile Industry Days to MDUFA Decision	36	0			
40th Percentile Industry Days to MDUFA Decision	44	0			
60th Percentile Industry Days to MDUFA Decision	54	0			
80th Percentile Industry Days to MDUFA Decision	65	0			
Maximum Industry Days to MDUFA Decision	76	0			
Average Total Days to MDUFA Decision	337.75	N/A			
20th Percentile Total Days to MDUFA Decision	303	0			
40th Percentile Total Days to MDUFA Decision	363	0			
60th Percentile Total Days to MDUFA Decision	373	0			
80th Percentile Total Days to MDUFA Decision	385	0			
Maximum Total Days to MDUFA Decision	396	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	41			
Number with MDUFA Decision	55	6			
Number of Withdrawal	3	0			
Number of Not Approvable	7	0			
Number of Deleted	0	0			
Rate of Withdrawal	5.45%	0.00%			
Rate of Not Approvable	12.73%	0.00%			

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	1			
Number With MDUFA Decision	4	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	25.00%	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	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Goal Met	5	0			
PMAs Pending MDUFA Decision	1	2			
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	8			
Non-MDUFA Decision	0	0			
MDUFA Decision	10	1			
MDUFA Decision Goal Met	10	1			
PMAs Pending MDUFA Decision	5	7			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

***Includes submission that went to panel**

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	3	5			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0			
Number Not Accepted for Filing Review on First Cycle	6	1			
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	16.67%			

***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	6			
Number Accepted	3	5			
Completed RTF	8	6			
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	6			
SI Goal Met	8	5			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	8	5			
Average Number of FDA Days to Substantive Interaction	82.00	90.00			
20th Percentile FDA Days to Substantive Interaction	87	90			
40th Percentile FDA Days to Substantive Interaction	90	90			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	8	6			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	0			
MDUFA Decision Goal Met	4	0			
PMAs Pending MDUFA Decision	4	6			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	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	6			
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	14			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	19	12			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	1			
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	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	14			
Number Accepted	19	13			
Completed RTF	20	12			
Number Not Filed	0	1			
Rate of Submissions Not Filed	0.00%	8.33%			

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	11			
SI Goal Met	20	10			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 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	10			
Average Number of FDA Days to Substantive Interaction	88.25	88.20			
20th Percentile FDA Days to Substantive Interaction	86	86			
40th Percentile FDA Days to Substantive Interaction	90	90			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	17	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	17	5			
MDUFA Decision Goal Met	17	5			
PMAs Pending MDUFA Decision	0	6			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	5			
Average FDA Days to MDUFA Decision	177.65	172.60			
20th Percentile FDA Days to MDUFA Decision	172	172			
40th Percentile FDA Days to MDUFA Decision	177	178			
60th Percentile FDA Days to MDUFA Decision	180	179			
80th Percentile FDA Days to MDUFA Decision	180	180			
Maximum FDA Days to MDUFA Decision	271	180			
Average Industry Days to MDUFA Decision	64.29	8.00			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	23	0			
60th Percentile Industry Days to MDUFA Decision	47	4			
80th Percentile Industry Days to MDUFA Decision	113	14			
Maximum Industry Days to MDUFA Decision	271	30			
Average Total Days to MDUFA Decision	241.94	180.60			
20th Percentile Total Days to MDUFA Decision	176	172			
40th Percentile Total Days to MDUFA Decision	201	178			
60th Percentile Total Days to MDUFA Decision	236	183			
80th Percentile Total Days to MDUFA Decision	305	194			
Maximum Total Days to MDUFA Decision	442	210			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	17	11			
Number with MDUFA Decision	17	5			
Number of Withdrawal	1	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	5.88%	0.00%			
Rate of Not Approvable	17.65%	0.00%			

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

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

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

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	3			
SI Goal Met	3	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 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	2			
Average Number of FDA Days to Substantive Interaction	88.33	80.50			
20th Percentile FDA Days to Substantive Interaction	87	75			
40th Percentile FDA Days to Substantive Interaction	88	79			
60th Percentile FDA Days to Substantive Interaction	88	82			
80th Percentile FDA Days to Substantive Interaction	89	86			
Maximum FDA Days to Substantive Interaction	90	90			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	9	5			
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 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6			
Number Accepted	9	5			
Completed RTF	9	5			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0.00%	0.00%			

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	9	5			
SI Goal Met	9	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 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	3			
Average Number of FDA Days to Substantive Interaction	88.78	88.67			
20th Percentile FDA Days to Substantive Interaction	88	88			
40th Percentile FDA Days to Substantive Interaction	90	89			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	89			
Maximum FDA Days to Substantive Interaction	90	89			

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	4			
Non-MDUFA Decision	0	0			
MDUFA Decision	8	0			
MDUFA Decision Goal Met	8	0			
PMAs Pending MDUFA Decision	1	4			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	4			
Number with MDUFA Decision	8	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	12.50%	N/A			

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	5			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	5	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	1	1			
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	20.00%			

***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	5			
Number Accepted	5	4			
Completed RTF	6	3			
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	3			
SI Goal Met	5	2			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	83.33%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	6	2			
Average Number of FDA Days to Substantive Interaction	88.50	89.00			
20th Percentile FDA Days to Substantive Interaction	88	88			
40th Percentile FDA Days to Substantive Interaction	90	89			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	91	90			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	6	0			
Average FDA Days to MDUFA Decision	175.33	N/A			
20th Percentile FDA Days to MDUFA Decision	179	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	55.17	N/A			
20th Percentile Industry Days to MDUFA Decision	0	0			
40th Percentile Industry Days to MDUFA Decision	37	0			
60th Percentile Industry Days to MDUFA Decision	71	0			
80th Percentile Industry Days to MDUFA Decision	101	0			
Maximum Industry Days to MDUFA Decision	122	0			
Average Total Days to MDUFA Decision	230.50	N/A			
20th Percentile Total Days to MDUFA Decision	180	0			
40th Percentile Total Days to MDUFA Decision	217	0			
60th Percentile Total Days to MDUFA Decision	251	0			
80th Percentile Total Days to MDUFA Decision	281	0			
Maximum Total Days to MDUFA Decision	301	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	3			
Number with MDUFA Decision	6	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	16.67%	N/A			

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

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

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

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	5	3			
SI Goal Met	5	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 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	2			
Average Number of FDA Days to Substantive Interaction	85.40	87.00			
20th Percentile FDA Days to Substantive Interaction	84	87			
40th Percentile FDA Days to Substantive Interaction	86	87			
60th Percentile FDA Days to Substantive Interaction	87	87			
80th Percentile FDA Days to Substantive Interaction	88	87			
Maximum FDA Days to Substantive Interaction	88	87			

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	5	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	3	0			
MDUFA Decision Goal Met	3	0			
PMAs Pending MDUFA Decision	2	3			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	0			
Average FDA Days to MDUFA Decision	170.00	N/A			
20th Percentile FDA Days to MDUFA Decision	165	0			
40th Percentile FDA Days to MDUFA Decision	169	0			
60th Percentile FDA Days to MDUFA Decision	172	0			
80th Percentile FDA Days to MDUFA Decision	175	0			
Maximum FDA Days to MDUFA Decision	178	0			
Average Industry Days to MDUFA Decision	89.33	N/A			
20th Percentile Industry Days to MDUFA Decision	38	0			
40th Percentile Industry Days to MDUFA Decision	77	0			
60th Percentile Industry Days to MDUFA Decision	111	0			
80th Percentile Industry Days to MDUFA Decision	142	0			
Maximum Industry Days to MDUFA Decision	172	0			
Average Total Days to MDUFA Decision	259.33	N/A			
20th Percentile Total Days to MDUFA Decision	210	0			
40th Percentile Total Days to MDUFA Decision	241	0			
60th Percentile Total Days to MDUFA Decision	274	0			
80th Percentile Total Days to MDUFA Decision	309	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	3			
Number with MDUFA Decision	3	0			
Number of Withdrawal	0	0			
Number of Not Approvable	2	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	66.67%	N/A			

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	13			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	21	10			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	1			
Number Not Accepted for Filing Review on First Cycle	0	2			
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	16.67%			

***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	13			
Number Accepted	21	10			
Completed RTF	21	10			
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	10			
SI Goal Met	21	5			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	5			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	21	5			
Average Number of FDA Days to Substantive Interaction	88.14	89.40			
20th Percentile FDA Days to Substantive Interaction	87	89			
40th Percentile FDA Days to Substantive Interaction	87	90			
60th Percentile FDA Days to Substantive Interaction	89	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	20	10			
Non-MDUFA Decision	0	0			
MDUFA Decision	15	1			
MDUFA Decision Goal Met	15	1			
PMAs Pending MDUFA Decision	5	9			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	1	0			
Non-MDUFA Decision	0	0			
MDUFA Decision	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	15	1			
Average FDA Days to MDUFA Decision	158.13	180.00			
20th Percentile FDA Days to MDUFA Decision	136	180			
40th Percentile FDA Days to MDUFA Decision	178	180			
60th Percentile FDA Days to MDUFA Decision	179	180			
80th Percentile FDA Days to MDUFA Decision	180	180			
Maximum FDA Days to MDUFA Decision	180	180			
Average Industry Days to MDUFA Decision	101.93	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	120	0			
80th Percentile Industry Days to MDUFA Decision	232	0			
Maximum Industry Days to MDUFA Decision	289	0			
Average Total Days to MDUFA Decision	260.07	180.00			
20th Percentile Total Days to MDUFA Decision	179	180			
40th Percentile Total Days to MDUFA Decision	191	180			
60th Percentile Total Days to MDUFA Decision	282	180			
80th Percentile Total Days to MDUFA Decision	350	180			
Maximum Total Days to MDUFA Decision	469	180			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	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	10			
Number with MDUFA Decision	15	1			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	6.67%	0.00%			
Rate of Not Approvable	0.00%	0.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0			
Number With MDUFA Decision	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	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	5	0			
MDUFA Decision Goal Met	5	0			
PMAs Pending MDUFA Decision	1	2			
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	8			
Non-MDUFA Decision	0	0			
MDUFA Decision	10	1			
MDUFA Decision Goal Met	10	1			
PMAs Pending MDUFA Decision	5	7			
PMAs Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0	1			
Number Closed Before First RTA Action	0	0			
Number Accepted First RTA Review	0	1			
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	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	0.00%			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

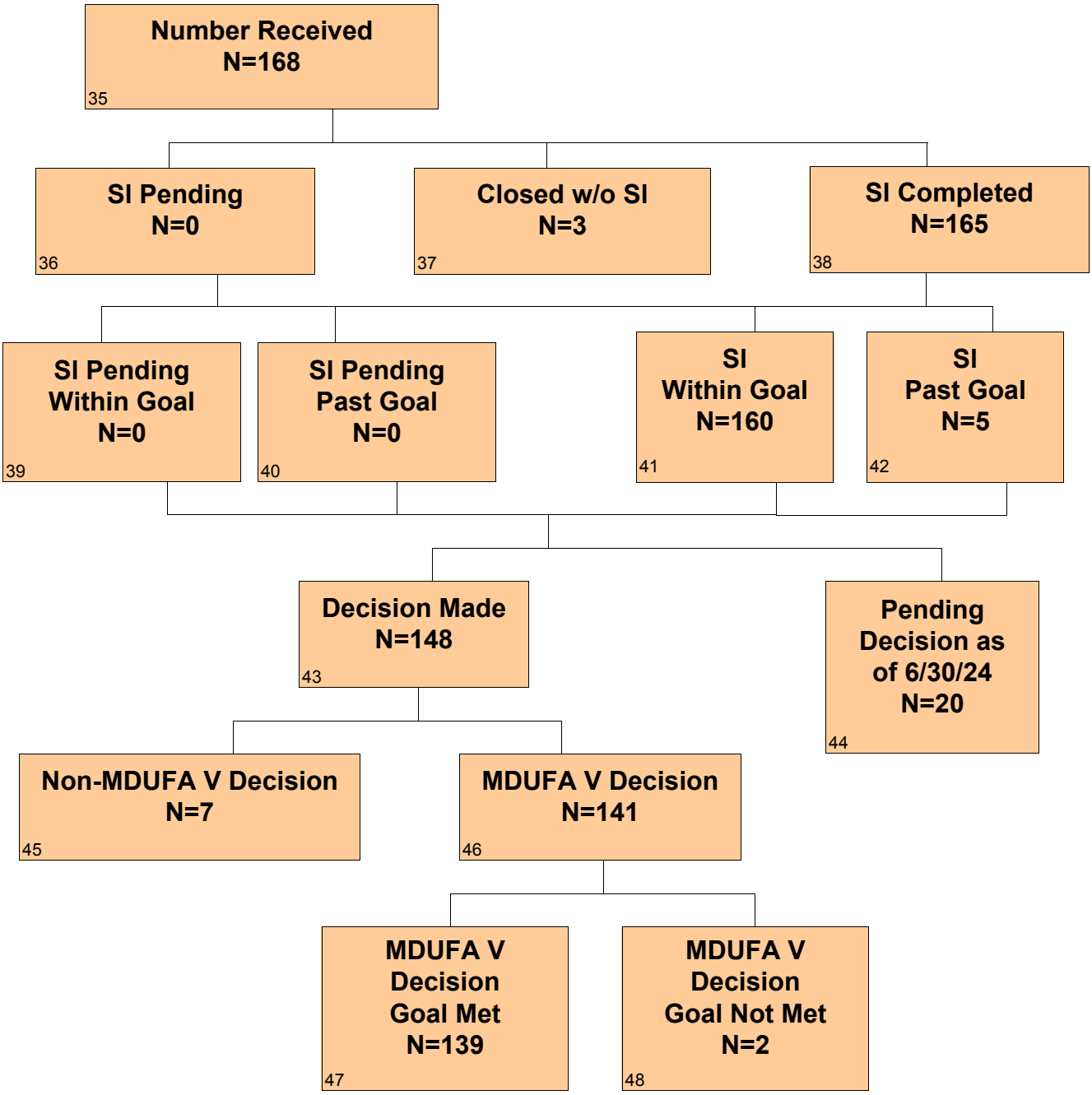
***Includes submission that went to panel**

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

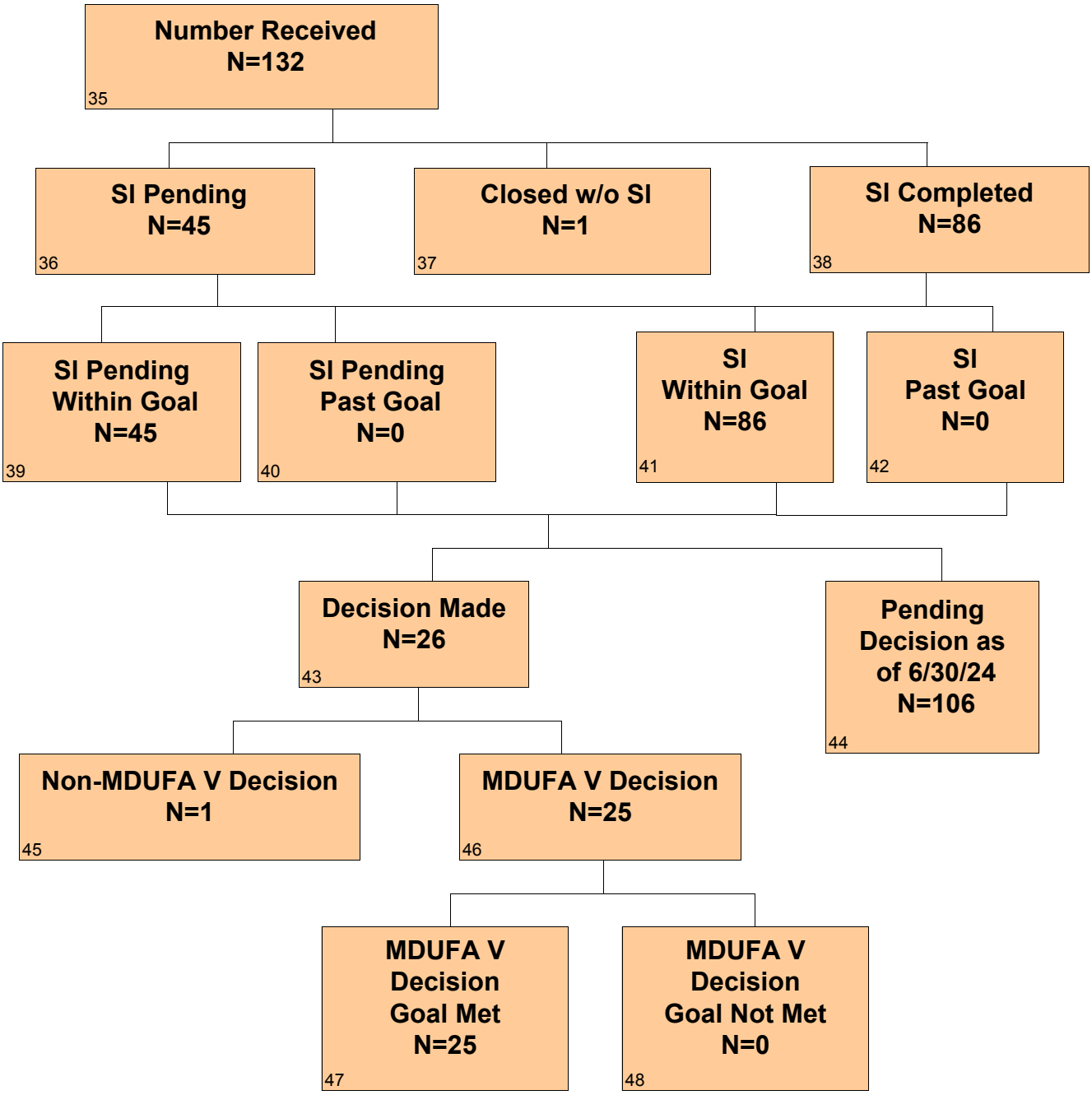
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Goal Met	N/A	N/A		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

***Includes submission that went to panel**

CDRH PMA 180 Day Supplements - FY 2023 as of 6/30/24



CDRH PMA 180 Day Supplements - FY 2024 as of 6/30/24



Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	168	132			
SI Goal Met	160	86			
SI Goal Not Met	5	0			
SI Pending Within Goal	0	45			
SI Pending Past Goal	0	0			
Closed Without SI	3	1			
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	132			
Non-MDUFA Decision	7	1			
MDUFA Decision	141	25			
MDUFA Decision Goal Met	139	25			
Supplements Pending MDUFA Decision	20	106			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	98.58%	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	132			
Number with MDUFA Decision	141	25			
Number of Not Approvable	4	0			
Rate of Not Approvable	2.84%	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	14			
SI Goal Met	16	8			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	6			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	16	14			
Non-MDUFA Decision	1	0			
MDUFA Decision	12	2			
MDUFA Decision Goal Met	12	2			
Supplements Pending MDUFA Decision	3	12			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	14			
Number with MDUFA Decision	12	2			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	56	52			
SI Goal Met	55	32			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	19			
SI Pending Past Goal	0	0			
Closed Without SI	1	1			
Current SI Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	56	52			
Non-MDUFA Decision	3	1			
MDUFA Decision	48	7			
MDUFA Decision Goal Met	48	7			
Supplements Pending MDUFA Decision	5	44			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	56	52			
Number with MDUFA Decision	48	7			
Number of Not Approvable	1	0			
Rate of Not Approvable	2.08%	0.00%			

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	14			
SI Goal Met	20	11			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	95.24%	100.00%			

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	21	14			
Non-MDUFA Decision	0	0			
MDUFA Decision	20	5			
MDUFA Decision Goal Met	20	5			
Supplements Pending MDUFA Decision	1	9			
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	14			
Number with MDUFA Decision	20	5			
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	4			
SI Goal Met	8	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

Table 2.2 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	4			
Non-MDUFA Decision	0	0			
MDUFA Decision	3	1			
MDUFA Decision Goal Met	3	1			
Supplements Pending MDUFA Decision	5	3			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8	4			
Number with MDUFA Decision	3	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	23	15			
SI Goal Met	20	9			
SI Goal Not Met	3	0			
SI Pending Within Goal	0	6			
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	15			
Non-MDUFA Decision	0	0			
MDUFA Decision	21	5			
MDUFA Decision Goal Met	19	5			
Supplements Pending MDUFA Decision	2	10			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	90.48%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	15			
Number with MDUFA Decision	21	5			
Number of Not Approvable	2	0			
Rate of Not Approvable	9.52%	0.00%			

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	7	3			
SI Goal Met	7	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	7	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	6	0			
MDUFA Decision Goal Met	6	0			
Supplements Pending MDUFA Decision	1	3			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	#DIV/0!			

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	3			
Number with MDUFA Decision	6	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	29			
SI Goal Met	33	22			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	7			
SI Pending Past Goal	0	0			
Closed Without SI	2	0			
Current SI Performance Percent Goal Met	97.06%	100.00%			

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	36	29			
Non-MDUFA Decision	3	0			
MDUFA Decision	31	5			
MDUFA Decision Goal Met	31	5			
Supplements Pending MDUFA Decision	2	24			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	36	29			
Number with MDUFA Decision	31	5			
Number of Not Approvable	1	0			
Rate of Not Approvable	3.23%	0.00%			

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

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

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

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

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

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

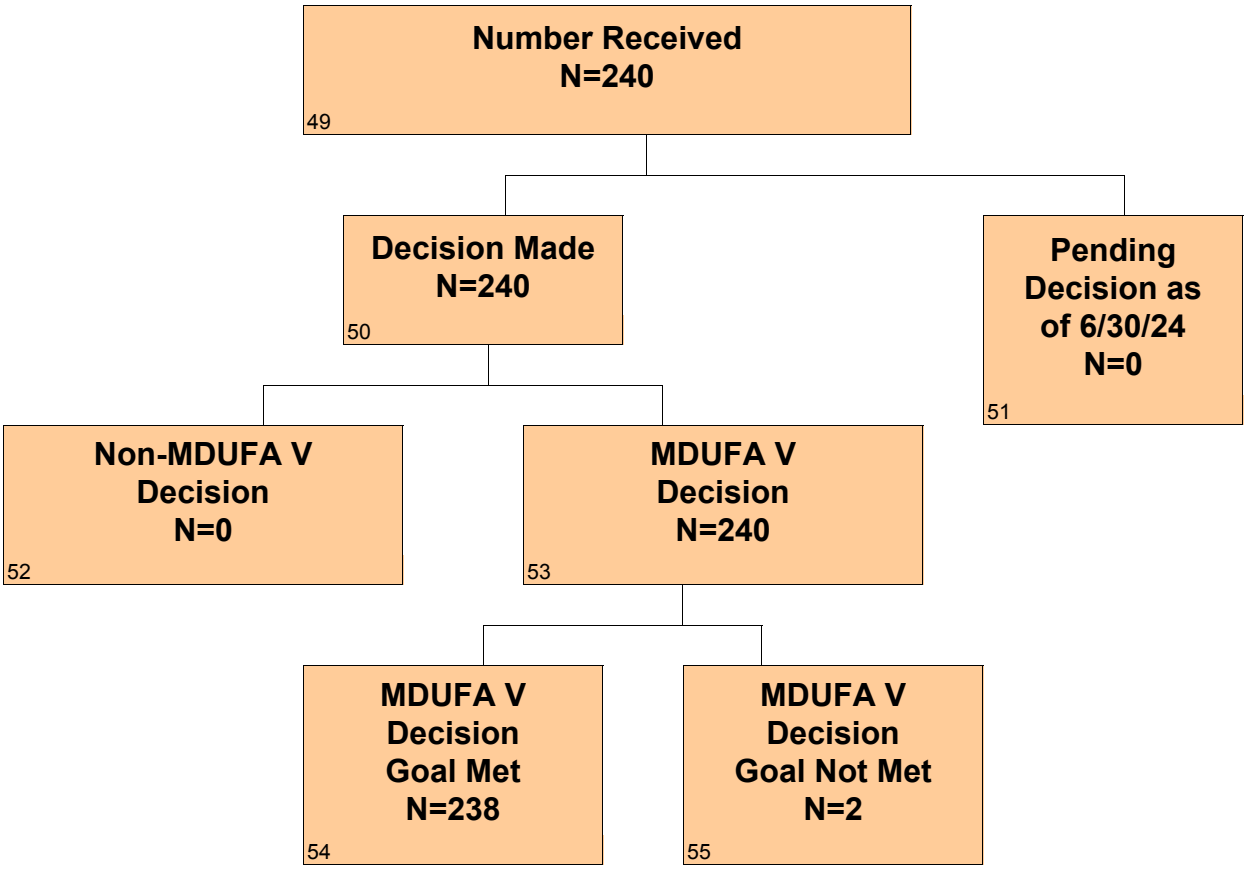
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

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

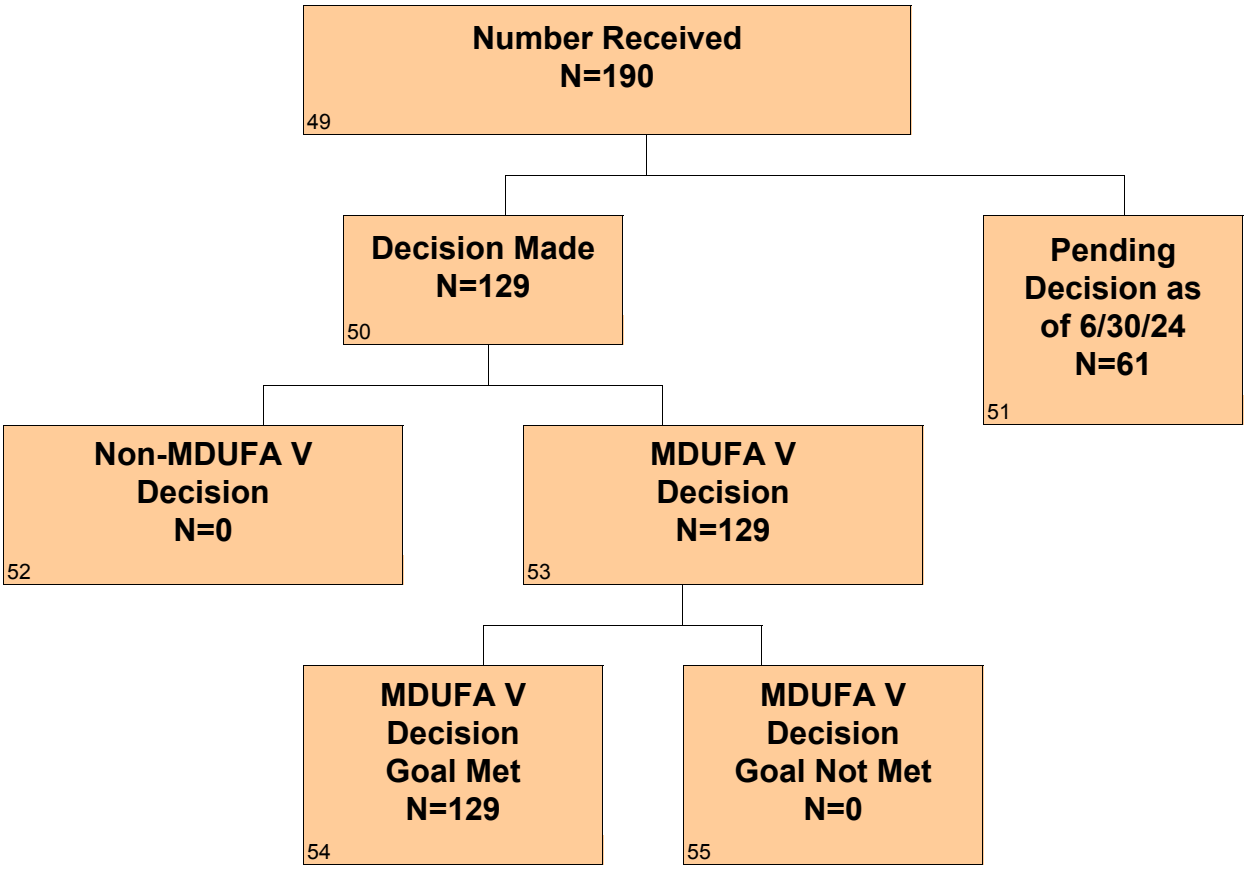
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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 6/30/24



CDRH PMA Real Time Supplements - FY 2024 as of 6/30/24



Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	240	190			
Non-MDUFA Decision	0	0			
MDUFA Decision	240	129			
MDUFA Decision Goal Met	238	129			
Supplements Pending MDUFA Decision	0	61			
Supplements Pending MDUFA Decision Past Goal	0	1			
Current Performance Percent Goal Met	99.17%	99.23%			

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	190			
Number With MDUFA Decision	240	129			
Number of Not Approvable	11	2			
Rate of Not Approvable	4.58%	1.55%			

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	13			
Non-MDUFA Decision	0	0			
MDUFA Decision	24	10			
MDUFA Decision Goal Met	24	10			
Supplements Pending MDUFA Decision	0	3			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	24	13			
Number With MDUFA Decision	24	10			
Number of Not Approvable	3	1			
Rate of Not Approvable	12.50%	10.00%			

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	92			
Non-MDUFA Decision	0	0			
MDUFA Decision	136	63			
MDUFA Decision Goal Met	136	63			
Supplements Pending MDUFA Decision	0	29			
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	92			
Number With MDUFA Decision	136	63			
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	14			
Non-MDUFA Decision	0	0			
MDUFA Decision	19	10			
MDUFA Decision Goal Met	18	10			
Supplements Pending MDUFA Decision	0	4			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	94.74%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	19	14			
Number With MDUFA Decision	19	10			
Number of Not Approvable	2	1			
Rate of Not Approvable	10.53%	10.00%			

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	6			
Non-MDUFA Decision	0	0			
MDUFA Decision	7	6			
MDUFA Decision Goal Met	7	6			
Supplements Pending MDUFA Decision	0	0			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

Table 3.2 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	6			
Number With MDUFA Decision	7	6			
Number of Not Approvable	2	0			
Rate of Not Approvable	28.57%	0.00%			

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	16	30			
Non-MDUFA Decision	0	0			
MDUFA Decision	16	16			
MDUFA Decision Goal Met	15	16			
Supplements Pending MDUFA Decision	0	14			
Supplements Pending MDUFA Decision Past Goal	0	1			
Current Performance Percent Goal Met	93.75%	94.12%			

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	30			
Number With MDUFA Decision	16	16			
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	6			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	4			
MDUFA Decision Goal Met	4	4			
Supplements Pending MDUFA Decision	0	2			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	6			
Number With MDUFA Decision	4	4			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	32	28			
Non-MDUFA Decision	0	0			
MDUFA Decision	32	19			
MDUFA Decision Goal Met	32	19			
Supplements Pending MDUFA Decision	0	9			
Supplements Pending MDUFA Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	32	28			
Number With MDUFA Decision	32	19			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

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

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

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

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

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

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

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

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

Section 4 Pre-Market Report Submissions

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

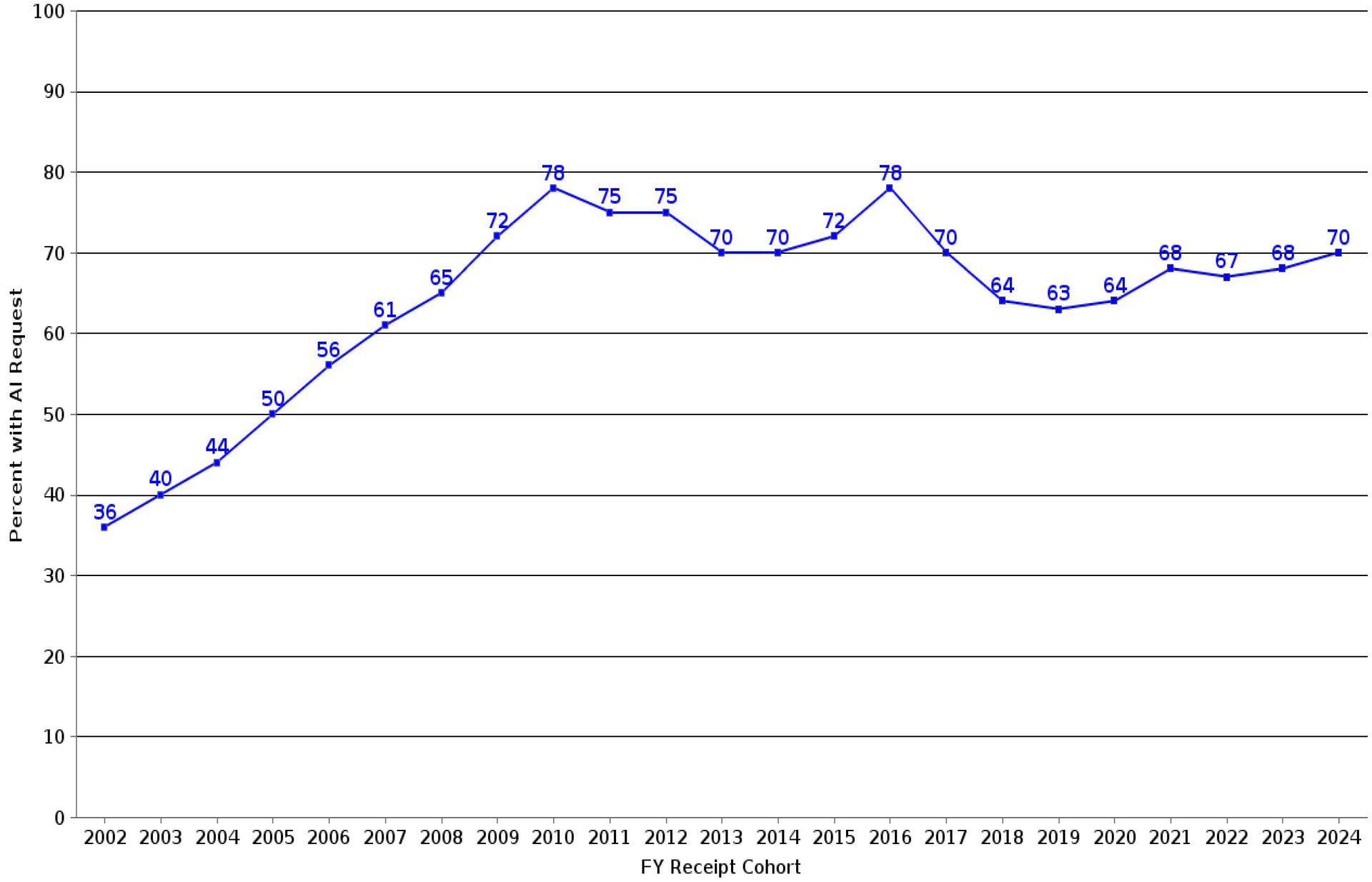
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q3FY2024

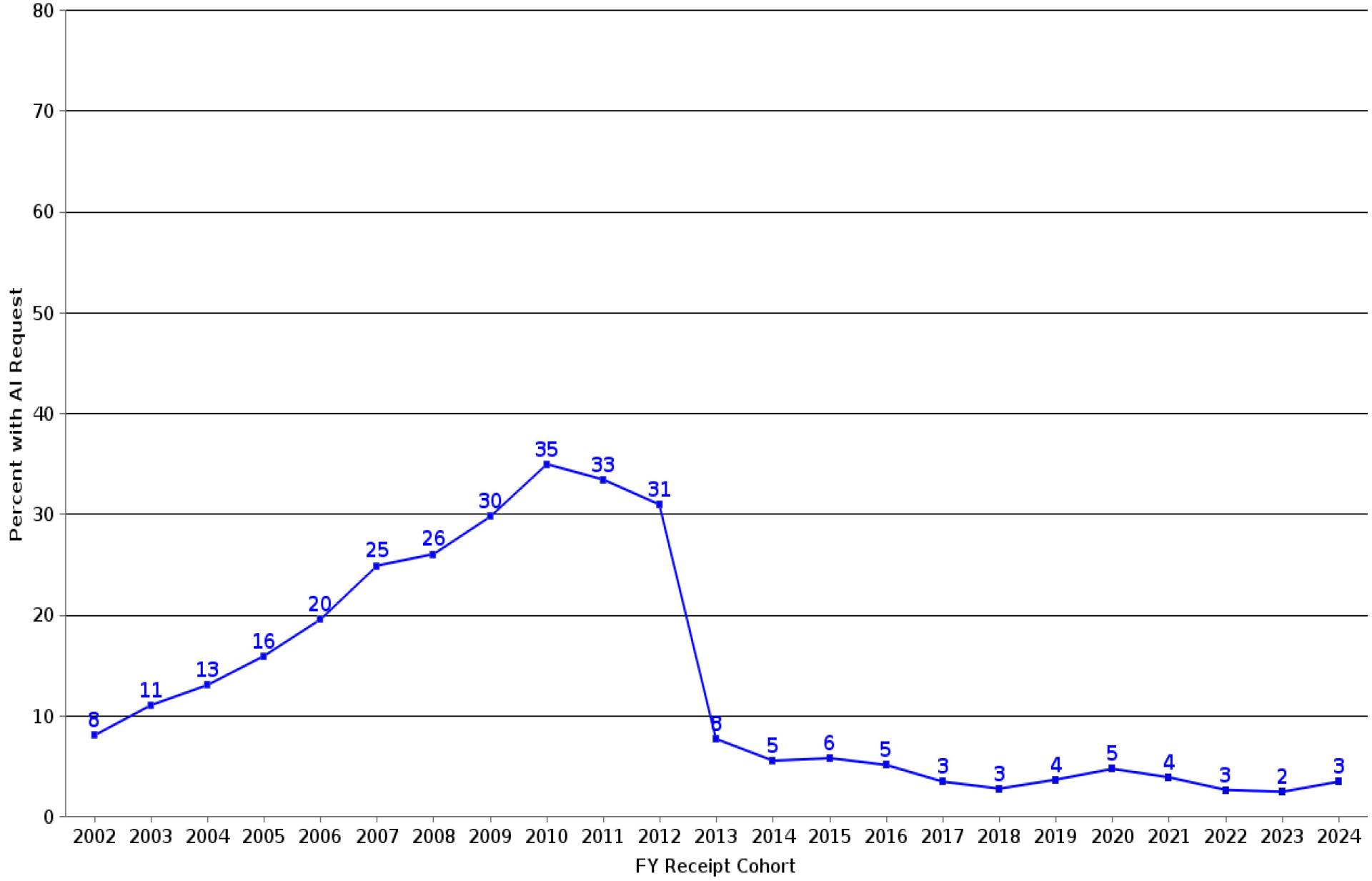
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 4/30/24

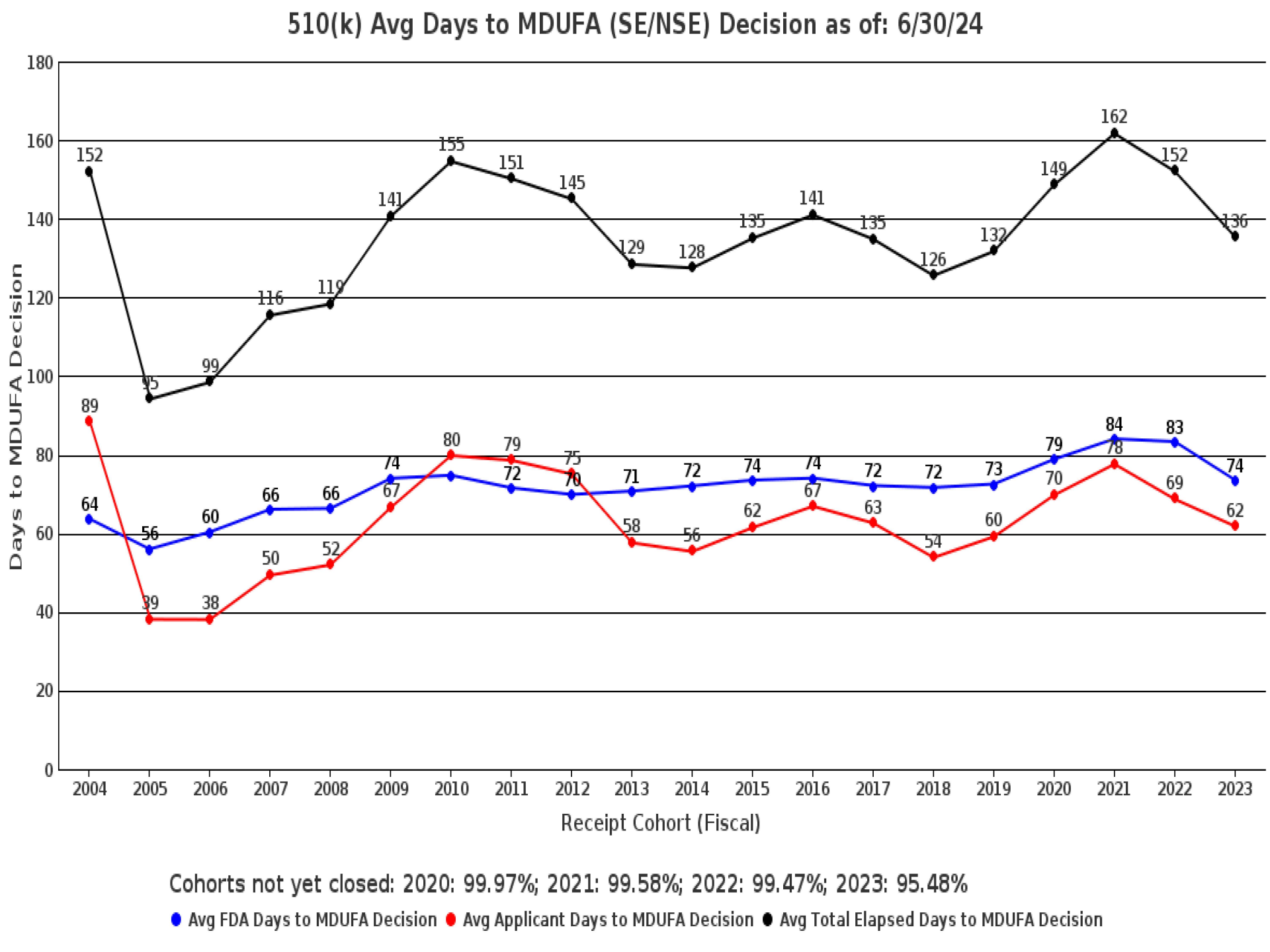
■ % with 1st Cycle AI Request

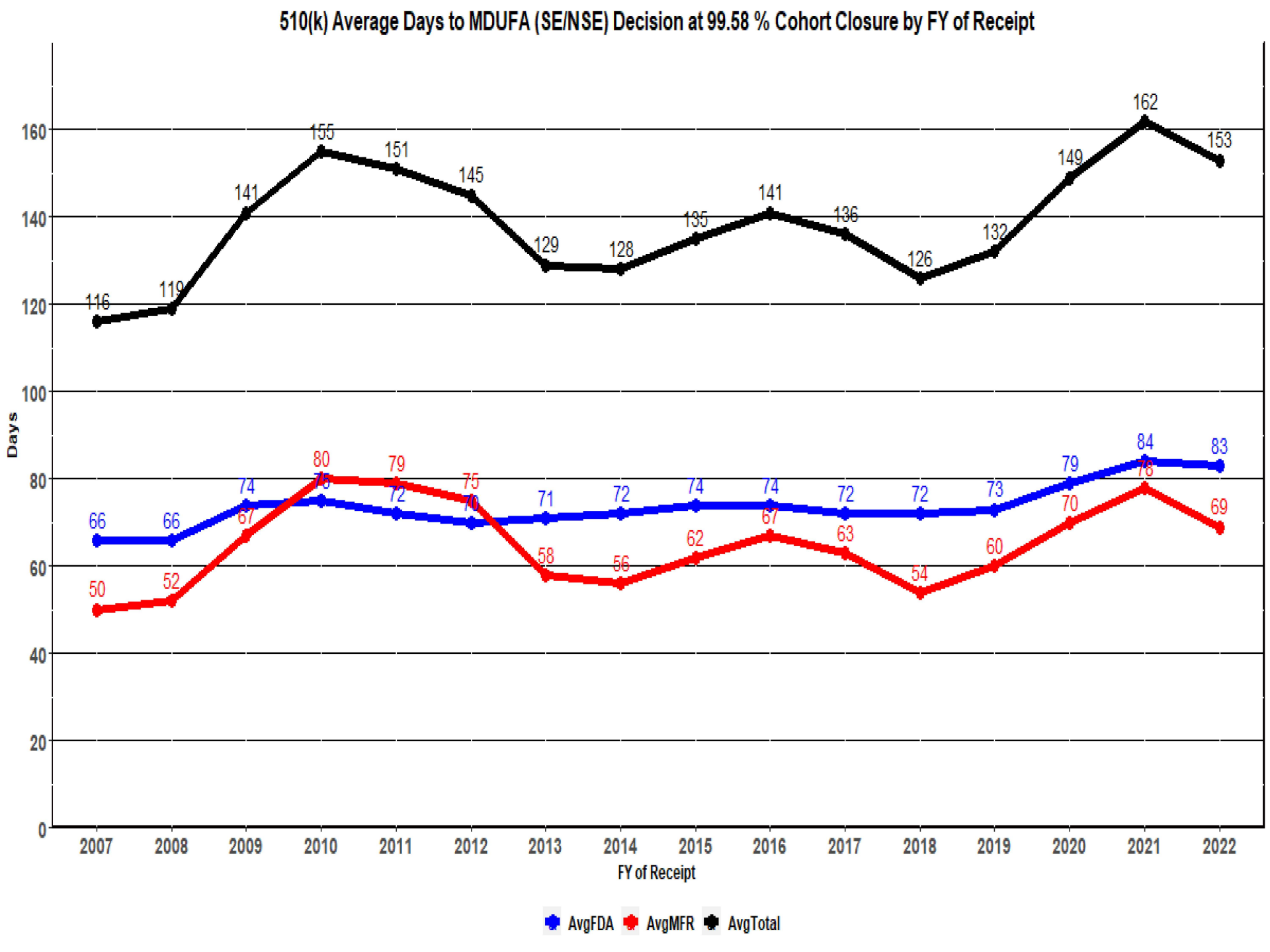
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 11/30/23

■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 6/30/24
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2020: 99.97%; 2021: 99.58%; 2022: 99.47%; 2023: 95.48%
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 99.58 % 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
116
119
141
155
151
145
129
128
135
141
136
126
132
149
162
153
66
66
74
75
72
70
71
72
74
74
72
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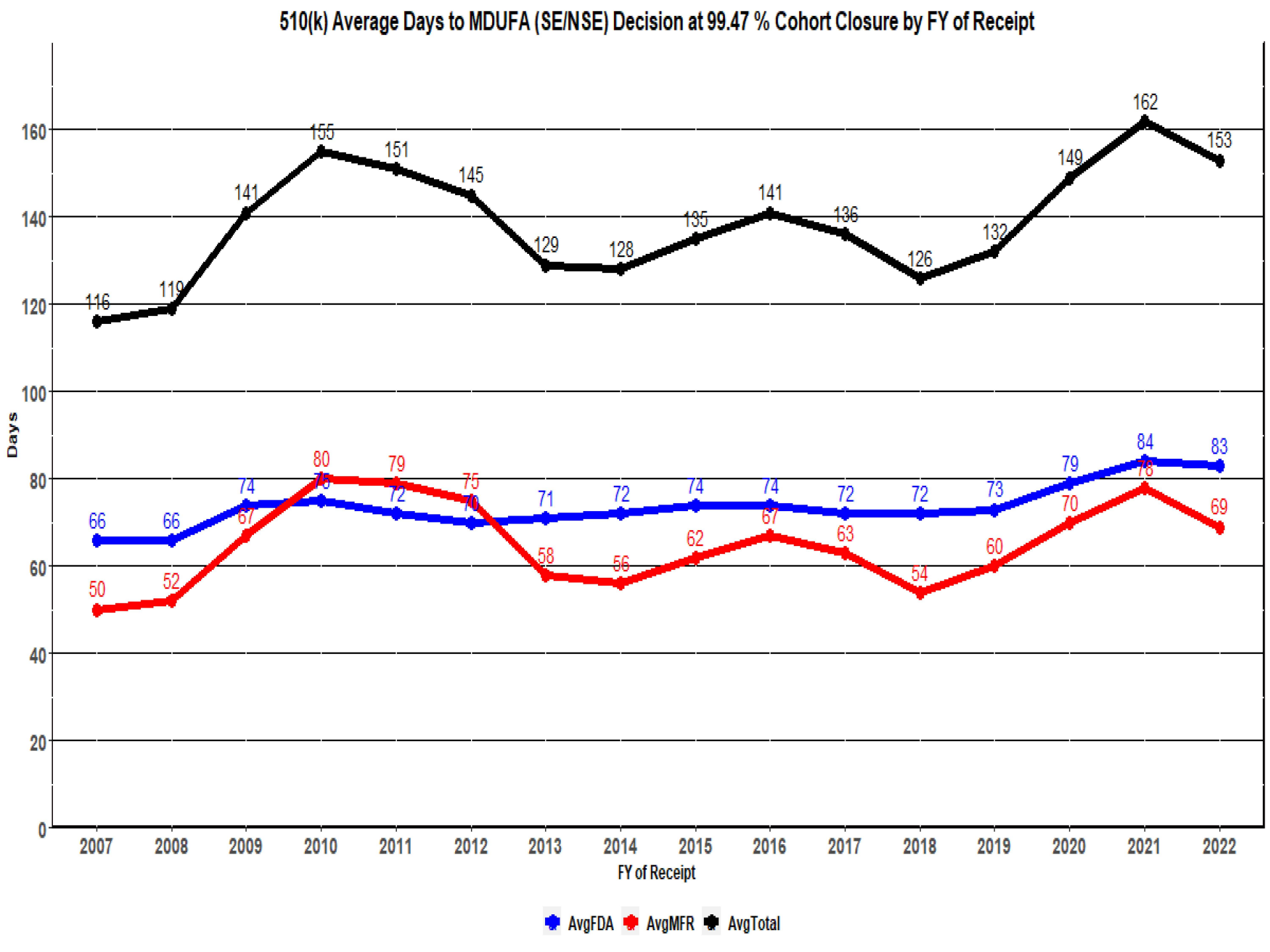
58
56
62
67
63
54
60
70
78
69


510(k) Average Days to MDUFA (SE/NSE) Decision at 99.47 % 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
116
119
141
155
151
145
129
128
135
141
136
126
132
149
162
153
66
66
74
76
72
70
71
72
74
74
72
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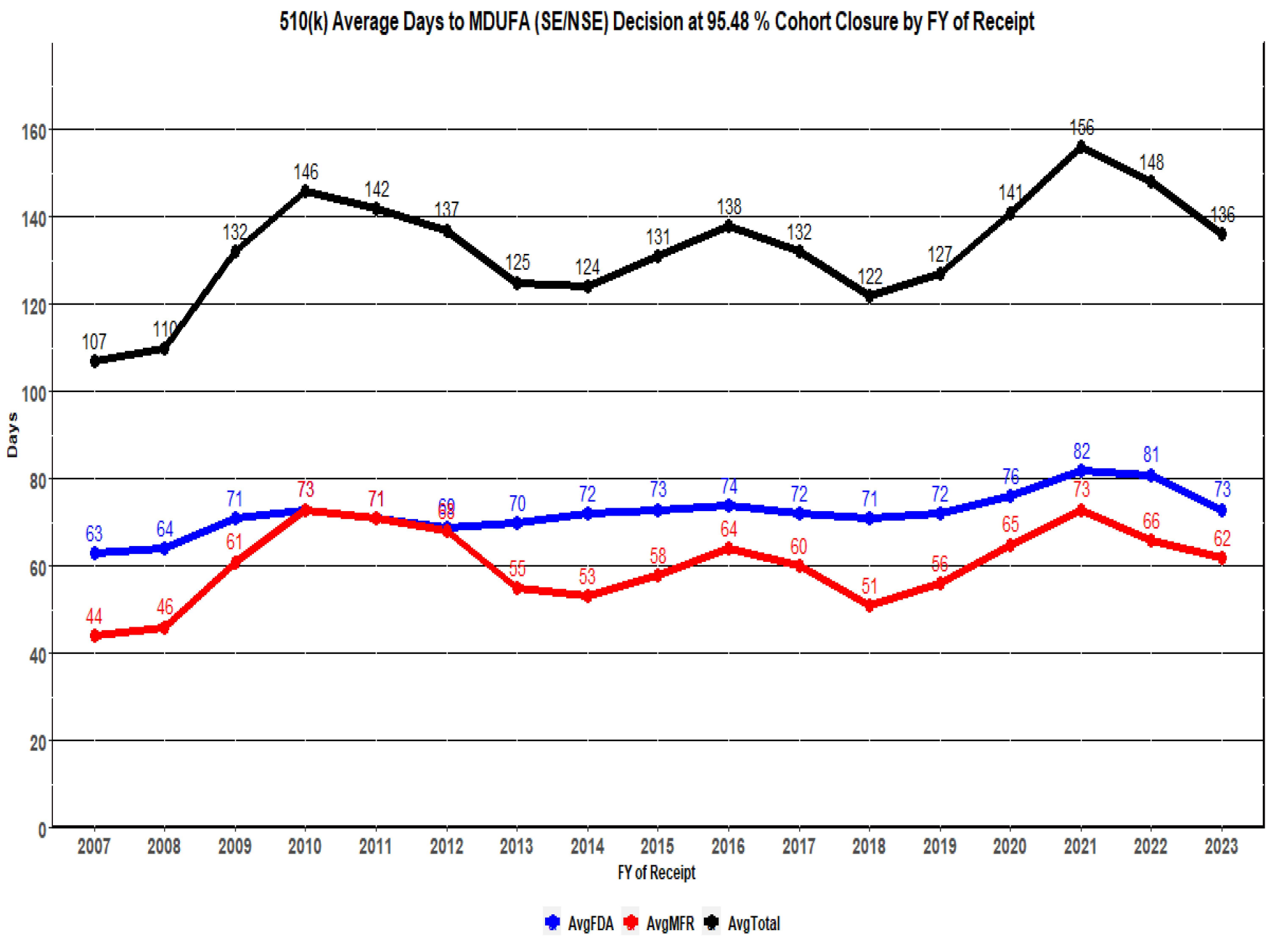
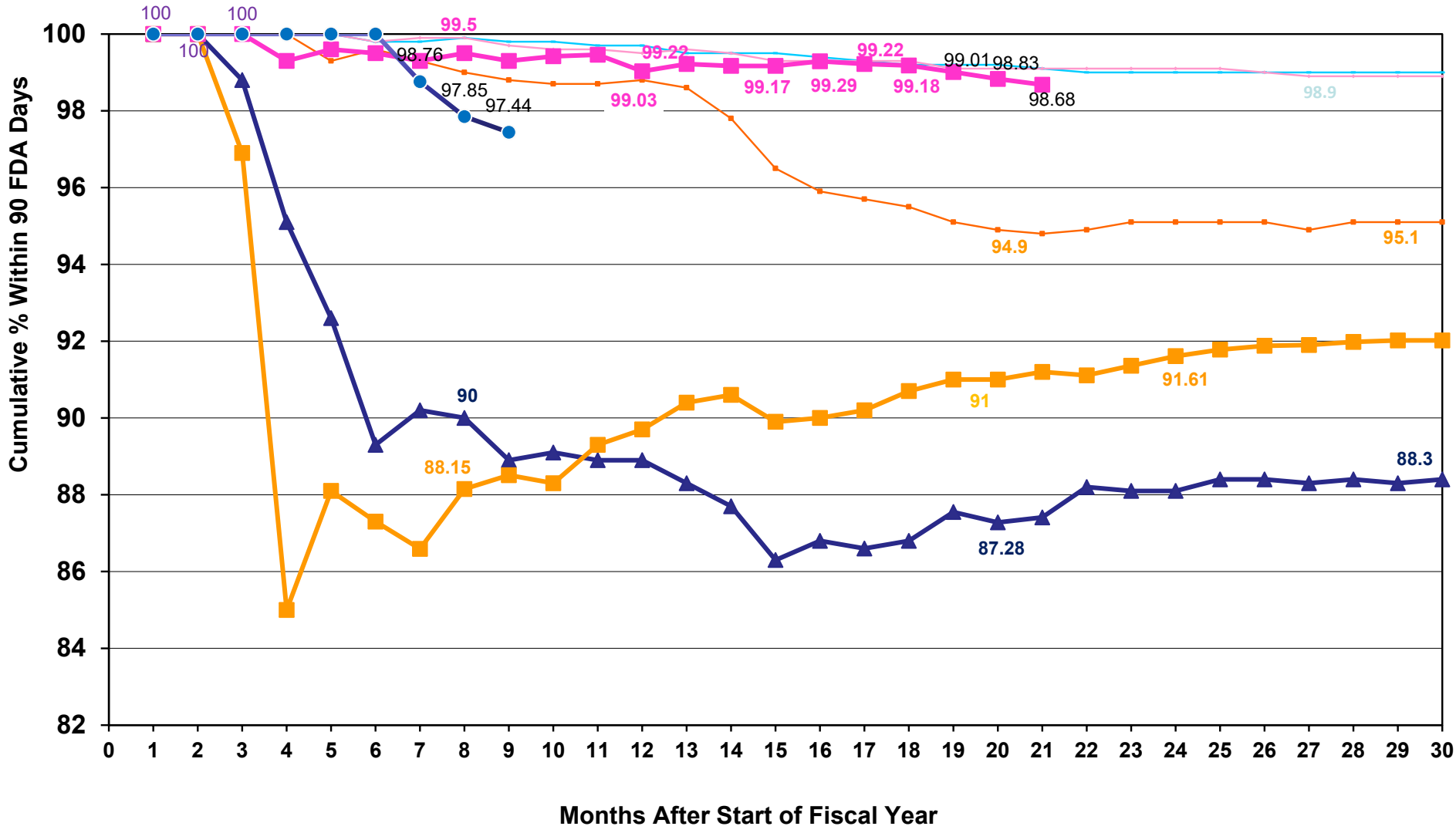
70
78
69

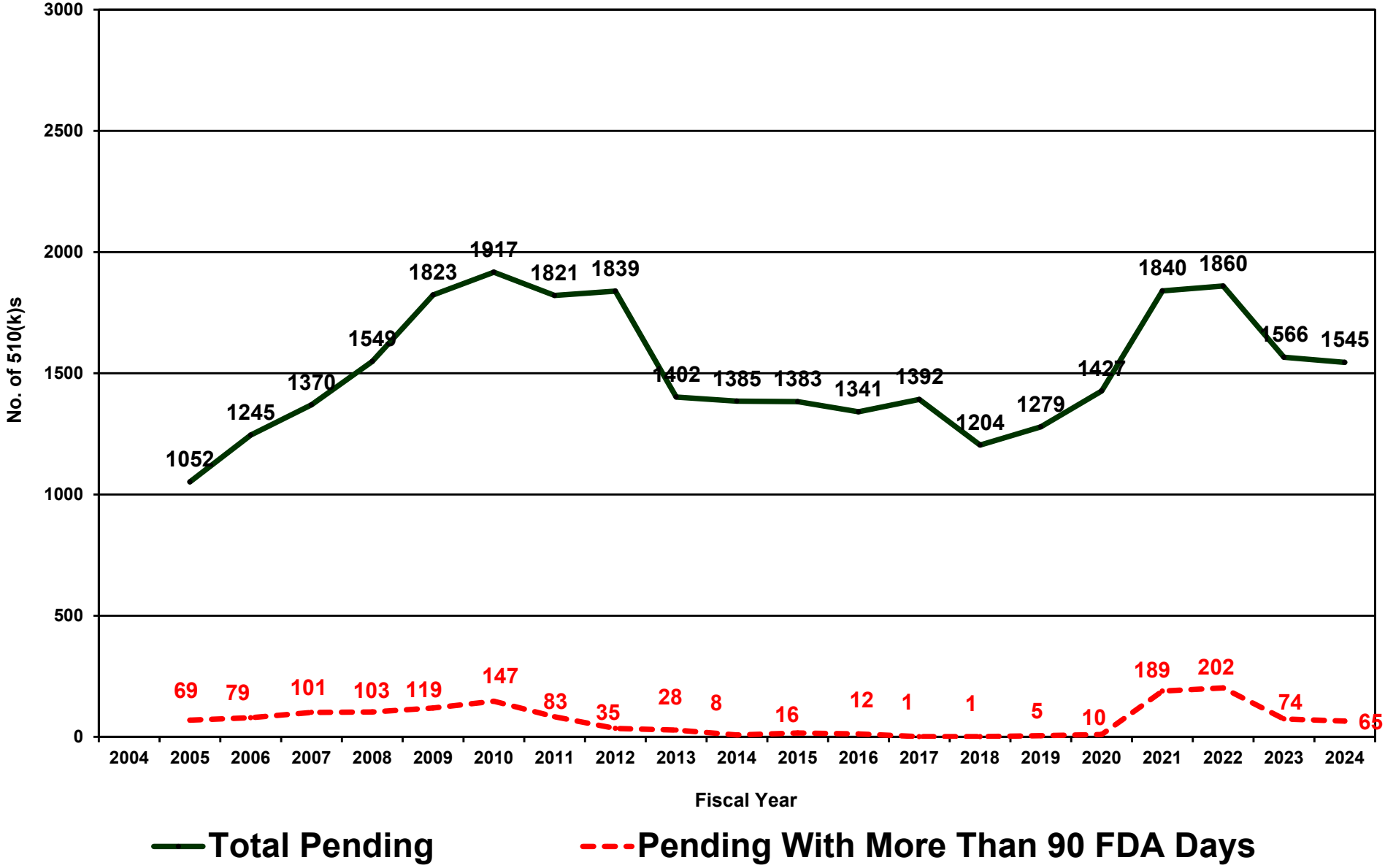

510(k) Average Days to MDUFA (SE/NSE) Decision at 95.48 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
AvgFDA
AvgMFR
AvgTotal
107
110
132
146
142
137
125
124
131
138
132
122
127
141
156
148
136
63
64
71
73
71
69
70
72
73
74
72
71
72
76
82
81
73
44
46
61
73
71
68
55
53
58
64
60
51
56
65
73
66
62

Trend in 510(k) MDUFA Decision Goal Performance

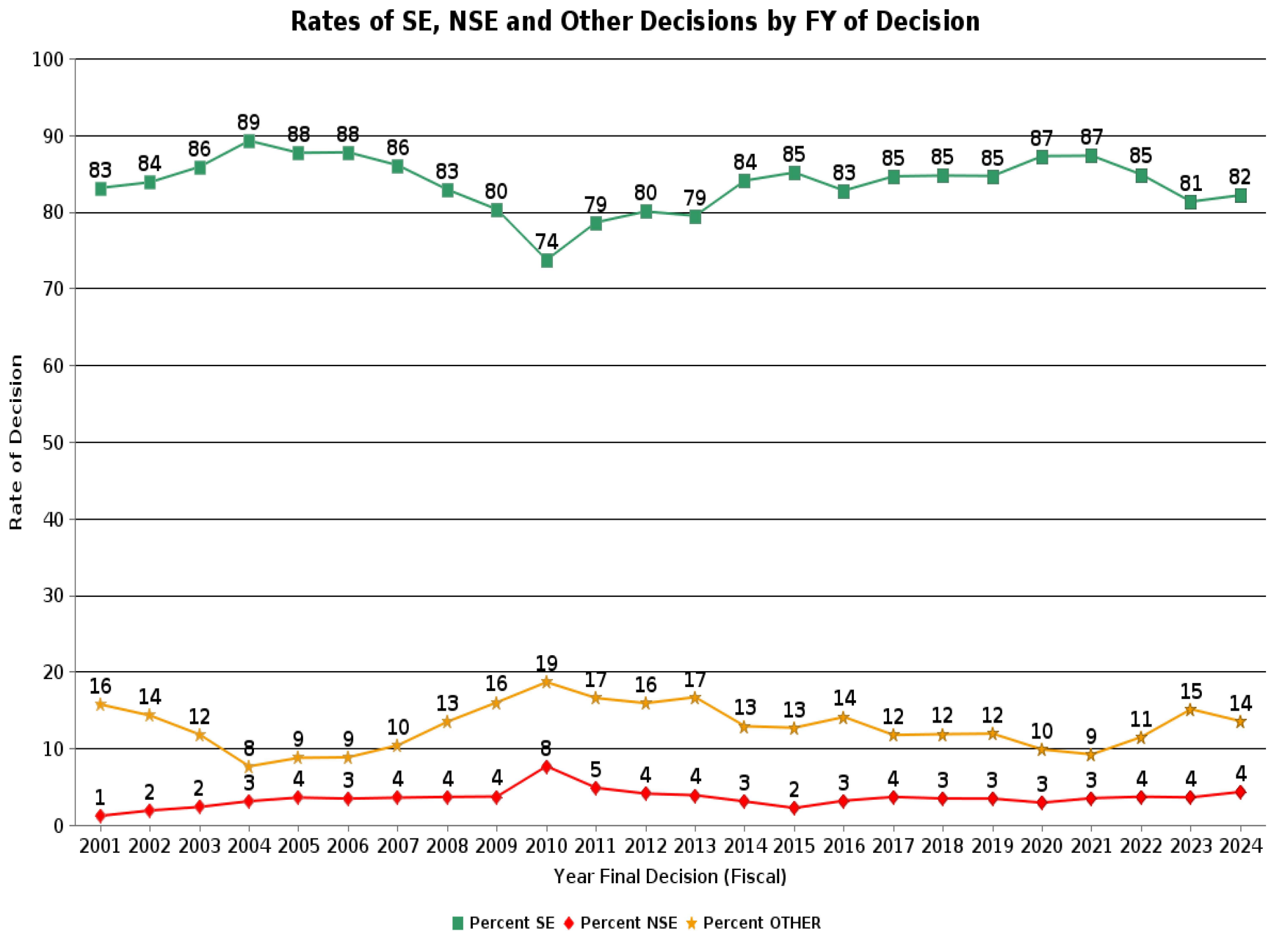
Comparison of FY18 – FY24 Receipt Cohorts



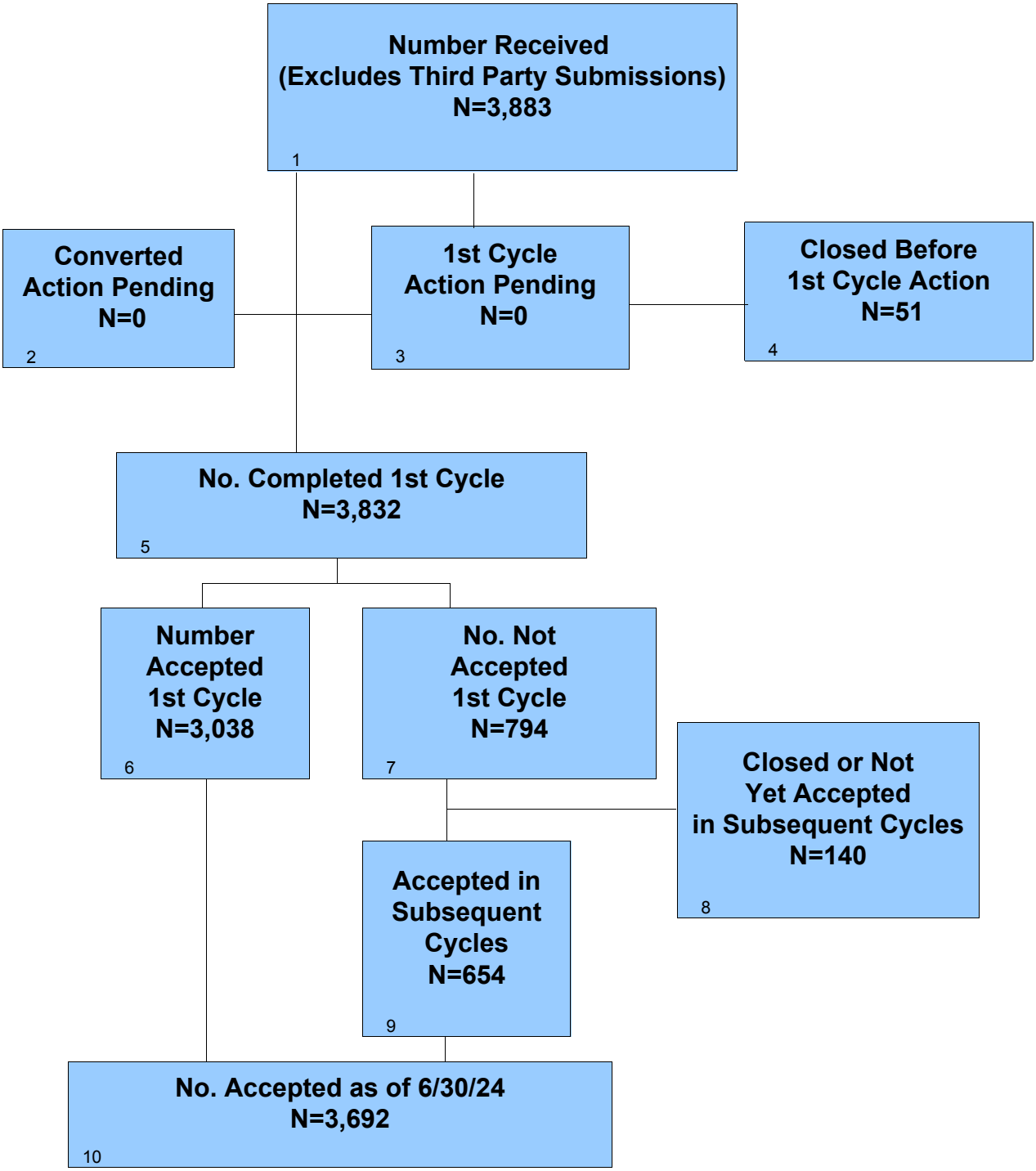
510(k)s Pending at End of Quarter/Year



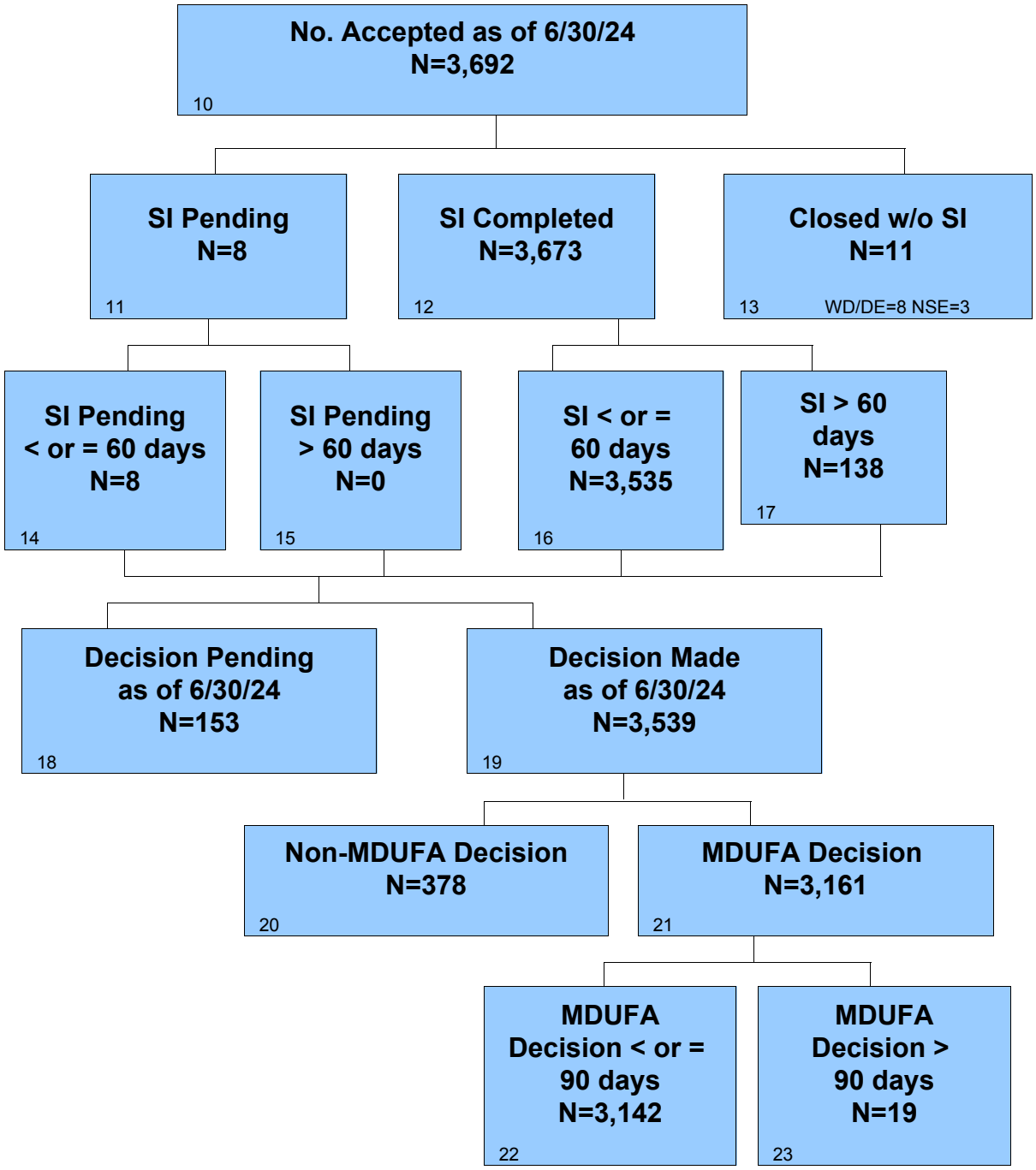
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


Rates of SE, NSE and Other Decisions by FY of Decision
Rate of Decision
100
90
80
70
60
50
40
30
20
10
0
83 84 86 89 88 88 86 83 80 74 79 80 79 84 85 83 85 85 85 87 87 85 81 82
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15 14
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

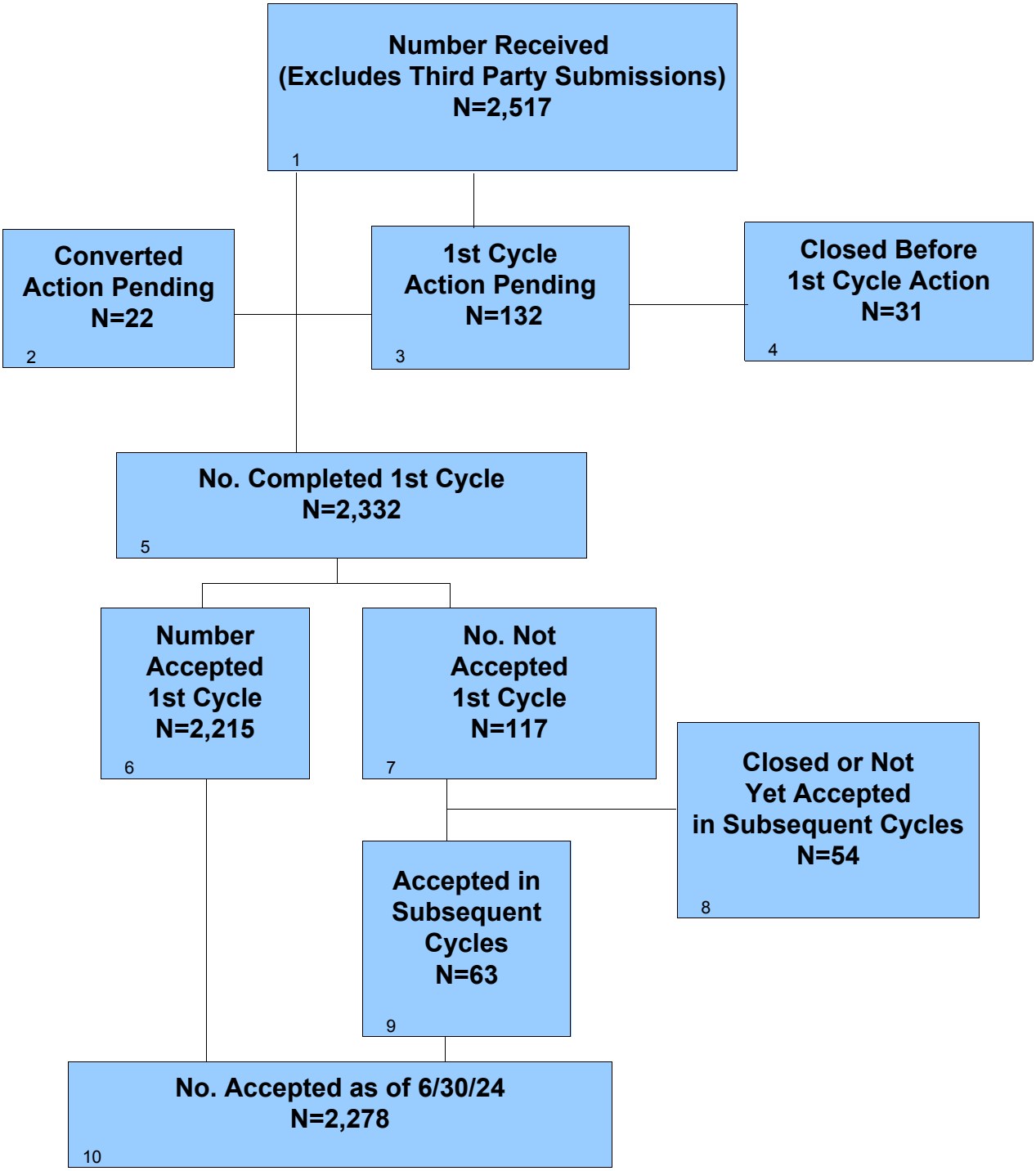
CDRH 510(k)s - FY 2023
as of 6/30/24



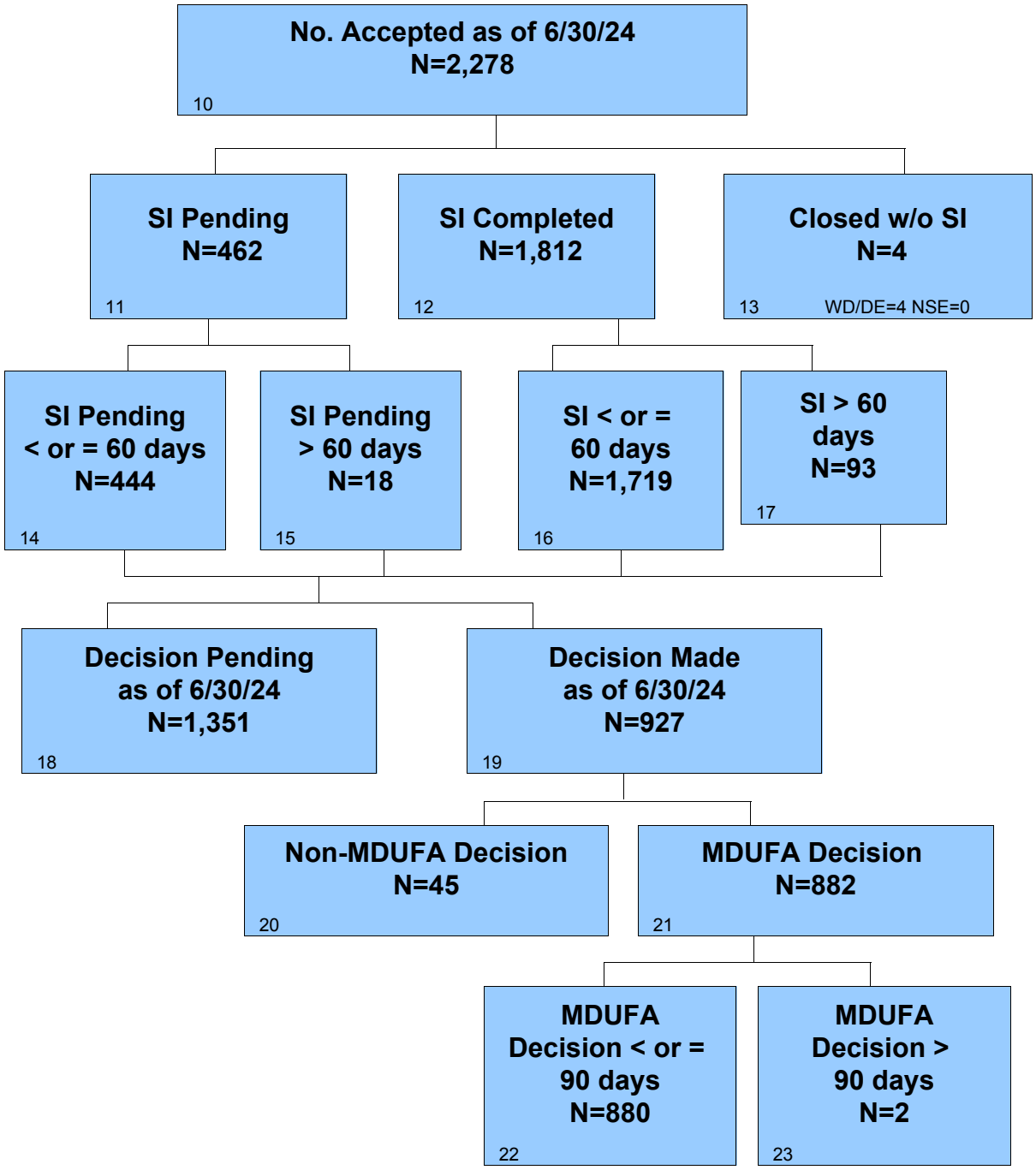
CDRH 510(k)s - FY 2023
as of 6/30/24 Continued



CDRH 510(k)s - FY 2024
as of 6/30/24



CDRH 510(k)s - FY 2024
as of 6/30/24 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,883	2,517			
Closed Before First RTA or TS Action [1]	51	31			
Number Accepted or Passed TS on First Cycle [2]	3,020	2,200			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	18	15			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	154			
Number Not Accepted or Failed TS on First Cycle [2]	794	117			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.72%	5.02%			

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	3,692	2,278			
Deleted or Withdrawn Prior to SI	8	4			
SI Within 60 FDA Days	3,535	1,719			
SI Over 60 FDA Days	138	93			
SI Pending Within 60 FDA Days	8	444			
SI Pending Over 60 FDA Days	0	18			
510(k)s NSE Without SI	3	0			
Current SI Performance Percent Within 60 FDA Days	96.16%	93.93%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	3,673	1,812			
Average Number of FDA Days to Substantive Interaction	52.72	51.85			
20th Percentile FDA Days to Substantive Interaction	48	45			
40th Percentile FDA Days to Substantive Interaction	57	56			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	212	95			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	3,692	2,278			
Non-MDUFA V Decision	378	45			
MDUFA V Decision (SE/NSE)	3,161	882			
MDUFA V Decision Within 90 FDA Days	3,142	880			
510(k)s Pending MDUFA V Decision	153	1,351			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	18	19			
Current Performance Percent Within 90 FDA Days	98.84%	97.67%			

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	1.65	1.42			
Number With MDUFA V Decision	3161	882			
Average Number of FDA Days to MDUFA V Decision	74.49	63.67			
20th Percentile FDA Days to MDUFA V Decision	57	29			
40th Percentile FDA Days to MDUFA V Decision	84	57			
60th Percentile FDA Days to MDUFA V Decision	88	85			
80th Percentile FDA Days to MDUFA V Decision	90	89			
Maximum FDA Days to MDUFA V Decision	276	98			
Average Number of Industry Days to MDUFA V Decision	63.18	21.86			
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	65	5			
80th Percentile Industry Days to MDUFA V Decision	144	45			
Maximum Industry Days to MDUFA V Decision	367	190			
Average Number of Total Days to MDUFA V Decision	137.51	85.25			
20th Percentile Total Days to MDUFA V Decision	58	30			
40th Percentile Total Days to MDUFA V Decision	93	59			
60th Percentile Total Days to MDUFA V Decision	150	90			
80th Percentile Total Days to MDUFA V Decision	230	130			
Maximum Total Days to MDUFA V Decision	517	265			

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	3,692	2,278			
Number With MDUFA V Decision	3,161	882			
Number of SE Decision	3,030	871			
Number of NSE Decision	131	11			
Number of Withdrawal	209	32			
Number of Deleted	161	9			
Rate of SE Decision	95.86%	98.75%			
Rate of NSE Decision	4.14%	1.25%			
Rate of Withdrawal	5.66%	1.40%			
Rate of Deleted	4.36%	0.40%			

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	19	2			
Mean FDA Days for Submissions that Missed the Goal	121.26	94.50			
Mean Industry Days for Submissions that Missed the Goal	131.32	75.00			

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	5			
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	5			
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	267	158			
Non-MDUFA V Decision	48	2			
MDUFA V Decision (SE/NSE)	211	59			
MDUFA V Decision Within 90 FDA Days	211	59			
510(k)s Pending MDUFA V Decision	8	97			
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	587	374			
Closed Before First RTA or TS Action [1]	8	4			
Number Accepted or Passed TS on First Cycle [2]	317	315			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	2			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	18			
Number Not Accepted or Failed TS on First Cycle [2]	259	35			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.73%	9.94%			

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	535	336			
Deleted or Withdrawn Prior to SI	2	0			
SI Within 60 FDA Days	426	212			
SI Over 60 FDA Days	102	60			
SI Pending Within 60 FDA Days	4	62			
SI Pending Over 60 FDA Days	0	2			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	80.53%	77.37%			

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	528	272			
Average Number of FDA Days to Substantive Interaction	56.93	55.38			
20th Percentile FDA Days to Substantive Interaction	55	51			
40th Percentile FDA Days to Substantive Interaction	58	58			
60th Percentile FDA Days to Substantive Interaction	60	60			
80th Percentile FDA Days to Substantive Interaction	60	61			
Maximum FDA Days to Substantive Interaction	212	80			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	535	336			
Non-MDUFA V Decision	69	5			
MDUFA V Decision (SE/NSE)	416	99			
MDUFA V Decision Within 90 FDA Days	408	98			
510(k)s Pending MDUFA V Decision	50	232			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	5	1			
Current Performance Percent Within 90 FDA Days	96.91%	98.00%			

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	1.75	1.53			
Number With MDUFA V Decision	416	99			
Average Number of FDA Days to MDUFA V Decision	82.49	72.07			
20th Percentile FDA Days to MDUFA V Decision	81	58			
40th Percentile FDA Days to MDUFA V Decision	88	83			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	90			
Maximum FDA Days to MDUFA V Decision	276	98			
Average Number of Industry Days to MDUFA V Decision	71.81	29.78			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	35	0			
60th Percentile Industry Days to MDUFA V Decision	76	23			
80th Percentile Industry Days to MDUFA V Decision	151	57			
Maximum Industry Days to MDUFA V Decision	271	179			
Average Number of Total Days to MDUFA V Decision	154.03	101.25			
20th Percentile Total Days to MDUFA V Decision	87	58			
40th Percentile Total Days to MDUFA V Decision	123	89			
60th Percentile Total Days to MDUFA V Decision	166	109			
80th Percentile Total Days to MDUFA V Decision	240	141			
Maximum Total Days to MDUFA V Decision	361	265			

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	535	336			
Number With MDUFA V Decision	416	99			
Number of SE Decision	385	97			
Number of NSE Decision	31	2			
Number of Withdrawal	37	4			
Number of Deleted	31	1			
Rate of SE Decision	92.55%	97.98%			
Rate of NSE Decision	7.45%	2.02%			
Rate of Withdrawal	6.92%	1.19%			
Rate of Deleted	5.79%	0.30%			

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	8	1			
Mean FDA Days for Submissions that Missed the Goal	144.25	98.00			
Mean Industry Days for Submissions that Missed the Goal	124.88	108.00			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	381	277			
Closed Before First RTA or TS Action [1]	8	3			
Number Accepted or Passed TS on First Cycle [2]	334	251			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	2			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	14			
Number Not Accepted or Failed TS on First Cycle [2]	38	7			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.19%	2.69%			

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	367	258			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	357	197			
SI Over 60 FDA Days	10	18			
SI Pending Within 60 FDA Days	0	40			
SI Pending Over 60 FDA Days	0	3			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.28%	90.37%			

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	367	215			
Average Number of FDA Days to Substantive Interaction	51.41	50.88			
20th Percentile FDA Days to Substantive Interaction	44	30			
40th Percentile FDA Days to Substantive Interaction	55	56			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	78			

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	367	258			
Non-MDUFA V Decision	31	5			
MDUFA V Decision (SE/NSE)	325	104			
MDUFA V Decision Within 90 FDA Days	321	104			
510(k)s Pending MDUFA V Decision	11	149			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2	1			
Current Performance Percent Within 90 FDA Days	98.17%	99.05%			

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	1.70	1.42			
Number With MDUFA V Decision	325	104			
Average Number of FDA Days to MDUFA V Decision	73.11	59.45			
20th Percentile FDA Days to MDUFA V Decision	55	29			
40th Percentile FDA Days to MDUFA V Decision	84	52			
60th Percentile FDA Days to MDUFA V Decision	88	74			
80th Percentile FDA Days to MDUFA V Decision	90	88			
Maximum FDA Days to MDUFA V Decision	95	90			
Average Number of Industry Days to MDUFA V Decision	68.97	26.61			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	25	0			
60th Percentile Industry Days to MDUFA V Decision	73	8			
80th Percentile Industry Days to MDUFA V Decision	150	58			
Maximum Industry Days to MDUFA V Decision	339	190			
Average Number of Total Days to MDUFA V Decision	141.95	84.63			
20th Percentile Total Days to MDUFA V Decision	57	29			
40th Percentile Total Days to MDUFA V Decision	106	56			
60th Percentile Total Days to MDUFA V Decision	160	90			
80th Percentile Total Days to MDUFA V Decision	231	135			
Maximum Total Days to MDUFA V Decision	427	254			

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	367	258			
Number With MDUFA V Decision	325	104			
Number of SE Decision	304	104			
Number of NSE Decision	21	0			
Number of Withdrawal	15	3			
Number of Deleted	16	0			
Rate of SE Decision	93.54%	100.00%			
Rate of NSE Decision	6.46%	0.00%			
Rate of Withdrawal	4.09%	1.16%			
Rate of Deleted	4.36%	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	1			
Non-MDUFA V Decision	N/A	0			
MDUFA V Decision (SE/NSE)	N/A	0			
MDUFA V Decision Within 90 FDA Days	N/A	0			
510(k)s Pending MDUFA V Decision	N/A	1			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	0			
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	481	316			
Closed Before First RTA or TS Action [1]	5	8			
Number Accepted or Passed TS on First Cycle [2]	391	266			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	1			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	30			
Number Not Accepted or Failed TS on First Cycle [2]	83	11			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	17.44%	3.96%			

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	463	275			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	451	223			
SI Over 60 FDA Days	10	0			
SI Pending Within 60 FDA Days	1	50			
SI Pending Over 60 FDA Days	0	2			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.83%	99.11%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	461	223			
Average Number of FDA Days to Substantive Interaction	54.96	53.07			
20th Percentile FDA Days to Substantive Interaction	55	49			
40th Percentile FDA Days to Substantive Interaction	58	57			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	77	60			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	463	275			
Non-MDUFA V Decision	50	8			
MDUFA V Decision (SE/NSE)	398	83			
MDUFA V Decision Within 90 FDA Days	397	82			
510(k)s Pending MDUFA V Decision	15	184			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	6			
Current Performance Percent Within 90 FDA Days	99.00%	92.13%			

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	1.77	1.54			
Number With MDUFA V Decision	398	83			
Average Number of FDA Days to MDUFA V Decision	79.78	65.80			
20th Percentile FDA Days to MDUFA V Decision	78	29			
40th Percentile FDA Days to MDUFA V Decision	88	58			
60th Percentile FDA Days to MDUFA V Decision	89	87			
80th Percentile FDA Days to MDUFA V Decision	90	89			
Maximum FDA Days to MDUFA V Decision	93	91			
Average Number of Industry Days to MDUFA V Decision	84.16	28.07			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	45	0			
60th Percentile Industry Days to MDUFA V Decision	105	21			
80th Percentile Industry Days to MDUFA V Decision	171	58			
Maximum Industry Days to MDUFA V Decision	354	138			
Average Number of Total Days to MDUFA V Decision	163.57	92.71			
20th Percentile Total Days to MDUFA V Decision	87	29			
40th Percentile Total Days to MDUFA V Decision	131	85			
60th Percentile Total Days to MDUFA V Decision	191	103			
80th Percentile Total Days to MDUFA V Decision	254	145			
Maximum Total Days to MDUFA V Decision	443	224			

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	463	275			
Number With MDUFA V Decision	398	83			
Number of SE Decision	374	79			
Number of NSE Decision	24	4			
Number of Withdrawal	23	7			
Number of Deleted	26	0			
Rate of SE Decision	93.97%	95.18%			
Rate of NSE Decision	6.03%	4.82%			
Rate of Withdrawal	4.97%	2.55%			
Rate of Deleted	5.62%	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	1			
Mean FDA Days for Submissions that Missed the Goal	93.00	91.00			
Mean Industry Days for Submissions that Missed the Goal	192.00	42.00			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	715	455			
Closed Before First RTA or TS Action [1]	10	3			
Number Accepted or Passed TS on First Cycle [2]	562	396			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	7			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	30			
Number Not Accepted or Failed TS on First Cycle [2]	142	19			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.14%	4.50%			

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	680	412			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	674	323			
SI Over 60 FDA Days	5	3			
SI Pending Within 60 FDA Days	0	83			
SI Pending Over 60 FDA Days	0	3			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	99.26%	98.18%			

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	679	326			
Average Number of FDA Days to Substantive Interaction	52.68	51.98			
20th Percentile FDA Days to Substantive Interaction	50	47			
40th Percentile FDA Days to Substantive Interaction	56	57			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	122	63			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	680	412			
Non-MDUFA V Decision	78	7			
MDUFA V Decision (SE/NSE)	571	167			
MDUFA V Decision Within 90 FDA Days	569	167			
510(k)s Pending MDUFA V Decision	31	238			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	5	6			
Current Performance Percent Within 90 FDA Days	98.78%	96.53%			

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	1.60	1.40			
Number With MDUFA V Decision	571	167			
Average Number of FDA Days to MDUFA V Decision	74.89	64.86			
20th Percentile FDA Days to MDUFA V Decision	57	30			
40th Percentile FDA Days to MDUFA V Decision	83	58			
60th Percentile FDA Days to MDUFA V Decision	87	85			
80th Percentile FDA Days to MDUFA V Decision	89	89			
Maximum FDA Days to MDUFA V Decision	101	90			
Average Number of Industry Days to MDUFA V Decision	51.18	19.25			
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	42	0			
80th Percentile Industry Days to MDUFA V Decision	107	37			
Maximum Industry Days to MDUFA V Decision	357	179			
Average Number of Total Days to MDUFA V Decision	126.18	84.11			
20th Percentile Total Days to MDUFA V Decision	59	30			
40th Percentile Total Days to MDUFA V Decision	87	64			
60th Percentile Total Days to MDUFA V Decision	125	90			
80th Percentile Total Days to MDUFA V Decision	194	118			
Maximum Total Days to MDUFA V Decision	447	265			

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	680	412			
Number With MDUFA V Decision	571	167			
Number of SE Decision	555	166			
Number of NSE Decision	16	1			
Number of Withdrawal	48	4			
Number of Deleted	30	2			
Rate of SE Decision	97.20%	99.40%			
Rate of NSE Decision	2.80%	0.60%			
Rate of Withdrawal	7.06%	0.97%			
Rate of Deleted	4.41%	0.49%			

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	315	209			
Closed Before First RTA or TS Action [1]	3	3			
Number Accepted or Passed TS on First Cycle [2]	214	180			
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	7			
Number Not Accepted or Failed TS on First Cycle [2]	97	19			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	31.09%	9.55%			

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	294	193			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	281	131			
SI Over 60 FDA Days	11	12			
SI Pending Within 60 FDA Days	2	43			
SI Pending Over 60 FDA Days	0	7			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.23%	87.33%			

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	292	143			
Average Number of FDA Days to Substantive Interaction	54.60	54.87			
20th Percentile FDA Days to Substantive Interaction	56	52			
40th Percentile FDA Days to Substantive Interaction	58	58			
60th Percentile FDA Days to Substantive Interaction	60	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	80	95			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	294	193			
Non-MDUFA V Decision	24	3			
MDUFA V Decision (SE/NSE)	248	59			
MDUFA V Decision Within 90 FDA Days	244	59			
510(k)s Pending MDUFA V Decision	22	131			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	3			
Current Performance Percent Within 90 FDA Days	98.39%	95.16%			

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	1.72	1.49			
Number With MDUFA V Decision	248	59			
Average Number of FDA Days to MDUFA V Decision	77.30	68.25			
20th Percentile FDA Days to MDUFA V Decision	58	45			
40th Percentile FDA Days to MDUFA V Decision	87	61			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	89			
Maximum FDA Days to MDUFA V Decision	150	90			
Average Number of Industry Days to MDUFA V Decision	71.98	24.63			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	30	0			
60th Percentile Industry Days to MDUFA V Decision	77	12			
80th Percentile Industry Days to MDUFA V Decision	160	59			
Maximum Industry Days to MDUFA V Decision	367	139			
Average Number of Total Days to MDUFA V Decision	148.63	92.88			
20th Percentile Total Days to MDUFA V Decision	60	45			
40th Percentile Total Days to MDUFA V Decision	112	72			
60th Percentile Total Days to MDUFA V Decision	164	101			
80th Percentile Total Days to MDUFA V Decision	247	142			
Maximum Total Days to MDUFA V Decision	517	228			

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	294	193			
Number With MDUFA V Decision	248	59			
Number of SE Decision	233	56			
Number of NSE Decision	15	3			
Number of Withdrawal	9	0			
Number of Deleted	12	3			
Rate of SE Decision	93.95%	94.92%			
Rate of NSE Decision	6.05%	5.08%			
Rate of Withdrawal	3.06%	0.00%			
Rate of Deleted	4.08%	1.55%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	0			
Mean FDA Days for Submissions that Missed the Goal	123.25	N/A			
Mean Industry Days for Submissions that Missed the Goal	213.75	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	622	397			
Closed Before First RTA or TS Action [1]	6	1			
Number Accepted or Passed TS on First Cycle [2]	519	358			
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]	0	26			
Number Not Accepted or Failed TS on First Cycle [2]	94	11			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.26%	2.97%			

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	608	363			
Deleted or Withdrawn Prior to SI	1	2			
SI Within 60 FDA Days	606	283			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	1	78			
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	606	283			
Average Number of FDA Days to Substantive Interaction	49.87	48.42			
20th Percentile FDA Days to Substantive Interaction	30	29			
40th Percentile FDA Days to Substantive Interaction	56	54			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	60	60			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	608	363			
Non-MDUFA V Decision	48	7			
MDUFA V Decision (SE/NSE)	547	199			
MDUFA V Decision Within 90 FDA Days	547	199			
510(k)s Pending MDUFA V Decision	13	157			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	1			
Current Performance Percent Within 90 FDA Days	99.45%	99.50%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48	1.25			
Number With MDUFA V Decision	547	199			
Average Number of FDA Days to MDUFA V Decision	65.57	56.40			
20th Percentile FDA Days to MDUFA V Decision	30	28			
40th Percentile FDA Days to MDUFA V Decision	59	49			
60th Percentile FDA Days to MDUFA V Decision	85	64			
80th Percentile FDA Days to MDUFA V Decision	89	87			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	41.05	10.39			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	16	0			
80th Percentile Industry Days to MDUFA V Decision	91	12			
Maximum Industry Days to MDUFA V Decision	338	133			
Average Number of Total Days to MDUFA V Decision	106.63	67.07			
20th Percentile Total Days to MDUFA V Decision	30	28			
40th Percentile Total Days to MDUFA V Decision	60	49			
60th Percentile Total Days to MDUFA V Decision	98	68			
80th Percentile Total Days to MDUFA V Decision	176	100			
Maximum Total Days to MDUFA V Decision	428	216			

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	608	363			
Number With MDUFA V Decision	547	199			
Number of SE Decision	538	198			
Number of NSE Decision	9	1			
Number of Withdrawal	35	6			
Number of Deleted	11	1			
Rate of SE Decision	98.35%	99.50%			
Rate of NSE Decision	1.65%	0.50%			
Rate of Withdrawal	5.76%	1.65%			
Rate of Deleted	1.81%	0.28%			

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	184			
Closed Before First RTA or TS Action [1]	7	8			
Number Accepted or Passed TS on First Cycle [2]	242	155			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	5	2			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	10			
Number Not Accepted or Failed TS on First Cycle [2]	40	9			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.94%	5.42%			

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	269	161			
Deleted or Withdrawn Prior to SI	3	0			
SI Within 60 FDA Days	264	133			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	28			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	2	0			
Current SI Performance Percent Within 60 FDA Days	99.25%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	264	133			
Average Number of FDA Days to Substantive Interaction	52.56	50.39			
20th Percentile FDA Days to Substantive Interaction	47	42			
40th Percentile FDA Days to Substantive Interaction	56	55			
60th Percentile FDA Days to Substantive Interaction	58	57			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	60	60			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	161			
Non-MDUFA V Decision	48	2			
MDUFA V Decision (SE/NSE)	213	59			
MDUFA V Decision Within 90 FDA Days	213	59			
510(k)s Pending MDUFA V Decision	8	100			
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	1.57	1.29			
Number With MDUFA V Decision	213	59			
Average Number of FDA Days to MDUFA V Decision	75.93	62.92			
20th Percentile FDA Days to MDUFA V Decision	58	30			
40th Percentile FDA Days to MDUFA V Decision	87	56			
60th Percentile FDA Days to MDUFA V Decision	89	88			
80th Percentile FDA Days to MDUFA V Decision	90	90			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	77.14	16.59			
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	104	0			
80th Percentile Industry Days to MDUFA V Decision	177	36			
Maximum Industry Days to MDUFA V Decision	361	108			
Average Number of Total Days to MDUFA V Decision	152.88	79.51			
20th Percentile Total Days to MDUFA V Decision	59	30			
40th Percentile Total Days to MDUFA V Decision	90	62			
60th Percentile Total Days to MDUFA V Decision	194	90			
80th Percentile Total Days to MDUFA V Decision	265	105			
Maximum Total Days to MDUFA V Decision	451	197			

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	269	161			
Number With MDUFA V Decision	213	59			
Number of SE Decision	205	59			
Number of NSE Decision	8	0			
Number of Withdrawal	27	1			
Number of Deleted	21	1			
Rate of SE Decision	96.24%	100.00%			
Rate of NSE Decision	3.76%	0.00%			
Rate of Withdrawal	10.04%	0.62%			
Rate of Deleted	7.81%	0.62%			

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	3			
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	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 6.9 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	267	158			
Non-MDUFA V Decision	48	2			
MDUFA V Decision (SE/NSE)	211	59			
MDUFA V Decision Within 90 FDA Days	211	59			
510(k)s Pending MDUFA V Decision	8	97			
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	305			
Closed Before First RTA or TS Action [1]	4	1			
Number Accepted or Passed TS on First Cycle [2]	441	279			
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	19			
Number Not Accepted or Failed TS on First Cycle [2]	41	6			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.47%	2.11%			

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	280			
Deleted or Withdrawn Prior to SI	0	2			
SI Within 60 FDA Days	476	217			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	60			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100.00%	99.54%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	476	217			
Average Number of FDA Days to Substantive Interaction	49.51	50.35			
20th Percentile FDA Days to Substantive Interaction	35	43			
40th Percentile FDA Days to Substantive Interaction	53	56			
60th Percentile FDA Days to Substantive Interaction	57	58			
80th Percentile FDA Days to Substantive Interaction	59	59			
Maximum FDA Days to Substantive Interaction	60	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	280			
Non-MDUFA V Decision	30	8			
MDUFA V Decision (SE/NSE)	443	112			
MDUFA V Decision Within 90 FDA Days	443	112			
510(k)s Pending MDUFA V Decision	3	160			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	1			
Current Performance Percent Within 90 FDA Days	100.00%	99.12%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.61			
Number With MDUFA V Decision	443	112			
Average Number of FDA Days to MDUFA V Decision	71.44	67.69			
20th Percentile FDA Days to MDUFA V Decision	52	42			
40th Percentile FDA Days to MDUFA V Decision	79	60			
60th Percentile FDA Days to MDUFA V Decision	86	87			
80th Percentile FDA Days to MDUFA V Decision	89	89			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	63.16	31.47			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	24	2			
60th Percentile Industry Days to MDUFA V Decision	61	29			
80th Percentile Industry Days to MDUFA V Decision	138	58			
Maximum Industry Days to MDUFA V Decision	210	176			
Average Number of Total Days to MDUFA V Decision	134.43	99.16			
20th Percentile Total Days to MDUFA V Decision	56	48			
40th Percentile Total Days to MDUFA V Decision	107	77			
60th Percentile Total Days to MDUFA V Decision	146	113			
80th Percentile Total Days to MDUFA V Decision	216	146			
Maximum Total Days to MDUFA V Decision	272	265			

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	280			
Number With MDUFA V Decision	443	112			
Number of SE Decision	436	112			
Number of NSE Decision	7	0			
Number of Withdrawal	15	7			
Number of Deleted	14	1			
Rate of SE Decision	98.42%	100.00%			
Rate of NSE Decision	1.58%	0.00%			
Rate of Withdrawal	3.15%	2.50%			
Rate of Deleted	2.94%	0.36%			

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	1			
Non-MDUFA V Decision	N/A	0			
MDUFA V Decision (SE/NSE)	N/A	0			
MDUFA V Decision Within 90 FDA Days	N/A	0			
510(k)s Pending MDUFA V Decision	N/A	1			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	0			
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

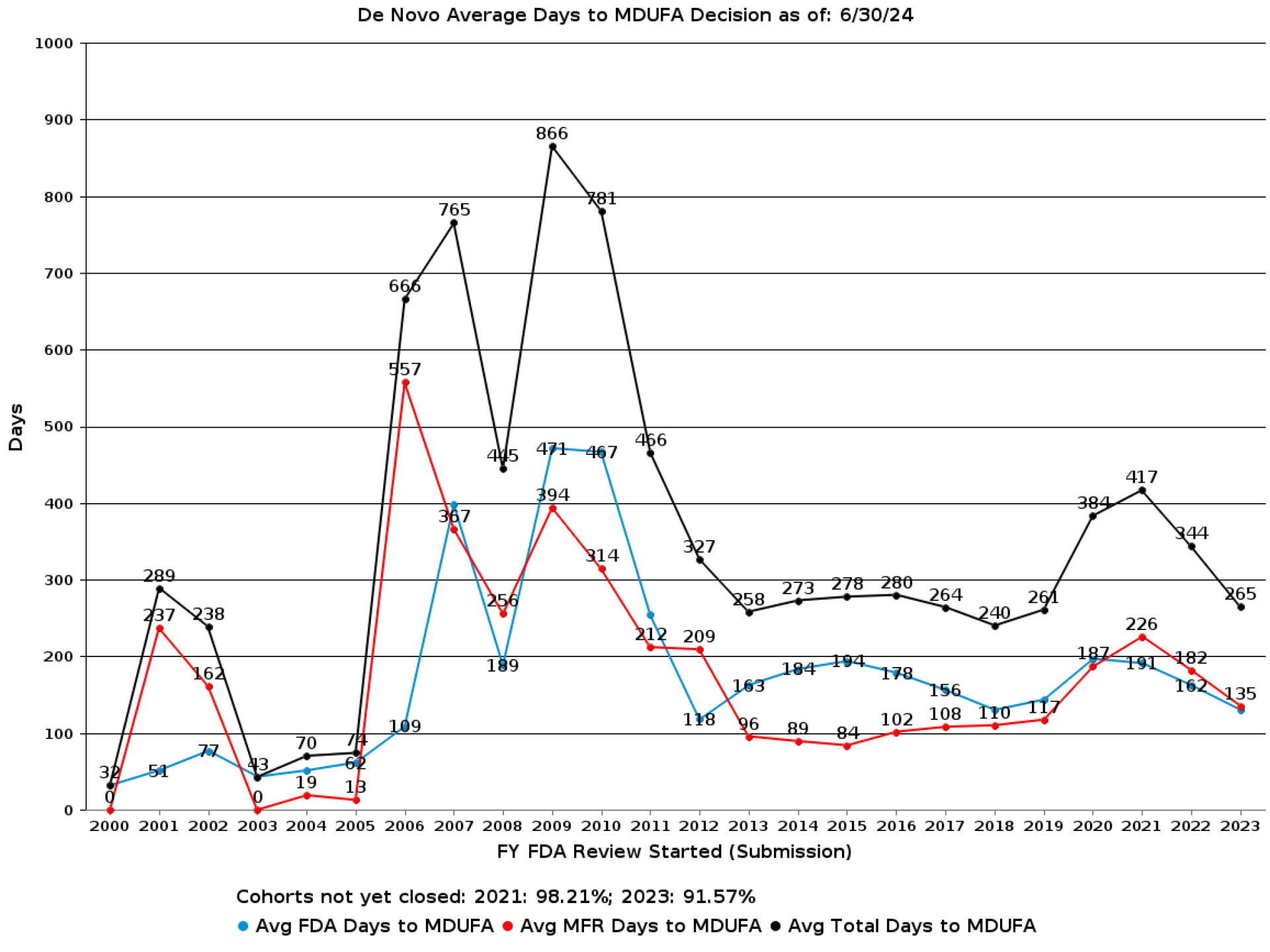
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A			
Non-MDUFA V Decision	N/A	N/A			
MDUFA V Decision (SE/NSE)	N/A	N/A			
MDUFA V Decision Within 90 FDA Days	N/A	N/A			
510(k)s Pending MDUFA V Decision	N/A	N/A			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A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

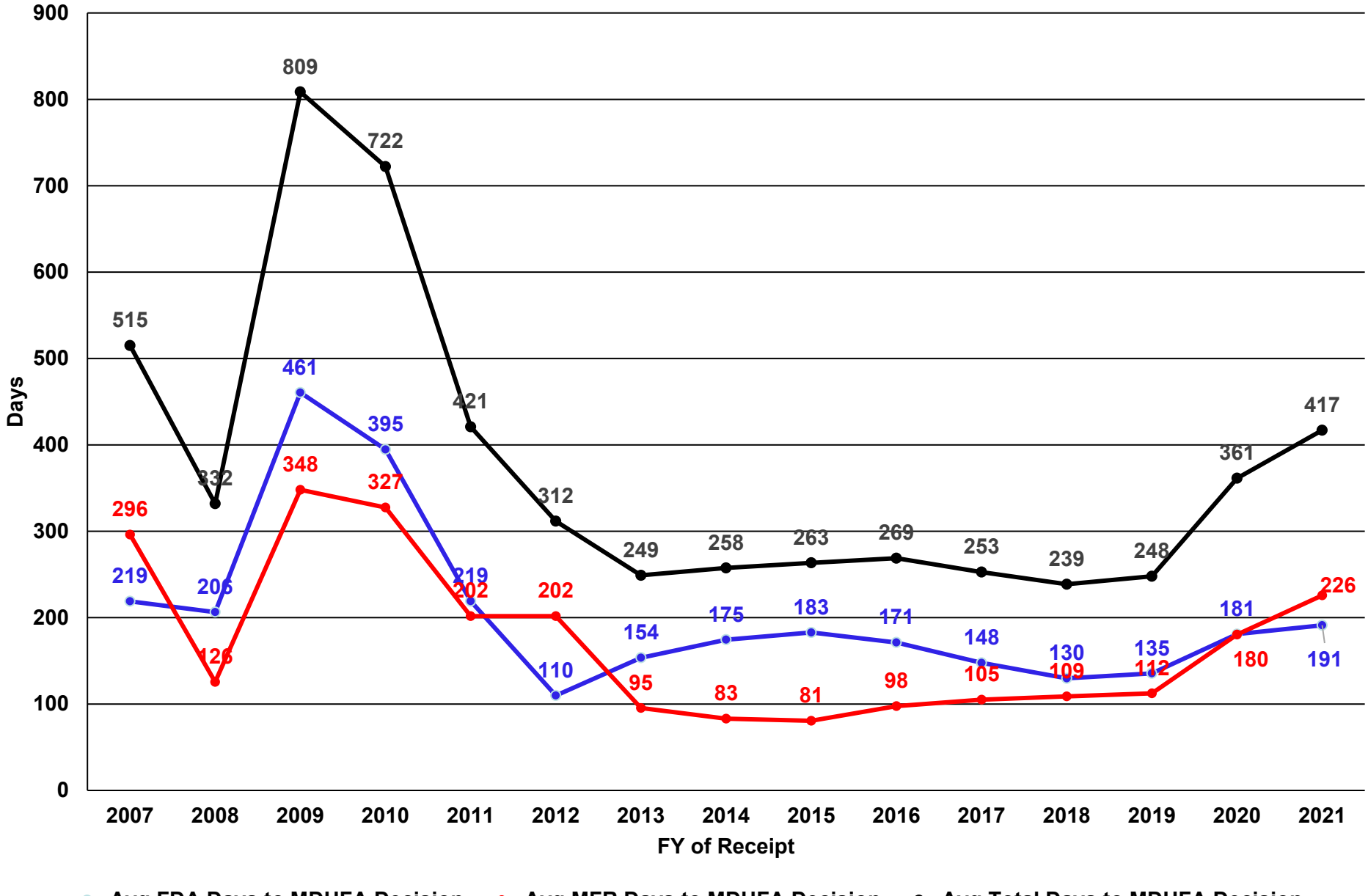
De Novos

Q3FY2024


De Novo Average Days to MDUFA Decision as of: 6/30/24
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2021: 98.21%; 2023: 91.57%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

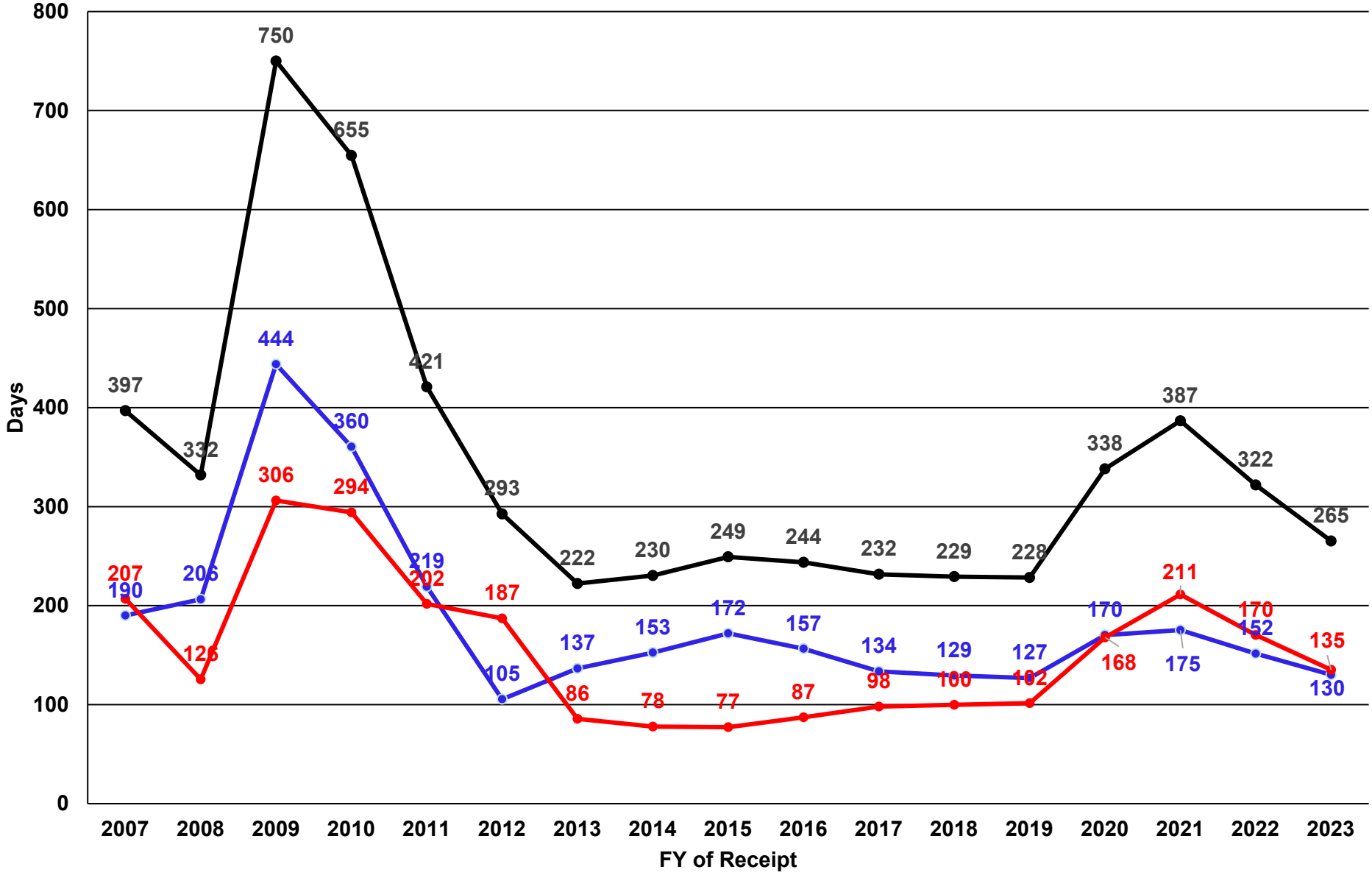
Average Time to MDUFA Decision: De Novos

(98.22% closure comparison)

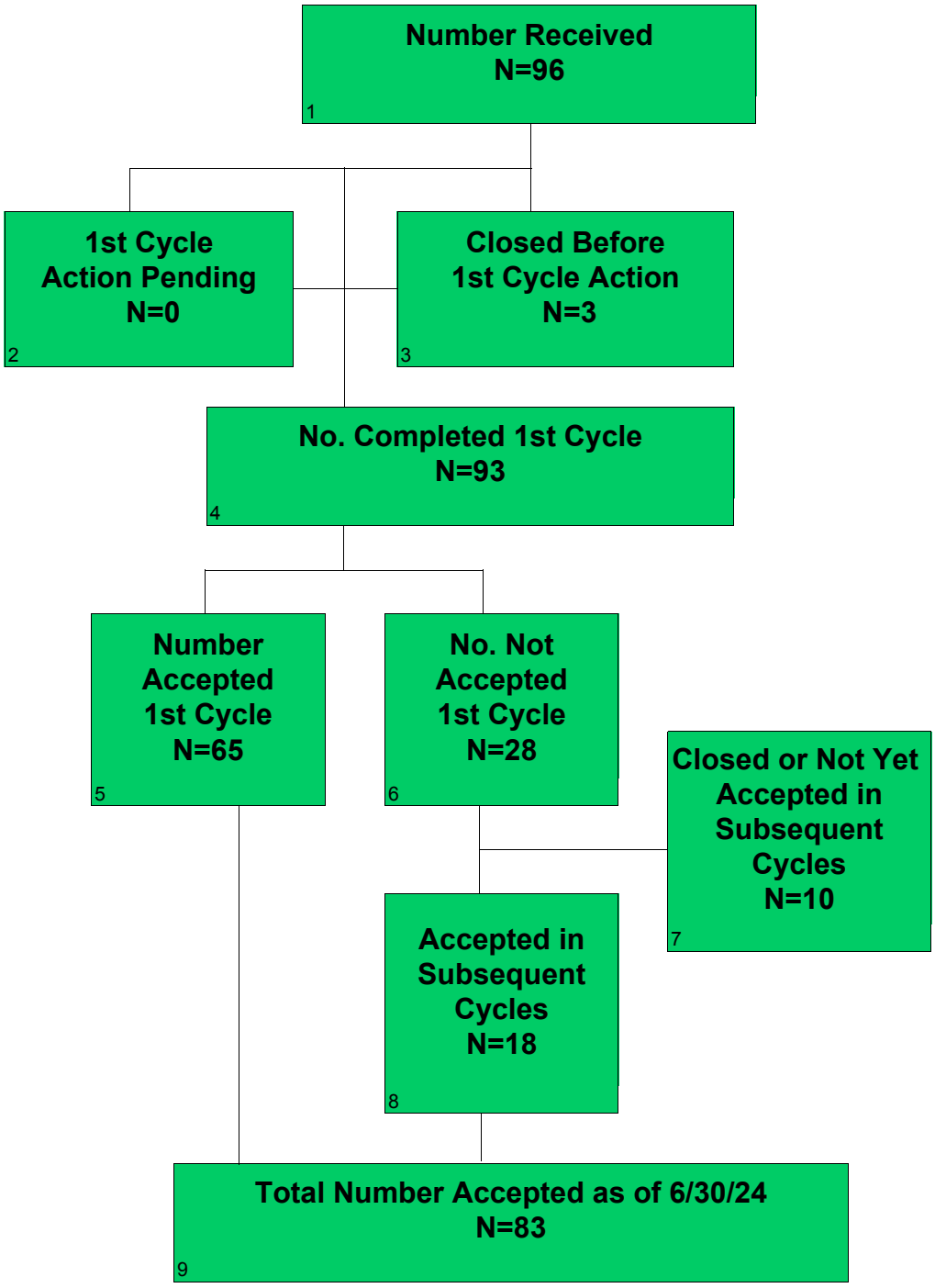


Average Time to MDUFA Decision: De Novos

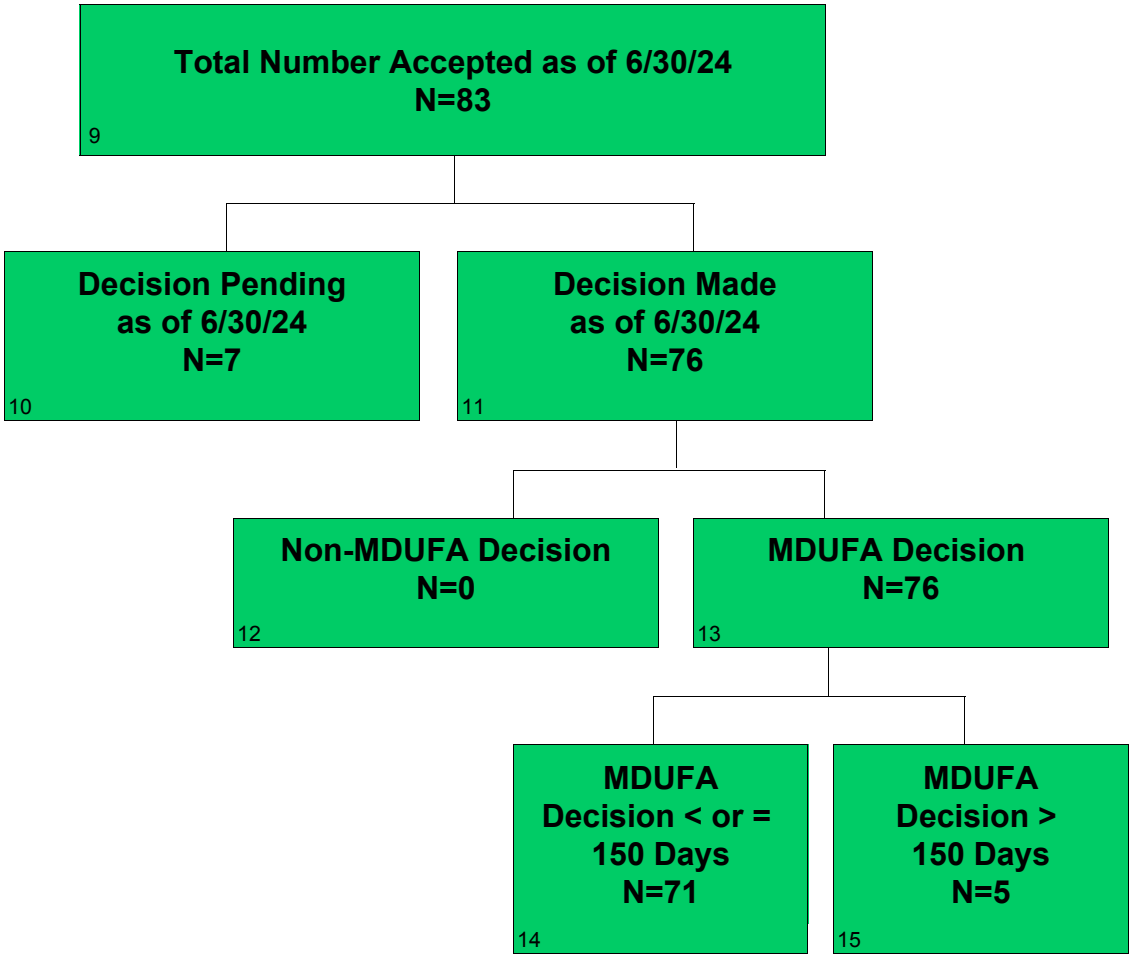
(91.57% closure comparison)



CDRH De Novo - FY 2023
as of 6/30/24



CDRH De Novo - FY 2023
as of 6/30/24 Continued



CDRH De Novo - FY 2024
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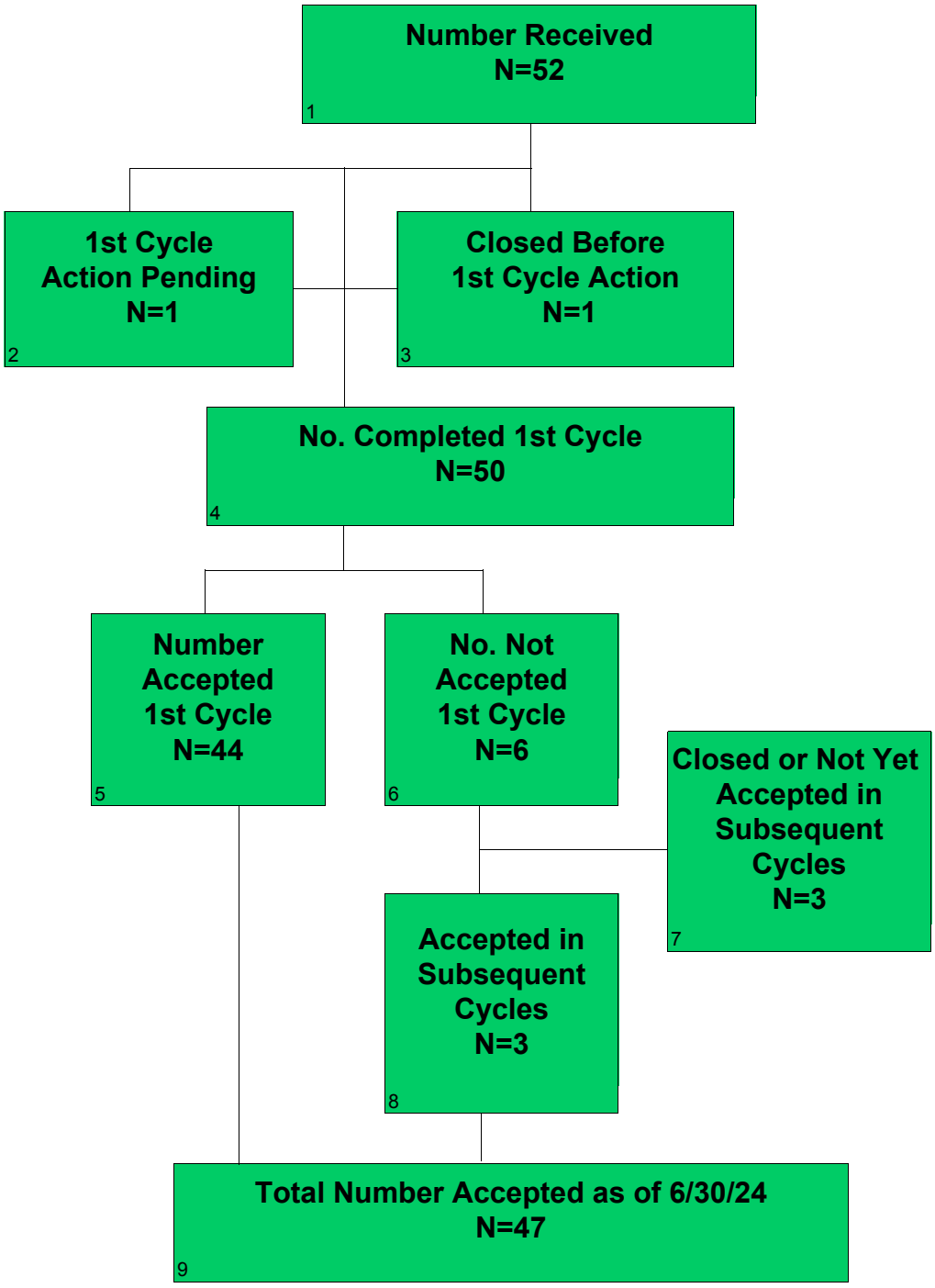
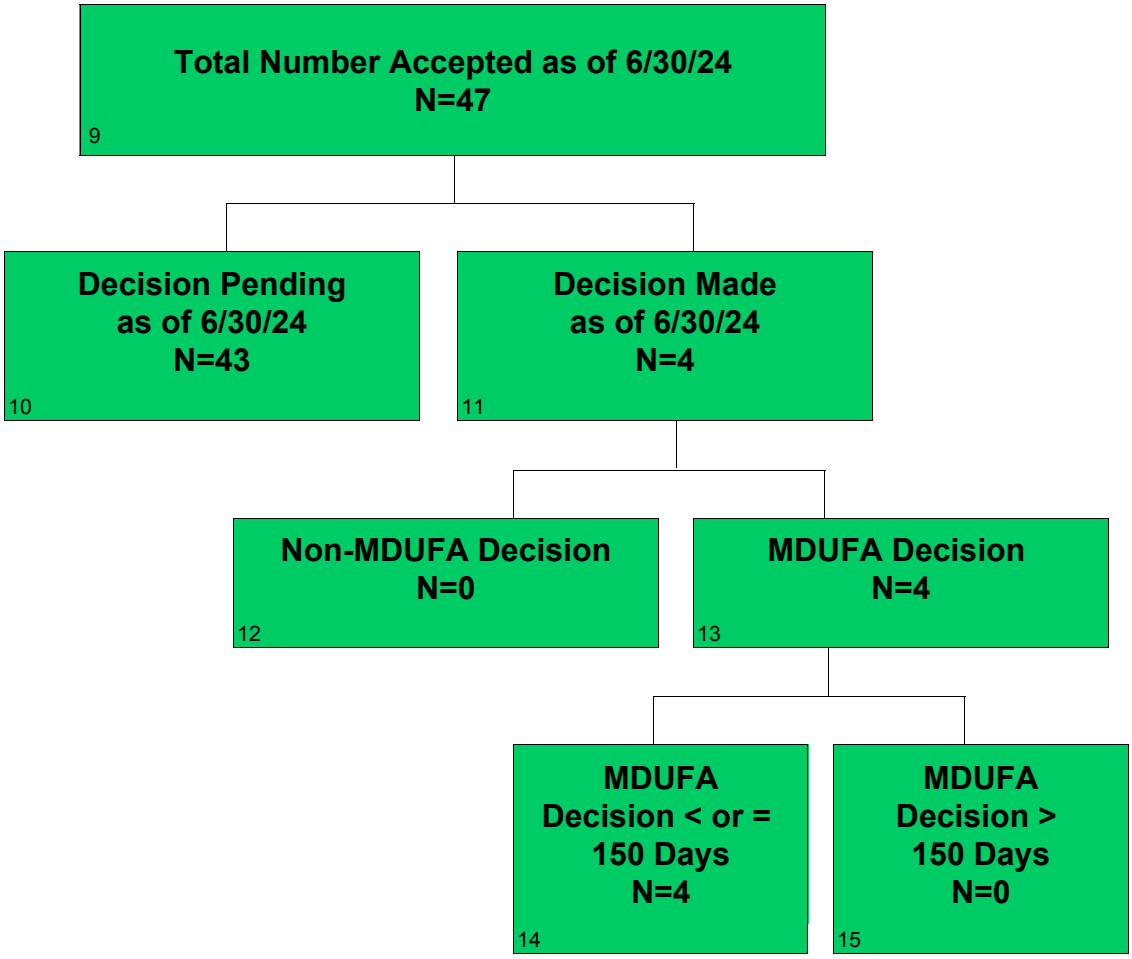


CDRH De Novo - FY 2024
as of 6/30/24 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96	52			
Closed Before First RTA or TS Action	3	1			
Number Accepted or Passed TS on First Cycle	65	44			
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	28	6			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	12.00%			

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 (see box 5 in flowchart).

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	83	47			
Non-MDUFA Decision	0	0			
MDUFA Decision	76	4			
MDUFA Decision Within 150 FDA Days	71	4			
De Novos Pending MDUFA Decision	7	43			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	93.42%	100.00%			

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.64	1.00			
Number With MDUFA Decision	76	4			
Average FDA Days to MDUFA Decision	130.12	85.00			
20th Percentile FDA Days to MDUFA Decision	75	74			
40th Percentile FDA Days to MDUFA Decision	148	77			
60th Percentile FDA Days to MDUFA Decision	150	82			
80th Percentile FDA Days to MDUFA Decision	150	94			
Maximum FDA Days to MDUFA Decision	251	109			
Average Industry Days to MDUFA Decision	135.13	45.75			
20th Percentile Industry Days to MDUFA Decision	64	0			
40th Percentile Industry Days to MDUFA Decision	150	0			
60th Percentile Industry Days to MDUFA Decision	178	0			
80th Percentile Industry Days to MDUFA Decision	181	73			
Maximum Industry Days to MDUFA Decision	350	183			
Average Total Days to MDUFA Decision	265.25	130.75			
20th Percentile Total Days to MDUFA Decision	206	79			
40th Percentile Total Days to MDUFA Decision	255	89			
60th Percentile Total Days to MDUFA Decision	300	104			
80th Percentile Total Days to MDUFA Decision	329	169			
Maximum Total Days to MDUFA Decision	437	258			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	83	47			
Number With MDUFA Decision	76	4			
Number With Granted Decision	34	1			
Number With Declined Decision	17	1			
Number of Withdrawal	15	1			
Number of Deleted	10	1			
Rate of Granted Decision	44.74%	25.00%			
Rate of Declined Decision	22.37%	25.00%			
Rate of Withdrawal	19.74%	25.00%			
Rate of Deleted	13.16%	25.00%			

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

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

Table 8.6 CDRH - LDT De Novo MDUFA V Decision Metrics

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	17	1			
MDUFA Decision Within 150 FDA Days	17	1			
De Novos Pending MDUFA Decision	2	10			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

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	9			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	6	6			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted or Failed TS on First Cycle	6	3			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	33.33%			

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

Table 8.2 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	7			
Non-MDUFA Decision	0	0			
MDUFA Decision	11	1			
MDUFA Decision Within 150 FDA Days	8	1			
De Novos Pending MDUFA Decision	0	6			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	72.73%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.00			
Number With MDUFA Decision	11	1			
Average FDA Days to MDUFA Decision	130.82	84.00			
20th Percentile FDA Days to MDUFA Decision	73	84			
40th Percentile FDA Days to MDUFA Decision	75	84			
60th Percentile FDA Days to MDUFA Decision	150	84			
80th Percentile FDA Days to MDUFA Decision	178	84			
Maximum FDA Days to MDUFA Decision	251	84			
Average Industry Days to MDUFA Decision	137.45	N/A			
20th Percentile Industry Days to MDUFA Decision	81	0			
40th Percentile Industry Days to MDUFA Decision	152	0			
60th Percentile Industry Days to MDUFA Decision	178	0			
80th Percentile Industry Days to MDUFA Decision	182	0			
Maximum Industry Days to MDUFA Decision	189	0			
Average Total Days to MDUFA Decision	268.27	84.00			
20th Percentile Total Days to MDUFA Decision	231	84			
40th Percentile Total Days to MDUFA Decision	255	84			
60th Percentile Total Days to MDUFA Decision	262	84			
80th Percentile Total Days to MDUFA Decision	328	84			
Maximum Total Days to MDUFA Decision	343	84			

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	7			
Number With MDUFA Decision	11	1			
Number With Granted Decision	5	0			
Number With Declined Decision	1	0			
Number of Withdrawal	1	1			
Number of Deleted	4	0			
Rate of Granted Decision	45.45%	0.00%			
Rate of Declined Decision	9.09%	0.00%			
Rate of Withdrawal	9.09%	100.00%			
Rate of Deleted	36.36%	0.00%			

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	3			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	10	3			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	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	3			
Non-MDUFA Decision	0	0			
MDUFA Decision	10	0			
MDUFA Decision Within 150 FDA Days	10	0			
De Novos Pending MDUFA Decision	0	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 OHT2 - Office of Cardiovascular Devices
De Novo Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	N/A			
Number With MDUFA Decision	10	0			
Average FDA Days to MDUFA Decision	137.10	N/A			
20th Percentile FDA Days to MDUFA Decision	140	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	114.40	N/A			
20th Percentile Industry Days to MDUFA Decision	47	0			
40th Percentile Industry Days to MDUFA Decision	90	0			
60th Percentile Industry Days to MDUFA Decision	178	0			
80th Percentile Industry Days to MDUFA Decision	180	0			
Maximum Industry Days to MDUFA Decision	183	0			
Average Total Days to MDUFA Decision	251.50	N/A			
20th Percentile Total Days to MDUFA Decision	197	0			
40th Percentile Total Days to MDUFA Decision	238	0			
60th Percentile Total Days to MDUFA Decision	267	0			
80th Percentile Total Days to MDUFA Decision	328	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	3			
Number With MDUFA Decision	10	0			
Number With Granted Decision	6	0			
Number With Declined Decision	3	0			
Number of Withdrawal	0	0			
Number of Deleted	1	0			
Rate of Granted Decision	60.00%	N/A			
Rate of Declined Decision	30.00%	N/A			
Rate of Withdrawal	0.00%	N/A			
Rate of Deleted	10.00%	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 Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	11	4			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	9	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	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	4			
Non-MDUFA Decision	0	0			
MDUFA Decision	11	0			
MDUFA Decision Within 150 FDA Days	11	0			
De Novos Pending MDUFA Decision	0	4			
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	1.55	N/A			
Number With MDUFA Decision	11	0			
Average FDA Days to MDUFA Decision	128.45	N/A			
20th Percentile FDA Days to MDUFA Decision	74	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	150	0			
Average Industry Days to MDUFA Decision	122.73	N/A			
20th Percentile Industry Days to MDUFA Decision	83	0			
40th Percentile Industry Days to MDUFA Decision	124	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	214	0			
Average Total Days to MDUFA Decision	251.18	N/A			
20th Percentile Total Days to MDUFA Decision	231	0			
40th Percentile Total Days to MDUFA Decision	247	0			
60th Percentile Total Days to MDUFA Decision	274	0			
80th Percentile Total Days to MDUFA Decision	293	0			
Maximum Total Days to MDUFA Decision	330	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	4			
Number With MDUFA Decision	11	0			
Number With Granted Decision	7	0			
Number With Declined Decision	1	0			
Number of Withdrawal	1	0			
Number of Deleted	2	0			
Rate of Granted Decision	63.64%	N/A			
Rate of Declined Decision	9.09%	N/A			
Rate of Withdrawal	9.09%	N/A			
Rate of Deleted	18.18%	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 Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	12			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	11	11			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	1			
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	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	14	0			
MDUFA Decision Within 150 FDA Days	12	0			
De Novos Pending MDUFA Decision	1	11			
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	1.79	N/A			
Number With MDUFA Decision	14	0			
Average FDA Days to MDUFA Decision	126.29	N/A			
20th Percentile FDA Days to MDUFA Decision	74	0			
40th Percentile FDA Days to MDUFA Decision	148	0			
60th Percentile FDA Days to MDUFA Decision	149	0			
80th Percentile FDA Days to MDUFA Decision	150	0			
Maximum FDA Days to MDUFA Decision	203	0			
Average Industry Days to MDUFA Decision	131.64	N/A			
20th Percentile Industry Days to MDUFA Decision	76	0			
40th Percentile Industry Days to MDUFA Decision	152	0			
60th Percentile Industry Days to MDUFA Decision	180	0			
80th Percentile Industry Days to MDUFA Decision	181	0			
Maximum Industry Days to MDUFA Decision	198	0			
Average Total Days to MDUFA Decision	257.93	N/A			
20th Percentile Total Days to MDUFA Decision	224	0			
40th Percentile Total Days to MDUFA Decision	253	0			
60th Percentile Total Days to MDUFA Decision	293	0			
80th Percentile Total Days to MDUFA Decision	329	0			
Maximum Total Days to MDUFA Decision	346	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	11			
Number With MDUFA Decision	14	0			
Number With Granted Decision	7	0			
Number With Declined Decision	2	0			
Number of Withdrawal	4	0			
Number of Deleted	1	0			
Rate of Granted Decision	50.00%	N/A			
Rate of Declined Decision	14.29%	N/A			
Rate of Withdrawal	28.57%	N/A			
Rate of Deleted	7.14%	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	2	0			
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A			
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	10	9			
Closed Before First RTA or TS Action	1	0			
Number Accepted or Passed TS on First Cycle	5	8			
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0			
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted or Failed TS on First Cycle	4	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	11.11%			

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	9	9			
Non-MDUFA Decision	0	0			
MDUFA Decision	6	1			
MDUFA Decision Within 150 FDA Days	6	1			
De Novos Pending MDUFA Decision	3	8			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00	1.00			
Number With MDUFA Decision	6	1			
Average FDA Days to MDUFA Decision	149.67	75.00			
20th Percentile FDA Days to MDUFA Decision	149	75			
40th Percentile FDA Days to MDUFA Decision	150	75			
60th Percentile FDA Days to MDUFA Decision	150	75			
80th Percentile FDA Days to MDUFA Decision	150	75			
Maximum FDA Days to MDUFA Decision	150	75			
Average Industry Days to MDUFA Decision	124.17	183.00			
20th Percentile Industry Days to MDUFA Decision	56	183			
40th Percentile Industry Days to MDUFA Decision	150	183			
60th Percentile Industry Days to MDUFA Decision	166	183			
80th Percentile Industry Days to MDUFA Decision	173	183			
Maximum Industry Days to MDUFA Decision	181	183			
Average Total Days to MDUFA Decision	273.83	258.00			
20th Percentile Total Days to MDUFA Decision	205	258			
40th Percentile Total Days to MDUFA Decision	300	258			
60th Percentile Total Days to MDUFA Decision	316	258			
80th Percentile Total Days to MDUFA Decision	323	258			
Maximum Total Days to MDUFA Decision	330	258			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	9			
Number With MDUFA Decision	6	1			
Number With Granted Decision	1	0			
Number With Declined Decision	5	0			
Number of Withdrawal	0	0			
Number of Deleted	0	1			
Rate of Granted Decision	16.67%	0.00%			
Rate of Declined Decision	83.33%	0.00%			
Rate of Withdrawal	0.00%	0.00%			
Rate of Deleted	0.00%	100.00%			

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	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	2	0			
MDUFA Decision Within 150 FDA Days	2	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	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	1.50	N/A			
Number With MDUFA Decision	2	0			
Average FDA Days to MDUFA Decision	148.50	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	149	0			
80th Percentile FDA Days to MDUFA Decision	149	0			
Maximum FDA Days to MDUFA Decision	149	0			
Average Industry Days to MDUFA Decision	90.00	N/A			
20th Percentile Industry Days to MDUFA Decision	36	0			
40th Percentile Industry Days to MDUFA Decision	72	0			
60th Percentile Industry Days to MDUFA Decision	108	0			
80th Percentile Industry Days to MDUFA Decision	144	0			
Maximum Industry Days to MDUFA Decision	180	0			
Average Total Days to MDUFA Decision	238.50	N/A			
20th Percentile Total Days to MDUFA Decision	184	0			
40th Percentile Total Days to MDUFA Decision	220	0			
60th Percentile Total Days to MDUFA Decision	257	0			
80th Percentile Total Days to MDUFA Decision	293	0			
Maximum Total Days to MDUFA Decision	329	0			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	3	0			
Number With MDUFA Decision	2	0			
Number With Granted Decision	2	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 Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	12			
Closed Before First RTA or TS Action	1	1			
Number Accepted or Passed TS on First Cycle	17	10			
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	5	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	9.09%			

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	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	18	1			
MDUFA Decision Within 150 FDA Days	18	1			
De Novos Pending MDUFA Decision	2	10			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.56	1.00			
Number With MDUFA Decision	18	1			
Average FDA Days to MDUFA Decision	126.00	72.00			
20th Percentile FDA Days to MDUFA Decision	80	72			
40th Percentile FDA Days to MDUFA Decision	137	72			
60th Percentile FDA Days to MDUFA Decision	149	72			
80th Percentile FDA Days to MDUFA Decision	150	72			
Maximum FDA Days to MDUFA Decision	150	72			
Average Industry Days to MDUFA Decision	165.22	N/A			
20th Percentile Industry Days to MDUFA Decision	130	0			
40th Percentile Industry Days to MDUFA Decision	176	0			
60th Percentile Industry Days to MDUFA Decision	179	0			
80th Percentile Industry Days to MDUFA Decision	181	0			
Maximum Industry Days to MDUFA Decision	350	0			
Average Total Days to MDUFA Decision	291.22	72.00			
20th Percentile Total Days to MDUFA Decision	249	72			
40th Percentile Total Days to MDUFA Decision	294	72			
60th Percentile Total Days to MDUFA Decision	328	72			
80th Percentile Total Days to MDUFA Decision	330	72			
Maximum Total Days to MDUFA Decision	437	72			

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	11			
Number With MDUFA Decision	18	1			
Number With Granted Decision	4	1			
Number With Declined Decision	5	0			
Number of Withdrawal	8	0			
Number of Deleted	1	0			
Rate of Granted Decision	22.22%	100.00%			
Rate of Declined Decision	27.78%	0.00%			
Rate of Withdrawal	44.44%	0.00%			
Rate of Deleted	5.56%	0.00%			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	11			
Non-MDUFA Decision	0	0			
MDUFA Decision	17	1			
MDUFA Decision Within 150 FDA Days	17	1			
De Novos Pending MDUFA Decision	2	10			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	3			
Closed Before First RTA or TS Action	0	0			
Number Accepted or Passed TS on First Cycle	4	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	0			
Number Not Accepted or Failed TS on First Cycle	0	1			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	33.33%			

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

Table 8.2 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	2			
Non-MDUFA Decision	0	0			
MDUFA Decision	4	1			
MDUFA Decision Within 150 FDA Days	4	1			
De Novos Pending MDUFA Decision	0	1			
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100.00%	100.00%			

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

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

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

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

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

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

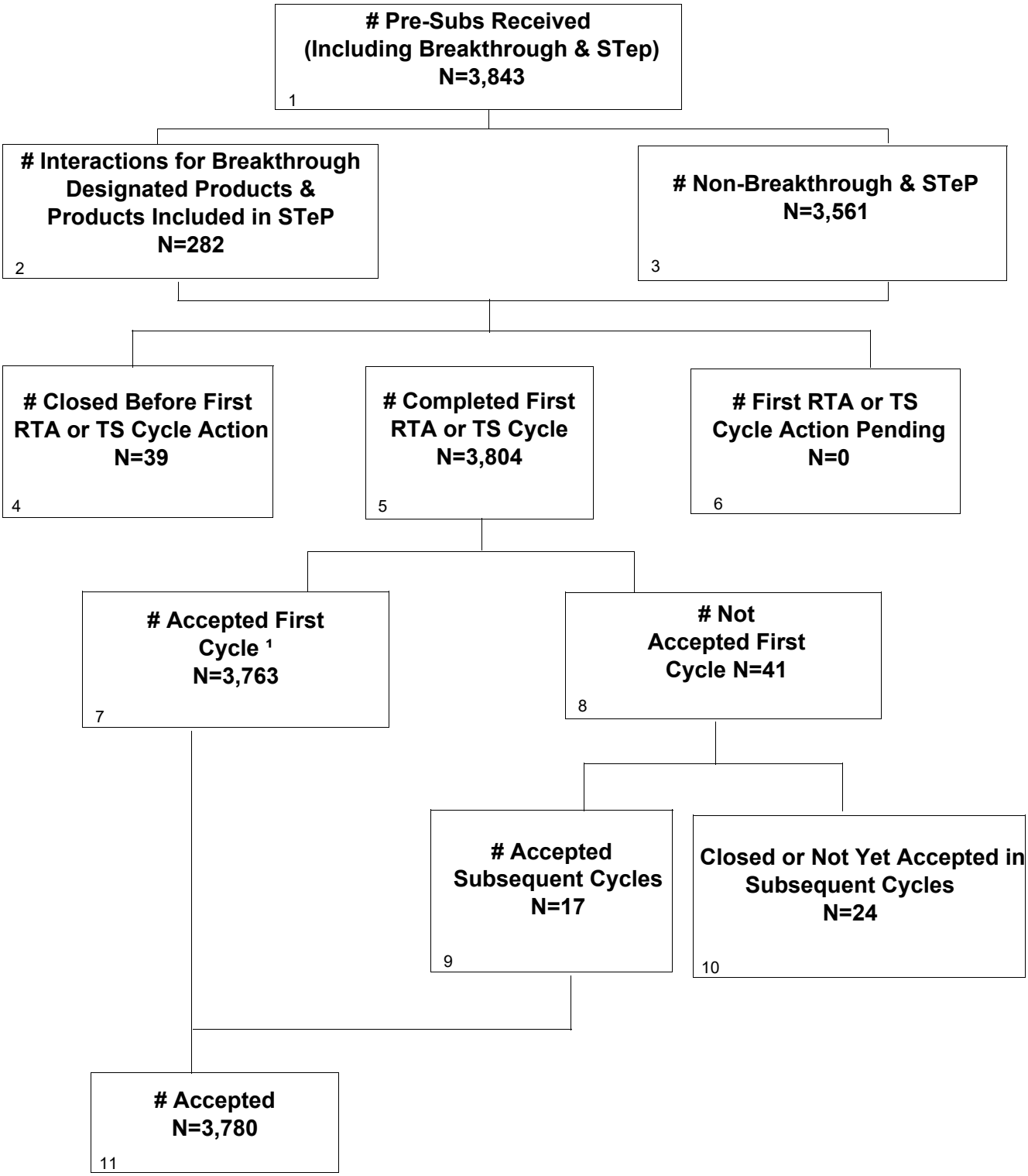
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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

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

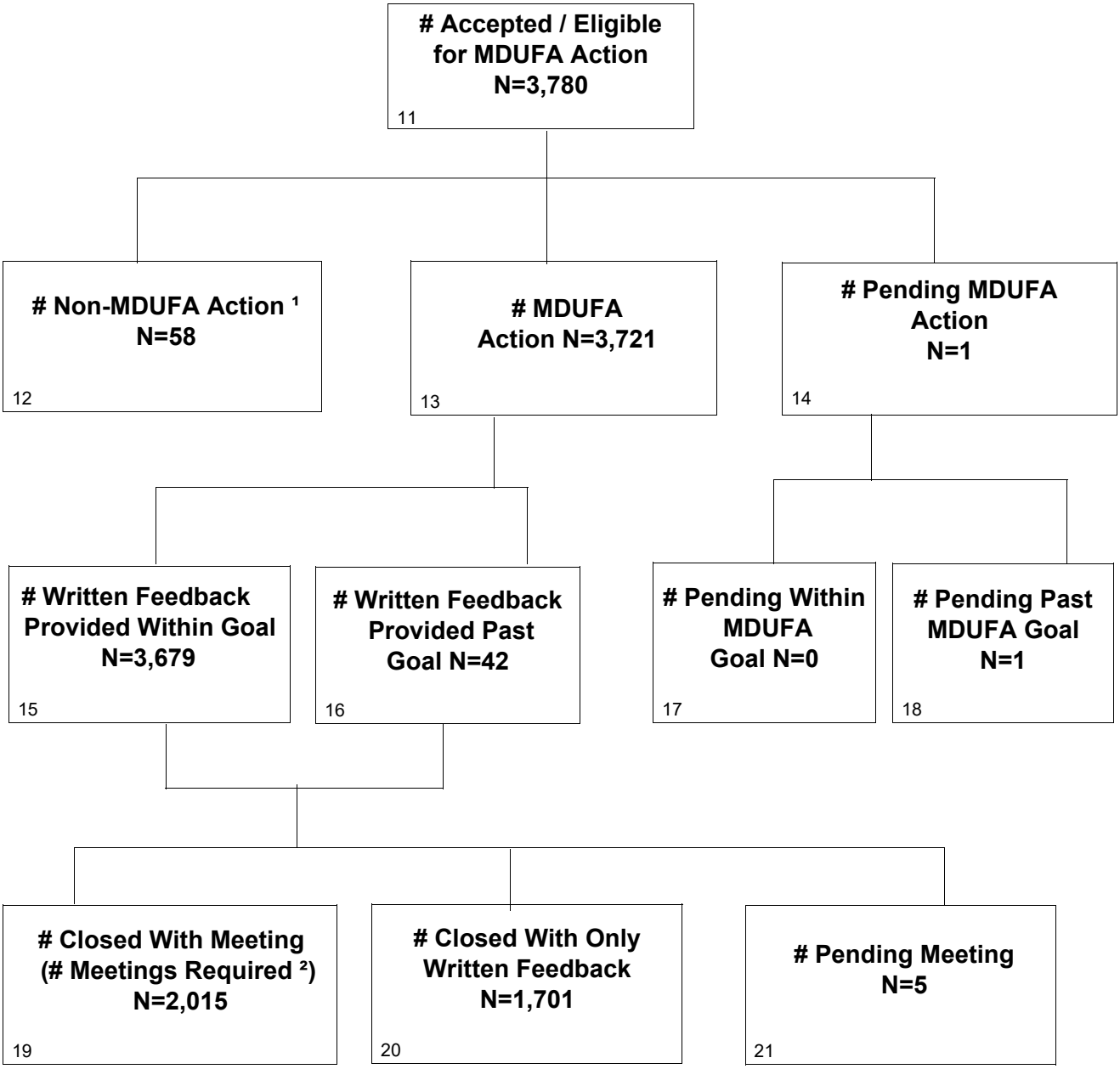
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A			
Non-MDUFA Decision	N/A	N/A			
MDUFA Decision	N/A	N/A			
MDUFA Decision Within 150 FDA Days	N/A	N/A			
De Novos Pending MDUFA Decision	N/A	N/A			
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A			
Current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

CDRH Pre-Sub - FY 2023
as of 6/30/24



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

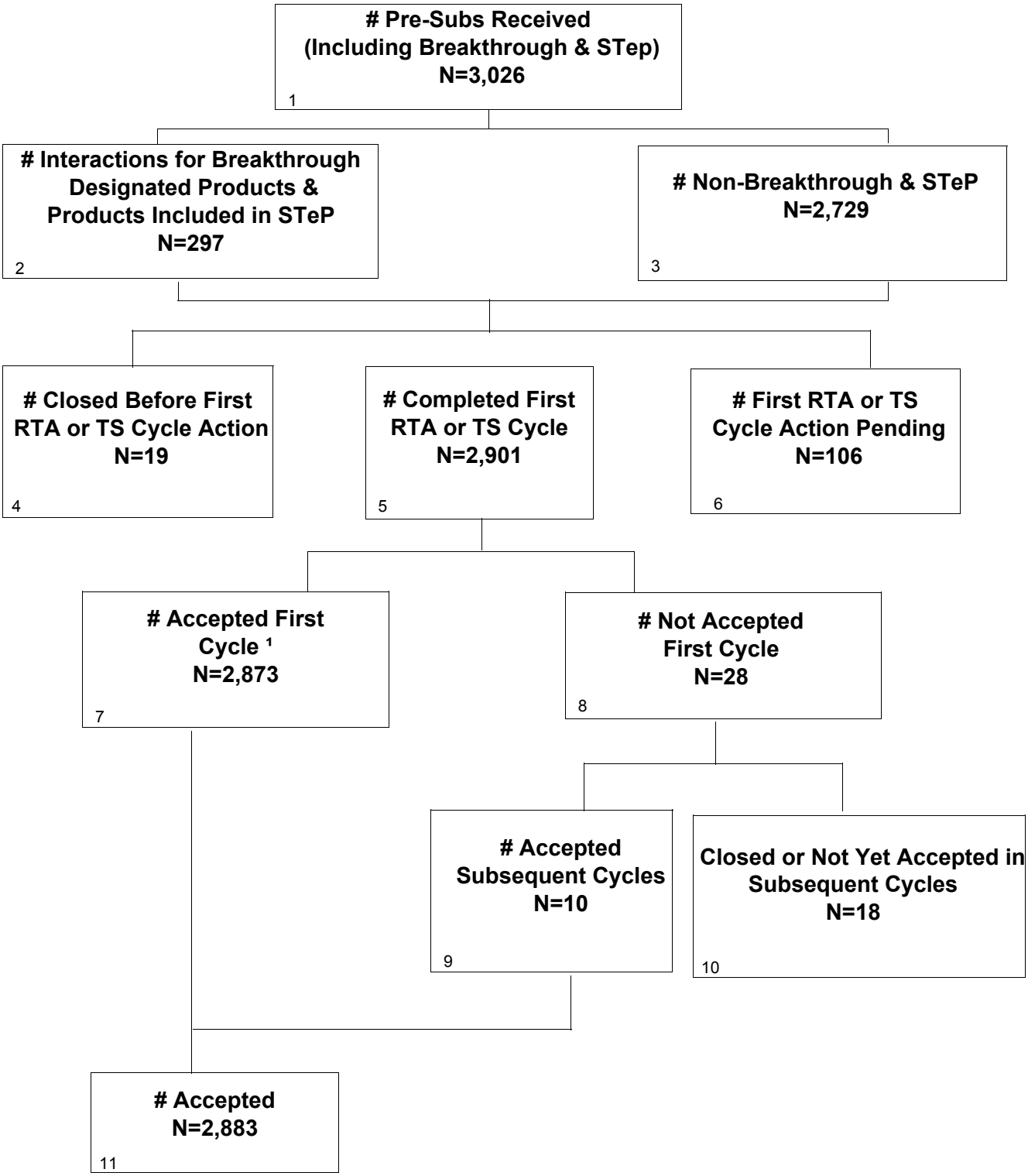
CDRH Pre-Sub - FY 2023
as of 6/30/24 Continued



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

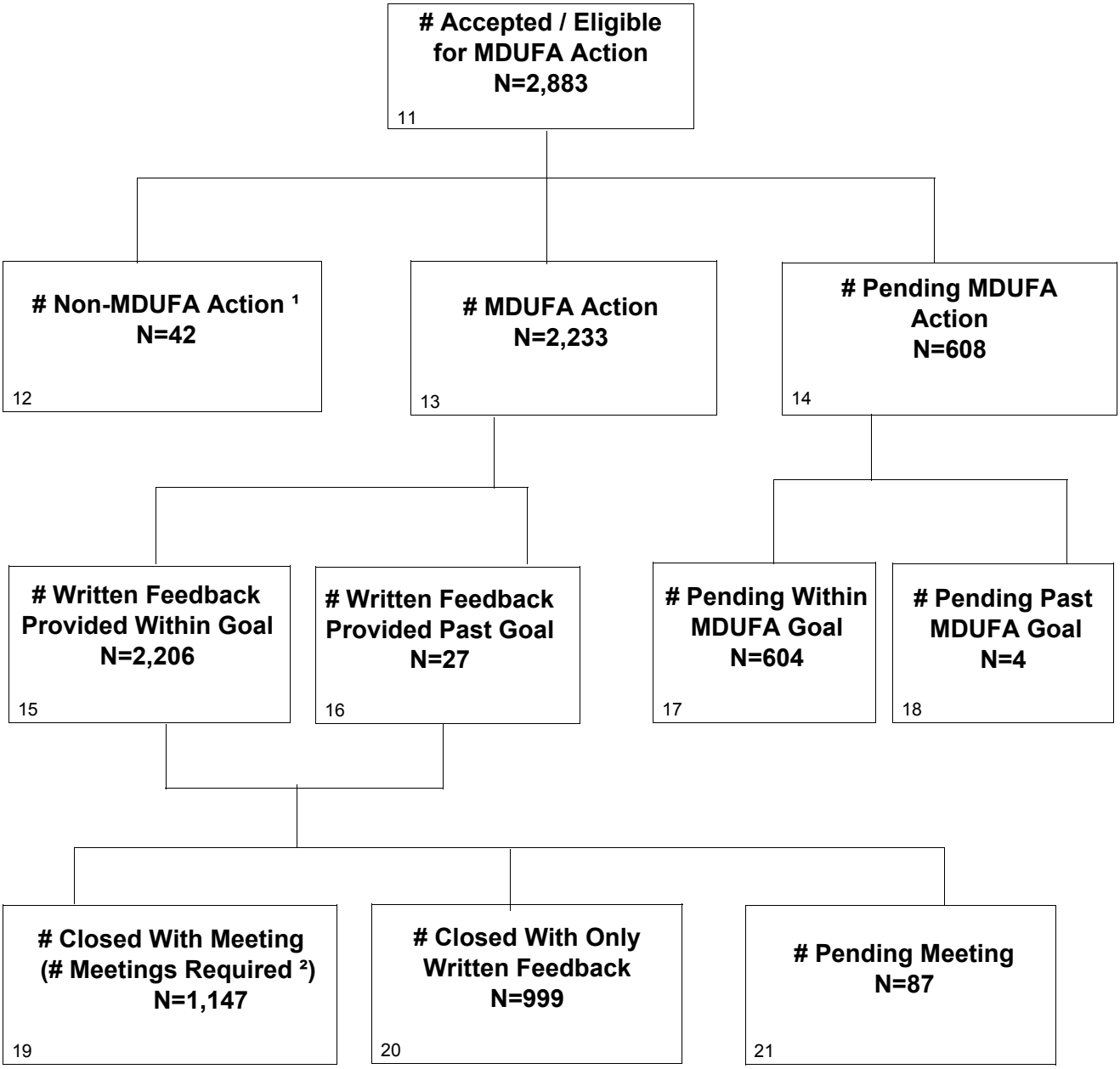
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 6/30/24



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

CDRH Pre-Sub - FY 2024
as of 6/30/24 Continued



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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,843	3,026			
Interactions for Breakthrough Designated Products & Products Included in STeP	282	297			
Number Closed Before First RTA Action	39	19			
Number Accepted First RTA Cycle [1]	3,642	2,807			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	66			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	106			
Number Not Accepted First RTA Cycle	41	28			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.97%			

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	2,883			
Number with Non-MDUFA Action [3]	58	42			
Number with MDUFA Action	3,721	2,233			
Written Feedback Provided Within Goal	3,679	2,206			
Number Pending MDUFA Action	1	608			
Pending MDUFA Action Past Goal	1	4			
Number in MDUFA Cohort (up to max 4300)[4]	3,722	2,841			
Current Performance Percent Within Goal	98.84%	98.61%			

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	2,233			
Average FDA Days to Written Feedback	62.20	61.60			
20th Percentile FDA Days to Written Feedback	56	55			
40th Percentile FDA Days to Written Feedback	64	64			
60th Percentile FDA Days to Written Feedback	68	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	141	113			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	136	88			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.51			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	2,014	1,147			
Meeting Minutes Submitted Within 15 Days of Meeting	1,530	877			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	58			
Meeting Minutes Past 15 Days of Meeting	434	174			
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	38			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.97%	80.53%			

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	446	352			
Interactions for Breakthrough Designated Products & Products Included in STeP	20	18			
Number Closed Before First RTA Action	4	4			
Number Accepted First RTA Cycle [1]	412	322			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	14			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	9			
Number Not Accepted First RTA Cycle	10	3			
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.26%	0.88%			

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	437	338			
Number with Non-MDUFA Action [3]	12	10			
Number with MDUFA Action	425	257			
Written Feedback Provided Within Goal	412	249			
Number Pending MDUFA Action	0	71			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	425	328			
Current Performance Percent Within Goal	96.94%	96.89%			

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	425	257			
Average FDA Days to Written Feedback	65.28	65.54			
20th Percentile FDA Days to Written Feedback	62	62			
40th Percentile FDA Days to Written Feedback	66	67			
60th Percentile FDA Days to Written Feedback	69	69			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	141	101			

Table 9.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	30	12			
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.17			

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	139			
Meeting Minutes Submitted Within 15 Days of Meeting	179	110			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	7			
Meeting Minutes Past 15 Days of Meeting	59	19			
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	83.33%			

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	723	540			
Interactions for Breakthrough Designated Products & Products Included in STeP	72	60			
Number Closed Before First RTA Action	6	2			
Number Accepted First RTA Cycle [1]	700	510			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	13			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	13			
Number Not Accepted First RTA Cycle	4	2			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.38%			

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	716	523			
Number with Non-MDUFA Action [3]	4	3			
Number with MDUFA Action	711	426			
Written Feedback Provided Within Goal	696	419			
Number Pending MDUFA Action	1	94			
Pending MDUFA Action Past Goal	1	2			
Number in MDUFA Cohort (up to max 4300)[4]	712	520			
Current Performance Percent Within Goal	97.75%	97.90%			

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	711	426			
Average FDA Days to Written Feedback	59.33	58.80			
20th Percentile FDA Days to Written Feedback	50	49			
40th Percentile FDA Days to Written Feedback	60	60			
60th Percentile FDA Days to Written Feedback	66	65			
80th Percentile FDA Days to Written Feedback	69	69			
Maximum FDA Days to Written Feedback	103	113			

Table 9.4 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	33	17			
Average Days to Scheduling for Meetings Scheduled After Day 30	38.09	36.76			

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]	406	224			
Meeting Minutes Submitted Within 15 Days of Meeting	308	159			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6			
Meeting Minutes Past 15 Days of Meeting	91	49			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	10			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.86%	72.94%			

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	370			
Interactions for Breakthrough Designated Products & Products Included in STeP	41	50			
Number Closed Before First RTA Action	5	3			
Number Accepted First RTA Cycle [1]	440	336			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	10			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	13			
Number Not Accepted First RTA Cycle	6	8			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.31%	2.26%			

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	348			
Number with Non-MDUFA Action [3]	10	7			
Number with MDUFA Action	445	270			
Written Feedback Provided Within Goal	441	268			
Number Pending MDUFA Action	0	71			
Pending MDUFA Action Past Goal	0	1			
Number in MDUFA Cohort (up to max 4300)[4]	445	341			
Current Performance Percent Within Goal	99.10%	98.89%			

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	270			
Average FDA Days to Written Feedback	62.09	60.68			
20th Percentile FDA Days to Written Feedback	56	53			
40th Percentile FDA Days to Written Feedback	64	63			
60th Percentile FDA Days to Written Feedback	67	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	78	75			

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	8			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	45.00			

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]	257	143			
Meeting Minutes Submitted Within 15 Days of Meeting	202	117			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	9			
Meeting Minutes Past 15 Days of Meeting	49	16			
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.60%	87.31%			

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	313			
Interactions for Breakthrough Designated Products & Products Included in STeP	21	25			
Number Closed Before First RTA Action	4	4			
Number Accepted First RTA Cycle [1]	343	278			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	8			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	18			
Number Not Accepted First RTA Cycle	5	5			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.40%	1.72%			

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	289			
Number with Non-MDUFA Action [3]	9	7			
Number with MDUFA Action	345	206			
Written Feedback Provided Within Goal	345	205			
Number Pending MDUFA Action	0	76			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	345	282			
Current Performance Percent Within Goal	100.00%	99.51%			

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	206			
Average FDA Days to Written Feedback	60.53	61.14			
20th Percentile FDA Days to Written Feedback	54	54			
40th Percentile FDA Days to Written Feedback	62	63			
60th Percentile FDA Days to Written Feedback	65	67			
80th Percentile FDA Days to Written Feedback	69	70			
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	8			
Average Days to Scheduling for Meetings Scheduled After Day 30	37.71	39.50			

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]	198	106			
Meeting Minutes Submitted Within 15 Days of Meeting	153	83			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	37	15			
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.27%	82.18%			

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	327			
Interactions for Breakthrough Designated Products & Products Included in STeP	42	34			
Number Closed Before First RTA Action	5	1			
Number Accepted First RTA Cycle [1]	371	301			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	6			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	11			
Number Not Accepted First RTA Cycle	4	8			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.54%			

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	310			
Number with Non-MDUFA Action [3]	5	3			
Number with MDUFA Action	385	226			
Written Feedback Provided Within Goal	383	220			
Number Pending MDUFA Action	0	81			
Pending MDUFA Action Past Goal	0	1			
Number in MDUFA Cohort (up to max 4300)[4]	385	307			
Current Performance Percent Within Goal	99.48%	96.92%			

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	226			
Average FDA Days to Written Feedback	66.13	66.47			
20th Percentile FDA Days to Written Feedback	64	65			
40th Percentile FDA Days to Written Feedback	68	69			
60th Percentile FDA Days to Written Feedback	70	70			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	108	81			

Table 9.4 CDRH- OHT5 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	25	28			
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	38.86			

Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	249	132			
Meeting Minutes Submitted Within 15 Days of Meeting	177	100			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	65	22			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.08%	78.74%			

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	221			
Interactions for Breakthrough Designated Products & Products Included in STeP	52	58			
Number Closed Before First RTA Action	5	1			
Number Accepted First RTA Cycle [1]	280	211			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	4			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	4			
Number Not Accepted First RTA Cycle	5	1			
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.69%	0.46%			

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	215			
Number with Non-MDUFA Action [3]	8	5			
Number with MDUFA Action	284	174			
Written Feedback Provided Within Goal	280	171			
Number Pending MDUFA Action	0	36			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	284	210			
Current Performance Percent Within Goal	98.59%	98.28%			

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	174			
Average FDA Days to Written Feedback	58.56	55.34			
20th Percentile FDA Days to Written Feedback	45	42			
40th Percentile FDA Days to Written Feedback	58	54			
60th Percentile FDA Days to Written Feedback	65	63			
80th Percentile FDA Days to Written Feedback	69	68			
Maximum FDA Days to Written Feedback	97	92			

Table 9.4 CDRH- OHT6 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	4	2			
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50			

Table 9.5 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	128	77			
Meeting Minutes Submitted Within 15 Days of Meeting	94	55			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	8			
Meeting Minutes Past 15 Days of Meeting	30	8			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.44%	79.71%			

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	699			
Interactions for Breakthrough Designated Products & Products Included in STeP	29	47			
Number Closed Before First RTA Action	9	4			
Number Accepted First RTA Cycle [1]	835	658			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	9			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	27			
Number Not Accepted First RTA Cycle	3	1			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.15%			

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	667			
Number with Non-MDUFA Action [3]	7	7			
Number with MDUFA Action	863	515			
Written Feedback Provided Within Goal	859	515			
Number Pending MDUFA Action	0	145			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	863	660			
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	515			
Average FDA Days to Written Feedback	63.71	62.95			
20th Percentile FDA Days to Written Feedback	60	59			
40th Percentile FDA Days to Written Feedback	66	65			
60th Percentile FDA Days to Written Feedback	69	68			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	75	70			

Table 9.4 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	9			
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	42.22			

Table 9.5 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	320	207			
Meeting Minutes Submitted Within 15 Days of Meeting	257	161			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	13			
Meeting Minutes Past 15 Days of Meeting	59	27			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	82.99%			

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	204			
Interactions for Breakthrough Designated Products & Products Included in STeP	5	5			
Number Closed Before First RTA Action	1	0			
Number Accepted First RTA Cycle [1]	261	191			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	2			
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	11			
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	193			
Number with Non-MDUFA Action [3]	3	0			
Number with MDUFA Action	263	159			
Written Feedback Provided Within Goal	263	159			
Number Pending MDUFA Action	0	34			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	263	193			
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	159			
Average FDA Days to Written Feedback	60.53	60.45			
20th Percentile FDA Days to Written Feedback	55	53			
40th Percentile FDA Days to Written Feedback	60	61			
60th Percentile FDA Days to Written Feedback	64	65			
80th Percentile FDA Days to Written Feedback	67	68			
Maximum FDA Days to Written Feedback	70	70			

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

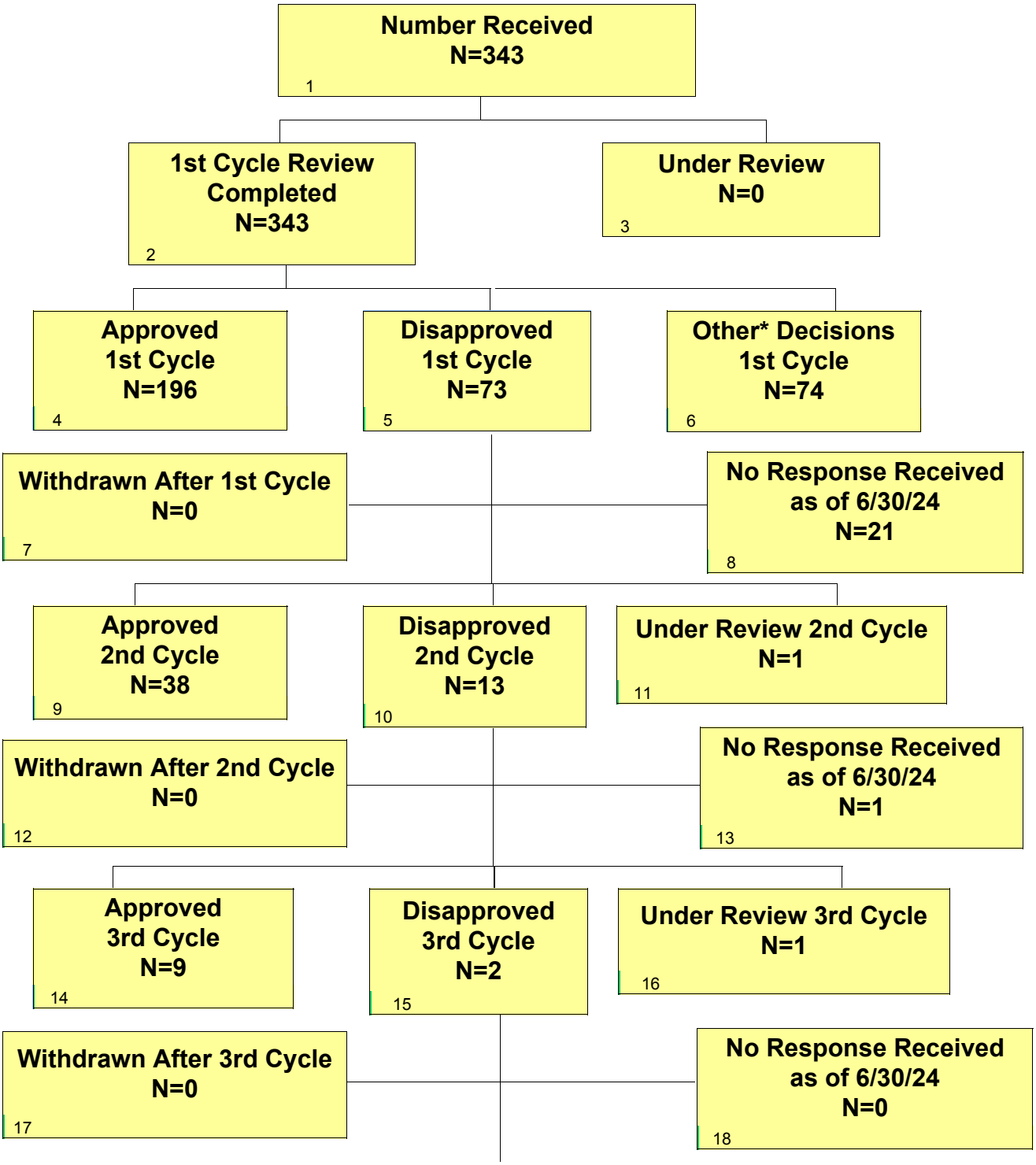
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4			
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25			

Table 9.5 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	207	119			
Meeting Minutes Submitted Within 15 Days of Meeting	160	92			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	44	18			
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	4			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.29%	80.70%			

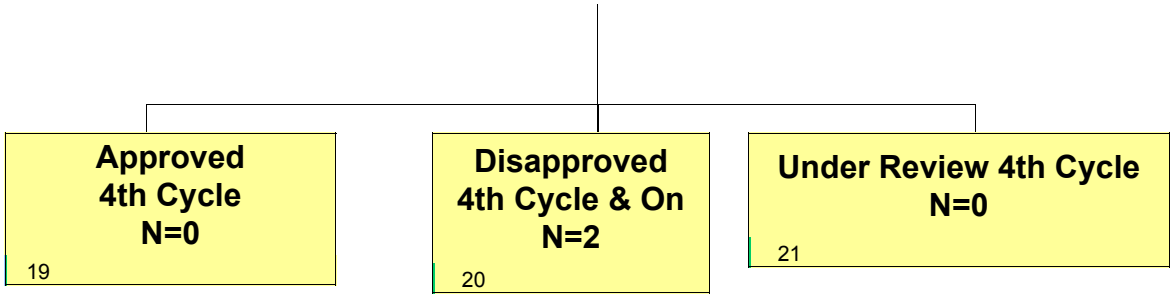
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 6/30/24

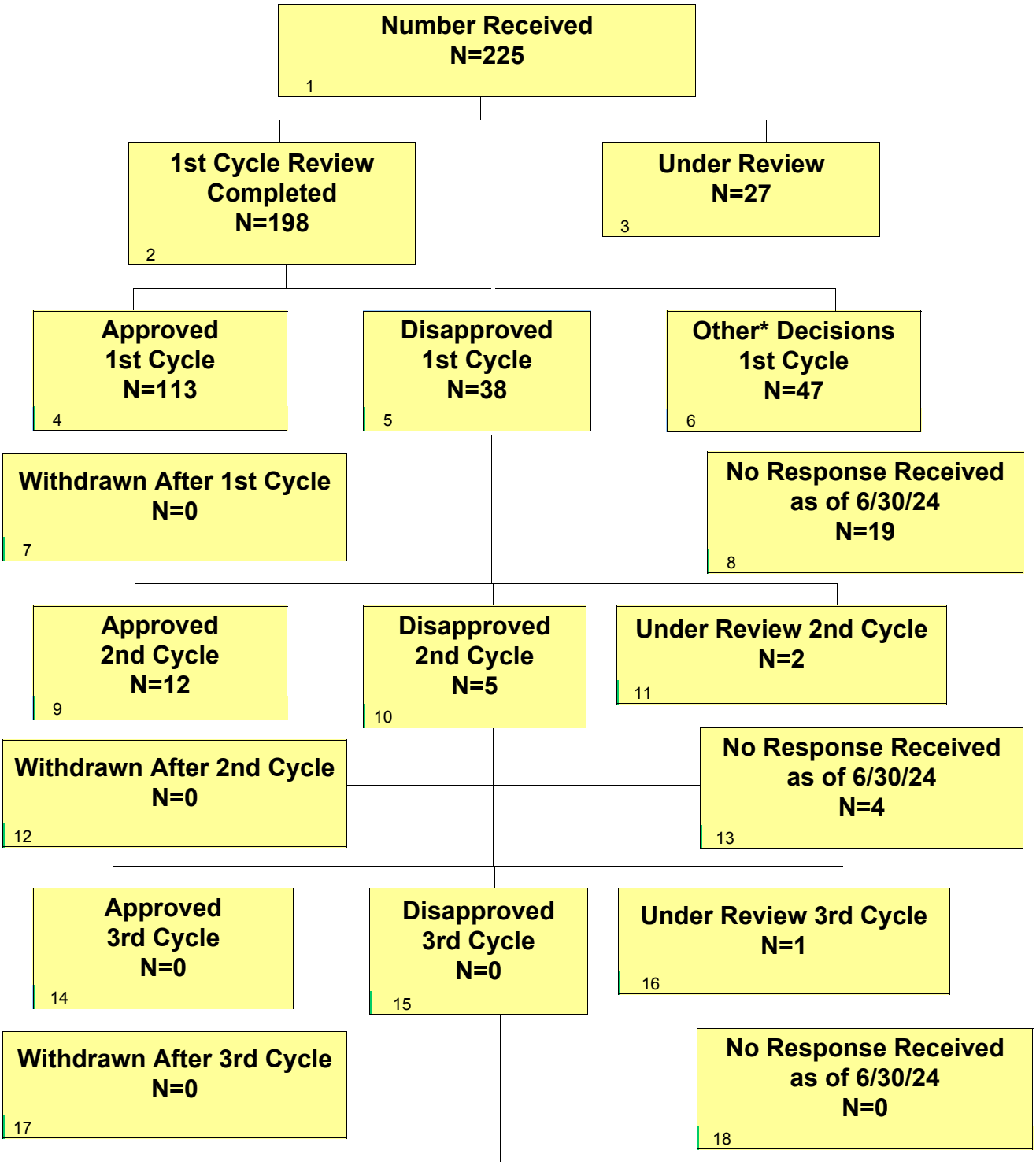


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 6/30/24

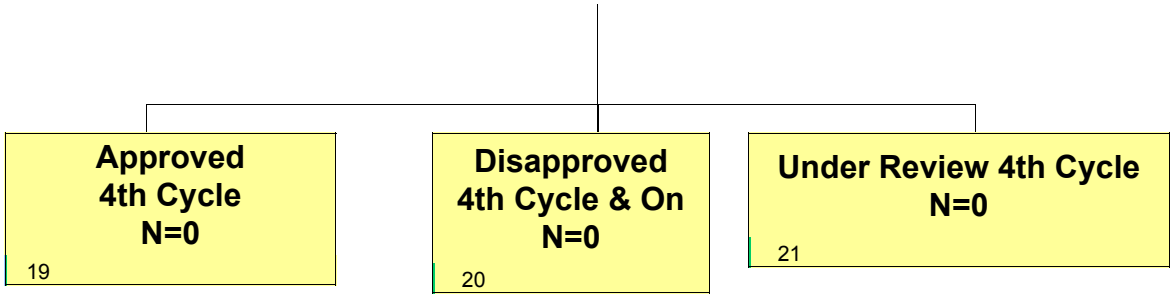


CDRH IDEs - FY 2024
as of 6/30/24



*** Other decisions include withdrawn (N=5), withdrawn and converted (N=25), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=7), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 6/30/24



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343	225			
Average Number of Cycles to IDE Approval or Conditional Approval	1.26	1.10			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.26	0.10			

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	27			
Average Number of Cycles to IDE Approval or Conditional Approval	1.37	1.07			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.37	0.07			

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	62			
Average Number of Cycles to IDE Approval or Conditional Approval	1.45	1.23			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.45	0.23			

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	30			
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.11			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.11			

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	35	12			
Average Number of Cycles to IDE Approval or Conditional Approval	1.10	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10	0.00			

Table 10.1 OHT5 - Office of Neurological and Physical Medicine Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	43			
Average Number of Cycles to IDE Approval or Conditional Approval	1.21	1.05			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.21	0.05			

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	27	15			
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	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	30			
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	6			
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.00			

Section 11 CLIA Waiver Annual Metrics

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	19			
Closed before Teleconference	0			
Teleconferences Held	17			
Teleconferences Held Within 14 Days	17			
Teleconferences Pending	2			
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	2			
Closed before Written Feedback	0			
Written Feedback Provided	1			
Written Feedback Provided Within 21 Days	1			
Written Feedback Pending	1			
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	25			
Closed before Written Feedback	0			
Written Feedback Provided	20			
Written Feedback Provided Within 40 Days	20			
Written Feedback Pending	5			
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	14			
Closed before Teleconference	0			
Teleconferences Held	12			
Teleconferences Held Within 14 Days	12			
Teleconferences Pending	2			
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	2			
Closed before Written Feedback	0			
Written Feedback Provided	1			
Written Feedback Provided Within 21 Days	1			
Written Feedback Pending	1			
Written Feedback Pending Over 21 Days	0			
Current Performance Percent Within 21 Days	100.00%			

Table 13.3 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested	19			
Closed before Written Feedback	0			
Written Feedback Provided	16			
Written Feedback Provided Within 40 Days	16			
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	5			
Closed before Teleconference	0			
Teleconferences Held	5			
Teleconferences Held Within 14 Days	5			
Teleconferences Pending	0			
Teleconferences Pending Over 14 Days	0			
Current Performance Percent Within 14 Days	100.00%			

Table 13.2 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 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	6			
Closed before Written Feedback	0			
Written Feedback Provided	4			
Written Feedback Provided Within 40 Days	4			
Written Feedback Pending	2			
Written Feedback Pending Over 40 Days	0			
Current Performance Percent Within 40 Days	100.00%			

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 (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (Without Panel Review) MDUFA V Performance Metric – Rates of Withdrawal, Not Approvable and Deleted - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number With MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.10 and Tables 1.10.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Rate of Withdrawal, Not Approvable and Deleted - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number With MDUFA Decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.11 and Tables 1.11.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Table 1.12 and Tables 1.12.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Tables 1.13 and Tables 1.13.x LDT PMA Originals and Panel-Track Supplements MDUFA V Metric* - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decision	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decision	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements MDUFA V Metric* - Definitions

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goal – Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA (other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA Decision	Supplements received (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements Pending MDUFA Decision	Number of supplements received (line 1) that do not have a MDUFA decision or a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 2.3 and Tables 2.3.x PMA 180 Day Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

Table 2.4 and Tables 2.4.x PMA 180 Day Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA V decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x PMA Real Time Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) within goal.
5	Supplements Pending MDUFA Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA decision and are not closed with a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x PMA Real Time Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

Table 3.3 and Tables 3.3.x **PMA Real Time PMA Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements(No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

Table 5.2 **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number With a Decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY Closed	Number with a decision (line 2) divided by Number Filed (line 1).

Table 5.3 **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-Year Rolling Average Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number With a MDUFA Decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number With a MDUFA Decision After Trimming the Upper and Lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA V decision and 5% of submissions with the highest number of Total Days to MDUFA V decision.
3	Three-Year Rolling Average Total Time to MDUFA Decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA V Performance (Quarterly Data Exclude Third Party Review)

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1st 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).

Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goal – Definitions

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent 510k definitions.
2	Deleted or Withdrawn Prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made as of the quarter end date and before any SI action: WTDR, DELE.
3	SI Within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI Over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI Pending within 60 FDA days	Submissions that are awaiting SI and where 60 days have not yet elapsed.
6	SI Pending over 60 FDA days	Submissions that are awaiting SI and where 60 days have elapsed.
7	510(k)s NSE Without SI	Number of 510(k) submissions that are closed with an NSE decision and did not have an SI.
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) expressed as a percentage of the sum of the number of submissions that received an SI (line 3 and line 4), the number of submissions that missed the SI goal or are awaiting SI after 60 days as of quarter end (line 6), and the number of submissions that were found NSE without receiving an SI (line 7).

Table 6.3 and Tables 6.3.x **510(k) Substantive Interaction Metric – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interaction	Number of 510(k) submissions RTA accepted or passed TS in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 6.4 and Tables 6.4.x 510(k) MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA Decision	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA Decisions (line 3) and pending submissions that have missed the MDUFA goal (line 6).

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA V Decision– Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days to MDUFA V decision.

Table 6.6 and Tables 6.6.x 510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision– Definitions

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

Table 6.7 and Tables 6.7.x 510(k) Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA V Decision Metric– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of LDT submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA Decision over 90 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA decision within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA Decision (line 3) and pending LDT submissions that already missed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA V decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA Decision within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA Decision (line 3) and pending non-LDT IVD submissions that already missed the MDUFA goal (line 6).

Section 7 510(k) Annual General Metrics (Annual data includes Third Party reviews)

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

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA/TS review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

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

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Currently Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA V decision and the 2% of submissions with the highest number of Total Days to MDUFA decision.
7	Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

Table 7.3 CDRH - 510(k) Third Party Performance – Definitions

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90th Percentile FDA Days to MDUFA Decision	The 90th percentile of FDA days to MDUFA decision on 3rd Party 510(k) submissions received in this fiscal year

Section 8 De Novo MDUFA V Performance

Table 8.1 and Tables 8.1.x De Novo Acceptance Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1st 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).

Tables 8.2 and Tables 8.2.x De Novo MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent De Novo definitions.
2	Non-MDUFA Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA V Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already have missed the MDUFA goal (line 6).

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA decision (line 2).
2	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days to MDUFA decision.

Table 8.4 and Tables 8.4.x De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA V Decisions	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA decision (line 2).

Table 8.5 and Tables 8.5.x De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions

#	Measure	Description
1	Number of Submissions that Mssed the Goal	Number of submissions with MDUFA decision made beyond 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Tables 8.6 and Tables 8.6.x LDT De Novo MDUFA V Decision Metrics – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA V Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA V Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA V Decision over 150 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA V review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA Decisions (line 3) and pending LDT submissions that have missed the MDUFA goal (line 6).

Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA Decisions (line 3) and pending non-LDT IVD submissions that have missed the MDUFA goal (line 6).

Section 8 Annual Metrics for De Novo Requests

Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions

#	Measure	Description
1	Number Accepted	Number of De Novo submissions accepted in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept/Technical Screening	Average number of days in the first RTA/TS review cycle

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of Pre-Subs received in this fiscal year (includes Q-Sub types tracked as Pre-Sub Meeting, Pre-Sub Written Feedback, Breakthrough Interaction, and STeP Interaction).
2	Interactions for Breakthrough Designated Products & Products Included in STeP	Number of Breakthrough Interactions and STeP Interactions received in this fiscal year (excludes submissions tracked as Pre-Sub Meeting and Pre-Sub Written Feedback).
3	Number Closed Before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
4	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer and submissions considered accepted upon receipt
5	Number Without First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that had a "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.
6	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
7	Number Not Accepted First RTA Cycle	Number of submissions received in this fiscal year (line 1) that had a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
8	Rate of Submissions Not Accepted for Review on First RTA Cycle	Number Not Accepted First RTA Cycle (line7) expressed as a percentage of the sum of the Number Accepted First RTA Cycle (line 4), Number Without First Cycle RTA Review and > 15 Days Since Date Received (line 5), and Number Not Accepted First RTA Cycle (line 7).

Table 9.2 and Tables 9.2.x MDUFA V Pre-Sub Performance Goals – Definitions

#	Measure	Description
1	Number Accepted / Eligible for MDUFA Action	Number of submissions that passed via the RTA process as of quarter end date and Breakthrough/STeP Interactions
2	Number with Non-MDUFA Action	Number of submissions accepted (line 1) and closed with a non-MDUFA action (WTDR, JPND, JTRX, CLLR). Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.
3	Number with MDUFA Action	Number of submissions accepted (line 1) with a MDUFA action (EMAL, EMFB).
4	Written Feedback Provided Within Goal	Number of submissions with a MDUFA action (line 3) made by the MDUFA review goal (day 70 or 5 days prior to the meeting, whichever is sooner).
5	Number Pending MDUFA Action	Number of submissions accepted (line 1) still under review and pending feedback.
6	Pending MDUFA Action Past Goal	Number of submissions pending a MDUFA action (line 5) that have already missed the MDUFA review goal.
7	Number in MDUFA Cohort (up to max 4300)	Number of submissions accepted with a MDUFA action (line 3) plus the number of submissions accepted and pending a MDUFA action (line 5). If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.
8	Current Performance Percent Within Goal	Number of submissions with MDUFA actions made by the MDUFA review goal (line 4) expressed as a percentage of the sum of the number of submissions with a MDUFA action (line 3) and the number of submissions pending a MDUFA action and already passed the MDUFA review goal (line 6).

Table 9.3 and Tables 9.3.x MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort) – Definitions

#	Measure	Description
1	Number with Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA V Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB) EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA V Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20th Percentile FDA Days to Written Feedback	20th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
4	40th Percentile FDA Days to Written Feedback	40th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
5	60th Percentile FDA Days to Written Feedback	60th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
6	80th Percentile FDA Days to Written Feedback	80th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100th percentile) to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).

Table 9.4 and Tables 9.4.x MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort) - Definitions

#	Measure	Description
1	Meetings Not Scheduled by Day 30	Number of Pre-Subs for which a Meeting was Requested and a Meeting Date was not confirmed by the reviewer in CTS by day 30.
2	Average Days to Scheduling for Meetings Scheduled After Day 30	Average days to confirming a Meeting Date in CTS for Meetings not scheduled by Day 30 (line 1).

Table 9.5 and Tables 9.5.x MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort) - Definitions

#	Measure	Description
1	Number of Meetings Required	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date. Number of meetings requested and then held after written feedback is provided.
2	Meeting Minutes Submitted Within 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date.
3	Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter).
4	Meeting Minutes Past 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date.
5	Meeting Minutes Not Submitted and >15 Days Since Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter).
6	Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5).

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn within 90 FDA days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all CLIA Waivers with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 11.3 CLIA Waiver (without Panel Review) MDUFA V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 150 FDA Days	Number of submissions with MDUFA V decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA V Decision for more than 150 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA V Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.4 CLIA Waiver (with Panel Review) MDUFA V Decision Performance Goals) – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 320 FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

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

Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 12.2 **Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 12.3 **Dual 510(k) and CLIA Waiver (without panel review) MDUFA V Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 180 FDA Days	Number of submissions with MDUFA V decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 180 FDA days	Number of submissions pending MDUFA V Decision for more than 180 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA V Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 320FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for FDA days, Industry days, and Total days.

Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision, and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for FDA days, Industry days, and Total days.

Section 13 Total Product Life Cycle Advisory Program (TAP)

Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions

#	Measure	Description
1	Teleconferences Requested	Number of Teleconferences requested
2	Closed before Teleconference	Number of Teleconferences Requested (line 1) that were closed with a final decision before Teleconference Held (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Teleconferences Held	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON))
4	Teleconferences Held Within 14 Days	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON)) within 14 days
5	Teleconferences Pending	Number of Teleconferences Requested (line 1) that are under review without a final decision
6	Teleconferences Pending Over 14 Days	Number of Teleconferences Requested (line 1) that are under review without a final decision and where 14 days have elapsed.
7	Current Performance Percent Within 14 Days	Number of Teleconferences Held Within 14 Days (line 4) expressed as a percentage of the sum of the Teleconferences Held (line 3) and Teleconferences Pending Over 14 Days (line 6)

Table 13.2 TAP Written Feedback (Biocompatibility/Sterility) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on Biocompatibility and Sterility topics(s)
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 21 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 21 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 21 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 21 days have elapsed.
7	Current Performance Percent Within 21 Days	Number of Written Feedback Provided Within 21 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 21 Days (line 6)

Table 13.3 TAP Written Feedback (Other) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on topics(s) other than Biocompatibility and Sterility
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 40 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 40 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 40 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 40 days have elapsed.
7	Current Performance Percent Within 40 Days	Number of Written Feedback Provided Within 40 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 40 Days (line 6)

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 30 June 2024

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	3	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	0			
Average Number of FDA Days to Substantive Interaction	88.33	0.00			
20th Percentile FDA Days to Substantive Interaction	87	0.00			
40th Percentile FDA Days to Substantive Interaction	88	0.00			
60th Percentile FDA Days to Substantive Interaction	88	0.00			
80th Percentile FDA Days to Substantive Interaction	89	0.00			
Maximum FDA Days to Substantive Interaction	90	0.00			

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	3	0			
Average FDA Days to MDUFA V Decision	177.00	0.00			
20th Percentile FDA Days to MDUFA V Decision	175	0			
40th Percentile FDA Days to MDUFA V Decision	178	0			
60th Percentile FDA Days to MDUFA V Decision	179	0			
80th Percentile FDA Days to MDUFA V Decision	180	0			
Maximum FDA Days to MDUFA V Decision	180	0			
Average Industry Days to MDUFA V Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	0	0			
80th Percentile Industry Days to MDUFA V Decision	0	0			
Maximum Industry Days to MDUFA V Decision	0	0			
Average Total Days to MDUFA V Decision	177.00	0.00			
20th Percentile Total Days to MDUFA V Decision	175	0			
40th Percentile Total Days to MDUFA V Decision	178	0			
60th Percentile Total Days to MDUFA V Decision	179	0			
80th Percentile Total Days to MDUFA V Decision	180	0			
Maximum Total Days to MDUFA V Decision	180	0			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	0	0			
Average FDA Days to MDUFA V Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA V Decision	0	0			
40th Percentile FDA Days to MDUFA V Decision	0	0			
60th Percentile FDA Days to MDUFA V Decision	0	0			
80th Percentile FDA Days to MDUFA V Decision	0	0			
Maximum FDA Days to MDUFA V Decision	0	0			
Average Industry Days to MDUFA V Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	0	0			
80th Percentile Industry Days to MDUFA V Decision	0.00	0.00			
Maximum Industry Days to MDUFA V Decision	0	0			
Average Total Days to MDUFA V Decision	0	0			
20th Percentile Total Days to MDUFA V Decision	0	0			
40th Percentile Total Days to MDUFA V Decision	0	0			
60th Percentile Total Days to MDUFA V Decision	0	0			
80th Percentile Total Days to MDUFA V Decision	0	0			
Maximum Total Days to MDUFA V Decision	0	0			

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

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

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

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

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

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

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

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

Table 1.13 CBER - LDT PMA Original and Panel-Track Supplements Metric*

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	4	4			
SI Goal Met	2	1			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	1			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	50.00%	50.00%			

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	4	4			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	4	1			
MDUFA V Decision Goal Met	3	1			
Supplements Pending MDUFA V Decision	0	3			
Supplements Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	75.00%	100.00%			

Table 2.3 CBER - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	4			
Number with MDUFA V Decision	4	1			
Number of Not Approvable	1	0			
Rate of Not Approvable	25.00%	0.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A			
Mean Industry Days for Submissions that Missed the Goal	121.00	N/A			

Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	3	1			
Non-MDUFA V Decision	0	0			
MDUFA V Decision	3	1			
MDUFA V Decision Goal Met	3	1			
Supplements Pending MDUFA V Decision	0	0			
Supplements Pending MDUFA V Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 3.2 CBER - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	1			
Number With MDUFA V Decision	3	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

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

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

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	41	23			
Closed Before First RTA or TS Action [1]	0	0			
Number Accepted or Passed TS on First Cycle [2]	30	20			
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	1			
Number Not Accepted or Failed TS on First Cycle [2]	11	2			
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	9.09%			

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible for SI	39	22			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	37	13			
SI Over 60 FDA Days	2	0			
SI Pending Within 60 FDA Days	0	9			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	94.87%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	39	13			
Average Number of FDA Days to Substantive Interaction	55.53	55.38			
20th Percentile FDA Days to Substantive Interaction	51	56			
40th Percentile FDA Days to Substantive Interaction	56	57			
60th Percentile FDA Days to Substantive Interaction	59	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	90	60			

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	39	22			
Non-MDUFA V Decision	3	0			
MDUFA V Decision (SE/NSE)	35	5			
MDUFA V Decision Within 90 FDA Days	35	5			
510(k)s Pending MDUFA V Decision	1	17			
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.31	1.20			
Number With MDUFA V Decision	35	5			
Average Number of FDA Days to MDUFA V Decision	77.00	74.40			
20th Percentile FDA Days to MDUFA V Decision	67	69			
40th Percentile FDA Days to MDUFA V Decision	83	83			
60th Percentile FDA Days to MDUFA V Decision	88	86			
80th Percentile FDA Days to MDUFA V Decision	90	88			
Maximum FDA Days to MDUFA V Decision	90	90			
Average Number of Industry Days to MDUFA V Decision	44.86	16.60			
20th Percentile Industry Days to MDUFA V Decision	0	0			
40th Percentile Industry Days to MDUFA V Decision	0	0			
60th Percentile Industry Days to MDUFA V Decision	0	0			
80th Percentile Industry Days to MDUFA V Decision	98	17			
Maximum Industry Days to MDUFA V Decision	315	83			
Average Number of Total Days to MDUFA V Decision	121.86	91.00			
20th Percentile Total Days to MDUFA V Decision	81	69			
40th Percentile Total Days to MDUFA V Decision	88	83			
60th Percentile Total Days to MDUFA V Decision	90	86			
80th Percentile Total Days to MDUFA V Decision	90	104			
Maximum Total Days to MDUFA V Decision	375	173			

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	39	22			
Number With MDUFA V Decision	35	5			
Number of SE Decision	34	5			
Number of NSE Decision	1	0			
Number of Withdrawal	2	0			
Number of Deleted	1	0			
Rate of SE Decision	97.14%	100.00%			
Rate of NSE Decision	2.86%	0.00%			
Rate of Withdrawal	5.13%	0.00%			
Rate of Deleted	2.56%	0.00%			

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

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

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

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

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	8	3			
Non-MDUFA V Decision	0	0			
MDUFA V Decision (SE/NSE)	8	0			
MDUFA V Decision Within 90 FDA Days	8	0			
510(k)s Pending MDUFA V Decision	0	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			

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	41			
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]	58	39			
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2	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	1			
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	2.44%			

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	41			
Number with Non-MDUFA Action [3]	3	0			
Number with MDUFA Action	57	33			
Written Feedback Provided Within Goal	54	33			
Number Pending MDUFA Action	0	6			
Pending MDUFA Action Past Goal	0	0			
Number in MDUFA Cohort (up to max 4300)[4]	58	39			
Current Performance Percent Within Goal	94.74%	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	33			
Average FDA Days to Written Feedback	59.38	59.52			
20th Percentile FDA Days to Written Feedback	54	51			
40th Percentile FDA Days to Written Feedback	60	60			
60th Percentile FDA Days to Written Feedback	64	65			
80th Percentile FDA Days to Written Feedback	69	69			
Maximum FDA Days to Written Feedback	72	70			

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	24	13			
Meeting Minutes Submitted Within 15 Days of Meeting	21	11			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	3	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	84.62%			

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	13			
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.00			

BLA

CBER – Annual General Metric Report for BLAs
****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

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

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
10	Q1	Select Updates for the 506J Guidance: 506J Device List and Additional Notifications www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-506j-guidance-506j-device-list-and-additional-notifications	11/17/2023	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List
11	Q1	Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions	11/17/2023	Yes	No	N/A	No
12	Q1	[4]Data Standard Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	12/13/2023	Yes	No	N/A	No
13	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/19/2023	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
14	Q1	510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review	12/21/2023	Yes	Yes	Section 2502 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List
15	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations	12/22/2023	Yes	Yes	Section 3607(a) of the Food and Drug Omnibus Reform Act (FDORA)	No
16	Q2	[4]Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled	01/08/2024	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
17	Q2	Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/characterization-metallic-coatings-andor-calcium-phosphate-coatings-orthopedic-devices	01/23/2024	Yes	No	N/A	No
18	Q2	Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical	01/30/2024	Yes	No	N/A	No
19	Q2	Use of Data Monitoring Committees in Clinical Trials www.fda.gov/regulatory-information/search-fda-guidance-documents/use-data-monitoring-committees-clinical-trials	02/13/2024	Yes	No	N/A	No
20	Q2	Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-medical-device-user-fee-small-business-qualification-and-certification-guidance	02/22/2024	Yes	No	N/A	A-List
21	Q2	Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards www.fda.gov/regulatory-information/search-fda-guidance-documents/key-information-and-facilitating-understanding-informed-consent-guidance-sponsors-investigators-and	03/01/2024	No	No	N/A	No
22	Q2	Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-premarket-cybersecurity-guidance-section-524b-fdc-act	03/13/2024	Yes	No	N/A	A-List
23	Q2	Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-thermal-effects-medical-devices-produce-tissue-heating-andor-cooling	03/15/2024	Yes	No	N/A	No

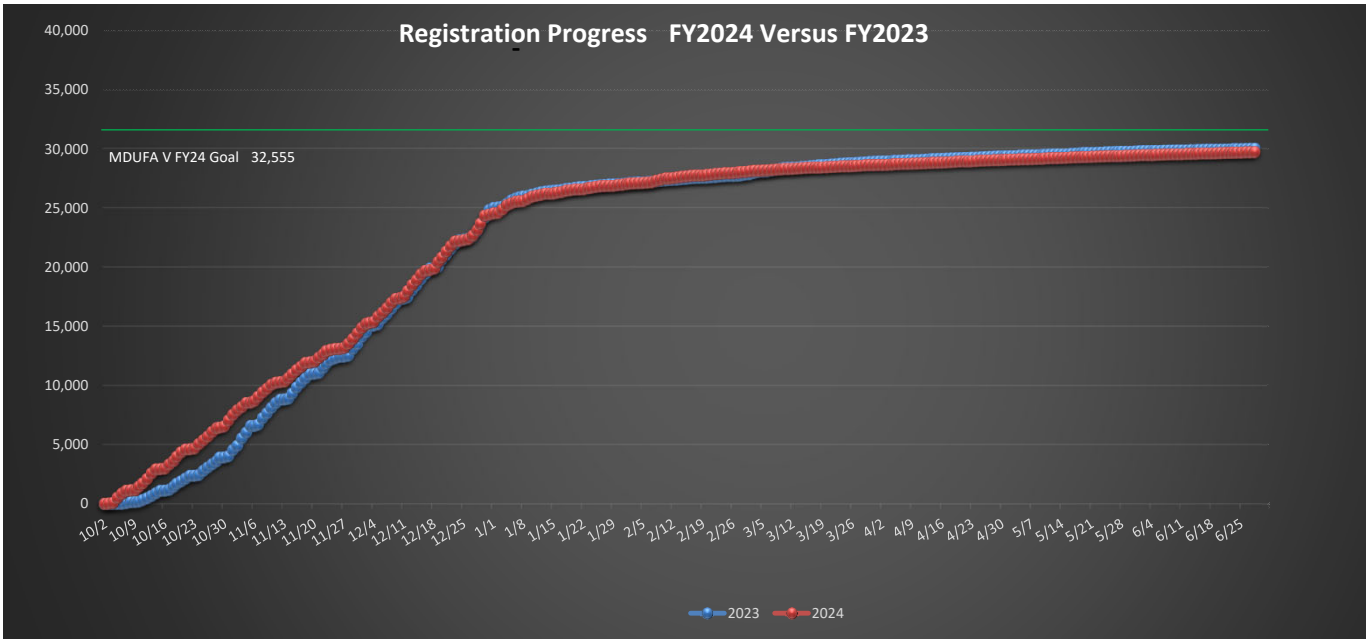
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
24	Q2	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program-draft-guidance	03/15/2024	Yes	Yes	MDUFA V Commitment Letter II.A.	A-List
25	Q2	Animal Studies for Dental Bone Grafting Material Devices - Premarket Notification (510(k)) Submissions: Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions	03/29/2024	Yes	No	N/A	No
26	Q3	[4]Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	04/16/2024	Yes	No	N/A	No
27	Q3	Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564: Draft Guidance for Laboratory Manufacturers and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-in-vitro-diagnostic-devices-immediate-public-health-response-absence	05/06/2024	No	No	N/A	A-List
28	Q3	Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency: Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-tests-during-section-564-declared-emergency	05/06/2024	No	No	N/A	A-List
29	Q3	Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices	05/10/2024	Yes	No	N/A	A-List

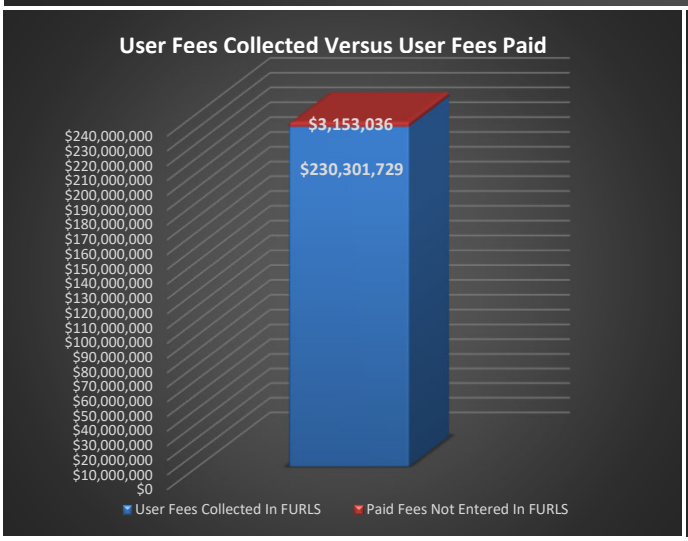
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
30	Q3	Processes and Practices Applicable to Bioresearch Monitoring Inspections: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	06/05/2024	Yes	No	N/A	No
31	Q3	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection: Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection	06/20/2024	No	No	N/A	No
32	Q3	[4]Laboratory Developed Tests: Small Entity Compliance Guide: Guidance for Laboratory Manufacturers and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/laboratory-developed-tests-small-entity-compliance-guide	06/25/2024	No	No	N/A	No
33	Q3	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies	06/26/2024	Yes	Yes	Section 3602 of the Food and Drug Omnibus Reform Act (FDORA)	No
34	Q3	Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/essential-drug-delivery-outputs-devices-intended-deliver-drugs-and-biological-products	06/28/2024	Yes	No	N/A	No

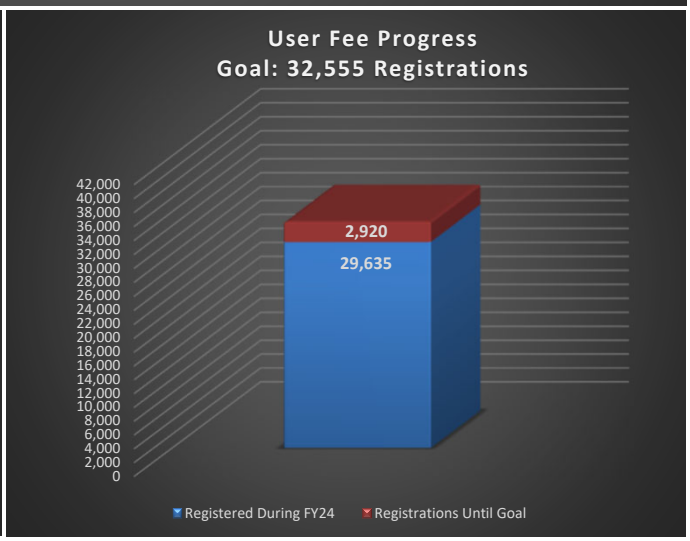
MDUFA V Registrations - 3rd Quarter Summary FY2024*

Current Active Registrations by Type	FY24 Q3			FY23 Year End Active Totals			FY24 vs End FY23
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,526	12,077	18,603	6,677	12,332	19,009	97.86%
Contract Manufacturer	1,233	1,924	3,157	1,243	1,893	3,136	100.67%
Contract Sterilizer	78	177	255	76	169	245	104.08%
Specification Developer	1,582	556	2,138	1,668	557	2,225	96.09%
Reprocessor of Single Use Devices	29	3	32	34	3	37	86.49%
U.S. Manufacturer of Export Only Devices	118	0	118	127	0	127	92.91%
Repackager/Relabeler	1,060	184	1,244	1,116	221	1,337	93.04%
Remanufacturer	16	12	28	14	9	23	121.74%
Foreign Exporter/Private Label Distributor		1,083	1,083		1,132	1,132	95.67%
Initial Importer	3,215		3,215	3,357		3,357	95.77%
Unknown	0	13	13	6	11	17	76.47%
Total:	**13,857**	**16,029**	**29,886**	**14,318**	**16,327**	**30,645**	**97.52%**

*Note: This data is current as of 06/29/2024







FY 2024 Medical Device User Fee Collections as of June 30, 2024 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$230,794,197	-$572,816	$230,221,382		
Application Fees	$75,764,276	-$1,253,764	$74,510,512		
Total	**$306,558,473**	**-$1,826,579**	**$304,731,894**	**$362,381,000**	**84%**

Medical Device User Fee Collection History Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,738,775	$34,425,417	$28,031,569
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,794,823	$56,962,602	$63,699,312	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,306,430	$122,346,416	$136,098,825	$147,165,318	$137,782,995
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,896,895	$208,692,116	$215,697,178	$275,338,627	$269,130,850
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$322,347,363	$304,731,894			

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

CDRH Data 3rd Quarter FY 2024 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	7	0
PMA	7	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	1
De Novo Classification	5	29
180-Day Supplements	3	9
Real-Time Supplements	0	20
510(k)s	26	1,271
30-day Notices /135 day supplements*	9	36
513(g)s	0	46
PMA Annual Report	0	33
Total	**50**	**1,445**

[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**