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1st Quarter FY 2025 Package
MDUFA V (FY 2023-2027) Performance
February 27, 2025

Welcome –

FDA MDUFA Performance — Actions through December 31, 2024

- Report on performance goals for 1st Quarter FY 2025

Guidance Development

Registration and Listing

Qualitative Update on Finances – 1st Quarter FY 2025

- User fee receipts through the 1st Quarter FY 2025

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

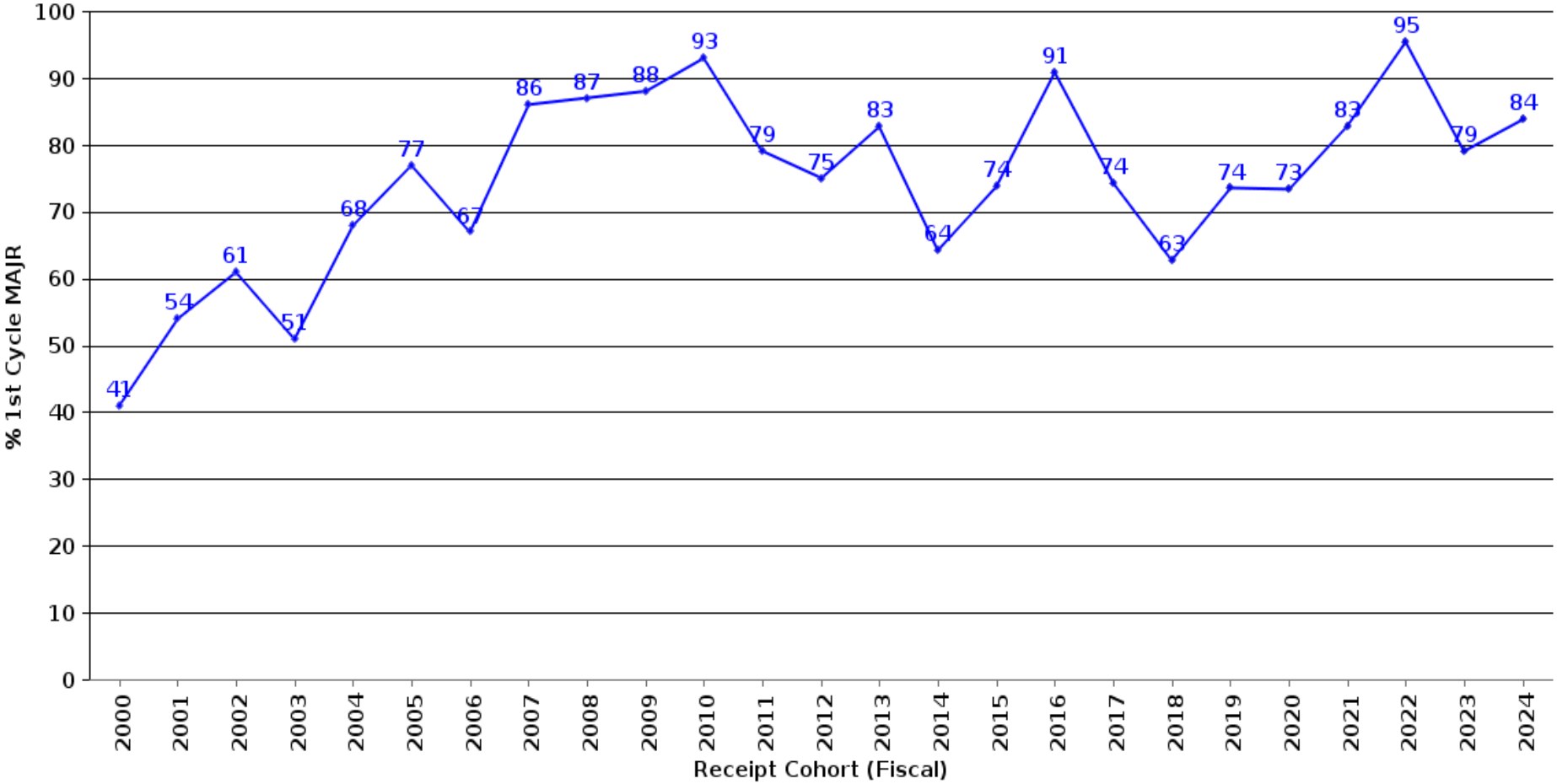
OHT8: Office of Radiological Health

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

PMAs

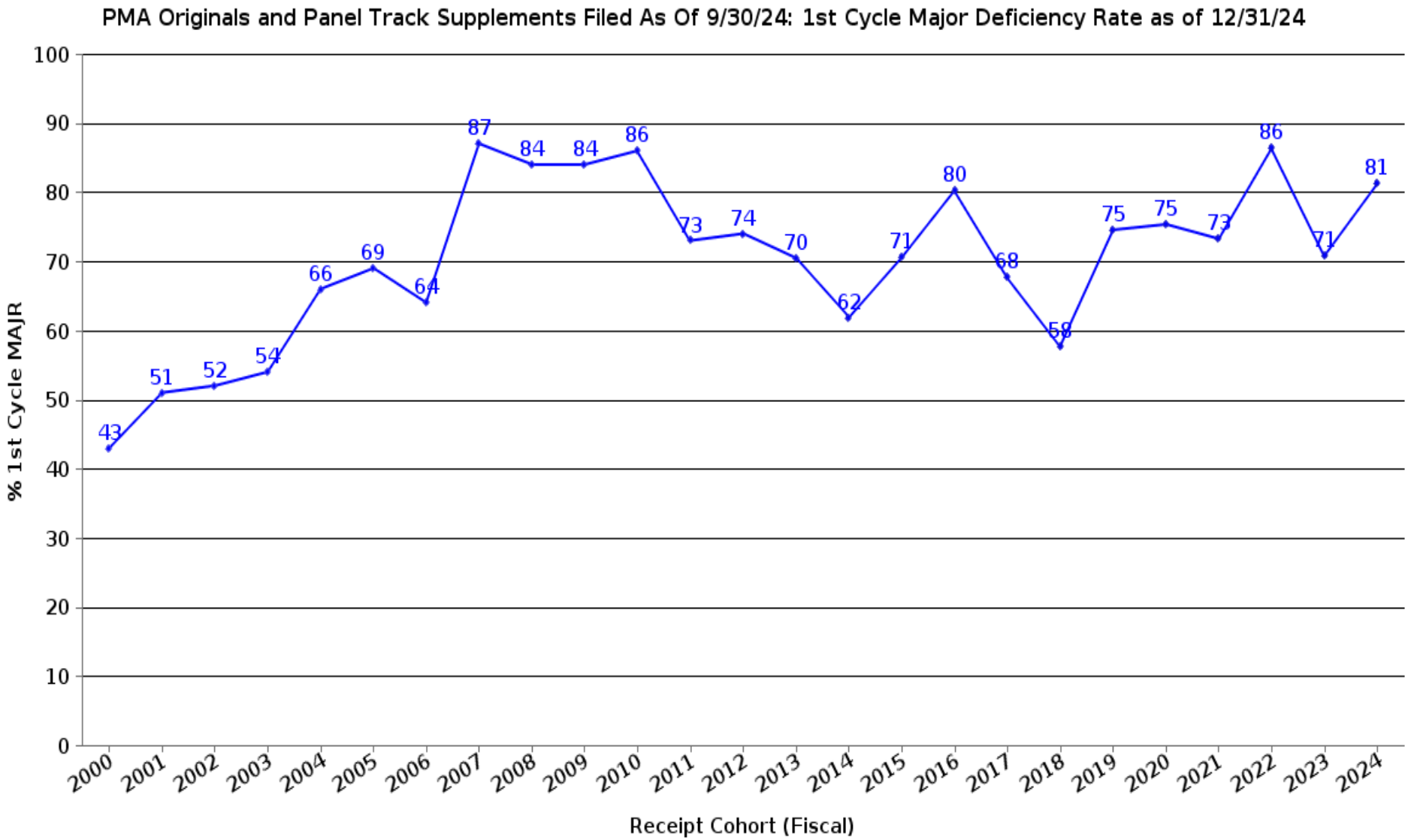
Q1FY2025

PMA Originals Filed As Of 9/30/24: 1st Cycle Major Deficiency Rate as of 12/31/24



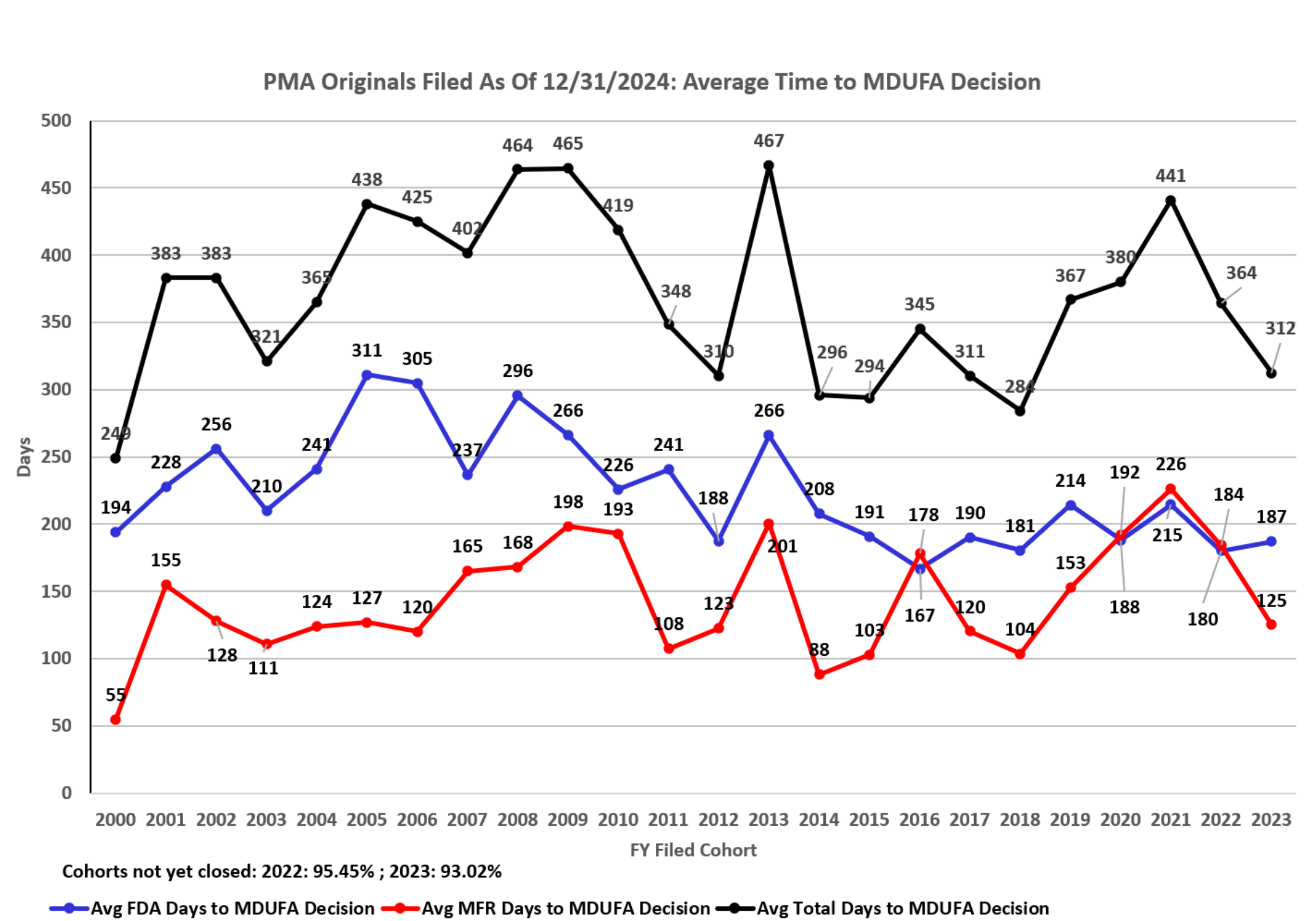
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 9/30/24.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

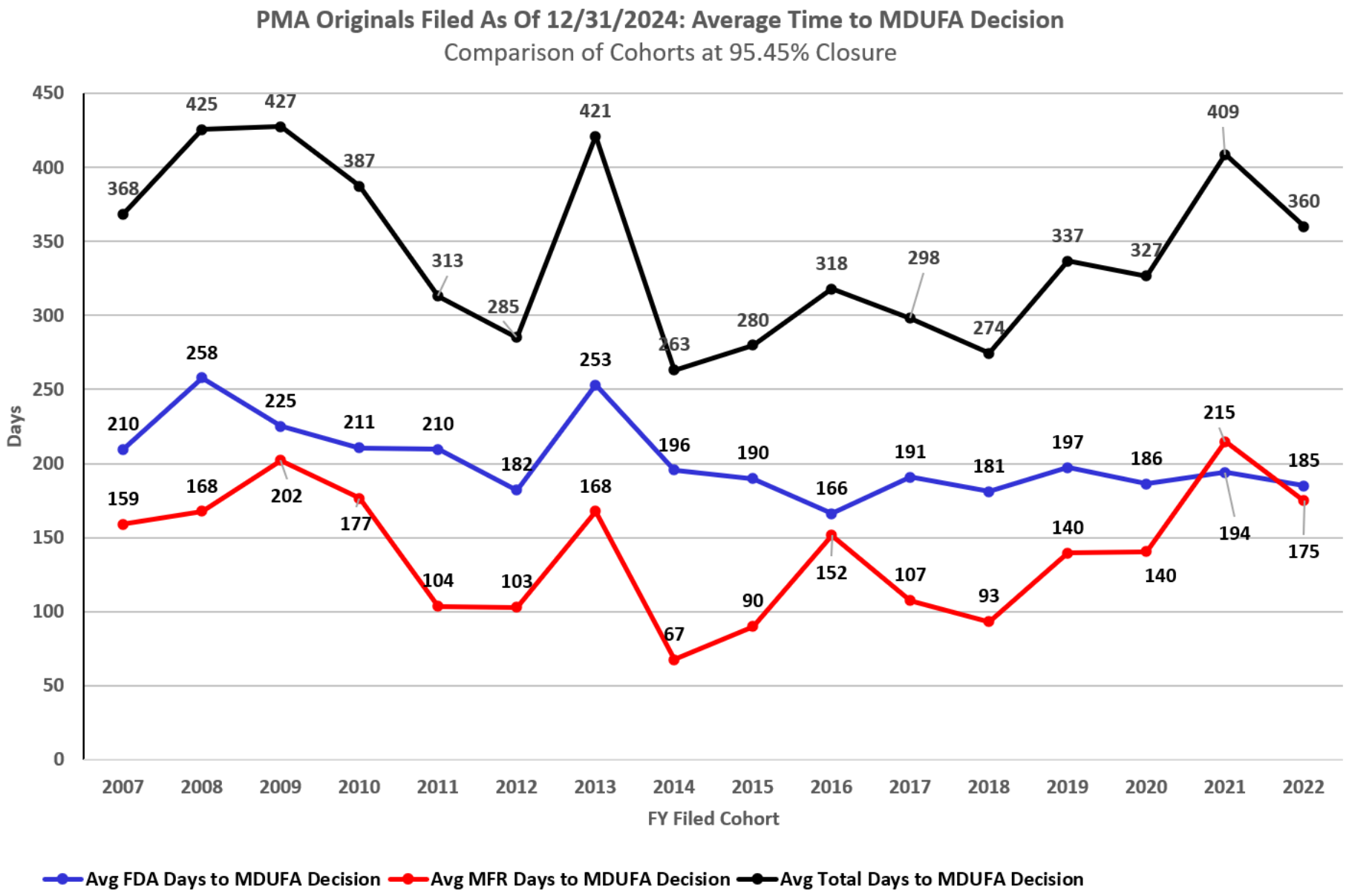
◆ % 1st Cycle MAJR PMAO

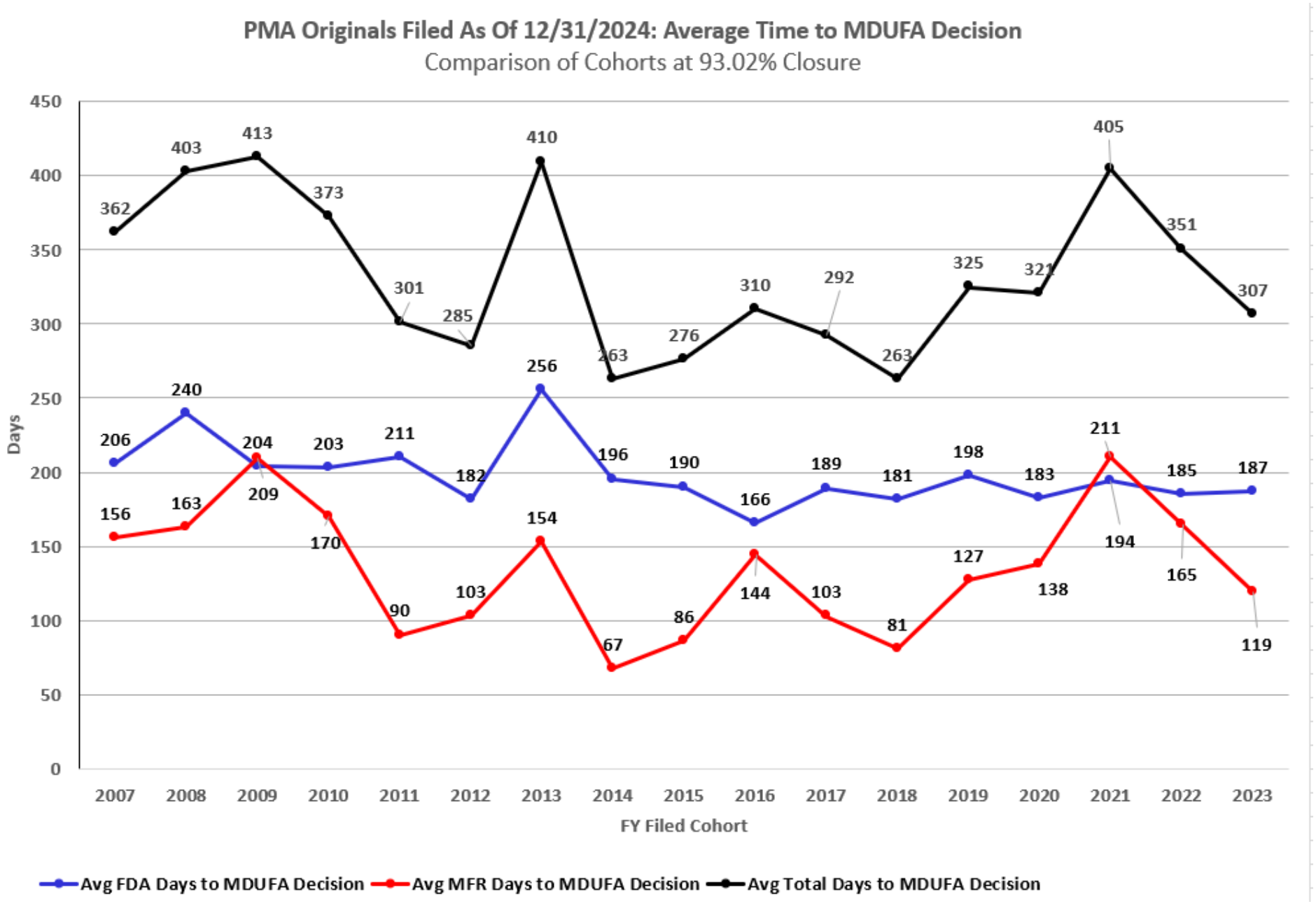


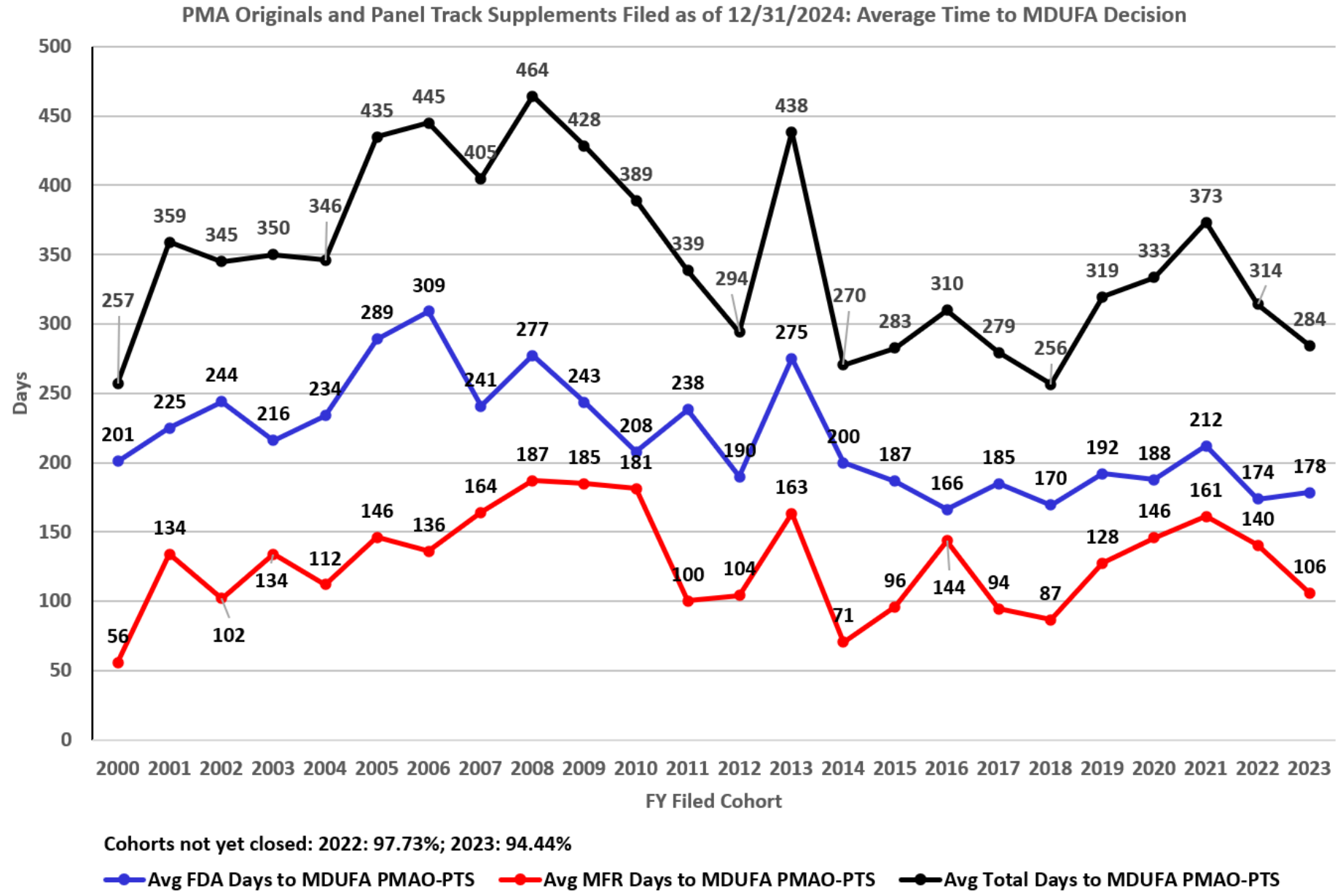
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 9/30/24. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

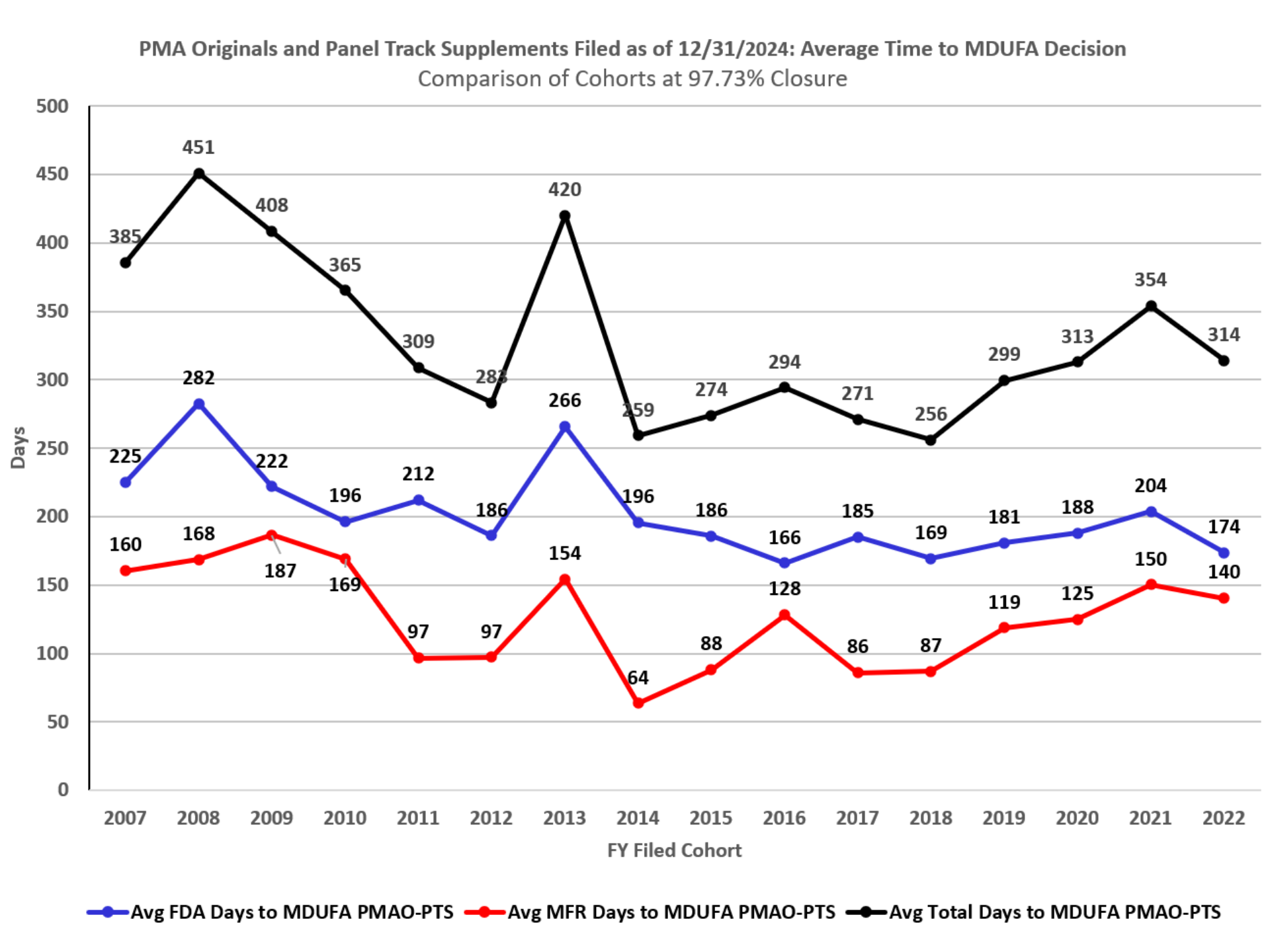
◆ % 1st Cycle MAJR PMAO/PTS

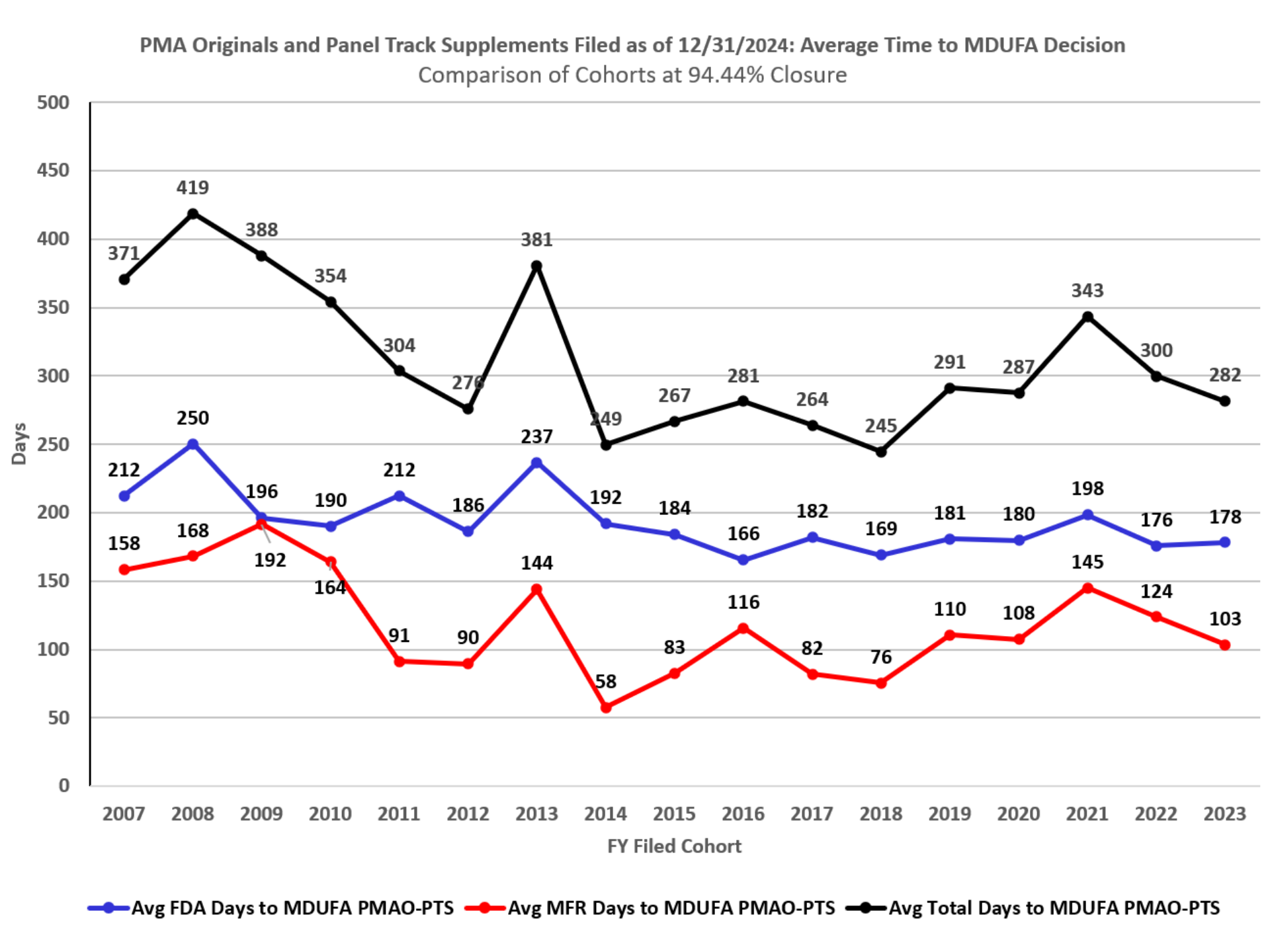

PMA Originals Filed As Of 12/31/2024: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
FY Filed Cohort
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 380 441 364 312
194 228 256 210 241 311 305 237 296 266 226 241 188 266 208 191 178 190 181 214 192 215 184 187
55 155 128 111 124 127 120 165 168 198 193 108 123 201 88 103 167 120 104 153 188 226 180 125
Cohorts not yet closed: 2022: 95.45% ; 2023: 93.02%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 12/31/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 95.45% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
0 50 100 150 200 250 300 350 400 450
368 425 427 387 313 285 421 263 280 318 298 274 337 327 409 360
210 258 225 211 210 182 253 196 190 166 191 181 197 186 194 185
159 168 202 177 104 103 168 67 90 152 107 93 140 140 215 175
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

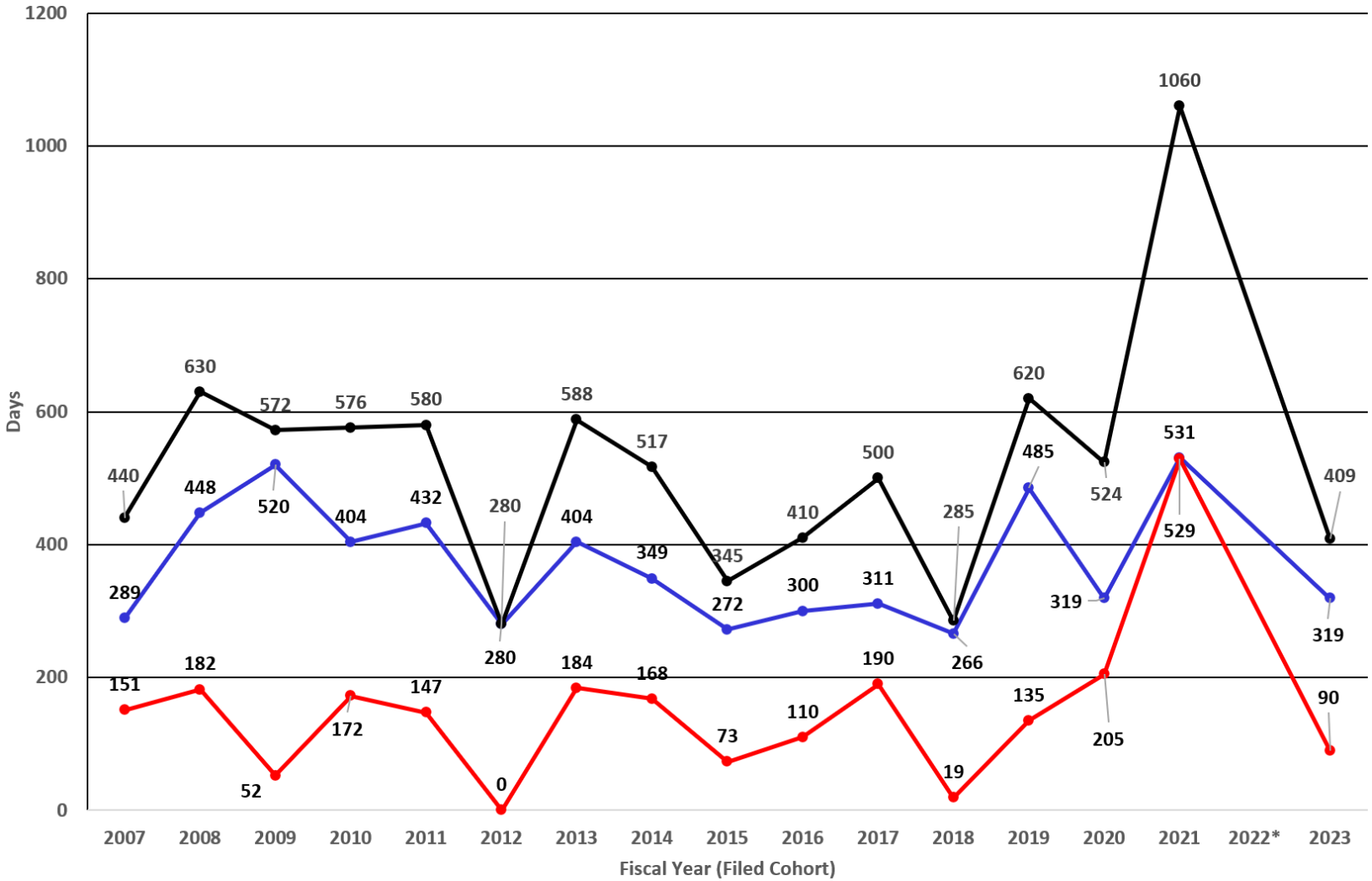

PMA Originals Filed As Of 12/31/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 93.02% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
362 403 413 373 301 285 410 263 276 310 292 263 325 321 405 351 307
206 240 204 203 211 182 256 196 190 166 189 181 198 183 211 185 187
156 163 209 170 90 103 154 67 86 144 103 81 127 138 194 165 119
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed as of 12/31/2024: Average Time to MDUFA Decision
Days
FY Filed Cohort
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 256 319 333 373 314 284
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 188 212 174 178
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 87 128 146 161 140 106
Cohorts not yet closed: 2022: 97.73%; 2023: 94.44%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS


PMA Originals and Panel Track Supplements Filed as of 12/31/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 97.73% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
385
451
408
365
309
283
420
259
274
294
271
256
299
313
354
314
225
282
222
196
212
186
266
196
186
166
185
169
181
188
204
174
160
168
187
169
97
97
154
64
88
128
86
87
119
125
150
140
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS


PMA Originals and Panel Track Supplements Filed as of 12/31/2024: Average Time to MDUFA Decision
Comparison of Cohorts at 94.44% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
371
419
388
354
304
270
381
249
267
281
264
245
291
287
343
300
282
212
250
196
190
212
186
237
192
184
166
182
169
181
180
198
176
178
158
168
192
164
91
90
144
58
83
116
82
76
110
108
145
124
103
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

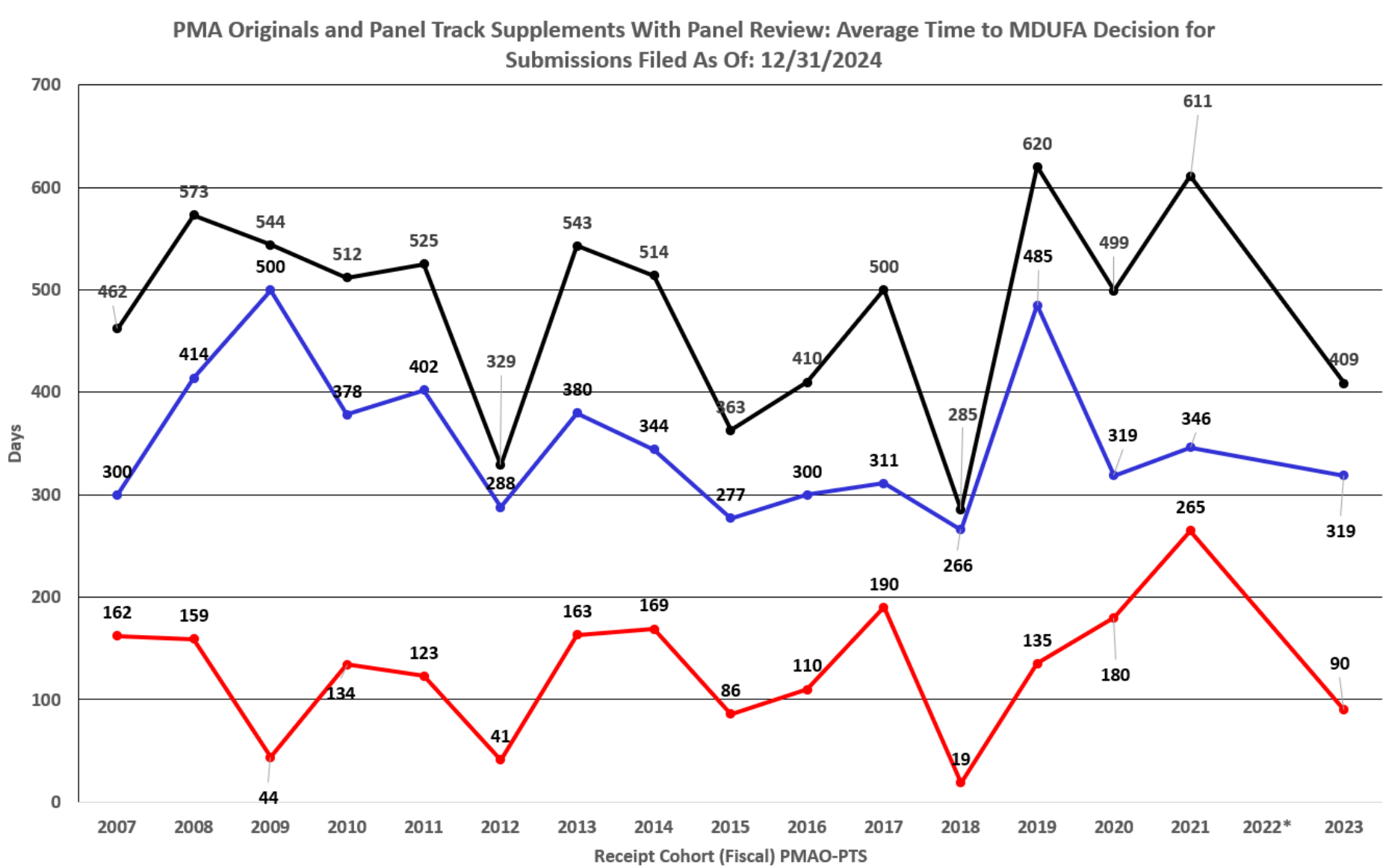
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 12/31/2024



Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2021 = 1/1; 2023 = 4/4

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

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

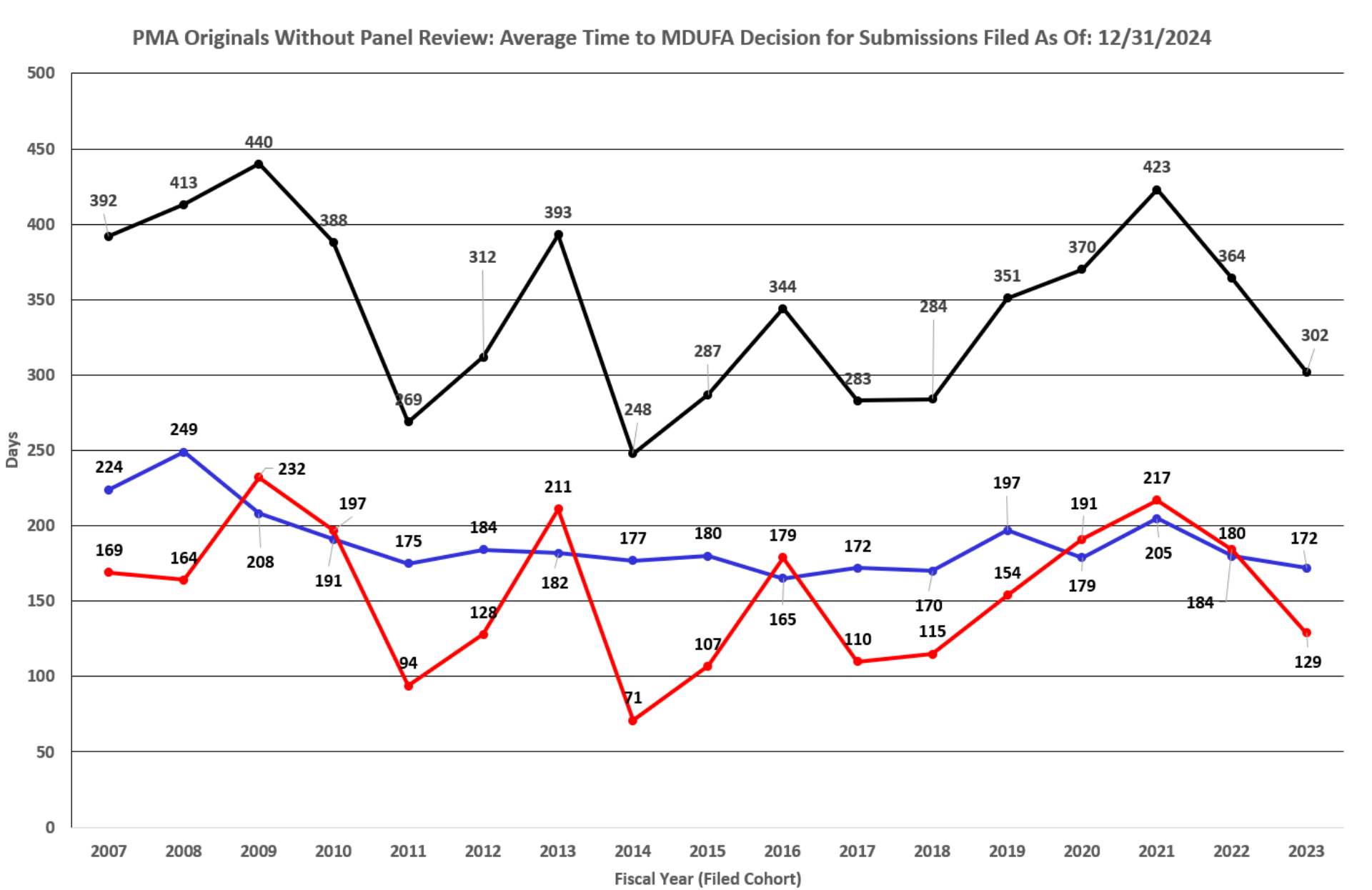


Numbers Closed/Filed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013 = 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/2; 2023 = 4/4

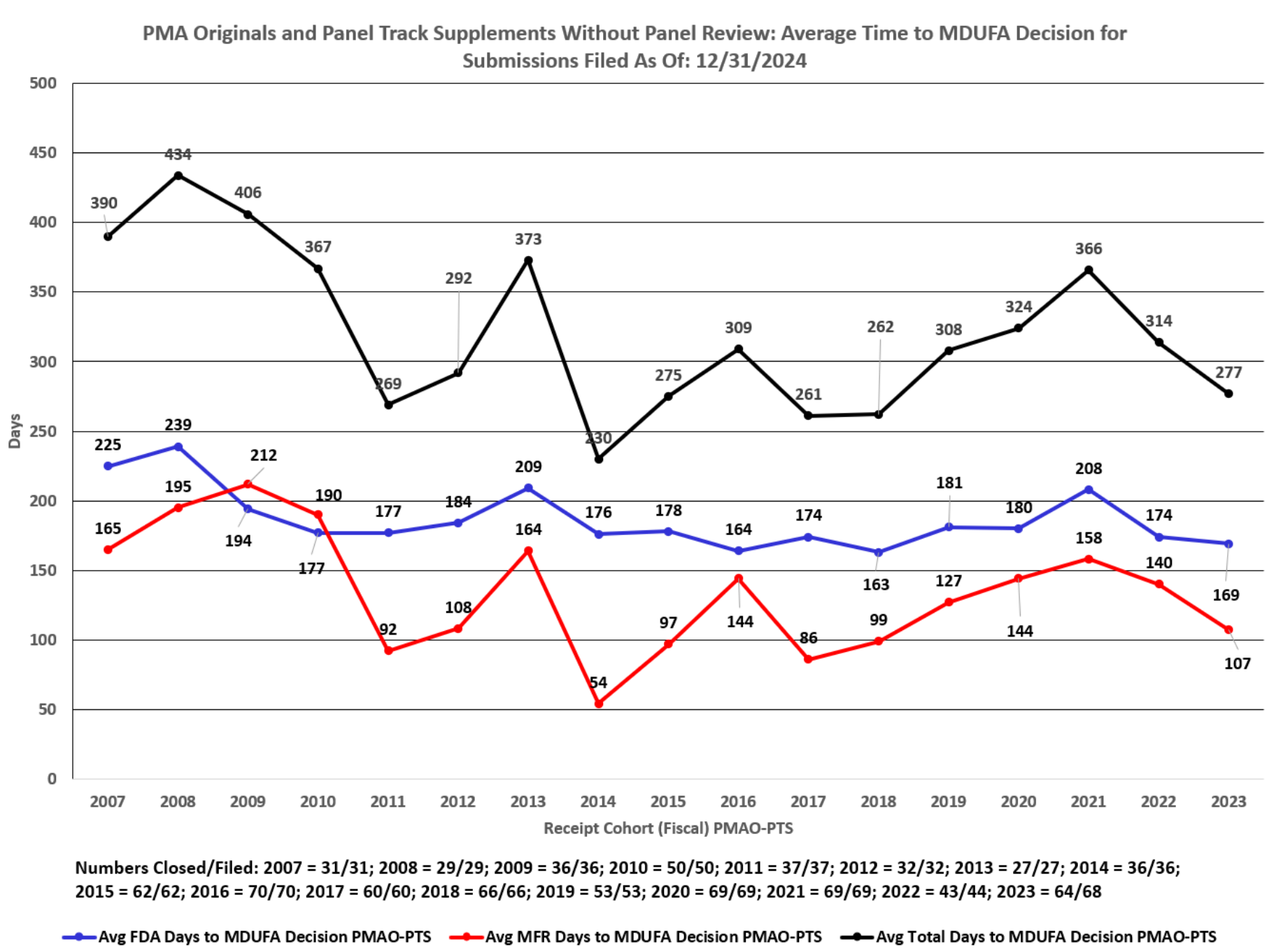
***Note: For FY22, there were no applicable MDUFA decisions for PMA Originals and Panel Track Supplements with Panel Review**

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

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

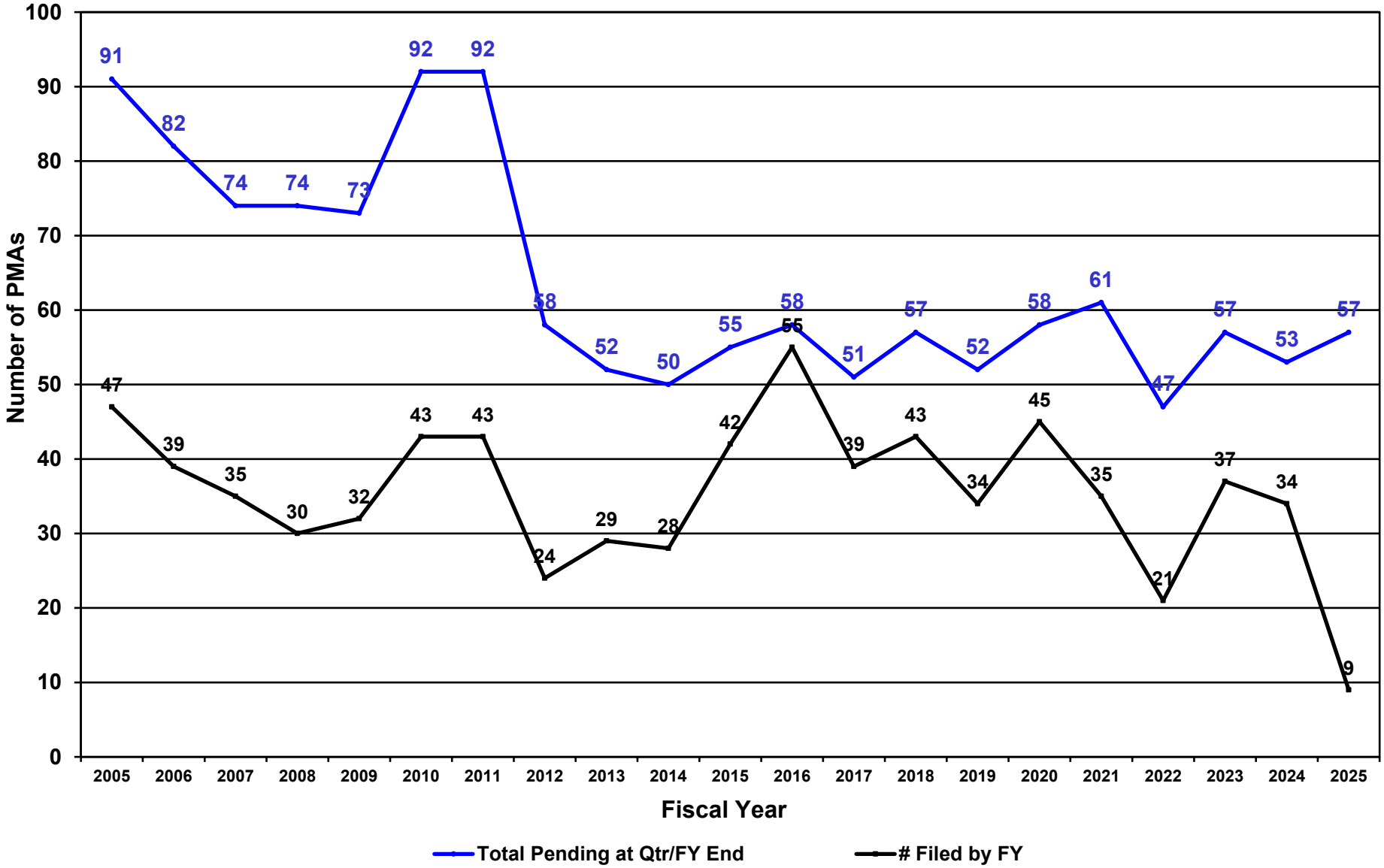


Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 21/22; 2023 = 36/39



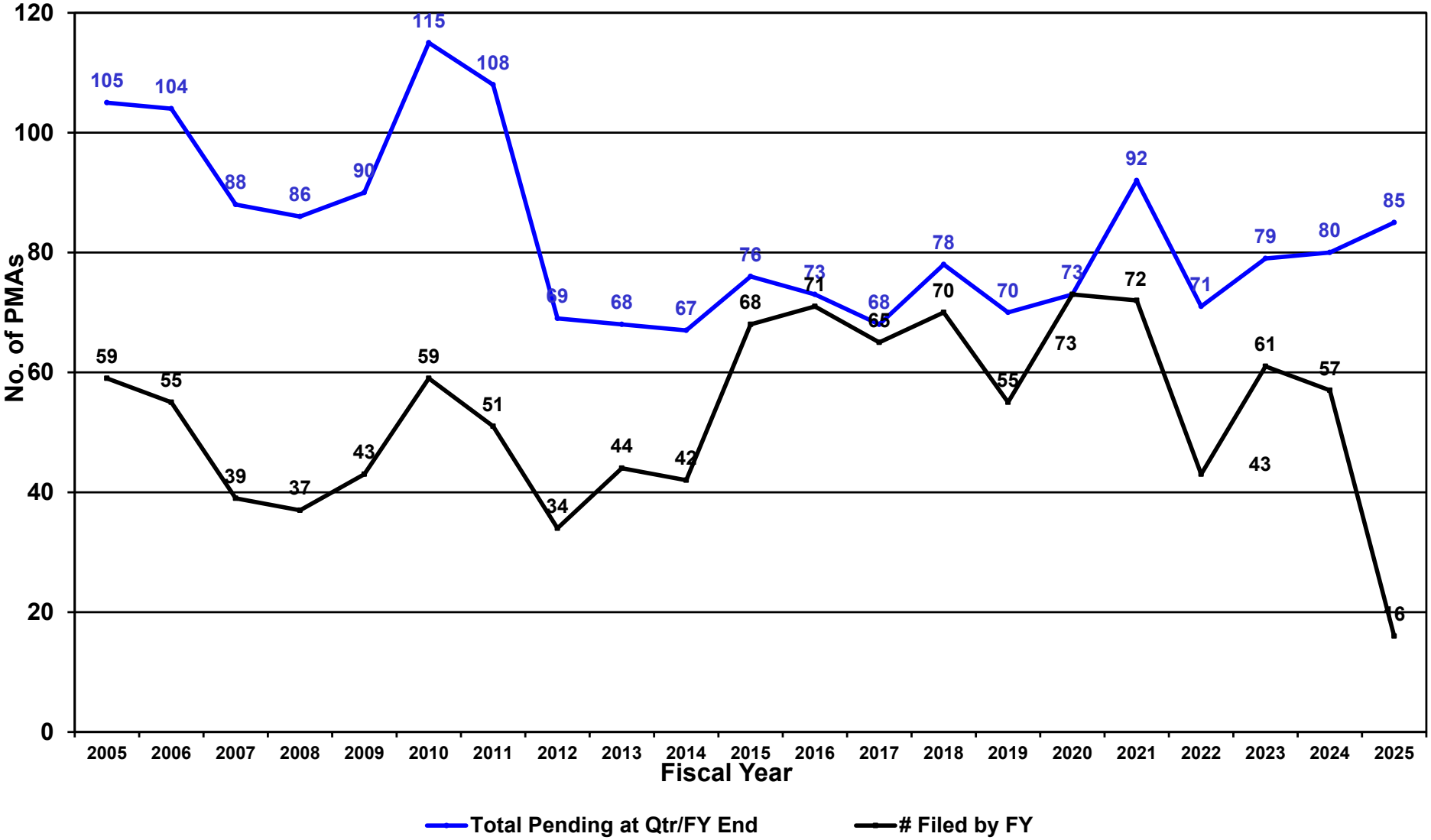
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

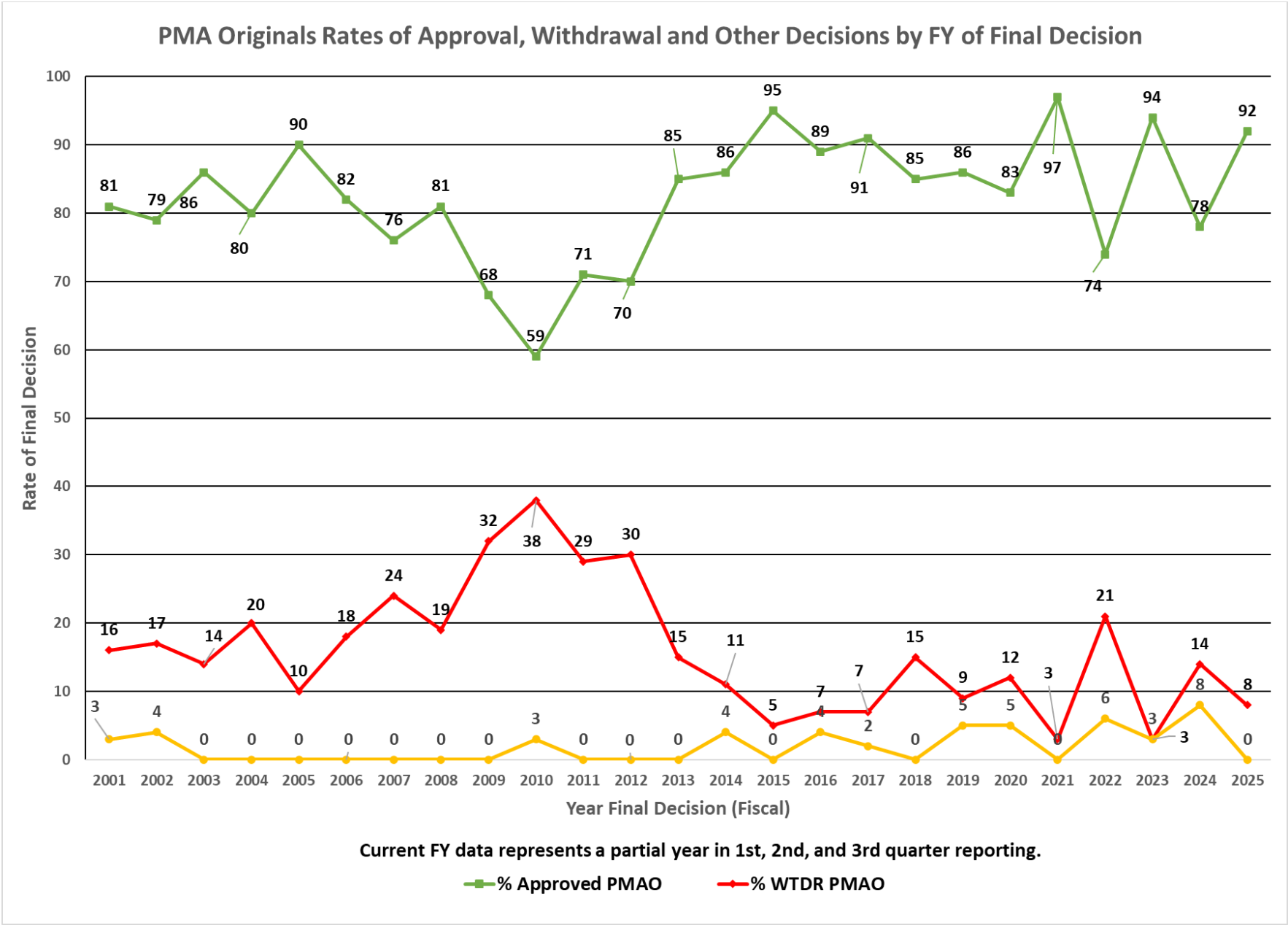


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

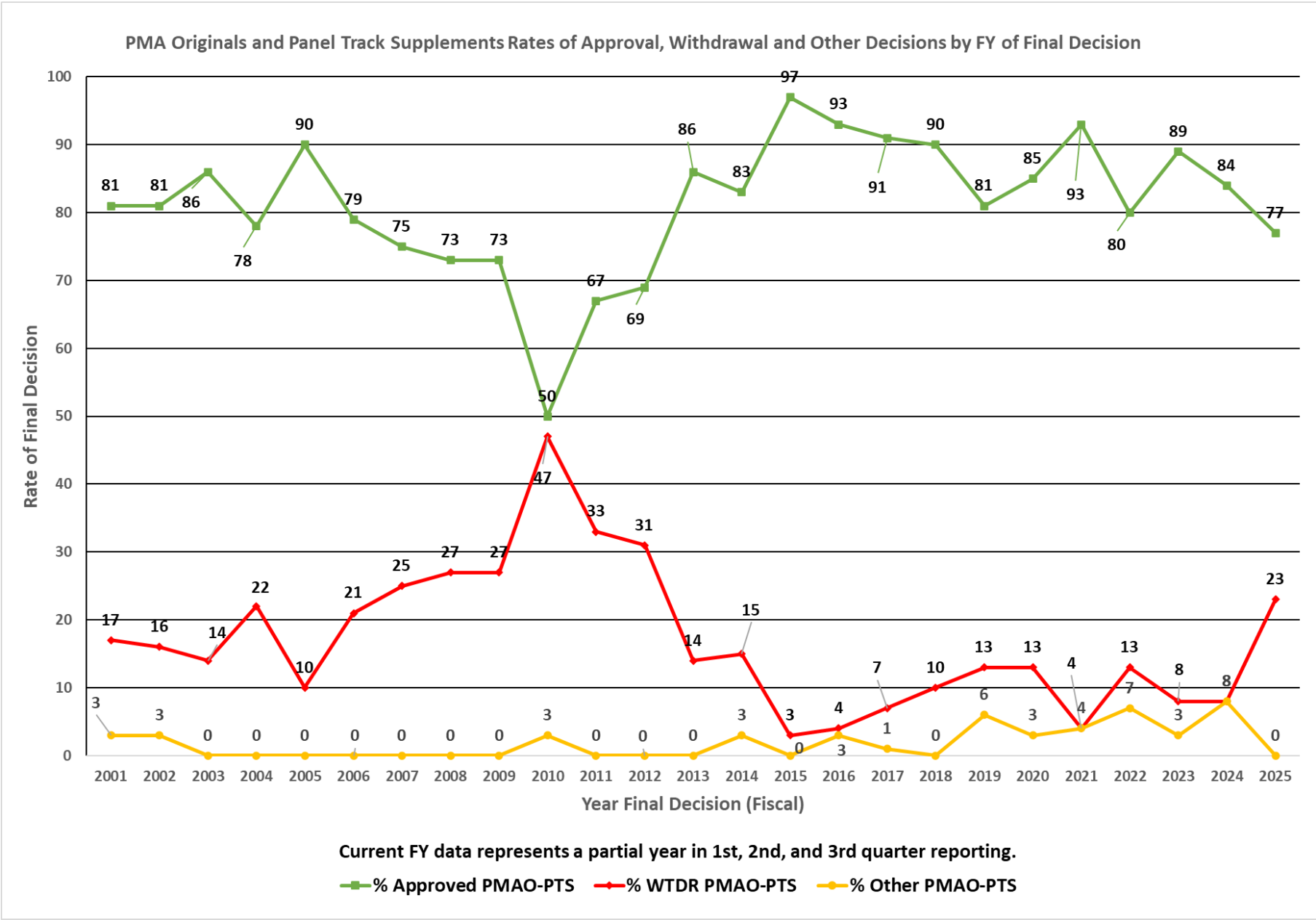
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



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

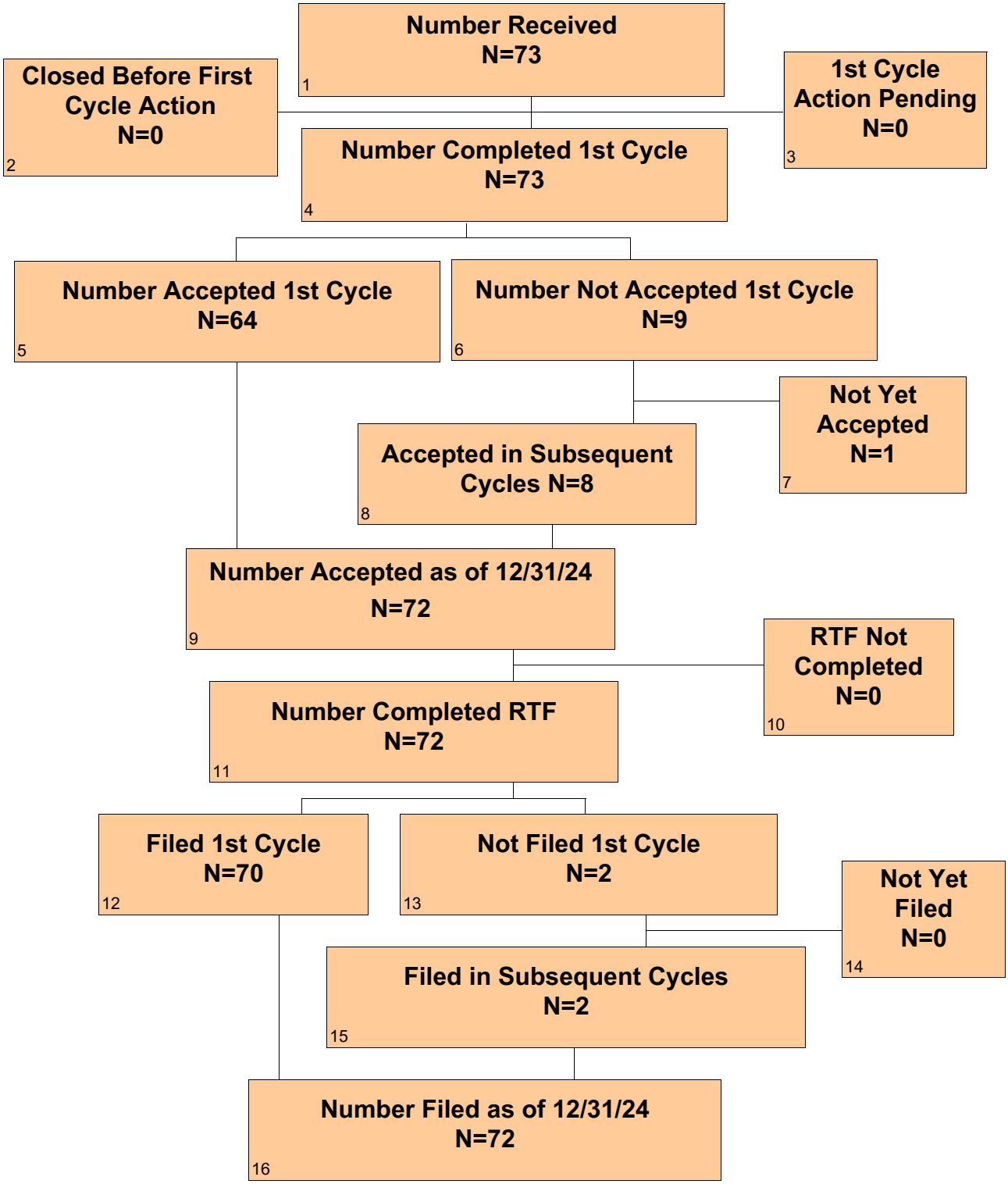


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

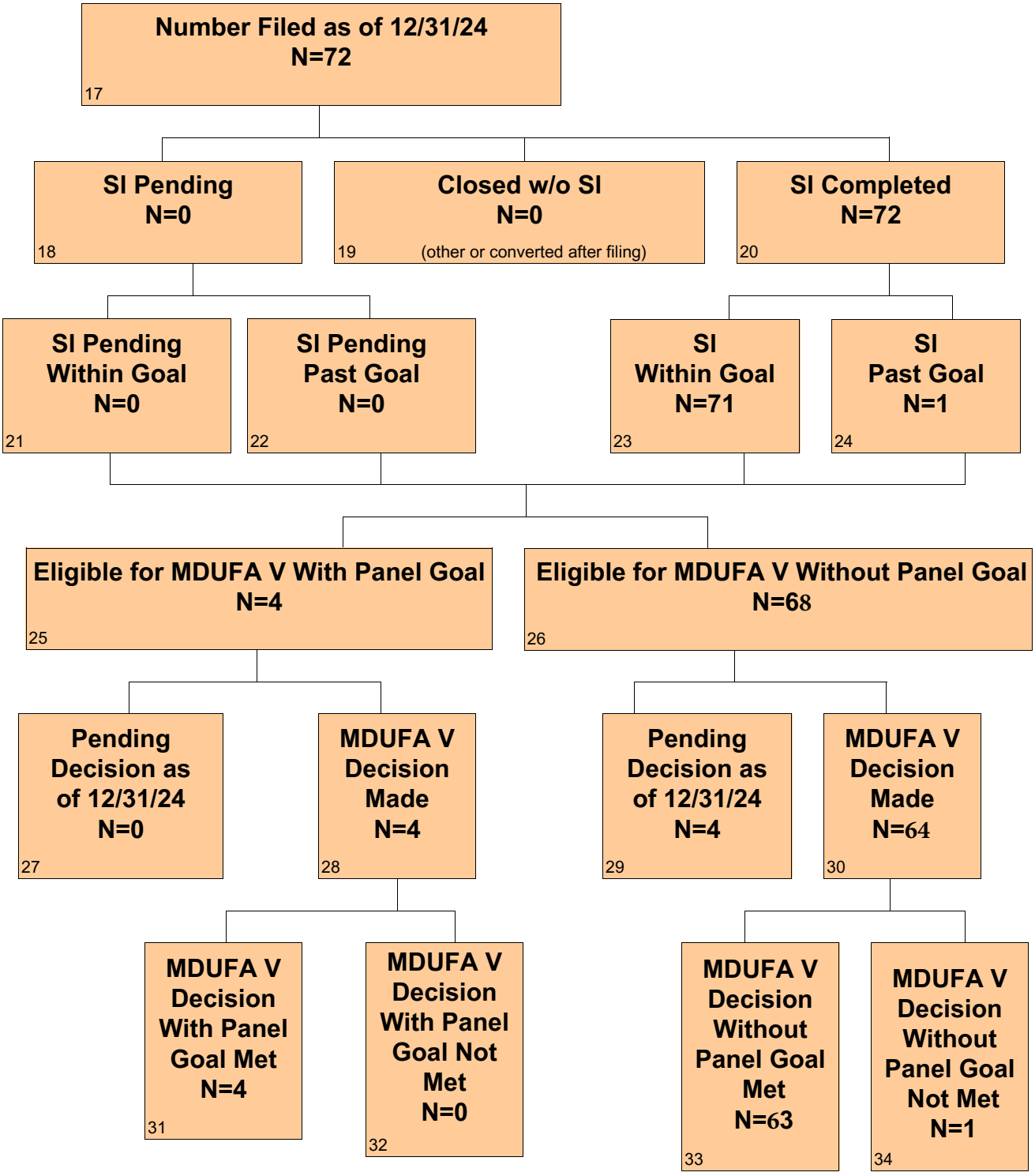


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

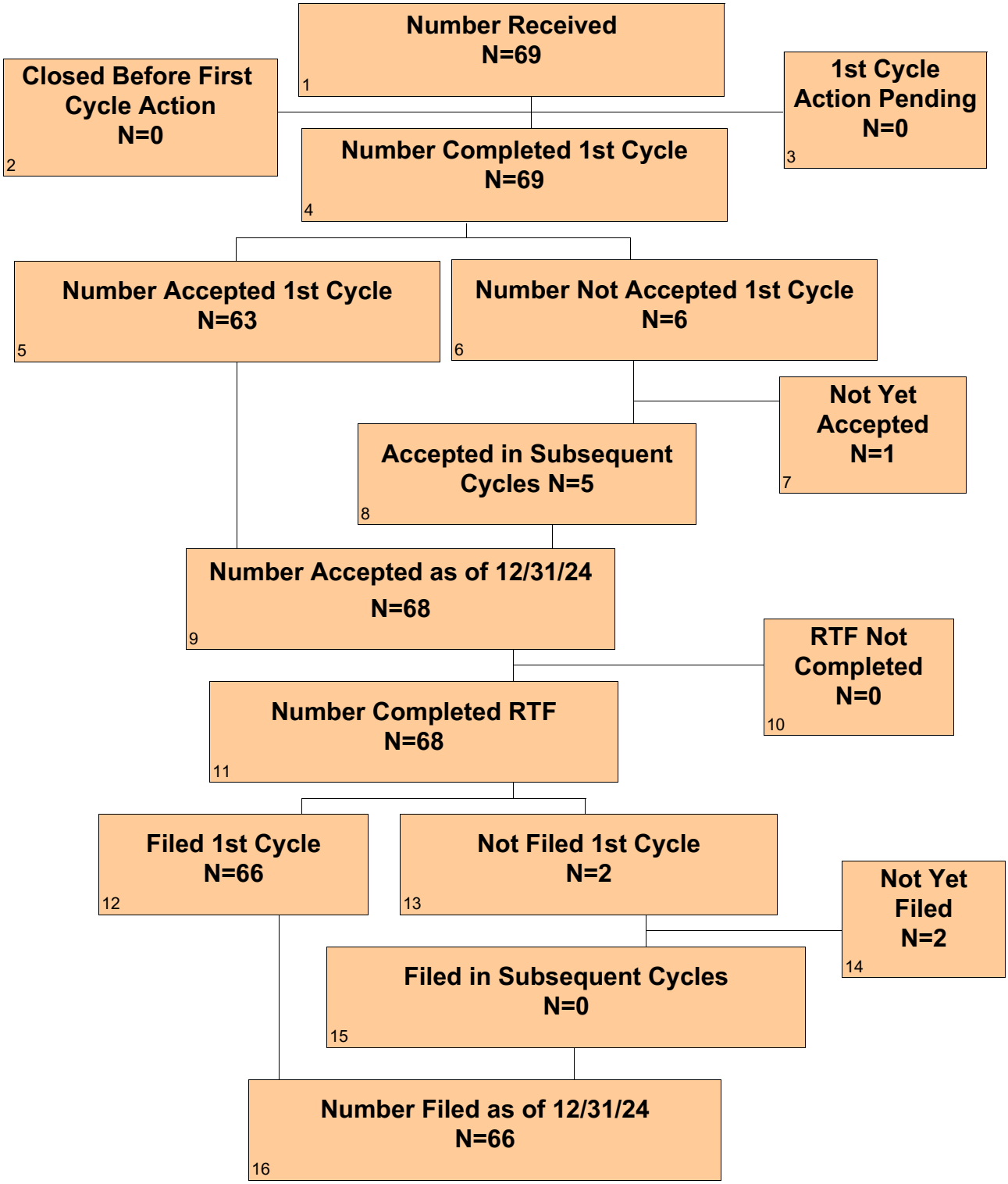
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/24



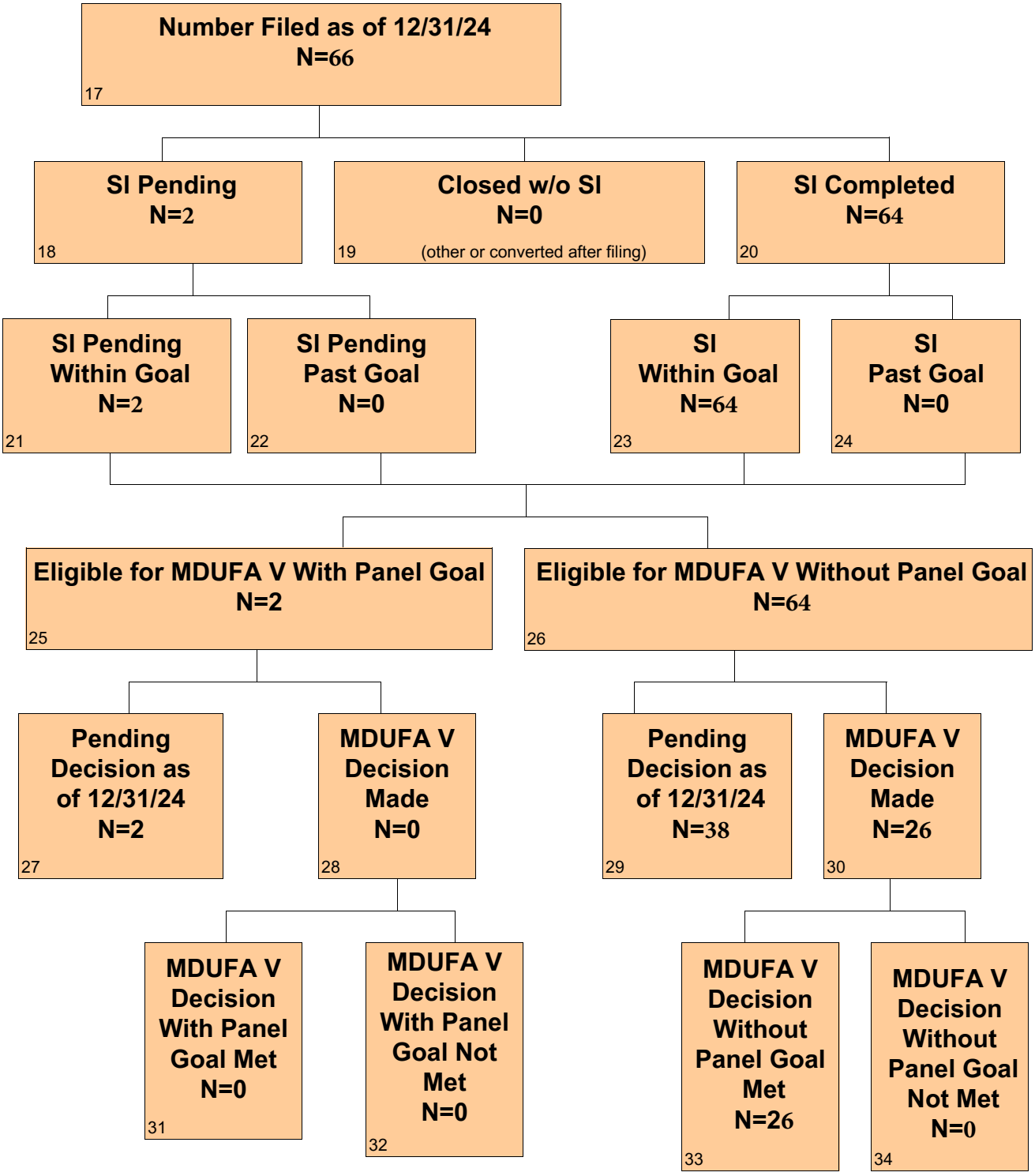
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/24 Continued



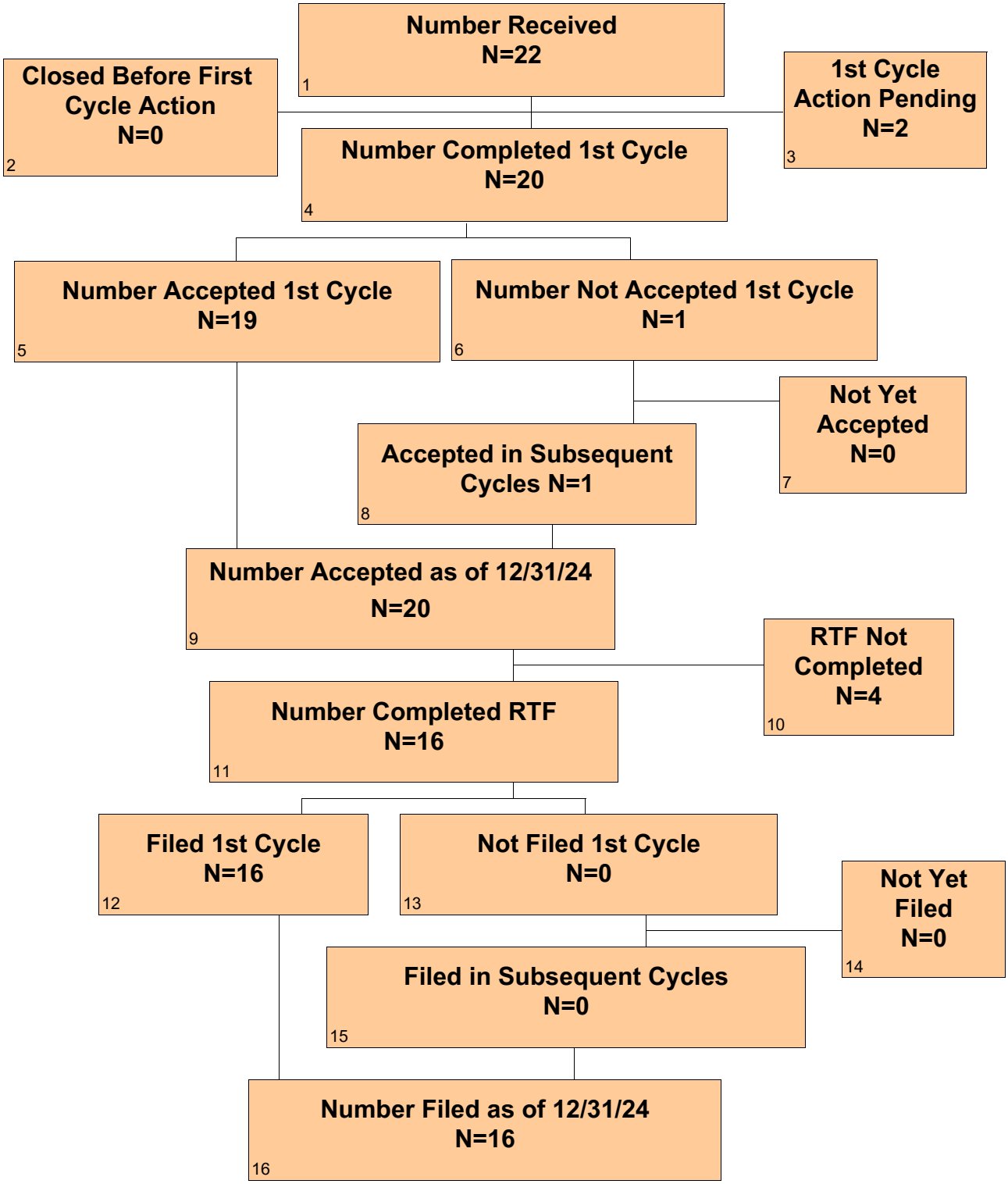
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 12/31/24



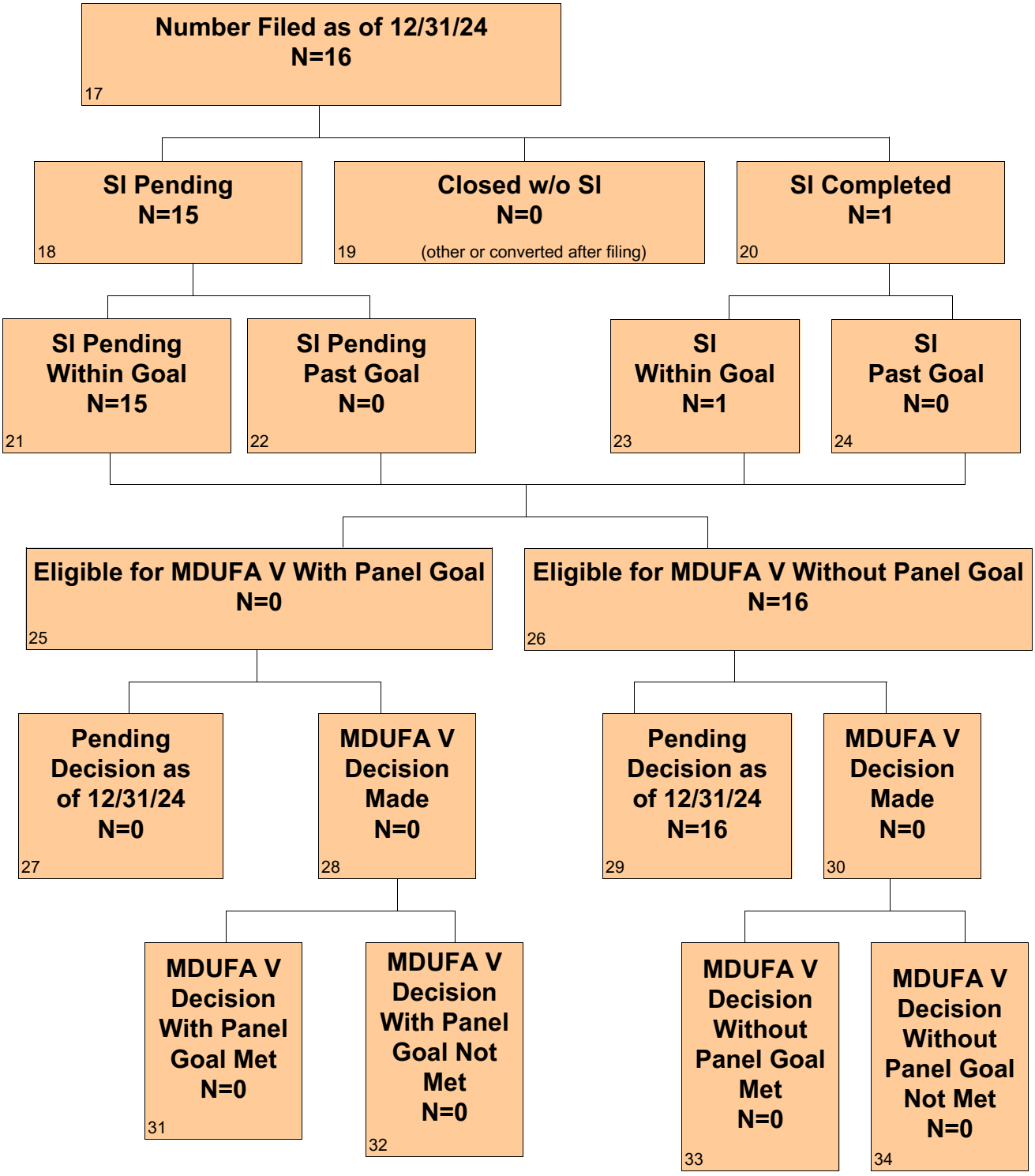
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 12/31/24 Continued



CDRH PMA Original and Panel Track Supplements - FY 2025 as of 12/31/24



CDRH PMA Original and Panel Track Supplements - FY 2025 as of 12/31/24 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	69	22		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	64	61	19		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	0		
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	2		
Number Not Accepted for Filing Review on First Cycle	9	6	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.70%	5.00%		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	22		
Number Accepted	64	63	19		
Completed RTF	72	68	16		
Number Not Filed	2	2	0		
Rate of Submissions Not Filed	2.78%	2.94%	0.00%		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	72	66	16		
SI Goal Met	71	64	1		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	2	15		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	98.61%	100.00%	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	64	1		
Average Number of FDA Days to Substantive Interaction	87.42	88.14	74.00		
20th Percentile FDA Days to Substantive Interaction	86	88	74		
40th Percentile FDA Days to Substantive Interaction	88	89	74		
60th Percentile FDA Days to Substantive Interaction	90	90	74		
80th Percentile FDA Days to Substantive Interaction	90	90	74		
Maximum FDA Days to Substantive Interaction	91	90	74		

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	68	64	16		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	64	26	0		
MDUFA Decision Goal Met	63	26	0		
PMAs Pending MDUFA Decision	4	38	16		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.44%	100.00%	N/A		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	4	2	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	0	0		
MDUFA Decision Goal Met	4	0	0		
PMAs Pending MDUFA Decision	0	2	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	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	64	26	0		
Average FDA Days to MDUFA Decision	169.39	171.12	N/A		
20th Percentile FDA Days to MDUFA Decision	171	173	0		
40th Percentile FDA Days to MDUFA Decision	178	178	0		
60th Percentile FDA Days to MDUFA Decision	180	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	271	180	0		
Average Industry Days to MDUFA Decision	107.16	61.88	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	37	29	0		
60th Percentile Industry Days to MDUFA Decision	86	51	0		
80th Percentile Industry Days to MDUFA Decision	254	125	0		
Maximum Industry Days to MDUFA Decision	356	249	0		
Average Total Days to MDUFA Decision	276.55	233.00	N/A		
20th Percentile Total Days to MDUFA Decision	179	180	0		
40th Percentile Total Days to MDUFA Decision	218	198	0		
60th Percentile Total Days to MDUFA Decision	266	231	0		
80th Percentile Total Days to MDUFA Decision	392	305	0		
Maximum Total Days to MDUFA Decision	536	358	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	4	0	0		
Average FDA Days to MDUFA Decision	319.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	318	0	0		
40th Percentile FDA Days to MDUFA Decision	318	0	0		
60th Percentile FDA Days to MDUFA Decision	320	0	0		
80th Percentile FDA Days to MDUFA Decision	320	0	0		
Maximum FDA Days to MDUFA Decision	320	0	0		
Average Industry Days to MDUFA Decision	90.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	51	0	0		
40th Percentile Industry Days to MDUFA Decision	61	0	0		
60th Percentile Industry Days to MDUFA Decision	72	0	0		
80th Percentile Industry Days to MDUFA Decision	120	0	0		
Maximum Industry Days to MDUFA Decision	186	0	0		
Average Total Days to MDUFA Decision	409.00	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	370	0	0		
40th Percentile Total Days to MDUFA Decision	381	0	0		
60th Percentile Total Days to MDUFA Decision	392	0	0		
80th Percentile Total Days to MDUFA Decision	439	0	0		
Maximum Total Days to MDUFA Decision	504	0	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	68	64	16		
Number with MDUFA Decision	64	26	0		
Number of Withdrawal	3	2	0		
Number of Not Approvable	10	4	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	4.69%	7.69%	N/A		
Rate of Not Approvable	15.63%	15.38%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	4	2	0		
Number With MDUFA Decision	4	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	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	1	0	0		
Mean FDA Days for Submissions that Missed the Goal	191.00	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	5	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	1	0		
MDUFA Decision Goal Met	6	1	0		
PMAs Pending MDUFA Decision	0	4	1		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	10	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	13	5	0		
MDUFA Decision Goal Met	13	5	0		
PMAs Pending MDUFA Decision	2	5	2		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

***Includes submission that went to panel**

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	2		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	2		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	6	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%	0.00%		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	2		
Number Accepted	3	6	2		
Completed RTF	8	7	1		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	12.50%	0.00%	0.00%		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	7	1		
SI Goal Met	8	7	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	8	7	0		
Average Number of FDA Days to Substantive Interaction	82.00	89.43	N/A		
20th Percentile FDA Days to Substantive Interaction	87	88	0		
40th Percentile FDA Days to Substantive Interaction	90	90	0		
60th Percentile FDA Days to Substantive Interaction	90	90	0		
80th Percentile FDA Days to Substantive Interaction	90	90	0		
Maximum FDA Days to Substantive Interaction	90	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	8	7	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	7	4	0		
MDUFA Decision Goal Met	7	4	0		
PMAs Pending MDUFA Decision	1	3	1		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	7	4	0		
Average FDA Days to MDUFA Decision	144.86	180.00	N/A		
20th Percentile FDA Days to MDUFA Decision	107	180	0		
40th Percentile FDA Days to MDUFA Decision	176	180	0		
60th Percentile FDA Days to MDUFA Decision	180	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
Average Industry Days to MDUFA Decision	197.14	91.50	N/A		
20th Percentile Industry Days to MDUFA Decision	59	43	0		
40th Percentile Industry Days to MDUFA Decision	166	73	0		
60th Percentile Industry Days to MDUFA Decision	289	112	0		
80th Percentile Industry Days to MDUFA Decision	305	140	0		
Maximum Industry Days to MDUFA Decision	356	163	0		
Average Total Days to MDUFA Decision	342.00	271.50	N/A		
20th Percentile Total Days to MDUFA Decision	238	223	0		
40th Percentile Total Days to MDUFA Decision	309	253	0		
60th Percentile Total Days to MDUFA Decision	433	292	0		
80th Percentile Total Days to MDUFA Decision	481	320	0		
Maximum Total Days to MDUFA Decision	536	343	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	0		
Average FDA Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	8	7	1		
Number with MDUFA Decision	7	4	0		
Number of Withdrawal	1	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	14.29%	0.00%	N/A		
Rate of Not Approvable	0.00%	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	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20	10		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	19	17	9		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	1		
Number Not Accepted for Filing Review on First Cycle	1	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	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	20	10		
Number Accepted	19	19	9		
Completed RTF	20	20	8		
Number Not Filed	0	1	0		
Rate of Submissions Not Filed	0.00%	5.00%	0.00%		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	20	19	8		
SI Goal Met	20	18	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	1	7		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	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	18	1		
Average Number of FDA Days to Substantive Interaction	88.25	88.11	74.00		
20th Percentile FDA Days to Substantive Interaction	86	86	74		
40th Percentile FDA Days to Substantive Interaction	90	89	74		
60th Percentile FDA Days to Substantive Interaction	90	90	74		
80th Percentile FDA Days to Substantive Interaction	90	90	74		
Maximum FDA Days to Substantive Interaction	90	90	74		

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	18	8		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	17	10	0		
MDUFA Decision Goal Met	17	10	0		
PMAs Pending MDUFA Decision	0	8	8		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	3	1	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	0	0		
MDUFA Decision Goal Met	3	0	0		
PMAs Pending MDUFA Decision	0	1	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	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	10	0		
Average FDA Days to MDUFA Decision	177.65	174.30	N/A		
20th Percentile FDA Days to MDUFA Decision	172	174	0		
40th Percentile FDA Days to MDUFA Decision	177	178	0		
60th Percentile FDA Days to MDUFA Decision	180	179	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	271	180	0		
Average Industry Days to MDUFA Decision	64.29	13.90	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	23	0	0		
60th Percentile Industry Days to MDUFA Decision	47	14	0		
80th Percentile Industry Days to MDUFA Decision	113	29	0		
Maximum Industry Days to MDUFA Decision	271	51	0		
Average Total Days to MDUFA Decision	241.94	188.20	N/A		
20th Percentile Total Days to MDUFA Decision	176	178	0		
40th Percentile Total Days to MDUFA Decision	201	179	0		
60th Percentile Total Days to MDUFA Decision	236	192	0		
80th Percentile Total Days to MDUFA Decision	305	199	0		
Maximum Total Days to MDUFA Decision	442	231	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	0	0		
Average FDA Days to MDUFA Decision	319.33	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	319	0	0		
40th Percentile FDA Days to MDUFA Decision	320	0	0		
60th Percentile FDA Days to MDUFA Decision	320	0	0		
80th Percentile FDA Days to MDUFA Decision	320	0	0		
Maximum FDA Days to MDUFA Decision	320	0	0		
Average Industry Days to MDUFA Decision	58.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	47	0	0		
40th Percentile Industry Days to MDUFA Decision	54	0	0		
60th Percentile Industry Days to MDUFA Decision	61	0	0		
80th Percentile Industry Days to MDUFA Decision	68	0	0		
Maximum Industry Days to MDUFA Decision	76	0	0		
Average Total Days to MDUFA Decision	377.33	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	366	0	0		
40th Percentile Total Days to MDUFA Decision	373	0	0		
60th Percentile Total Days to MDUFA Decision	381	0	0		
80th Percentile Total Days to MDUFA Decision	388	0	0		
Maximum Total Days to MDUFA Decision	396	0	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	18	8		
Number with MDUFA Decision	17	10	0		
Number of Withdrawal	1	0	0		
Number of Not Approvable	3	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	5.88%	0.00%	N/A		
Rate of Not Approvable	17.65%	0.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	1	0		
Number With MDUFA Decision	3	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	0		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	0		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	14.29%	N/A		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	0		
Number Accepted	3	6	0		
Completed RTF	3	7	0		
Number Not Filed	0	1	0		
Rate of Submissions Not Filed	0.00%	14.29%	N/A		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	6	0		
SI Goal Met	3	5	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	1	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	5	0		
Average Number of FDA Days to Substantive Interaction	88.33	85.40	N/A		
20th Percentile FDA Days to Substantive Interaction	87	85	0		
40th Percentile FDA Days to Substantive Interaction	88	88	0		
60th Percentile FDA Days to Substantive Interaction	88	89	0		
80th Percentile FDA Days to Substantive Interaction	89	90	0		
Maximum FDA Days to Substantive Interaction	90	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	6	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	1	0		
MDUFA Decision Goal Met	2	1	0		
PMAs Pending MDUFA Decision	0	5	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	66.67%	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	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	1	0		
Average FDA Days to MDUFA Decision	180.67	169.00	N/A		
20th Percentile FDA Days to MDUFA Decision	175	169	0		
40th Percentile FDA Days to MDUFA Decision	178	169	0		
60th Percentile FDA Days to MDUFA Decision	181	169	0		
80th Percentile FDA Days to MDUFA Decision	186	169	0		
Maximum FDA Days to MDUFA Decision	191	169	0		
Average Industry Days to MDUFA Decision	18.67	189.00	N/A		
20th Percentile Industry Days to MDUFA Decision	11	189	0		
40th Percentile Industry Days to MDUFA Decision	22	189	0		
60th Percentile Industry Days to MDUFA Decision	28	189	0		
80th Percentile Industry Days to MDUFA Decision	28	189	0		
Maximum Industry Days to MDUFA Decision	28	189	0		
Average Total Days to MDUFA Decision	199.33	358.00	N/A		
20th Percentile Total Days to MDUFA Decision	187	358	0		
40th Percentile Total Days to MDUFA Decision	196	358	0		
60th Percentile Total Days to MDUFA Decision	204	358	0		
80th Percentile Total Days to MDUFA Decision	211	358	0		
Maximum Total Days to MDUFA Decision	219	358	0		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	6	0		
Number with MDUFA Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	33.33%	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	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0		
Mean FDA Days for Submissions that Missed the Goal	191.00	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	2		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	9	6	1		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	0	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%	50.00%		

***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	2		
Number Accepted	9	6	1		
Completed RTF	9	6	1		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	9	6	1		
SI Goal Met	9	6	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	9	6	0		
Average Number of FDA Days to Substantive Interaction	88.78	89.33	N/A		
20th Percentile FDA Days to Substantive Interaction	88	89	0		
40th Percentile FDA Days to Substantive Interaction	90	89	0		
60th Percentile FDA Days to Substantive Interaction	90	90	0		
80th Percentile FDA Days to Substantive Interaction	90	90	0		
Maximum FDA Days to Substantive Interaction	90	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	9	5	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	0	0		
MDUFA Decision Goal Met	8	0	0		
PMAs Pending MDUFA Decision	1	5	1		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	1	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	0		
Average FDA Days to MDUFA Decision	179.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	178	0	0		
40th Percentile FDA Days to MDUFA Decision	179	0	0		
60th Percentile FDA Days to MDUFA Decision	180	0	0		
80th Percentile FDA Days to MDUFA Decision	180	0	0		
Maximum FDA Days to MDUFA Decision	180	0	0		
Average Industry Days to MDUFA Decision	60.38	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	32	0	0		
60th Percentile Industry Days to MDUFA Decision	53	0	0		
80th Percentile Industry Days to MDUFA Decision	64	0	0		
Maximum Industry Days to MDUFA Decision	264	0	0		
Average Total Days to MDUFA Decision	239.38	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	179	0	0		
40th Percentile Total Days to MDUFA Decision	210	0	0		
60th Percentile Total Days to MDUFA Decision	233	0	0		
80th Percentile Total Days to MDUFA Decision	244	0	0		
Maximum Total Days to MDUFA Decision	444	0	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	0		
Average FDA Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	5	1		
Number with MDUFA Decision	8	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	12.50%	N/A	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	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	2		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	5	6	2		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	1	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	14.29%	0.00%		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	2		
Number Accepted	5	6	2		
Completed RTF	6	7	2		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	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	7	2		
SI Goal Met	5	7	0		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	83.33%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	6	7	0		
Average Number of FDA Days to Substantive Interaction	88.50	86.43	N/A		
20th Percentile FDA Days to Substantive Interaction	88	86	0		
40th Percentile FDA Days to Substantive Interaction	90	89	0		
60th Percentile FDA Days to Substantive Interaction	90	90	0		
80th Percentile FDA Days to Substantive Interaction	90	90	0		
Maximum FDA Days to Substantive Interaction	91	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	7	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	3	0		
MDUFA Decision Goal Met	6	3	0		
PMAs Pending MDUFA Decision	0	4	2		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	3	0		
Average FDA Days to MDUFA Decision	175.33	147.33	N/A		
20th Percentile FDA Days to MDUFA Decision	179	123	0		
40th Percentile FDA Days to MDUFA Decision	180	158	0		
60th Percentile FDA Days to MDUFA Decision	180	176	0		
80th Percentile FDA Days to MDUFA Decision	180	177	0		
Maximum FDA Days to MDUFA Decision	180	178	0		
Average Industry Days to MDUFA Decision	55.17	129.67	N/A		
20th Percentile Industry Days to MDUFA Decision	0	63	0		
40th Percentile Industry Days to MDUFA Decision	37	90	0		
60th Percentile Industry Days to MDUFA Decision	71	133	0		
80th Percentile Industry Days to MDUFA Decision	101	191	0		
Maximum Industry Days to MDUFA Decision	122	249	0		
Average Total Days to MDUFA Decision	230.50	277.00	N/A		
20th Percentile Total Days to MDUFA Decision	180	240	0		
40th Percentile Total Days to MDUFA Decision	217	267	0		
60th Percentile Total Days to MDUFA Decision	251	291	0		
80th Percentile Total Days to MDUFA Decision	281	314	0		
Maximum Total Days to MDUFA Decision	301	337	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	0		
Average FDA Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	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	7	2		
Number with MDUFA Decision	6	3	0		
Number of Withdrawal	0	1	0		
Number of Not Approvable	1	2	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	33.33%	N/A		
Rate of Not Approvable	16.67%	66.67%	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	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	2		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	4	3	1		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	1		
Number Not Accepted for Filing Review on First Cycle	1	0	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	20.00%	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 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	2		
Number Accepted	4	3	1		
Completed RTF	5	3	1		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	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	1		
SI Goal Met	5	3	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	5	3	0		
Average Number of FDA Days to Substantive Interaction	85.40	88.00	N/A		
20th Percentile FDA Days to Substantive Interaction	84	87	0		
40th Percentile FDA Days to Substantive Interaction	86	87	0		
60th Percentile FDA Days to Substantive Interaction	87	88	0		
80th Percentile FDA Days to Substantive Interaction	88	89	0		
Maximum FDA Days to Substantive Interaction	88	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	5	3	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	5	2	0		
MDUFA Decision Goal Met	5	2	0		
PMAs Pending MDUFA Decision	0	1	1		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	5	2	0		
Average FDA Days to MDUFA Decision	173.80	179.00	N/A		
20th Percentile FDA Days to MDUFA Decision	169	178	0		
40th Percentile FDA Days to MDUFA Decision	175	179	0		
60th Percentile FDA Days to MDUFA Decision	178	179	0		
80th Percentile FDA Days to MDUFA Decision	179	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
Average Industry Days to MDUFA Decision	194.80	144.50	N/A		
20th Percentile Industry Days to MDUFA Decision	77	144	0		
40th Percentile Industry Days to MDUFA Decision	142	144	0		
60th Percentile Industry Days to MDUFA Decision	243	145	0		
80th Percentile Industry Days to MDUFA Decision	351	145	0		
Maximum Industry Days to MDUFA Decision	356	145	0		
Average Total Days to MDUFA Decision	368.60	323.50	N/A		
20th Percentile Total Days to MDUFA Decision	241	323	0		
40th Percentile Total Days to MDUFA Decision	309	323	0		
60th Percentile Total Days to MDUFA Decision	417	324	0		
80th Percentile Total Days to MDUFA Decision	530	324	0		
Maximum Total Days to MDUFA Decision	536	325	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	0		
Average FDA Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	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	1		
Number with MDUFA Decision	5	2	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	3	2	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	60.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	4		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	21	14	4		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	2	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	12.50%	0.00%		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	4		
Number Accepted	21	14	4		
Completed RTF	21	15	3		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	4.76%	0.00%	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	15	3		
SI Goal Met	21	15	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	21	15	0		
Average Number of FDA Days to Substantive Interaction	88.14	88.60	N/A		
20th Percentile FDA Days to Substantive Interaction	87	88	0		
40th Percentile FDA Days to Substantive Interaction	87	89	0		
60th Percentile FDA Days to Substantive Interaction	89	89	0		
80th Percentile FDA Days to Substantive Interaction	90	90	0		
Maximum FDA Days to Substantive Interaction	90	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	20	15	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	18	6	0		
MDUFA Decision Goal Met	18	6	0		
PMAs Pending MDUFA Decision	2	9	3		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	1	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Goal Met	1	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	18	6	0		
Average FDA Days to MDUFA Decision	161.78	169.50	N/A		
20th Percentile FDA Days to MDUFA Decision	136	173	0		
40th Percentile FDA Days to MDUFA Decision	179	180	0		
60th Percentile FDA Days to MDUFA Decision	180	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
Average Industry Days to MDUFA Decision	141.17	39.50	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	36	38	0		
60th Percentile Industry Days to MDUFA Decision	182	51	0		
80th Percentile Industry Days to MDUFA Decision	285	64	0		
Maximum Industry Days to MDUFA Decision	354	84	0		
Average Total Days to MDUFA Decision	302.94	209.00	N/A		
20th Percentile Total Days to MDUFA Decision	179	180	0		
40th Percentile Total Days to MDUFA Decision	214	208	0		
60th Percentile Total Days to MDUFA Decision	312	218	0		
80th Percentile Total Days to MDUFA Decision	465	231	0		
Maximum Total Days to MDUFA Decision	534	244	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	1	0	0		
Average FDA Days to MDUFA Decision	318.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	318	0	0		
40th Percentile FDA Days to MDUFA Decision	318	0	0		
60th Percentile FDA Days to MDUFA Decision	318	0	0		
80th Percentile FDA Days to MDUFA Decision	318	0	0		
Maximum FDA Days to MDUFA Decision	318	0	0		
Average Industry Days to MDUFA Decision	186.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	186	0	0		
40th Percentile Industry Days to MDUFA Decision	186	0	0		
60th Percentile Industry Days to MDUFA Decision	186	0	0		
80th Percentile Industry Days to MDUFA Decision	186	0	0		
Maximum Industry Days to MDUFA Decision	186	0	0		
Average Total Days to MDUFA Decision	504.00	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	504	0	0		
40th Percentile Total Days to MDUFA Decision	504	0	0		
60th Percentile Total Days to MDUFA Decision	504	0	0		
80th Percentile Total Days to MDUFA Decision	504	0	0		
Maximum Total Days to MDUFA Decision	504	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	15	3		
Number with MDUFA Decision	18	6	0		
Number of Withdrawal	1	1	0		
Number of Not Approvable	1	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	5.56%	16.67%	N/A		
Rate of Not Approvable	5.56%	0.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0	0		
Number With MDUFA Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	5	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	1	0		
MDUFA Decision Goal Met	6	1	0		
PMAs Pending MDUFA Decision	0	4	1		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	10	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	13	5	0		
MDUFA Decision Goal Met	13	5	0		
PMAs Pending MDUFA Decision	2	5	2		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

***Includes submission that went to panel**

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

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	0	3	0		
Average Number of FDA Days to Substantive Interaction	N/A	89.33	N/A		
20th Percentile FDA Days to Substantive Interaction	0	89	0		
40th Percentile FDA Days to Substantive Interaction	0	90	0		
60th Percentile FDA Days to Substantive Interaction	0	90	0		
80th Percentile FDA Days to Substantive Interaction	0	90	0		
Maximum FDA Days to Substantive Interaction	0	90	0		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	3	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	3	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	0		
Average FDA Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	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	0		
Average FDA Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	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	3	0		
Number with MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

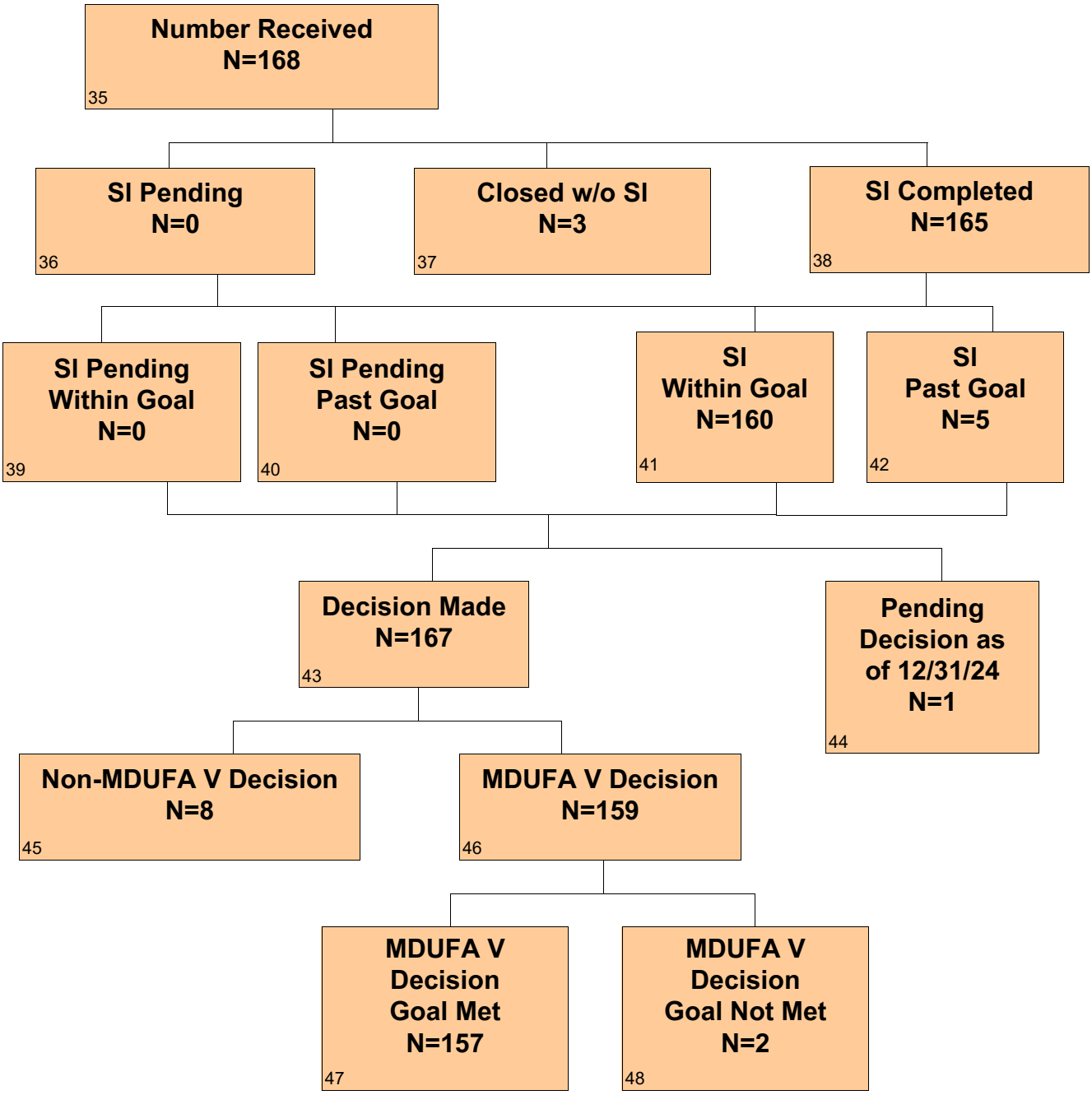
***Includes submission that went to panel**

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

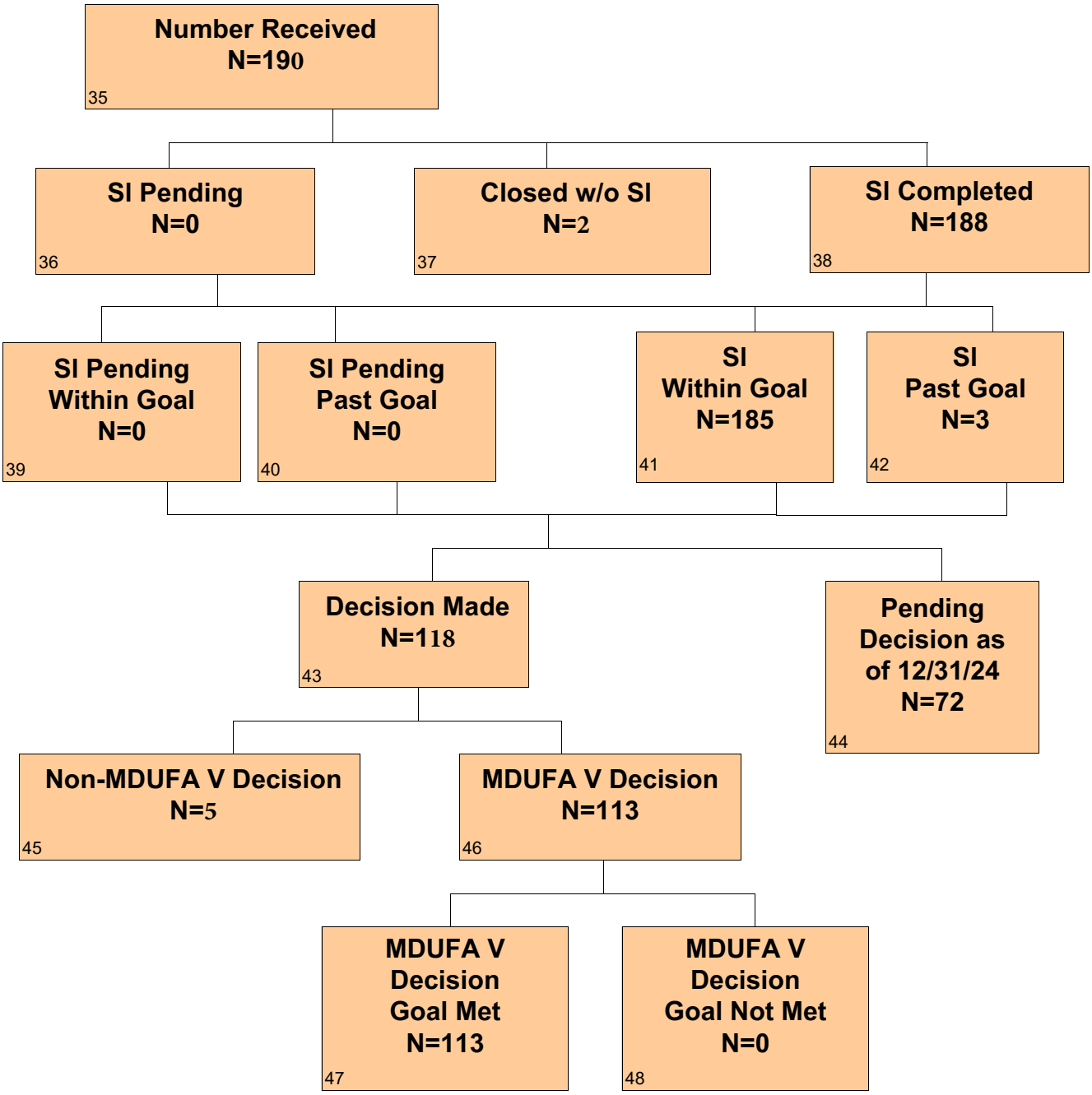
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A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

***Includes submission that went to panel**

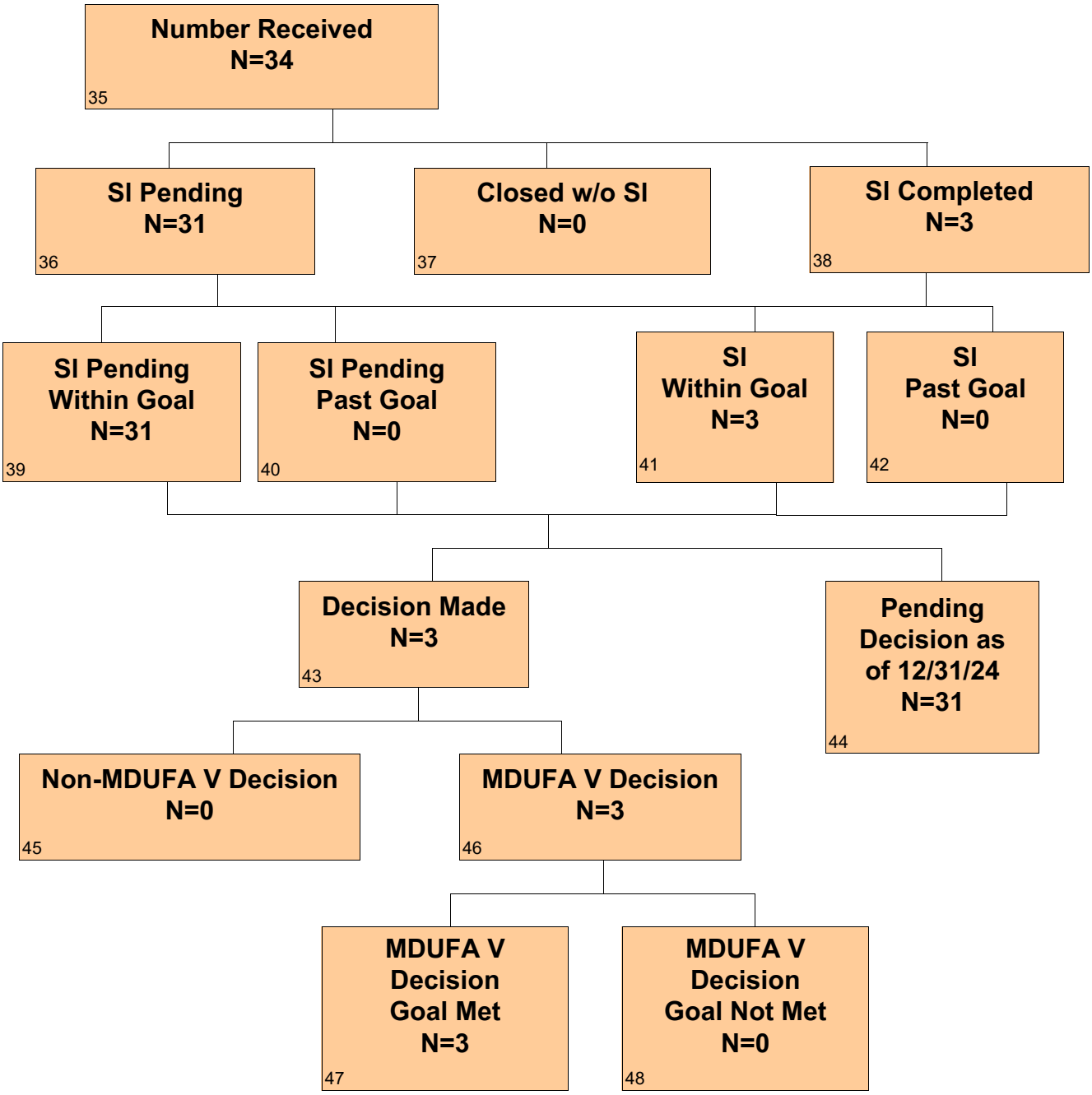
CDRH PMA 180 Day Supplements - FY 2023 as of 12/31/24



CDRH PMA 180 Day Supplements - FY 2024 as of 12/31/24



CDRH PMA 180 Day Supplements - FY 2025 as of 12/31/24



Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	168	190	34		
SI Goal Met	160	185	3		
SI Goal Not Met	5	3	0		
SI Pending Within Goal	0	0	31		
SI Pending Past Goal	0	0	0		
Closed Without SI	3	2	0		
Current SI Performance Percent Goal Met	96.97%	98.40%	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	190	34		
Non-MDUFA Decision	8	5	0		
MDUFA Decision	159	113	3		
MDUFA Decision Goal Met	157	113	3		
Supplements Pending MDUFA Decision	1	72	31		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.74%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	168	190	34		
Number with MDUFA Decision	159	113	3		
Number of Not Approvable	7	11	0		
Rate of Not Approvable	4.40%	9.73%	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	3	0		
Mean FDA Days for Submissions that Missed the Goal	197.00	186.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	77.00	0.00	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	15	3		
SI Goal Met	16	15	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	16	15	3		
Non-MDUFA Decision	1	0	0		
MDUFA Decision	15	4	0		
MDUFA Decision Goal Met	15	4	0		
Supplements Pending MDUFA Decision	0	11	3		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	15	3		
Number with MDUFA Decision	15	4	0		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	6.67%	25.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	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	81	8		
SI Goal Met	55	80	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	0	0	0		
Closed Without SI	1	1	0		
Current SI Performance Percent Goal Met	100.00%	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	81	8		
Non-MDUFA Decision	3	4	0		
MDUFA Decision	53	50	1		
MDUFA Decision Goal Met	53	50	1		
Supplements Pending MDUFA Decision	0	27	7		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	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	81	8		
Number with MDUFA Decision	53	50	1		
Number of Not Approvable	1	9	0		
Rate of Not Approvable	1.89%	18.00%	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	3	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	186.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	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	17	6		
SI Goal Met	20	17	2		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	95.24%	100.00%	100.00%		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	21	17	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	21	9	2		
MDUFA Decision Goal Met	21	9	2		
Supplements Pending MDUFA Decision	0	8	4		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	17	6		
Number with MDUFA Decision	21	9	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	12	1		
SI Goal Met	8	12	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	8	12	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	9	0		
MDUFA Decision Goal Met	8	9	0		
Supplements Pending MDUFA Decision	0	3	1		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8	12	1		
Number with MDUFA Decision	8	9	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	N/A		

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	23	20	2		
SI Goal Met	20	17	0		
SI Goal Not Met	3	3	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	86.96%	85.00%	N/A		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	23	20	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	22	14	0		
MDUFA Decision Goal Met	20	14	0		
Supplements Pending MDUFA Decision	1	6	2		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	90.91%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	2		
Number with MDUFA Decision	22	14	0		
Number of Not Approvable	2	0	0		
Rate of Not Approvable	9.09%	0.00%	N/A		

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	5	3		
Number with MDUFA Decision	7	3	0		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	14.29%	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	38	11		
SI Goal Met	33	37	0		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	11		
SI Pending Past Goal	0	0	0		
Closed Without SI	2	1	0		
Current SI Performance Percent Goal Met	97.06%	100.00%	N/A		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	36	38	11		
Non-MDUFA Decision	4	1	0		
MDUFA Decision	32	23	0		
MDUFA Decision Goal Met	32	23	0		
Supplements Pending MDUFA Decision	0	14	11		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	36	38	11		
Number with MDUFA Decision	32	23	0		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	6.25%	4.35%	N/A		

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

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

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

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

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

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

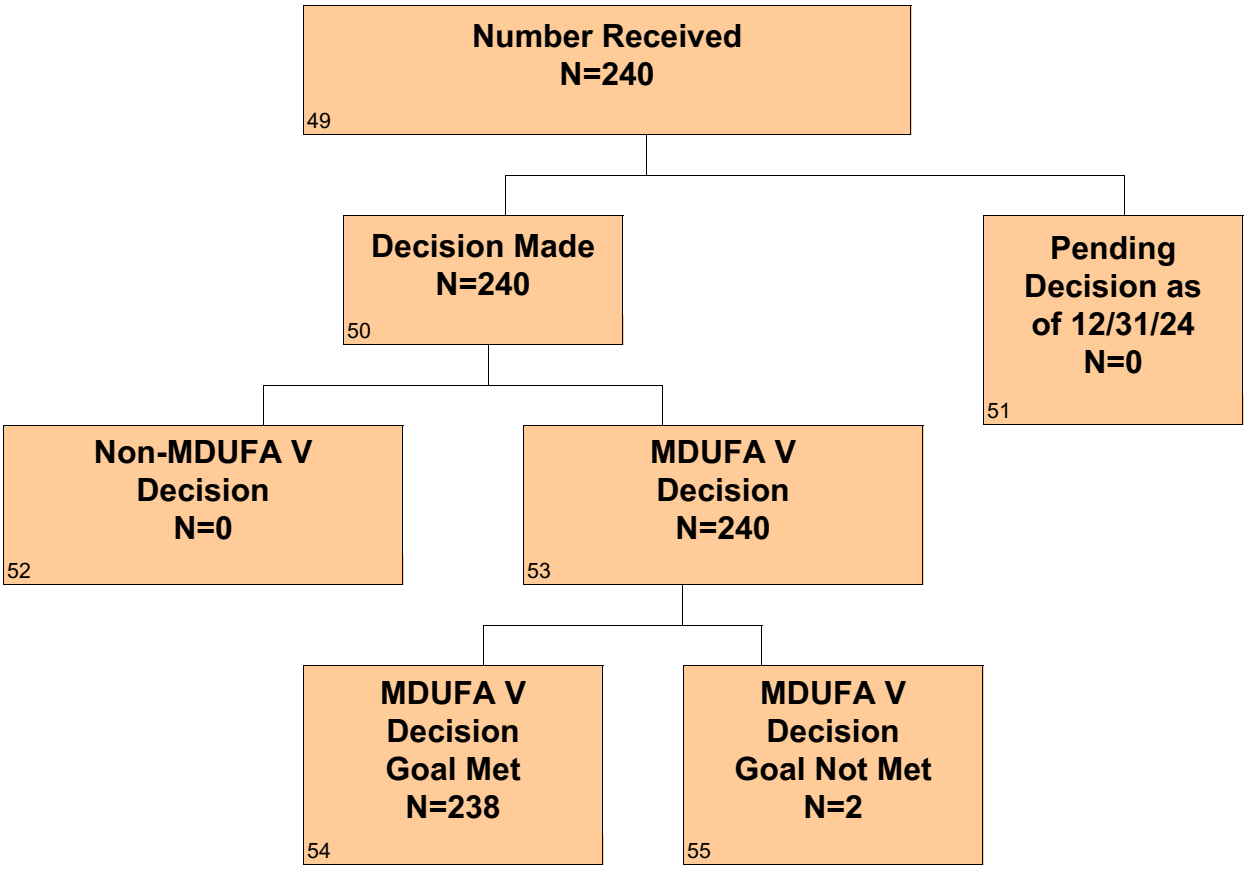
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

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

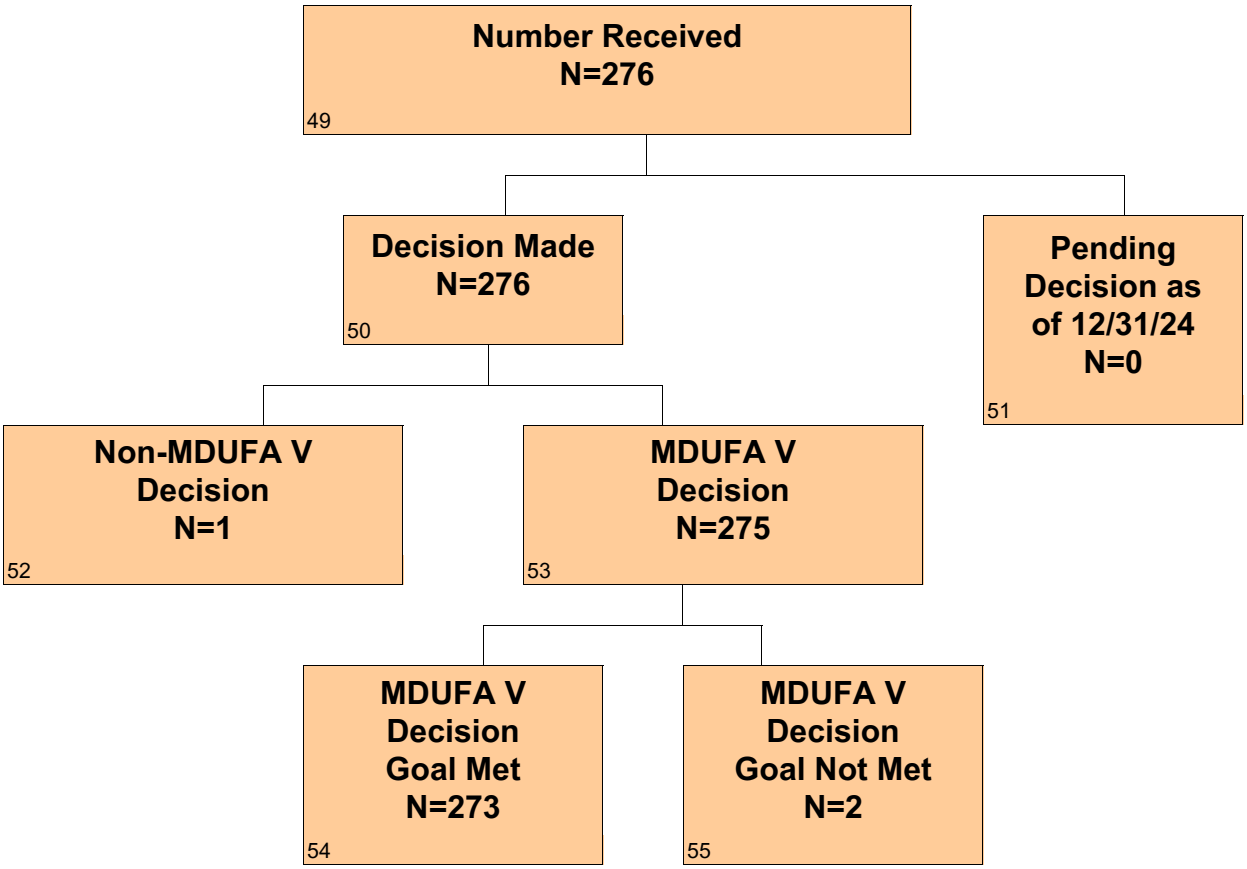
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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

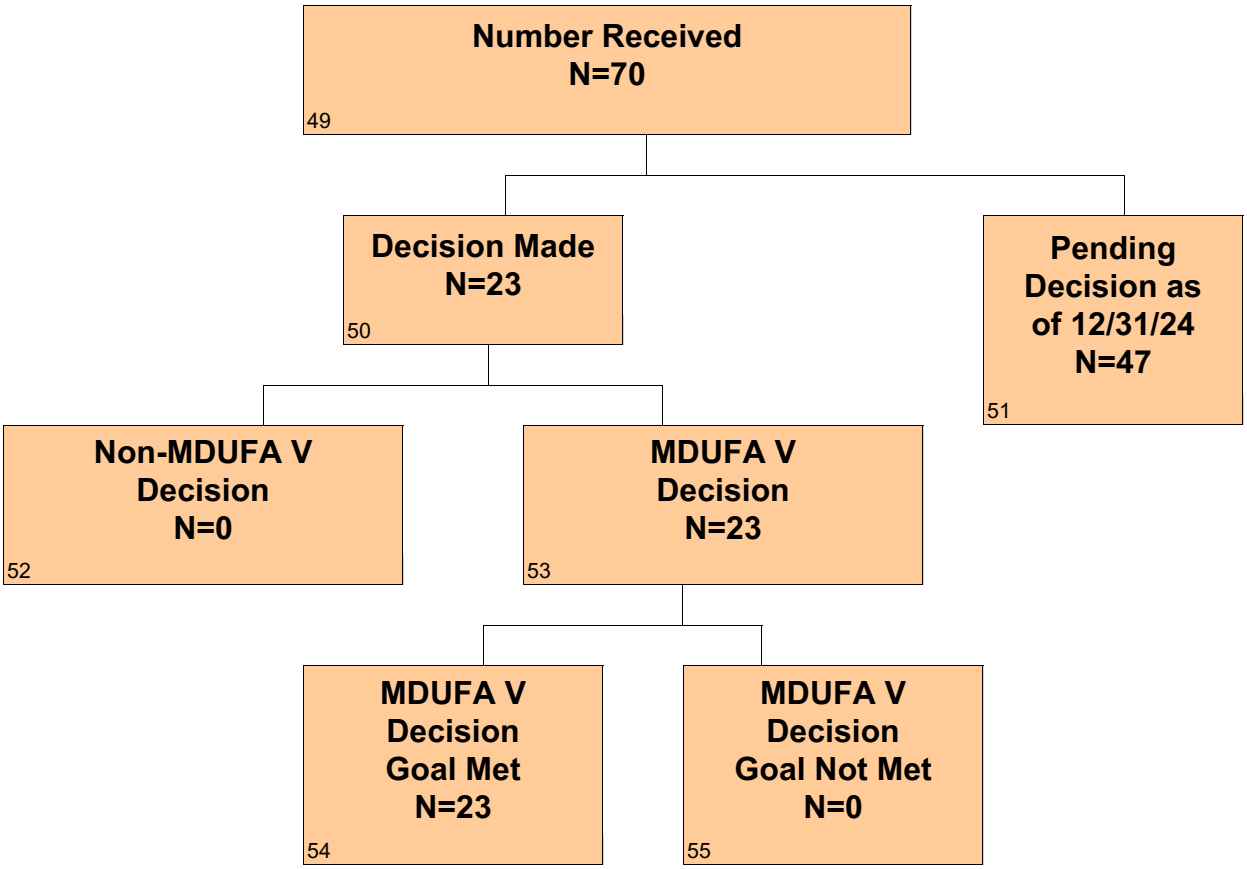
CDRH PMA Real Time Supplements - FY 2023 as of 12/31/24



CDRH PMA Real Time Supplements - FY 2024 as of 12/31/24



CDRH PMA Real Time Supplements - FY 2025 as of 12/31/24



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	276	70		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	240	275	23		
MDUFA Decision Goal Met	238	273	23		
Supplements Pending MDUFA Decision	0	0	47		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.17%	99.27%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	240	276	70		
Number With MDUFA Decision	240	275	23		
Number of Not Approvable	11	10	2		
Rate of Not Approvable	4.58%	3.64%	8.70%		

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	2	0		
Mean FDA Days for Submissions that Missed the Goal	109.50	119.50	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	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	19	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	24	19	2		
MDUFA Decision Goal Met	24	19	2		
Supplements Pending MDUFA Decision	0	0	7		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	24	19	9		
Number With MDUFA Decision	24	19	2		
Number of Not Approvable	3	2	0		
Rate of Not Approvable	12.50%	10.53%	0.00%		

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	136	142	31		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	136	142	11		
MDUFA Decision Goal Met	136	142	11		
Supplements Pending MDUFA Decision	0	0	20		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	136	142	31		
Number With MDUFA Decision	136	142	11		
Number of Not Approvable	4	1	2		
Rate of Not Approvable	2.94%	0.70%	18.18%		

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	19	23	2		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	19	22	2		
MDUFA Decision Goal Met	18	21	2		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	94.74%	95.45%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	19	23	2		
Number With MDUFA Decision	19	22	2		
Number of Not Approvable	2	4	0		
Rate of Not Approvable	10.53%	18.18%	0.00%		

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	1	0		
Mean FDA Days for Submissions that Missed the Goal	92.00	91.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	10	4		
Number With MDUFA Decision	7	10	0		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	28.57%	10.00%	N/A		

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	16	37	19		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	16	37	8		
MDUFA Decision Goal Met	15	36	8		
Supplements Pending MDUFA Decision	0	0	11		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	93.75%	97.30%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	37	19		
Number With MDUFA Decision	16	37	8		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	2.70%	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	1	0		
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	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	11	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	11	0		
MDUFA Decision Goal Met	4	11	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	33	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	32	33	0		
MDUFA Decision Goal Met	32	33	0		
Supplements Pending MDUFA Decision	0	0	5		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	32	33	5		
Number With MDUFA Decision	32	33	0		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	3.03%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	2	1	0		
MDUFA Decision Goal Met	2	1	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

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

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

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

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2024 and December 31, 2024.

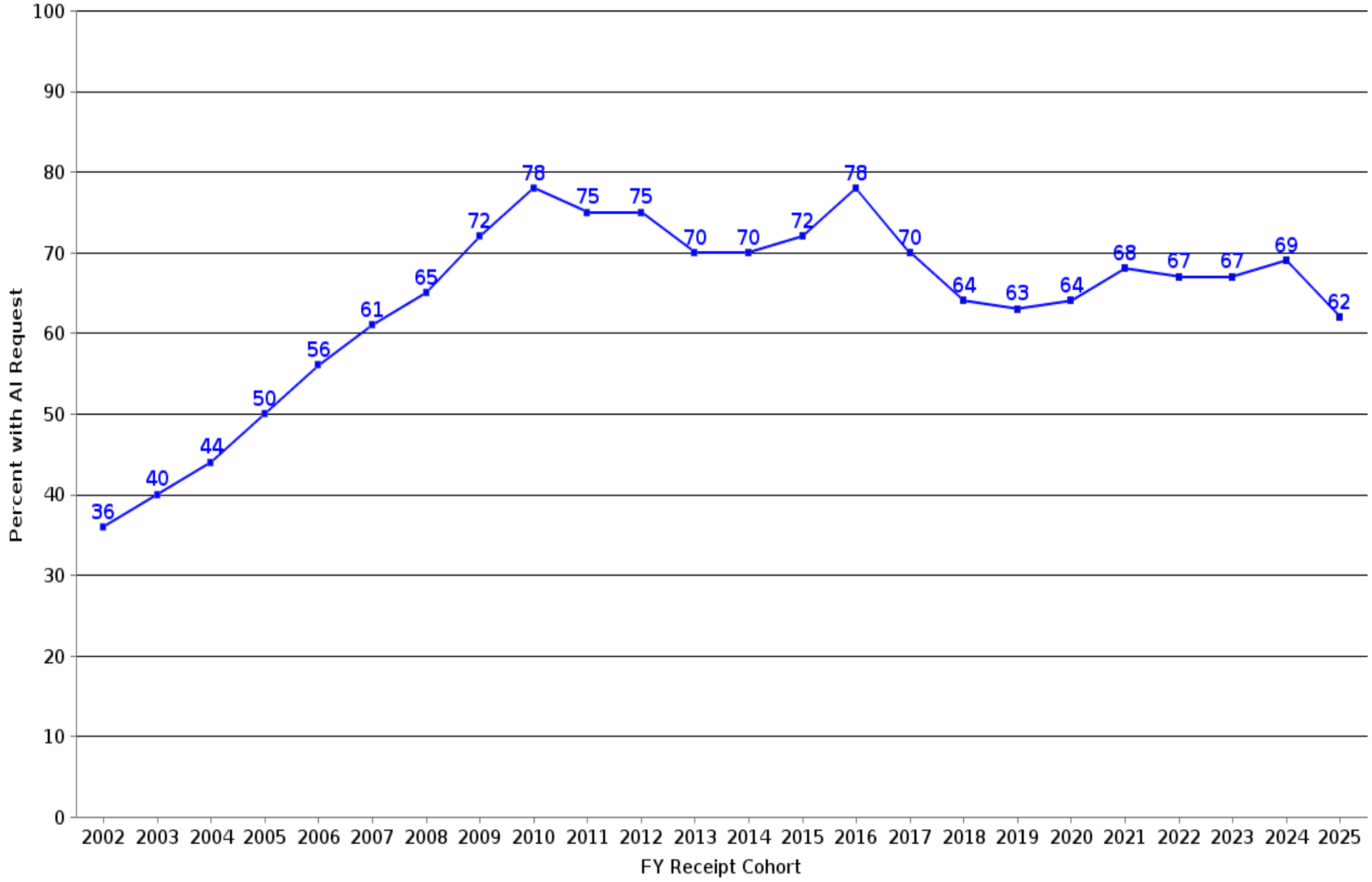
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q1FY2025

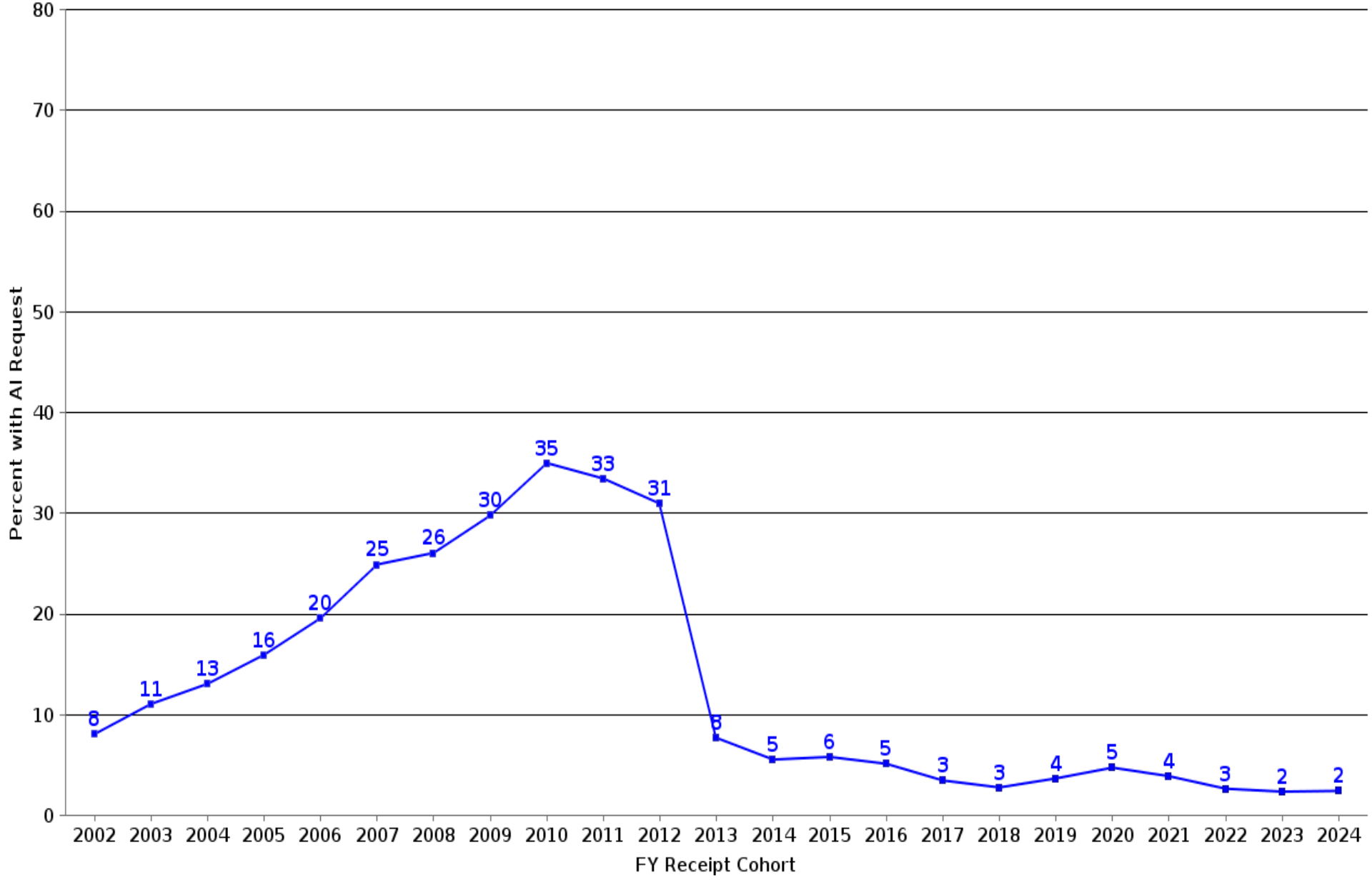
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 10/31/24

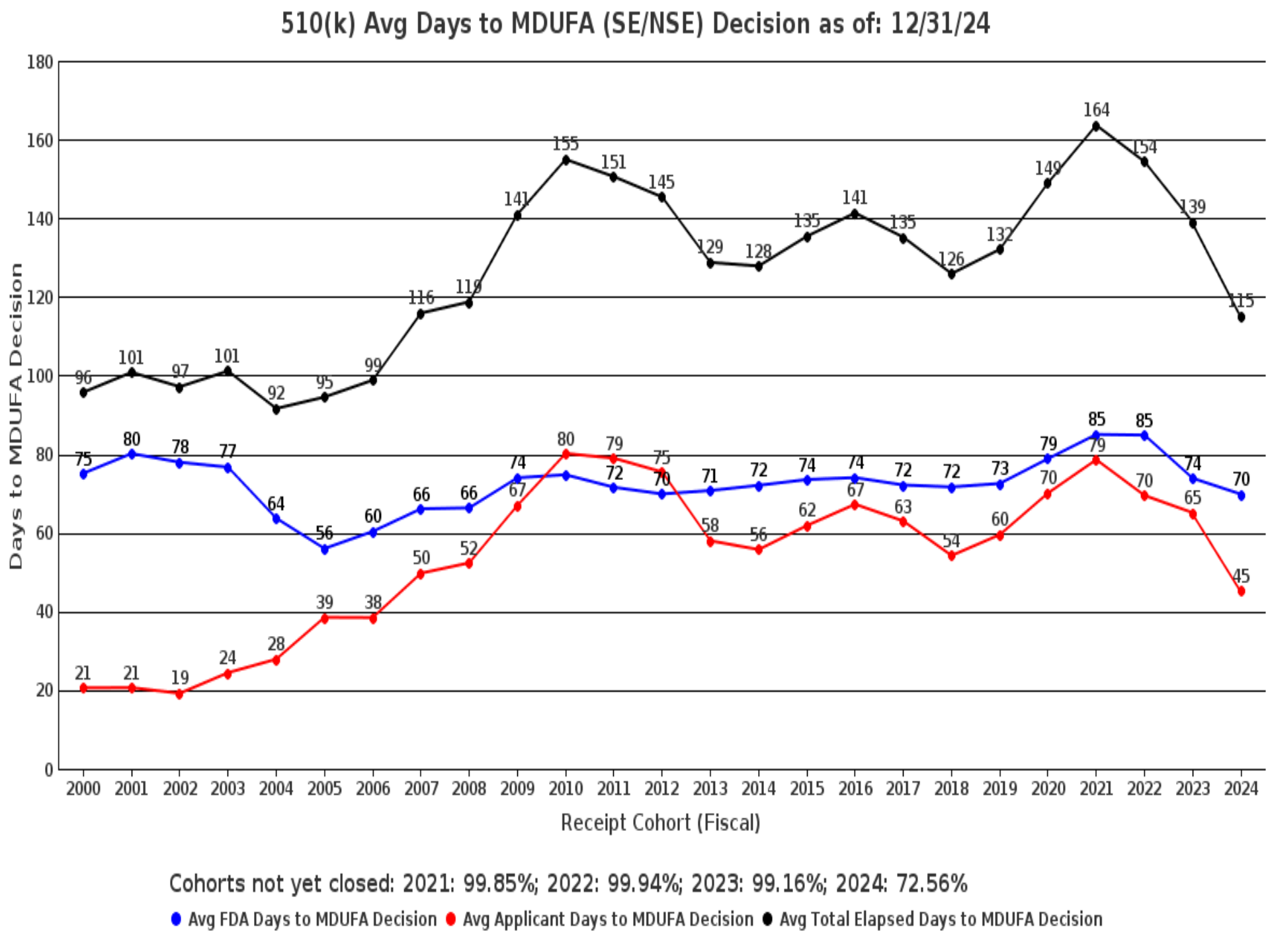
■ % with 1st Cycle AI Request

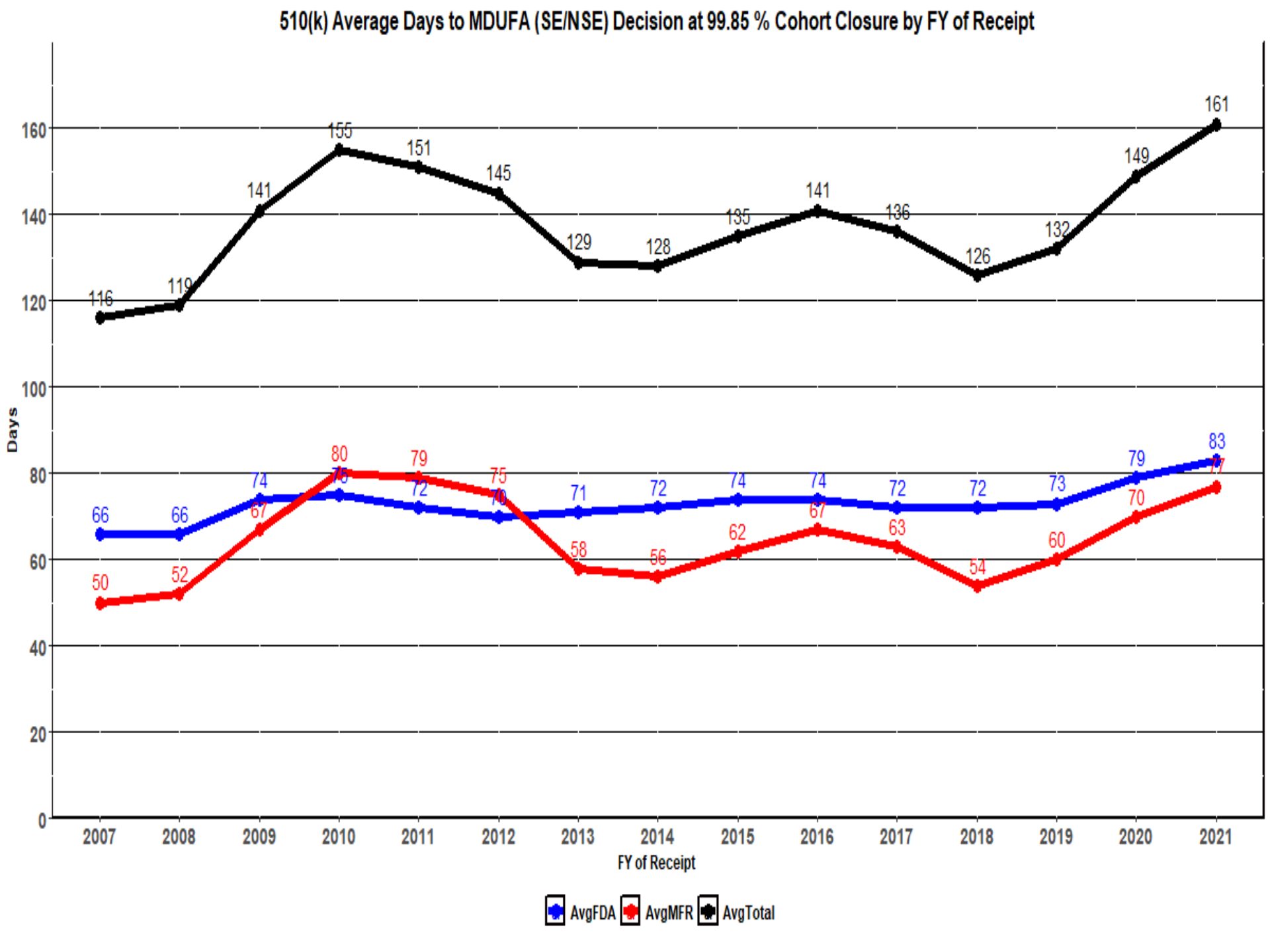
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 5/31/24

■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 12/31/24
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2021: 99.85%; 2022: 99.94%; 2023: 99.16%; 2024: 72.56%
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 99.85 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
AvgFDA
AvgMFR
AvgTotal
116
119
141
155
151
145
129
128
135
141
136
126
132
149
161
66
66
74
75
72
70
71
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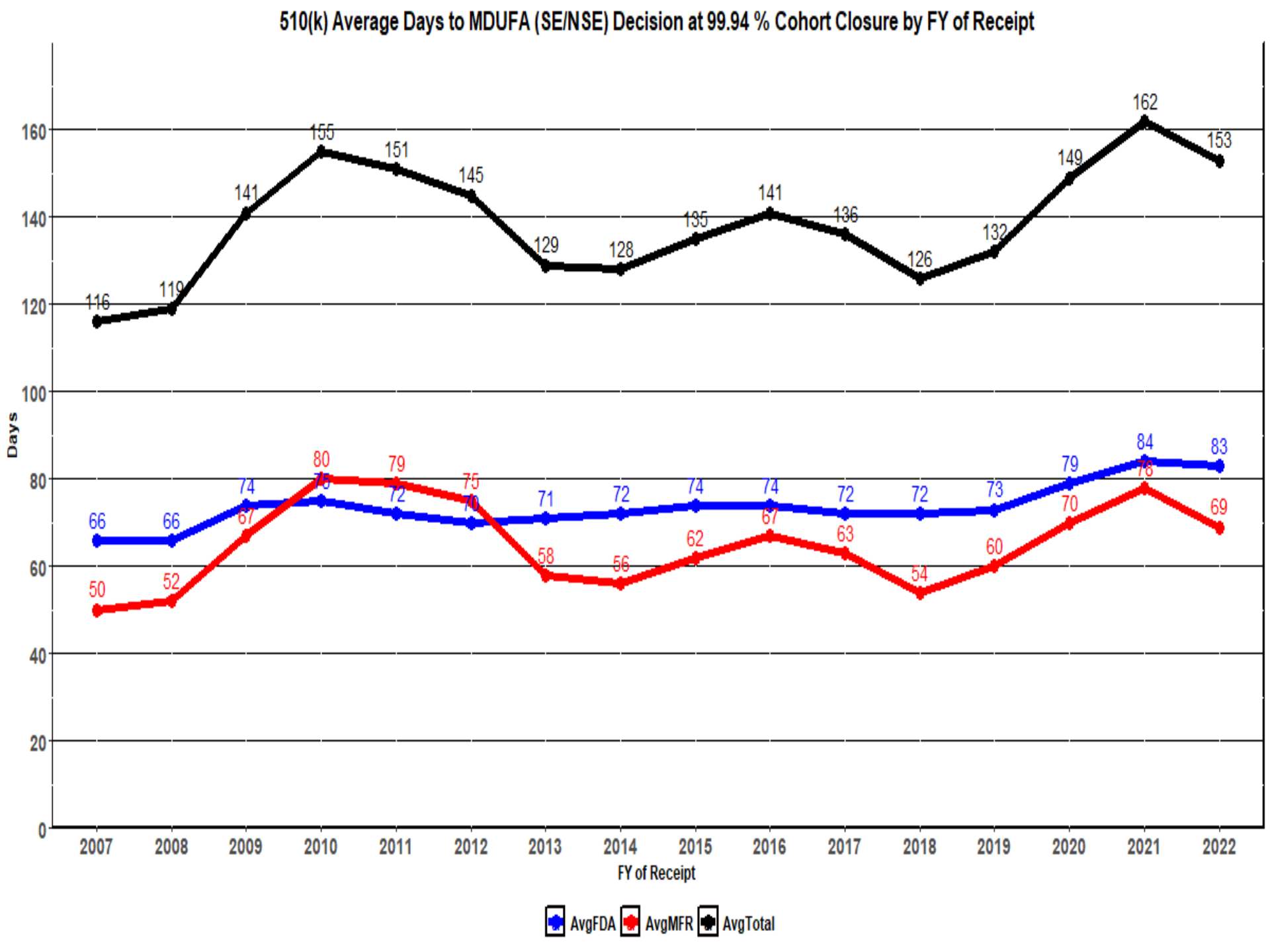
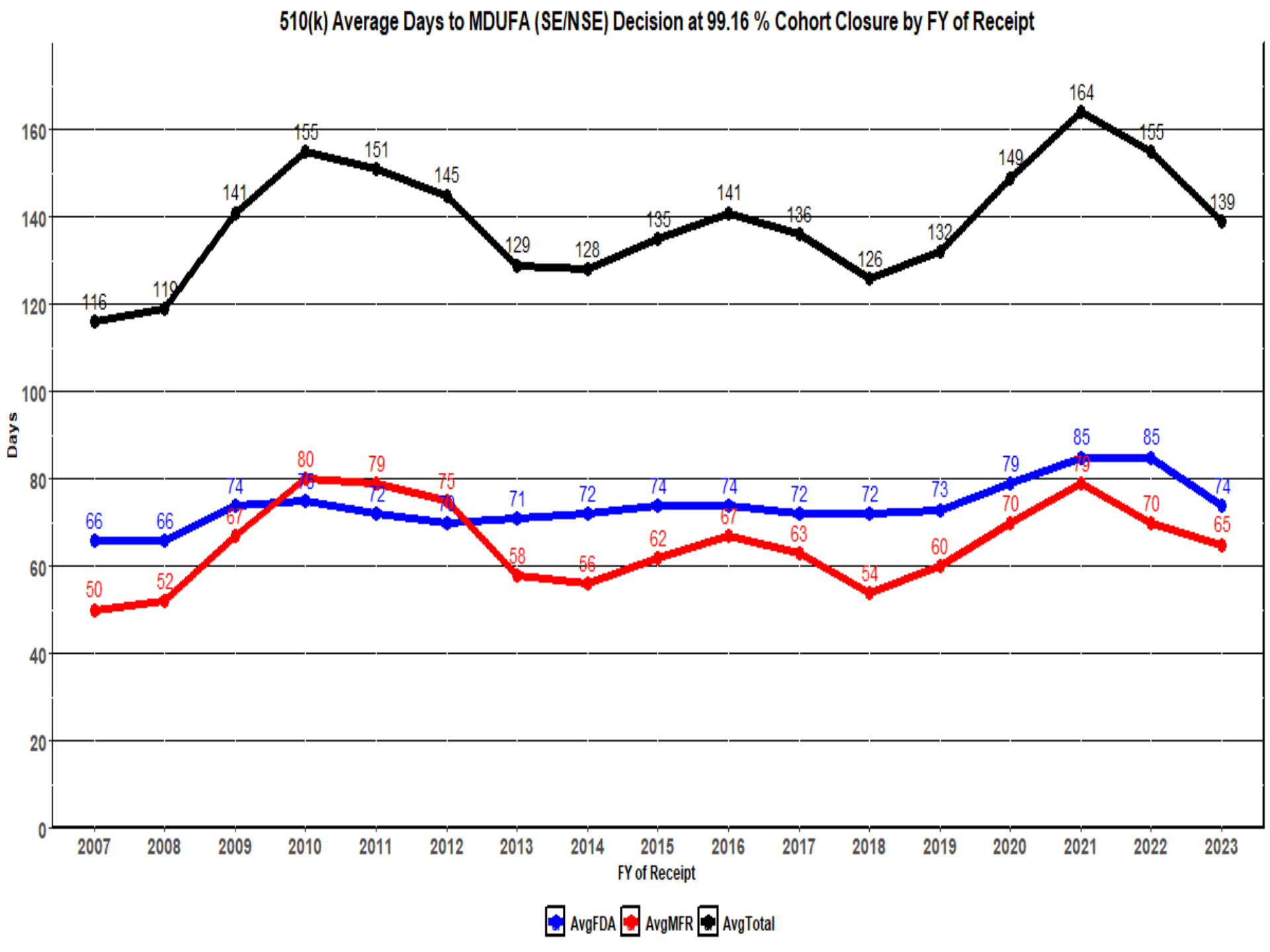
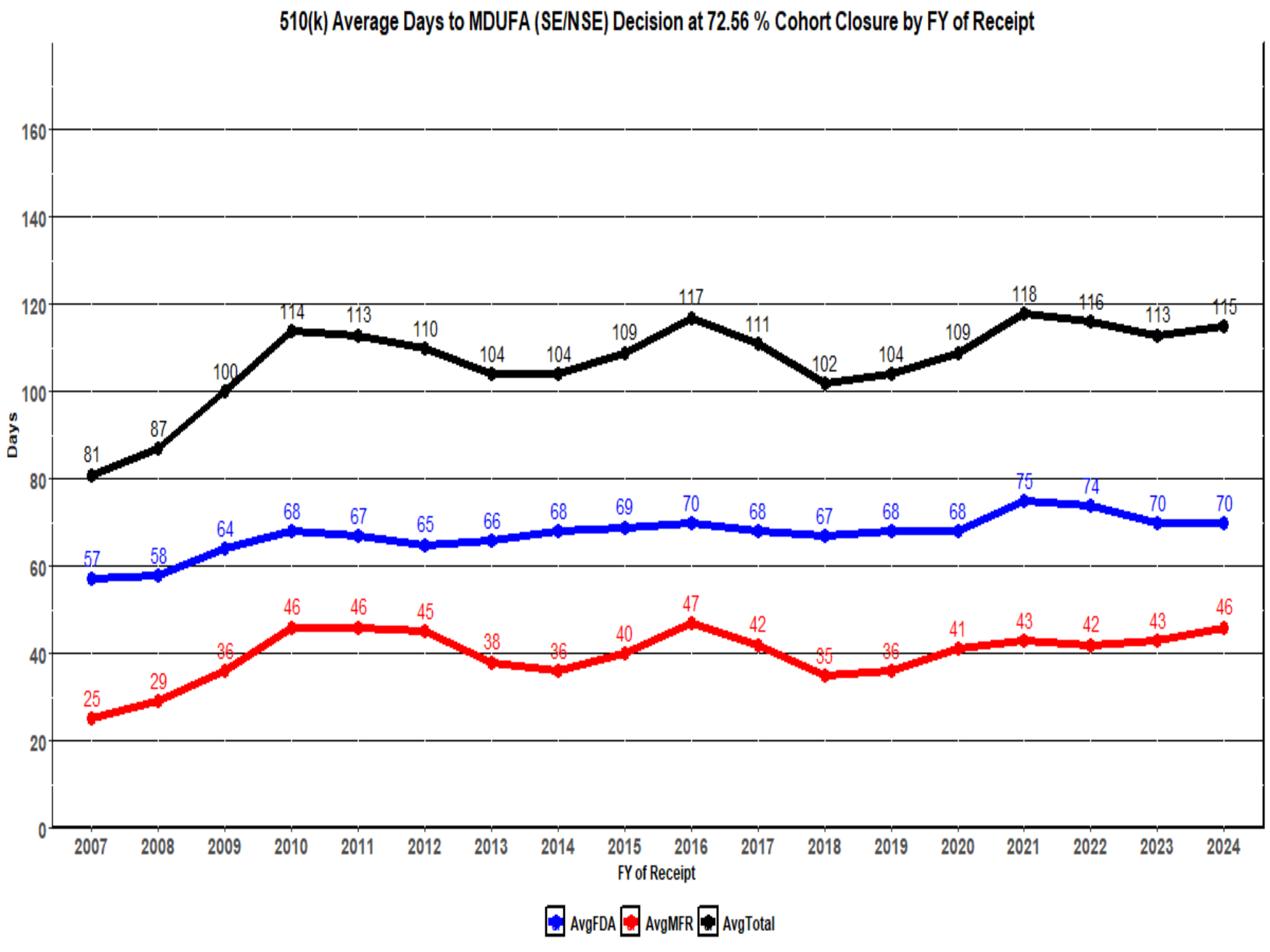
70
77

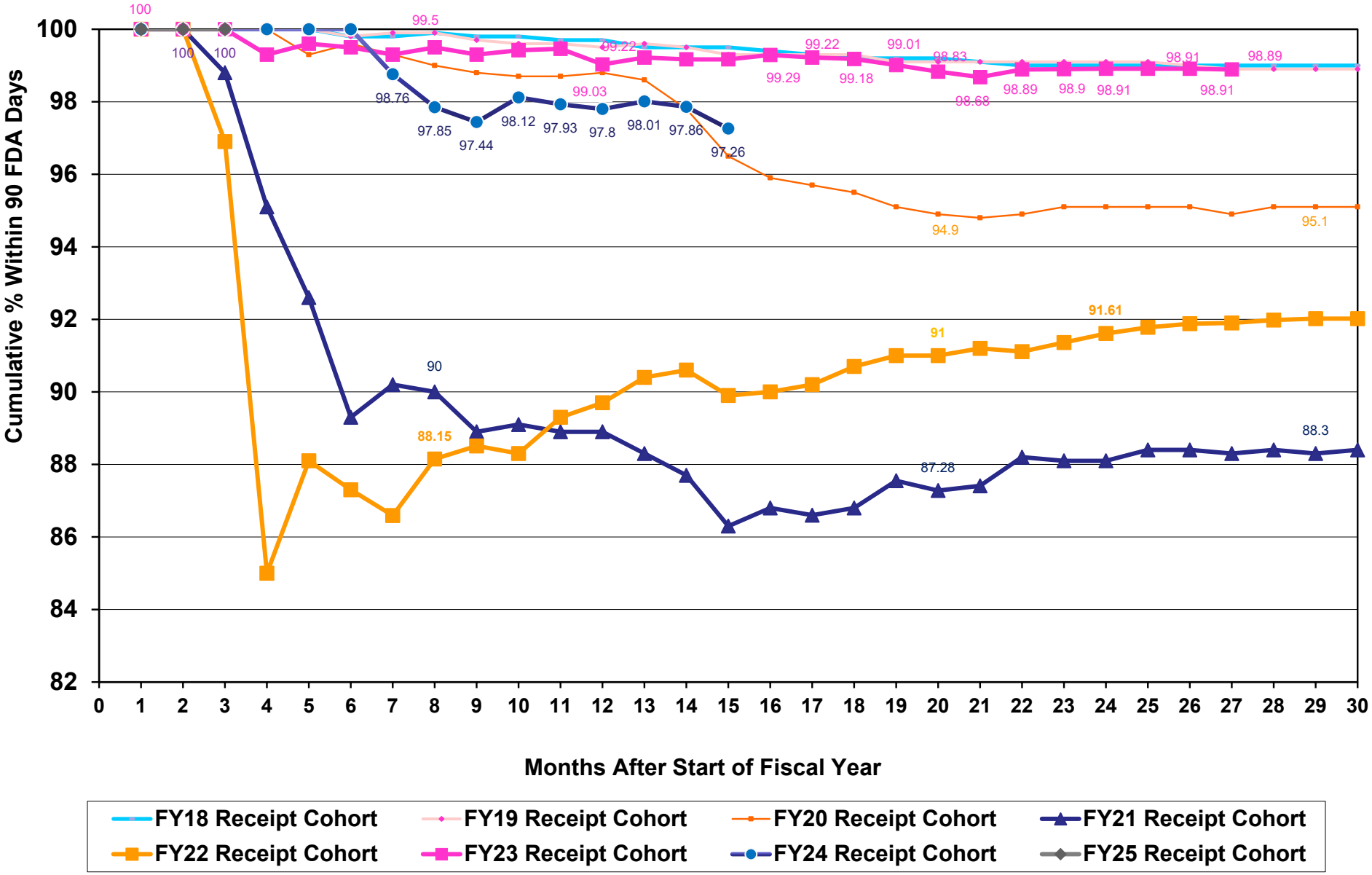

510(k) Average Days to MDUFA (SE/NSE) Decision at 99.94 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
AvgFDA
AvgMFR
AvgTotal
116
119
141
155
151
145
129
128
135
141
136
126
132
149
162
153
66
66
74
75
72
70
71
72
74
74
72
72
73
79
84
83
50
52
67
80
79
75
58
56
62
67
63
54
60
70
78
69


510(k) Average Days to MDUFA (SE/NSE) Decision at 99.16 % 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

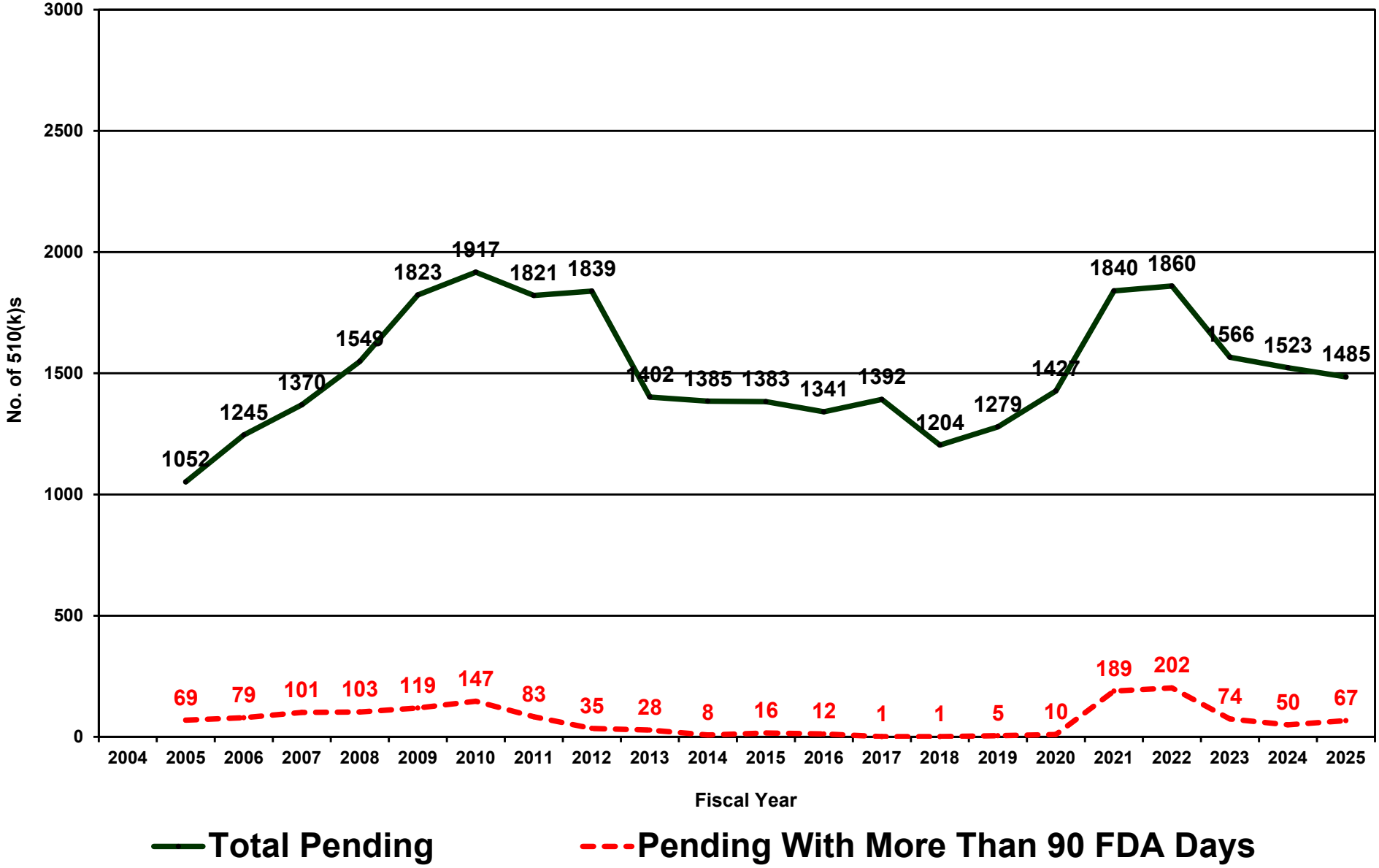

510(k) Average Days to MDUFA (SE/NSE) Decision at 72.56 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
FY of Receipt
81
87
100
114
113
110
104
104
109
117
111
102
104
109
118
116
113
115
57
58
64
68
67
65
66
68
69
70
68
67
68
68
75
74
70
70
25
29
36
46
46
45
38
36
40
47
42
35
36
41
43
42
43
46
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

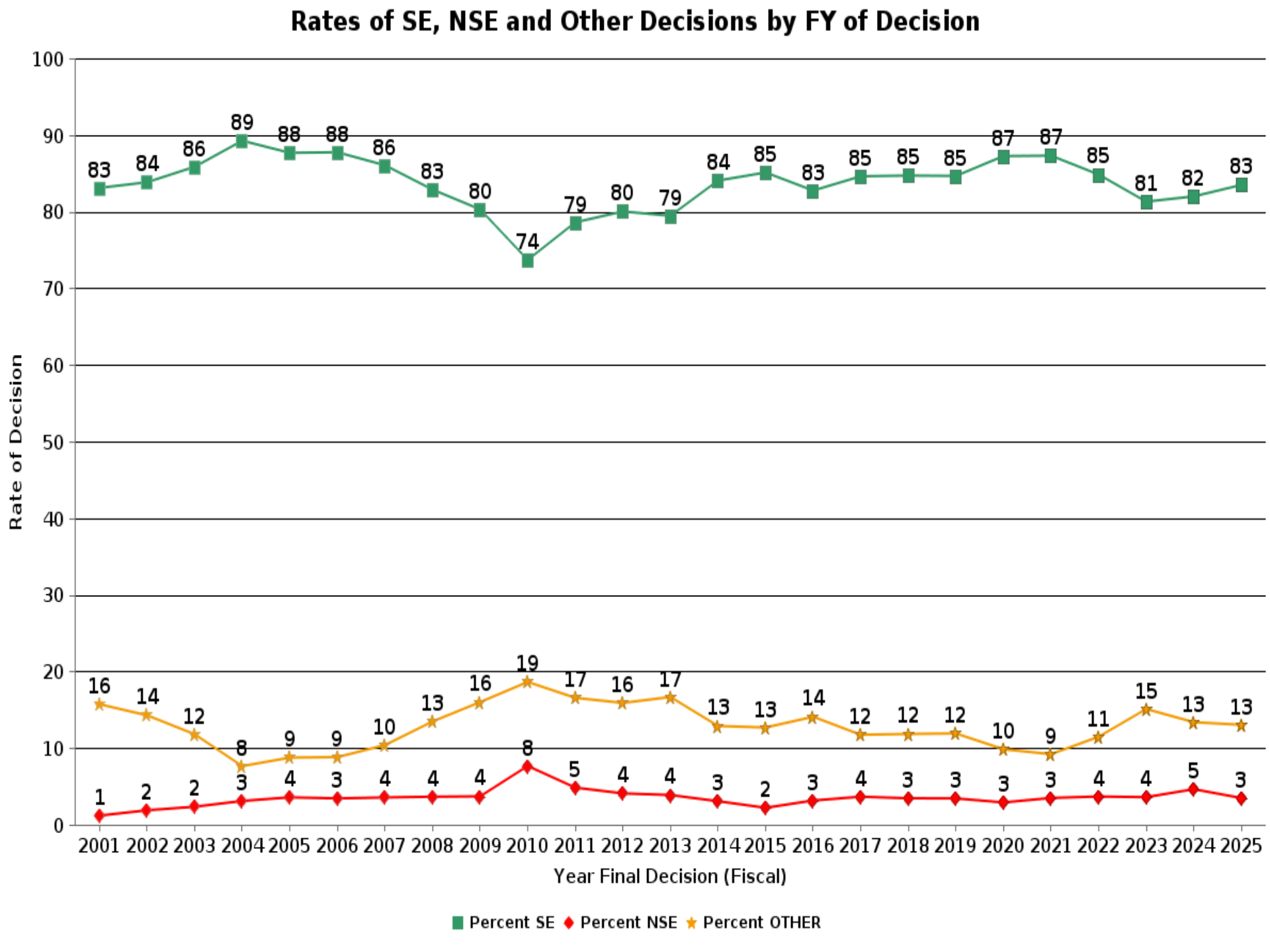
Comparison of FY18 – FY25 Receipt Cohorts



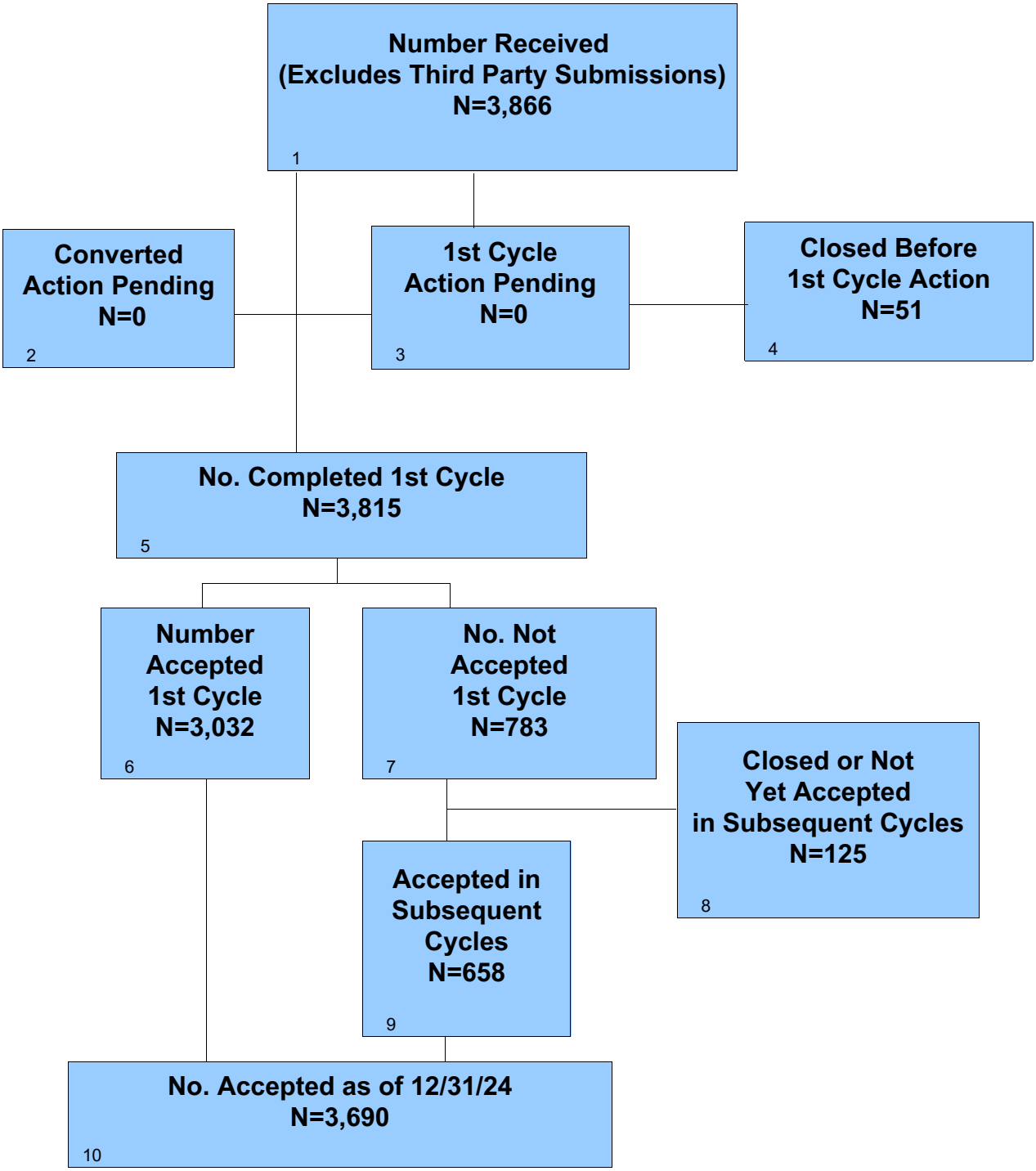
510(k)s Pending at End of Quarter/Year



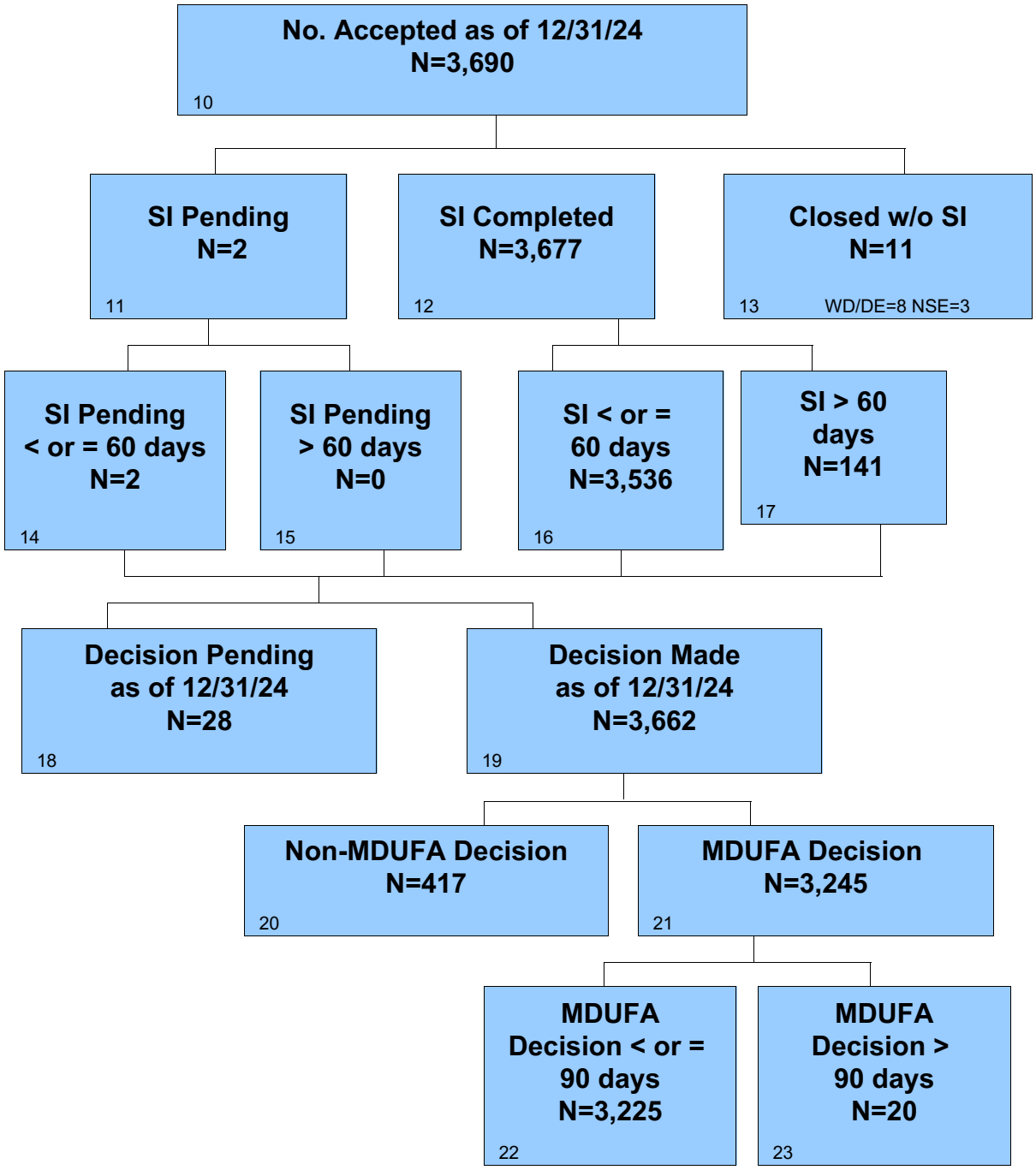
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


Rates of SE, NSE and Other Decisions by FY of Decision
Rate of Decision
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER
100
90
80
70
60
50
40
30
20
10
0
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
83 84 86 89 88 88 86 83 80 74 79 80 79 84 85 83 85 85 85 87 87 85 81 82 83
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15 13 13
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4 4 5 3

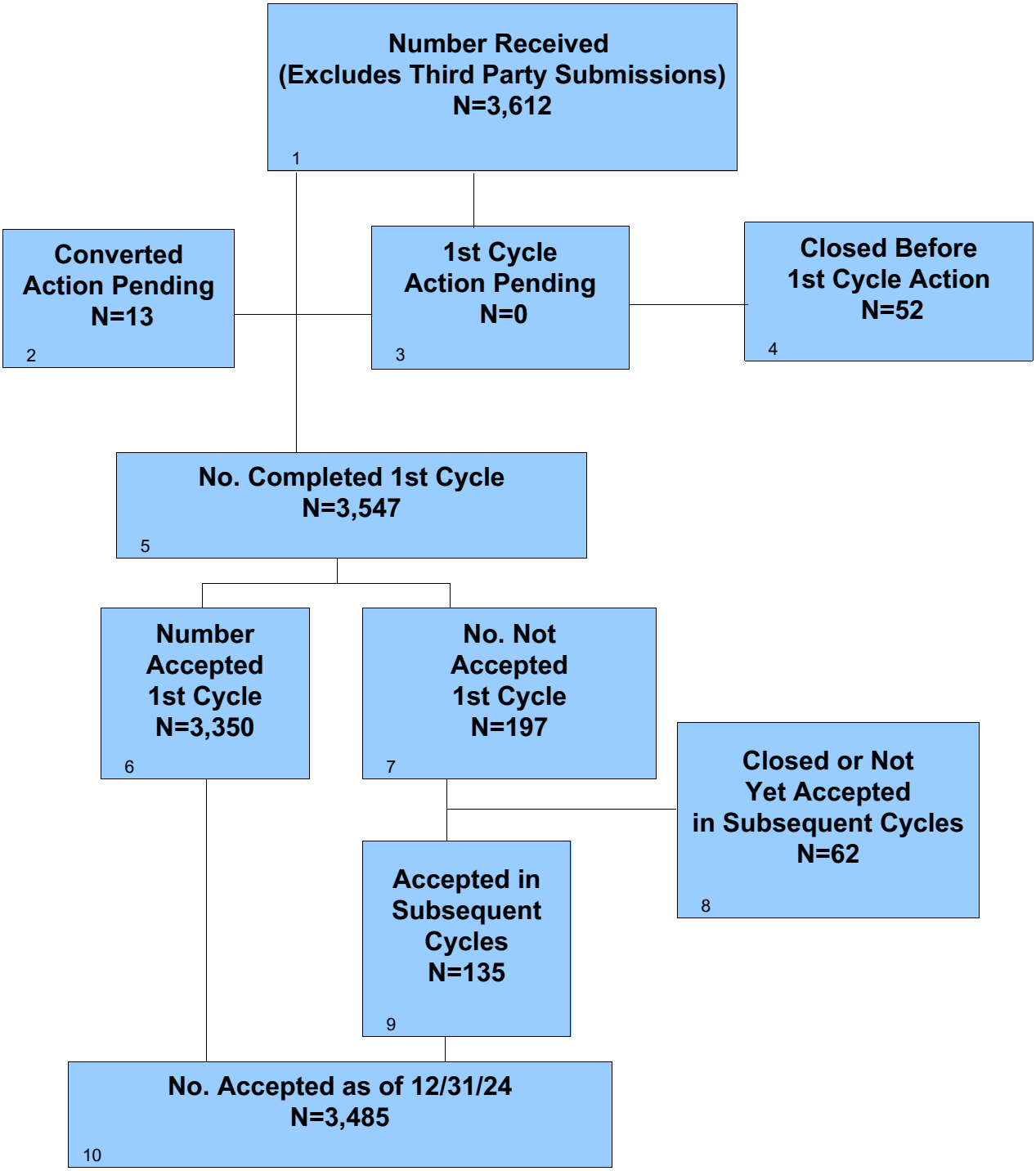
CDRH 510(k)s - FY 2023
as of 12/31/24



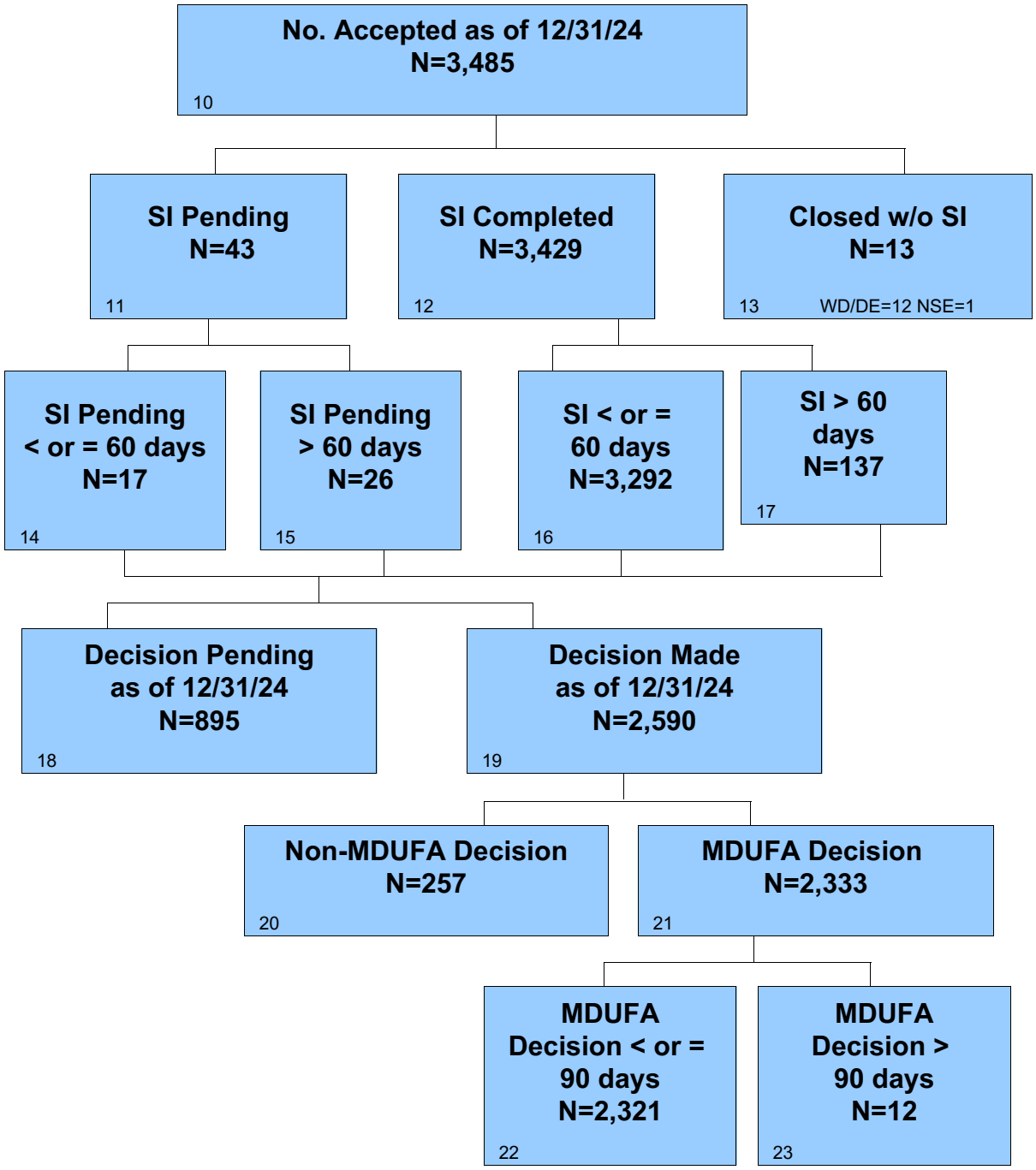
CDRH 510(k)s - FY 2023
as of 12/31/24 Continued



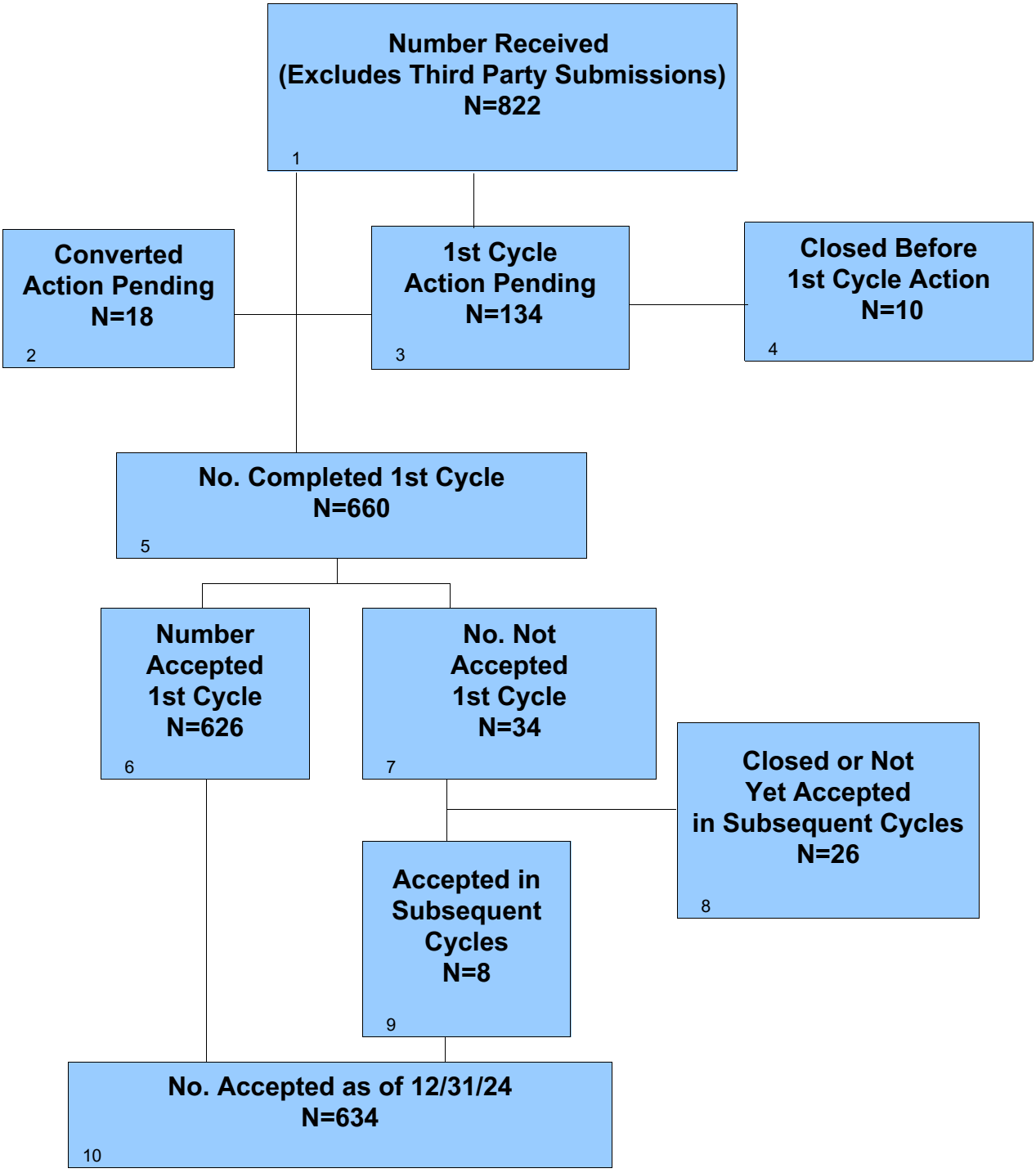
CDRH 510(k)s - FY 2024
as of 12/31/24



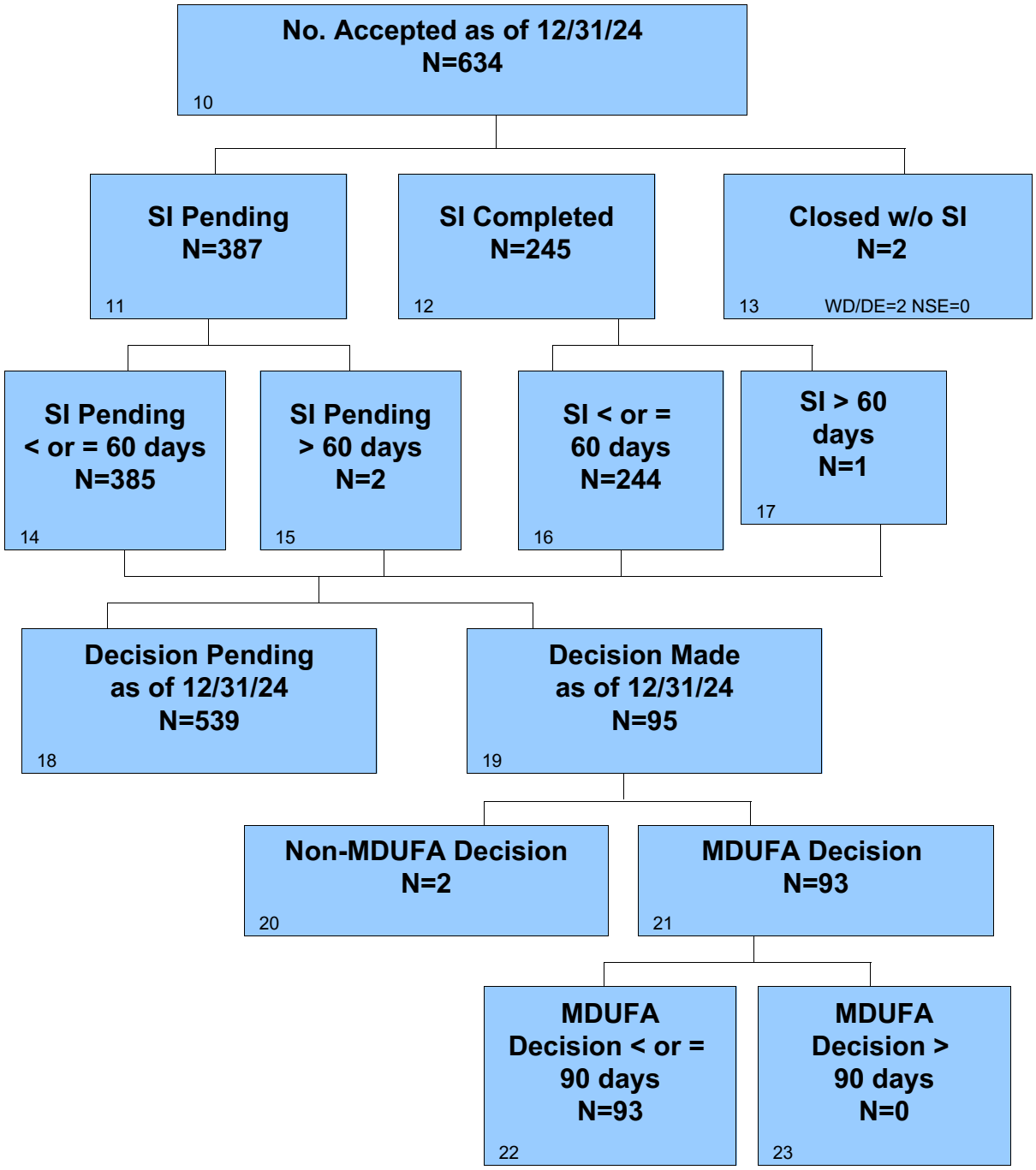
CDRH 510(k)s - FY 2024
as of 12/31/24 Continued



CDRH 510(k)s - FY 2025
as of 12/31/24



CDRH 510(k)s - FY 2025
as of 12/31/24 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	3,866	3,612	822		
Closed Before First RTA or TS Action [1]	51	52	10		
Number Accepted or Passed TS on First Cycle [2]	3,014	3,321	621		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	18	29	5		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	13	152		
Number Not Accepted or Failed TS on First Cycle [2]	783	197	34		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.52%	5.55%	5.15%		

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	3,690	3,485	634		
Deleted or Withdrawn Prior to SI	8	12	2		
SI Within 60 FDA Days	3,536	3,292	244		
SI Over 60 FDA Days	141	137	1		
SI Pending Within 60 FDA Days	2	17	385		
SI Pending Over 60 FDA Days	0	26	2		
510(k)s NSE Without SI	3	1	0		
Current SI Performance Percent Within 60 FDA Days	96.09%	95.25%	98.79%		

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	3,677	3,429	245		
Average Number of FDA Days to Substantive Interaction	52.72	52.46	43.59		
20th Percentile FDA Days to Substantive Interaction	48	48	27		
40th Percentile FDA Days to Substantive Interaction	57	57	42		
60th Percentile FDA Days to Substantive Interaction	59	59	54		
80th Percentile FDA Days to Substantive Interaction	60	60	59		
Maximum FDA Days to Substantive Interaction	212	95	62		

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	3,690	3,485	634		
Non-MDUFA V Decision	417	257	2		
MDUFA V Decision (SE/NSE)	3,245	2,333	93		
MDUFA V Decision Within 90 FDA Days	3,225	2,321	93		
510(k)s Pending MDUFA V Decision	28	895	539		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	9	50	0		
Current Performance Percent Within 90 FDA Days	99.11%	97.40%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.57	1.01		
Number With MDUFA V Decision	3,245	2,333	93		
Average Number of FDA Days to MDUFA V Decision	74.79	70.96	31.56		
20th Percentile FDA Days to MDUFA V Decision	57	49	23		
40th Percentile FDA Days to MDUFA V Decision	84	79	26		
60th Percentile FDA Days to MDUFA V Decision	88	87	29		
80th Percentile FDA Days to MDUFA V Decision	90	89	41		
Maximum FDA Days to MDUFA V Decision	276	120	85		
Average Number of Industry Days to MDUFA V Decision	66.18	46.36	0.04		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	14	0	0		
60th Percentile Industry Days to MDUFA V Decision	69	35	0		
80th Percentile Industry Days to MDUFA V Decision	151	104	0		
Maximum Industry Days to MDUFA V Decision	367	324	4		
Average Number of Total Days to MDUFA V Decision	140.79	117.18	31.60		
20th Percentile Total Days to MDUFA V Decision	59	53	23		
40th Percentile Total Days to MDUFA V Decision	97	88	26		
60th Percentile Total Days to MDUFA V Decision	154	119	29		
80th Percentile Total Days to MDUFA V Decision	237	187	41		
Maximum Total Days to MDUFA V Decision	517	413	85		

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	3,690	3,485	634		
Number With MDUFA V Decision	3,245	2,333	93		
Number of SE Decision	3,103	2,251	93		
Number of NSE Decision	142	82	0		
Number of Withdrawal	222	145	2		
Number of Deleted	187	105	0		
Rate of SE Decision	95.62%	96.49%	100.00%		
Rate of NSE Decision	4.38%	3.51%	0.00%		
Rate of Withdrawal	6.02%	4.16%	0.32%		
Rate of Deleted	5.07%	3.01%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	20	12	0		
Mean FDA Days for Submissions that Missed the Goal	124.45	98.25	N/A		
Mean Industry Days for Submissions that Missed the Goal	129.15	95.25	N/A		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	2	0		
MDUFA V Decision Within 90 FDA Days	2	2	0		
510(k)s Pending MDUFA V Decision	0	2	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	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	269	231	57		
Non-MDUFA V Decision	51	29	0		
MDUFA V Decision (SE/NSE)	217	138	10		
MDUFA V Decision Within 90 FDA Days	217	138	10		
510(k)s Pending MDUFA V Decision	1	64	47		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	580	546	110		
Closed Before First RTA or TS Action [1]	8	8	0		
Number Accepted or Passed TS on First Cycle [2]	315	476	83		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	4	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	2	24		
Number Not Accepted or Failed TS on First Cycle [2]	254	56	3		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.41%	10.45%	3.49%		

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	534	521	83		
Deleted or Withdrawn Prior to SI	2	2	1		
SI Within 60 FDA Days	425	427	22		
SI Over 60 FDA Days	105	83	0		
SI Pending Within 60 FDA Days	1	3	60		
SI Pending Over 60 FDA Days	0	6	0		
510(k)s NSE Without SI	1	0	0		
Current SI Performance Percent Within 60 FDA Days	80.04%	82.75%	100.00%		

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	530	510	22		
Average Number of FDA Days to Substantive Interaction	56.95	55.80	51.55		
20th Percentile FDA Days to Substantive Interaction	55	53	48		
40th Percentile FDA Days to Substantive Interaction	58	58	53		
60th Percentile FDA Days to Substantive Interaction	60	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	212	80	60		

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	534	521	83		
Non-MDUFA V Decision	80	40	1		
MDUFA V Decision (SE/NSE)	444	320	4		
MDUFA V Decision Within 90 FDA Days	435	316	4		
510(k)s Pending MDUFA V Decision	10	161	78		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	10	0		
Current Performance Percent Within 90 FDA Days	97.32%	95.76%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.76	1.67	1.25		
Number With MDUFA V Decision	444	320	4		
Average Number of FDA Days to MDUFA V Decision	82.87	80.35	37.25		
20th Percentile FDA Days to MDUFA V Decision	82	78	21		
40th Percentile FDA Days to MDUFA V Decision	88	87	32		
60th Percentile FDA Days to MDUFA V Decision	89	89	46		
80th Percentile FDA Days to MDUFA V Decision	90	90	54		
Maximum FDA Days to MDUFA V Decision	276	120	60		
Average Number of Industry Days to MDUFA V Decision	76.28	63.15	1.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	38	14	0		
60th Percentile Industry Days to MDUFA V Decision	86	65	0		
80th Percentile Industry Days to MDUFA V Decision	161	144	2		
Maximum Industry Days to MDUFA V Decision	353	324	4		
Average Number of Total Days to MDUFA V Decision	158.87	143.18	38.25		
20th Percentile Total Days to MDUFA V Decision	87	84	23		
40th Percentile Total Days to MDUFA V Decision	126	100	32		
60th Percentile Total Days to MDUFA V Decision	177	152	46		
80th Percentile Total Days to MDUFA V Decision	251	231	54		
Maximum Total Days to MDUFA V Decision	443	413	60		

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	534	521	83		
Number With MDUFA V Decision	444	320	4		
Number of SE Decision	409	303	4		
Number of NSE Decision	35	17	0		
Number of Withdrawal	40	19	1		
Number of Deleted	39	20	0		
Rate of SE Decision	92.12%	94.69%	100.00%		
Rate of NSE Decision	7.88%	5.31%	0.00%		
Rate of Withdrawal	7.49%	3.65%	1.20%		
Rate of Deleted	7.30%	3.84%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	9	4	0		
Mean FDA Days for Submissions that Missed the Goal	148.78	102.50	N/A		
Mean Industry Days for Submissions that Missed the Goal	120.78	119.25	N/A		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	380	384	61		
Closed Before First RTA or TS Action [1]	8	5	2		
Number Accepted or Passed TS on First Cycle [2]	333	360	41		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	6	1		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	1	10		
Number Not Accepted or Failed TS on First Cycle [2]	38	12	7		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.22%	3.17%	14.29%		

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	366	376	44		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	356	344	14		
SI Over 60 FDA Days	10	21	1		
SI Pending Within 60 FDA Days	0	4	29		
SI Pending Over 60 FDA Days	0	7	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	97.27%	92.47%	93.33%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	366	365	15		
Average Number of FDA Days to Substantive Interaction	51.42	51.05	44.80		
20th Percentile FDA Days to Substantive Interaction	44	30	28		
40th Percentile FDA Days to Substantive Interaction	56	56	38		
60th Percentile FDA Days to Substantive Interaction	59	59	56		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	86	85	62		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	366	376	44		
Non-MDUFA V Decision	34	27	0		
MDUFA V Decision (SE/NSE)	331	244	6		
MDUFA V Decision Within 90 FDA Days	327	242	6		
510(k)s Pending MDUFA V Decision	1	105	38		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	9	0		
Current Performance Percent Within 90 FDA Days	98.49%	95.65%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.66	1.00		
Number With MDUFA V Decision	331	244	6		
Average Number of FDA Days to MDUFA V Decision	73.39	68.09	44.00		
20th Percentile FDA Days to MDUFA V Decision	55	37	28		
40th Percentile FDA Days to MDUFA V Decision	84	60	30		
60th Percentile FDA Days to MDUFA V Decision	88	88	30		
80th Percentile FDA Days to MDUFA V Decision	90	89	64		
Maximum FDA Days to MDUFA V Decision	95	103	85		
Average Number of Industry Days to MDUFA V Decision	71.88	54.45	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	27	6	0		
60th Percentile Industry Days to MDUFA V Decision	78	49	0		
80th Percentile Industry Days to MDUFA V Decision	155	116	0		
Maximum Industry Days to MDUFA V Decision	360	234	0		
Average Number of Total Days to MDUFA V Decision	145.14	122.32	44.00		
20th Percentile Total Days to MDUFA V Decision	57	42	28		
40th Percentile Total Days to MDUFA V Decision	107	88	30		
60th Percentile Total Days to MDUFA V Decision	162	129	30		
80th Percentile Total Days to MDUFA V Decision	238	205	64		
Maximum Total Days to MDUFA V Decision	448	300	85		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	366	376	44		
Number With MDUFA V Decision	331	244	6		
Number of SE Decision	308	230	6		
Number of NSE Decision	23	14	0		
Number of Withdrawal	17	17	0		
Number of Deleted	17	8	0		
Rate of SE Decision	93.05%	94.26%	100.00%		
Rate of NSE Decision	6.95%	5.74%	0.00%		
Rate of Withdrawal	4.64%	4.52%	0.00%		
Rate of Deleted	4.64%	2.13%	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	2	0		
Mean FDA Days for Submissions that Missed the Goal	92.75	101.50	N/A		
Mean Industry Days for Submissions that Missed the Goal	82.50	87.50	N/A		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	480	460	107		
Closed Before First RTA or TS Action [1]	5	11	0		
Number Accepted or Passed TS on First Cycle [2]	391	429	87		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	2	1		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	1	16		
Number Not Accepted or Failed TS on First Cycle [2]	82	17	3		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	17.26%	3.79%	3.30%		

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	462	441	90		
Deleted or Withdrawn Prior to SI	1	0	0		
SI Within 60 FDA Days	451	434	40		
SI Over 60 FDA Days	10	0	0		
SI Pending Within 60 FDA Days	0	2	50		
SI Pending Over 60 FDA Days	0	5	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	97.83%	98.86%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	461	434	40		
Average Number of FDA Days to Substantive Interaction	54.95	53.07	47.13		
20th Percentile FDA Days to Substantive Interaction	55	49	29		
40th Percentile FDA Days to Substantive Interaction	58	57	51		
60th Percentile FDA Days to Substantive Interaction	59	59	56		
80th Percentile FDA Days to Substantive Interaction	60	60	59		
Maximum FDA Days to Substantive Interaction	77	60	60		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	462	441	90		
Non-MDUFA V Decision	53	39	0		
MDUFA V Decision (SE/NSE)	404	256	11		
MDUFA V Decision Within 90 FDA Days	403	255	11		
510(k)s Pending MDUFA V Decision	5	146	79		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	13	0		
Current Performance Percent Within 90 FDA Days	99.02%	94.80%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.78	1.68	1.00		
Number With MDUFA V Decision	404	256	11		
Average Number of FDA Days to MDUFA V Decision	79.91	71.86	32.45		
20th Percentile FDA Days to MDUFA V Decision	79	50	25		
40th Percentile FDA Days to MDUFA V Decision	88	83	28		
60th Percentile FDA Days to MDUFA V Decision	89	88	29		
80th Percentile FDA Days to MDUFA V Decision	90	90	38		
Maximum FDA Days to MDUFA V Decision	93	91	54		
Average Number of Industry Days to MDUFA V Decision	85.63	55.45	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	47	13	0		
60th Percentile Industry Days to MDUFA V Decision	106	57	0		
80th Percentile Industry Days to MDUFA V Decision	172	120	0		
Maximum Industry Days to MDUFA V Decision	354	216	0		
Average Number of Total Days to MDUFA V Decision	165.06	127.16	32.45		
20th Percentile Total Days to MDUFA V Decision	87	51	25		
40th Percentile Total Days to MDUFA V Decision	132	95	28		
60th Percentile Total Days to MDUFA V Decision	193	140	29		
80th Percentile Total Days to MDUFA V Decision	260	208	38		
Maximum Total Days to MDUFA V Decision	443	306	54		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	462	441	90		
Number With MDUFA V Decision	404	256	11		
Number of SE Decision	379	243	11		
Number of NSE Decision	25	13	0		
Number of Withdrawal	23	21	0		
Number of Deleted	29	16	0		
Rate of SE Decision	93.81%	94.92%	100.00%		
Rate of NSE Decision	6.19%	5.08%	0.00%		
Rate of Withdrawal	4.98%	4.76%	0.00%		
Rate of Deleted	6.28%	3.63%	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	0		
Mean FDA Days for Submissions that Missed the Goal	93.00	91.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	192.00	42.00	N/A		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	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	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	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	710	629	117		
Closed Before First RTA or TS Action [1]	10	6	2		
Number Accepted or Passed TS on First Cycle [2]	560	571	83		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	12	2		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	4	24		
Number Not Accepted or Failed TS on First Cycle [2]	139	36	6		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	19.86%	5.82%	6.59%		

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	678	607	87		
Deleted or Withdrawn Prior to SI	1	5	0		
SI Within 60 FDA Days	672	580	31		
SI Over 60 FDA Days	5	12	0		
SI Pending Within 60 FDA Days	0	2	54		
SI Pending Over 60 FDA Days	0	7	2		
510(k)s NSE Without SI	0	1	0		
Current SI Performance Percent Within 60 FDA Days	99.26%	96.67%	93.94%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	677	592	31		
Average Number of FDA Days to Substantive Interaction	52.63	52.82	44.03		
20th Percentile FDA Days to Substantive Interaction	49	49	28		
40th Percentile FDA Days to Substantive Interaction	56	57	49		
60th Percentile FDA Days to Substantive Interaction	58	58	54		
80th Percentile FDA Days to Substantive Interaction	60	60	57		
Maximum FDA Days to Substantive Interaction	122	66	60		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	678	607	87		
Non-MDUFA V Decision	88	54	0		
MDUFA V Decision (SE/NSE)	585	418	13		
MDUFA V Decision Within 90 FDA Days	583	417	13		
510(k)s Pending MDUFA V Decision	5	135	74		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2	14	0		
Current Performance Percent Within 90 FDA Days	99.32%	96.53%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.62	1.48	1.00		
Number With MDUFA V Decision	585	418	13		
Average Number of FDA Days to MDUFA V Decision	75.07	71.40	33.15		
20th Percentile FDA Days to MDUFA V Decision	58	52	25		
40th Percentile FDA Days to MDUFA V Decision	83	80	27		
60th Percentile FDA Days to MDUFA V Decision	87	87	29		
80th Percentile FDA Days to MDUFA V Decision	89	90	43		
Maximum FDA Days to MDUFA V Decision	101	92	78		
Average Number of Industry Days to MDUFA V Decision	55.63	34.63	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	45	17	0		
80th Percentile Industry Days to MDUFA V Decision	122	69	0		
Maximum Industry Days to MDUFA V Decision	359	180	0		
Average Number of Total Days to MDUFA V Decision	130.80	105.91	33.15		
20th Percentile Total Days to MDUFA V Decision	60	55	25		
40th Percentile Total Days to MDUFA V Decision	88	86	27		
60th Percentile Total Days to MDUFA V Decision	127	102	29		
80th Percentile Total Days to MDUFA V Decision	205	153	43		
Maximum Total Days to MDUFA V Decision	449	270	78		

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	678	607	87		
Number With MDUFA V Decision	585	418	13		
Number of SE Decision	569	414	13		
Number of NSE Decision	16	4	0		
Number of Withdrawal	52	30	0		
Number of Deleted	36	23	0		
Rate of SE Decision	97.26%	99.04%	100.00%		
Rate of NSE Decision	2.74%	0.96%	0.00%		
Rate of Withdrawal	7.67%	4.94%	0.00%		
Rate of Deleted	5.31%	3.79%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	1	0		
Mean FDA Days for Submissions that Missed the Goal	96.50	92.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	59.50	0.00	N/A		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	314	307	87		
Closed Before First RTA or TS Action [1]	3	3	1		
Number Accepted or Passed TS on First Cycle [2]	214	276	65		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	1	1		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	14		
Number Not Accepted or Failed TS on First Cycle [2]	96	27	6		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	30.87%	8.88%	8.33%		

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

Table 6.2 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	298	299	67		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	286	277	21		
SI Over 60 FDA Days	11	19	0		
SI Pending Within 60 FDA Days	1	2	46		
SI Pending Over 60 FDA Days	0	1	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	96.30%	93.27%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	297	296	21		
Average Number of FDA Days to Substantive Interaction	54.65	54.85	44.00		
20th Percentile FDA Days to Substantive Interaction	56	53	29		
40th Percentile FDA Days to Substantive Interaction	58	57	39		
60th Percentile FDA Days to Substantive Interaction	60	59	52		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	80	95	60		

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	298	299	67		
Non-MDUFA V Decision	29	19	0		
MDUFA V Decision (SE/NSE)	263	202	7		
MDUFA V Decision Within 90 FDA Days	259	198	7		
510(k)s Pending MDUFA V Decision	6	78	60		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	2	0		
Current Performance Percent Within 90 FDA Days	98.48%	97.06%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.75	1.69	1.00		
Number With MDUFA V Decision	263	202	7		
Average Number of FDA Days to MDUFA V Decision	77.86	75.72	32.86		
20th Percentile FDA Days to MDUFA V Decision	59	57	29		
40th Percentile FDA Days to MDUFA V Decision	87	84	29		
60th Percentile FDA Days to MDUFA V Decision	89	88	30		
80th Percentile FDA Days to MDUFA V Decision	90	90	40		
Maximum FDA Days to MDUFA V Decision	150	101	44		
Average Number of Industry Days to MDUFA V Decision	76.83	57.41	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	35	20	0		
60th Percentile Industry Days to MDUFA V Decision	90	63	0		
80th Percentile Industry Days to MDUFA V Decision	168	119	0		
Maximum Industry Days to MDUFA V Decision	367	212	0		
Average Number of Total Days to MDUFA V Decision	154.24	133.28	32.86		
20th Percentile Total Days to MDUFA V Decision	61	60	29		
40th Percentile Total Days to MDUFA V Decision	118	101	29		
60th Percentile Total Days to MDUFA V Decision	175	148	30		
80th Percentile Total Days to MDUFA V Decision	254	209	40		
Maximum Total Days to MDUFA V Decision	517	280	44		

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	298	299	67		
Number With MDUFA V Decision	263	202	7		
Number of SE Decision	245	185	7		
Number of NSE Decision	18	17	0		
Number of Withdrawal	9	7	0		
Number of Deleted	17	11	0		
Rate of SE Decision	93.16%	91.58%	100.00%		
Rate of NSE Decision	6.84%	8.42%	0.00%		
Rate of Withdrawal	3.02%	2.34%	0.00%		
Rate of Deleted	5.70%	3.68%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	4	0		
Mean FDA Days for Submissions that Missed the Goal	123.25	95.75	N/A		
Mean Industry Days for Submissions that Missed the Goal	213.75	112.25	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	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	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	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	619	565	148		
Closed Before First RTA or TS Action [1]	6	4	3		
Number Accepted or Passed TS on First Cycle [2]	517	535	114		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	2	27		
Number Not Accepted or Failed TS on First Cycle [2]	93	24	4		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.17%	4.29%	3.39%		

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	605	550	114		
Deleted or Withdrawn Prior to SI	1	2	1		
SI Within 60 FDA Days	604	546	49		
SI Over 60 FDA Days	0	0	0		
SI Pending Within 60 FDA Days	0	2	64		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	604	546	49		
Average Number of FDA Days to Substantive Interaction	49.84	49.99	36.20		
20th Percentile FDA Days to Substantive Interaction	30	30	24		
40th Percentile FDA Days to Substantive Interaction	56	56	28		
60th Percentile FDA Days to Substantive Interaction	58	58	41		
80th Percentile FDA Days to Substantive Interaction	60	60	56		
Maximum FDA Days to Substantive Interaction	60	60	60		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	605	550	114		
Non-MDUFA V Decision	51	27	1		
MDUFA V Decision (SE/NSE)	554	429	35		
MDUFA V Decision Within 90 FDA Days	554	429	35		
510(k)s Pending MDUFA V Decision	0	94	78		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48	1.38	1.00		
Number With MDUFA V Decision	554	429	35		
Average Number of FDA Days to MDUFA V Decision	65.77	62.40	29.97		
20th Percentile FDA Days to MDUFA V Decision	30	29	20		
40th Percentile FDA Days to MDUFA V Decision	59	58	25		
60th Percentile FDA Days to MDUFA V Decision	85	82	29		
80th Percentile FDA Days to MDUFA V Decision	89	88	32		
Maximum FDA Days to MDUFA V Decision	90	90	77		
Average Number of Industry Days to MDUFA V Decision	42.92	27.43	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	18	0	0		
80th Percentile Industry Days to MDUFA V Decision	92	45	0		
Maximum Industry Days to MDUFA V Decision	354	247	0		
Average Number of Total Days to MDUFA V Decision	108.59	89.78	29.97		
20th Percentile Total Days to MDUFA V Decision	30	29	20		
40th Percentile Total Days to MDUFA V Decision	60	58	25		
60th Percentile Total Days to MDUFA V Decision	98	88	29		
80th Percentile Total Days to MDUFA V Decision	179	130	32		
Maximum Total Days to MDUFA V Decision	443	393	77		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	605	550	114		
Number With MDUFA V Decision	554	429	35		
Number of SE Decision	544	427	35		
Number of NSE Decision	10	2	0		
Number of Withdrawal	37	19	1		
Number of Deleted	12	8	0		
Rate of SE Decision	98.19%	99.53%	100.00%		
Rate of NSE Decision	1.81%	0.47%	0.00%		
Rate of Withdrawal	6.12%	3.45%	0.88%		
Rate of Deleted	1.98%	1.45%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	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	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	295	258	79		
Closed Before First RTA or TS Action [1]	7	13	1		
Number Accepted or Passed TS on First Cycle [2]	243	226	57		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	5	4	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	2	19		
Number Not Accepted or Failed TS on First Cycle [2]	40	13	2		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.89%	5.35%	3.39%		

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	271	235	57		
Deleted or Withdrawn Prior to SI	3	0	0		
SI Within 60 FDA Days	266	234	28		
SI Over 60 FDA Days	0	1	0		
SI Pending Within 60 FDA Days	0	0	29		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	2	0	0		
Current SI Performance Percent Within 60 FDA Days	99.25%	99.57%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	266	235	28		
Average Number of FDA Days to Substantive Interaction	52.54	51.03	42.36		
20th Percentile FDA Days to Substantive Interaction	47	42	27		
40th Percentile FDA Days to Substantive Interaction	56	55	42		
60th Percentile FDA Days to Substantive Interaction	58	58	50		
80th Percentile FDA Days to Substantive Interaction	60	60	57		
Maximum FDA Days to Substantive Interaction	60	81	60		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	271	235	57		
Non-MDUFA V Decision	51	29	0		
MDUFA V Decision (SE/NSE)	219	140	10		
MDUFA V Decision Within 90 FDA Days	219	140	10		
510(k)s Pending MDUFA V Decision	1	66	47		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.58	1.46	1.00		
Number With MDUFA V Decision	219	140	10		
Average Number of FDA Days to MDUFA V Decision	76.19	69.71	26.20		
20th Percentile FDA Days to MDUFA V Decision	59	35	19		
40th Percentile FDA Days to MDUFA V Decision	87	80	25		
60th Percentile FDA Days to MDUFA V Decision	89	88	27		
80th Percentile FDA Days to MDUFA V Decision	90	90	29		
Maximum FDA Days to MDUFA V Decision	90	90	49		
Average Number of Industry Days to MDUFA V Decision	80.56	49.51	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	117	30	0		
80th Percentile Industry Days to MDUFA V Decision	177	114	0		
Maximum Industry Days to MDUFA V Decision	361	227	0		
Average Number of Total Days to MDUFA V Decision	156.55	118.90	26.20		
20th Percentile Total Days to MDUFA V Decision	60	38	19		
40th Percentile Total Days to MDUFA V Decision	90	87	25		
60th Percentile Total Days to MDUFA V Decision	203	98	27		
80th Percentile Total Days to MDUFA V Decision	265	204	29		
Maximum Total Days to MDUFA V Decision	451	272	49		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	271	235	57		
Number With MDUFA V Decision	219	140	10		
Number of SE Decision	211	135	10		
Number of NSE Decision	8	5	0		
Number of Withdrawal	28	15	0		
Number of Deleted	23	14	0		
Rate of SE Decision	96.35%	96.43%	100.00%		
Rate of NSE Decision	3.65%	3.57%	0.00%		
Rate of Withdrawal	10.33%	6.38%	0.00%		
Rate of Deleted	8.49%	5.96%	0.00%		

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	2	0		
MDUFA V Decision Within 90 FDA Days	2	2	0		
510(k)s Pending MDUFA V Decision	0	2	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	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	269	231	57		
Non-MDUFA V Decision	51	29	0		
MDUFA V Decision (SE/NSE)	217	138	10		
MDUFA V Decision Within 90 FDA Days	217	138	10		
510(k)s Pending MDUFA V Decision	1	64	47		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	488	463	113		
Closed Before First RTA or TS Action [1]	4	2	1		
Number Accepted or Passed TS on First Cycle [2]	441	448	91		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	1	18		
Number Not Accepted or Failed TS on First Cycle [2]	41	12	3		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.47%	2.61%	3.19%		

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	456	92		
Deleted or Withdrawn Prior to SI	0	3	0		
SI Within 60 FDA Days	476	450	39		
SI Over 60 FDA Days	0	1	0		
SI Pending Within 60 FDA Days	0	2	53		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100.00%	99.78%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	476	451	39		
Average Number of FDA Days to Substantive Interaction	49.51	50.95	44.62		
20th Percentile FDA Days to Substantive Interaction	35	46	26		
40th Percentile FDA Days to Substantive Interaction	53	56	49		
60th Percentile FDA Days to Substantive Interaction	57	58	55		
80th Percentile FDA Days to Substantive Interaction	59	59	59		
Maximum FDA Days to Substantive Interaction	60	61	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	456	92		
Non-MDUFA V Decision	31	22	0		
MDUFA V Decision (SE/NSE)	445	324	7		
MDUFA V Decision Within 90 FDA Days	445	324	7		
510(k)s Pending MDUFA V Decision	0	110	85		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	2	0		
Current Performance Percent Within 90 FDA Days	100.00%	99.39%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.68	1.00		
Number With MDUFA V Decision	445	324	7		
Average Number of FDA Days to MDUFA V Decision	71.52	71.46	27.57		
20th Percentile FDA Days to MDUFA V Decision	52	47	21		
40th Percentile FDA Days to MDUFA V Decision	79	81	24		
60th Percentile FDA Days to MDUFA V Decision	86	87	26		
80th Percentile FDA Days to MDUFA V Decision	89	89	27		
Maximum FDA Days to MDUFA V Decision	90	90	51		
Average Number of Industry Days to MDUFA V Decision	63.68	48.47	N/A		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	24	18	0		
60th Percentile Industry Days to MDUFA V Decision	62	42	0		
80th Percentile Industry Days to MDUFA V Decision	138	92	0		
Maximum Industry Days to MDUFA V Decision	210	181	0		
Average Number of Total Days to MDUFA V Decision	135.03	119.80	27.57		
20th Percentile Total Days to MDUFA V Decision	56	57	21		
40th Percentile Total Days to MDUFA V Decision	107	98	24		
60th Percentile Total Days to MDUFA V Decision	146	126	26		
80th Percentile Total Days to MDUFA V Decision	222	178	27		
Maximum Total Days to MDUFA V Decision	272	270	51		

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	456	92		
Number With MDUFA V Decision	445	324	7		
Number of SE Decision	438	314	7		
Number of NSE Decision	7	10	0		
Number of Withdrawal	16	17	0		
Number of Deleted	14	5	0		
Rate of SE Decision	98.43%	96.91%	100.00%		
Rate of NSE Decision	1.57%	3.09%	0.00%		
Rate of Withdrawal	3.36%	3.73%	0.00%		
Rate of Deleted	2.94%	1.10%	0.00%		

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

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

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

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

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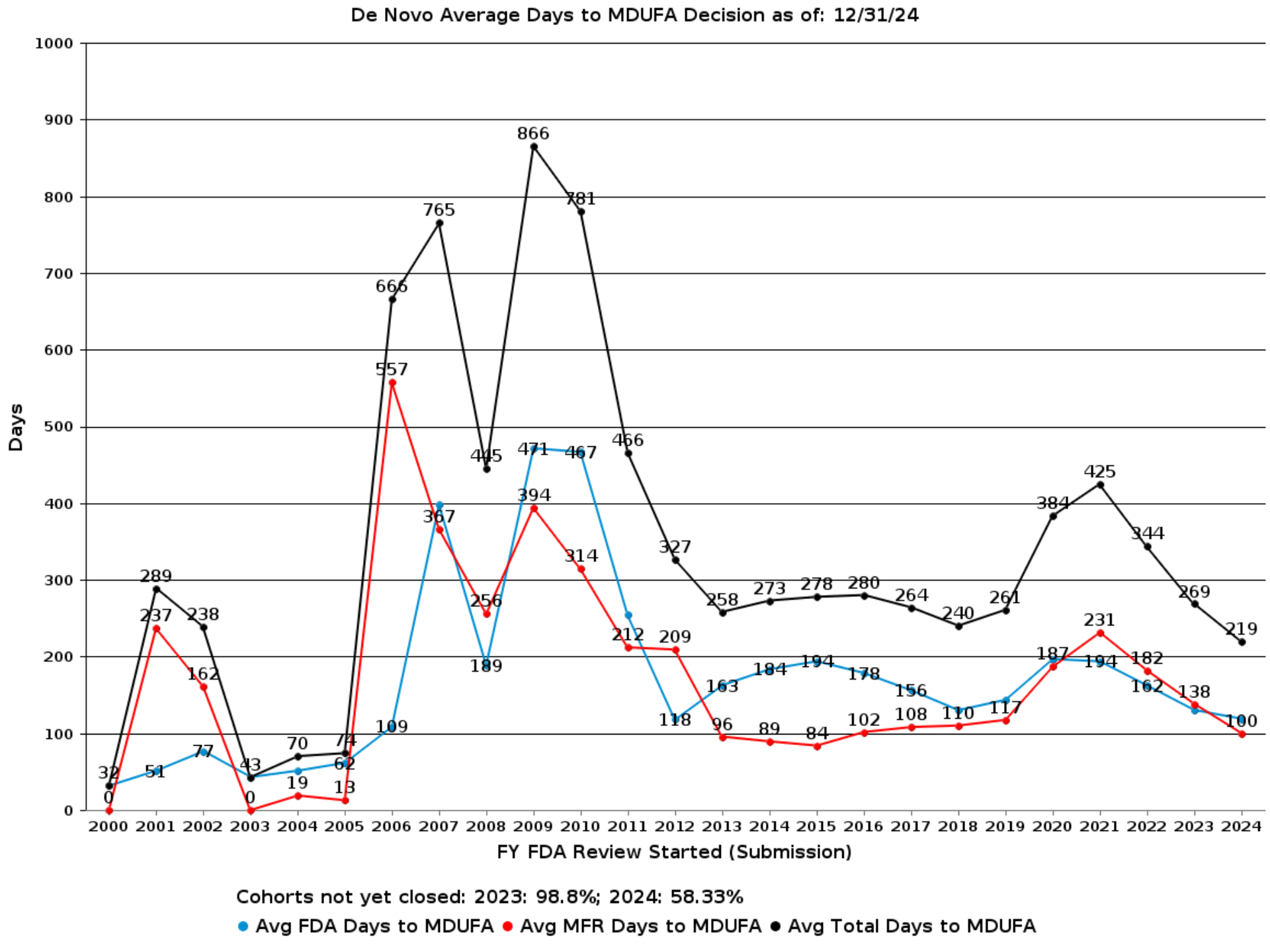
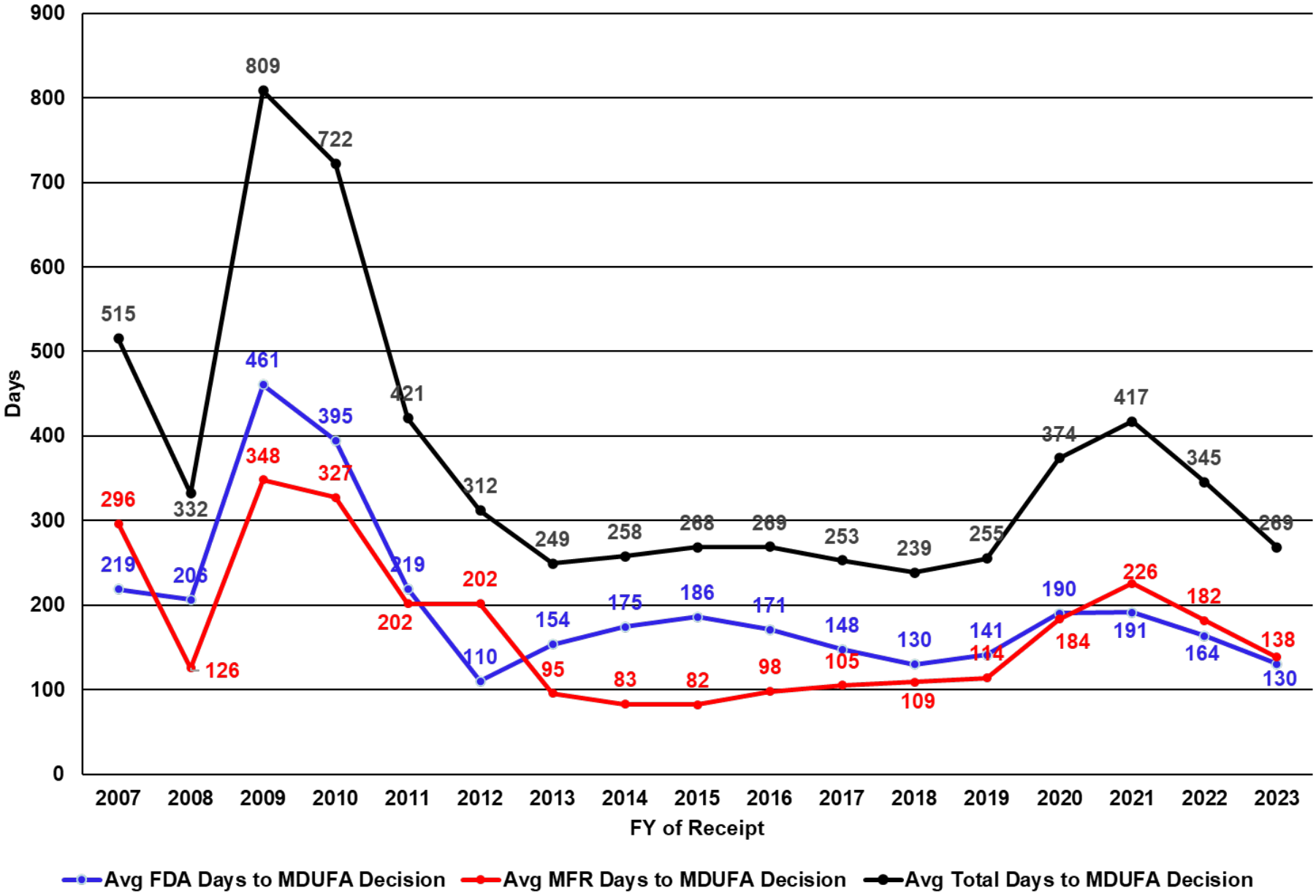

De Novo Average Days to MDUFA Decision as of: 12/31/24
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2023: 98.8%; 2024: 58.33%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

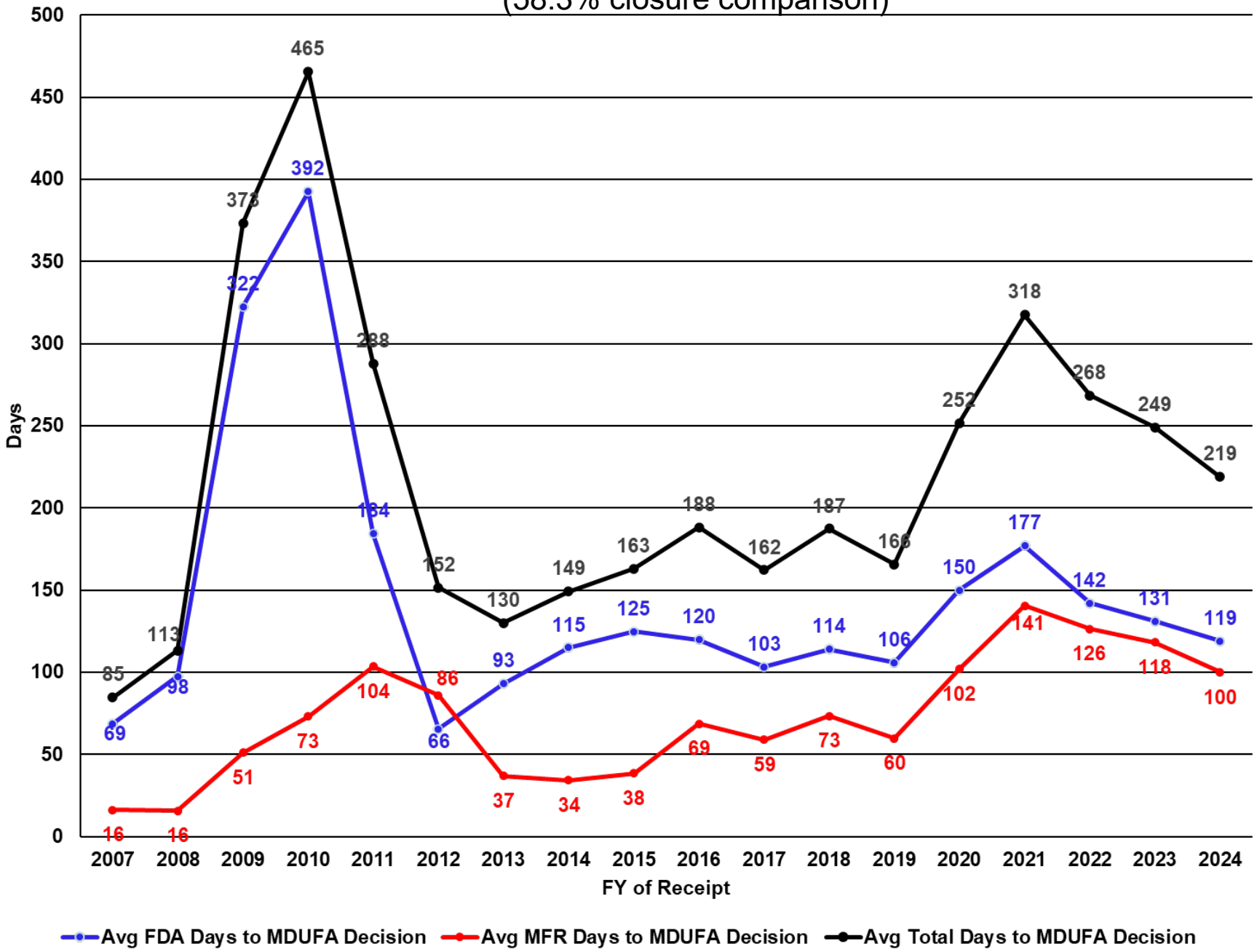
Average Time to MDUFA Decision: De Novos

(98.8% closure comparison)

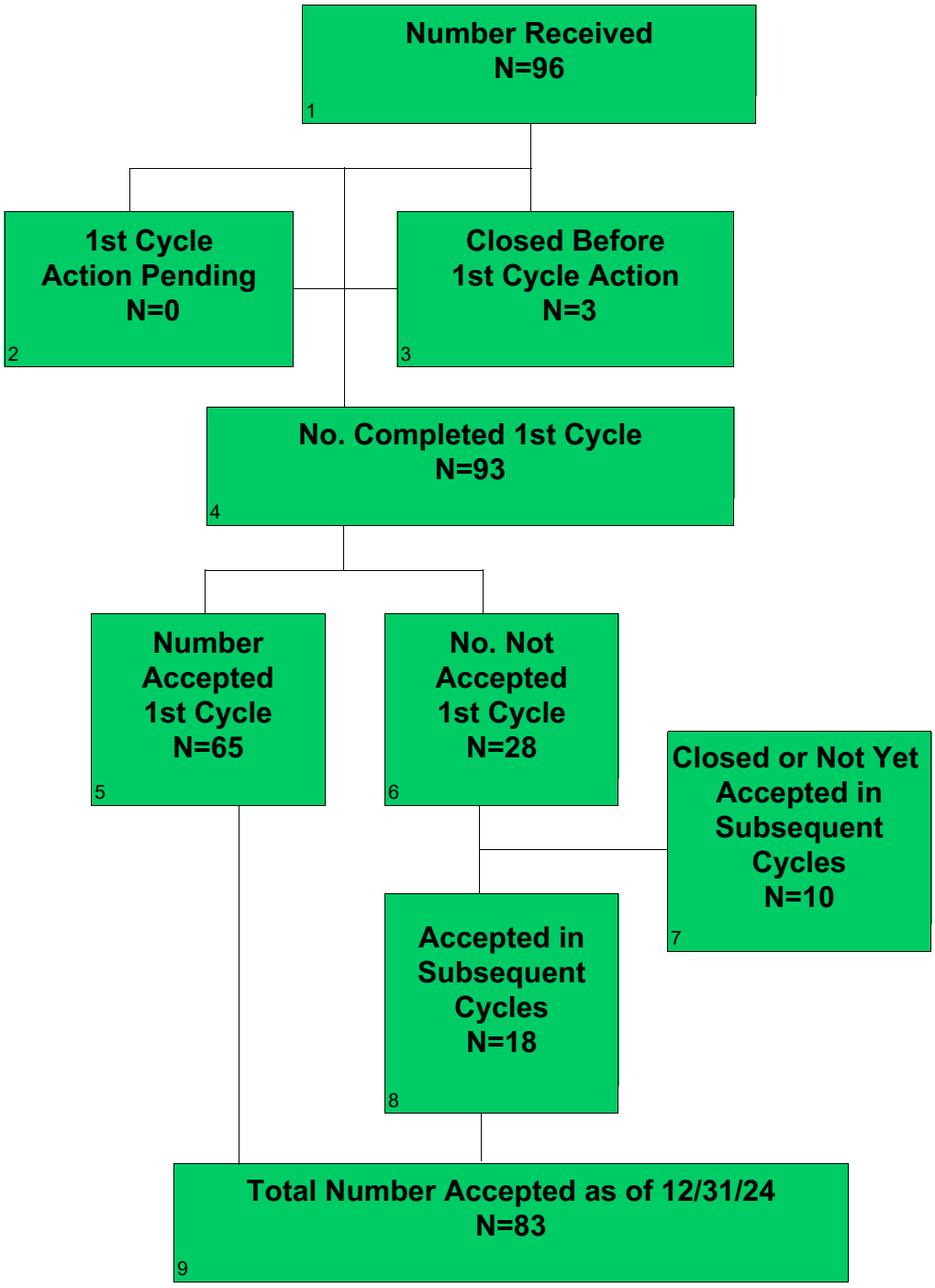


Average Time to MDUFA Decision: De Novos

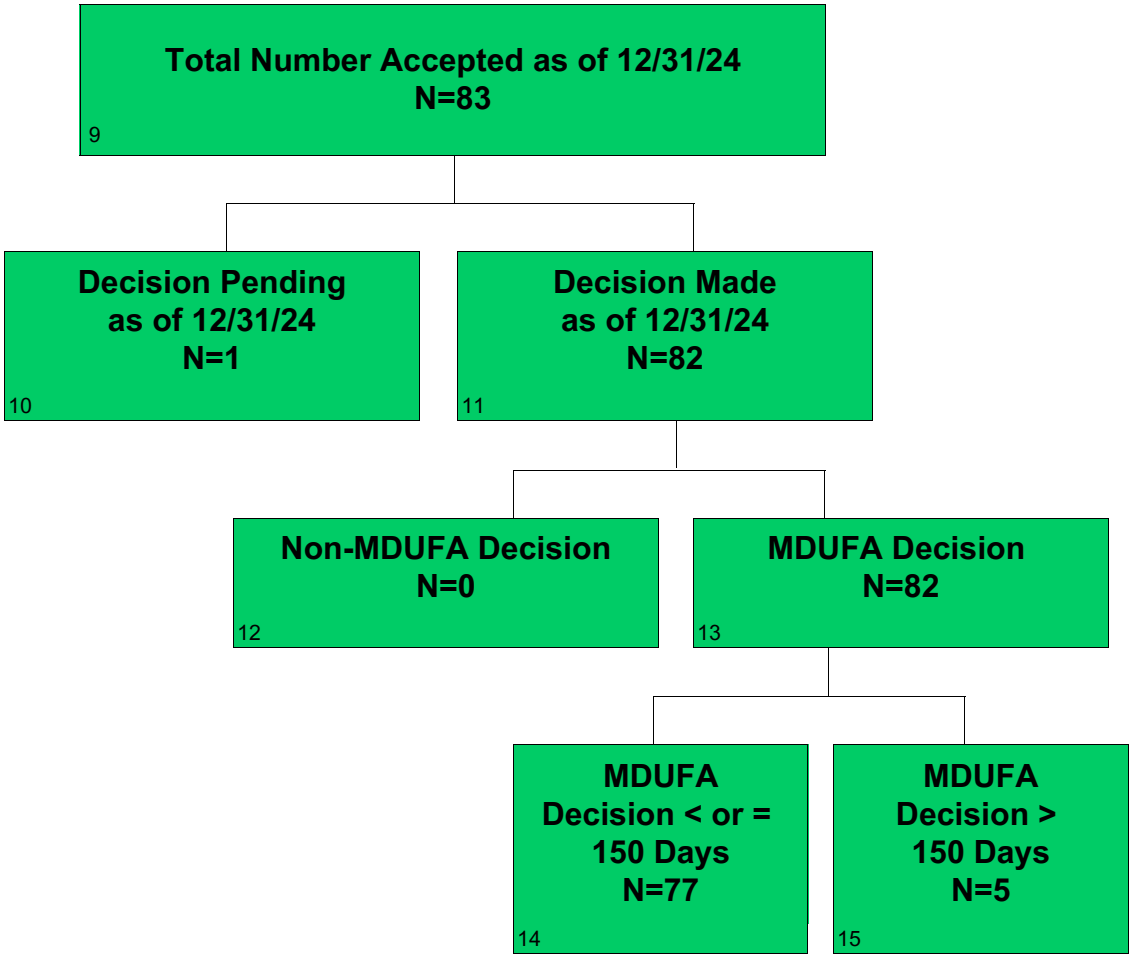
(58.3% closure comparison)



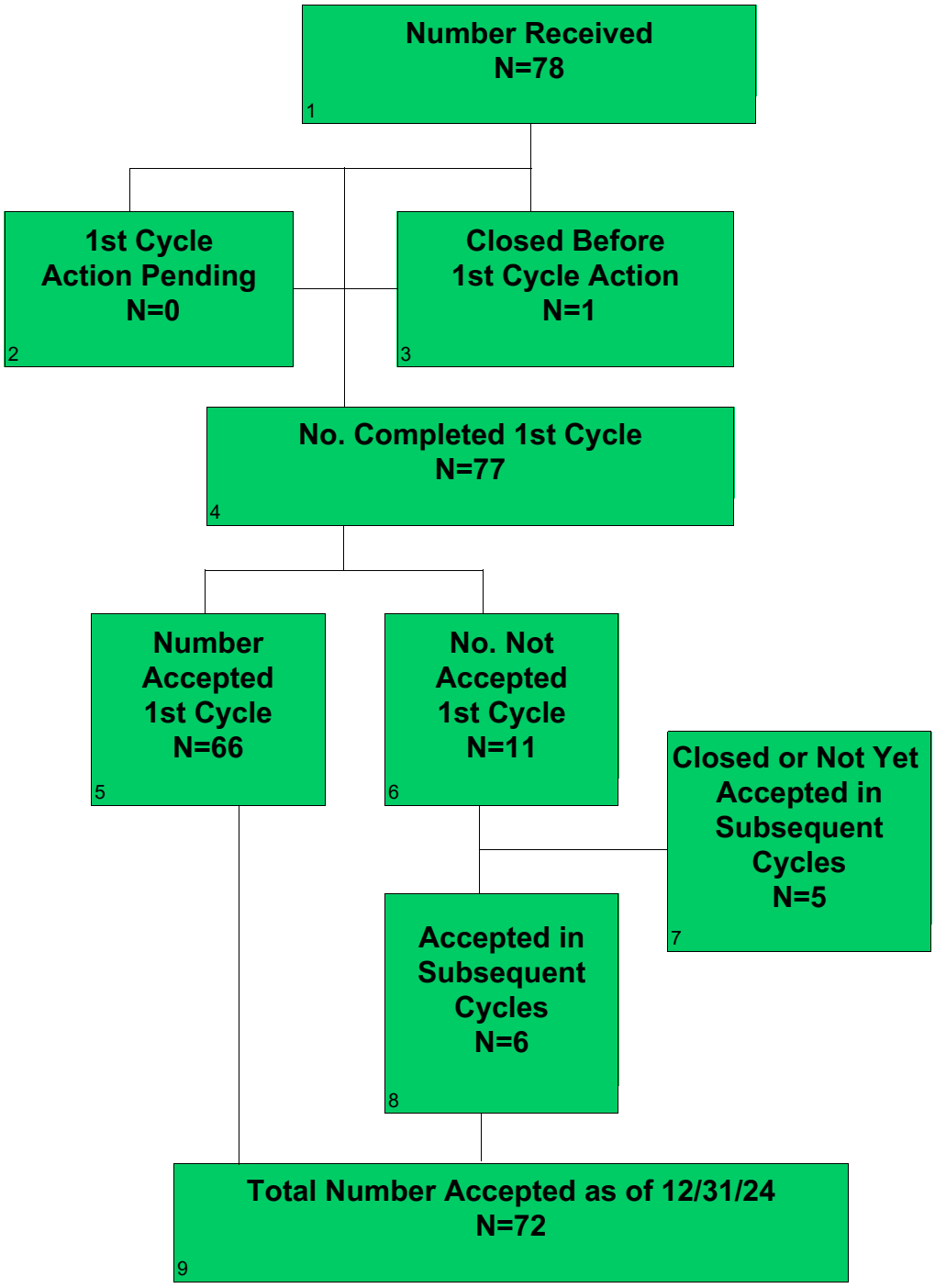
CDRH De Novo - FY 2023
as of 12/31/24



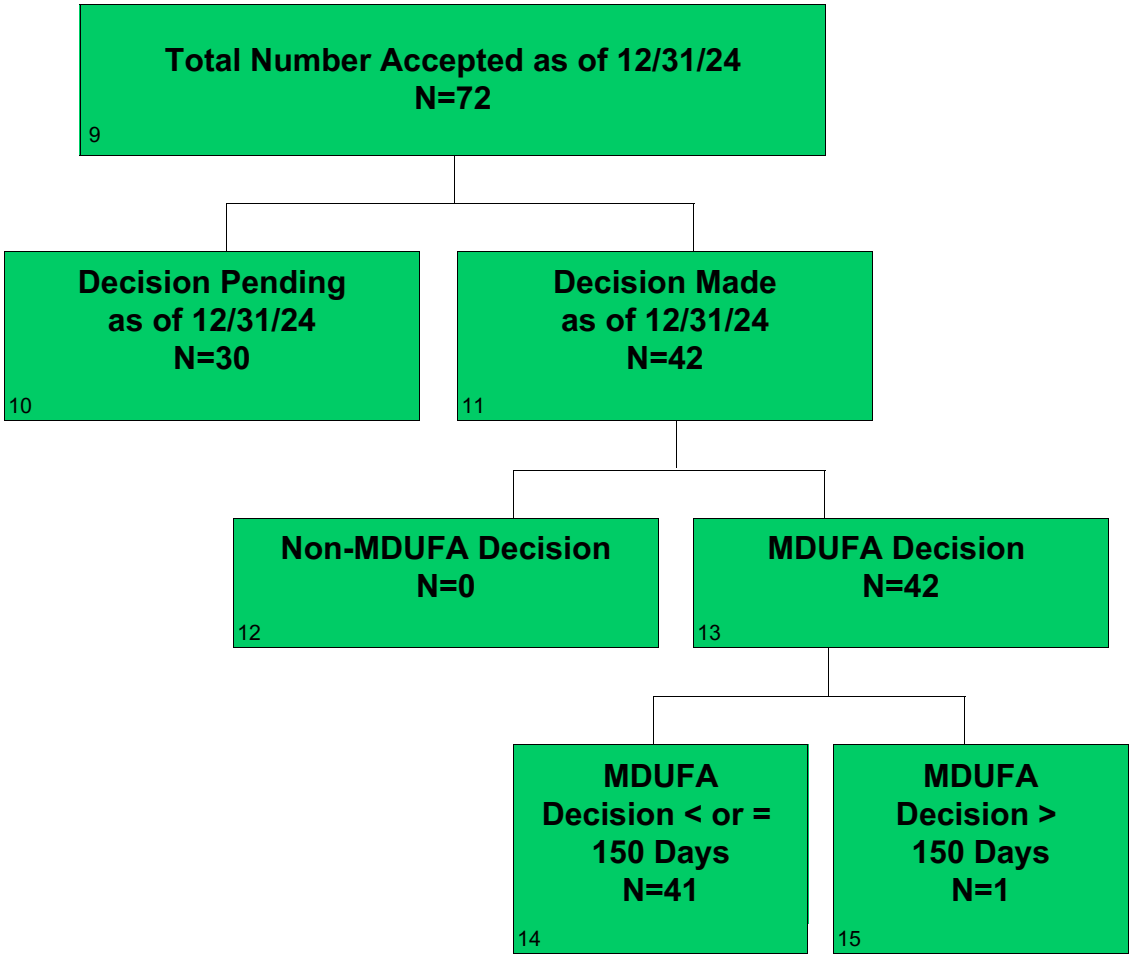
CDRH De Novo - FY 2023
as of 12/31/24 Continued



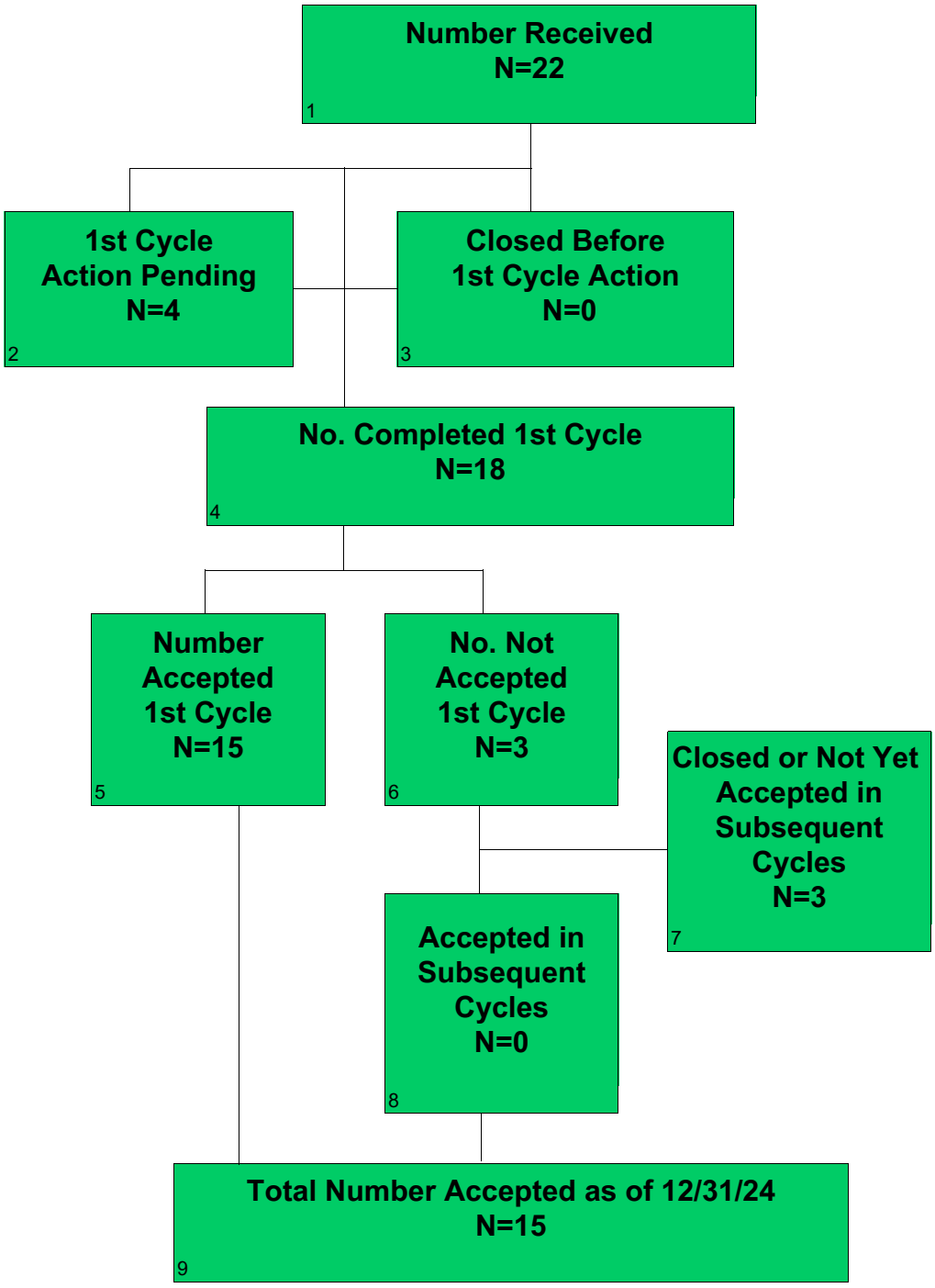
CDRH De Novo - FY 2024
as of 12/31/24



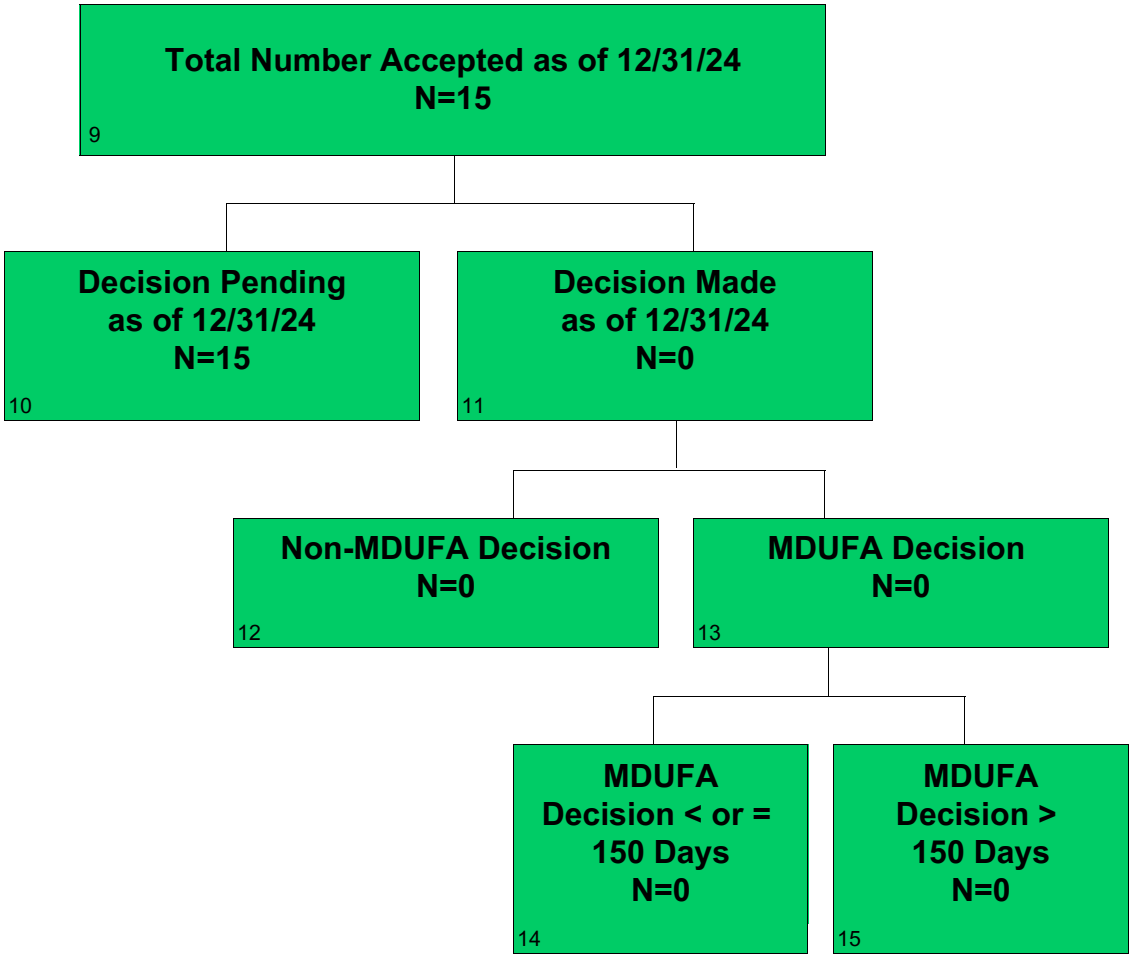
CDRH De Novo - FY 2024
as of 12/31/24 Continued



CDRH De Novo - FY 2025
as of 12/31/24



CDRH De Novo - FY 2025
as of 12/31/24 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96	78	22		
Closed Before First RTA or TS Action	3	1	0		
Number Accepted or Passed TS on First Cycle	65	66	15		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	4		
Number Not Accepted or Failed TS on First Cycle	28	11	3		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	16.67%		

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	72	15		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	82	42	0		
MDUFA Decision Within 150 FDA Days	77	41	0		
De Novos Pending MDUFA Decision	1	30	15		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	93.90%	97.62%	N/A		

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.52	N/A		
Number With MDUFA Decision	82	42	0		
Average FDA Days to MDUFA Decision	130.37	118.95	N/A		
20th Percentile FDA Days to MDUFA Decision	75	75	0		
40th Percentile FDA Days to MDUFA Decision	148	114	0		
60th Percentile FDA Days to MDUFA Decision	150	148	0		
80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	251	151	0		
Average Industry Days to MDUFA Decision	138.35	100.17	N/A		
20th Percentile Industry Days to MDUFA Decision	69	0	0		
40th Percentile Industry Days to MDUFA Decision	151	64	0		
60th Percentile Industry Days to MDUFA Decision	178	166	0		
80th Percentile Industry Days to MDUFA Decision	181	180	0		
Maximum Industry Days to MDUFA Decision	350	185	0		
Average Total Days to MDUFA Decision	268.72	219.12	N/A		
20th Percentile Total Days to MDUFA Decision	213	99	0		
40th Percentile Total Days to MDUFA Decision	256	206	0		
60th Percentile Total Days to MDUFA Decision	302	259	0		
80th Percentile Total Days to MDUFA Decision	329	325	0		
Maximum Total Days to MDUFA Decision	437	330	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	83	72	15		
Number With MDUFA Decision	82	42	0		
Number With Granted Decision	36	19	0		
Number With Declined Decision	18	10	0		
Number of Withdrawal	17	9	0		
Number of Deleted	11	4	0		
Rate of Granted Decision	43.90%	45.24%	N/A		
Rate of Declined Decision	21.95%	23.81%	N/A		
Rate of Withdrawal	20.73%	21.43%	N/A		
Rate of Deleted	13.41%	9.52%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	5	1	0		
Mean FDA Days for Submissions that Missed the Goal	194.80	151.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	111.20	150.00	N/A		

Table 8.6 CDRH - LDT De Novo MDUFA V Decision Metrics

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	10	0		
MDUFA Decision Within 150 FDA Days	19	10	0		
De Novos Pending MDUFA Decision	0	8	3		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

Section 8 - De Novo Office Level Metrics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	13	3		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	6	10	0		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	6	3	2		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	23.08%	100.00%		

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11	12	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	6	0		
MDUFA Decision Within 150 FDA Days	8	5	0		
De Novos Pending MDUFA Decision	0	6	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	72.73%	83.33%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.50	N/A		
Number With MDUFA Decision	11	6	0		
Average FDA Days to MDUFA Decision	130.82	113.17	N/A		
20th Percentile FDA Days to MDUFA Decision	73	75	0		
40th Percentile FDA Days to MDUFA Decision	75	84	0		
60th Percentile FDA Days to MDUFA Decision	150	147	0		
80th Percentile FDA Days to MDUFA Decision	178	149	0		
Maximum FDA Days to MDUFA Decision	251	151	0		
Average Industry Days to MDUFA Decision	137.45	100.33	N/A		
20th Percentile Industry Days to MDUFA Decision	81	0	0		
40th Percentile Industry Days to MDUFA Decision	152	136	0		
60th Percentile Industry Days to MDUFA Decision	178	139	0		
80th Percentile Industry Days to MDUFA Decision	182	150	0		
Maximum Industry Days to MDUFA Decision	189	177	0		
Average Total Days to MDUFA Decision	268.27	213.50	N/A		
20th Percentile Total Days to MDUFA Decision	231	84	0		
40th Percentile Total Days to MDUFA Decision	255	214	0		
60th Percentile Total Days to MDUFA Decision	262	283	0		
80th Percentile Total Days to MDUFA Decision	328	301	0		
Maximum Total Days to MDUFA Decision	343	326	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	12	0		
Number With MDUFA Decision	11	6	0		
Number With Granted Decision	5	3	0		
Number With Declined Decision	1	0	0		
Number of Withdrawal	1	3	0		
Number of Deleted	4	0	0		
Rate of Granted Decision	45.45%	50.00%	N/A		
Rate of Declined Decision	9.09%	0.00%	N/A		
Rate of Withdrawal	9.09%	50.00%	N/A		
Rate of Deleted	36.36%	0.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	3	1	0		
Mean FDA Days for Submissions That Missed the Goal	206.67	151.00	N/A		
Mean Industry Days for Submissions That Missed the Goal	122.33	150.00	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

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

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

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

Table 8.2 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	4	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	10	3	0		
MDUFA Decision Within 150 FDA Days	10	3	0		
De Novos Pending MDUFA Decision	0	1	1		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	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	1.67	N/A		
Number With MDUFA Decision	10	3	0		
Average FDA Days to MDUFA Decision	137.10	149.67	N/A		
20th Percentile FDA Days to MDUFA Decision	140	149	0		
40th Percentile FDA Days to MDUFA Decision	150	150	0		
60th Percentile FDA Days to MDUFA Decision	150	150	0		
80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	150	150	0		
Average Industry Days to MDUFA Decision	114.40	119.00	N/A		
20th Percentile Industry Days to MDUFA Decision	47	71	0		
40th Percentile Industry Days to MDUFA Decision	90	142	0		
60th Percentile Industry Days to MDUFA Decision	178	178	0		
80th Percentile Industry Days to MDUFA Decision	180	179	0		
Maximum Industry Days to MDUFA Decision	183	180	0		
Average Total Days to MDUFA Decision	251.50	268.67	N/A		
20th Percentile Total Days to MDUFA Decision	197	220	0		
40th Percentile Total Days to MDUFA Decision	238	291	0		
60th Percentile Total Days to MDUFA Decision	267	328	0		
80th Percentile Total Days to MDUFA Decision	328	329	0		
Maximum Total Days to MDUFA Decision	329	330	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	4	1		
Number With MDUFA Decision	10	3	0		
Number With Granted Decision	6	2	0		
Number With Declined Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Deleted	1	0	0		
Rate of Granted Decision	60.00%	66.67%	N/A		
Rate of Declined Decision	30.00%	33.33%	N/A		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Deleted	10.00%	0.00%	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	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	11	8	2		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	9	7	1		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	2	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	12.50%	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	8	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	3	0		
MDUFA Decision Within 150 FDA Days	11	3	0		
De Novos Pending MDUFA Decision	0	5	1		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	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	2.00	N/A		
Number With MDUFA Decision	11	3	0		
Average FDA Days to MDUFA Decision	128.45	147.33	N/A		
20th Percentile FDA Days to MDUFA Decision	74	146	0		
40th Percentile FDA Days to MDUFA Decision	148	148	0		
60th Percentile FDA Days to MDUFA Decision	150	149	0		
80th Percentile FDA Days to MDUFA Decision	150	149	0		
Maximum FDA Days to MDUFA Decision	150	149	0		
Average Industry Days to MDUFA Decision	122.73	180.00	N/A		
20th Percentile Industry Days to MDUFA Decision	83	179	0		
40th Percentile Industry Days to MDUFA Decision	124	180	0		
60th Percentile Industry Days to MDUFA Decision	163	180	0		
80th Percentile Industry Days to MDUFA Decision	180	181	0		
Maximum Industry Days to MDUFA Decision	214	181	0		
Average Total Days to MDUFA Decision	251.18	327.33	N/A		
20th Percentile Total Days to MDUFA Decision	231	326	0		
40th Percentile Total Days to MDUFA Decision	247	327	0		
60th Percentile Total Days to MDUFA Decision	274	328	0		
80th Percentile Total Days to MDUFA Decision	293	329	0		
Maximum Total Days to MDUFA Decision	330	329	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	8	1		
Number With MDUFA Decision	11	3	0		
Number With Granted Decision	7	1	0		
Number With Declined Decision	1	1	0		
Number of Withdrawal	1	1	0		
Number of Deleted	2	0	0		
Rate of Granted Decision	63.64%	33.33%	N/A		
Rate of Declined Decision	9.09%	33.33%	N/A		
Rate of Withdrawal	9.09%	33.33%	N/A		
Rate of Deleted	18.18%	0.00%	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	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	14	2		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	11	11	2		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	9	3	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	21.43%	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	12	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	10	0		
MDUFA Decision Within 150 FDA Days	13	10	0		
De Novos Pending MDUFA Decision	0	2	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	86.67%	100.00%	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	1.80	1.40	N/A		
Number With MDUFA Decision	15	10	0		
Average FDA Days to MDUFA Decision	126.87	113.90	N/A		
20th Percentile FDA Days to MDUFA Decision	75	74	0		
40th Percentile FDA Days to MDUFA Decision	143	88	0		
60th Percentile FDA Days to MDUFA Decision	148	148	0		
80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	203	150	0		
Average Industry Days to MDUFA Decision	134.87	119.90	N/A		
20th Percentile Industry Days to MDUFA Decision	80	0	0		
40th Percentile Industry Days to MDUFA Decision	156	158	0		
60th Percentile Industry Days to MDUFA Decision	180	170	0		
80th Percentile Industry Days to MDUFA Decision	181	180	0		
Maximum Industry Days to MDUFA Decision	198	185	0		
Average Total Days to MDUFA Decision	261.73	233.80	N/A		
20th Percentile Total Days to MDUFA Decision	228	139	0		
40th Percentile Total Days to MDUFA Decision	254	232	0		
60th Percentile Total Days to MDUFA Decision	302	281	0		
80th Percentile Total Days to MDUFA Decision	329	325	0		
Maximum Total Days to MDUFA Decision	346	330	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	12	2		
Number With MDUFA Decision	15	10	0		
Number With Granted Decision	7	6	0		
Number With Declined Decision	2	1	0		
Number of Withdrawal	5	2	0		
Number of Deleted	1	1	0		
Rate of Granted Decision	46.67%	60.00%	N/A		
Rate of Declined Decision	13.33%	10.00%	N/A		
Rate of Withdrawal	33.33%	20.00%	N/A		
Rate of Deleted	6.67%	10.00%	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	0		
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	10	12	6		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	5	11	6		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	4	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	8.33%	0.00%		

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	9	12	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	8	0		
MDUFA Decision Within 150 FDA Days	8	8	0		
De Novos Pending MDUFA Decision	1	4	6		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00	1.63	N/A		
Number With MDUFA Decision	8	8	0		
Average FDA Days to MDUFA Decision	140.38	113.13	N/A		
20th Percentile FDA Days to MDUFA Decision	149	76	0		
40th Percentile FDA Days to MDUFA Decision	150	85	0		
60th Percentile FDA Days to MDUFA Decision	150	144	0		
80th Percentile FDA Days to MDUFA Decision	150	149	0		
Maximum FDA Days to MDUFA Decision	150	150	0		
Average Industry Days to MDUFA Decision	134.88	76.50	N/A		
20th Percentile Industry Days to MDUFA Decision	94	0	0		
40th Percentile Industry Days to MDUFA Decision	151	26	0		
60th Percentile Industry Days to MDUFA Decision	167	109	0		
80th Percentile Industry Days to MDUFA Decision	178	151	0		
Maximum Industry Days to MDUFA Decision	183	183	0		
Average Total Days to MDUFA Decision	275.25	189.63	N/A		
20th Percentile Total Days to MDUFA Decision	226	82	0		
40th Percentile Total Days to MDUFA Decision	292	157	0		
60th Percentile Total Days to MDUFA Decision	304	256	0		
80th Percentile Total Days to MDUFA Decision	320	263	0		
Maximum Total Days to MDUFA Decision	330	322	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	12	6		
Number With MDUFA Decision	8	8	0		
Number With Granted Decision	2	2	0		
Number With Declined Decision	5	5	0		
Number of Withdrawal	0	0	0		
Number of Deleted	1	1	0		
Rate of Granted Decision	25.00%	25.00%	N/A		
Rate of Declined Decision	62.50%	62.50%	N/A		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Deleted	12.50%	12.50%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

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

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

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	3	2	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	0	0		
MDUFA Decision Within 150 FDA Days	3	0	0		
De Novos Pending MDUFA Decision	0	2	1		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	N/A	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	1.67	N/A	N/A		
Number With MDUFA Decision	3	0	0		
Average FDA Days to MDUFA Decision	149.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	148	0	0		
40th Percentile FDA Days to MDUFA Decision	149	0	0		
60th Percentile FDA Days to MDUFA Decision	149	0	0		
80th Percentile FDA Days to MDUFA Decision	150	0	0		
Maximum FDA Days to MDUFA Decision	150	0	0		
Average Industry Days to MDUFA Decision	119.33	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	71	0	0		
40th Percentile Industry Days to MDUFA Decision	142	0	0		
60th Percentile Industry Days to MDUFA Decision	178	0	0		
80th Percentile Industry Days to MDUFA Decision	179	0	0		
Maximum Industry Days to MDUFA Decision	180	0	0		
Average Total Days to MDUFA Decision	268.33	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	220	0	0		
40th Percentile Total Days to MDUFA Decision	292	0	0		
60th Percentile Total Days to MDUFA Decision	328	0	0		
80th Percentile Total Days to MDUFA Decision	329	0	0		
Maximum Total Days to MDUFA Decision	329	0	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	2	1		
Number With MDUFA Decision	3	0	0		
Number With Granted Decision	2	0	0		
Number With Declined Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	0	0		
Rate of Granted Decision	66.67%	N/A	N/A		
Rate of Declined Decision	33.33%	N/A	N/A		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Deleted	0.00%	N/A	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	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	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	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	6		
Closed Before First RTA or TS Action	1	1	0		
Number Accepted or Passed TS on First Cycle	17	17	3		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	2		
Number Not Accepted or Failed TS on First Cycle	5	2	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	25.00%		

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

Table 8.2 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	18	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	10	0		
MDUFA Decision Within 150 FDA Days	20	10	0		
De Novos Pending MDUFA Decision	0	8	3		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.60	1.40	N/A		
Number With MDUFA Decision	20	10	0		
Average FDA Days to MDUFA Decision	127.95	113.40	N/A		
20th Percentile FDA Days to MDUFA Decision	85	73	0		
40th Percentile FDA Days to MDUFA Decision	140	103	0		
60th Percentile FDA Days to MDUFA Decision	149	138	0		
80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	150	150	0		
Average Industry Days to MDUFA Decision	167.85	72.10	N/A		
20th Percentile Industry Days to MDUFA Decision	139	0	0		
40th Percentile Industry Days to MDUFA Decision	175	24	0		
60th Percentile Industry Days to MDUFA Decision	179	64	0		
80th Percentile Industry Days to MDUFA Decision	182	179	0		
Maximum Industry Days to MDUFA Decision	350	185	0		
Average Total Days to MDUFA Decision	295.80	185.50	N/A		
20th Percentile Total Days to MDUFA Decision	252	112	0		
40th Percentile Total Days to MDUFA Decision	299	166	0		
60th Percentile Total Days to MDUFA Decision	328	213	0		
80th Percentile Total Days to MDUFA Decision	330	257	0		
Maximum Total Days to MDUFA Decision	437	328	0		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	20	18	3		
Number With MDUFA Decision	20	10	0		
Number With Granted Decision	5	5	0		
Number With Declined Decision	5	1	0		
Number of Withdrawal	9	2	0		
Number of Deleted	1	2	0		
Rate of Granted Decision	25.00%	50.00%	N/A		
Rate of Declined Decision	25.00%	10.00%	N/A		
Rate of Withdrawal	45.00%	20.00%	N/A		
Rate of Deleted	5.00%	20.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Within 150 FDA Days	1	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	10	0		
MDUFA Decision Within 150 FDA Days	19	10	0		
De Novos Pending MDUFA Decision	0	8	3		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	1		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	4	4	1		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	0	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	20.00%	0.00%		

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.25	1.50	N/A		
Number With MDUFA Decision	4	2	0		
Average FDA Days to MDUFA Decision	108.75	124.00	N/A		
20th Percentile FDA Days to MDUFA Decision	70	115	0		
40th Percentile FDA Days to MDUFA Decision	89	121	0		
60th Percentile FDA Days to MDUFA Decision	133	127	0		
80th Percentile FDA Days to MDUFA Decision	149	133	0		
Maximum FDA Days to MDUFA Decision	150	139	0		
Average Industry Days to MDUFA Decision	130.50	88.00	N/A		
20th Percentile Industry Days to MDUFA Decision	83	35	0		
40th Percentile Industry Days to MDUFA Decision	132	70	0		
60th Percentile Industry Days to MDUFA Decision	169	106	0		
80th Percentile Industry Days to MDUFA Decision	186	141	0		
Maximum Industry Days to MDUFA Decision	193	176	0		
Average Total Days to MDUFA Decision	239.25	212.00	N/A		
20th Percentile Total Days to MDUFA Decision	190	150	0		
40th Percentile Total Days to MDUFA Decision	258	191	0		
60th Percentile Total Days to MDUFA Decision	265	233	0		
80th Percentile Total Days to MDUFA Decision	297	274	0		
Maximum Total Days to MDUFA Decision	343	315	0		

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

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

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

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

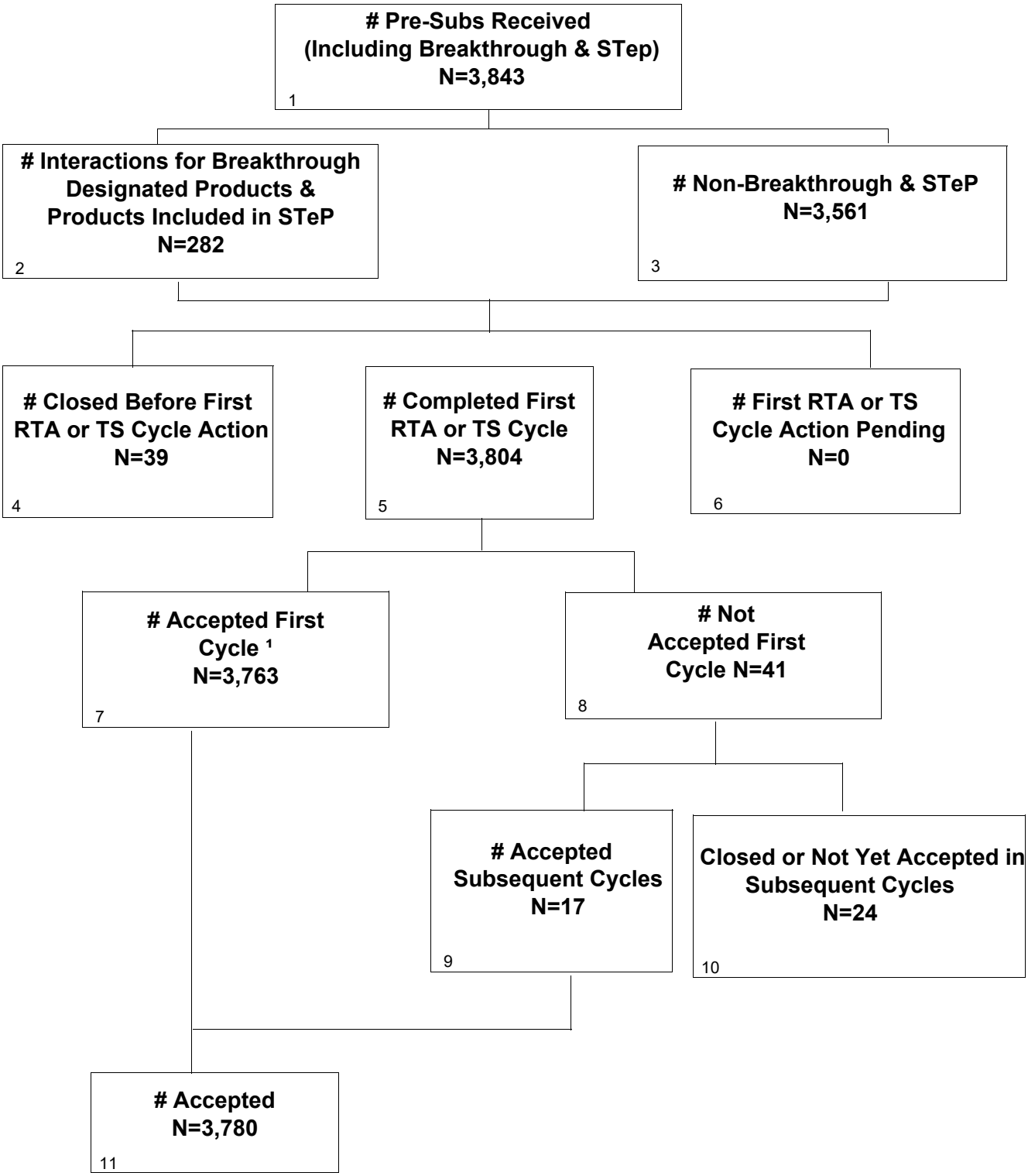
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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

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

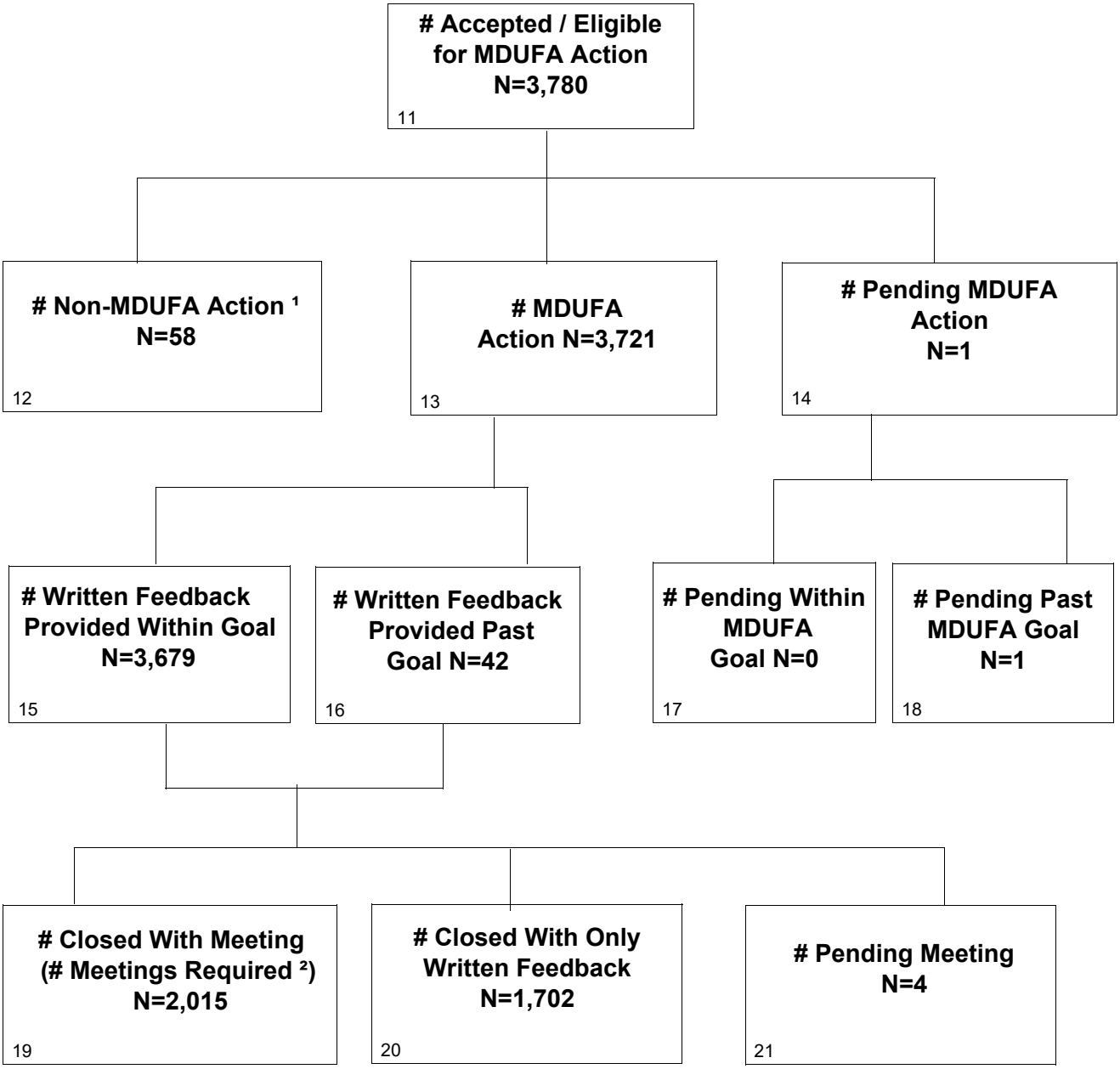
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A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

CDRH Pre-Sub - FY 2023
as of 12/31/24



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.

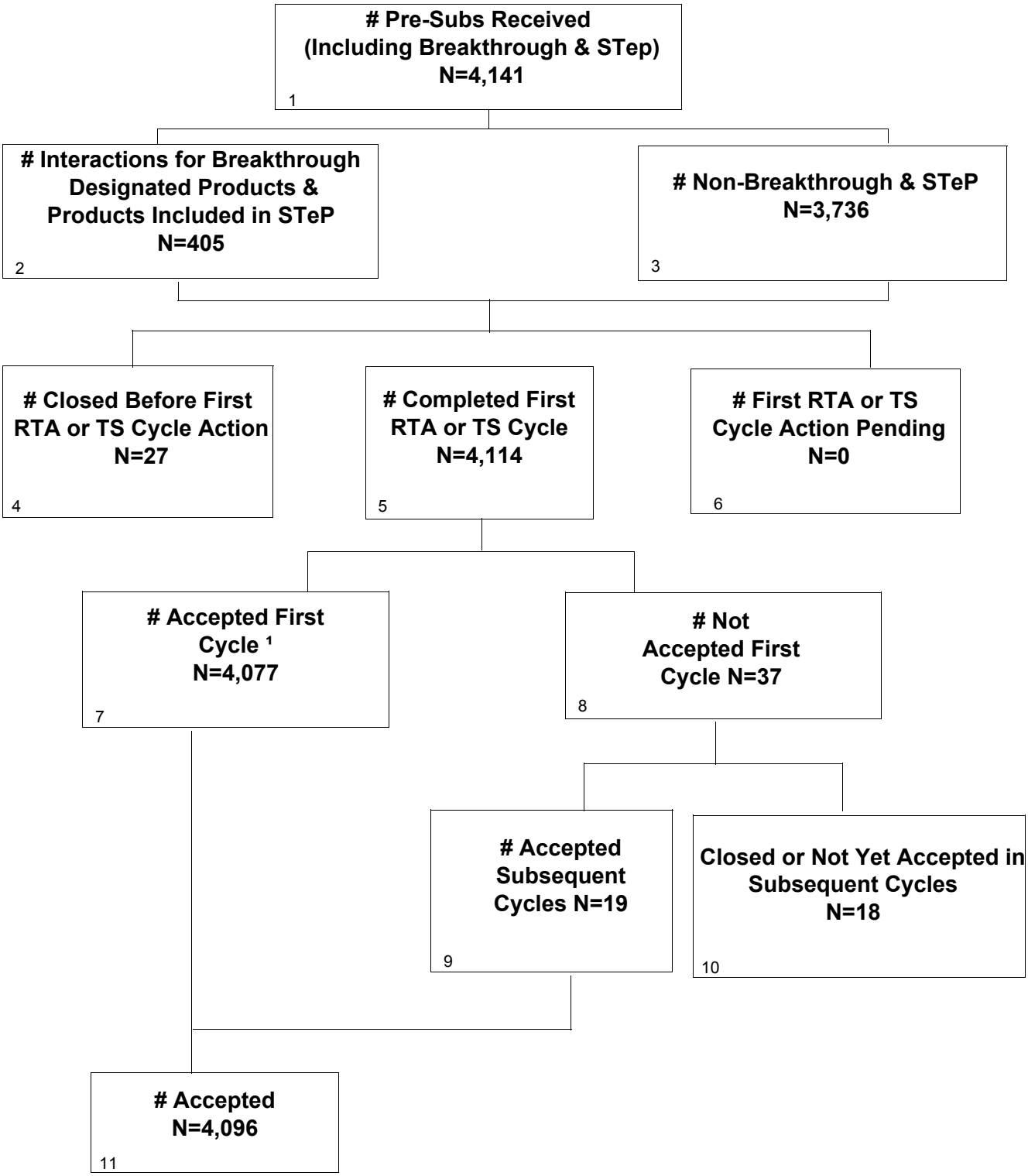
CDRH Pre-Sub - FY 2023
as of 12/31/24 Continued



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.

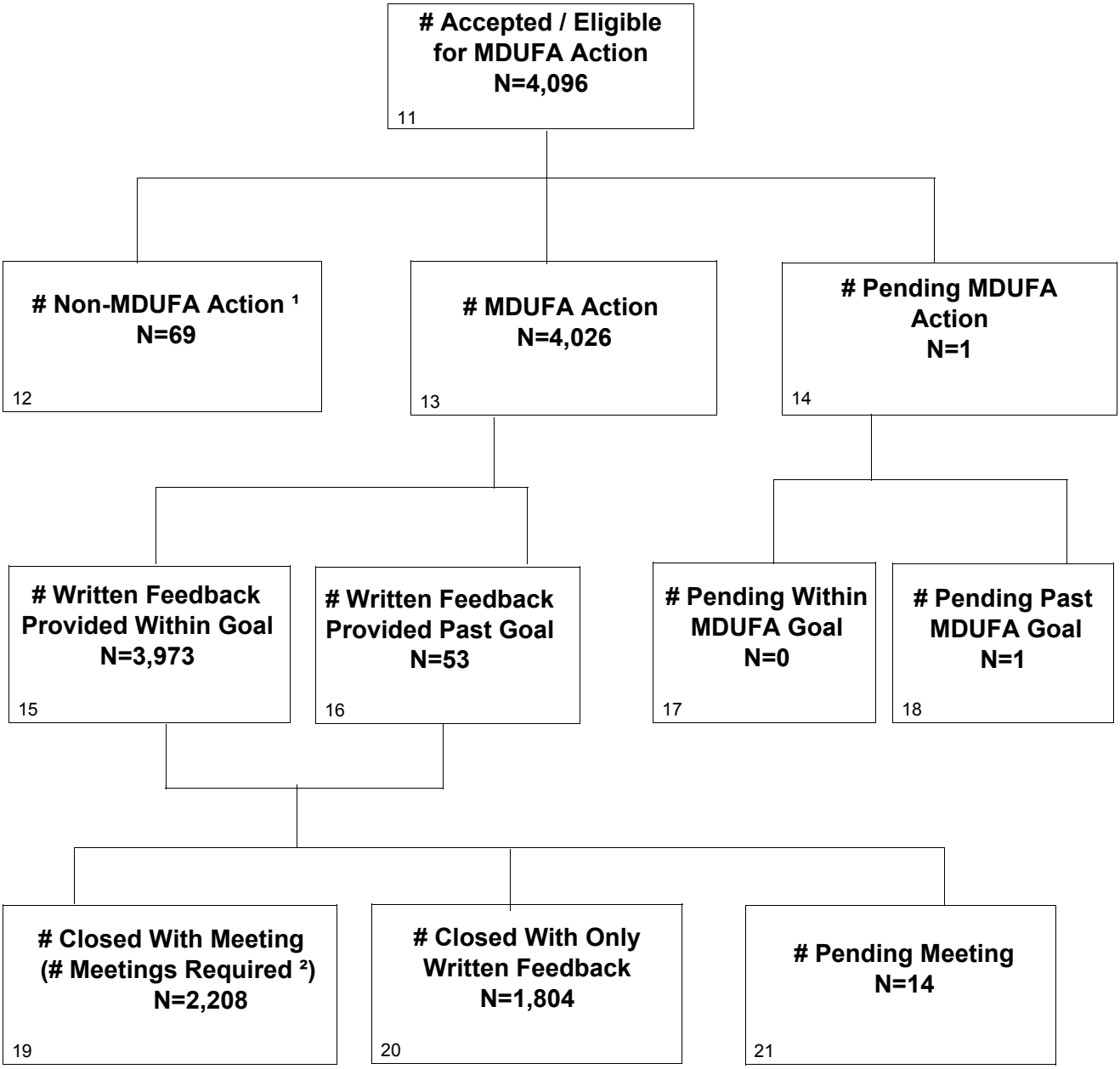
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 12/31/24



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.

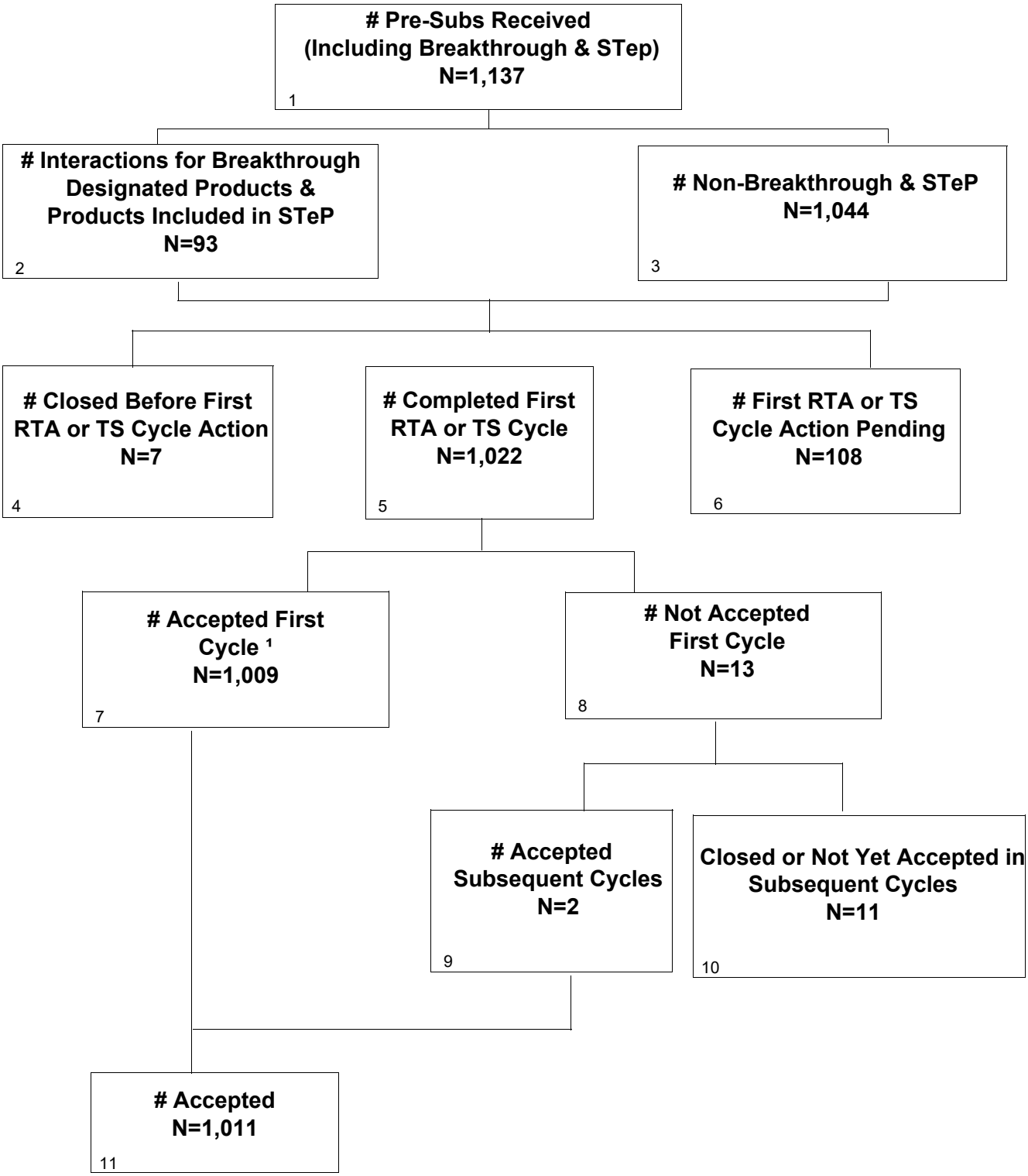
CDRH Pre-Sub - FY 2024
as of 12/31/24 Continued



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.

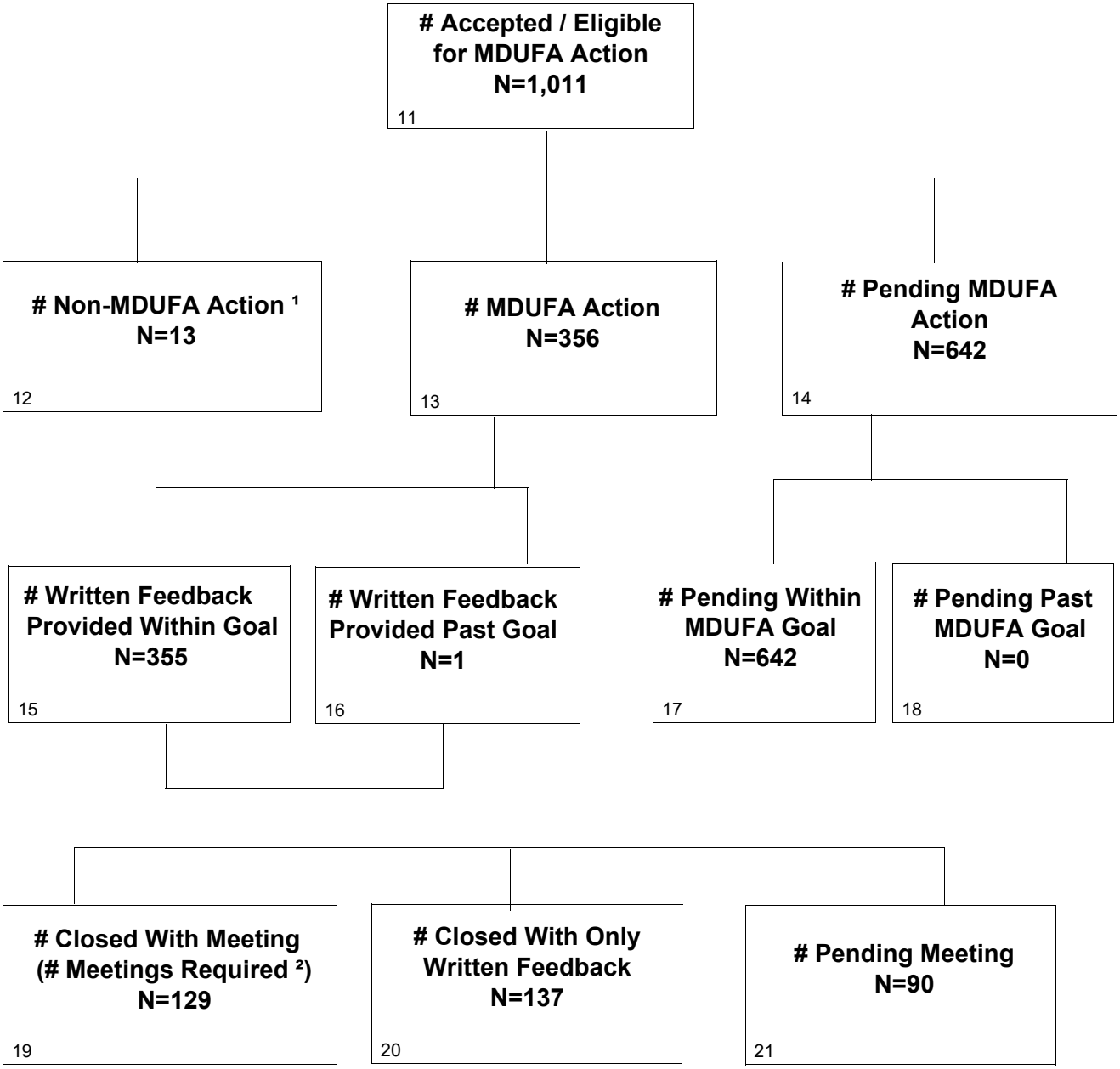
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2025
as of 12/31/24



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 2025
as of 12/31/24 Continued



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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,843	4,141	1,137		
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	93		
Number Closed Before First RTA Action	39	27	7		
Number Accepted First RTA Cycle [1]	3,642	3,980	980		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	97	29		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	108		
Number Not Accepted First RTA Cycle	41	37	13		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	1.27%		

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

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

Table 9.2 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	4,096	1,011		
Number with Non-MDUFA Action [3]	58	69	13		
Number with MDUFA Action	3,721	4,026	356		
Written Feedback Provided Within Goal	3,679	3,973	355		
Number Pending MDUFA Action	1	1	642		
Pending MDUFA Action Past Goal	1	1	0		
Number in MDUFA Cohort (up to max 4300)[4]	3,722	4,027	998		
Current Performance Percent Within Goal	98.84%	98.66%	99.72%		

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	4,026	356		
Average FDA Days to Written Feedback	62.20	62.25	56.88		
20th Percentile FDA Days to Written Feedback	56	56	48		
40th Percentile FDA Days to Written Feedback	64	64	57		
60th Percentile FDA Days to Written Feedback	68	67	62		
80th Percentile FDA Days to Written Feedback	70	70	67		
Maximum FDA Days to Written Feedback	141	245	72		

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	130	23		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	38.39		

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	2,208	129		
Meeting Minutes Submitted Within 15 Days of Meeting	1,530	1,778	94		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6	26		
Meeting Minutes Past 15 Days of Meeting	434	348	4		
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	76	5		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.97%	80.74%	91.26%		

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

Section 9 Pre-Sub Office Level Metrics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	444	493	131		
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	5		
Number Closed Before First RTA Action	4	6	1		
Number Accepted First RTA Cycle [1]	411	462	111		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	20	2		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	14		
Number Not Accepted First RTA Cycle	9	5	3		
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.59%		

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

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

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

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	435	486	114		
Number with Non-MDUFA Action [3]	12	12	1		
Number with MDUFA Action	423	474	42		
Written Feedback Provided Within Goal	410	461	42		
Number Pending MDUFA Action	0	0	71		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	423	474	113		
Current Performance Percent Within Goal	96.93%	97.26%	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 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	423	474	42		
Average FDA Days to Written Feedback	65.34	65.27	58.74		
20th Percentile FDA Days to Written Feedback	62	62	55		
40th Percentile FDA Days to Written Feedback	66	66	61		
60th Percentile FDA Days to Written Feedback	69	69	63		
80th Percentile FDA Days to Written Feedback	70	70	68		
Maximum FDA Days to Written Feedback	141	101	70		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	30	23	8		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	34.75		

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	276	14		
Meeting Minutes Submitted Within 15 Days of Meeting	179	225	9		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2	5		
Meeting Minutes Past 15 Days of Meeting	59	38	0		
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	11	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	82.12%	100.00%		

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

Table 9.1 OHT2 - Office of Cardiovascular Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	721	745	181		
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	19		
Number Closed Before First RTA Action	6	2	0		
Number Accepted First RTA Cycle [1]	698	726	155		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	14	6		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	19		
Number Not Accepted First RTA Cycle	4	3	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.62%		

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

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

Table 9.2 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	714	741	161		
Number with Non-MDUFA Action [3]	4	4	1		
Number with MDUFA Action	709	736	66		
Written Feedback Provided Within Goal	694	715	66		
Number Pending MDUFA Action	1	1	94		
Pending MDUFA Action Past Goal	1	1	0		
Number in MDUFA Cohort (up to max 4300)[4]	710	737	160		
Current Performance Percent Within Goal	97.75%	97.01%	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 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	709	736	66		
Average FDA Days to Written Feedback	59.29	59.66	53.74		
20th Percentile FDA Days to Written Feedback	50	51	44		
40th Percentile FDA Days to Written Feedback	60	61	54		
60th Percentile FDA Days to Written Feedback	66	65	59		
80th Percentile FDA Days to Written Feedback	69	69	65		
Maximum FDA Days to Written Feedback	103	113	70		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	32	21	3		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.19	36.90	32.33		

Table 9.5 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	403	422	28		
Meeting Minutes Submitted Within 15 Days of Meeting	306	316	20		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	1	5		
Meeting Minutes Past 15 Days of Meeting	90	86	1		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	19	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.93%	75.06%	86.96%		

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	461	507	133		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	14		
Number Closed Before First RTA Action	5	4	0		
Number Accepted First RTA Cycle [1]	438	481	111		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	11	1		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	17		
Number Not Accepted First RTA Cycle	6	11	4		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.19%	3.45%		

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	453	496	112		
Number with Non-MDUFA Action [3]	10	11	0		
Number with MDUFA Action	443	485	37		
Written Feedback Provided Within Goal	439	482	37		
Number Pending MDUFA Action	0	0	75		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	443	485	112		
Current Performance Percent Within Goal	99.10%	99.38%	100.00%		

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

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

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

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

Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	443	485	37		
Average FDA Days to Written Feedback	62.12	61.75	59.32		
20th Percentile FDA Days to Written Feedback	56	56	50		
40th Percentile FDA Days to Written Feedback	64	63	59		
60th Percentile FDA Days to Written Feedback	67	67	63		
80th Percentile FDA Days to Written Feedback	70	70	69		
Maximum FDA Days to Written Feedback	78	78	70		

Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	13	12	1		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	43.50	67.00		

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]	255	264	17		
Meeting Minutes Submitted Within 15 Days of Meeting	200	220	12		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	4		
Meeting Minutes Past 15 Days of Meeting	49	35	1		
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	9	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.43%	83.33%	92.31%		

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	386	467	148		
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	9		
Number Closed Before First RTA Action	4	5	2		
Number Accepted First RTA Cycle [1]	366	440	128		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	14	7		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	11		
Number Not Accepted First RTA Cycle	7	8	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.83%	1.73%	0.00%		

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

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

Table 9.2 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	378	459	135		
Number with Non-MDUFA Action [3]	11	18	2		
Number with MDUFA Action	367	441	49		
Written Feedback Provided Within Goal	367	439	48		
Number Pending MDUFA Action	0	0	84		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	367	441	133		
Current Performance Percent Within Goal	100.00%	99.55%	97.96%		

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

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

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

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

Table 9.3 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	367	441	49		
Average FDA Days to Written Feedback	60.58	61.89	55.96		
20th Percentile FDA Days to Written Feedback	55	56	46		
40th Percentile FDA Days to Written Feedback	62	63	55		
60th Percentile FDA Days to Written Feedback	65	67	60		
80th Percentile FDA Days to Written Feedback	69	70	64		
Maximum FDA Days to Written Feedback	70	70	72		

Table 9.4 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	15	15	2		
Average Days to Scheduling for Meetings Scheduled After Day 30	37.53	40.00	33.50		

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]	211	234	16		
Meeting Minutes Submitted Within 15 Days of Meeting	162	182	15		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	1		
Meeting Minutes Past 15 Days of Meeting	41	44	0		
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	8	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.78%	77.78%	100.00%		

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

Table 9.1 OHT5 - Office of Neurological and Physical Medicine Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	396	426	122		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	11		
Number Closed Before First RTA Action	5	3	1		
Number Accepted First RTA Cycle [1]	370	404	104		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	10	3		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	11		
Number Not Accepted First RTA Cycle	4	9	3		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.13%	2.73%		

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

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

Table 9.2 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	389	419	108		
Number with Non-MDUFA Action [3]	5	5	3		
Number with MDUFA Action	384	414	30		
Written Feedback Provided Within Goal	382	406	30		
Number Pending MDUFA Action	0	0	75		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	384	414	105		
Current Performance Percent Within Goal	99.48%	98.07%	100.00%		

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

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

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

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

Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	384	414	30		
Average FDA Days to Written Feedback	66.14	67.29	61.77		
20th Percentile FDA Days to Written Feedback	64	65	54		
40th Percentile FDA Days to Written Feedback	68	69	66		
60th Percentile FDA Days to Written Feedback	70	70	69		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	108	245	70		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	25	39	3		
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	39.26	41.67		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	248	255	6		
Meeting Minutes Submitted Within 15 Days of Meeting	177	204	4		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3	2		
Meeting Minutes Past 15 Days of Meeting	64	41	0		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	7	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.37%	80.95%	100.00%		

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

Table 9.1 OHT6 - Office of Orthopedic Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	287	293	78		
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	14		
Number Closed Before First RTA Action	5	1	1		
Number Accepted First RTA Cycle [1]	268	285	68		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	7	2		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	6		
Number Not Accepted First RTA Cycle	4	0	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.42%	0.00%	1.41%		

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

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

Table 9.2 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	280	292	70		
Number with Non-MDUFA Action [3]	6	8	2		
Number with MDUFA Action	274	284	29		
Written Feedback Provided Within Goal	270	279	29		
Number Pending MDUFA Action	0	0	39		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	274	284	68		
Current Performance Percent Within Goal	98.54%	98.24%	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 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	274	284	29		
Average FDA Days to Written Feedback	58.45	56.88	53.17		
20th Percentile FDA Days to Written Feedback	45	43	42		
40th Percentile FDA Days to Written Feedback	58	57	56		
60th Percentile FDA Days to Written Feedback	65	64	60		
80th Percentile FDA Days to Written Feedback	69	68	62		
Maximum FDA Days to Written Feedback	97	92	70		

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	2		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	33.00		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	123	128	9		
Meeting Minutes Submitted Within 15 Days of Meeting	91	102	7		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	1		
Meeting Minutes Past 15 Days of Meeting	28	17	0		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	9	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.98%	79.69%	87.50%		

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

Table 9.1 OHT7 - Office of In Vitro Diagnostics
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	880	924	257		
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	17		
Number Closed Before First RTA Action	9	5	2		
Number Accepted First RTA Cycle [1]	833	903	225		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	15	8		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	22		
Number Not Accepted First RTA Cycle	3	1	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%	0.00%		

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

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

Table 9.2 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	868	918	233		
Number with Non-MDUFA Action [3]	7	11	4		
Number with MDUFA Action	861	907	76		
Written Feedback Provided Within Goal	857	906	76		
Number Pending MDUFA Action	0	0	153		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	861	907	229		
Current Performance Percent Within Goal	99.54%	99.89%	100.00%		

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

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

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

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

Table 9.3 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	861	907	76		
Average FDA Days to Written Feedback	63.70	63.09	57.03		
20th Percentile FDA Days to Written Feedback	60	59	49		
40th Percentile FDA Days to Written Feedback	66	65	56		
60th Percentile FDA Days to Written Feedback	69	68	63		
80th Percentile FDA Days to Written Feedback	70	70	66		
Maximum FDA Days to Written Feedback	75	71	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	14	3		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	43.00		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	320	415	24		
Meeting Minutes Submitted Within 15 Days of Meeting	257	356	15		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	6		
Meeting Minutes Past 15 Days of Meeting	59	49	2		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	10	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	85.78%	83.33%		

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

Table 9.1 OHT8 - Office of Radiological Health
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	268	286	87		
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	4		
Number Closed Before First RTA Action	1	1	0		
Number Accepted First RTA Cycle [1]	258	279	78		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	6	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	8		
Number Not Accepted First RTA Cycle	4	0	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.50%	0.00%	1.27%		

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

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

Table 9.2 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	263	285	78		
Number with Non-MDUFA Action [3]	3	0	0		
Number with MDUFA Action	260	285	27		
Written Feedback Provided Within Goal	260	285	27		
Number Pending MDUFA Action	0	0	51		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	260	285	78		
Current Performance Percent Within Goal	100.00%	100.00%	100.00%		

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

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

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

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

Table 9.3 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	260	285	27		
Average FDA Days to Written Feedback	60.55	60.68	58.15		
20th Percentile FDA Days to Written Feedback	55	55	51		
40th Percentile FDA Days to Written Feedback	60	62	57		
60th Percentile FDA Days to Written Feedback	64	65	62		
80th Percentile FDA Days to Written Feedback	67	69	64		
Maximum FDA Days to Written Feedback	70	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)

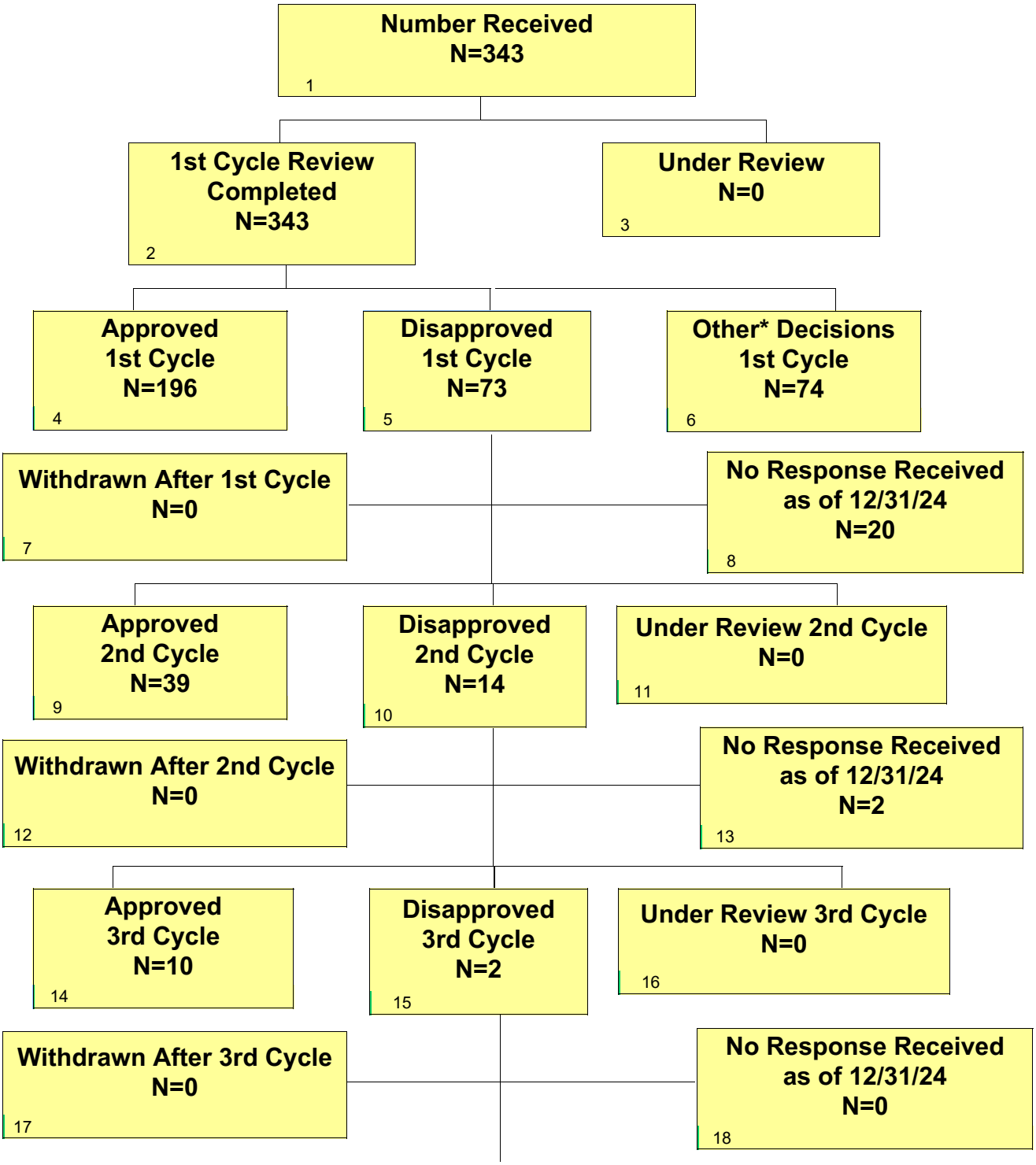
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4	1		
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	54.00		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	205	214	15		
Meeting Minutes Submitted Within 15 Days of Meeting	158	173	12		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	2		
Meeting Minutes Past 15 Days of Meeting	44	38	0		
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.07%	80.84%	92.31%		

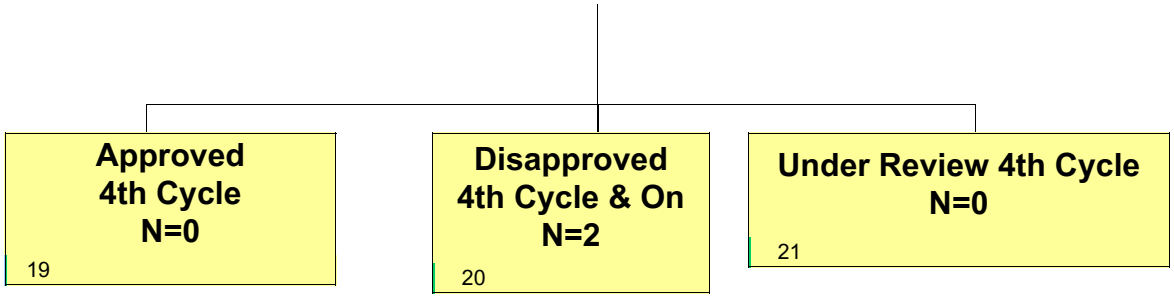
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 12/31/24

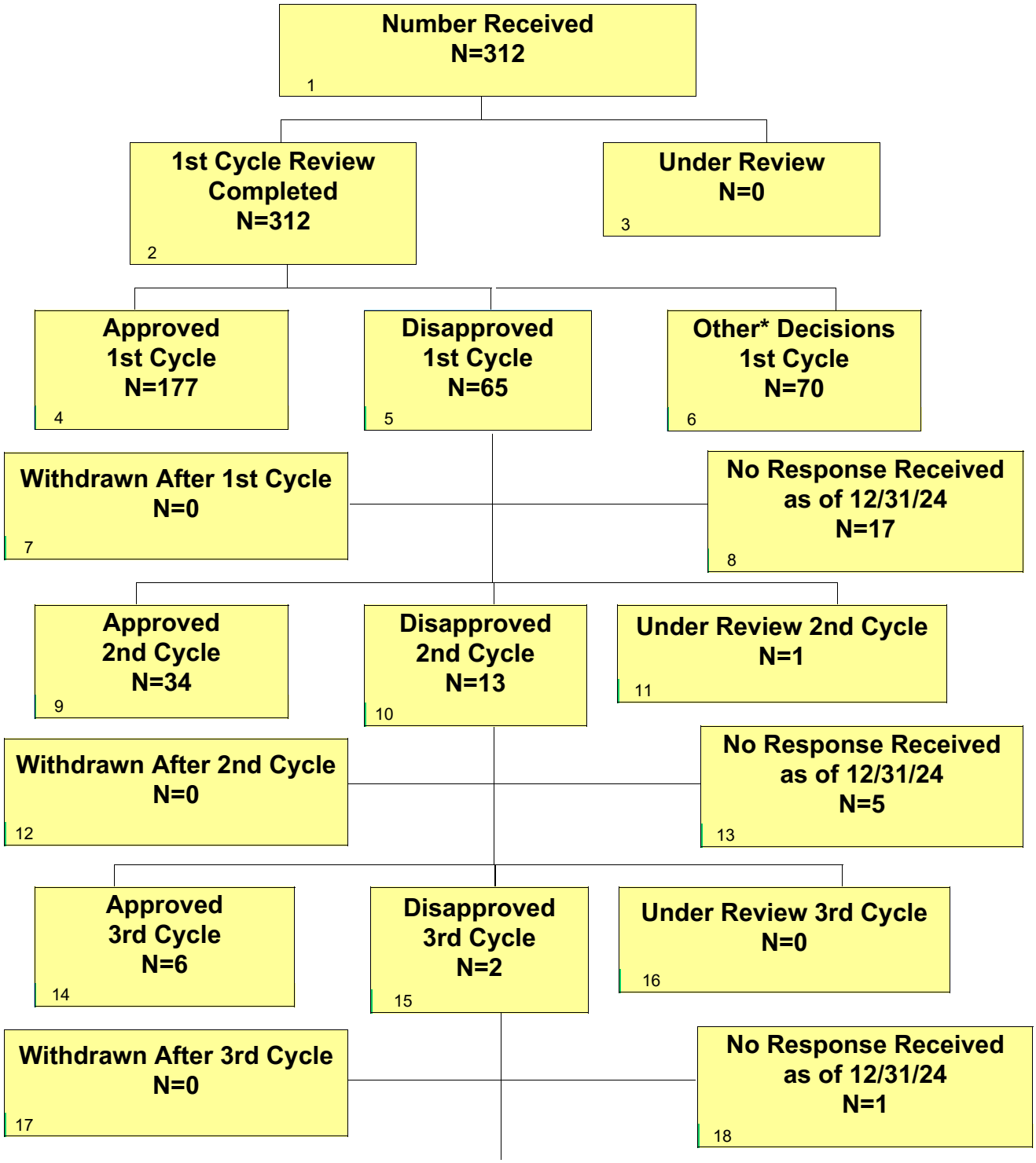


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 12/31/24

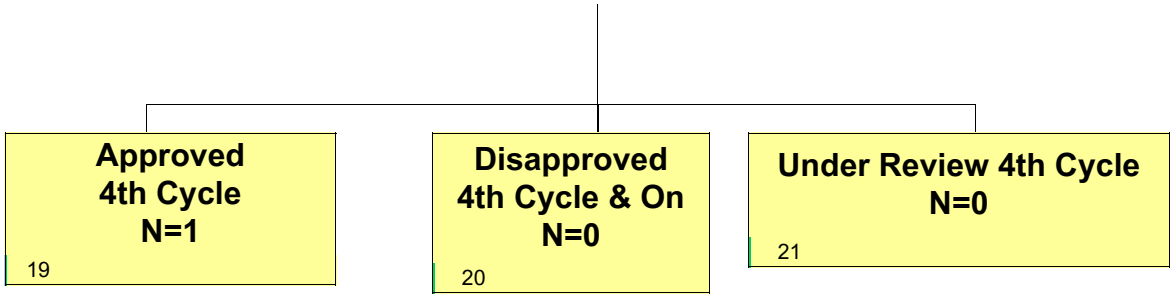


CDRH IDEs - FY 2024
as of 12/31/24

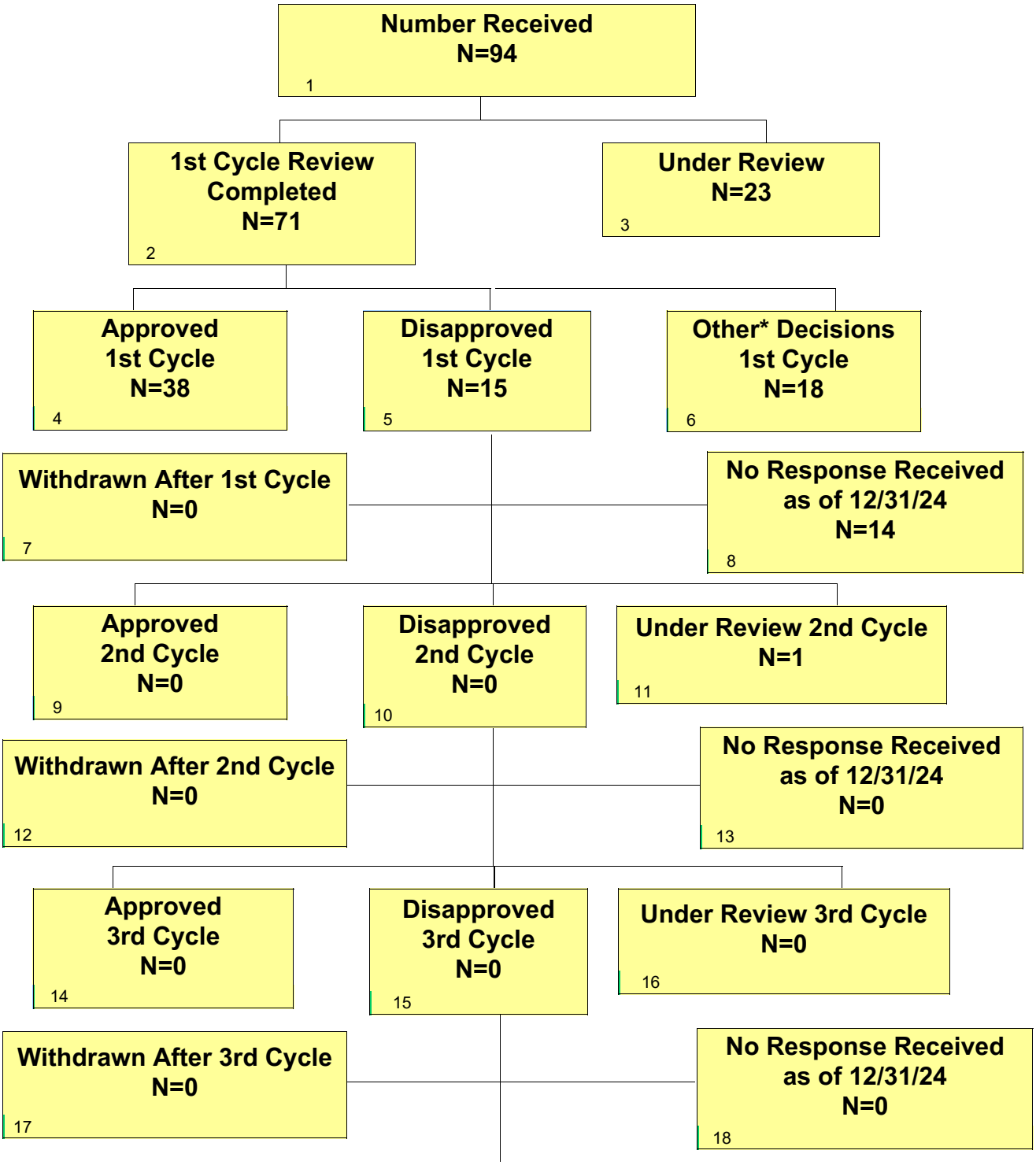


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 12/31/24

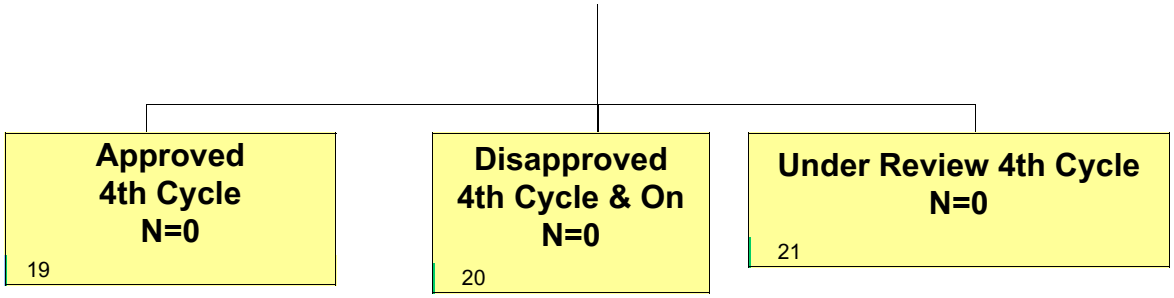


CDRH IDEs - FY 2025
as of 12/31/24



*** Other decisions include withdrawn (N=5), withdrawn and converted (N=11), RTA (N=0), nonsignificant risk device (N=2), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=0), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2025
as of 12/31/24



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	312	94		
Average Number of Cycles to IDE Approval or Conditional Approval	1.27	1.22	1.03		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.27	0.22	0.03		

Section 10 IDE - Office Level Metric

Table 10.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	41	32	9		
Average Number of Cycles to IDE Approval or Conditional Approval	1.38	1.21	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.38	0.21	0.00		

Table 10.1 OHT2 - Office of Cardiovascular Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	82	23		
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.36	1.08		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.36	0.08		

Table 10.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	35	41	7		
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.29	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.29	0.00		

Table 10.1 OHT4 - Office of Surgical and Infection Control Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	38	17	13		
Average Number of Cycles to IDE Approval or Conditional Approval	1.10	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10	0.00	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	75	63	24		
Average Number of Cycles to IDE Approval or Conditional Approval	1.22	1.22	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.22	0.22	0.00		

Table 10.1 OHT6 - Office of Orthopedic Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	26	23	7		
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	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	43	9		
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00	0.00		

Table 10.1 OHT8 - Office of Radiological Health
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	8	11	2		
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.00	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		31	13		
Closed before Teleconference		0	0		
Teleconferences Held		31	13		
Teleconferences Held Within 14 Days		30	13		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		96.77%	100.00%		

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

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	4		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	4		
Written Feedback Provided Within 21 Days		3	3		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	75.00%		

Table 13.3 CDRH - TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		44	13		
Closed before Written Feedback		0	0		
Written Feedback Provided		44	10		
Written Feedback Provided Within 40 Days		44	10		
Written Feedback Pending		0	3		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

TAP Pilot Enrollment Data

Table 13.4 - TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	47	12		
Enrollment Requests Accepted	12	40	11		
Enrollment Requests Not Accepted	7	7	1		
Enrollment Requests Pending	0	0	0		

Section 13 TAP Documents - Office Level Metric

Table 13.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP Pilot Enrollment Data

Table 13.4 - TAP Pilot Enrollment Data	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	1		
Enrollment Requests Accepted	0	0	1		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

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

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		21	9		
Closed before Teleconference		0	0		
Teleconferences Held		21	9		
Teleconferences Held Within 14 Days		20	9		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		95.24%	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	2		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	2		
Written Feedback Provided Within 21 Days		3	1		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	50.00%		

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

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		34	9		
Closed before Written Feedback		0	0		
Written Feedback Provided		34	7		
Written Feedback Provided Within 40 Days		34	7		
Written Feedback Pending		0	2		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

Table 13.4 - OHT2 - Office of Cardiovascular Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	21	6		
Enrollment Requests Accepted	12	16	5		
Enrollment Requests Not Accepted	7	5	1		
Enrollment Requests Pending	0	0	0		

Table 13.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	1	0		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	1	0		
Enrollment Requests Pending	0	0	0		

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

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT4 - Office of Surgical and Infection Control Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	0		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

Table 13.1 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		10	4		
Closed before Teleconference		0	0		
Teleconferences Held		10	4		
Teleconferences Held Within 14 Days		10	4		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		100.00%	100.00%		

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

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	2		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	2		
Written Feedback Provided Within 21 Days		0	2		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	100.00%		

Table 13.3 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		10	4		
Closed before Written Feedback		0	0		
Written Feedback Provided		10	3		
Written Feedback Provided Within 40 Days		10	3		
Written Feedback Pending		0	1		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

Table 13.4 - OHT5 - Office of Neurological and Physical Medicine Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	25	3		
Enrollment Requests Accepted	0	24	3		
Enrollment Requests Not Accepted	0	1	0		
Enrollment Requests Pending	0	0	0		

Table 13.1 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT6 - Office of Orthopedic Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	0		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

Table 13.1 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT7 - Office of In Vitro Diagnostics
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	0		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

Table 13.1 OHT8 - Office of Radiological Health
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT8 - Office of Radiological Health
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	2		
Enrollment Requests Accepted	0	0	2		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

Table 1.1 and Tables 1.1.x **PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Closed Before First RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Filing Review on First Cycle	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

Table 1.2 and Tables 1.2.x **PMA Originals and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of Submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

Table 1.3 and Tables 1.3.x **PMA Originals and Panel Track Supplements Substantive Interaction Performance Goal - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 1.4 and Tables 1.4.x **PMA Originals and Panel Track Supplements Substantive Interaction Metric – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average Number of FDA Days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20th Percentile FDA Days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA Days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA Days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA Days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA Days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 1.5 and Tables 1.5.x PMA Originals and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal - Definitions

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

Table 1.6 and Tables 1.6.x PMA Originals and Panel Track Supplements (With Panel Review) MDUFA V Decision Performance Goal - Definitions

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

Table 1.7 and Tables 1.7.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.8 and Tables 1.8.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

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

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

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

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

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

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

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

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

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

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

*Includes submissions that went to panel

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

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

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

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

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

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

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

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

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

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

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

Section 3 PMA Real Time Supplements

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

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

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

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

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

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

Section 5 PMA Annual Metrics and Goals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 De Novo MDUFA V Performance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

Section 9 Pre-Submissions

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

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

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

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

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

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

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

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

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

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 13 Total Product Life Cycle Advisory Program (TAP)

Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions

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

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

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

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

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

Table 13.4 TAP Pilot Enrollment Data– Definitions

#	Measure	Description
1	Enrollment Requests Received	Number of TAP Pilot Enrollment Requests received in the fiscal year.
2	Enrollment Requests Accepted	Number of TAP Pilot Enrollment Requests accepted in the fiscal year.
3	Enrollment Requests Not Accepted	Number of TAP Pilot Enrollment Requests not accepted in the fiscal year.
4	Enrollment Requests Pending	Number of TAP Pilot Enrollment Requests still under review.

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 31 December 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	0		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	3	0	0		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	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	0		
Number Accepted	3	0	0		
Completed RTF	3	0	0		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	N/A	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	0		
SI Goal Met	3	0	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	N/A	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	0		
Average Number of FDA Days to Substantive Interaction	88.33	0.00	0.00		
20th Percentile FDA Days to Substantive Interaction	87	0.00	0.00		
40th Percentile FDA Days to Substantive Interaction	88	0.00	0.00		
60th Percentile FDA Days to Substantive Interaction	88	0.00	0.00		
80th Percentile FDA Days to Substantive Interaction	89	0.00	0.00		
Maximum FDA Days to Substantive Interaction	90	0.00	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	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	3	0	0		
MDUFA V Decision Goal Met	3	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	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	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	0		
Average FDA Days to MDUFA V Decision	177.00	0.00	0.00		
20th Percentile FDA Days to MDUFA V Decision	175	0	0		
40th Percentile FDA Days to MDUFA V Decision	178	0	0		
60th Percentile FDA Days to MDUFA V Decision	179	0	0		
80th Percentile FDA Days to MDUFA V Decision	180	0	0		
Maximum FDA Days to MDUFA V Decision	180	0	0		
Average Industry Days to MDUFA V Decision	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	0	0	0		
Maximum Industry Days to MDUFA V Decision	0	0	0		
Average Total Days to MDUFA V Decision	177.00	0.00	0.00		
20th Percentile Total Days to MDUFA V Decision	175	0	0		
40th Percentile Total Days to MDUFA V Decision	178	0	0		
60th Percentile Total Days to MDUFA V Decision	179	0	0		
80th Percentile Total Days to MDUFA V Decision	180	0	0		
Maximum Total Days to MDUFA V Decision	180	0	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	0		
Average FDA Days to MDUFA V Decision	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA V Decision	0	0	0		
40th Percentile FDA Days to MDUFA V Decision	0	0	0		
60th Percentile FDA Days to MDUFA V Decision	0	0	0		
80th Percentile FDA Days to MDUFA V Decision	0	0	0		
Maximum FDA Days to MDUFA V Decision	0	0	0		
Average Industry Days to MDUFA V Decision	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	0.00	0.00	0.00		
Maximum Industry Days to MDUFA V Decision	0	0	0		
Average Total Days to MDUFA V Decision	0	0	0		
20th Percentile Total Days to MDUFA V Decision	0	0	0		
40th Percentile Total Days to MDUFA V Decision	0	0	0		
60th Percentile Total Days to MDUFA V Decision	0	0	0		
80th Percentile Total Days to MDUFA V Decision	0	0	0		
Maximum Total Days to MDUFA V Decision	0	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	0		
Number with MDUFA V Decision	3	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	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	0		
Number With MDUFA V Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	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	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

***Includes submission that went to panel**

Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	4	5	2		
SI Goal Met	2	5	0		
SI Goal Not Met	2	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	50.00%	100.00%	N/A		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	4	5	2		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	4	4	0		
MDUFA V Decision Goal Met	3	4	0		
Supplements Pending MDUFA V Decision	0	1	2		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	75.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	2		
Number with MDUFA V Decision	4	4	0		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	25.00%	0.00%	N/A		

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

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

Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	3	2	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	3	2	1		
MDUFA V Decision Goal Met	3	2	1		
Supplements Pending MDUFA V Decision	0	0	0		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	1		
Number With MDUFA V Decision	3	2	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	34	8		
Closed Before First RTA or TS Action [1]	0	1	0		
Number Accepted or Passed TS on First Cycle [2]	30	27	6		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	1		
Number Not Accepted or Failed TS on First Cycle [2]	11	6	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	18.18%	14.29%		

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	33	8		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	37	29	3		
SI Over 60 FDA Days	2	1	0		
SI Pending Within 60 FDA Days	0	3	5		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	94.87%	96.67%	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	30	3		
Average Number of FDA Days to Substantive Interaction	55.53	57.07	48.30		
20th Percentile FDA Days to Substantive Interaction	51	57	48		
40th Percentile FDA Days to Substantive Interaction	56	58	52		
60th Percentile FDA Days to Substantive Interaction	59	59	48		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	90	60	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	33	8		
Non-MDUFA V Decision	3	1	0		
MDUFA V Decision (SE/NSE)	36	21	1		
MDUFA V Decision Within 90 FDA Days	36	20	1		
510(k)s Pending MDUFA V Decision	0	11	7		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	95.24%	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	1.33	1.19	1.00		
Number With MDUFA V Decision	36	21	1		
Average Number of FDA Days to MDUFA V Decision	77.33	78.10	26.00		
20th Percentile FDA Days to MDUFA V Decision	69	60	26		
40th Percentile FDA Days to MDUFA V Decision	84	79	26		
60th Percentile FDA Days to MDUFA V Decision	89	86	26		
80th Percentile FDA Days to MDUFA V Decision	90	88	26		
Maximum FDA Days to MDUFA V Decision	90	105	26		
Average Number of Industry Days to MDUFA V Decision	48.92	48.67	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	115	82	0		
Maximum Industry Days to MDUFA V Decision	315	180	0		
Average Number of Total Days to MDUFA V Decision	126.25	127.52	26.00		
20th Percentile Total Days to MDUFA V Decision	81	73	26		
40th Percentile Total Days to MDUFA V Decision	88	86	26		
60th Percentile Total Days to MDUFA V Decision	90	90	26		
80th Percentile Total Days to MDUFA V Decision	90	168	26		
Maximum Total Days to MDUFA V Decision	375	266	26		

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	33	8		
Number With MDUFA V Decision	36	21	1		
Number of SE Decision	35	17	1		
Number of NSE Decision	1	4	0		
Number of Withdrawal	2	0	0		
Number of Deleted	1	1	0		
Rate of SE Decision	97.22%	80.95%	100.00%		
Rate of NSE Decision	2.78%	19.05%	0.00%		
Rate of Withdrawal	5.13%	0.00%	0.00%		
Rate of Deleted	2.56%	3.03%	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	0	0	0		
MDUFA V Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA V Decision	0	0	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	N/A	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	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	8	3	0		
MDUFA V Decision Within 90 FDA Days	8	3	0		
510(k)s Pending MDUFA V Decision	0	0	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	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	0		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	0	0	0		
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	1	0	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	1	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	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	0.00		
Number With MDUFA Decision	0	0	0		
Average FDA Days to MDUFA Decision	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
Average Industry Days to MDUFA Decision	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
Average Total Days to MDUFA Decision	0.00	0.00	0.00		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	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	0		
Number With MDUFA Decision	0	0	0		
Number With Granted Decision	0	0	0		
Number With Declined Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	0	0		
Rate of Granted Decision	N/A	N/A	N/A		
Rate of Declined Decision	N/A	N/A	N/A		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Deleted	N/A	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	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	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	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	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	68	62	17		
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	1		
Number Closed Before First RTA Action	7	1	1		
Number Accepted First RTA Cycle [1]	59	60	16		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted First RTA Cycle	0	1	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.64%	0.00%		

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

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

Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	61	61	16		
Number with Non-MDUFA Action [3]	3	0	0		
Number with MDUFA Action	58	61	5		
Written Feedback Provided Within Goal	55	61	5		
Number Pending MDUFA Action	0	0	11		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	58	61	16		
Current Performance Percent Within Goal	94.83%	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 CBER – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	58	61	5		
Average FDA Days to Written Feedback	59.38	60.79	57.43		
20th Percentile FDA Days to Written Feedback	55	54	47		
40th Percentile FDA Days to Written Feedback	60	61	59		
60th Percentile FDA Days to Written Feedback	64	65	65		
80th Percentile FDA Days to Written Feedback	69	69	68		
Maximum FDA Days to Written Feedback	72	70	69		

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	0		
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	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	31	2		
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	1		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	1		
Meeting Minutes Past 15 Days of Meeting	3	5	0		
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	83.87%	100.00%		

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

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	20	15	7		
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.00	0.00		

CBER – Annual General Metric Report for BLA/BLA Resubmissions
****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 2025

#	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	Endosseous Dental Implants and Endosseous Dental Implant Abutments - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and	10/15/2024	Yes	No	N/A	No
2	Q1	Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development	10/18/2024	Yes	No	N/A	No
3	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	11/21/2024	No	Yes	Section 2502 of the Food and Drug Omnibus Reform Act (FDORA)	A-List
4	Q1	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance	11/22/2024	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidance's that are substantially related to the process. CDRH provides the annotation of "no" for guidance's that contain a minimal amount of guidance related to the process.
[3] CDRH Proposed Guidance Development | FDA

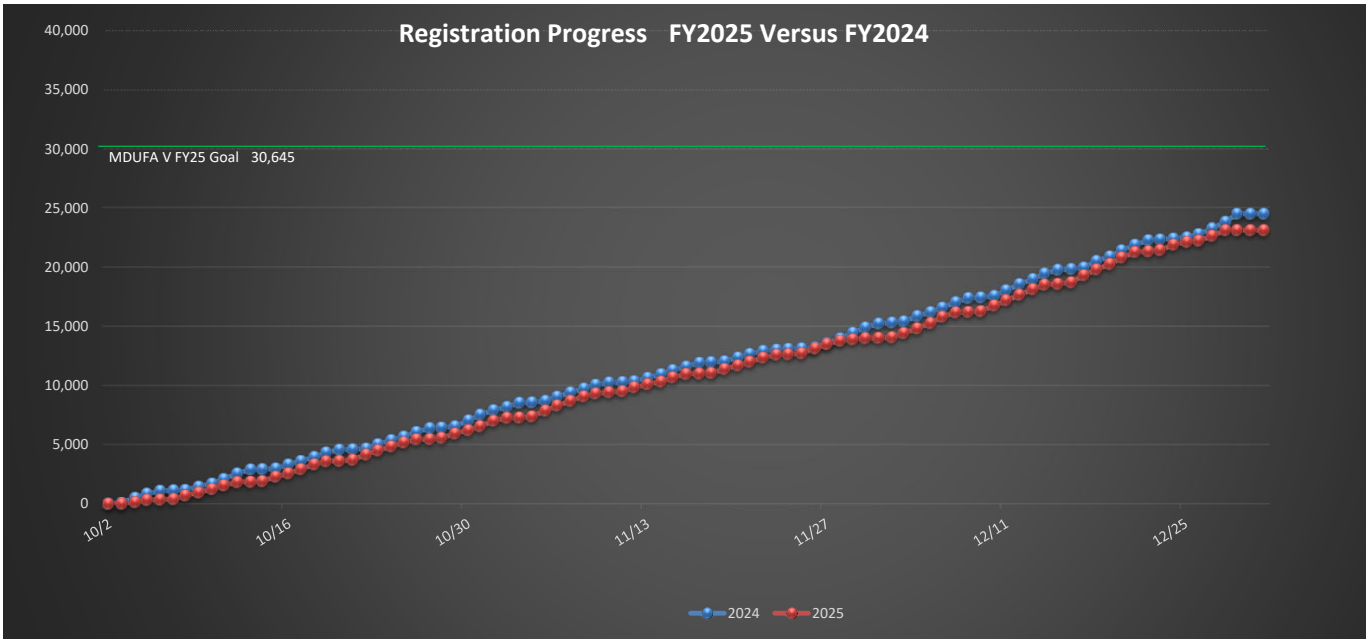
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
5	Q1	[4]Orthopedic Non-Spinal Bone Plates, Screws, and Washers - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions	11/22/2024	Yes	No	N/A	No
6	Q1	[5]Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices	11/26/2024	Yes	No	N/A	No
7	Q1	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence	12/04/2024	Yes	No	N/A	A-List
8	Q1	[4]Global Unique Device Identification Database (GUDID) www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-gudid	12/17/2024	No	No	N/A	No
9	Q1	Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices	12/30/2024	Yes	No	N/A	No

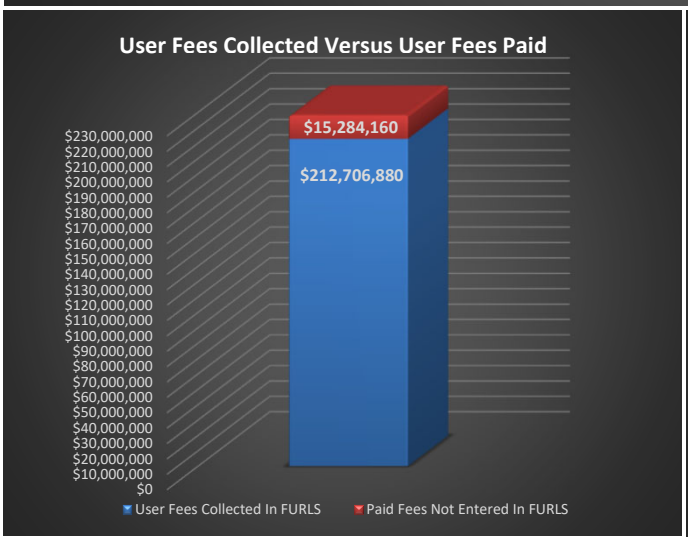
[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)
[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

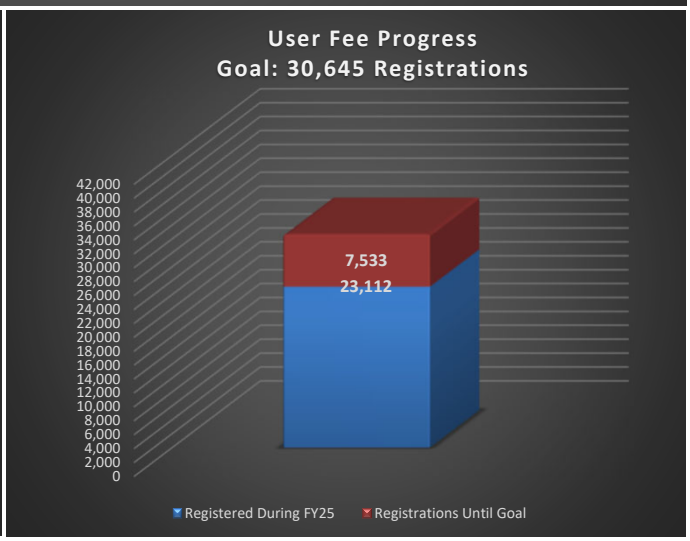
MDUFA V Registrations - 1st Quarter Summary FY2025*

Current Active Registrations by Type	FY25 Q1			FY24 Year End Active Totals			FY25 vs End FY24
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,127	9,482	14,608	6,585	12,235	18,819	77.62%
Contract Manufacturer	993	1,676	2,669	1,249	1,967	3,216	82.99%
Contract Sterilizer	66	151	217	79	178	257	84.44%
Specification Developer	1,129	455	1,584	1,608	563	2,171	72.96%
Reprocessor of Single Use Devices	15	2	17	29	3	32	53.13%
U.S. Manufacturer of Export Only Devices	78	0	78	118	0	118	66.10%
Repackager/Relabeler	754	141	895	1,082	189	1,271	70.42%
Remanufacturer	7	5	12	17	14	31	38.71%
Foreign Exporter/Private Label Distributor		829	829		1,097	1,097	75.57%
Initial Importer	2,321		2,321	3,256		3,256	71.28%
Unknown	4	4	8	1	10	11	72.73%
Total:	**10,494**	**12,745**	**23,239**	**14,024**	**16,256**	**30,280**	**76.75%**

*Note: This data is current as of 12/27/2024







Q1 FY 2025 Medical Device User Fee Collections as December 31, 2024 Excludes Unearned Revenue					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$231,921,904	-$156,133	$231,765,771		
Application Fees	$28,825,598	-$203,013	$28,622,585		
Total	**$260,747,503**	**-$359,146**	**$260,388,356**	**$393,710,000**	**66%**
Medical Device User Fee Collection History Excludes Unearned Revenue, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,738,775	$34,425,417	$28,031,569
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,794,823	$56,962,602	$63,699,312	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,306,430	$122,346,416	$136,098,825	$147,165,318	$137,782,995
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,896,895	$208,692,116	$215,697,178	$275,338,627	$269,130,850
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$322,347,363	$340,209,427	$260,388,356		

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

CDRH Data 1st Quarter FY 2025 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	0	0
PMA		
PDP		
PMR		
BLA		
BLA efficacy supplement		
Panel Track Supplements		
De Novo Classification		
180-Day Supplements		
Real-Time Supplements		
510(k)s		
30-day Notices /135 day supplements*		
513(g)s		
PMA Annual Report		
Total	**0**	**0**

[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**