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

August 27, 2025, 1:00 – 2:00 pm
Teams

Welcome –

FDA MDUFA Performance — Actions through June 30, 2025

- Report on performance goals for 3rd Quarter FY 2025

Guidance Development

Registration and Listing

Qualitative Update on Finances – 3rd Quarter FY 2025

- User fee receipts through the 3rd Quarter

Annual Hiring Goals Update

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 30 June 2025

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

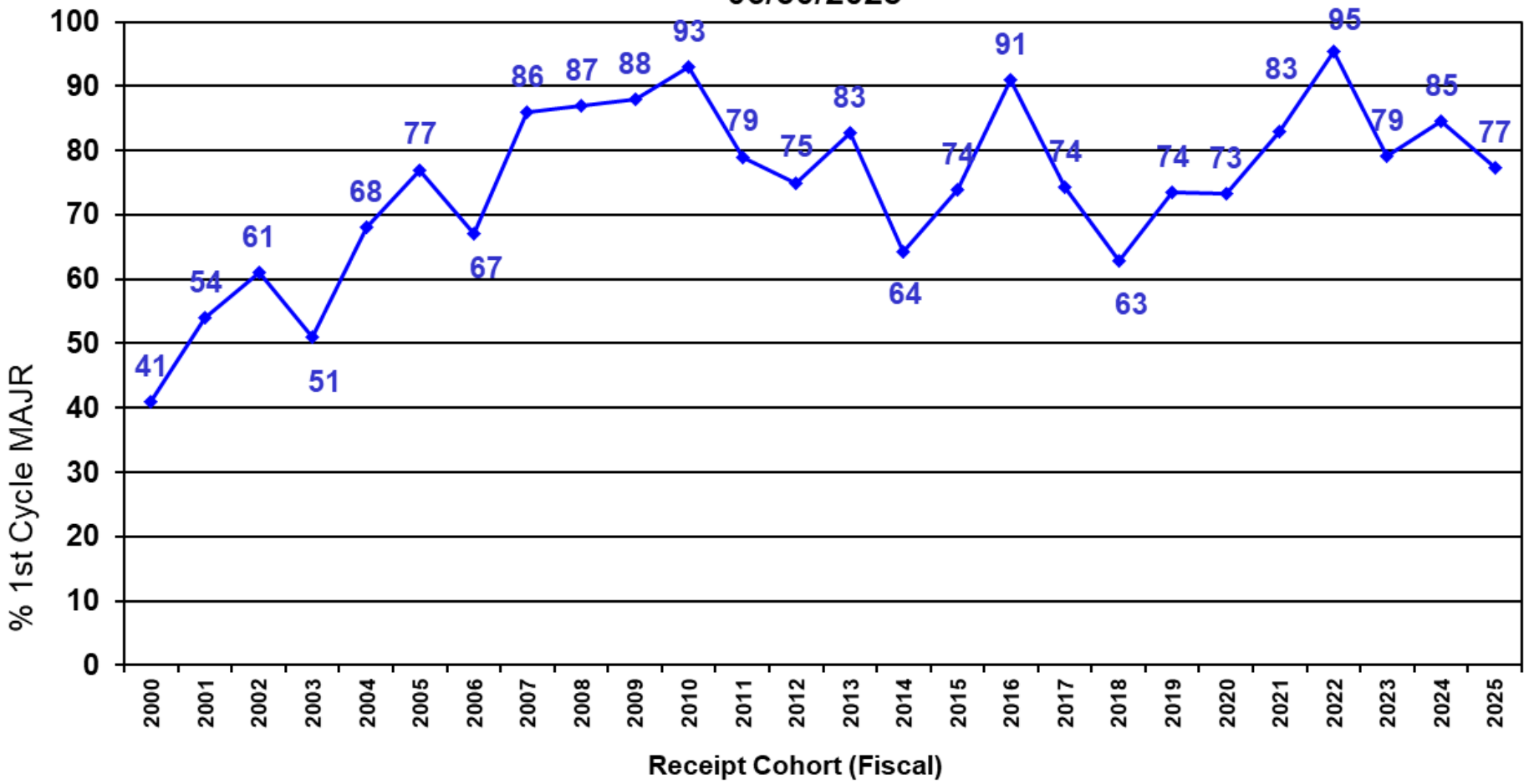
OHT8: Office of Radiological Health

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

PMAs

Q3FY2025

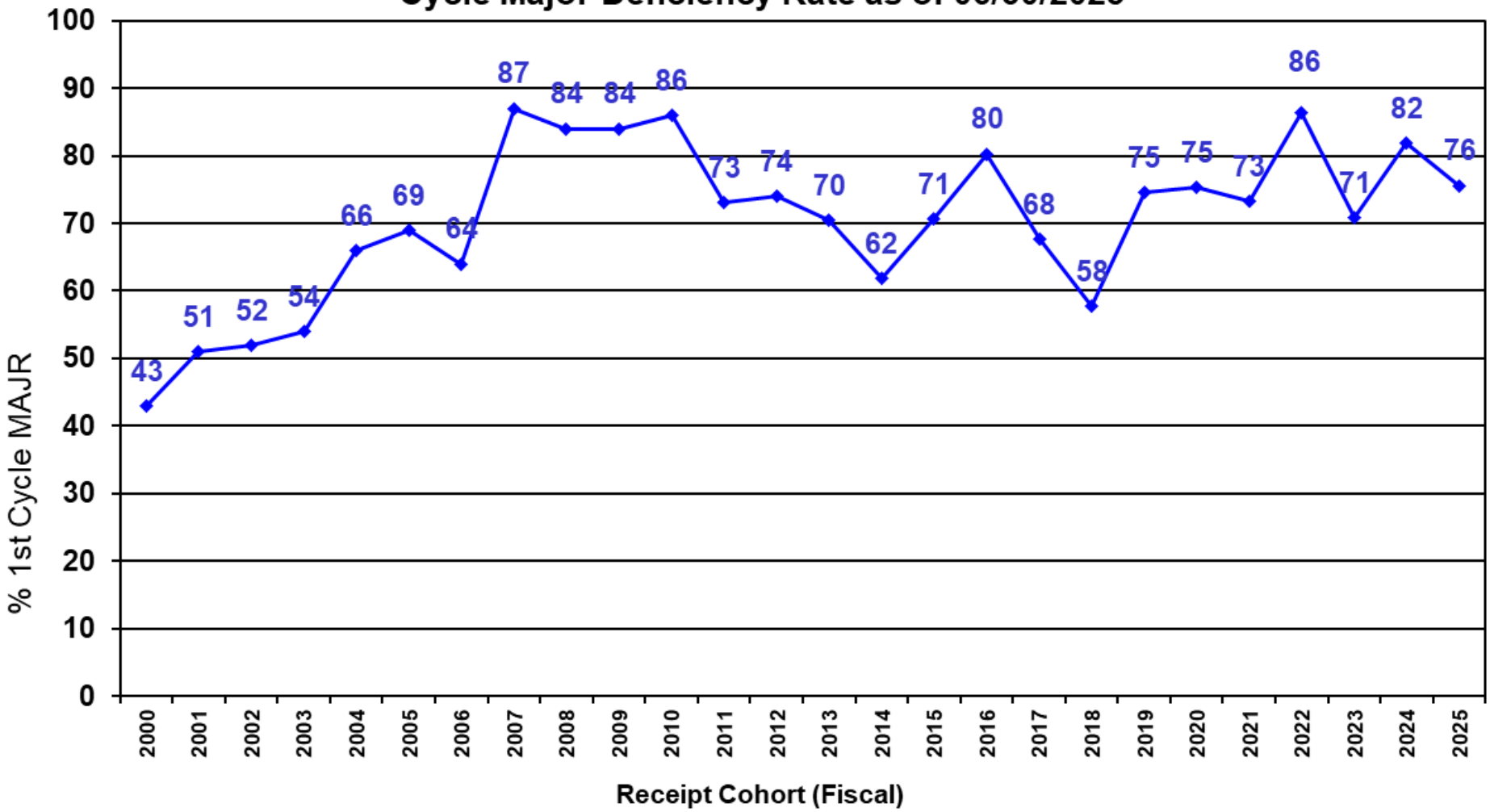
PMA Originals Filed as of 03/31/2025: 1st Cycle Major Deficiency Rate as of 06/30/2025



Data are based upon the number of submissions that received a major deficienecy letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 3/31/25.
Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

% 1st Cycle MAJR PMAO/PTS

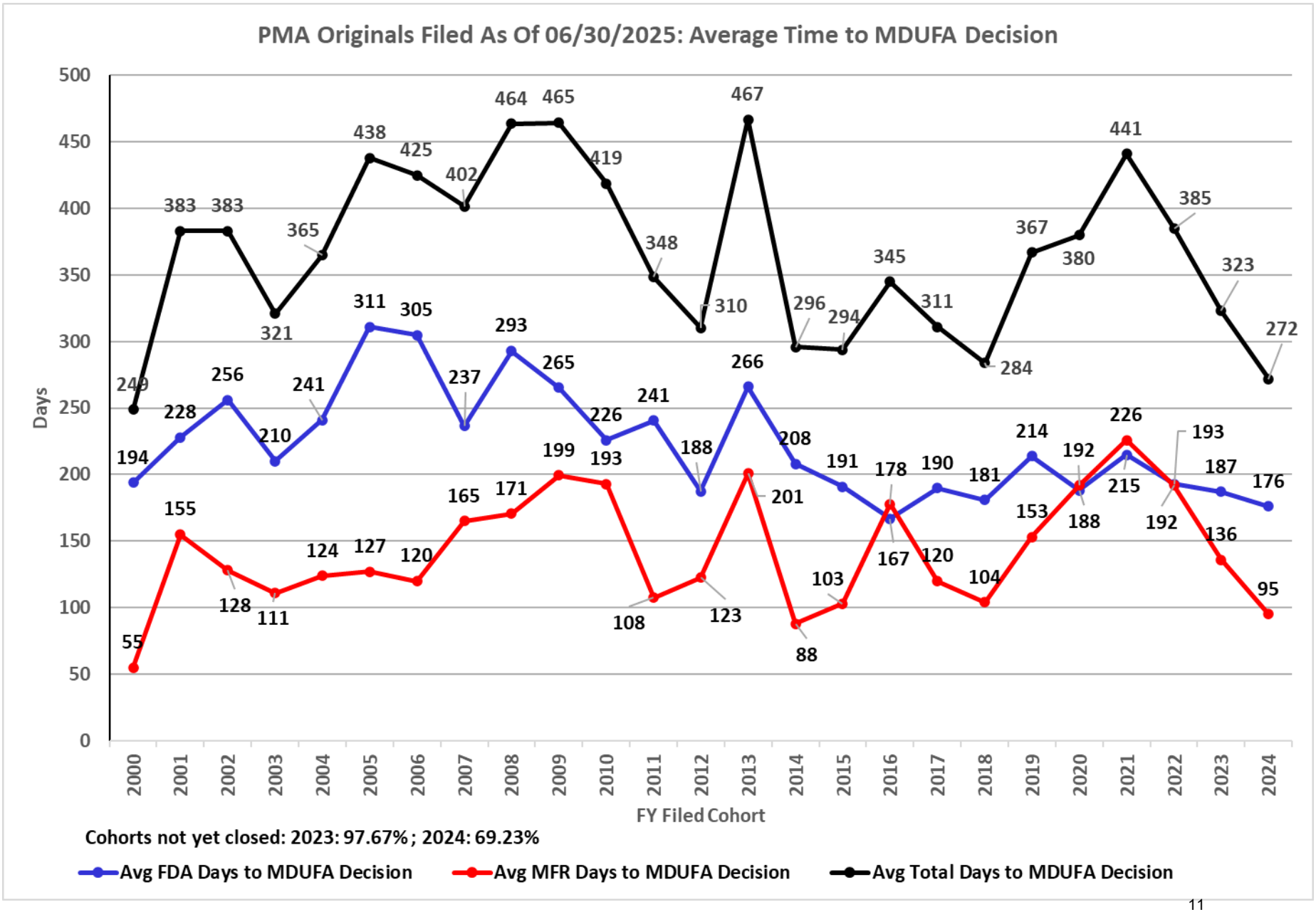
PMA Originals and Panel track Supplements Filed as of 03/31/2025: 1st Cycle Major Deficiency Rate as of 06/30/2025

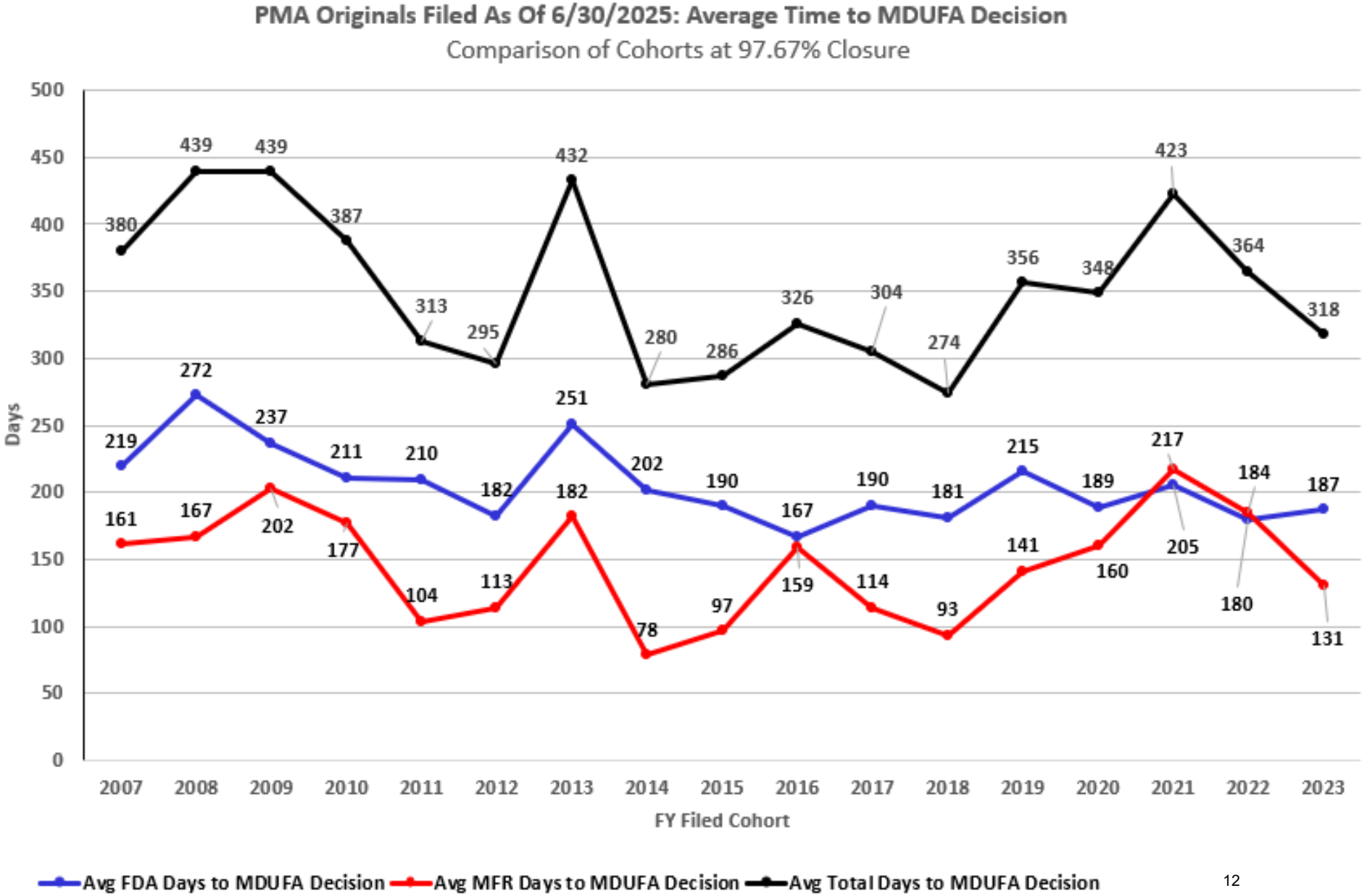


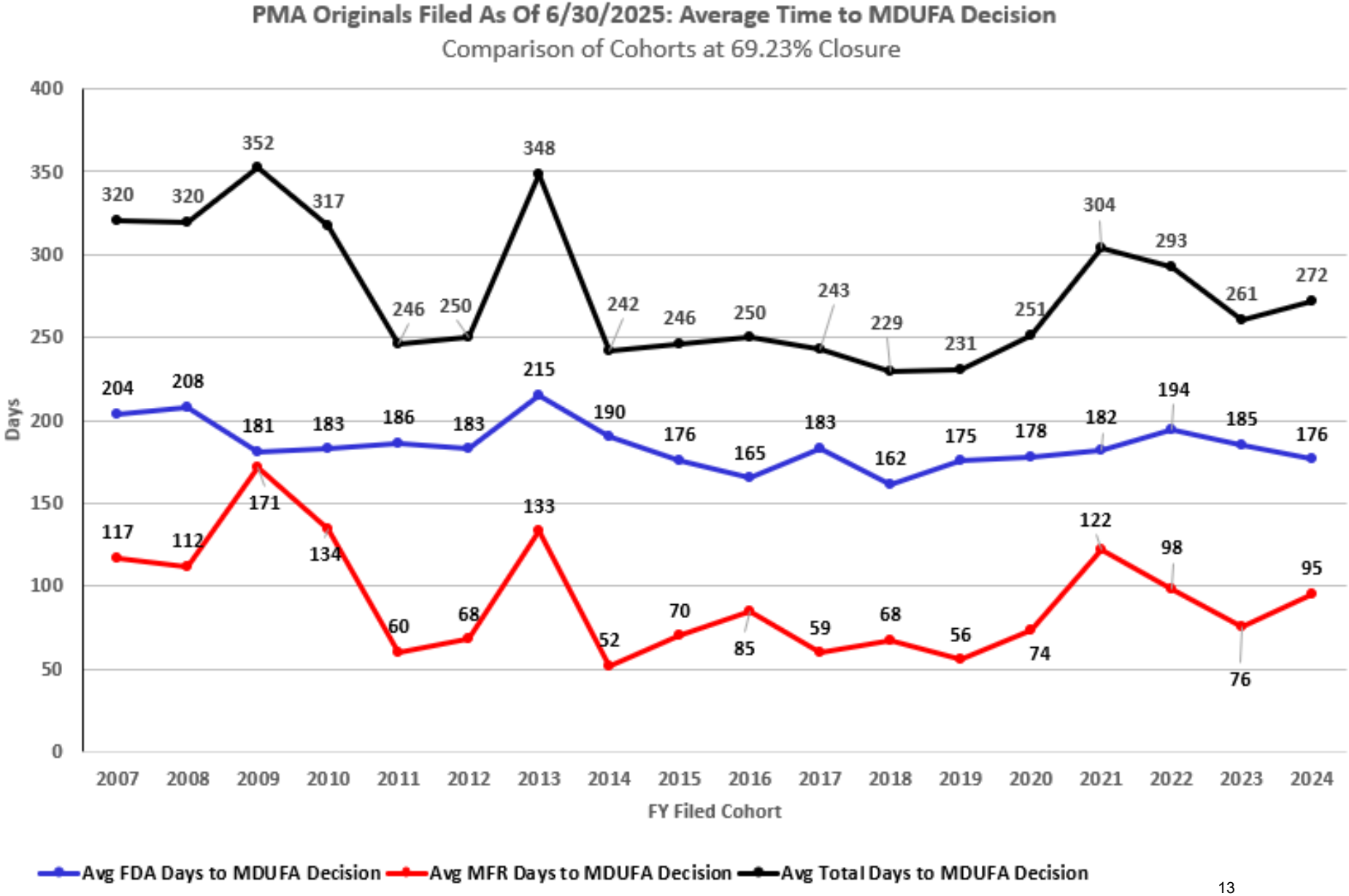
Data are based upon the number of submissions that received a major deficienecy letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 3/31/25.

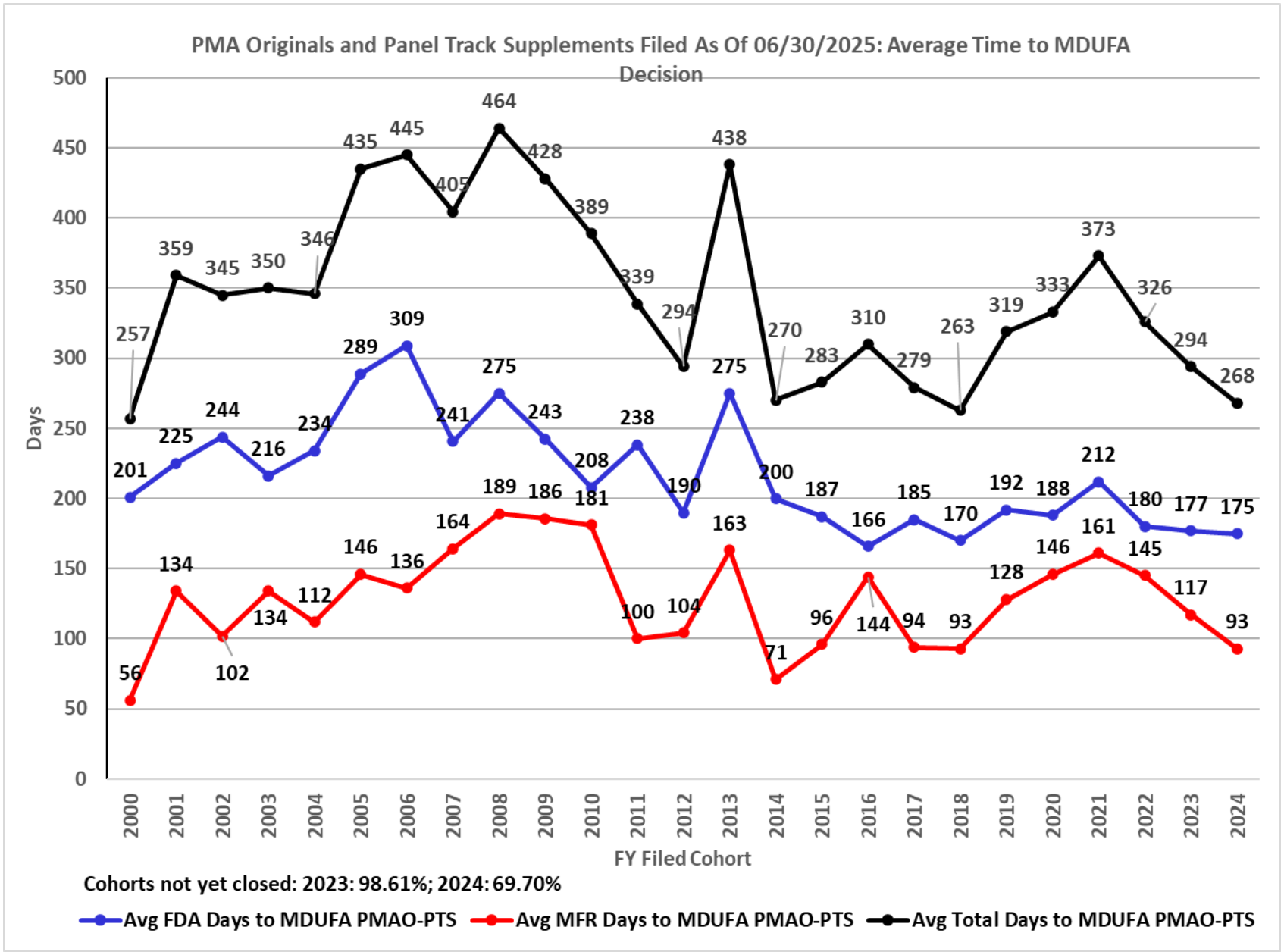
Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

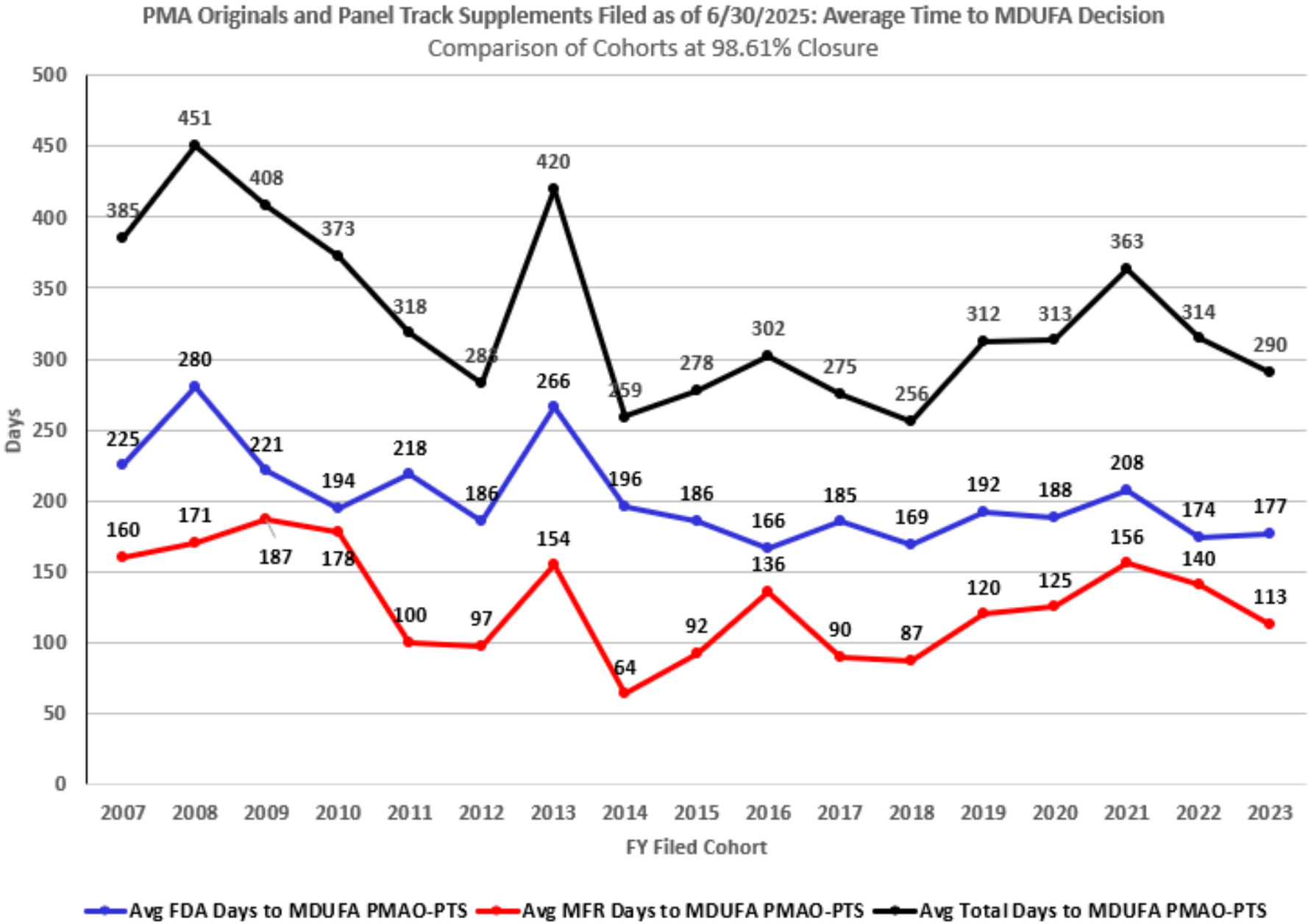
% 1st Cycle MAJR PMAO/PTS

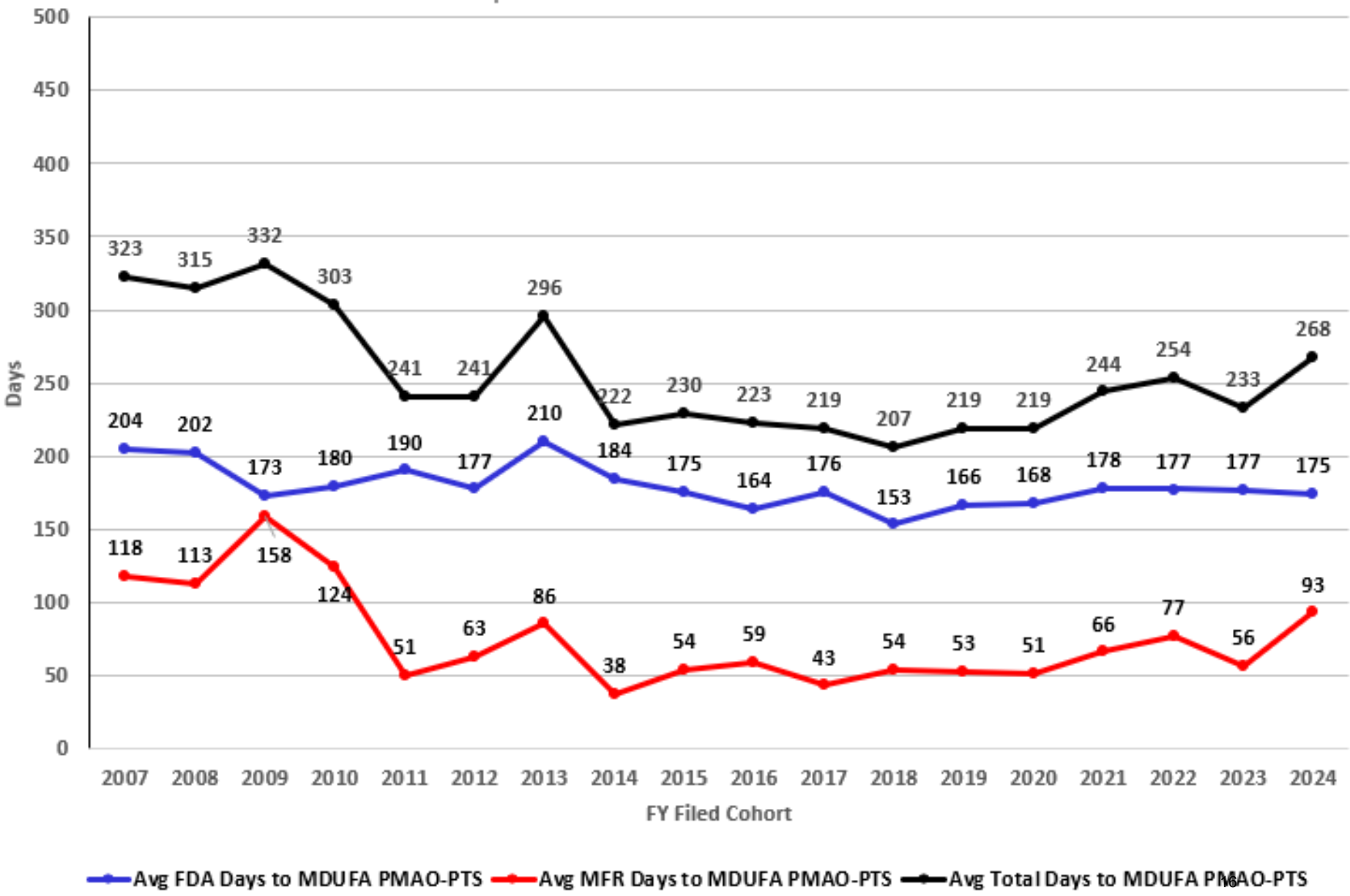

PMA Originals Filed As Of 06/30/2025: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2023: 97.67%; 2024: 69.23%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 6/30/2025: Average Time to MDUFA Decision
Comparison of Cohorts at 97.67% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
FY Filed Cohort
380 439 439 387 313 295 432 280 286 326 304 274 356 348 423 364 318
219 272 237 211 210 182 251 202 190 167 190 181 215 189 205 184 187
161 167 202 177 104 113 182 78 97 159 114 93 141 160 217 180 131
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

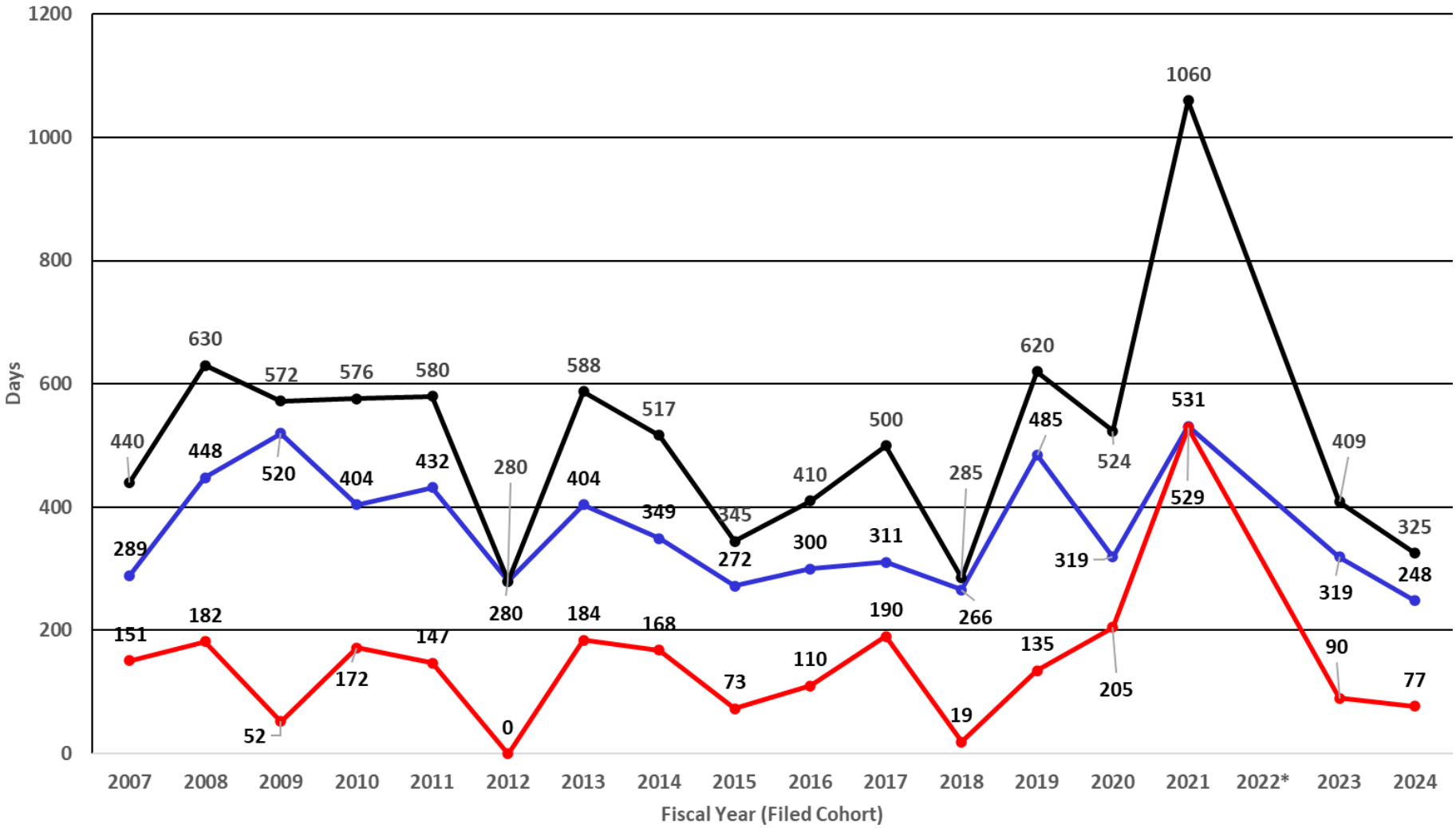

PMA Originals Filed As Of 6/30/2025: Average Time to MDUFA Decision
Comparison of Cohorts at 69.23% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024
0 50 100 150 200 250 300 350 400
320 320 352 317 246 250 348 242 246 250 243 229 231 251 304 293 261 272
204 208 181 183 186 183 215 190 176 165 183 162 175 178 182 194 185 176
117 112 171 134 60 68 133 52 70 85 59 68 56 74 122 98 76 95
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed As Of 06/30/2025: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2023: 98.61%; 2024: 69.70%
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 6/30/2025: Average Time to MDUFA Decision
Comparison of Cohorts at 98.61% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
385 451 408 373 318 283 420 259 278 302 275 256 312 313 363 314 290
225 280 221 194 218 186 266 196 186 166 185 169 192 188 208 174 177
160 171 187 178 100 97 154 64 92 136 90 87 120 125 156 140 113
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 6/30/2025: Average Time to MDUFA Decision
Comparison of Cohorts at 69.70% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
323 315 332 303 241 241 296 222 230 223 219 207 219 219 244 254 233 268
204 202 173 180 190 177 210 184 175 164 176 153 166 168 178 177 177 175
118 113 158 124 51 63 86 38 54 59 43 54 53 51 66 77 56 93
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

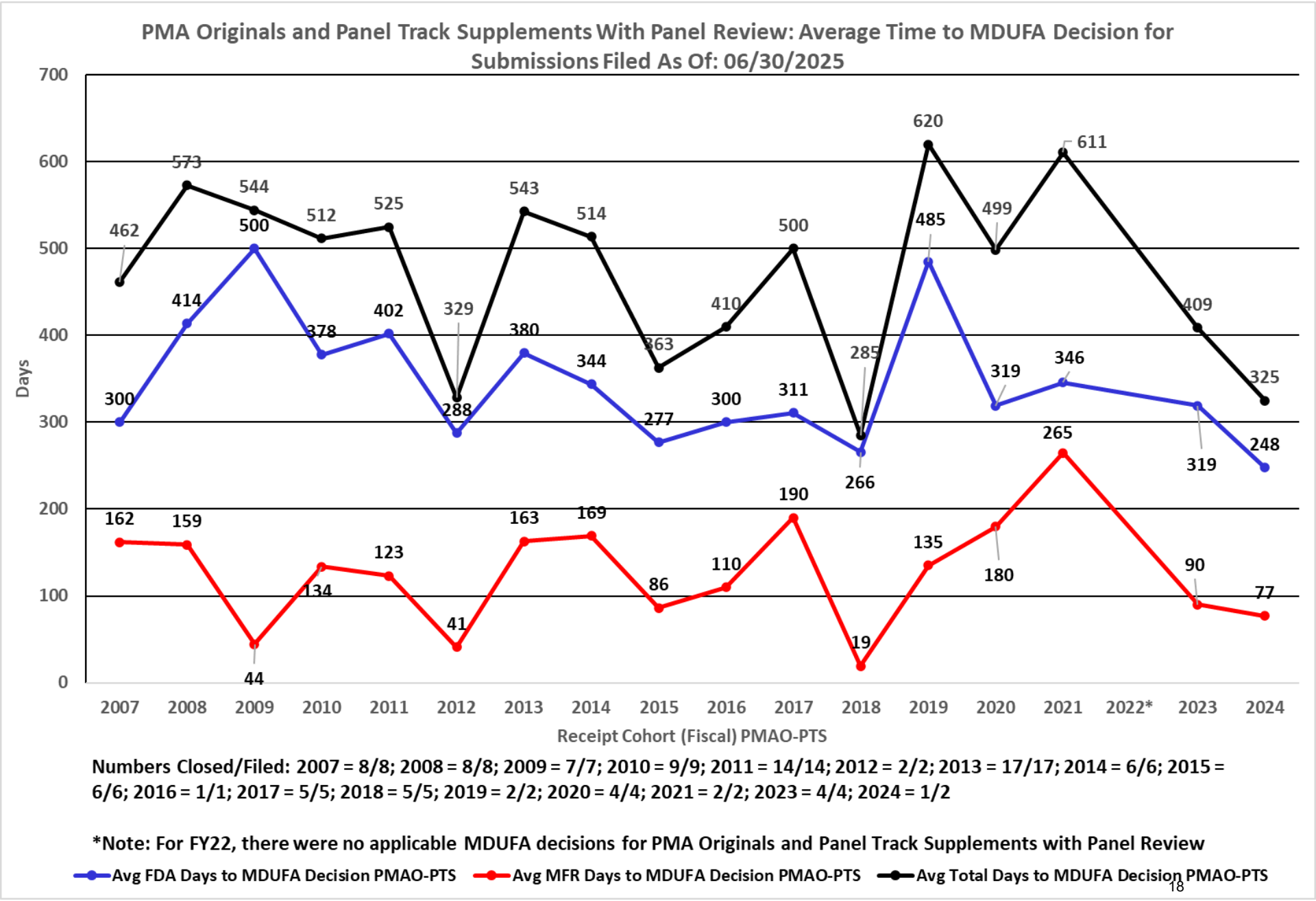
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 06/30/2025



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; 2024 = 1/1

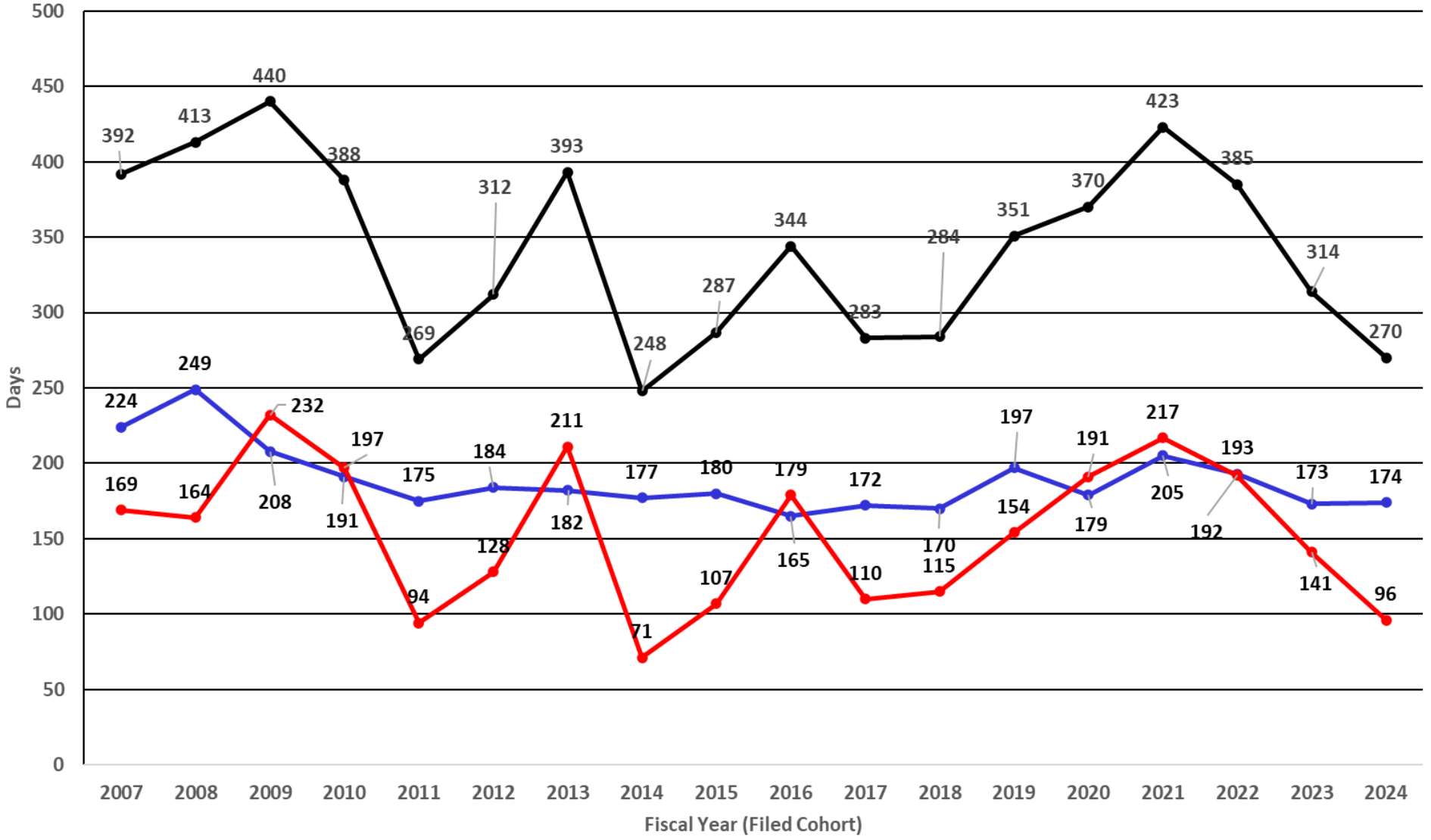
***Note: For FY22, there were no applicable MDUFA decisions for PMA Originals with Panel Review**

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



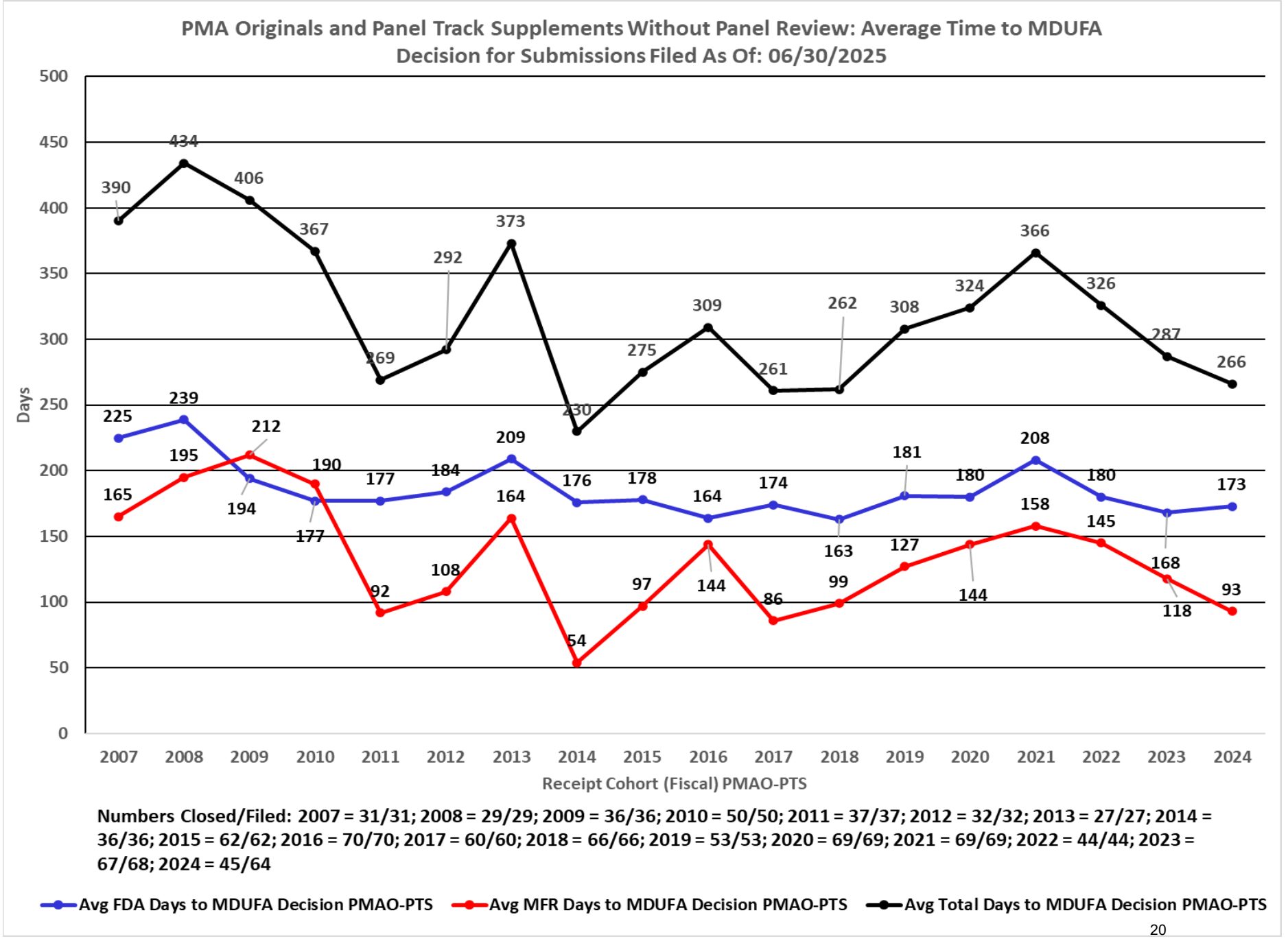
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.

PMA Originals Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 06/30/2025



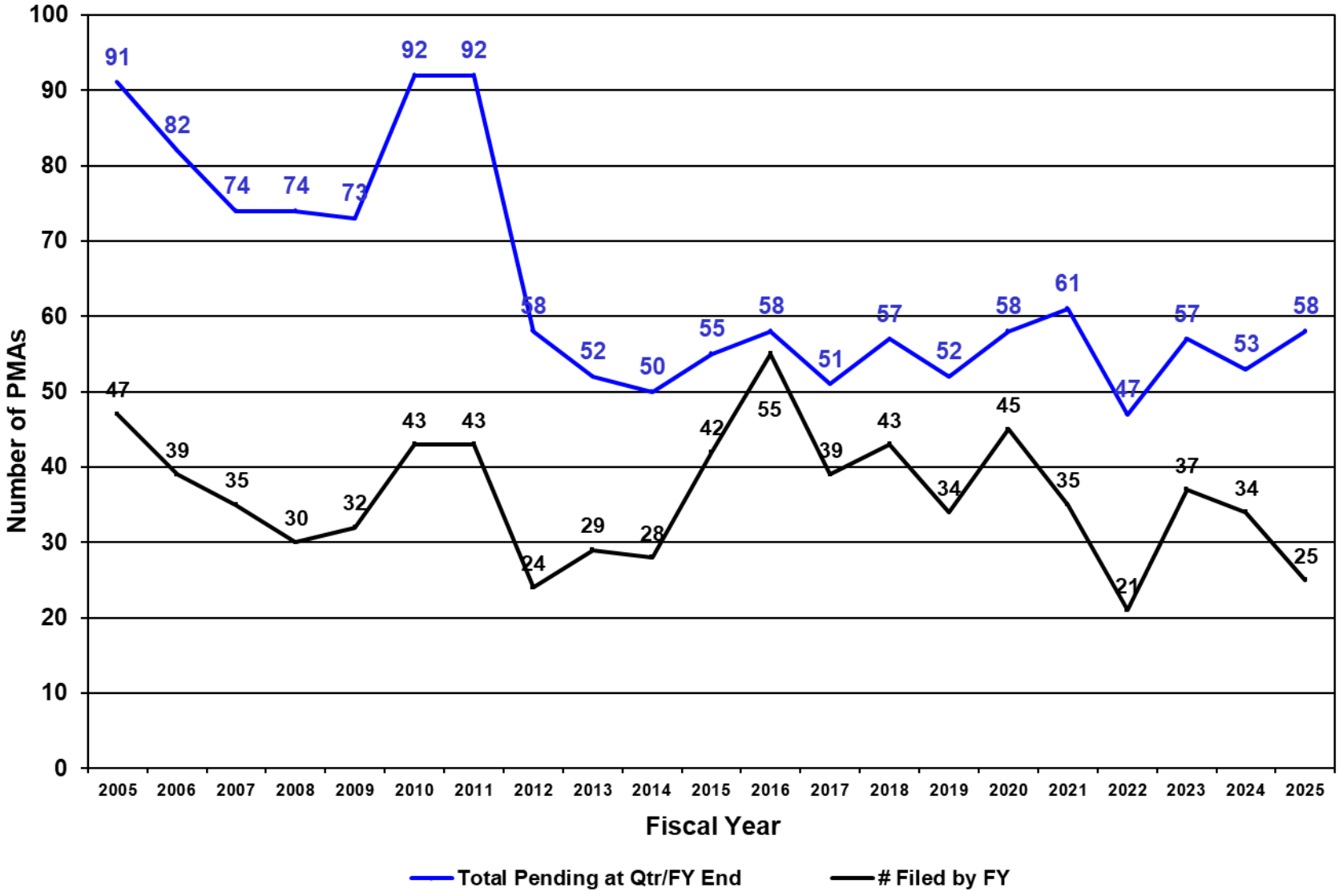
Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 22/22; 2023 = 38/39; 2024 = 26/38

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



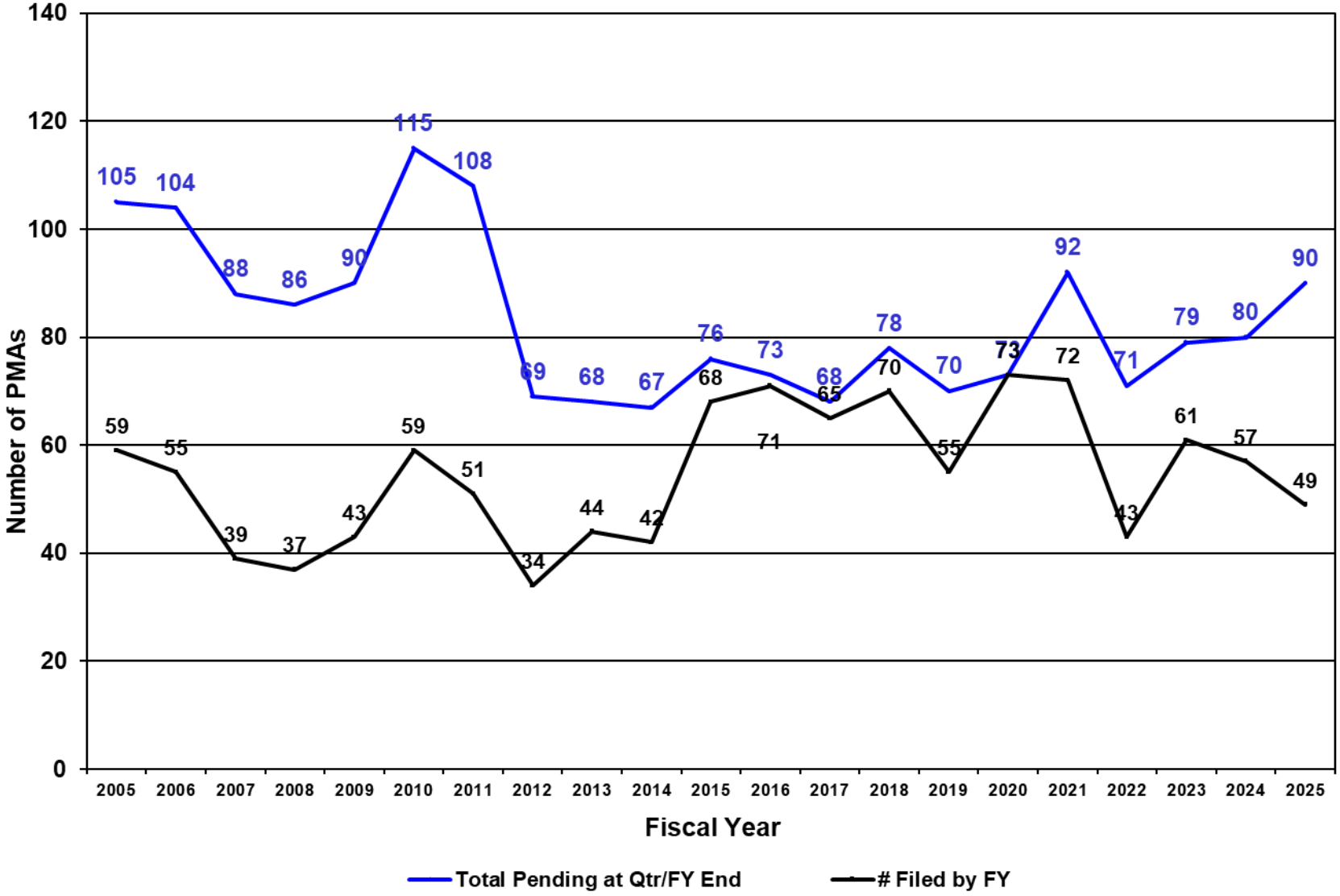
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

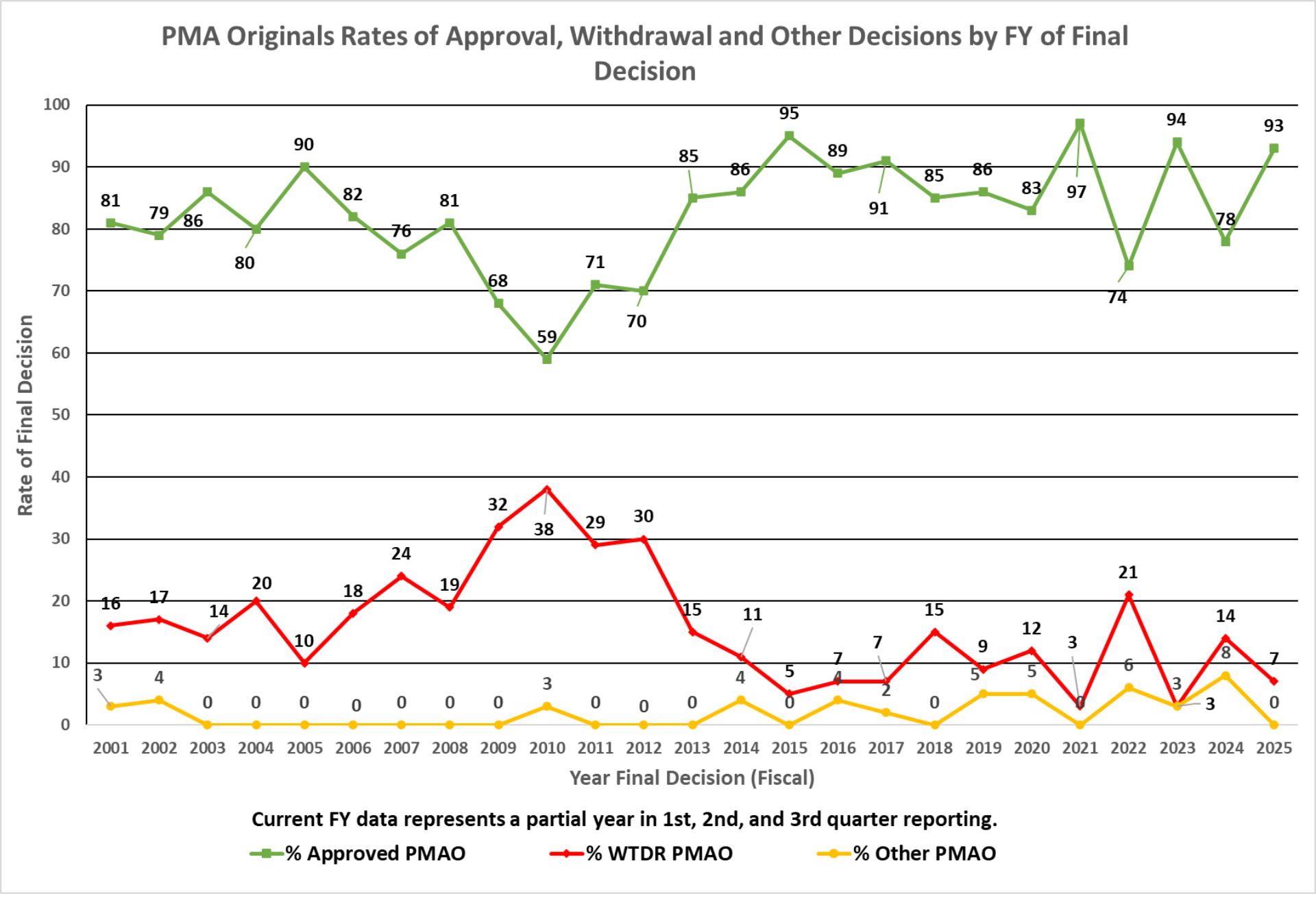


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

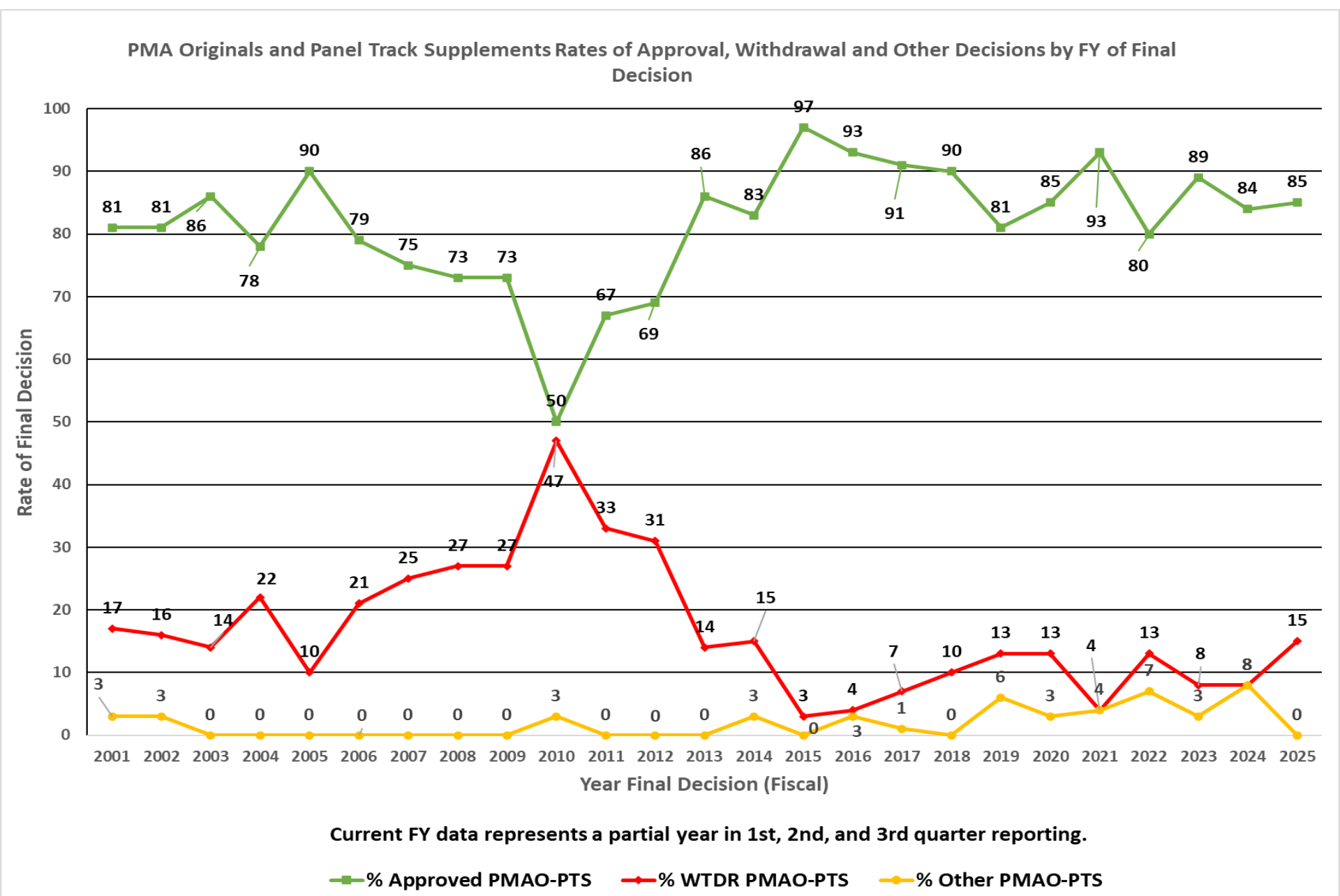
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



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

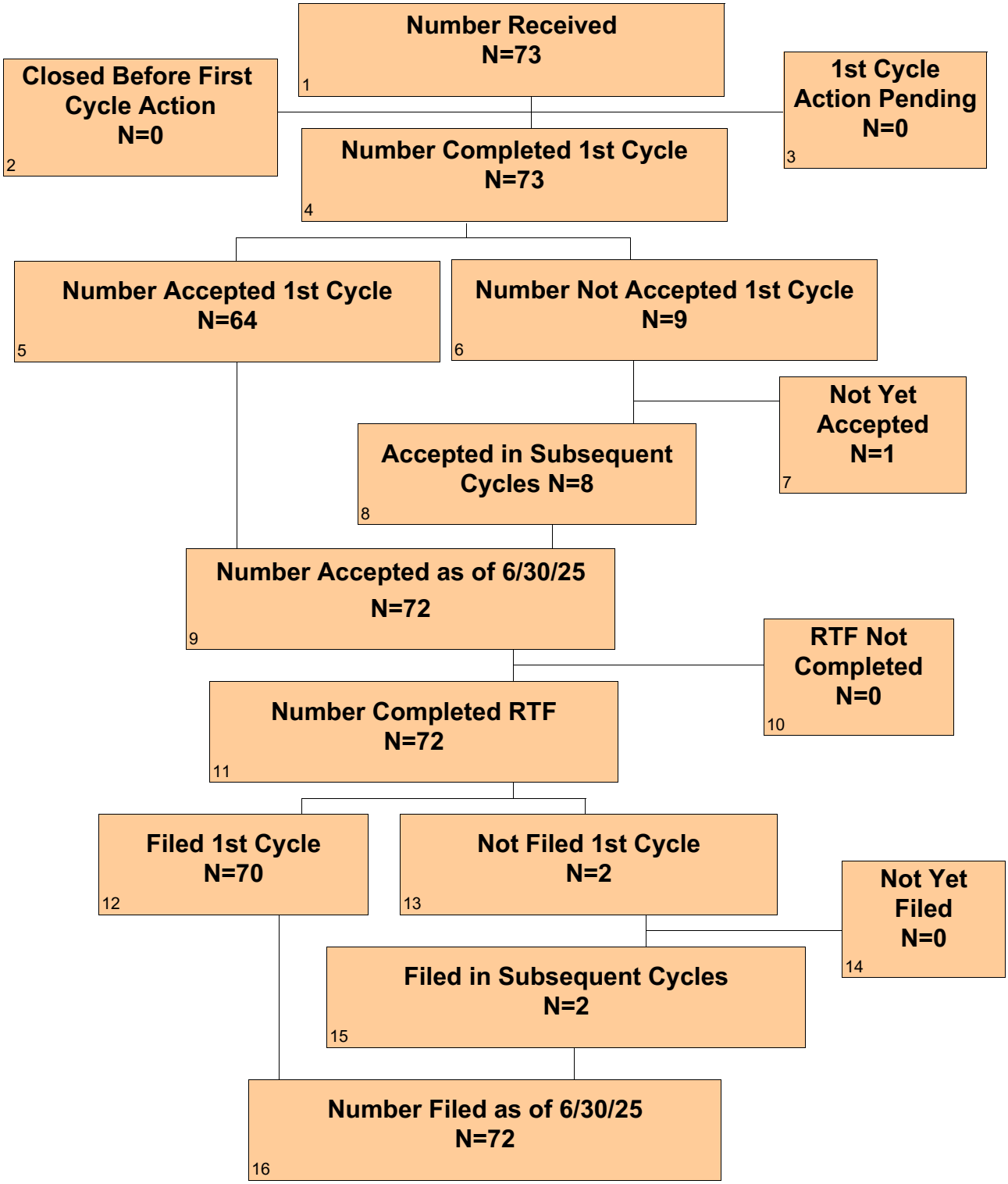


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

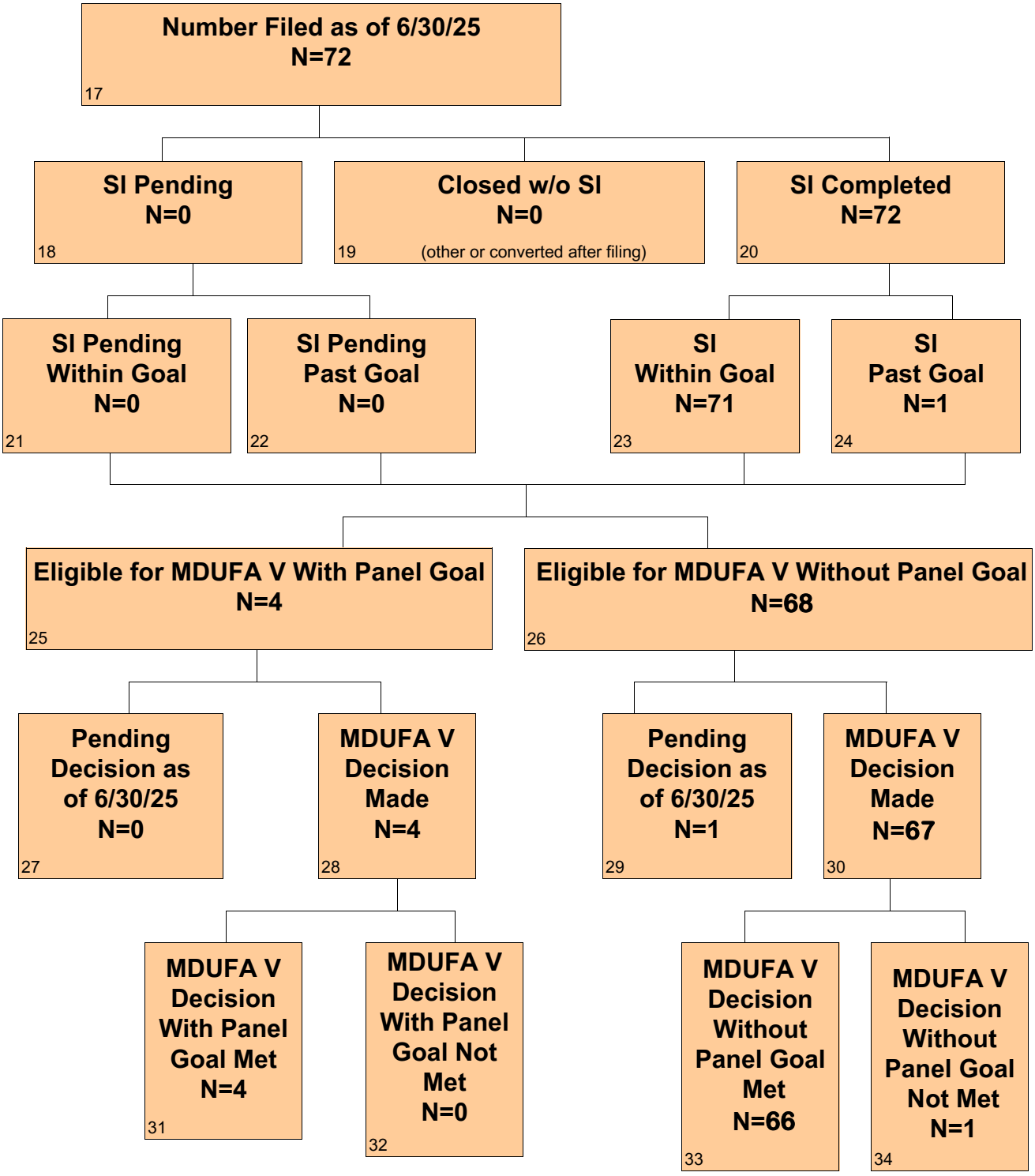


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

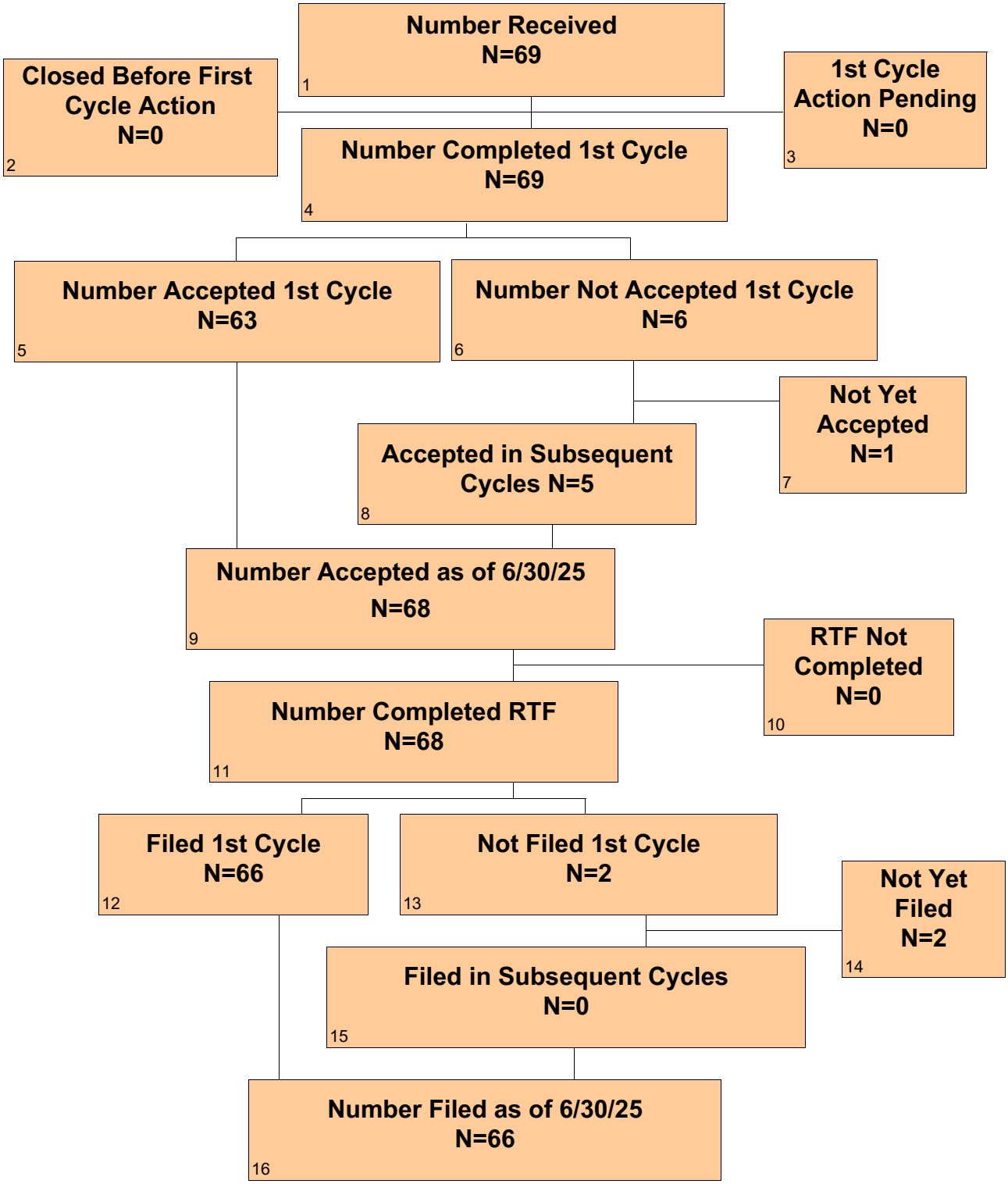
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/25



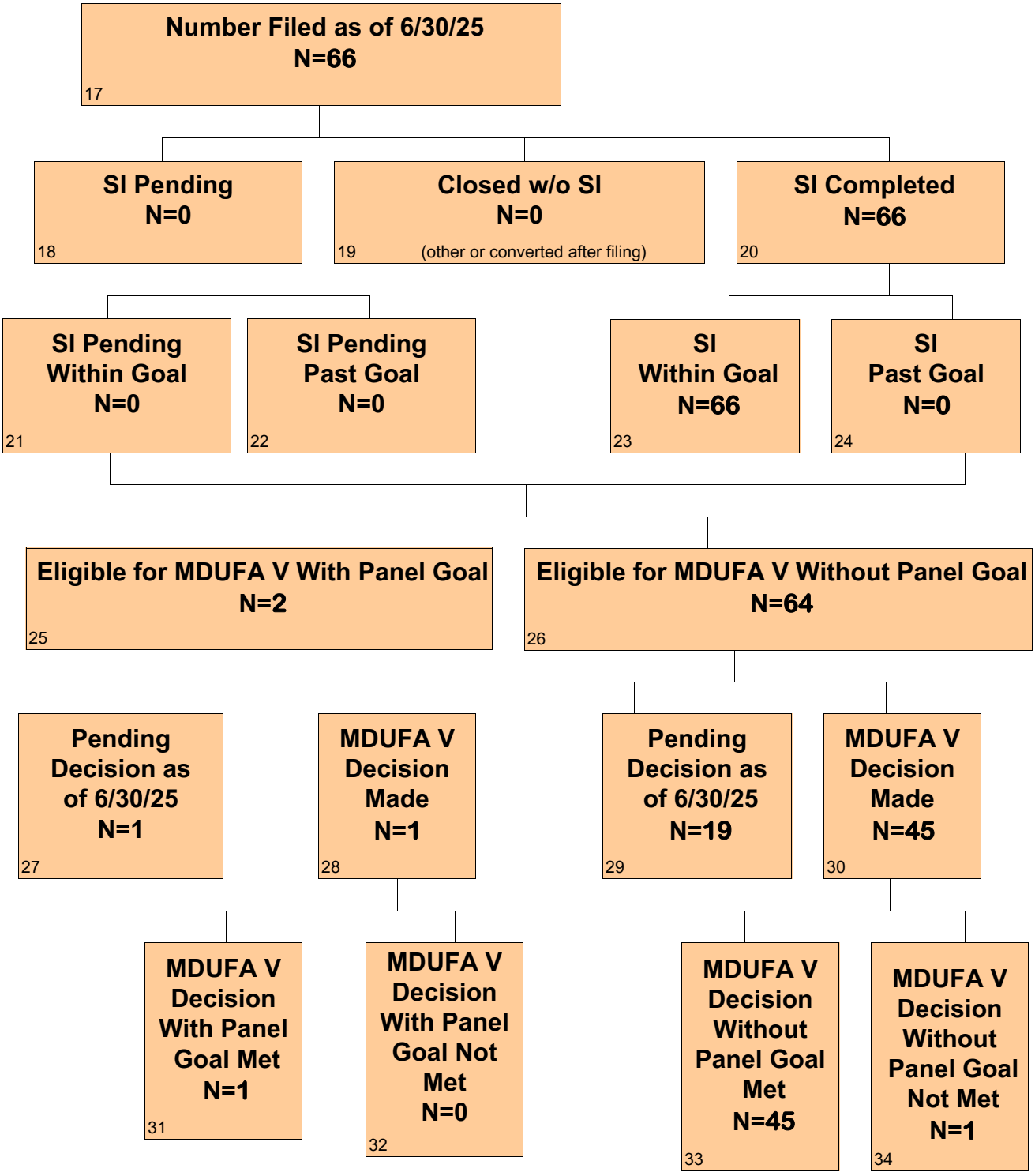
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/25 Con't



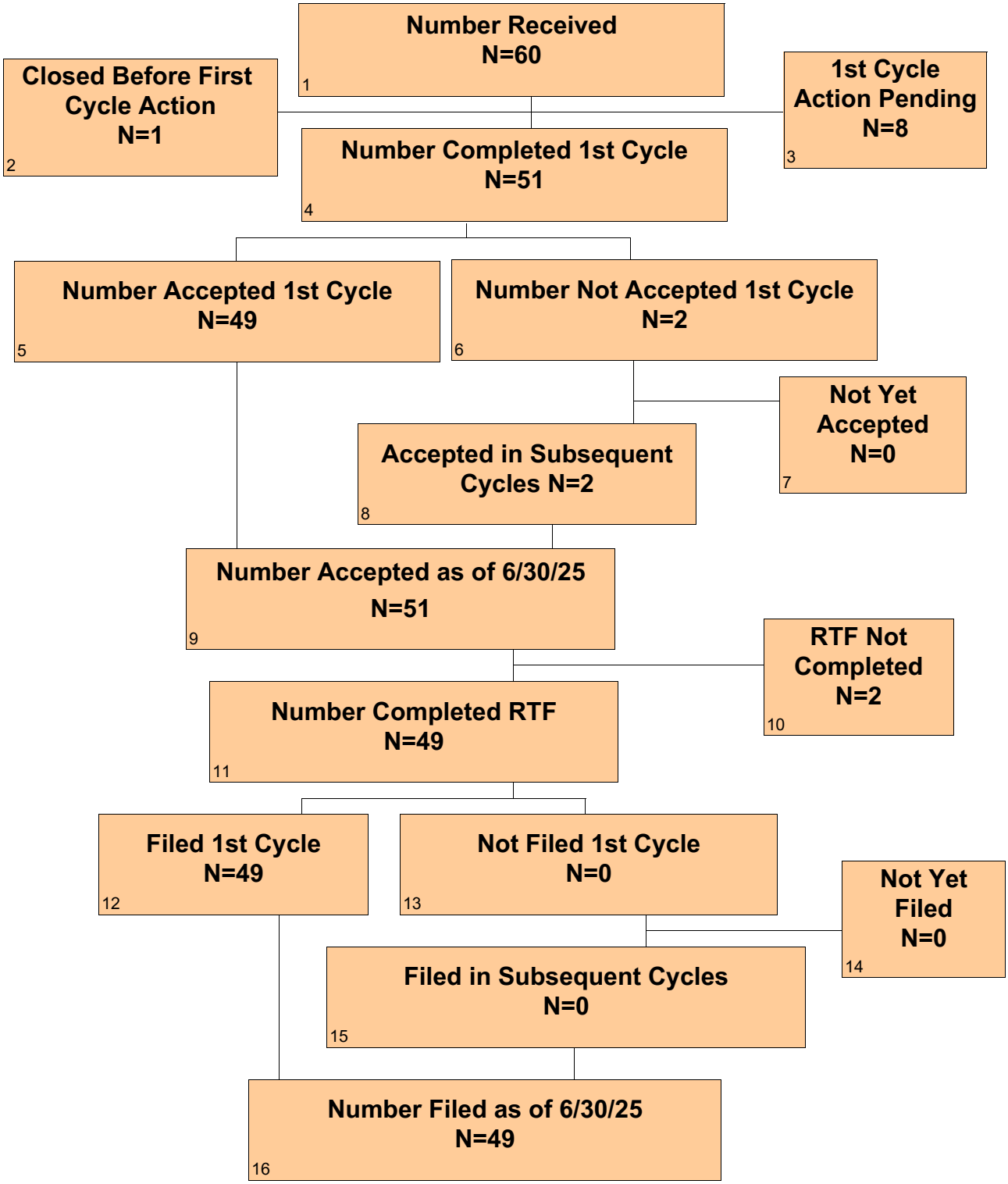
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 6/30/25



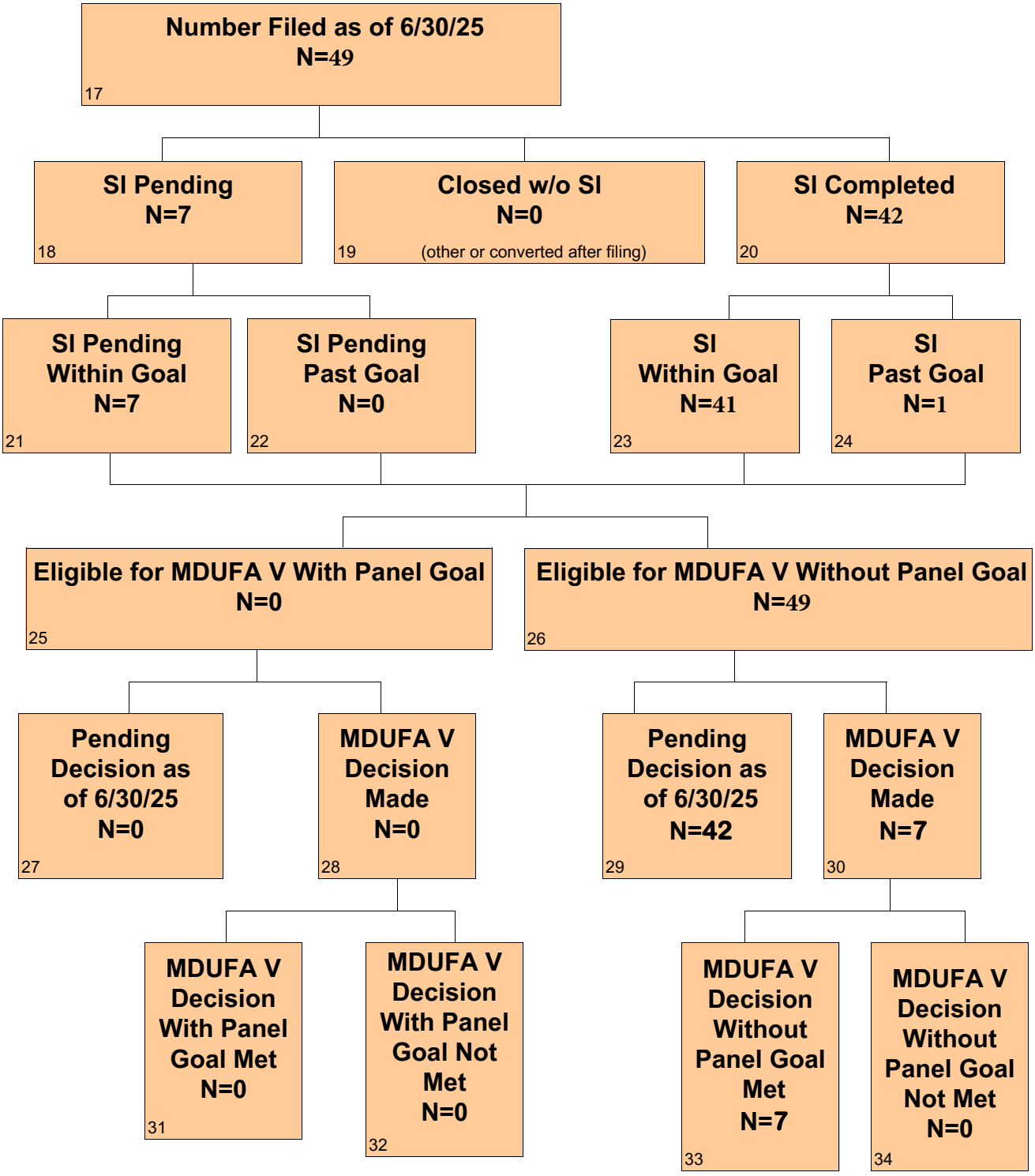
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 6/30/25 Con't



CDRH PMA Original and Panel Track Supplements - FY 2025 as of 6/30/25



CDRH PMA Original and Panel Track Supplements - FY 2025 as of 6/30/25 Con't



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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	60		
Number Closed Before First RTA Action	0	0	1		
Number Accepted First RTA Review	64	61	49		
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	8		
Number Not Accepted for Filing Review on First Cycle	9	6	2		
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.70%	3.92%		

***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	60		
Number Accepted	64	63	49		
Completed RTF	72	68	49		
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	49		
SI Goal Met	71	66	41		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	98.61%	100.00%	97.62%		

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	66	42		
Average Number of FDA Days to Substantive Interaction	87.42	89.12	85.95		
20th Percentile FDA Days to Substantive Interaction	86	88	85		
40th Percentile FDA Days to Substantive Interaction	88	89	88		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	91	153	102		

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	49		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	67	45	7		
MDUFA Decision Goal Met	66	44	7		
PMAs Pending MDUFA Decision	1	19	42		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.51%	97.78%	100.00%		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	4	2	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	1	0		
MDUFA Decision Goal Met	4	1	0		
PMAs Pending MDUFA Decision	0	1	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	67	45	7		
Average FDA Days to MDUFA Decision	168.43	173.04	163.43		
20th Percentile FDA Days to MDUFA Decision	171	176	161		
40th Percentile FDA Days to MDUFA Decision	178	178	170		
60th Percentile FDA Days to MDUFA Decision	180	180	176		
80th Percentile FDA Days to MDUFA Decision	180	180	179		
Maximum FDA Days to MDUFA Decision	271	228	180		
Average Industry Days to MDUFA Decision	118.27	93.22	9.43		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	39	34	0		
60th Percentile Industry Days to MDUFA Decision	98	76	6		
80th Percentile Industry Days to MDUFA Decision	277	168	11		
Maximum Industry Days to MDUFA Decision	362	365	45		
Average Total Days to MDUFA Decision	286.70	266.27	172.86		
20th Percentile Total Days to MDUFA Decision	179	180	168		
40th Percentile Total Days to MDUFA Decision	218	212	178		
60th Percentile Total Days to MDUFA Decision	281	246	183		
80th Percentile Total Days to MDUFA Decision	444	338	189		
Maximum Total Days to MDUFA Decision	536	537	205		

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	1	0		
Average FDA Days to MDUFA Decision	319.00	248.00	N/A		
20th Percentile FDA Days to MDUFA Decision	318	248	0		
40th Percentile FDA Days to MDUFA Decision	318	248	0		
60th Percentile FDA Days to MDUFA Decision	320	248	0		
80th Percentile FDA Days to MDUFA Decision	320	248	0		
Maximum FDA Days to MDUFA Decision	320	248	0		
Average Industry Days to MDUFA Decision	90.00	77.00	N/A		
20th Percentile Industry Days to MDUFA Decision	51	77	0		
40th Percentile Industry Days to MDUFA Decision	61	77	0		
60th Percentile Industry Days to MDUFA Decision	72	77	0		
80th Percentile Industry Days to MDUFA Decision	120	77	0		
Maximum Industry Days to MDUFA Decision	186	77	0		
Average Total Days to MDUFA Decision	409.00	325.00	N/A		
20th Percentile Total Days to MDUFA Decision	370	325	0		
40th Percentile Total Days to MDUFA Decision	381	325	0		
60th Percentile Total Days to MDUFA Decision	392	325	0		
80th Percentile Total Days to MDUFA Decision	439	325	0		
Maximum Total Days to MDUFA Decision	504	325	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	49		
Number with MDUFA Decision	67	45	7		
Number of Withdrawal	3	2	0		
Number of Not Approvable	12	6	0		
Number of Deleted	1	1	0		
Rate of Withdrawal	4.48%	4.44%	0.00%		
Rate of Not Approvable	17.91%	13.33%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	4	2	0		
Number With MDUFA Decision	4	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	0.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	0		
Mean FDA Days for Submissions that Missed the Goal	191.00	228.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	0.00	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	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	2	0		
MDUFA Decision Goal Met	6	2	0		
PMAs Pending MDUFA Decision	0	3	4		
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	10		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	7	1		
MDUFA Decision Goal Met	15	7	1		
PMAs Pending MDUFA Decision	0	3	9		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

***Includes submission that went to panel**

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	6		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	6		
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	6		
Number Accepted	3	6	6		
Completed RTF	8	7	6		
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	6		
SI Goal Met	8	7	5		
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%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	8	7	5		
Average Number of FDA Days to Substantive Interaction	82.00	89.43	88.60		
20th Percentile FDA Days to Substantive Interaction	87	88	87		
40th Percentile FDA Days to Substantive Interaction	90	90	89		
60th Percentile FDA Days to Substantive Interaction	90	90	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	90	90	90		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	8	7	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	7	0		
MDUFA Decision Goal Met	8	7	0		
PMAs Pending MDUFA Decision	0	0	6		
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	8	7	0		
Average FDA Days to MDUFA Decision	138.00	180.00	N/A		
20th Percentile FDA Days to MDUFA Decision	90	180	0		
40th Percentile FDA Days to MDUFA Decision	157	180	0		
60th Percentile FDA Days to MDUFA Decision	179	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	217.75	145.43	N/A		
20th Percentile Industry Days to MDUFA Decision	65	65	0		
40th Percentile Industry Days to MDUFA Decision	247	102	0		
60th Percentile Industry Days to MDUFA Decision	295	148	0		
80th Percentile Industry Days to MDUFA Decision	337	236	0		
Maximum Industry Days to MDUFA Decision	362	311	0		
Average Total Days to MDUFA Decision	355.75	325.43	N/A		
20th Percentile Total Days to MDUFA Decision	245	245	0		
40th Percentile Total Days to MDUFA Decision	354	282	0		
60th Percentile Total Days to MDUFA Decision	456	328	0		
80th Percentile Total Days to MDUFA Decision	478	416	0		
Maximum Total Days to MDUFA Decision	536	491	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	6		
Number with MDUFA Decision	8	7	0		
Number of Withdrawal	1	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	1	0	0		
Rate of Withdrawal	12.50%	0.00%	N/A		
Rate of Not Approvable	0.00%	14.29%	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	22		
Number Closed Before First RTA Action	0	0	1		
Number Accepted First RTA Review	19	17	16		
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	4		
Number Not Accepted for Filing Review on First Cycle	1	1	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%	5.88%		

***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	22		
Number Accepted	19	19	16		
Completed RTF	20	20	15		
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	15		
SI Goal Met	20	19	13		
SI Goal Not Met	0	0	1		
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%	92.86%		

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	19	14		
Average Number of FDA Days to Substantive Interaction	88.25	88.11	88.57		
20th Percentile FDA Days to Substantive Interaction	86	87	88		
40th Percentile FDA Days to Substantive Interaction	90	88	89		
60th Percentile FDA Days to Substantive Interaction	90	90	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	90	90	102		

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	15		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	17	17	5		
MDUFA Decision Goal Met	17	16	5		
PMAs Pending MDUFA Decision	0	1	10		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	94.12%	100.00%		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	17	5		
Average FDA Days to MDUFA Decision	177.65	179.12	175.40		
20th Percentile FDA Days to MDUFA Decision	172	177	173		
40th Percentile FDA Days to MDUFA Decision	177	178	176		
60th Percentile FDA Days to MDUFA Decision	180	180	178		
80th Percentile FDA Days to MDUFA Decision	180	180	179		
Maximum FDA Days to MDUFA Decision	271	228	180		
Average Industry Days to MDUFA Decision	64.29	54.18	4.20		
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	25	4		
80th Percentile Industry Days to MDUFA Decision	113	50	10		
Maximum Industry Days to MDUFA Decision	271	357	11		
Average Total Days to MDUFA Decision	241.94	233.29	179.60		
20th Percentile Total Days to MDUFA Decision	176	178	175		
40th Percentile Total Days to MDUFA Decision	201	184	178		
60th Percentile Total Days to MDUFA Decision	236	204	182		
80th Percentile Total Days to MDUFA Decision	305	230	187		
Maximum Total Days to MDUFA Decision	442	537	190		

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	1	0		
Average FDA Days to MDUFA Decision	319.33	248.00	N/A		
20th Percentile FDA Days to MDUFA Decision	319	248	0		
40th Percentile FDA Days to MDUFA Decision	320	248	0		
60th Percentile FDA Days to MDUFA Decision	320	248	0		
80th Percentile FDA Days to MDUFA Decision	320	248	0		
Maximum FDA Days to MDUFA Decision	320	248	0		
Average Industry Days to MDUFA Decision	58.00	77.00	N/A		
20th Percentile Industry Days to MDUFA Decision	47	77	0		
40th Percentile Industry Days to MDUFA Decision	54	77	0		
60th Percentile Industry Days to MDUFA Decision	61	77	0		
80th Percentile Industry Days to MDUFA Decision	68	77	0		
Maximum Industry Days to MDUFA Decision	76	77	0		
Average Total Days to MDUFA Decision	377.33	325.00	N/A		
20th Percentile Total Days to MDUFA Decision	366	325	0		
40th Percentile Total Days to MDUFA Decision	373	325	0		
60th Percentile Total Days to MDUFA Decision	381	325	0		
80th Percentile Total Days to MDUFA Decision	388	325	0		
Maximum Total Days to MDUFA Decision	396	325	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	15		
Number with MDUFA Decision	17	17	5		
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%	0.00%		
Rate of Not Approvable	17.65%	0.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	1	0		
Number With MDUFA Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	0.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	1	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	228.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	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	3		
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	1		
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%	0.00%		

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	3		
Number Accepted	3	6	2		
Completed RTF	3	7	2		
Number Not Filed	0	1	0		
Rate of Submissions Not Filed	0.00%	14.29%	0.00%		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	6	2		
SI Goal Met	3	6	2		
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%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	6	2		
Average Number of FDA Days to Substantive Interaction	88.33	96.67	87.50		
20th Percentile FDA Days to Substantive Interaction	87	88	86		
40th Percentile FDA Days to Substantive Interaction	88	88	87		
60th Percentile FDA Days to Substantive Interaction	88	90	88		
80th Percentile FDA Days to Substantive Interaction	89	90	89		
Maximum FDA Days to Substantive Interaction	90	153	90		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	6	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	2	0		
MDUFA Decision Goal Met	2	2	0		
PMAs Pending MDUFA Decision	0	4	2		
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	2	0		
Average FDA Days to MDUFA Decision	180.67	174.50	N/A		
20th Percentile FDA Days to MDUFA Decision	175	171	0		
40th Percentile FDA Days to MDUFA Decision	178	173	0		
60th Percentile FDA Days to MDUFA Decision	181	176	0		
80th Percentile FDA Days to MDUFA Decision	186	178	0		
Maximum FDA Days to MDUFA Decision	191	180	0		
Average Industry Days to MDUFA Decision	18.67	138.00	N/A		
20th Percentile Industry Days to MDUFA Decision	11	107	0		
40th Percentile Industry Days to MDUFA Decision	22	128	0		
60th Percentile Industry Days to MDUFA Decision	28	148	0		
80th Percentile Industry Days to MDUFA Decision	28	169	0		
Maximum Industry Days to MDUFA Decision	28	189	0		
Average Total Days to MDUFA Decision	199.33	312.50	N/A		
20th Percentile Total Days to MDUFA Decision	187	285	0		
40th Percentile Total Days to MDUFA Decision	196	303	0		
60th Percentile Total Days to MDUFA Decision	204	322	0		
80th Percentile Total Days to MDUFA Decision	211	340	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	2		
Number with MDUFA Decision	3	2	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	8		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	9	6	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	3		
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%	20.00%		

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

Table 1.2 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	8		
Number Accepted	9	6	4		
Completed RTF	9	6	5		
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	5		
SI Goal Met	9	6	4		
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%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	9	6	4		
Average Number of FDA Days to Substantive Interaction	88.78	89.33	87.00		
20th Percentile FDA Days to Substantive Interaction	88	89	86		
40th Percentile FDA Days to Substantive Interaction	90	89	86		
60th Percentile FDA Days to Substantive Interaction	90	90	88		
80th Percentile FDA Days to Substantive Interaction	90	90	88		
Maximum FDA Days to Substantive Interaction	90	90	89		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	9	5	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	3	0		
MDUFA Decision Goal Met	8	3	0		
PMAs Pending MDUFA Decision	1	2	5		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	1	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	3	0		
Average FDA Days to MDUFA Decision	179.00	148.33	N/A		
20th Percentile FDA Days to MDUFA Decision	178	124	0		
40th Percentile FDA Days to MDUFA Decision	179	159	0		
60th Percentile FDA Days to MDUFA Decision	180	177	0		
80th Percentile FDA Days to MDUFA Decision	180	178	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
Average Industry Days to MDUFA Decision	60.38	258.67	N/A		
20th Percentile Industry Days to MDUFA Decision	0	176	0		
40th Percentile Industry Days to MDUFA Decision	32	295	0		
60th Percentile Industry Days to MDUFA Decision	53	356	0		
80th Percentile Industry Days to MDUFA Decision	64	361	0		
Maximum Industry Days to MDUFA Decision	264	365	0		
Average Total Days to MDUFA Decision	239.38	407.00	N/A		
20th Percentile Total Days to MDUFA Decision	179	324	0		
40th Percentile Total Days to MDUFA Decision	210	411	0		
60th Percentile Total Days to MDUFA Decision	233	469	0		
80th Percentile Total Days to MDUFA Decision	244	500	0		
Maximum Total Days to MDUFA Decision	444	530	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	5		
Number with MDUFA Decision	8	3	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	1	0		
Number of Deleted	0	1	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	12.50%	33.33%	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	5		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	5	6	5		
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	5		
Number Accepted	5	6	5		
Completed RTF	6	7	5		
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	5		
SI Goal Met	5	7	5		
SI Goal Not Met	1	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	83.33%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	6	7	5		
Average Number of FDA Days to Substantive Interaction	88.50	86.43	89.00		
20th Percentile FDA Days to Substantive Interaction	88	86	88		
40th Percentile FDA Days to Substantive Interaction	90	89	89		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	91	90	90		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	7	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	5	0		
MDUFA Decision Goal Met	6	5	0		
PMAs Pending MDUFA Decision	0	2	5		
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	5	0		
Average FDA Days to MDUFA Decision	175.33	159.40	N/A		
20th Percentile FDA Days to MDUFA Decision	179	158	0		
40th Percentile FDA Days to MDUFA Decision	180	177	0		
60th Percentile FDA Days to MDUFA Decision	180	177	0		
80th Percentile FDA Days to MDUFA Decision	180	178	0		
Maximum FDA Days to MDUFA Decision	180	178	0		
Average Industry Days to MDUFA Decision	55.17	92.00	N/A		
20th Percentile Industry Days to MDUFA Decision	0	29	0		
40th Percentile Industry Days to MDUFA Decision	37	57	0		
60th Percentile Industry Days to MDUFA Decision	71	84	0		
80th Percentile Industry Days to MDUFA Decision	101	133	0		
Maximum Industry Days to MDUFA Decision	122	249	0		
Average Total Days to MDUFA Decision	230.50	251.40	N/A		
20th Percentile Total Days to MDUFA Decision	180	207	0		
40th Percentile Total Days to MDUFA Decision	217	234	0		
60th Percentile Total Days to MDUFA Decision	251	261	0		
80th Percentile Total Days to MDUFA Decision	281	291	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	5		
Number with MDUFA Decision	6	5	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%	20.00%	N/A		
Rate of Not Approvable	16.67%	40.00%	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	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	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	2		
Completed RTF	5	3	2		
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	2		
SI Goal Met	5	3	2		
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%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	5	3	2		
Average Number of FDA Days to Substantive Interaction	85.40	88.00	83.50		
20th Percentile FDA Days to Substantive Interaction	84	87	81		
40th Percentile FDA Days to Substantive Interaction	86	87	83		
60th Percentile FDA Days to Substantive Interaction	87	88	84		
80th Percentile FDA Days to Substantive Interaction	88	89	86		
Maximum FDA Days to Substantive Interaction	88	90	88		

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	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	5	2	1		
MDUFA Decision Goal Met	5	2	1		
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%	100.00%		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	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	1		
Average FDA Days to MDUFA Decision	173.80	179.00	107.00		
20th Percentile FDA Days to MDUFA Decision	169	178	107		
40th Percentile FDA Days to MDUFA Decision	175	179	107		
60th Percentile FDA Days to MDUFA Decision	178	179	107		
80th Percentile FDA Days to MDUFA Decision	179	180	107		
Maximum FDA Days to MDUFA Decision	180	180	107		
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	107.00		
20th Percentile Total Days to MDUFA Decision	241	323	107		
40th Percentile Total Days to MDUFA Decision	309	323	107		
60th Percentile Total Days to MDUFA Decision	417	324	107		
80th Percentile Total Days to MDUFA Decision	530	324	107		
Maximum Total Days to MDUFA Decision	536	325	107		

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	2		
Number with MDUFA Decision	5	2	1		
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%	0.00%		
Rate of Not Approvable	60.00%	100.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	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	14		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	21	14	14		
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	14		
Number Accepted	21	14	14		
Completed RTF	21	15	14		
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	14		
SI Goal Met	21	15	10		
SI Goal Not Met	0	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	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	21	15	10		
Average Number of FDA Days to Substantive Interaction	88.14	88.60	79.20		
20th Percentile FDA Days to Substantive Interaction	87	88	84		
40th Percentile FDA Days to Substantive Interaction	87	89	86		
60th Percentile FDA Days to Substantive Interaction	89	89	88		
80th Percentile FDA Days to Substantive Interaction	90	90	89		
Maximum FDA Days to Substantive Interaction	90	90	90		

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	20	15	14		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	9	1		
MDUFA Decision Goal Met	20	9	1		
PMAs Pending MDUFA Decision	0	6	13		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	1	0	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	20	9	1		
Average FDA Days to MDUFA Decision	163.30	170.33	160.00		
20th Percentile FDA Days to MDUFA Decision	136	167	160		
40th Percentile FDA Days to MDUFA Decision	178	179	160		
60th Percentile FDA Days to MDUFA Decision	179	180	160		
80th Percentile FDA Days to MDUFA Decision	180	180	160		
Maximum FDA Days to MDUFA Decision	180	180	160		
Average Industry Days to MDUFA Decision	162.25	50.56	45.00		
20th Percentile Industry Days to MDUFA Decision	0	0	45		
40th Percentile Industry Days to MDUFA Decision	68	31	45		
60th Percentile Industry Days to MDUFA Decision	236	48	45		
80th Percentile Industry Days to MDUFA Decision	322	72	45		
Maximum Industry Days to MDUFA Decision	354	189	45		
Average Total Days to MDUFA Decision	325.55	220.89	205.00		
20th Percentile Total Days to MDUFA Decision	179	177	205		
40th Percentile Total Days to MDUFA Decision	247	208	205		
60th Percentile Total Days to MDUFA Decision	364	216	205		
80th Percentile Total Days to MDUFA Decision	502	236	205		
Maximum Total Days to MDUFA Decision	534	368	205		

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	14		
Number with MDUFA Decision	20	9	1		
Number of Withdrawal	1	1	0		
Number of Not Approvable	3	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	5.00%	11.11%	0.00%		
Rate of Not Approvable	15.00%	0.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0	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	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	2	0		
MDUFA Decision Goal Met	6	2	0		
PMAs Pending MDUFA Decision	0	3	4		
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	10		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	7	1		
MDUFA Decision Goal Met	15	7	1		
PMAs Pending MDUFA Decision	0	3	9		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0	3	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		

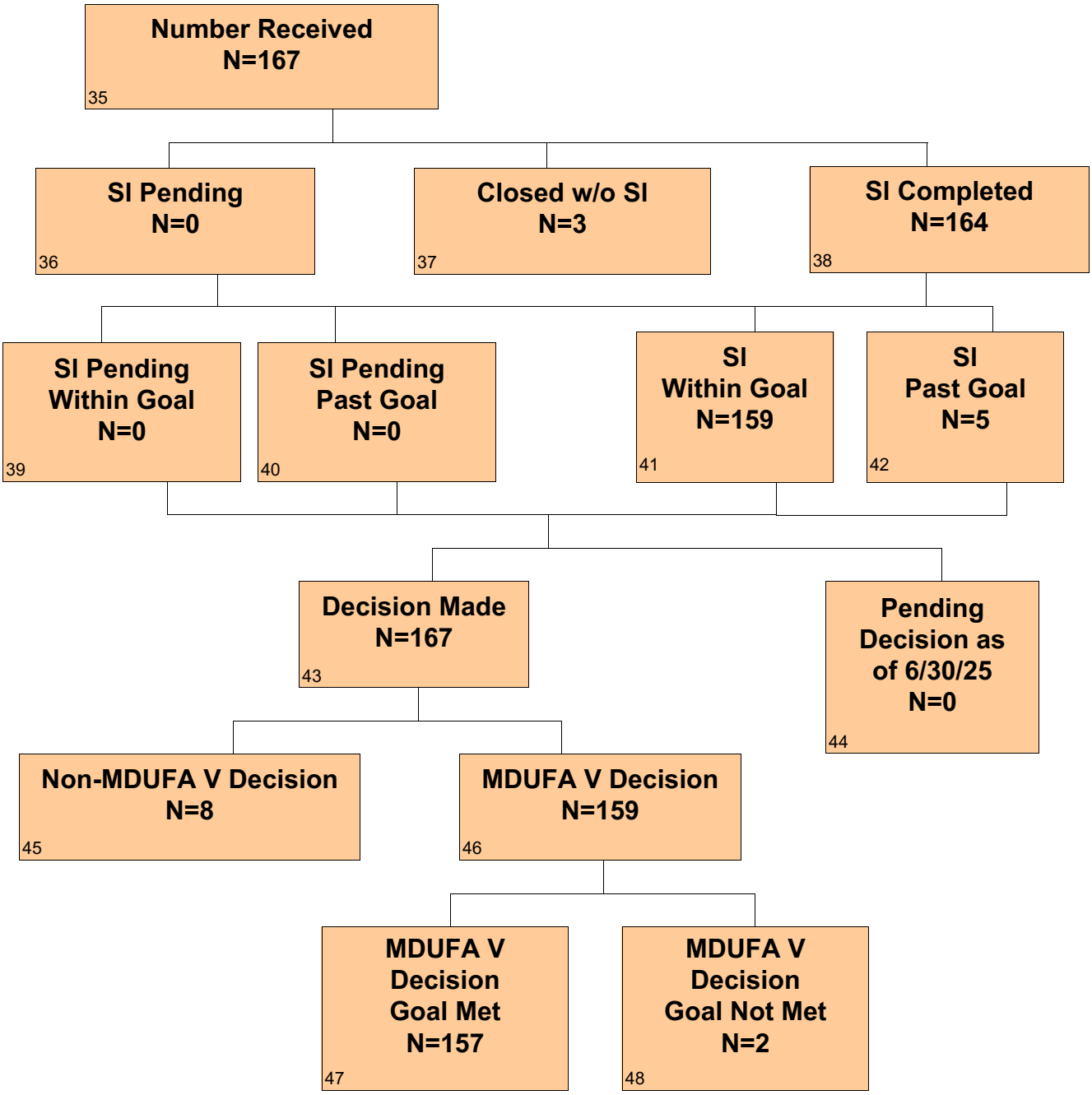
***Includes submission that went to panel**

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

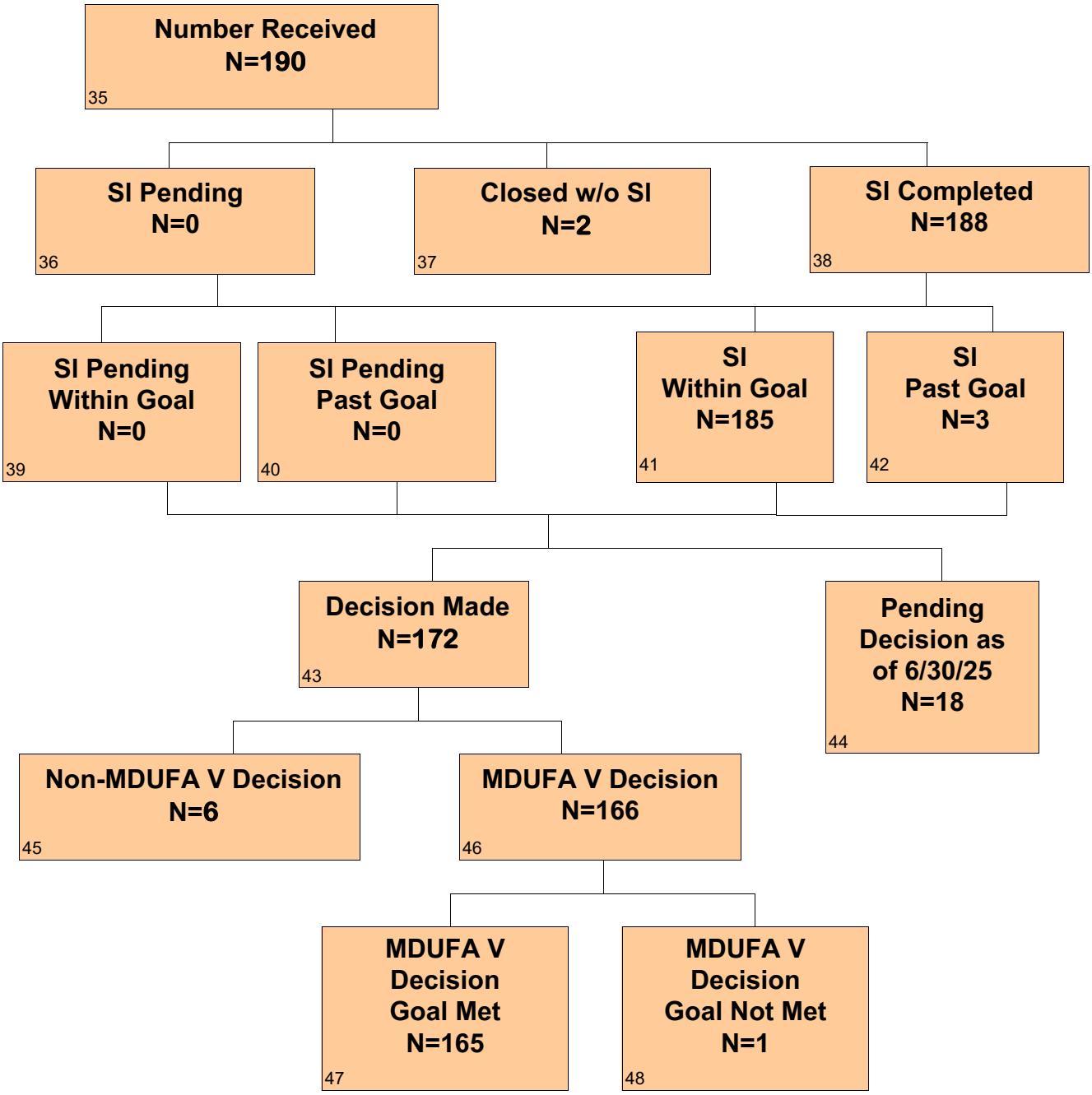
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A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

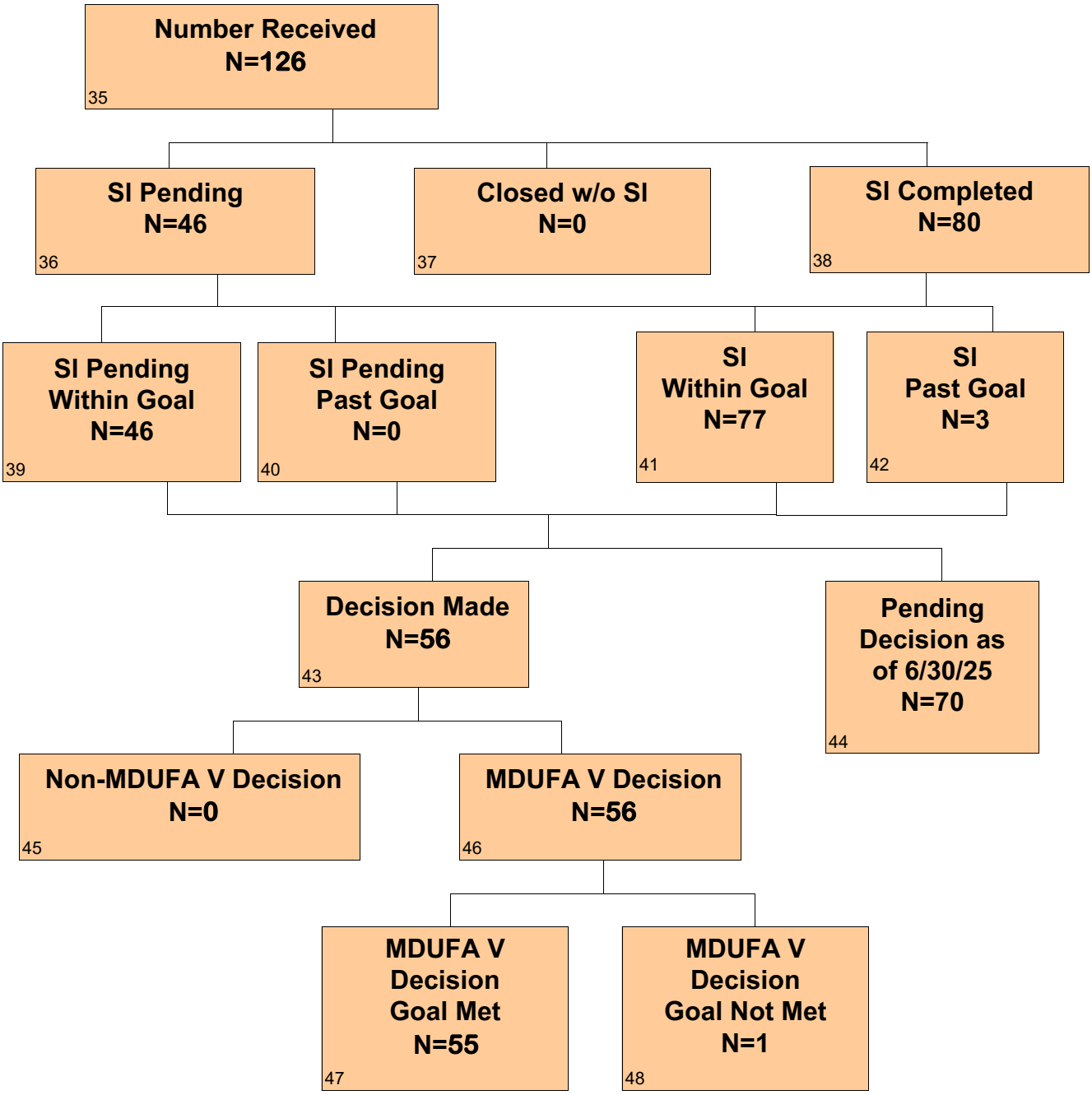
CDRH PMA 180 Day Supplements - FY 2023 as of 6/30/25



CDRH PMA 180 Day Supplements - FY 2024 as of 6/30/25



CDRH PMA 180 Day Supplements - FY 2025 as of 6/30/25



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	167	190	126		
SI Goal Met	159	185	77		
SI Goal Not Met	5	3	3		
SI Pending Within Goal	0	0	46		
SI Pending Past Goal	0	0	0		
Closed Without SI	3	2	0		
Current SI Performance Percent Goal Met	96.95%	98.40%	96.25%		

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	167	190	126		
Non-MDUFA Decision	8	6	0		
MDUFA Decision	159	166	56		
MDUFA Decision Goal Met	157	165	55		
Supplements Pending MDUFA Decision	0	18	70		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.74%	99.40%	98.21%		

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	167	190	126		
Number with MDUFA Decision	159	166	56		
Number of Not Approvable	7	12	0		
Rate of Not Approvable	4.40%	7.23%	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	1	1		
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	182.00		
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	0.00		

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	16	15	15		
SI Goal Met	16	15	10		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	5		
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 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	15		
Non-MDUFA Decision	1	0	0		
MDUFA Decision	15	8	6		
MDUFA Decision Goal Met	15	8	6		
Supplements Pending MDUFA Decision	0	7	9		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	15	15		
Number with MDUFA Decision	15	8	6		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	6.67%	12.50%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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 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	46		
SI Goal Met	55	80	24		
SI Goal Not Met	0	0	2		
SI Pending Within Goal	0	0	20		
SI Pending Past Goal	0	0	0		
Closed Without SI	1	1	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	92.31%		

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	46		
Non-MDUFA Decision	3	4	0		
MDUFA Decision	53	72	23		
MDUFA Decision Goal Met	53	72	23		
Supplements Pending MDUFA Decision	0	5	23		
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	46		
Number with MDUFA Decision	53	72	23		
Number of Not Approvable	1	10	0		
Rate of Not Approvable	1.89%	13.89%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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 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	12		
SI Goal Met	20	17	10		
SI Goal Not Met	1	0	1		
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	95.24%	100.00%	90.91%		

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	12		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	21	17	9		
MDUFA Decision Goal Met	21	17	8		
Supplements Pending MDUFA Decision	0	0	3		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	88.89%		

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	12		
Number with MDUFA Decision	21	17	9		
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	1		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	182.00		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00		

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	7		
SI Goal Met	8	12	5		
SI Goal Not Met	0	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	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	8	12	7		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	11	2		
MDUFA Decision Goal Met	8	11	2		
Supplements Pending MDUFA Decision	0	1	5		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8	12	7		
Number with MDUFA Decision	8	11	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	21		
SI Goal Met	20	17	10		
SI Goal Not Met	3	3	0		
SI Pending Within Goal	0	0	11		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	86.96%	85.00%	100.00%		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	23	20	21		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	23	18	8		
MDUFA Decision Goal Met	21	17	8		
Supplements Pending MDUFA Decision	0	2	13		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	91.30%	94.44%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	21		
Number with MDUFA Decision	23	18	8		
Number of Not Approvable	3	0	0		
Rate of Not Approvable	13.04%	0.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	1	0		
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	N/A		

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	6	5	8		
SI Goal Met	6	5	6		
SI Goal Not Met	0	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	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	6	5	8		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	5	2		
MDUFA Decision Goal Met	6	5	2		
Supplements Pending MDUFA Decision	0	0	6		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	5	8		
Number with MDUFA Decision	6	5	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	16		
SI Goal Met	33	37	12		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	2	1	0		
Current SI Performance Percent Goal Met	97.06%	100.00%	100.00%		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	36	38	16		
Non-MDUFA Decision	4	2	0		
MDUFA Decision	32	33	6		
MDUFA Decision Goal Met	32	33	6		
Supplements Pending MDUFA Decision	0	3	10		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	36	38	16		
Number with MDUFA Decision	32	33	6		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	6.25%	3.03%	0.00%		

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

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

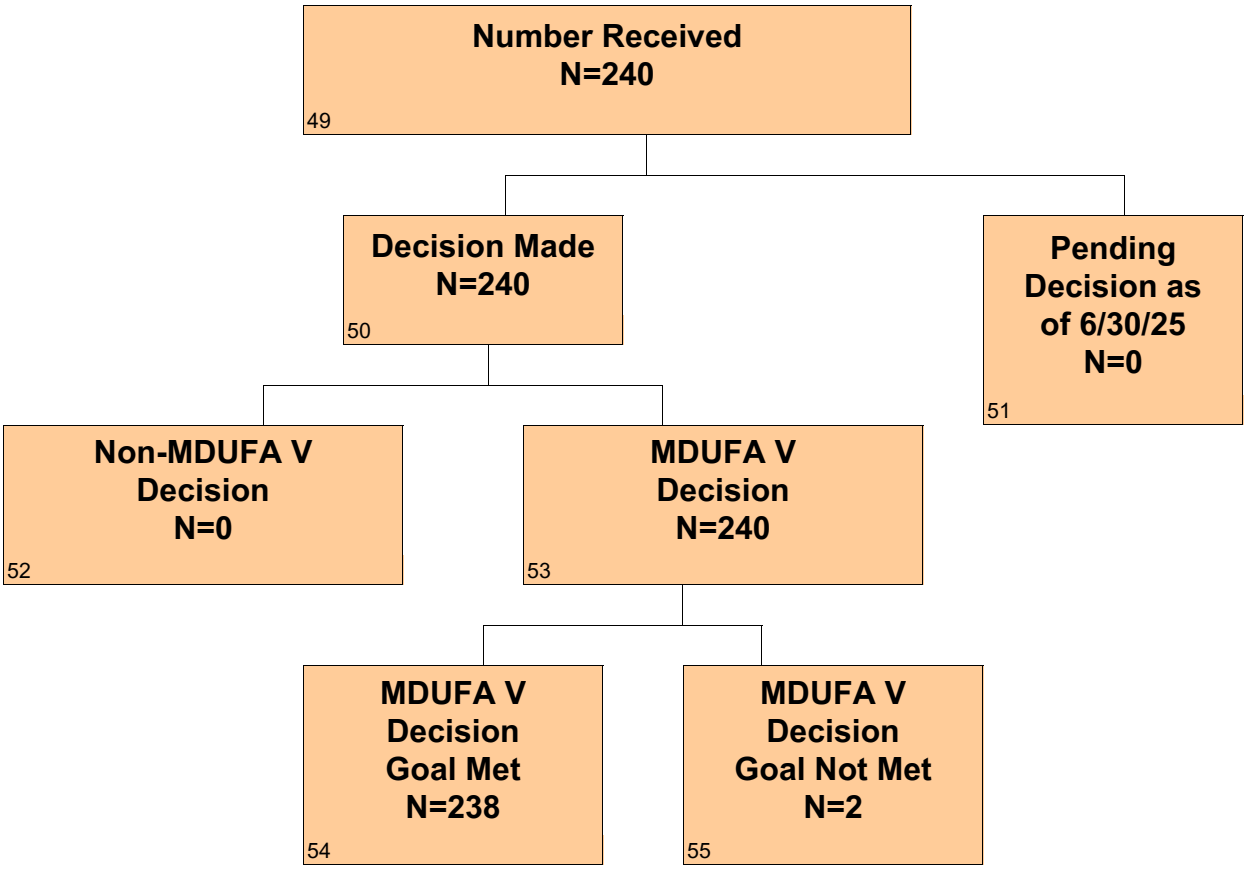
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

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

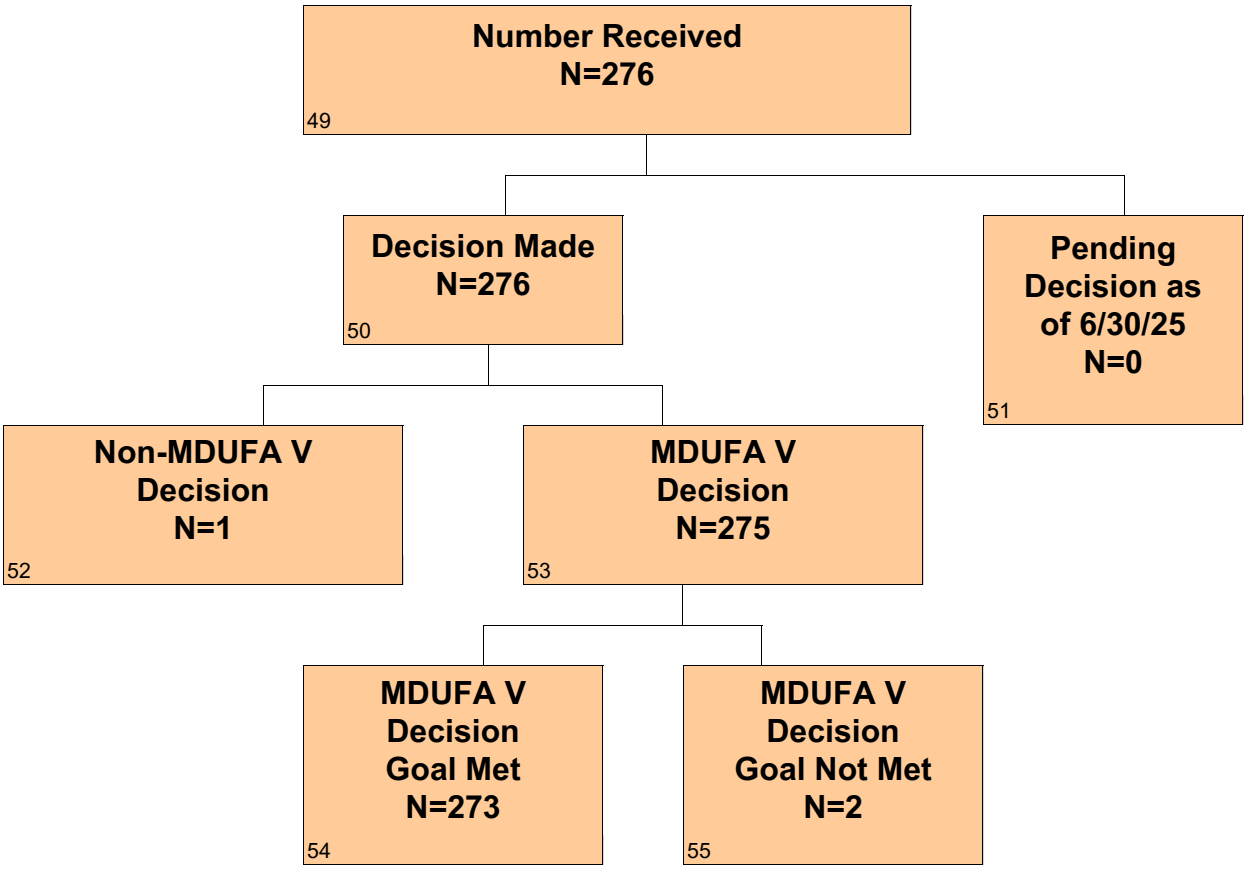
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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		

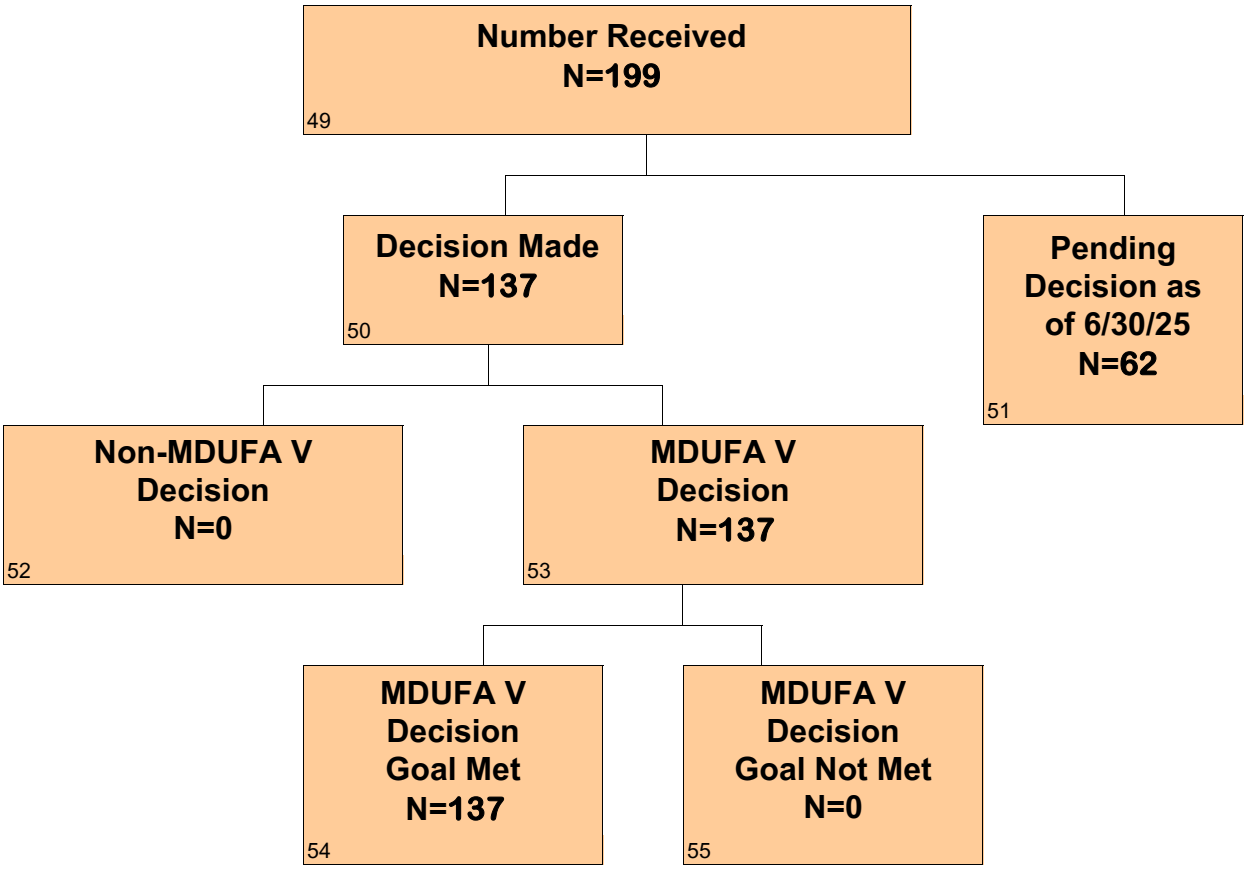
CDRH PMA Real Time Supplements - FY 2023 as of 6/30/25



CDRH PMA Real Time Supplements - FY 2024 as of 6/30/25



CDRH PMA Real Time Supplements - FY 2025 as of 6/30/25



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	199		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	240	275	137		
MDUFA Decision Goal Met	238	273	137		
Supplements Pending MDUFA Decision	0	0	62		
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	199		
Number With MDUFA Decision	240	275	137		
Number of Not Approvable	11	10	11		
Rate of Not Approvable	4.58%	3.64%	8.03%		

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	20		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	24	19	16		
MDUFA Decision Goal Met	24	19	16		
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%	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	20		
Number With MDUFA Decision	24	19	16		
Number of Not Approvable	3	2	1		
Rate of Not Approvable	12.50%	10.53%	6.25%		

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	96		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	136	142	61		
MDUFA Decision Goal Met	136	142	61		
Supplements Pending MDUFA Decision	0	0	35		
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	96		
Number With MDUFA Decision	136	142	61		
Number of Not Approvable	4	1	9		
Rate of Not Approvable	2.94%	0.70%	14.75%		

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	13		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	19	22	7		
MDUFA Decision Goal Met	18	21	7		
Supplements Pending MDUFA Decision	0	0	6		
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	13		
Number With MDUFA Decision	19	22	7		
Number of Not Approvable	2	4	1		
Rate of Not Approvable	10.53%	18.18%	14.29%		

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	7		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	7	10	6		
MDUFA Decision Goal Met	7	10	6		
Supplements Pending MDUFA Decision	0	0	1		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	10	7		
Number With MDUFA Decision	7	10	6		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	28.57%	10.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	39		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	16	37	29		
MDUFA Decision Goal Met	15	36	29		
Supplements Pending MDUFA Decision	0	0	10		
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	39		
Number With MDUFA Decision	16	37	29		
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	24		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	32	33	18		
MDUFA Decision Goal Met	32	33	18		
Supplements Pending MDUFA Decision	0	0	6		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	32	33	24		
Number With MDUFA Decision	32	33	18		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	3.03%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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 January 1, 2025 and March 31, 2025.

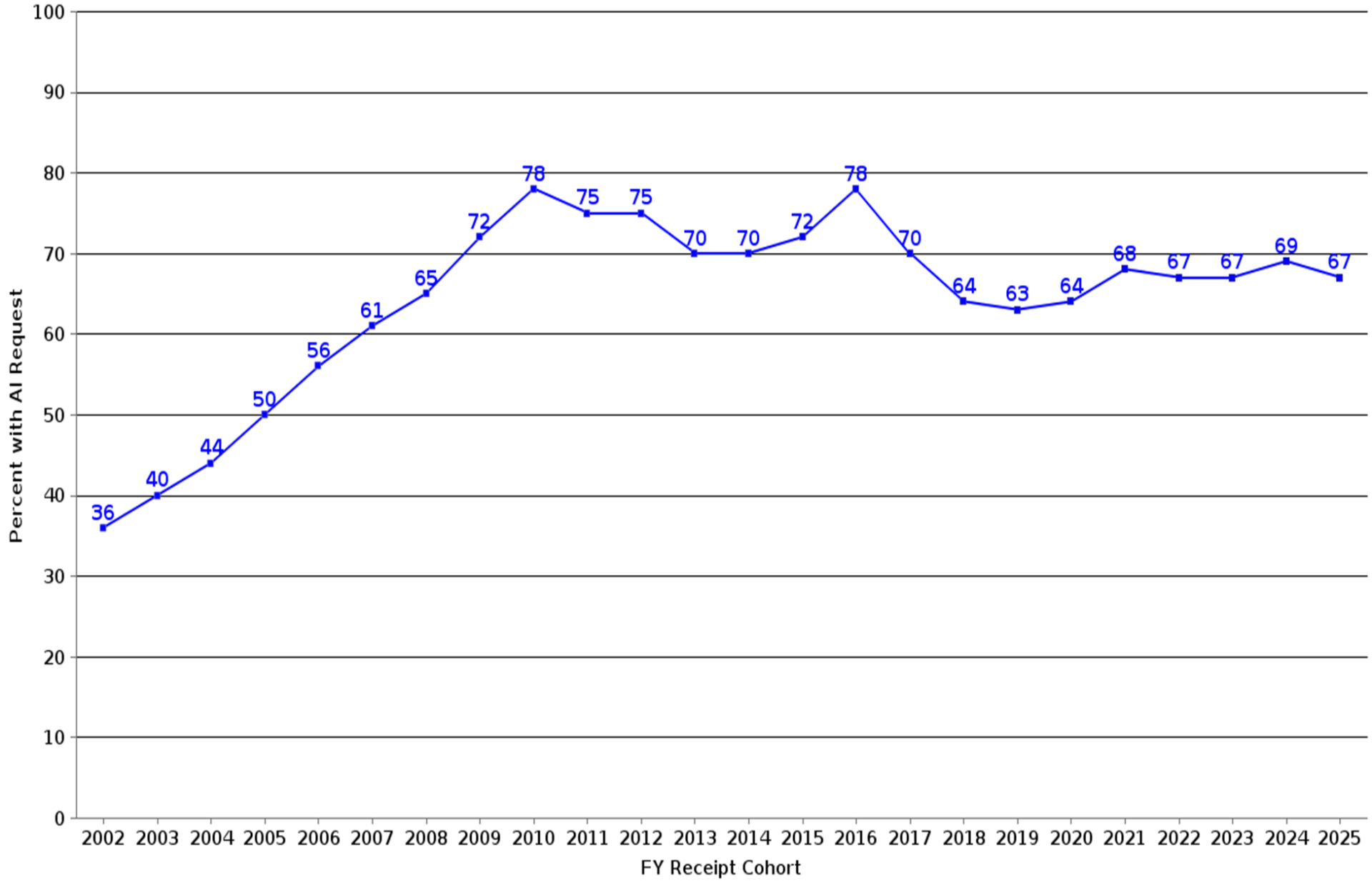
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q3FY2025

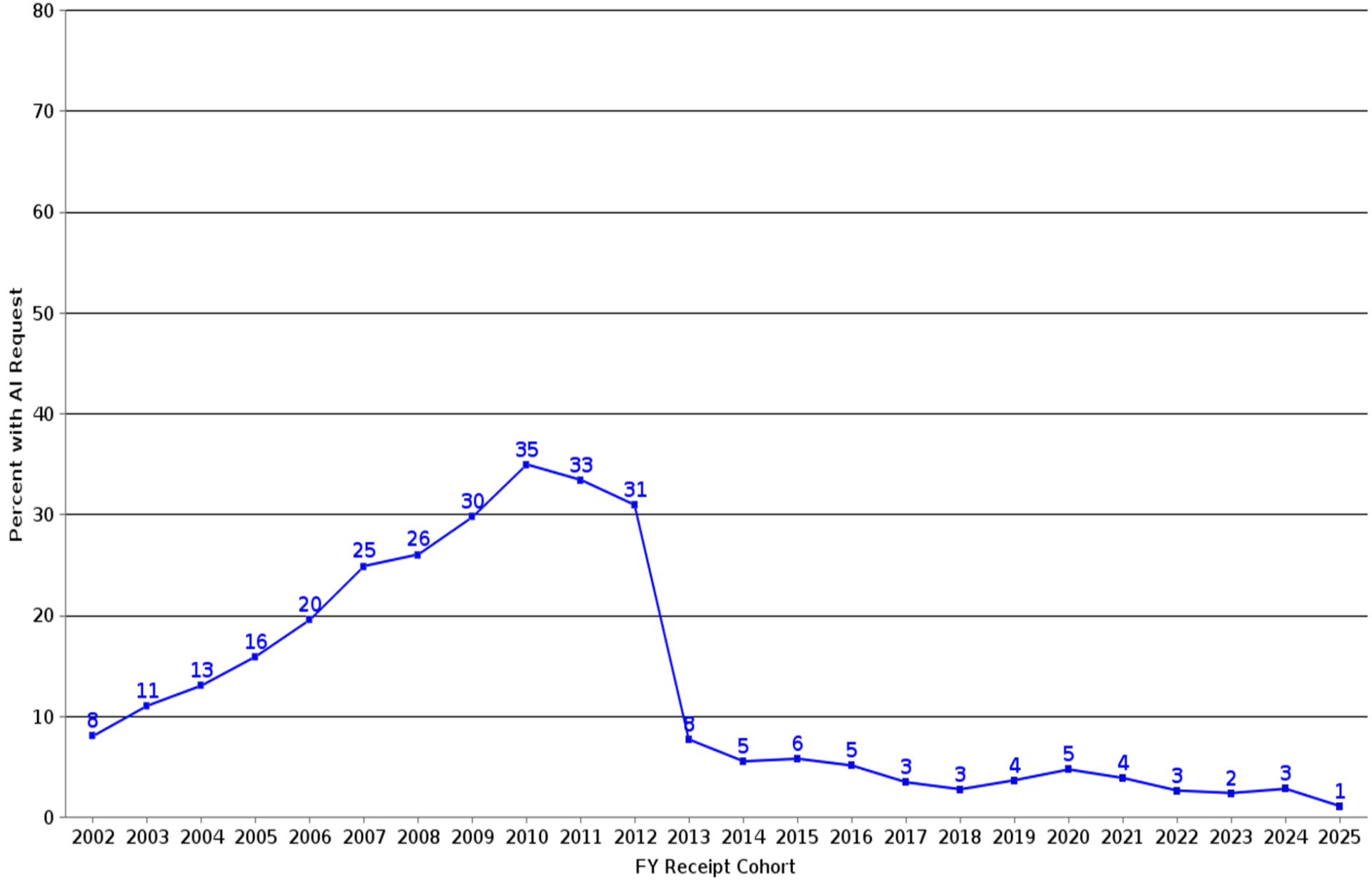
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 4/30/25

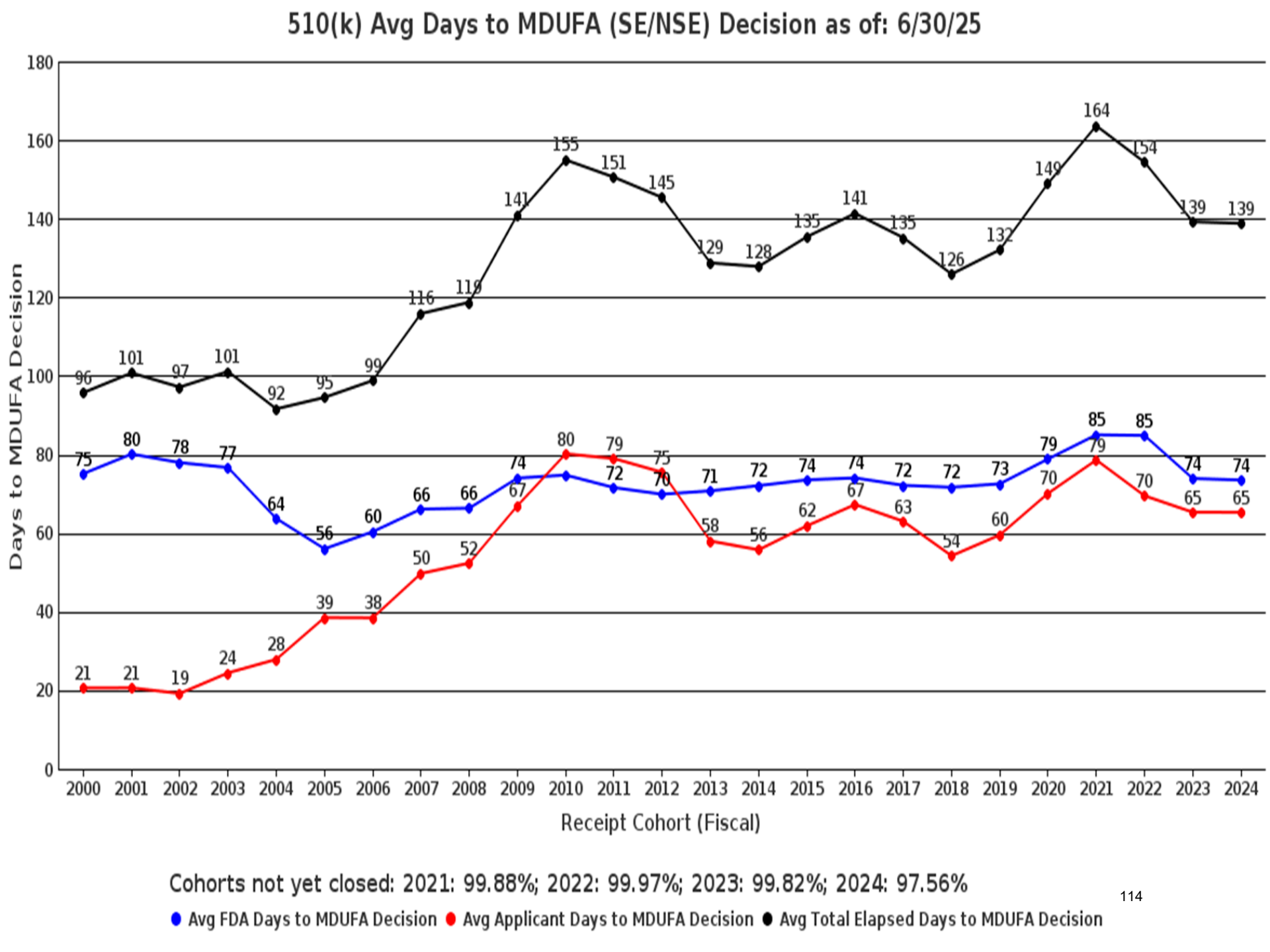
■ % with 1st Cycle AI Request

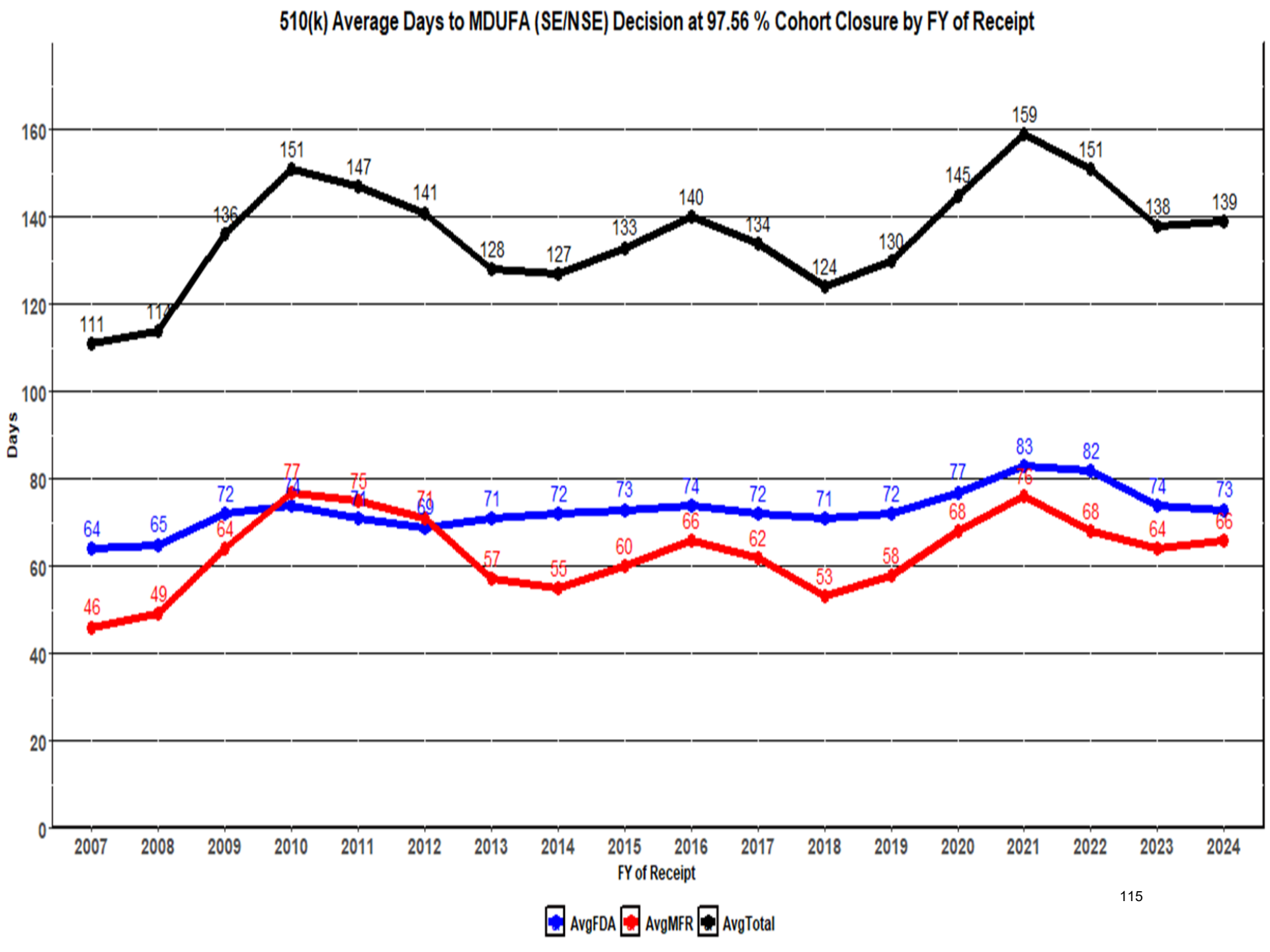
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 11/30/24

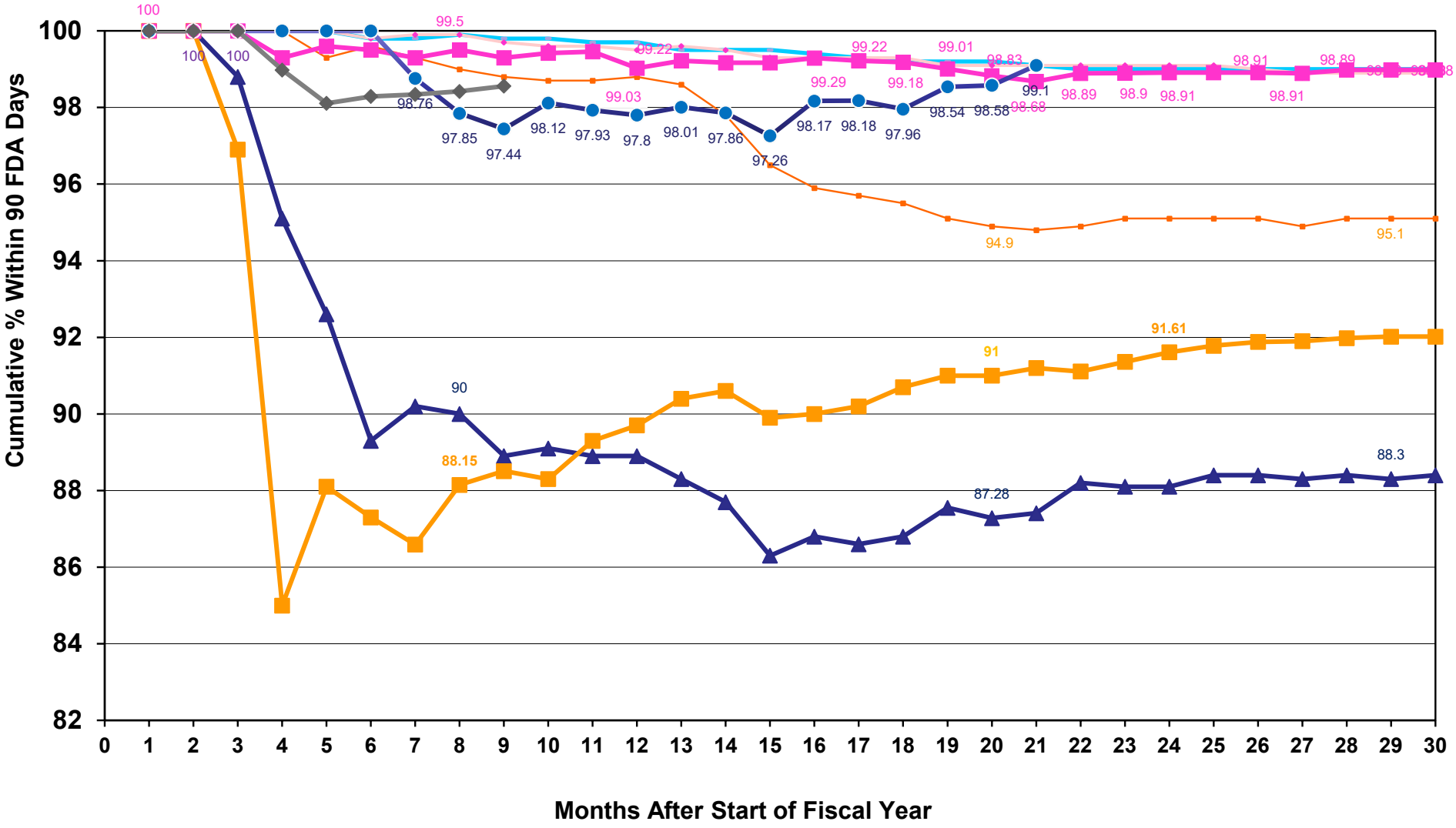
■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 6/30/25
Days to MDUFA Decision
Receipt Cohort (Fiscal)
0
20
40
60
80
100
120
140
160
180
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024
96 101 97 101 92 95 99 116 119 141 155 151 145 129 128 135 141 135 126 132 149 164 154 139 139
75 80 78 77 64 56 60 66 66 74 75 72 70 71 72 74 74 72 72 73 79 85 85 74 74
21 21 19 24 28 39 38 50 52 67 80 79 75 58 56 62 67 63 54 60 70 79 70 65 65
Cohorts not yet closed: 2021: 99.88%; 2022: 99.97%; 2023: 99.82%; 2024: 97.56%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision

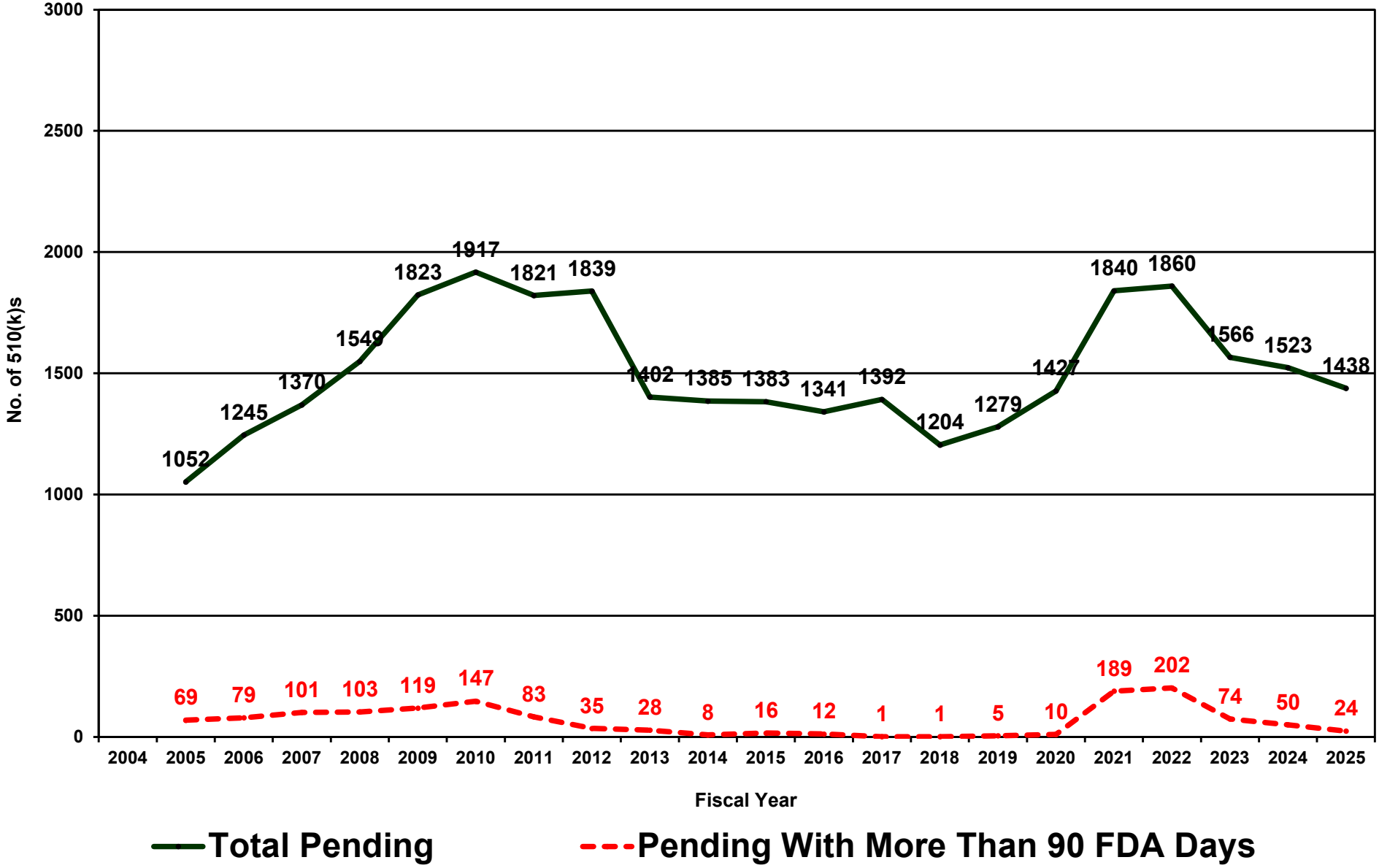

510(k) Average Days to MDUFA (SE/NSE) Decision at 97.56 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

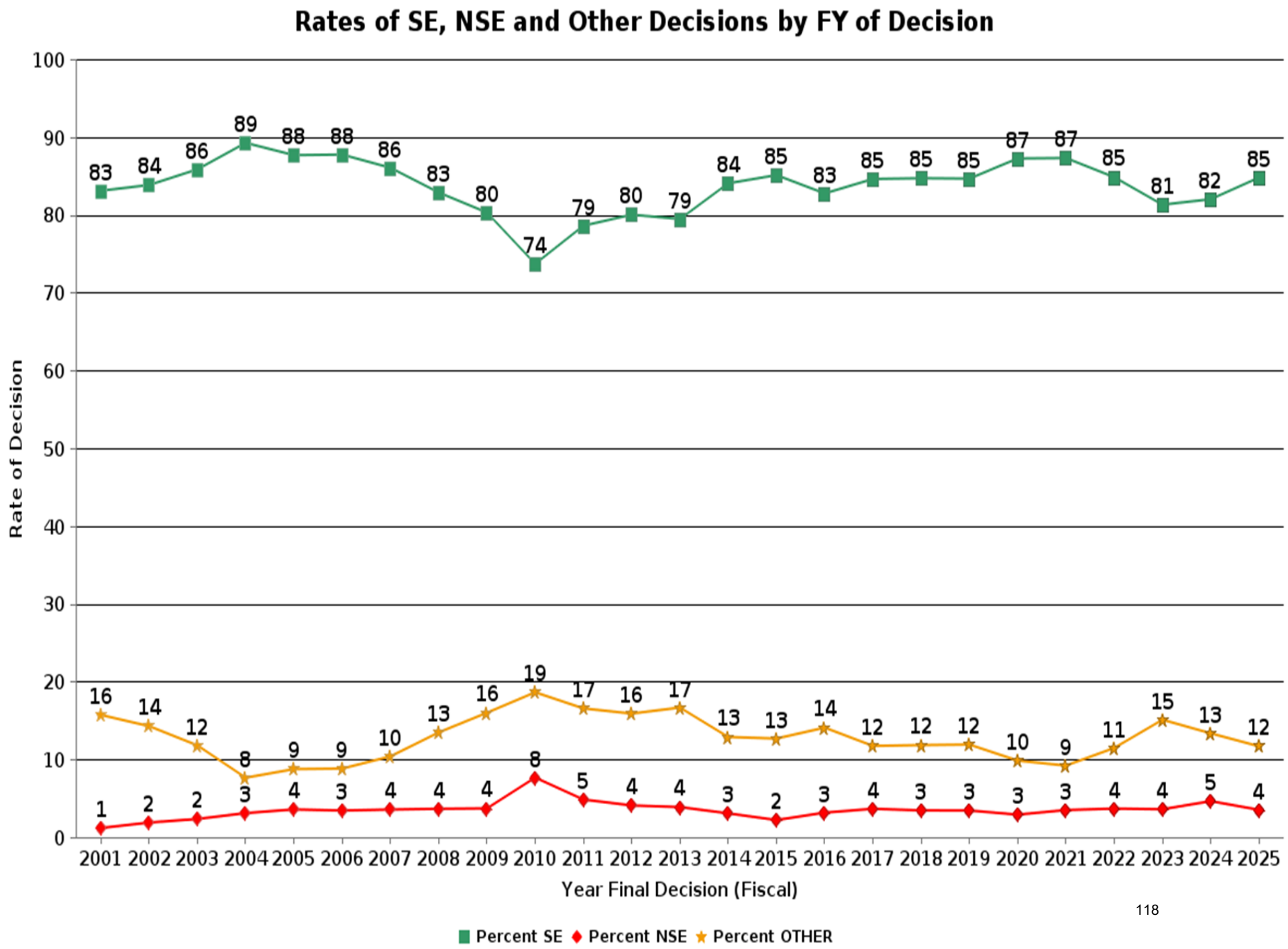
Comparison of FY18 – FY25 Receipt Cohorts



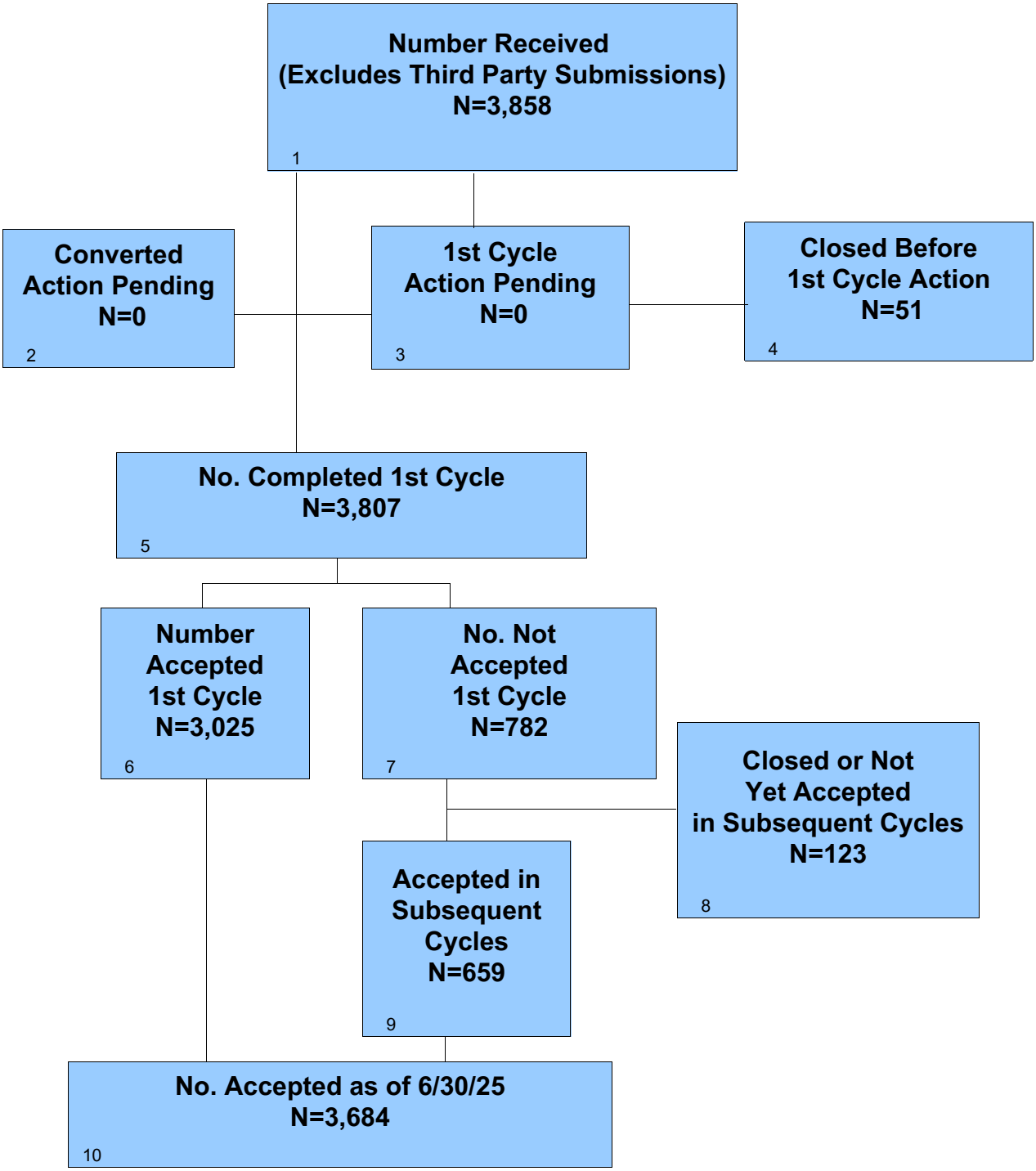
510(k)s Pending at End of Quarter/Year



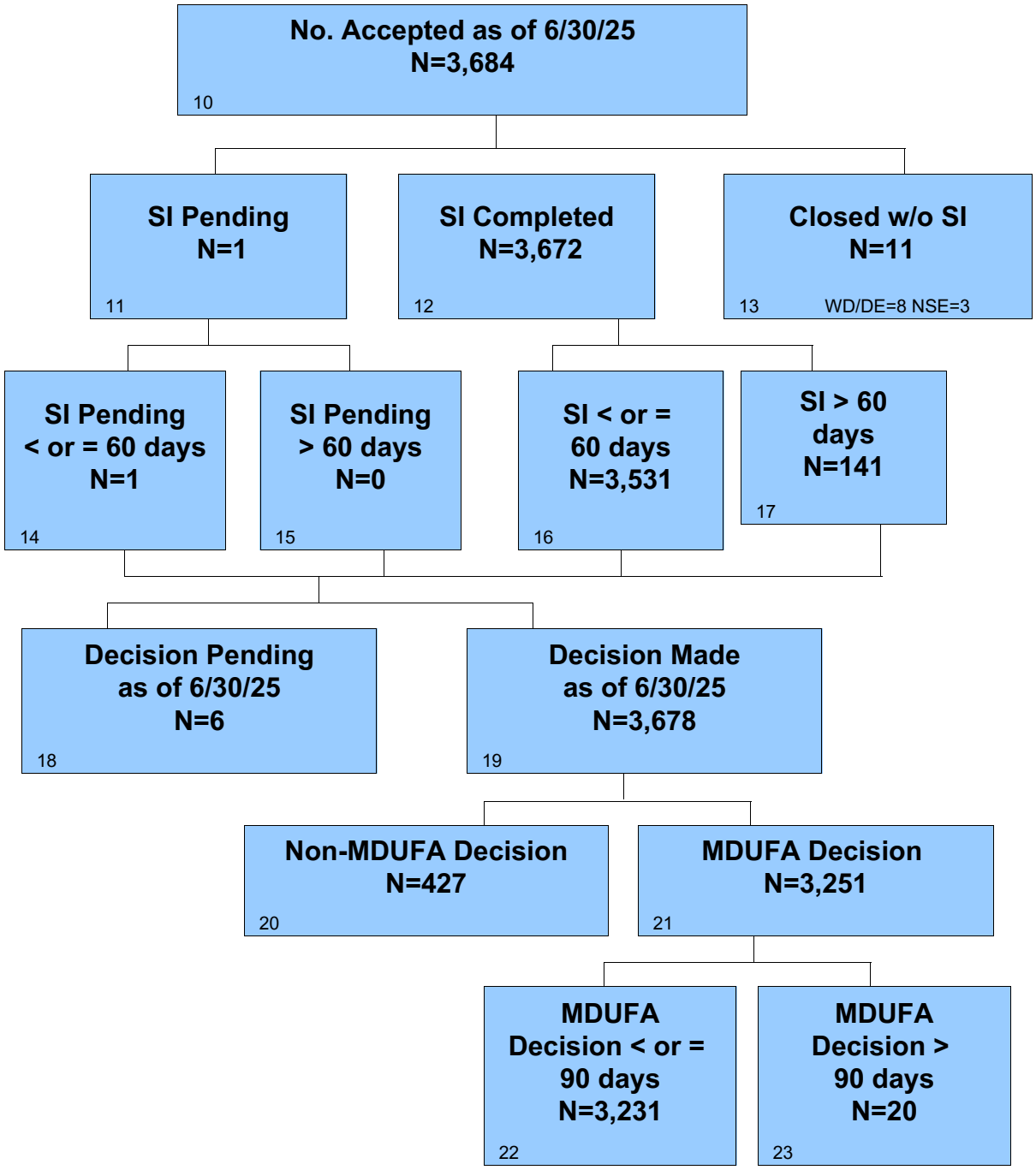
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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

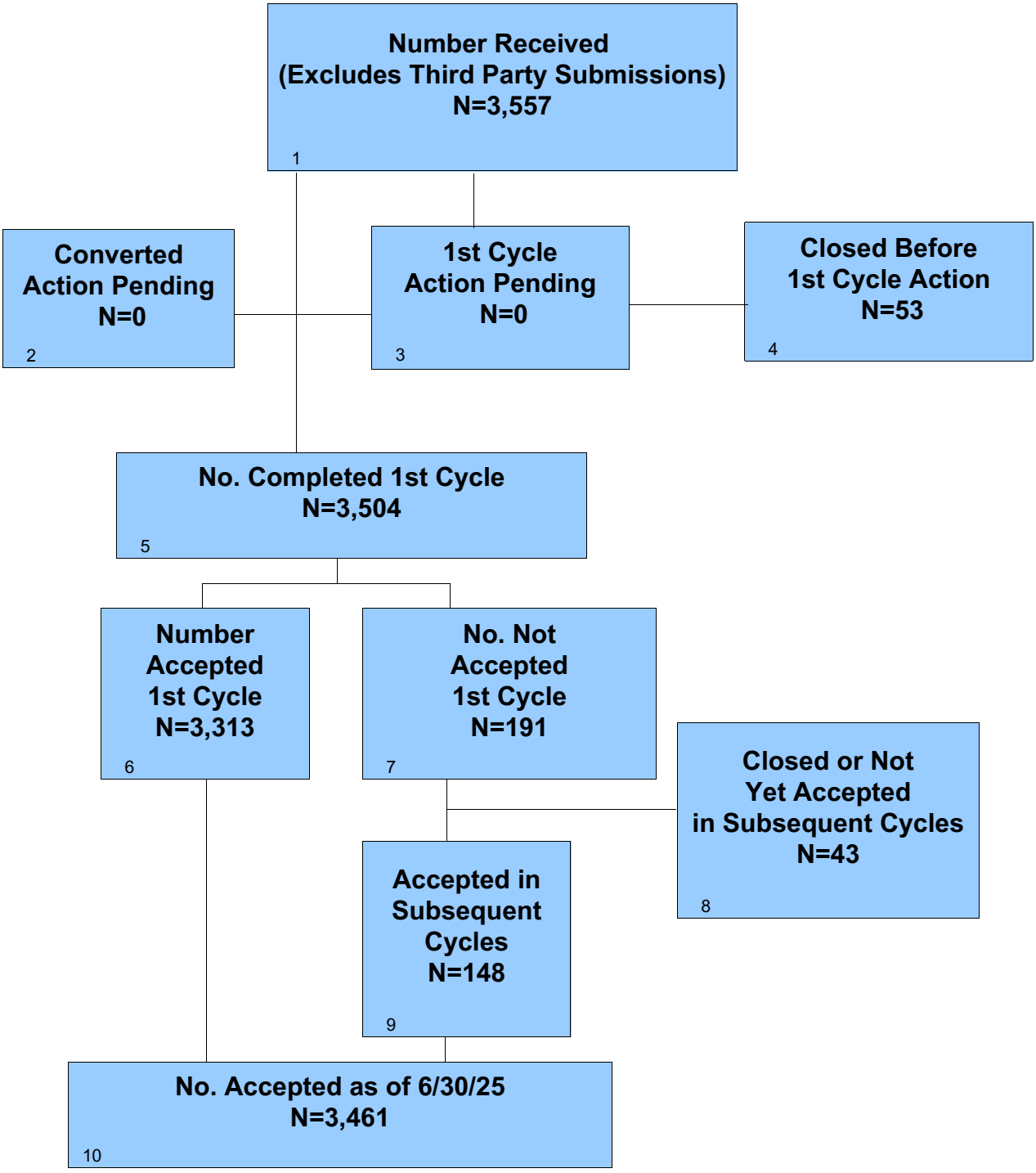
CDRH 510(k)s - FY 2023
as of 6/30/25



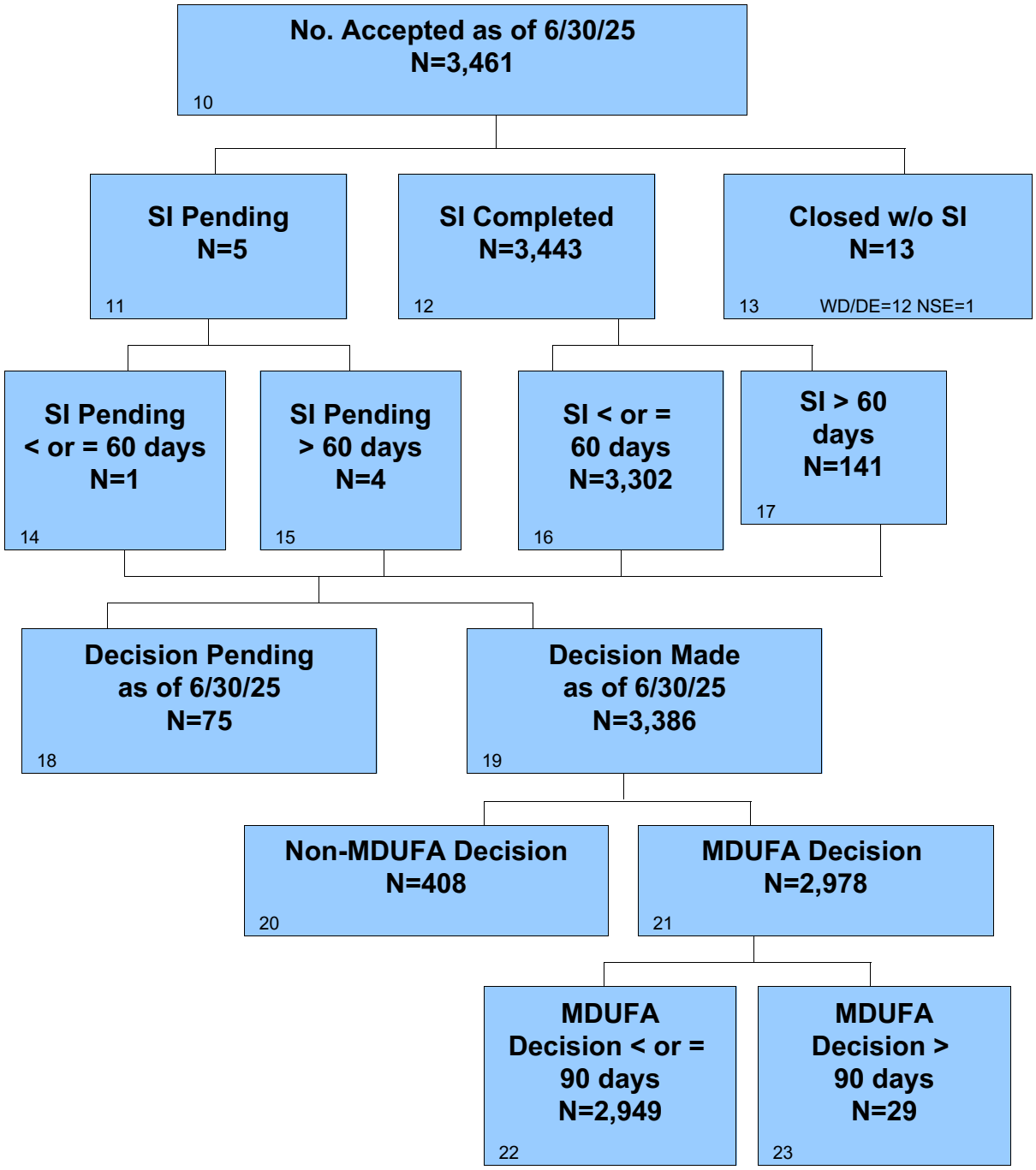
CDRH 510(k)s - FY 2023
as of 6/30/25 Continued



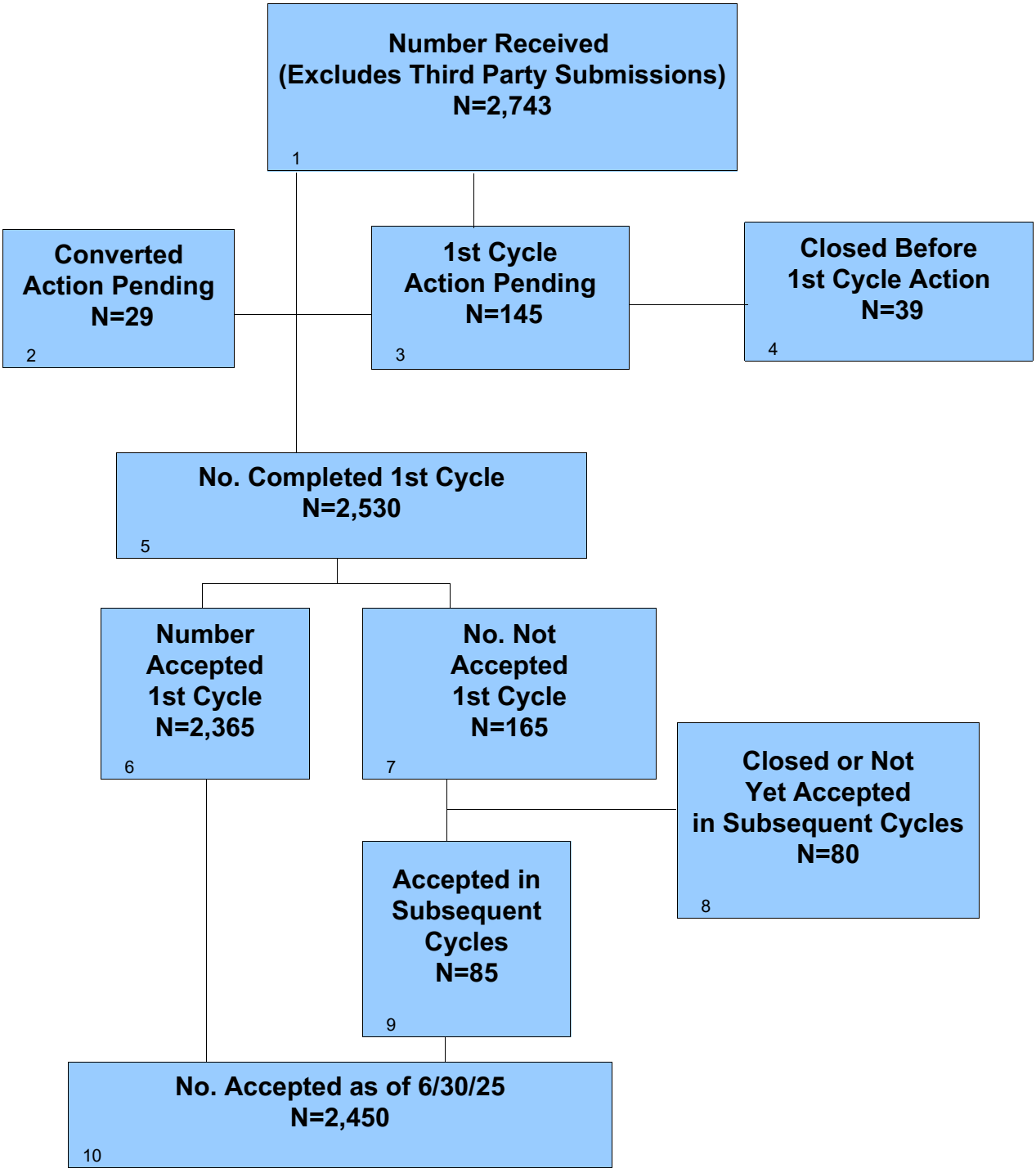
CDRH 510(k)s - FY 2024
as of 6/30/25



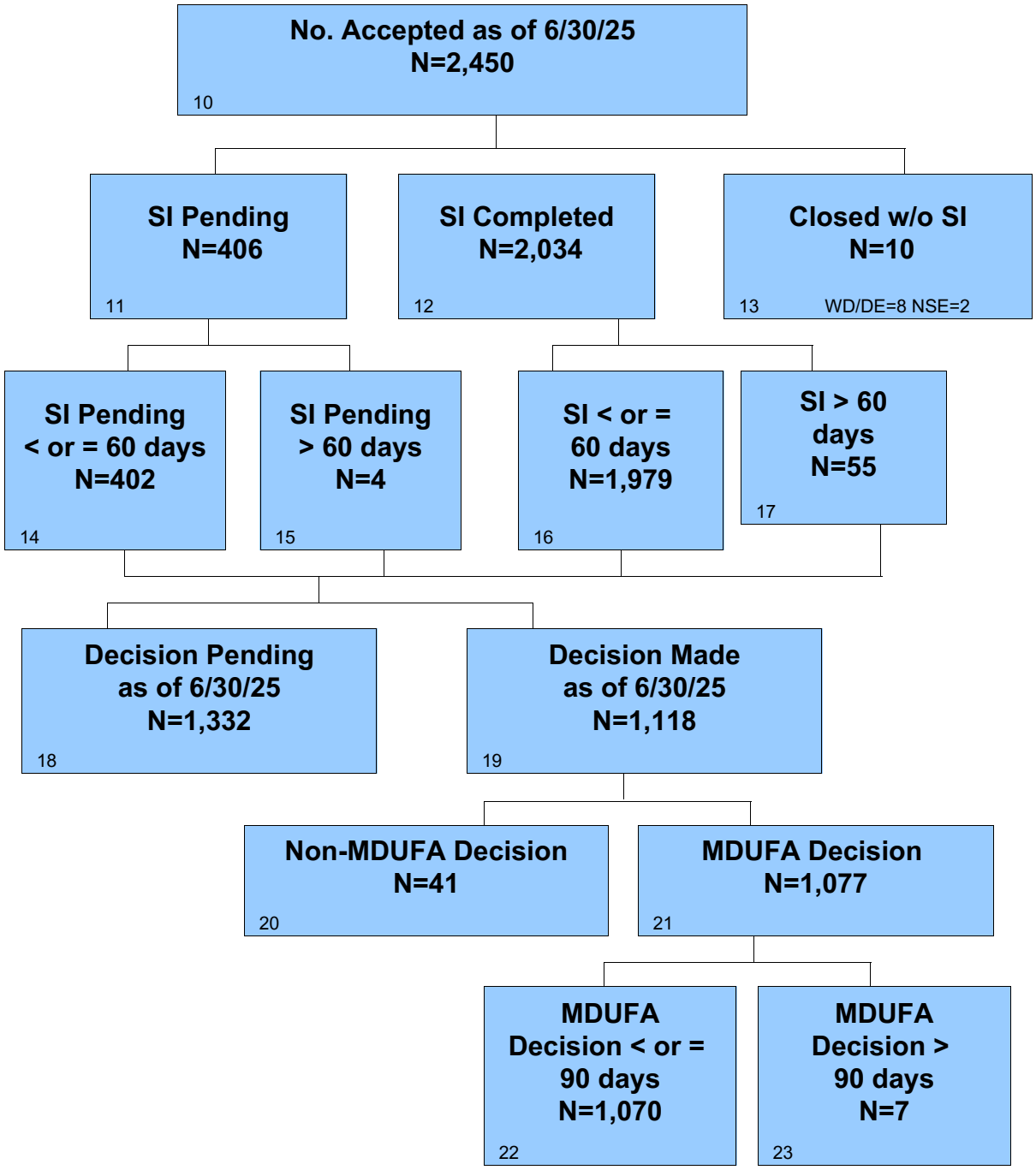
CDRH 510(k)s - FY 2024 as of 6/30/25 Continued



CDRH 510(k)s - FY 2025
as of 6/30/25



CDRH 510(k)s - FY 2025
as of 6/30/25 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	3,858	3,557	2,743		
Closed Before First RTA or TS Action [1]	51	53	39		
Number Accepted or Passed TS on First Cycle [2]	3,007	3,284	2,334		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	18	29	31		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	174		
Number Not Accepted or Failed TS on First Cycle [2]	782	191	165		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.54%	5.45%	6.52%		

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	3,684	3,461	2,450		
Deleted or Withdrawn Prior to SI	8	12	8		
SI Within 60 FDA Days	3,531	3,302	1,979		
SI Over 60 FDA Days	141	141	55		
SI Pending Within 60 FDA Days	1	1	402		
SI Pending Over 60 FDA Days	0	4	4		
510(k)s NSE Without SI	3	1	2		
Current SI Performance Percent Within 60 FDA Days	96.08%	95.77%	97.01%		

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	3,672	3,443	2,034		
Average Number of FDA Days to Substantive Interaction	52.71	52.46	51.63		
20th Percentile FDA Days to Substantive Interaction	48	48	43		
40th Percentile FDA Days to Substantive Interaction	57	57	56		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	212	95	115		

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	3,684	3,461	2,450		
Non-MDUFA V Decision	427	408	41		
MDUFA V Decision (SE/NSE)	3,251	2,978	1,077		
MDUFA V Decision Within 90 FDA Days	3,231	2,949	1,070		
510(k)s Pending MDUFA V Decision	6	75	1,332		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2	8	7		
Current Performance Percent Within 90 FDA Days	99.32%	98.76%	98.71%		

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	1.68	1.40		
Number With MDUFA V Decision	3251	2978	1077		
Average Number of FDA Days to MDUFA V Decision	74.82	74.44	64.32		
20th Percentile FDA Days to MDUFA V Decision	57	56	30		
40th Percentile FDA Days to MDUFA V Decision	84	84	58		
60th Percentile FDA Days to MDUFA V Decision	88	88	85		
80th Percentile FDA Days to MDUFA V Decision	90	90	89		
Maximum FDA Days to MDUFA V Decision	276	203	147		
Average Number of Industry Days to MDUFA V Decision	66.15	66.41	20.63		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	14	17	0		
60th Percentile Industry Days to MDUFA V Decision	70	70	1		
80th Percentile Industry Days to MDUFA V Decision	152	153	42		
Maximum Industry Days to MDUFA V Decision	367	361	199		
Average Number of Total Days to MDUFA V Decision	141.05	140.81	84.54		
20th Percentile Total Days to MDUFA V Decision	59	58	30		
40th Percentile Total Days to MDUFA V Decision	97	99	60		
60th Percentile Total Days to MDUFA V Decision	155	154	90		
80th Percentile Total Days to MDUFA V Decision	238	238	124		
Maximum Total Days to MDUFA V Decision	517	530	268		

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	3,684	3,461	2,450		
Number With MDUFA V Decision	3,251	2,978	1,077		
Number of SE Decision	3,106	2,846	1,064		
Number of NSE Decision	145	132	13		
Number of Withdrawal	224	224	31		
Number of Deleted	194	177	6		
Rate of SE Decision	95.54%	95.57%	98.79%		
Rate of NSE Decision	4.46%	4.43%	1.21%		
Rate of Withdrawal	6.08%	6.47%	1.27%		
Rate of Deleted	5.27%	5.11%	0.24%		

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	29	7		
Mean FDA Days for Submissions that Missed the Goal	124.45	106.31	101.57		
Mean Industry Days for Submissions that Missed the Goal	129.15	132.14	27.29		

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	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	3	0		
MDUFA V Decision Within 90 FDA Days	2	3	0		
510(k)s Pending MDUFA V Decision	0	1	1		
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	236	190		
Non-MDUFA V Decision	51	41	8		
MDUFA V Decision (SE/NSE)	218	189	79		
MDUFA V Decision Within 90 FDA Days	218	189	79		
510(k)s Pending MDUFA V Decision	0	6	103		
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	577	531	399		
Closed Before First RTA or TS Action [1]	8	8	5		
Number Accepted or Passed TS on First Cycle [2]	313	467	333		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	4	2		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	18		
Number Not Accepted or Failed TS on First Cycle [2]	253	52	41		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.46%	9.94%	10.90%		

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	533	514	348		
Deleted or Withdrawn Prior to SI	2	2	3		
SI Within 60 FDA Days	424	427	262		
SI Over 60 FDA Days	105	84	5		
SI Pending Within 60 FDA Days	1	1	77		
SI Pending Over 60 FDA Days	0	0	1		
510(k)s NSE Without SI	1	0	0		
Current SI Performance Percent Within 60 FDA Days	80.00%	83.56%	97.76%		

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	529	511	267		
Average Number of FDA Days to Substantive Interaction	56.96	55.79	53.75		
20th Percentile FDA Days to Substantive Interaction	55	53	49		
40th Percentile FDA Days to Substantive Interaction	58	57	56		
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	65		

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	533	514	348		
Non-MDUFA V Decision	84	61	9		
MDUFA V Decision (SE/NSE)	446	436	122		
MDUFA V Decision Within 90 FDA Days	437	430	121		
510(k)s Pending MDUFA V Decision	3	17	217		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0	0		
Current Performance Percent Within 90 FDA Days	97.76%	98.62%	99.18%		

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	1.77	1.54		
Number With MDUFA V Decision	446	436	122		
Average Number of FDA Days to MDUFA V Decision	82.90	82.15	73.43		
20th Percentile FDA Days to MDUFA V Decision	82	82	53		
40th Percentile FDA Days to MDUFA V Decision	88	87	85		
60th Percentile FDA Days to MDUFA V Decision	89	89	88		
80th Percentile FDA Days to MDUFA V Decision	90	90	89		
Maximum FDA Days to MDUFA V Decision	276	120	94		
Average Number of Industry Days to MDUFA V Decision	76.31	82.82	26.70		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	39	41	0		
60th Percentile Industry Days to MDUFA V Decision	87	98	19		
80th Percentile Industry Days to MDUFA V Decision	162	173	53		
Maximum Industry Days to MDUFA V Decision	353	356	155		
Average Number of Total Days to MDUFA V Decision	159.37	164.75	99.36		
20th Percentile Total Days to MDUFA V Decision	87	89	58		
40th Percentile Total Days to MDUFA V Decision	126	127	88		
60th Percentile Total Days to MDUFA V Decision	178	186	107		
80th Percentile Total Days to MDUFA V Decision	251	259	139		
Maximum Total Days to MDUFA V Decision	443	451	241		

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	533	514	348		
Number With MDUFA V Decision	446	436	122		
Number of SE Decision	411	406	119		
Number of NSE Decision	35	30	3		
Number of Withdrawal	41	29	8		
Number of Deleted	42	31	0		
Rate of SE Decision	92.15%	93.12%	97.54%		
Rate of NSE Decision	7.85%	6.88%	2.46%		
Rate of Withdrawal	7.69%	5.64%	2.30%		
Rate of Deleted	7.88%	6.03%	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	6	1		
Mean FDA Days for Submissions that Missed the Goal	148.78	102.67	94.00		
Mean Industry Days for Submissions that Missed the Goal	120.78	165.83	6.00		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	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	379	378	279		
Closed Before First RTA or TS Action [1]	8	6	7		
Number Accepted or Passed TS on First Cycle [2]	332	354	220		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	6	5		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	18		
Number Not Accepted or Failed TS on First Cycle [2]	38	12	29		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.24%	3.23%	11.42%		

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

Table 6.2 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	365	370	245		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	355	345	191		
SI Over 60 FDA Days	10	22	20		
SI Pending Within 60 FDA Days	0	0	32		
SI Pending Over 60 FDA Days	0	3	1		
510(k)s NSE Without SI	0	0	1		
Current SI Performance Percent Within 60 FDA Days	97.26%	93.24%	89.67%		

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	365	367	211		
Average Number of FDA Days to Substantive Interaction	51.40	51.09	52.39		
20th Percentile FDA Days to Substantive Interaction	44	30	30		
40th Percentile FDA Days to Substantive Interaction	56	56	57		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	86	85	86		

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	365	370	245		
Non-MDUFA V Decision	34	43	1		
MDUFA V Decision (SE/NSE)	331	311	93		
MDUFA V Decision Within 90 FDA Days	327	304	92		
510(k)s Pending MDUFA V Decision	0	16	151		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	7	2		
Current Performance Percent Within 90 FDA Days	98.79%	95.60%	96.84%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.74	1.48		
Number With MDUFA V Decision	331	311	93		
Average Number of FDA Days to MDUFA V Decision	73.39	72.16	62.04		
20th Percentile FDA Days to MDUFA V Decision	55	51	30		
40th Percentile FDA Days to MDUFA V Decision	84	81	57		
60th Percentile FDA Days to MDUFA V Decision	88	88	82		
80th Percentile FDA Days to MDUFA V Decision	90	90	88		
Maximum FDA Days to MDUFA V Decision	95	203	92		
Average Number of Industry Days to MDUFA V Decision	71.75	74.00	19.29		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	27	29	0		
60th Percentile Industry Days to MDUFA V Decision	78	85	14		
80th Percentile Industry Days to MDUFA V Decision	155	159	47		
Maximum Industry Days to MDUFA V Decision	360	360	110		
Average Number of Total Days to MDUFA V Decision	145.14	146.00	80.88		
20th Percentile Total Days to MDUFA V Decision	57	55	30		
40th Percentile Total Days to MDUFA V Decision	107	109	60		
60th Percentile Total Days to MDUFA V Decision	162	170	90		
80th Percentile Total Days to MDUFA V Decision	238	245	122		
Maximum Total Days to MDUFA V Decision	448	450	199		

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	365	370	245		
Number With MDUFA V Decision	331	311	93		
Number of SE Decision	308	288	90		
Number of NSE Decision	23	23	3		
Number of Withdrawal	17	25	1		
Number of Deleted	17	16	0		
Rate of SE Decision	93.05%	92.60%	96.77%		
Rate of NSE Decision	6.95%	7.40%	3.23%		
Rate of Withdrawal	4.66%	6.76%	0.41%		
Rate of Deleted	4.66%	4.32%	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	7	1		
Mean FDA Days for Submissions that Missed the Goal	92.75	118.14	92.00		
Mean Industry Days for Submissions that Missed the Goal	82.50	144.57	84.00		

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	477	446	367		
Closed Before First RTA or TS Action [1]	5	11	3		
Number Accepted or Passed TS on First Cycle [2]	389	417	322		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	2	3		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	25		
Number Not Accepted or Failed TS on First Cycle [2]	81	16	14		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	17.16%	3.68%	4.13%		

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	459	431	332		
Deleted or Withdrawn Prior to SI	1	0	1		
SI Within 60 FDA Days	448	429	265		
SI Over 60 FDA Days	10	0	8		
SI Pending Within 60 FDA Days	0	0	57		
SI Pending Over 60 FDA Days	0	1	1		
510(k)s NSE Without SI	0	1	0		
Current SI Performance Percent Within 60 FDA Days	97.82%	99.54%	96.72%		

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	458	429	273		
Average Number of FDA Days to Substantive Interaction	54.93	52.88	52.52		
20th Percentile FDA Days to Substantive Interaction	55	49	45		
40th Percentile FDA Days to Substantive Interaction	58	57	57		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	77	60	115		

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	459	431	332		
Non-MDUFA V Decision	54	67	5		
MDUFA V Decision (SE/NSE)	405	358	134		
MDUFA V Decision Within 90 FDA Days	404	356	132		
510(k)s Pending MDUFA V Decision	0	6	193		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	1	2		
Current Performance Percent Within 90 FDA Days	99.75%	99.16%	97.06%		

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	1.78	1.47		
Number With MDUFA V Decision	405	358	134		
Average Number of FDA Days to MDUFA V Decision	79.93	76.48	65.70		
20th Percentile FDA Days to MDUFA V Decision	79	58	29		
40th Percentile FDA Days to MDUFA V Decision	88	87	59		
60th Percentile FDA Days to MDUFA V Decision	89	89	86		
80th Percentile FDA Days to MDUFA V Decision	90	90	89		
Maximum FDA Days to MDUFA V Decision	93	160	147		
Average Number of Industry Days to MDUFA V Decision	85.37	81.26	25.52		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	48	41	0		
60th Percentile Industry Days to MDUFA V Decision	106	105	13		
80th Percentile Industry Days to MDUFA V Decision	172	169	43		
Maximum Industry Days to MDUFA V Decision	354	349	199		
Average Number of Total Days to MDUFA V Decision	165.30	157.91	90.87		
20th Percentile Total Days to MDUFA V Decision	87	67	29		
40th Percentile Total Days to MDUFA V Decision	133	123	61		
60th Percentile Total Days to MDUFA V Decision	193	192	97		
80th Percentile Total Days to MDUFA V Decision	260	257	131		
Maximum Total Days to MDUFA V Decision	443	438	246		

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	459	431	332		
Number With MDUFA V Decision	405	358	134		
Number of SE Decision	379	330	133		
Number of NSE Decision	26	28	1		
Number of Withdrawal	24	38	2		
Number of Deleted	29	27	2		
Rate of SE Decision	93.58%	92.18%	99.25%		
Rate of NSE Decision	6.42%	7.82%	0.75%		
Rate of Withdrawal	5.23%	8.82%	0.60%		
Rate of Deleted	6.32%	6.26%	0.60%		

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	2	2		
Mean FDA Days for Submissions that Missed the Goal	93.00	125.50	119.50		
Mean Industry Days for Submissions that Missed the Goal	192.00	51.50	12.50		

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	709	614	439		
Closed Before First RTA or TS Action [1]	10	6	6		
Number Accepted or Passed TS on First Cycle [2]	558	561	355		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	12	17		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	35		
Number Not Accepted or Failed TS on First Cycle [2]	140	35	26		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.03%	5.76%	6.53%		

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	677	598	386		
Deleted or Withdrawn Prior to SI	1	5	1		
SI Within 60 FDA Days	671	579	312		
SI Over 60 FDA Days	5	14	14		
SI Pending Within 60 FDA Days	0	0	57		
SI Pending Over 60 FDA Days	0	0	1		
510(k)s NSE Without SI	0	0	1		
Current SI Performance Percent Within 60 FDA Days	99.26%	97.64%	95.12%		

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	676	593	326		
Average Number of FDA Days to Substantive Interaction	52.62	52.83	52.35		
20th Percentile FDA Days to Substantive Interaction	49	49	48		
40th Percentile FDA Days to Substantive Interaction	56	57	57		
60th Percentile FDA Days to Substantive Interaction	58	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	122	66	105		

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	677	598	386		
Non-MDUFA V Decision	89	79	8		
MDUFA V Decision (SE/NSE)	587	506	177		
MDUFA V Decision Within 90 FDA Days	585	501	175		
510(k)s Pending MDUFA V Decision	1	13	201		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	2		
Current Performance Percent Within 90 FDA Days	99.66%	99.01%	97.77%		

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	1.59	1.33		
Number With MDUFA V Decision	587	506	177		
Average Number of FDA Days to MDUFA V Decision	75.12	74.21	64.36		
20th Percentile FDA Days to MDUFA V Decision	58	56	29		
40th Percentile FDA Days to MDUFA V Decision	83	84	59		
60th Percentile FDA Days to MDUFA V Decision	87	88	85		
80th Percentile FDA Days to MDUFA V Decision	89	90	89		
Maximum FDA Days to MDUFA V Decision	101	95	98		
Average Number of Industry Days to MDUFA V Decision	56.03	50.20	15.58		
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	47	38	0		
80th Percentile Industry Days to MDUFA V Decision	123	117	30		
Maximum Industry Days to MDUFA V Decision	359	351	178		
Average Number of Total Days to MDUFA V Decision	131.25	124.30	79.53		
20th Percentile Total Days to MDUFA V Decision	60	58	29		
40th Percentile Total Days to MDUFA V Decision	88	90	60		
60th Percentile Total Days to MDUFA V Decision	128	124	88		
80th Percentile Total Days to MDUFA V Decision	209	202	116		
Maximum Total Days to MDUFA V Decision	449	440	268		

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	677	598	386		
Number With MDUFA V Decision	587	506	177		
Number of SE Decision	570	501	176		
Number of NSE Decision	17	5	1		
Number of Withdrawal	52	40	6		
Number of Deleted	36	38	1		
Rate of SE Decision	97.10%	99.01%	99.44%		
Rate of NSE Decision	2.90%	0.99%	0.56%		
Rate of Withdrawal	7.68%	6.69%	1.55%		
Rate of Deleted	5.32%	6.35%	0.26%		

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	5	2		
Mean FDA Days for Submissions that Missed the Goal	96.50	92.20	94.50		
Mean Industry Days for Submissions that Missed the Goal	59.50	118.60	0.00		

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	306	275		
Closed Before First RTA or TS Action [1]	3	3	3		
Number Accepted or Passed TS on First Cycle [2]	214	275	234		
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	1	4		
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	15		
Number Not Accepted or Failed TS on First Cycle [2]	96	27	19		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	30.87%	8.91%	7.39%		

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 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	300	250		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	287	281	200		
SI Over 60 FDA Days	11	19	4		
SI Pending Within 60 FDA Days	0	0	46		
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	96.31%	93.67%	98.04%		

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	298	300	204		
Average Number of FDA Days to Substantive Interaction	54.67	54.90	51.18		
20th Percentile FDA Days to Substantive Interaction	56	53	31		
40th Percentile FDA Days to Substantive Interaction	58	58	57		
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	80	95	67		

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	300	250		
Non-MDUFA V Decision	33	31	2		
MDUFA V Decision (SE/NSE)	263	264	110		
MDUFA V Decision Within 90 FDA Days	259	255	110		
510(k)s Pending MDUFA V Decision	2	5	138		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0	1		
Current Performance Percent Within 90 FDA Days	98.11%	96.59%	99.10%		

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	1.78	1.48		
Number With MDUFA V Decision	263	264	110		
Average Number of FDA Days to MDUFA V Decision	77.86	78.38	66.13		
20th Percentile FDA Days to MDUFA V Decision	59	61	30		
40th Percentile FDA Days to MDUFA V Decision	87	87	59		
60th Percentile FDA Days to MDUFA V Decision	89	89	87		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	150	126	90		
Average Number of Industry Days to MDUFA V Decision	76.22	76.47	21.57		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	35	35	0		
60th Percentile Industry Days to MDUFA V Decision	90	91	9		
80th Percentile Industry Days to MDUFA V Decision	168	156	42		
Maximum Industry Days to MDUFA V Decision	367	268	181		
Average Number of Total Days to MDUFA V Decision	154.53	154.86	87.70		
20th Percentile Total Days to MDUFA V Decision	61	81	30		
40th Percentile Total Days to MDUFA V Decision	118	124	72		
60th Percentile Total Days to MDUFA V Decision	175	176	94		
80th Percentile Total Days to MDUFA V Decision	254	238	124		
Maximum Total Days to MDUFA V Decision	517	359	260		

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	300	250		
Number With MDUFA V Decision	263	264	110		
Number of SE Decision	245	245	107		
Number of NSE Decision	18	19	3		
Number of Withdrawal	9	10	2		
Number of Deleted	21	20	0		
Rate of SE Decision	93.16%	92.80%	97.27%		
Rate of NSE Decision	6.84%	7.20%	2.73%		
Rate of Withdrawal	3.02%	3.33%	0.80%		
Rate of Deleted	7.05%	6.67%	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	9	0		
Mean FDA Days for Submissions that Missed the Goal	123.25	103.11	N/A		
Mean Industry Days for Submissions that Missed the Goal	213.75	125.44	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	563	408		
Closed Before First RTA or TS Action [1]	6	4	5		
Number Accepted or Passed TS on First Cycle [2]	517	535	365		
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	0	25		
Number Not Accepted or Failed TS on First Cycle [2]	93	24	13		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.17%	4.29%	3.44%		

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	553	374		
Deleted or Withdrawn Prior to SI	1	2	1		
SI Within 60 FDA Days	604	551	320		
SI Over 60 FDA Days	0	0	1		
SI Pending Within 60 FDA Days	0	0	52		
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%	99.69%		

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	551	321		
Average Number of FDA Days to Substantive Interaction	49.84	50.05	48.43		
20th Percentile FDA Days to Substantive Interaction	30	30	29		
40th Percentile FDA Days to Substantive Interaction	56	56	56		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	59		
Maximum FDA Days to Substantive Interaction	60	60	61		

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	553	374		
Non-MDUFA V Decision	51	53	4		
MDUFA V Decision (SE/NSE)	554	492	223		
MDUFA V Decision Within 90 FDA Days	554	492	222		
510(k)s Pending MDUFA V Decision	0	8	147		
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%	99.55%		

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	1.46	1.24		
Number With MDUFA V Decision	554	492	223		
Average Number of FDA Days to MDUFA V Decision	65.77	65.38	55.37		
20th Percentile FDA Days to MDUFA V Decision	30	30	27		
40th Percentile FDA Days to MDUFA V Decision	59	59	52		
60th Percentile FDA Days to MDUFA V Decision	85	85	60		
80th Percentile FDA Days to MDUFA V Decision	89	88	87		
Maximum FDA Days to MDUFA V Decision	90	90	97		
Average Number of Industry Days to MDUFA V Decision	42.82	42.47	12.29		
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	12	0		
80th Percentile Industry Days to MDUFA V Decision	92	106	11		
Maximum Industry Days to MDUFA V Decision	354	247	167		
Average Number of Total Days to MDUFA V Decision	108.59	108.01	67.45		
20th Percentile Total Days to MDUFA V Decision	30	30	27		
40th Percentile Total Days to MDUFA V Decision	60	60	52		
60th Percentile Total Days to MDUFA V Decision	98	98	60		
80th Percentile Total Days to MDUFA V Decision	179	184	91		
Maximum Total Days to MDUFA V Decision	443	530	252		

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	553	374		
Number With MDUFA V Decision	554	492	223		
Number of SE Decision	544	484	223		
Number of NSE Decision	10	8	0		
Number of Withdrawal	37	37	3		
Number of Deleted	12	16	0		
Rate of SE Decision	98.19%	98.37%	100.00%		
Rate of NSE Decision	1.81%	1.63%	0.00%		
Rate of Withdrawal	6.12%	6.69%	0.80%		
Rate of Deleted	1.98%	2.89%	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	1		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	97.00		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	76.00		

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	216		
Closed Before First RTA or TS Action [1]	7	13	7		
Number Accepted or Passed TS on First Cycle [2]	243	228	186		
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	0	12		
Number Not Accepted or Failed TS on First Cycle [2]	40	13	11		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.89%	5.31%	5.58%		

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	240	191		
Deleted or Withdrawn Prior to SI	3	0	2		
SI Within 60 FDA Days	266	239	161		
SI Over 60 FDA Days	0	1	2		
SI Pending Within 60 FDA Days	0	0	26		
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%	99.58%	98.77%		

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	240	163		
Average Number of FDA Days to Substantive Interaction	52.54	51.18	50.75		
20th Percentile FDA Days to Substantive Interaction	47	43	42		
40th Percentile FDA Days to Substantive Interaction	56	55	56		
60th Percentile FDA Days to Substantive Interaction	58	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	60	81	67		

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	240	191		
Non-MDUFA V Decision	51	41	8		
MDUFA V Decision (SE/NSE)	220	192	79		
MDUFA V Decision Within 90 FDA Days	220	192	79		
510(k)s Pending MDUFA V Decision	0	7	104		
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	1.59	1.63	1.14		
Number With MDUFA V Decision	220	192	79		
Average Number of FDA Days to MDUFA V Decision	76.25	74.68	63.19		
20th Percentile FDA Days to MDUFA V Decision	59	52	28		
40th Percentile FDA Days to MDUFA V Decision	87	86	59		
60th Percentile FDA Days to MDUFA V Decision	89	89	87		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	90	90	90		
Average Number of Industry Days to MDUFA V Decision	80.81	79.06	10.20		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	2	0		
60th Percentile Industry Days to MDUFA V Decision	119	107	0		
80th Percentile Industry Days to MDUFA V Decision	177	174	0		
Maximum Industry Days to MDUFA V Decision	361	361	147		
Average Number of Total Days to MDUFA V Decision	157.05	153.74	73.39		
20th Percentile Total Days to MDUFA V Decision	60	59	28		
40th Percentile Total Days to MDUFA V Decision	90	90	59		
60th Percentile Total Days to MDUFA V Decision	205	195	87		
80th Percentile Total Days to MDUFA V Decision	265	260	90		
Maximum Total Days to MDUFA V Decision	451	451	237		

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	240	191		
Number With MDUFA V Decision	220	192	79		
Number of SE Decision	211	184	77		
Number of NSE Decision	9	8	2		
Number of Withdrawal	28	21	7		
Number of Deleted	23	20	1		
Rate of SE Decision	95.91%	95.83%	97.47%		
Rate of NSE Decision	4.09%	4.17%	2.53%		
Rate of Withdrawal	10.33%	8.75%	3.66%		
Rate of Deleted	8.49%	8.33%	0.52%		

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	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	3	0		
MDUFA V Decision Within 90 FDA Days	2	3	0		
510(k)s Pending MDUFA V Decision	0	1	1		
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	236	190		
Non-MDUFA V Decision	51	41	8		
MDUFA V Decision (SE/NSE)	218	189	79		
MDUFA V Decision Within 90 FDA Days	218	189	79		
510(k)s Pending MDUFA V Decision	0	6	103		
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	461	360		
Closed Before First RTA or TS Action [1]	4	2	3		
Number Accepted or Passed TS on First Cycle [2]	441	447	319		
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	0	26		
Number Not Accepted or Failed TS on First Cycle [2]	41	12	12		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.47%	2.61%	3.63%		

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

Table 6.2 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	455	324		
Deleted or Withdrawn Prior to SI	0	3	0		
SI Within 60 FDA Days	476	451	268		
SI Over 60 FDA Days	0	1	1		
SI Pending Within 60 FDA Days	0	0	55		
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%	99.63%		

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	452	269		
Average Number of FDA Days to Substantive Interaction	49.51	50.89	51.80		
20th Percentile FDA Days to Substantive Interaction	35	46	48		
40th Percentile FDA Days to Substantive Interaction	53	55	56		
60th Percentile FDA Days to Substantive Interaction	57	58	58		
80th Percentile FDA Days to Substantive Interaction	59	59	60		
Maximum FDA Days to Substantive Interaction	60	61	61		

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	476	455	324		
Non-MDUFA V Decision	31	33	4		
MDUFA V Decision (SE/NSE)	445	419	139		
MDUFA V Decision Within 90 FDA Days	445	419	139		
510(k)s Pending MDUFA V Decision	0	3	181		
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 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	1.76	1.60		
Number With MDUFA V Decision	445	419	139		
Average Number of FDA Days to MDUFA V Decision	71.52	74.71	70.02		
20th Percentile FDA Days to MDUFA V Decision	52	57	47		
40th Percentile FDA Days to MDUFA V Decision	79	84	77		
60th Percentile FDA Days to MDUFA V Decision	86	88	86		
80th Percentile FDA Days to MDUFA V Decision	89	89	88		
Maximum FDA Days to MDUFA V Decision	90	90	90		
Average Number of Industry Days to MDUFA V Decision	63.50	66.60	36.50		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	24	31	1		
60th Percentile Industry Days to MDUFA V Decision	62	70	32		
80th Percentile Industry Days to MDUFA V Decision	138	143	79		
Maximum Industry Days to MDUFA V Decision	182	226	161		
Average Number of Total Days to MDUFA V Decision	135.03	141.10	105.49		
20th Percentile Total Days to MDUFA V Decision	56	66	54		
40th Percentile Total Days to MDUFA V Decision	107	114	86		
60th Percentile Total Days to MDUFA V Decision	146	155	115		
80th Percentile Total Days to MDUFA V Decision	222	217	158		
Maximum Total Days to MDUFA V Decision	272	304	238		

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	455	324		
Number With MDUFA V Decision	445	419	139		
Number of SE Decision	438	408	139		
Number of NSE Decision	7	11	0		
Number of Withdrawal	16	24	2		
Number of Deleted	14	9	2		
Rate of SE Decision	98.43%	97.37%	100.00%		
Rate of NSE Decision	1.57%	2.63%	0.00%		
Rate of Withdrawal	3.36%	5.27%	0.62%		
Rate of Deleted	2.94%	1.98%	0.62%		

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

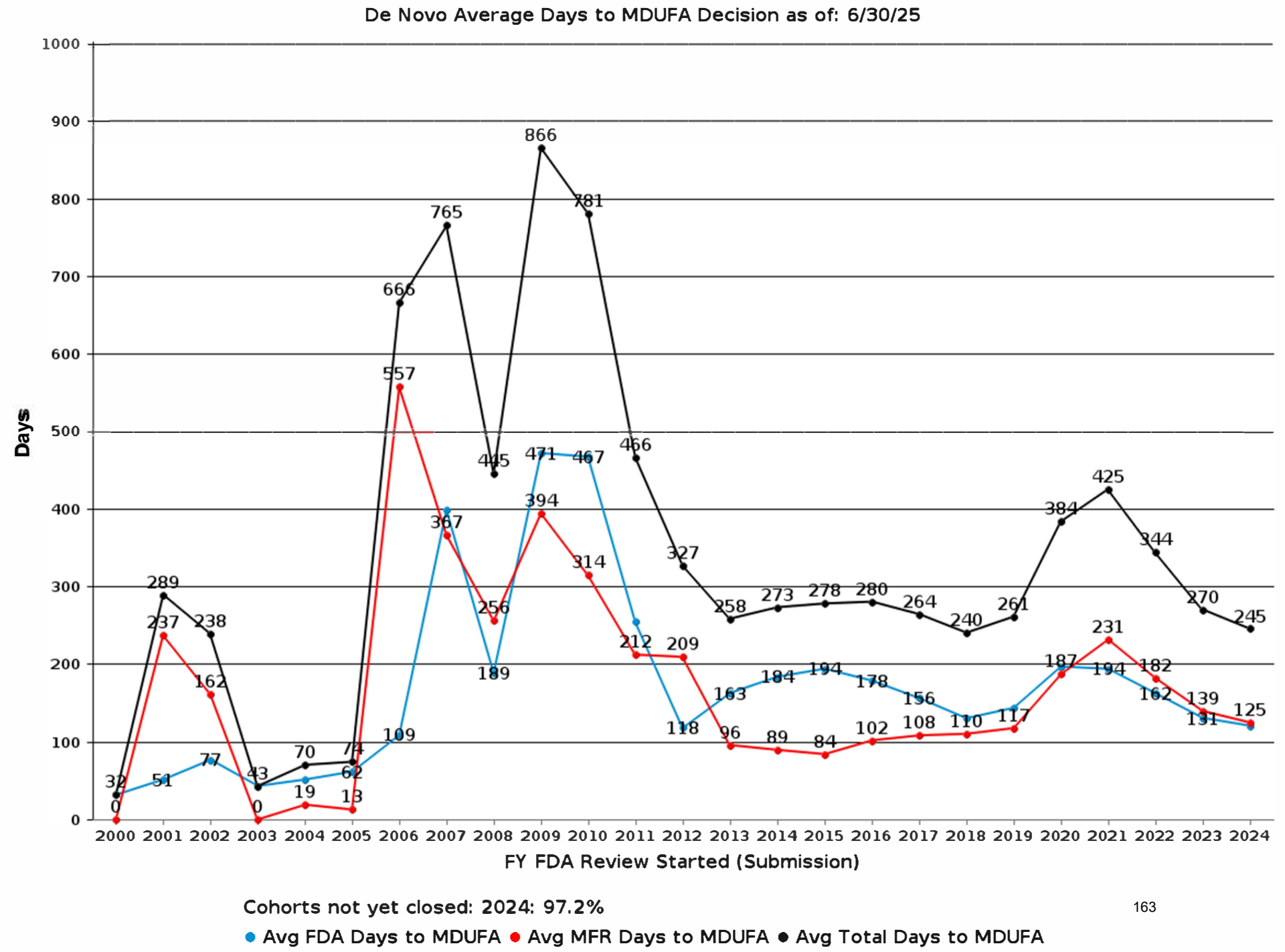
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90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

Q3FY2025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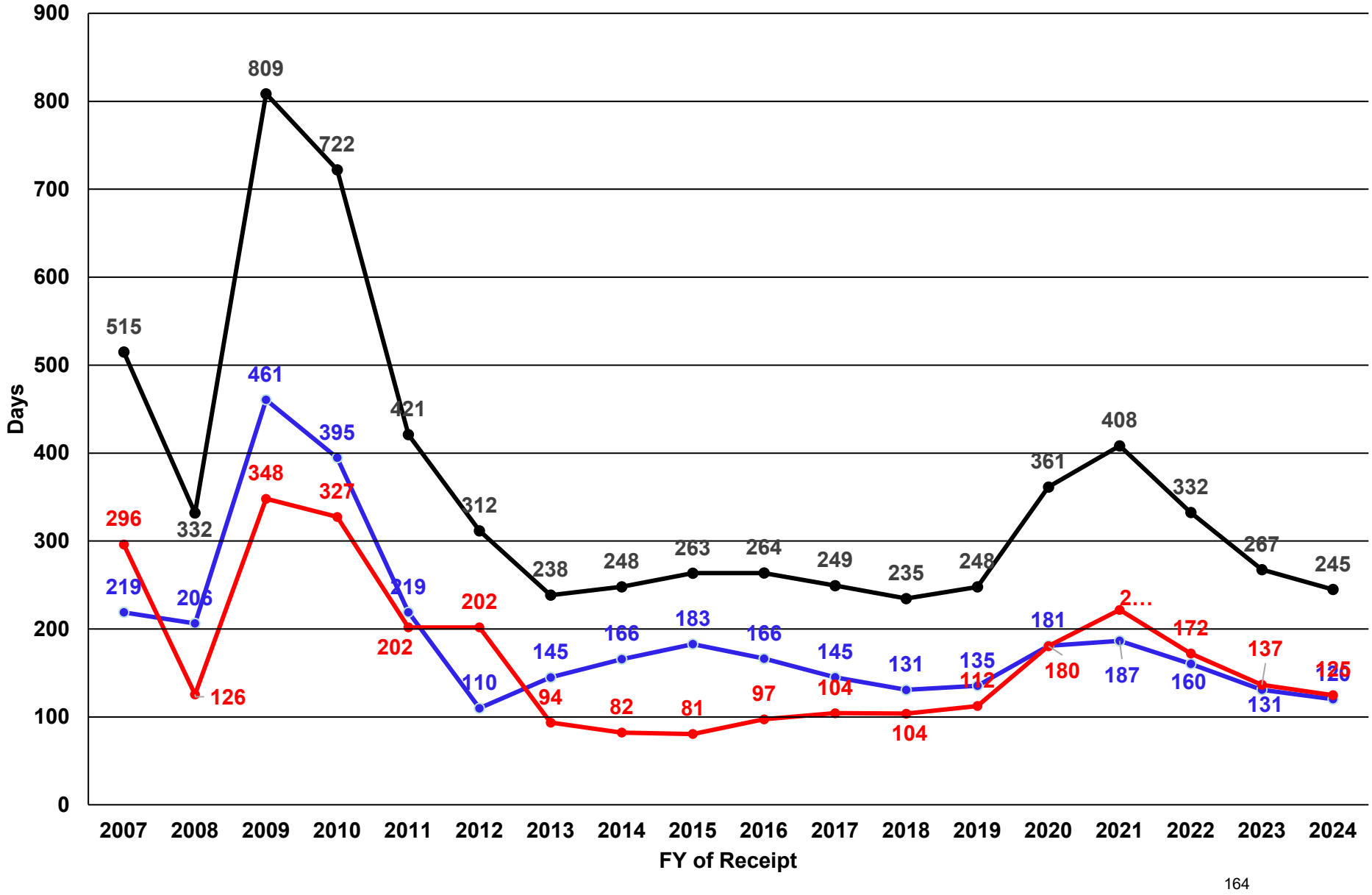
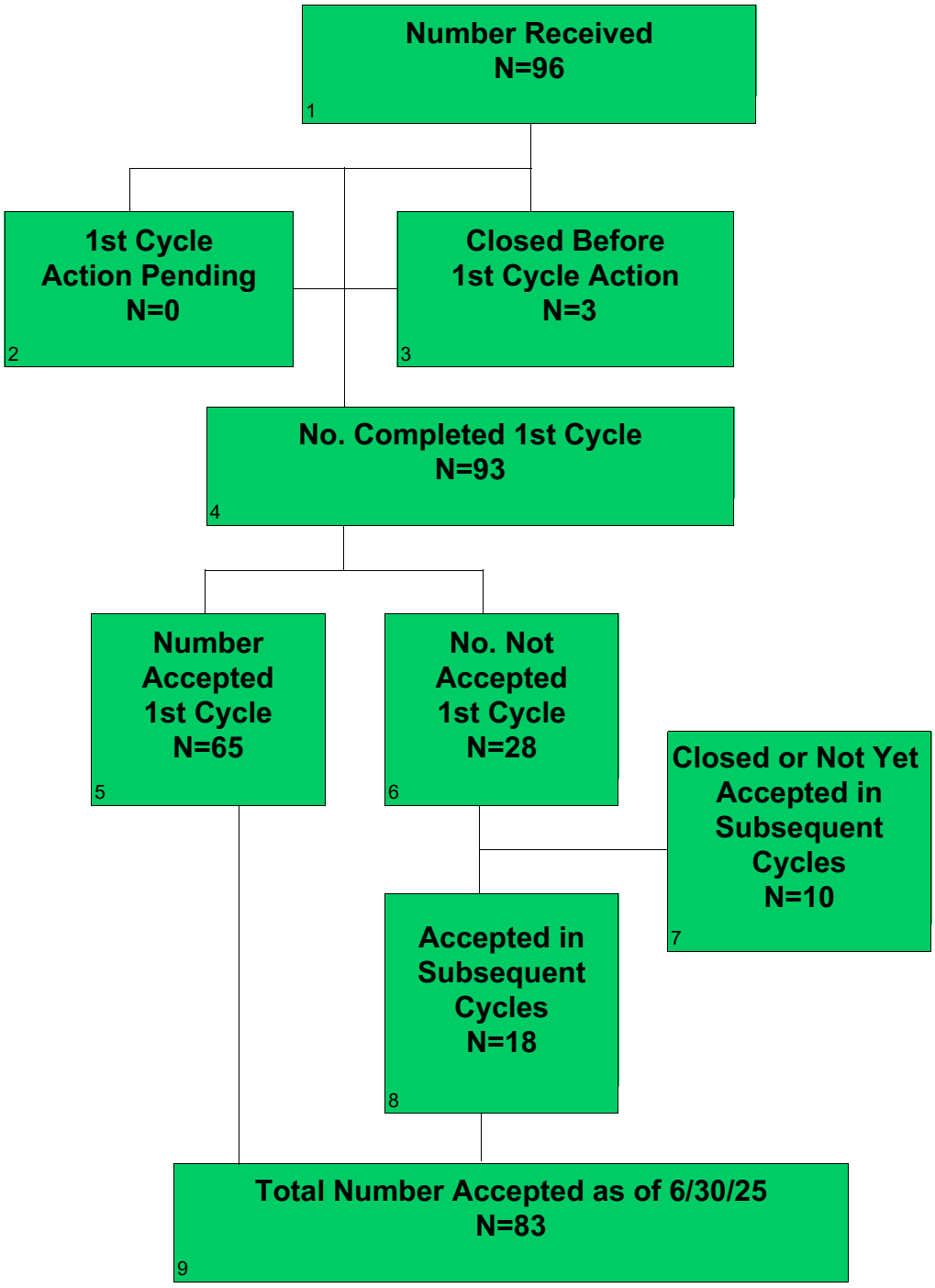
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2024: 97.2%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos

(97.2% closure comparison)



CDRH De Novo - FY 2023
as of 6/30/25



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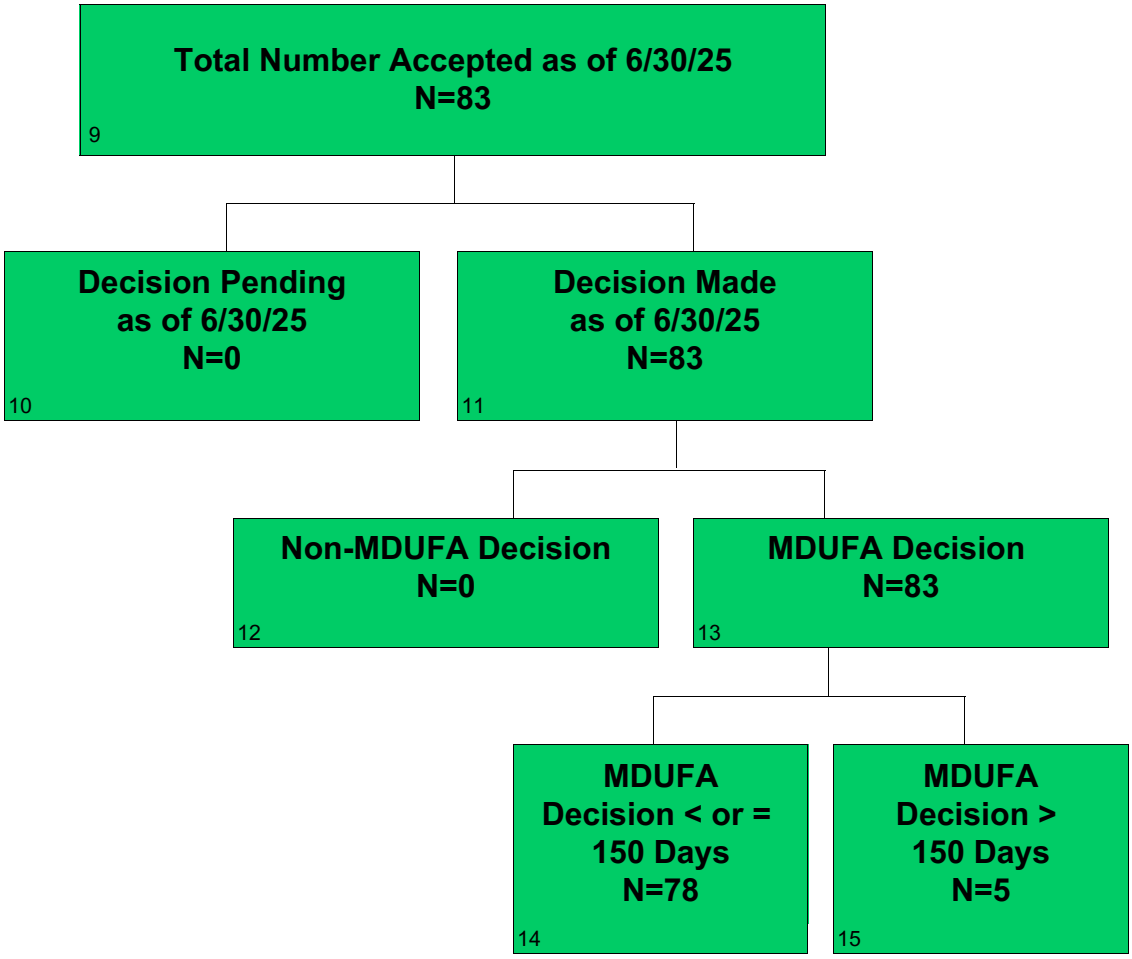

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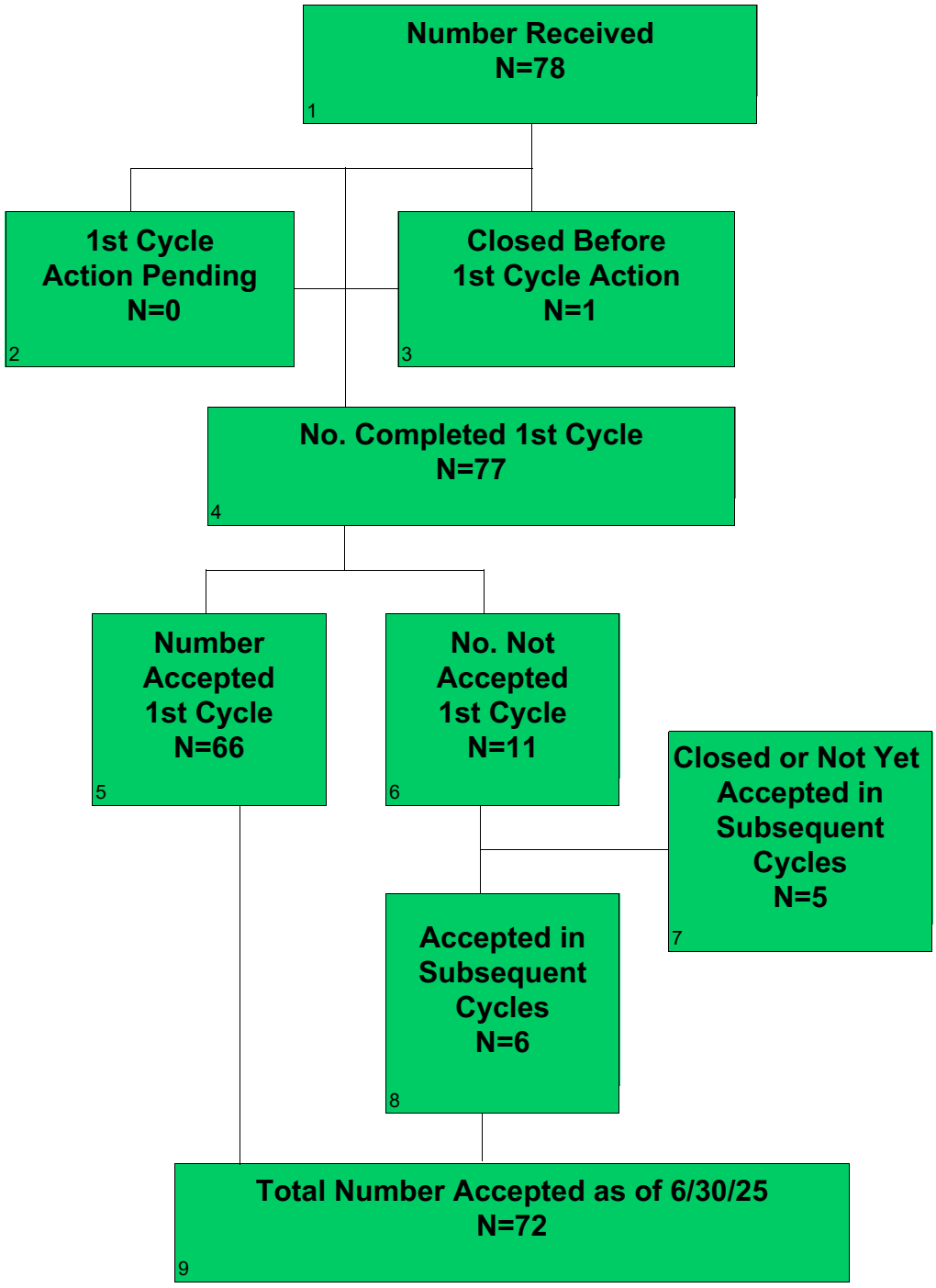

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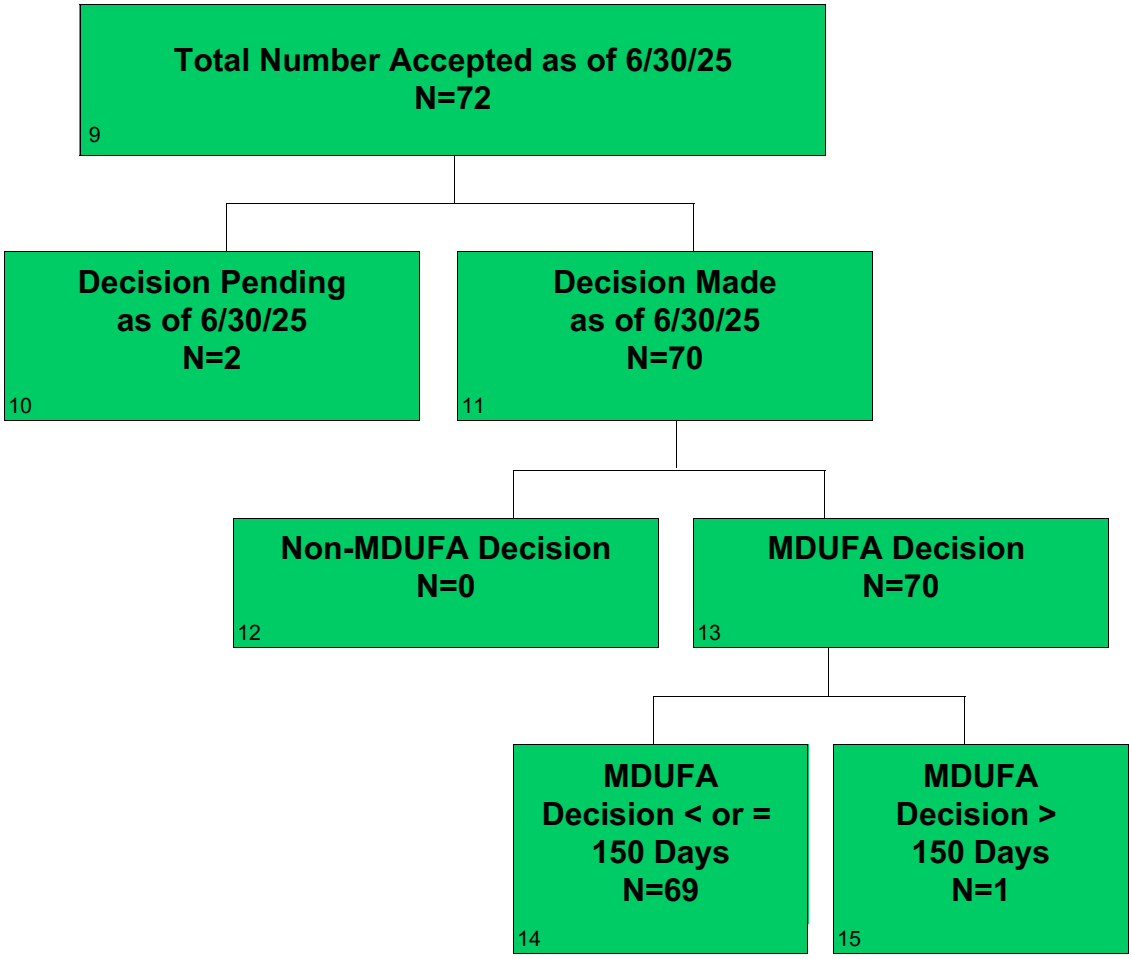

CDRH De Novo - FY 2025
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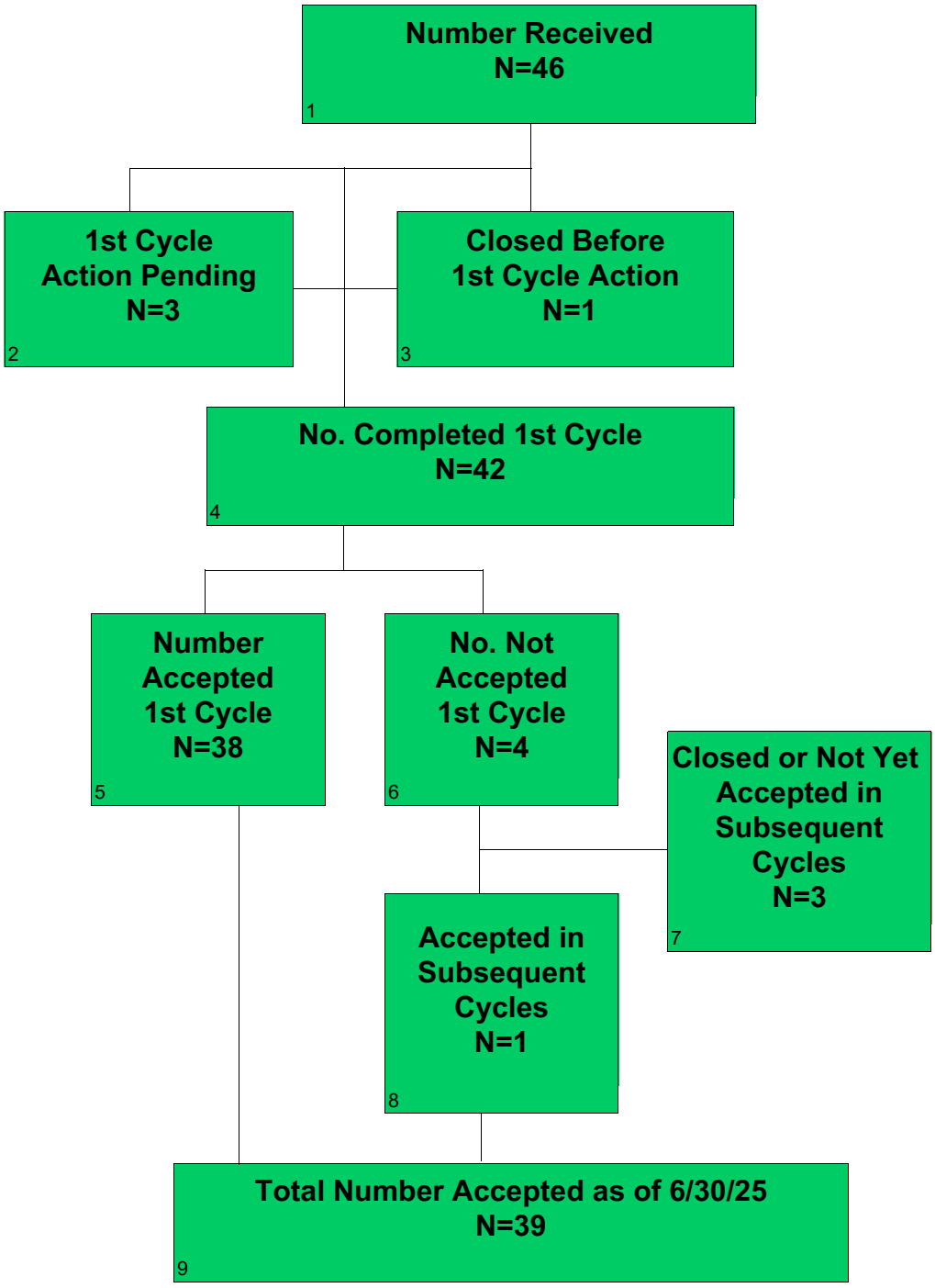

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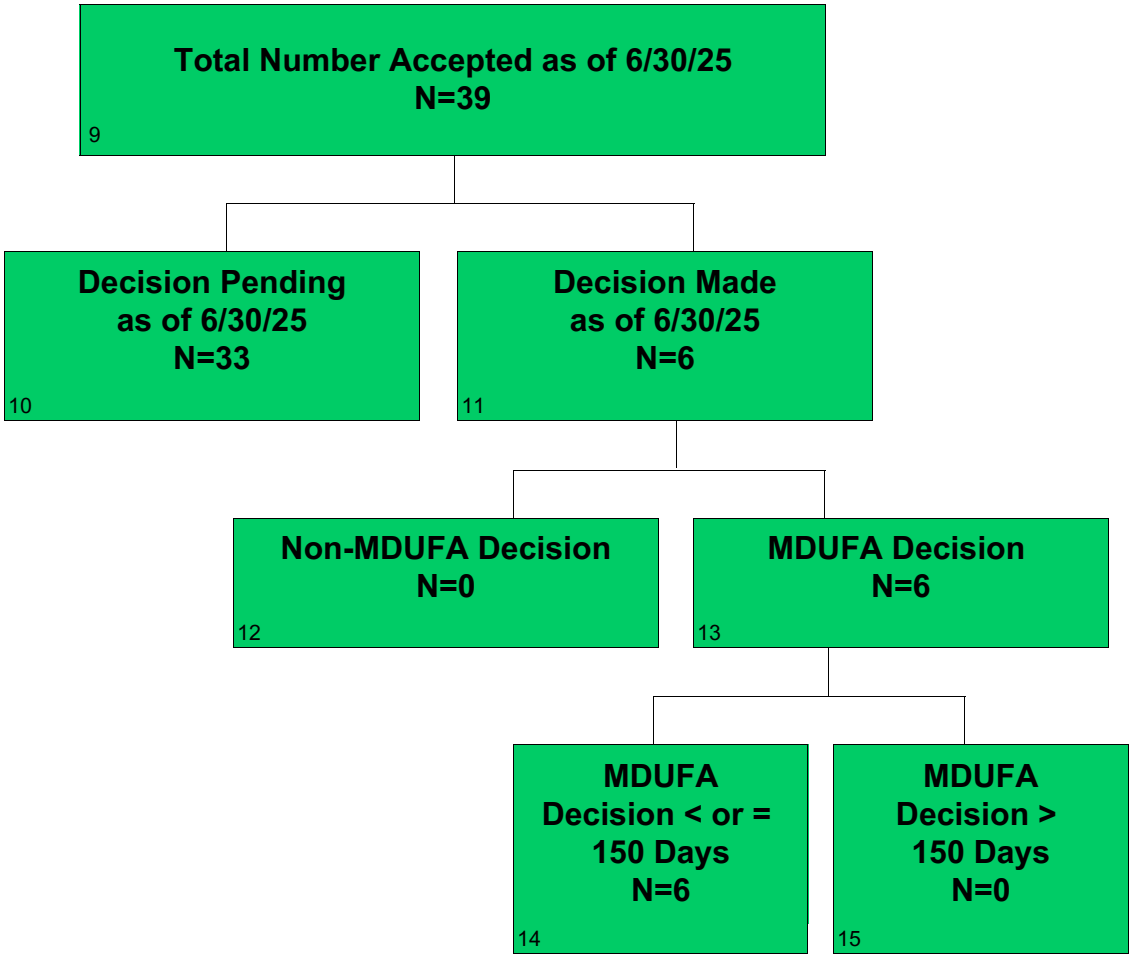


Section 8 De Novo Center Level Metrics

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	46		
Closed Before First RTA or TS Action	3	1	1		
Number Accepted or Passed TS on First Cycle	65	66	38		
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	3		
Number Not Accepted or Failed TS on First Cycle	28	11	4		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	9.52%		

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	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	83	72	39		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	83	70	6		
MDUFA Decision Within 150 FDA Days	78	69	6		
De Novos Pending MDUFA Decision	0	2	33		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	93.98%	98.57%	100.00%		

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.69	1.59	1.33		
Number With MDUFA Decision	83	70	6		
Average FDA Days to MDUFA Decision	130.60	120.59	119.50		
20th Percentile FDA Days to MDUFA Decision	75	75	60		
40th Percentile FDA Days to MDUFA Decision	148	127	150		
60th Percentile FDA Days to MDUFA Decision	150	149	150		
80th Percentile FDA Days to MDUFA Decision	150	150	150		
Maximum FDA Days to MDUFA Decision	251	151	150		
Average Industry Days to MDUFA Decision	139.47	124.69	75.33		
20th Percentile Industry Days to MDUFA Decision	72	26	0		
40th Percentile Industry Days to MDUFA Decision	152	140	31		
60th Percentile Industry Days to MDUFA Decision	178	177	58		
80th Percentile Industry Days to MDUFA Decision	181	180	181		
Maximum Industry Days to MDUFA Decision	350	185	182		
Average Total Days to MDUFA Decision	270.07	245.27	194.83		
20th Percentile Total Days to MDUFA Decision	214	170	150		
40th Percentile Total Days to MDUFA Decision	256	255	181		
60th Percentile Total Days to MDUFA Decision	303	278	208		
80th Percentile Total Days to MDUFA Decision	329	327	238		
Maximum Total Days to MDUFA Decision	437	330	242		

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	39		
Number With MDUFA Decision	83	70	6		
Number With Granted Decision	37	29	3		
Number With Declined Decision	18	17	1		
Number of Withdrawal	17	12	0		
Number of Deleted	11	12	2		
Rate of Granted Decision	44.58%	41.43%	50.00%		
Rate of Declined Decision	21.69%	24.29%	16.67%		
Rate of Withdrawal	20.48%	17.14%	0.00%		
Rate of Deleted	13.25%	17.14%	33.33%		

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	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	18	0		
MDUFA Decision Within 150 FDA Days	19	18	0		
De Novos Pending MDUFA Decision	0	0	5		
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 8.8 CDRH - De Novo Annual General Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	83	72	39		
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.23	11.44	11.95		

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	7		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	6	10	4		
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%	33.33%		

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11	12	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	11	0		
MDUFA Decision Within 150 FDA Days	8	10	0		
De Novos Pending MDUFA Decision	0	1	5		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	72.73%	90.91%	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	1.55	N/A		
Number With MDUFA Decision	11	11	0		
Average FDA Days to MDUFA Decision	130.82	115.64	N/A		
20th Percentile FDA Days to MDUFA Decision	73	73	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	150	0		
Maximum FDA Days to MDUFA Decision	251	151	0		
Average Industry Days to MDUFA Decision	137.45	127.45	N/A		
20th Percentile Industry Days to MDUFA Decision	81	122	0		
40th Percentile Industry Days to MDUFA Decision	152	136	0		
60th Percentile Industry Days to MDUFA Decision	178	150	0		
80th Percentile Industry Days to MDUFA Decision	182	181	0		
Maximum Industry Days to MDUFA Decision	189	181	0		
Average Total Days to MDUFA Decision	268.27	243.09	N/A		
20th Percentile Total Days to MDUFA Decision	231	214	0		
40th Percentile Total Days to MDUFA Decision	255	254	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	328	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	5		
Number With MDUFA Decision	11	11	0		
Number With Granted Decision	5	3	0		
Number With Declined Decision	1	3	0		
Number of Withdrawal	1	3	0		
Number of Deleted	4	2	0		
Rate of Granted Decision	45.45%	27.27%	N/A		
Rate of Declined Decision	9.09%	27.27%	N/A		
Rate of Withdrawal	9.09%	27.27%	N/A		
Rate of Deleted	36.36%	18.18%	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	4	1		
MDUFA Decision Within 150 FDA Days	10	4	1		
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%	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	1.75	1.00		
Number With MDUFA Decision	10	4	1		
Average FDA Days to MDUFA Decision	137.10	149.75	60.00		
20th Percentile FDA Days to MDUFA Decision	140	150	60		
40th Percentile FDA Days to MDUFA Decision	150	150	60		
60th Percentile FDA Days to MDUFA Decision	150	150	60		
80th Percentile FDA Days to MDUFA Decision	150	150	60		
Maximum FDA Days to MDUFA Decision	150	150	60		
Average Industry Days to MDUFA Decision	114.40	114.50	182.00		
20th Percentile Industry Days to MDUFA Decision	47	61	182		
40th Percentile Industry Days to MDUFA Decision	90	116	182		
60th Percentile Industry Days to MDUFA Decision	178	162	182		
80th Percentile Industry Days to MDUFA Decision	180	178	182		
Maximum Industry Days to MDUFA Decision	183	180	182		
Average Total Days to MDUFA Decision	251.50	264.25	242.00		
20th Percentile Total Days to MDUFA Decision	197	210	242		
40th Percentile Total Days to MDUFA Decision	238	266	242		
60th Percentile Total Days to MDUFA Decision	267	312	242		
80th Percentile Total Days to MDUFA Decision	328	328	242		
Maximum Total Days to MDUFA Decision	329	330	242		

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	4	1		
Number With Granted Decision	6	3	0		
Number With Declined Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Deleted	1	0	1		
Rate of Granted Decision	60.00%	75.00%	0.00%		
Rate of Declined Decision	30.00%	25.00%	0.00%		
Rate of Withdrawal	0.00%	0.00%	0.00%		
Rate of Deleted	10.00%	0.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	6		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	9	7	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	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	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	7	0		
MDUFA Decision Within 150 FDA Days	11	7	0		
De Novos Pending MDUFA Decision	0	1	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 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	1.86	N/A		
Number With MDUFA Decision	11	7	0		
Average FDA Days to MDUFA Decision	128.45	130.14	N/A		
20th Percentile FDA Days to MDUFA Decision	74	106	0		
40th Percentile FDA Days to MDUFA Decision	148	146	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	150	0		
Average Industry Days to MDUFA Decision	122.73	157.29	N/A		
20th Percentile Industry Days to MDUFA Decision	83	148	0		
40th Percentile Industry Days to MDUFA Decision	124	178	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	183	0		
Average Total Days to MDUFA Decision	251.18	287.43	N/A		
20th Percentile Total Days to MDUFA Decision	231	261	0		
40th Percentile Total Days to MDUFA Decision	247	281	0		
60th Percentile Total Days to MDUFA Decision	274	311	0		
80th Percentile Total Days to MDUFA Decision	293	327	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	6		
Number With MDUFA Decision	11	7	0		
Number With Granted Decision	7	2	0		
Number With Declined Decision	1	2	0		
Number of Withdrawal	1	2	0		
Number of Deleted	2	1	0		
Rate of Granted Decision	63.64%	28.57%	N/A		
Rate of Declined Decision	9.09%	28.57%	N/A		
Rate of Withdrawal	9.09%	28.57%	N/A		
Rate of Deleted	18.18%	14.29%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	5		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	11	11	4		
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	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	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	12	0		
MDUFA Decision Within 150 FDA Days	13	12	0		
De Novos Pending MDUFA Decision	0	0	4		
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	1.50	N/A		
Number With MDUFA Decision	15	12	0		
Average FDA Days to MDUFA Decision	126.87	119.92	N/A		
20th Percentile FDA Days to MDUFA Decision	75	74	0		
40th Percentile FDA Days to MDUFA Decision	143	117	0		
60th Percentile FDA Days to MDUFA Decision	148	150	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	129.00	N/A		
20th Percentile Industry Days to MDUFA Decision	80	29	0		
40th Percentile Industry Days to MDUFA Decision	156	165	0		
60th Percentile Industry Days to MDUFA Decision	180	174	0		
80th Percentile Industry Days to MDUFA Decision	181	179	0		
Maximum Industry Days to MDUFA Decision	198	185	0		
Average Total Days to MDUFA Decision	261.73	248.92	N/A		
20th Percentile Total Days to MDUFA Decision	228	164	0		
40th Percentile Total Days to MDUFA Decision	254	247	0		
60th Percentile Total Days to MDUFA Decision	302	319	0		
80th Percentile Total Days to MDUFA Decision	329	326	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	4		
Number With MDUFA Decision	15	12	0		
Number With Granted Decision	7	7	0		
Number With Declined Decision	2	2	0		
Number of Withdrawal	5	2	0		
Number of Deleted	1	1	0		
Rate of Granted Decision	46.67%	58.33%	N/A		
Rate of Declined Decision	13.33%	16.67%	N/A		
Rate of Withdrawal	33.33%	16.67%	N/A		
Rate of Deleted	6.67%	8.33%	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	13		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	5	11	12		
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	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	12		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	9	12	4		
MDUFA Decision Within 150 FDA Days	9	12	4		
De Novos Pending MDUFA Decision	0	0	8		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.11	1.67	1.50		
Number With MDUFA Decision	9	12	4		
Average FDA Days to MDUFA Decision	141.44	118.92	150.00		
20th Percentile FDA Days to MDUFA Decision	149	76	150		
40th Percentile FDA Days to MDUFA Decision	150	109	150		
60th Percentile FDA Days to MDUFA Decision	150	148	150		
80th Percentile FDA Days to MDUFA Decision	150	150	150		
Maximum FDA Days to MDUFA Decision	150	150	150		
Average Industry Days to MDUFA Decision	145.56	110.58	22.25		
20th Percentile Industry Days to MDUFA Decision	112	6	0		
40th Percentile Industry Days to MDUFA Decision	154	111	6		
60th Percentile Industry Days to MDUFA Decision	172	176	25		
80th Percentile Industry Days to MDUFA Decision	182	179	42		
Maximum Industry Days to MDUFA Decision	231	183	58		
Average Total Days to MDUFA Decision	287.00	229.50	172.25		
20th Percentile Total Days to MDUFA Decision	237	105	150		
40th Percentile Total Days to MDUFA Decision	300	255	156		
60th Percentile Total Days to MDUFA Decision	313	263	175		
80th Percentile Total Days to MDUFA Decision	326	326	192		
Maximum Total Days to MDUFA Decision	381	328	208		

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	12		
Number With MDUFA Decision	9	12	4		
Number With Granted Decision	3	3	3		
Number With Declined Decision	5	6	1		
Number of Withdrawal	0	1	0		
Number of Deleted	1	2	0		
Rate of Granted Decision	33.33%	25.00%	75.00%		
Rate of Declined Decision	55.56%	50.00%	25.00%		
Rate of Withdrawal	0.00%	8.33%	0.00%		
Rate of Deleted	11.11%	16.67%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	4		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	3	2	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	0		
Number Not Accepted or Failed TS on First Cycle	0	0	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	0.00%	25.00%		

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

Table 8.2 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	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	2	1		
MDUFA Decision Within 150 FDA Days	3	2	1		
De Novos Pending MDUFA Decision	0	0	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

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	1.50	1.00		
Number With MDUFA Decision	3	2	1		
Average FDA Days to MDUFA Decision	149.00	111.50	57.00		
20th Percentile FDA Days to MDUFA Decision	148	88	57		
40th Percentile FDA Days to MDUFA Decision	149	104	57		
60th Percentile FDA Days to MDUFA Decision	149	119	57		
80th Percentile FDA Days to MDUFA Decision	150	135	57		
Maximum FDA Days to MDUFA Decision	150	150	57		
Average Industry Days to MDUFA Decision	119.33	180.00	181.00		
20th Percentile Industry Days to MDUFA Decision	71	179	181		
40th Percentile Industry Days to MDUFA Decision	142	180	181		
60th Percentile Industry Days to MDUFA Decision	178	180	181		
80th Percentile Industry Days to MDUFA Decision	179	181	181		
Maximum Industry Days to MDUFA Decision	180	181	181		
Average Total Days to MDUFA Decision	268.33	291.50	238.00		
20th Percentile Total Days to MDUFA Decision	220	269	238		
40th Percentile Total Days to MDUFA Decision	292	284	238		
60th Percentile Total Days to MDUFA Decision	328	299	238		
80th Percentile Total Days to MDUFA Decision	329	314	238		
Maximum Total Days to MDUFA Decision	329	329	238		

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	3		
Number With MDUFA Decision	3	2	1		
Number With Granted Decision	2	1	0		
Number With Declined Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	1	1		
Rate of Granted Decision	66.67%	50.00%	0.00%		
Rate of Declined Decision	33.33%	0.00%	0.00%		
Rate of Withdrawal	0.00%	0.00%	0.00%		
Rate of Deleted	0.00%	50.00%	100.00%		

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	7		
Closed Before First RTA or TS Action	1	1	1		
Number Accepted or Passed TS on First Cycle	17	17	5		
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	5	2	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	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.

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	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	18	0		
MDUFA Decision Within 150 FDA Days	20	18	0		
De Novos Pending MDUFA Decision	0	0	5		
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	1.50	N/A		
Number With MDUFA Decision	20	18	0		
Average FDA Days to MDUFA Decision	127.95	116.61	N/A		
20th Percentile FDA Days to MDUFA Decision	85	73	0		
40th Percentile FDA Days to MDUFA Decision	140	113	0		
60th Percentile FDA Days to MDUFA Decision	149	148	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	114.33	N/A		
20th Percentile Industry Days to MDUFA Decision	139	16	0		
40th Percentile Industry Days to MDUFA Decision	175	101	0		
60th Percentile Industry Days to MDUFA Decision	179	175	0		
80th Percentile Industry Days to MDUFA Decision	182	181	0		
Maximum Industry Days to MDUFA Decision	350	185	0		
Average Total Days to MDUFA Decision	295.80	230.94	N/A		
20th Percentile Total Days to MDUFA Decision	252	155	0		
40th Percentile Total Days to MDUFA Decision	299	235	0		
60th Percentile Total Days to MDUFA Decision	328	256	0		
80th Percentile Total Days to MDUFA Decision	330	322	0		
Maximum Total Days to MDUFA Decision	437	329	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	5		
Number With MDUFA Decision	20	18	0		
Number With Granted Decision	5	9	0		
Number With Declined Decision	5	2	0		
Number of Withdrawal	9	3	0		
Number of Deleted	1	4	0		
Rate of Granted Decision	25.00%	50.00%	N/A		
Rate of Declined Decision	25.00%	11.11%	N/A		
Rate of Withdrawal	45.00%	16.67%	N/A		
Rate of Deleted	5.00%	22.22%	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	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	18	0		
MDUFA Decision Within 150 FDA Days	19	18	0		
De Novos Pending MDUFA Decision	0	0	5		
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	3		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	4	4	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	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	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	4	0		
MDUFA Decision Within 150 FDA Days	4	4	0		
De Novos Pending MDUFA Decision	0	0	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 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	4	0		
Average FDA Days to MDUFA Decision	108.75	117.75	N/A		
20th Percentile FDA Days to MDUFA Decision	70	95	0		
40th Percentile FDA Days to MDUFA Decision	89	115	0		
60th Percentile FDA Days to MDUFA Decision	133	133	0		
80th Percentile FDA Days to MDUFA Decision	149	143	0		
Maximum FDA Days to MDUFA Decision	150	149	0		
Average Industry Days to MDUFA Decision	130.50	118.50	N/A		
20th Percentile Industry Days to MDUFA Decision	83	70	0		
40th Percentile Industry Days to MDUFA Decision	132	129	0		
60th Percentile Industry Days to MDUFA Decision	169	164	0		
80th Percentile Industry Days to MDUFA Decision	186	178	0		
Maximum Industry Days to MDUFA Decision	193	181	0		
Average Total Days to MDUFA Decision	239.25	236.25	N/A		
20th Percentile Total Days to MDUFA Decision	190	197	0		
40th Percentile Total Days to MDUFA Decision	258	257	0		
60th Percentile Total Days to MDUFA Decision	265	264	0		
80th Percentile Total Days to MDUFA Decision	297	286	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	3		
Number With MDUFA Decision	4	4	0		
Number With Granted Decision	2	1	0		
Number With Declined Decision	0	1	0		
Number of Withdrawal	1	1	0		
Number of Deleted	1	1	0		
Rate of Granted Decision	50.00%	25.00%	N/A		
Rate of Declined Decision	0.00%	25.00%	N/A		
Rate of Withdrawal	25.00%	25.00%	N/A		
Rate of Deleted	25.00%	25.00%	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		

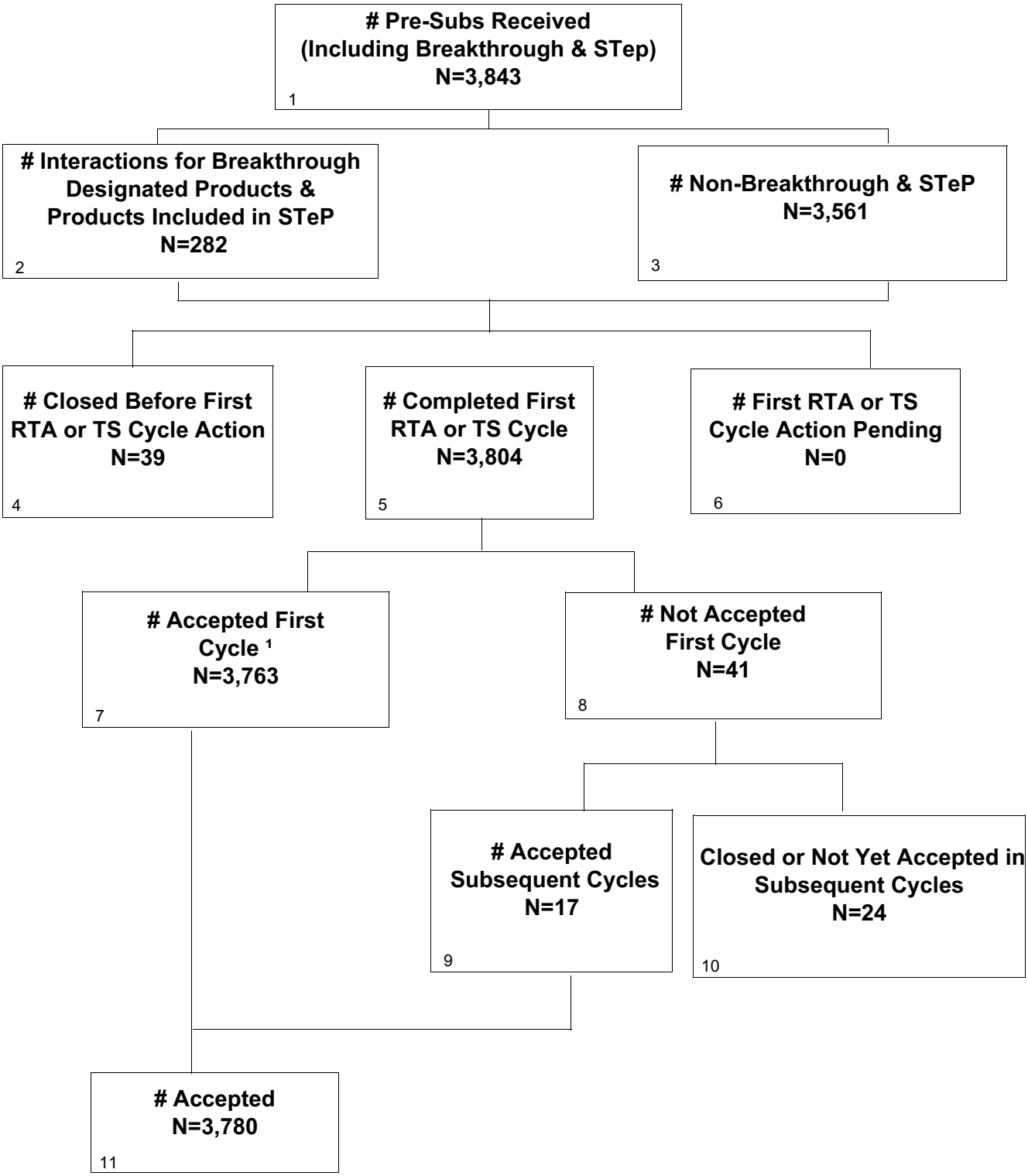
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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

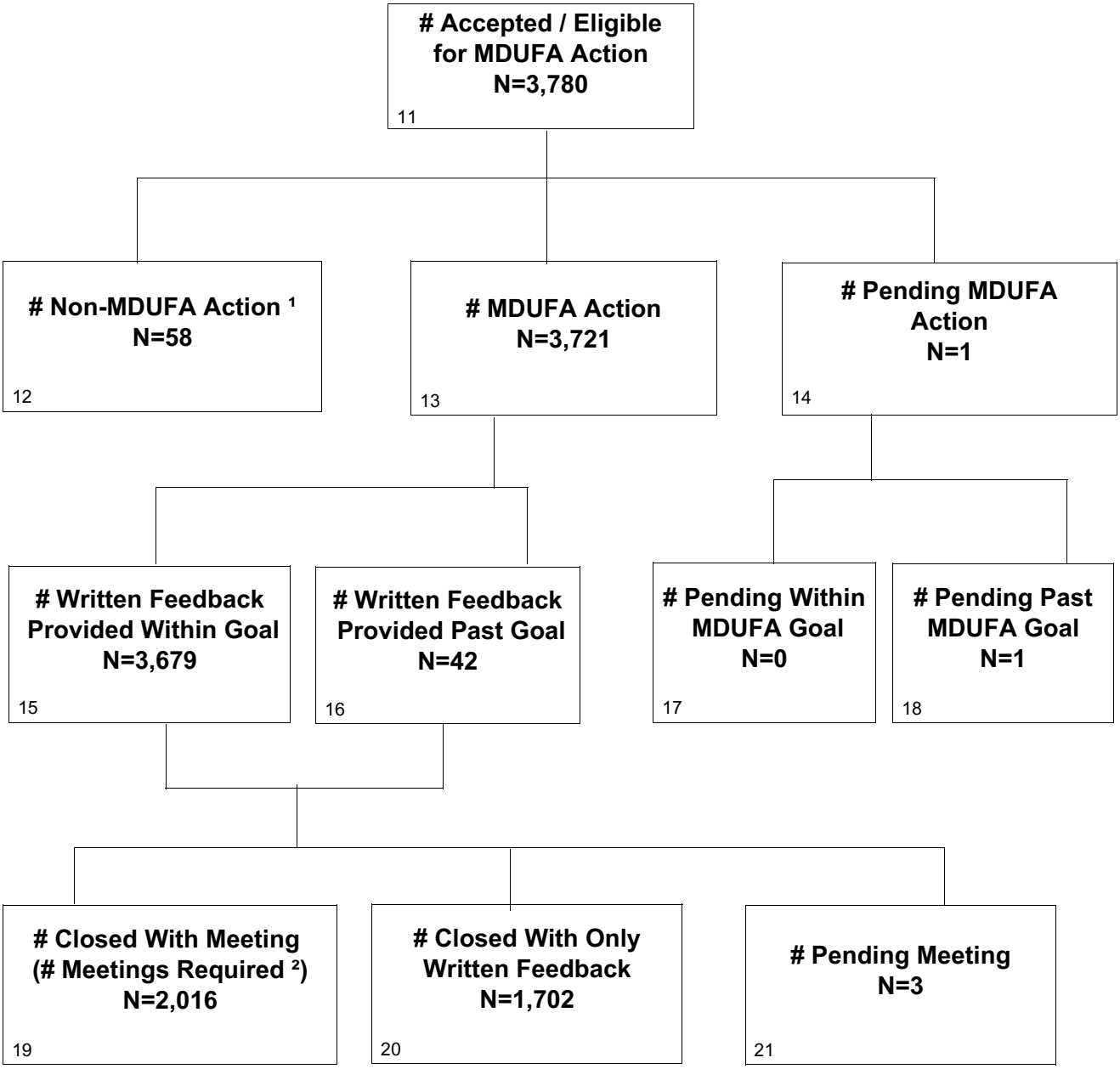
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A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

CDRH Pre-Sub - FY 2023
as of 6/30/25



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

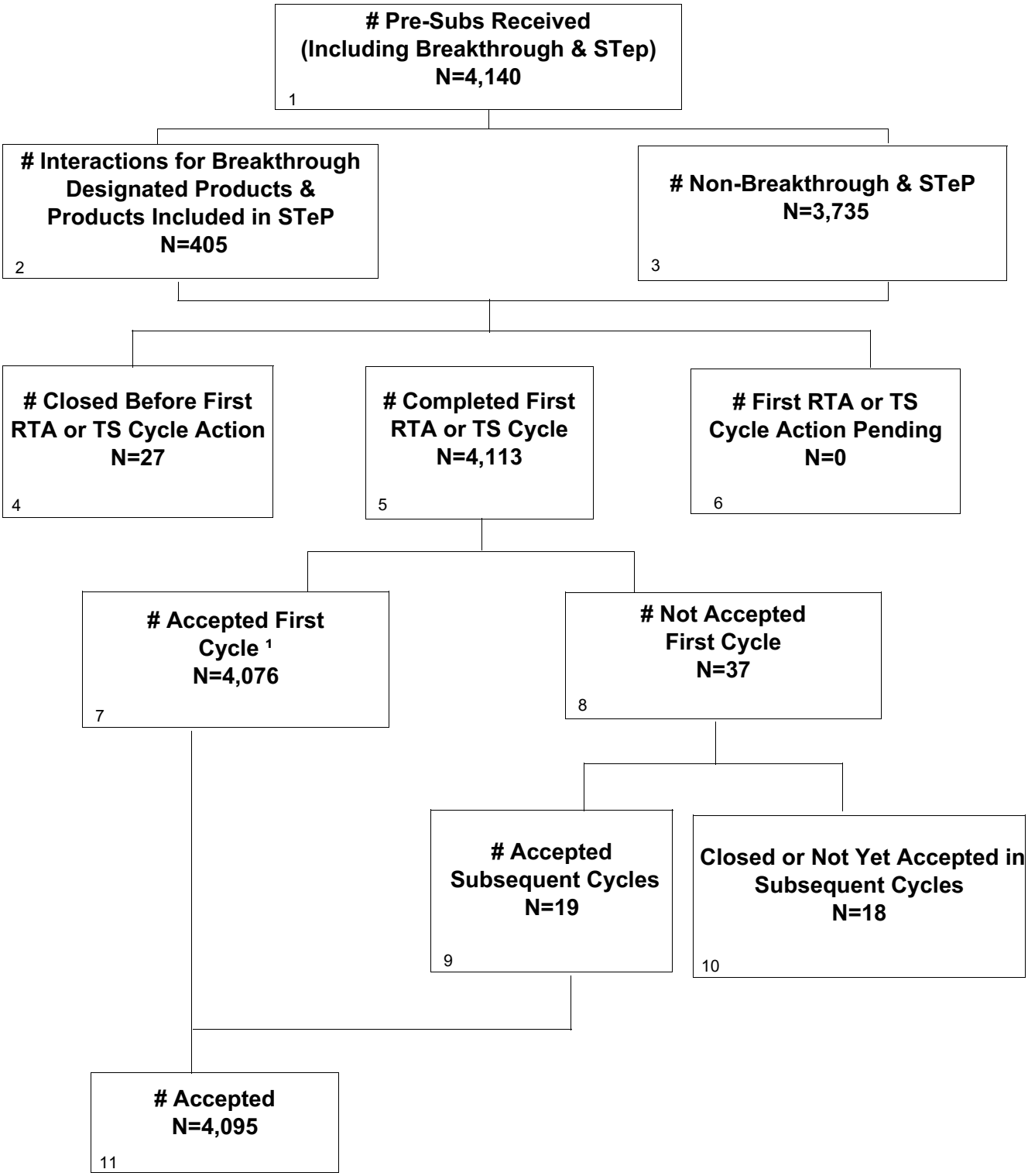
CDRH Pre-Sub - FY 2023
as of 6/30/25 Continued



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

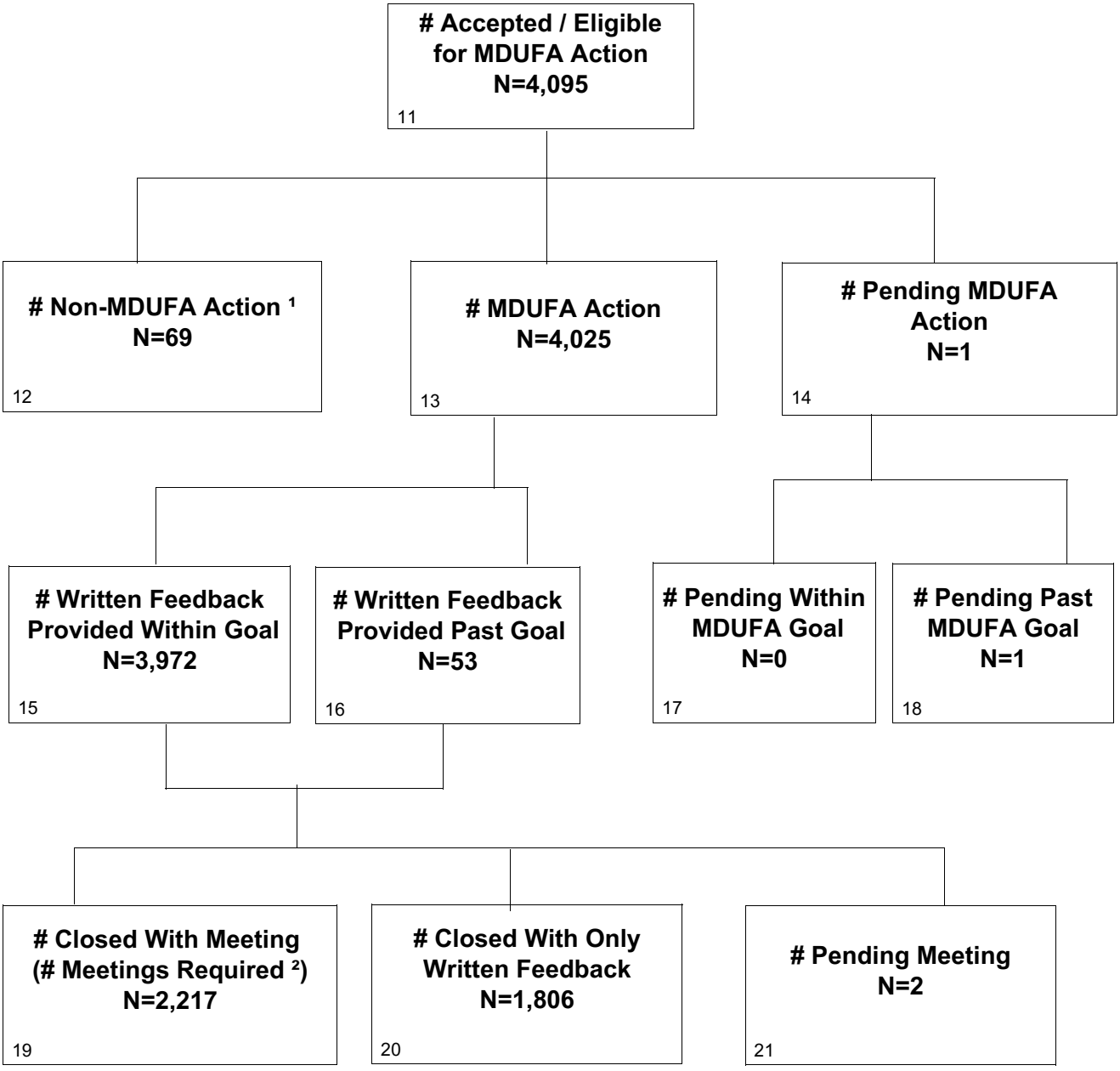
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 6/30/25



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

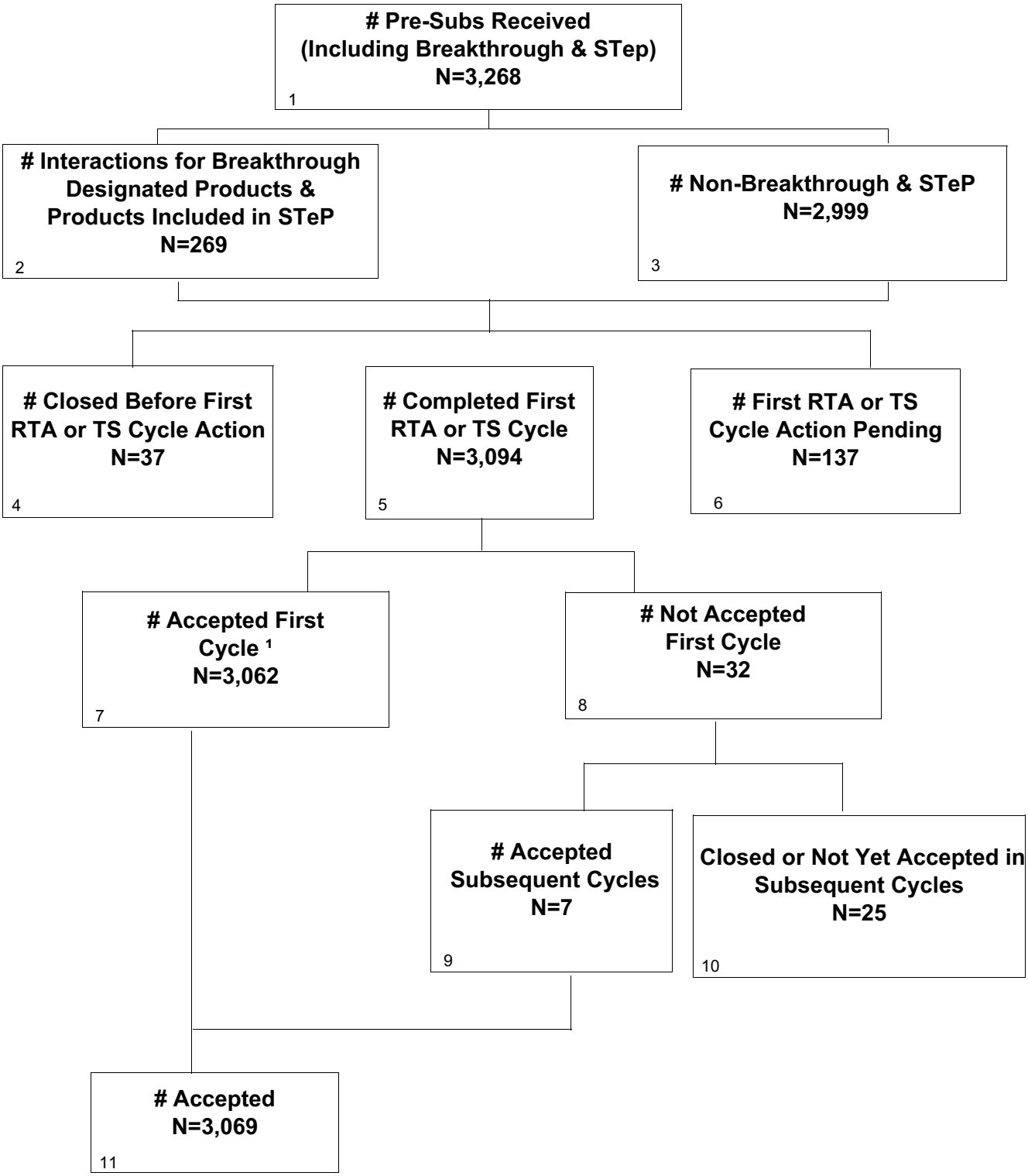
CDRH Pre-Sub - FY 2024
as of 6/30/25 Continued



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.

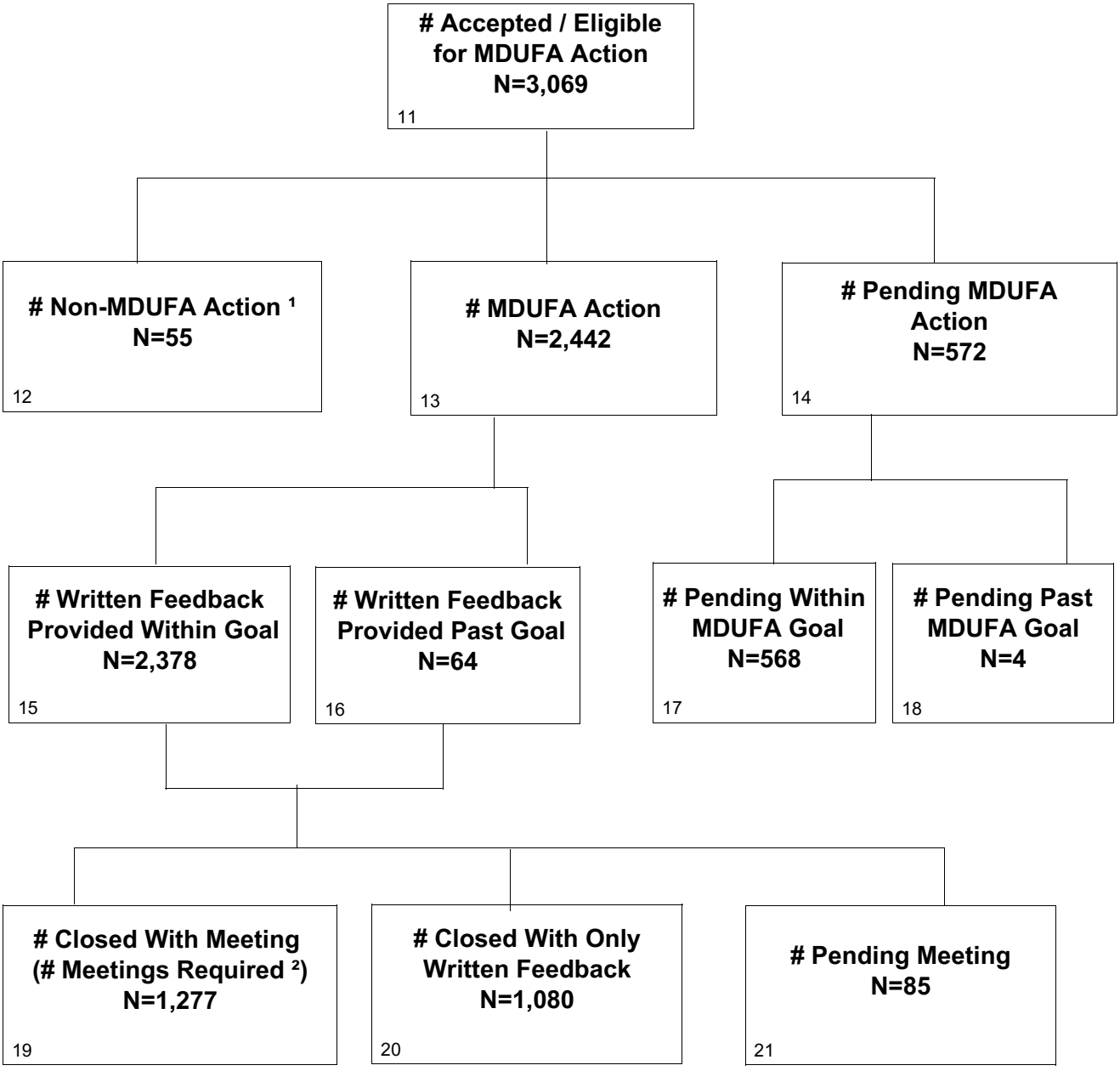
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2025
as of 6/30/25



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 6/30/25 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	4,140	3,268		
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	269		
Number Closed Before First RTA Action	39	27	37		
Number Accepted First RTA Cycle [1]	3,642	3,979	2,959		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	97	103		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	137		
Number Not Accepted First RTA Cycle	41	37	32		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	1.03%		

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	4,095	3,069		
Number with Non-MDUFA Action [3]	58	69	55		
Number with MDUFA Action	3,721	4,025	2,442		
Written Feedback Provided Within Goal	3,679	3,972	2,378		
Number Pending MDUFA Action	1	1	572		
Pending MDUFA Action Past Goal	1	1	4		
Number in MDUFA Cohort (up to max 4300)[4]	3,722	4,026	3,014		
Current Performance Percent Within Goal	98.84%	98.66%	97.22%		

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	4,025	2,442		
Average FDA Days to Written Feedback	62.20	62.25	61.21		
20th Percentile FDA Days to Written Feedback	56	56	55		
40th Percentile FDA Days to Written Feedback	64	64	63		
60th Percentile FDA Days to Written Feedback	68	67	67		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	141	245	141		

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	94		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	39.83		

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]	2,015	2,217	1,227		
Meeting Minutes Submitted Within 15 Days of Meeting	1,531	1,786	987		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	64		
Meeting Minutes Past 15 Days of Meeting	434	366	186		
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	65	40		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.98%	80.56%	81.37%		

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	258		
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	9		
Number Closed Before First RTA Action	4	6	2		
Number Accepted First RTA Cycle [1]	411	462	230		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	20	5		
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	7		
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.89%		

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	237		
Number with Non-MDUFA Action [3]	12	12	6		
Number with MDUFA Action	423	474	148		
Written Feedback Provided Within Goal	410	461	144		
Number Pending MDUFA Action	0	0	83		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	423	474	231		
Current Performance Percent Within Goal	96.93%	97.26%	97.30%		

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	148		
Average FDA Days to Written Feedback	65.34	65.27	63.70		
20th Percentile FDA Days to Written Feedback	62	62	59		
40th Percentile FDA Days to Written Feedback	66	66	66		
60th Percentile FDA Days to Written Feedback	69	69	69		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	141	101	81		

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	13		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	38.00		

Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	249	276	80		
Meeting Minutes Submitted Within 15 Days of Meeting	179	227	56		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	3		
Meeting Minutes Past 15 Days of Meeting	59	38	14		
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	11	7		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	82.25%	72.73%		

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	722	745	383		
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	30		
Number Closed Before First RTA Action	6	2	2		
Number Accepted First RTA Cycle [1]	699	726	343		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	14	16		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	21		
Number Not Accepted First RTA Cycle	4	3	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.28%		

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	715	741	359		
Number with Non-MDUFA Action [3]	4	4	3		
Number with MDUFA Action	710	736	236		
Written Feedback Provided Within Goal	695	715	215		
Number Pending MDUFA Action	1	1	120		
Pending MDUFA Action Past Goal	1	1	1		
Number in MDUFA Cohort (up to max 4300)[4]	711	737	356		
Current Performance Percent Within Goal	97.75%	97.01%	90.72%		

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 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	710	736	236		
Average FDA Days to Written Feedback	59.30	59.66	58.92		
20th Percentile FDA Days to Written Feedback	50	51	50		
40th Percentile FDA Days to Written Feedback	60	61	59		
60th Percentile FDA Days to Written Feedback	66	65	65		
80th Percentile FDA Days to Written Feedback	69	69	70		
Maximum FDA Days to Written Feedback	103	113	89		

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	12		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.19	36.90	35.75		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	404	424	122		
Meeting Minutes Submitted Within 15 Days of Meeting	306	318	90		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	9		
Meeting Minutes Past 15 Days of Meeting	91	90	16		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	16	7		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.74%	75.00%	79.65%		

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	509	279		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	26		
Number Closed Before First RTA Action	5	4	5		
Number Accepted First RTA Cycle [1]	438	483	238		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	11	8		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	23		
Number Not Accepted First RTA Cycle	6	11	5		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.18%	1.99%		

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	498	247		
Number with Non-MDUFA Action [3]	10	11	2		
Number with MDUFA Action	443	487	165		
Written Feedback Provided Within Goal	439	484	162		
Number Pending MDUFA Action	0	0	80		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	443	487	245		
Current Performance Percent Within Goal	99.10%	99.38%	98.18%		

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	487	165		
Average FDA Days to Written Feedback	62.12	61.72	62.18		
20th Percentile FDA Days to Written Feedback	56	56	57		
40th Percentile FDA Days to Written Feedback	64	63	63		
60th Percentile FDA Days to Written Feedback	67	67	67		
80th Percentile FDA Days to Written Feedback	70	70	69		
Maximum FDA Days to Written Feedback	78	78	79		

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	5		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	43.50	42.80		

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	267	79		
Meeting Minutes Submitted Within 15 Days of Meeting	200	221	69		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	49	39	4		
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	7	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.43%	82.77%	93.24%		

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	383	465	281		
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	17		
Number Closed Before First RTA Action	4	5	5		
Number Accepted First RTA Cycle [1]	363	438	246		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	14	20		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	10		
Number Not Accepted First RTA Cycle	7	8	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.85%	1.74%	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	375	457	266		
Number with Non-MDUFA Action [3]	11	18	8		
Number with MDUFA Action	364	439	176		
Written Feedback Provided Within Goal	364	437	171		
Number Pending MDUFA Action	0	0	82		
Pending MDUFA Action Past Goal	0	0	1		
Number in MDUFA Cohort (up to max 4300)[4]	364	439	258		
Current Performance Percent Within Goal	100.00%	99.54%	96.61%		

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

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

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

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

Table 9.3 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	364	439	176		
Average FDA Days to Written Feedback	60.57	61.87	58.90		
20th Percentile FDA Days to Written Feedback	55	56	50		
40th Percentile FDA Days to Written Feedback	62	63	60		
60th Percentile FDA Days to Written Feedback	65	67	65		
80th Percentile FDA Days to Written Feedback	69	70	69		
Maximum FDA Days to Written Feedback	70	70	85		

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	8		
Average Days to Scheduling for Meetings Scheduled After Day 30	37.53	40.00	40.38		

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]	208	235	97		
Meeting Minutes Submitted Within 15 Days of Meeting	161	183	73		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	4		
Meeting Minutes Past 15 Days of Meeting	39	48	18		
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	4	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.40%	77.87%	78.49%		

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	208		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	20		
Number Closed Before First RTA Action	5	3	1		
Number Accepted First RTA Cycle [1]	370	404	177		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	10	6		
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	4	9	7		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.13%	3.68%		

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	184		
Number with Non-MDUFA Action [3]	5	5	3		
Number with MDUFA Action	384	414	131		
Written Feedback Provided Within Goal	382	406	126		
Number Pending MDUFA Action	0	0	50		
Pending MDUFA Action Past Goal	0	0	3		
Number in MDUFA Cohort (up to max 4300)[4]	384	414	181		
Current Performance Percent Within Goal	99.48%	98.07%	94.03%		

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	131		
Average FDA Days to Written Feedback	66.14	67.29	64.75		
20th Percentile FDA Days to Written Feedback	64	65	62		
40th Percentile FDA Days to Written Feedback	68	69	67		
60th Percentile FDA Days to Written Feedback	70	70	70		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	108	245	78		

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	10		
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	39.26	36.10		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	249	257	69		
Meeting Minutes Submitted Within 15 Days of Meeting	178	205	53		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	64	43	8		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	9	3		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.49%	79.77%	82.81%		

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	288	294	146		
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	23		
Number Closed Before First RTA Action	5	1	1		
Number Accepted First RTA Cycle [1]	269	286	131		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	7	4		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	9		
Number Not Accepted First RTA Cycle	4	0	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.41%	0.00%	0.74%		

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

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

Table 9.2 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	281	293	135		
Number with Non-MDUFA Action [3]	6	8	7		
Number with MDUFA Action	275	285	93		
Written Feedback Provided Within Goal	271	280	93		
Number Pending MDUFA Action	0	0	35		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	275	285	128		
Current Performance Percent Within Goal	98.55%	98.25%	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	275	285	93		
Average FDA Days to Written Feedback	58.44	56.93	58.54		
20th Percentile FDA Days to Written Feedback	45	43	45		
40th Percentile FDA Days to Written Feedback	58	57	60		
60th Percentile FDA Days to Written Feedback	65	64	65		
80th Percentile FDA Days to Written Feedback	69	68	68		
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	3		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	35.00		

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]	124	129	42		
Meeting Minutes Submitted Within 15 Days of Meeting	91	103	27		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	29	17	9		
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	73.39%	79.84%	72.97%		

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	922	460		
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	28		
Number Closed Before First RTA Action	9	5	7		
Number Accepted First RTA Cycle [1]	833	901	415		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	15	15		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	23		
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	916	430		
Number with Non-MDUFA Action [3]	7	11	5		
Number with MDUFA Action	861	905	290		
Written Feedback Provided Within Goal	857	904	288		
Number Pending MDUFA Action	0	0	135		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	861	905	425		
Current Performance Percent Within Goal	99.54%	99.89%	99.31%		

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	905	290		
Average FDA Days to Written Feedback	63.70	63.11	61.81		
20th Percentile FDA Days to Written Feedback	60	59	56		
40th Percentile FDA Days to Written Feedback	66	65	64		
60th Percentile FDA Days to Written Feedback	69	68	67		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	75	71	89		

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	8		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	50.75		

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	126		
Meeting Minutes Submitted Within 15 Days of Meeting	257	356	100		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	59	53	19		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	85.78%	82.64%		

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	269	286	160		
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	8		
Number Closed Before First RTA Action	1	1	1		
Number Accepted First RTA Cycle [1]	259	279	152		
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	6	2		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	4		
Number Not Accepted First RTA Cycle	4	0	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.49%	0.00%	0.65%		

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	264	285	154		
Number with Non-MDUFA Action [3]	3	0	2		
Number with MDUFA Action	261	285	112		
Written Feedback Provided Within Goal	261	285	111		
Number Pending MDUFA Action	0	0	40		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	261	285	152		
Current Performance Percent Within Goal	100.00%	100.00%	99.11%		

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

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

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

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

Table 9.3 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	261	285	112		
Average FDA Days to Written Feedback	60.57	60.68	61.16		
20th Percentile FDA Days to Written Feedback	55	55	56		
40th Percentile FDA Days to Written Feedback	60	62	62		
60th Percentile FDA Days to Written Feedback	64	65	65		
80th Percentile FDA Days to Written Feedback	67	69	69		
Maximum FDA Days to Written Feedback	70	70	71		

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

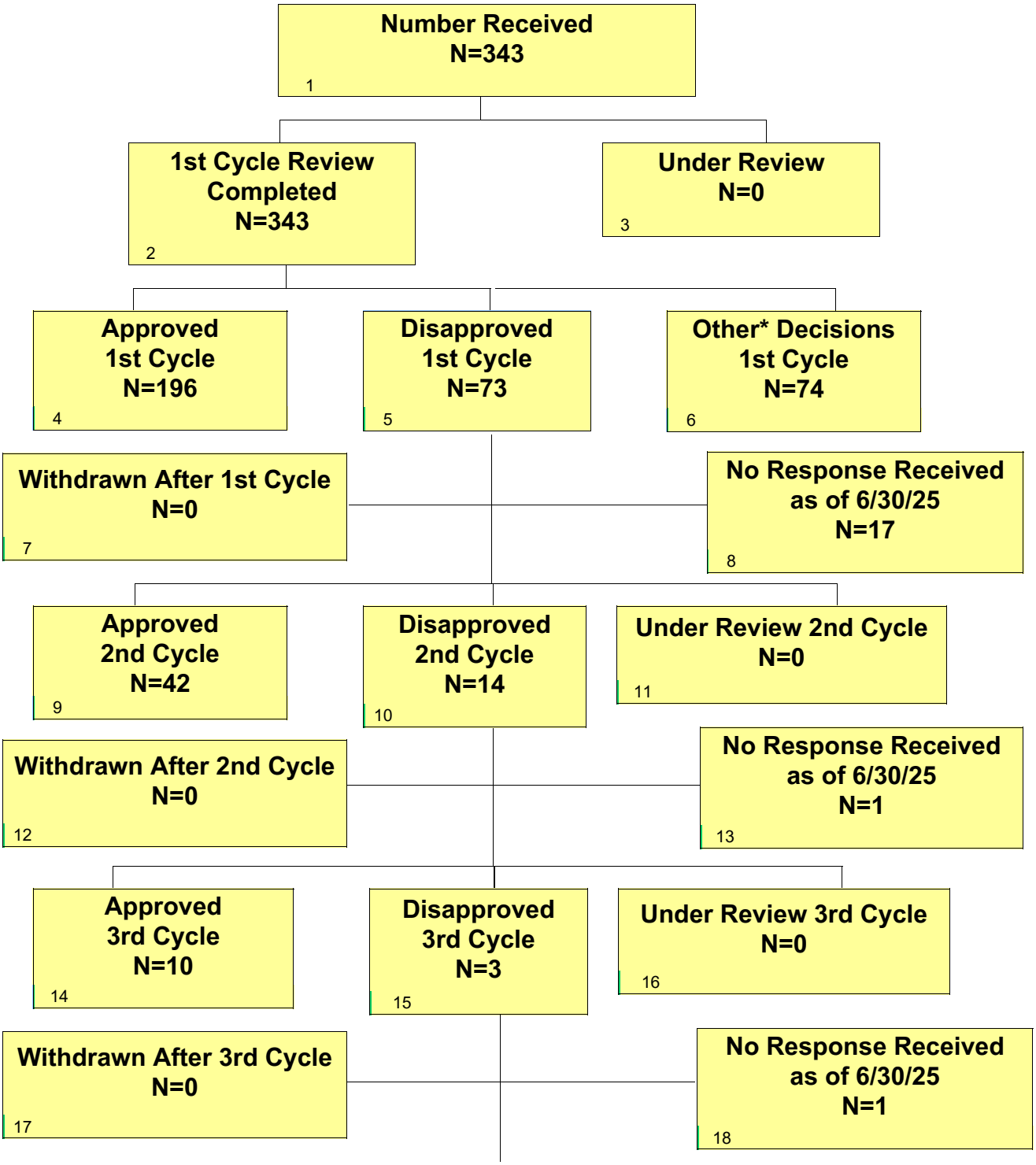
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4	1		
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	54.00		

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]	206	214	69		
Meeting Minutes Submitted Within 15 Days of Meeting	159	173	56		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	4		
Meeting Minutes Past 15 Days of Meeting	44	38	8		
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	77.18%	80.84%	86.15%		

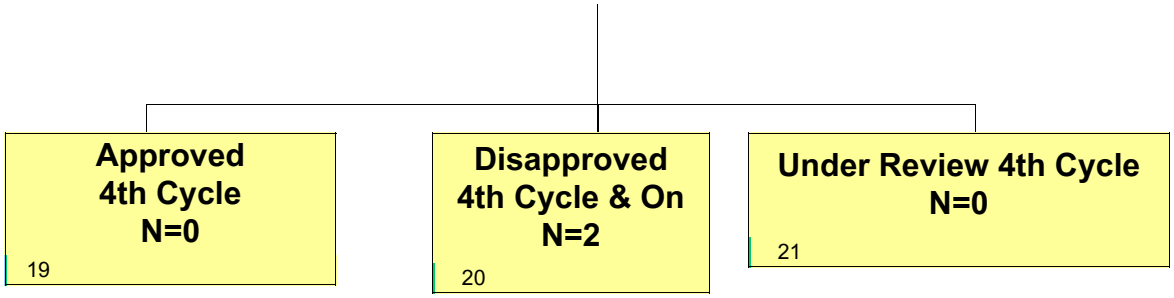
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 6/30/25

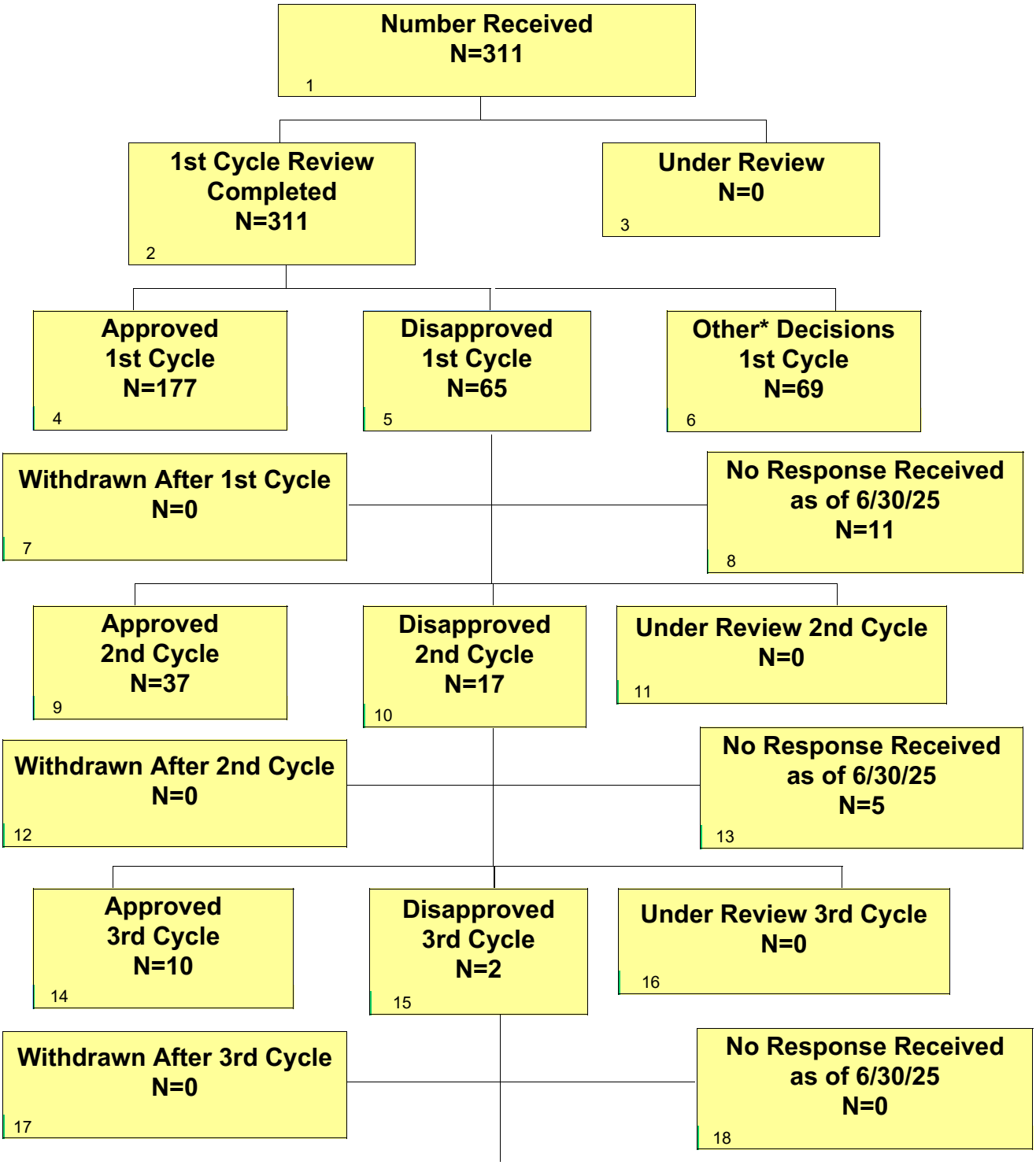


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 6/30/25

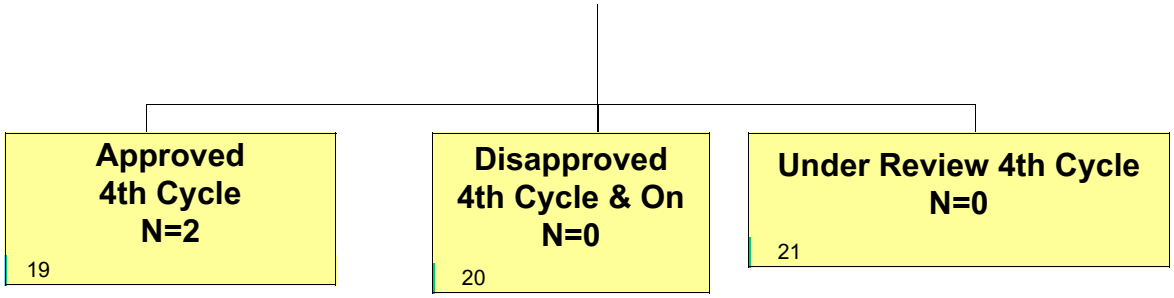


CDRH IDEs - FY 2024
as of 6/30/25

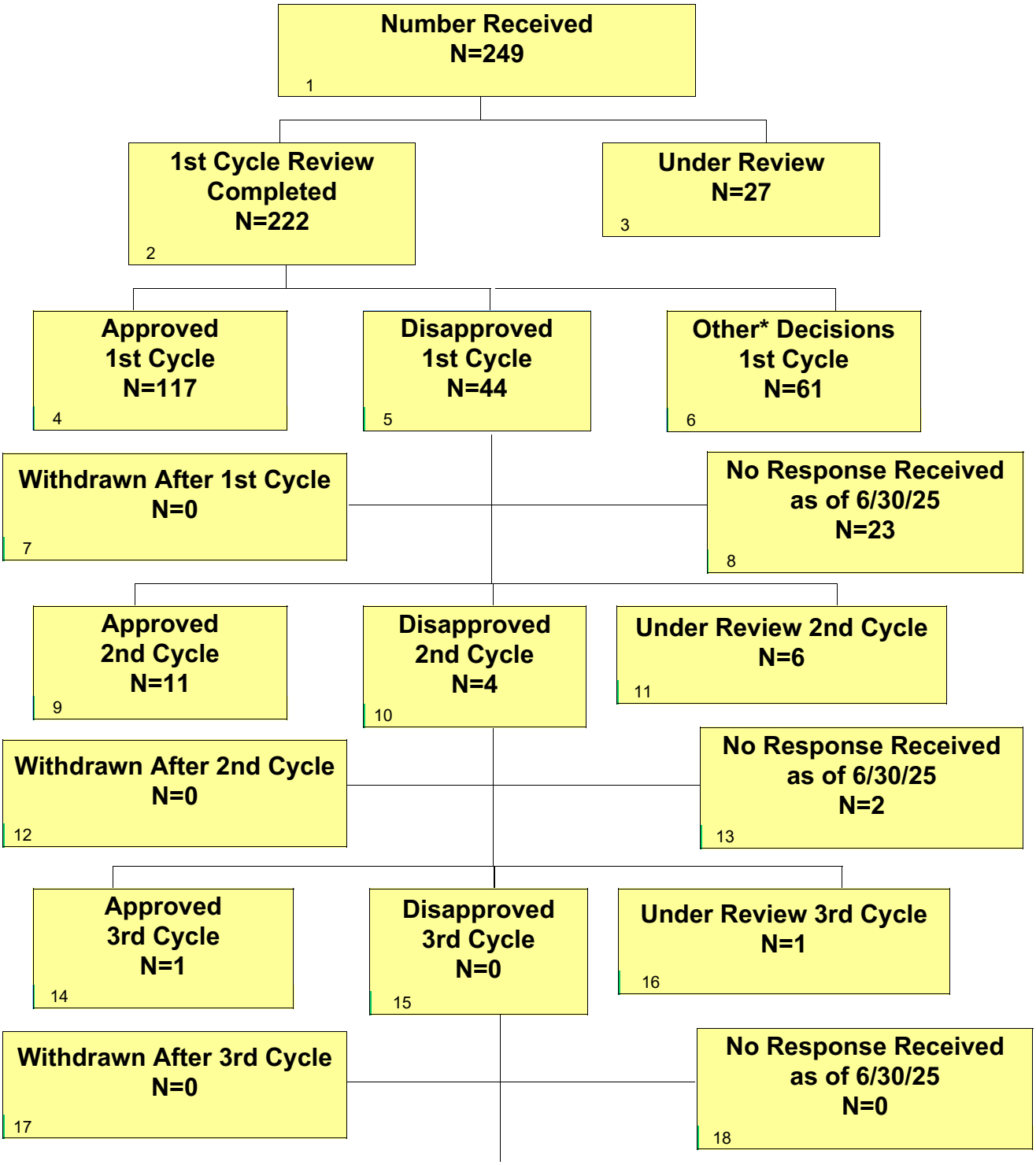


*** Other decisions include withdrawn (N=9), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 6/30/25

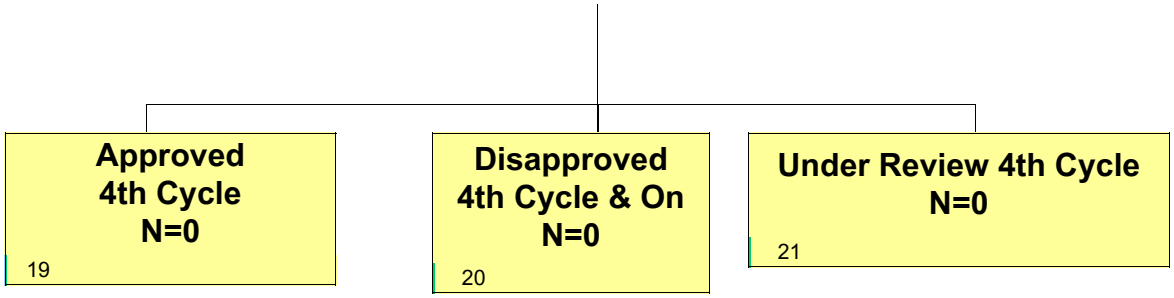


CDRH IDEs - FY 2025
as of 6/30/25



*** Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=15), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2025
as of 6/30/25



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	311	249		
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.28	1.10		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.28	0.10		

Section 10 IDE - Office Level Metric

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	42	32	19		
Average Number of Cycles to IDE Approval or Conditional Approval	1.39	1.21	1.25		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.39	0.21	0.25		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	81	52		
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.39	1.19		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.39	0.19		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	36	41	33		
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.31	1.06		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.31	0.06		

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	37	17	30		
Average Number of Cycles to IDE Approval or Conditional Approval	1.13	1.00	1.07		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.13	0.00	0.07		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	63	65		
Average Number of Cycles to IDE Approval or Conditional Approval	1.23	1.41	1.05		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.23	0.41	0.05		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	26	23	13		
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.29		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	0.29		

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	31		
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	6		
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.25	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.25	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	53		
Closed before Teleconference		0	0		
Teleconferences Held		31	48		
Teleconferences Held Within 14 Days		30	47		
Teleconferences Pending		0	5		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		96.77%	97.92%		

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

Performance Metric: 90% within 14 Days	FY2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	8		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	8		
Written Feedback Provided Within 21 Days		3	7		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	87.50%		

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

Performance Metric: 90% within 40 Days	FY2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		44	44		
Closed before Written Feedback		0	1		
Written Feedback Provided		44	39		
Written Feedback Provided Within 40 Days		44	39		
Written Feedback Pending		0	4		
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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	47	44		
Enrollment Requests Accepted	12	40	37		
Enrollment Requests Not Accepted	7	7	3		
Enrollment Requests Pending	0	0	4		

Section 13 TAP Documents - Office Level Metric

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received			2		
Enrollment Requests Accepted			2		
Enrollment Requests Not Accepted			0		
Enrollment Requests Pending			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	22		
Closed before Teleconference		0	0		
Teleconferences Held		21	20		
Teleconferences Held Within 14 Days		20	20		
Teleconferences Pending		0	2		
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	5		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	5		
Written Feedback Provided Within 21 Days		3	4		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	80.00%		

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	30		
Closed before Written Feedback		0	0		
Written Feedback Provided		34	28		
Written Feedback Provided Within 40 Days		34	28		
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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	21	13		
Enrollment Requests Accepted	12	16	11		
Enrollment Requests Not Accepted	7	5	1		
Enrollment Requests Pending	0	0	1		

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					

Closed before Teleconference					
Teleconferences Held					
Teleconferences Held Within 14 Days					
Teleconferences Pending					
Teleconferences Pending Over 14 Days					
Current Performance Percent Within 14 Days					

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					
Closed before Written Feedback					
Written Feedback Provided					
Written Feedback Provided Within 21 Days					
Written Feedback Pending					
Written Feedback Pending Over 21 Days					
Current Performance Percent Within 21 Days					

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					
Closed before Written Feedback					
Written Feedback Provided					
Written Feedback Provided Within 40 Days					
Written Feedback Pending					
Written Feedback Pending Over 40 Days					
Current Performance Percent Within 40 Days					

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

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

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

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested					
Closed before Teleconference					
Teleconferences Held					
Teleconferences Held Within 14 Days					
Teleconferences Pending					
Teleconferences Pending Over 14 Days					

Current Performance Percent Within 14 Days					

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					
Closed before Written Feedback					
Written Feedback Provided					
Written Feedback Provided Within 21 Days					
Written Feedback Pending					
Written Feedback Pending Over 21 Days					
Current Performance Percent Within 21 Days					

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					
Closed before Written Feedback					
Written Feedback Provided					
Written Feedback Provided Within 40 Days					
Written Feedback Pending					
Written Feedback Pending Over 40 Days					
Current Performance Percent Within 40 Days					

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

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

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	24		
Closed before Teleconference		0	0		
Teleconferences Held		10	24		
Teleconferences Held Within 14 Days		10	23		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		100.00%	95.83%		

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	3		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	3		
Written Feedback Provided Within 21 Days		0	3		
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	12		
Closed before Written Feedback		0	1		
Written Feedback Provided		10	10		
Written Feedback Provided Within 40 Days		10	10		
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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		25	10		
Enrollment Requests Accepted		24	9		
Enrollment Requests Not Accepted		1	0		
Enrollment Requests Pending		0	1		

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			6		
Closed before Teleconference			0		
Teleconferences Held			3		
Teleconferences Held Within 14 Days			3		
Teleconferences Pending			3		
Teleconferences Pending Over 14 Days			0		
Current Performance Percent Within 14 Days			100.00%		

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

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested			0		
Closed before Written Feedback			0		

Written Feedback Provided			0		
Written Feedback Provided Within 21 Days			0		
Written Feedback Pending			0		
Written Feedback Pending Over 21 Days			0		
Current Performance Percent Within 21 Days			N/A		

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

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested			1		
Closed before Written Feedback			0		
Written Feedback Provided			0		
Written Feedback Provided Within 40 Days			0		
Written Feedback Pending			1		
Written Feedback Pending Over 40 Days			0		
Current Performance Percent Within 40 Days			N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received			11		
Enrollment Requests Accepted			10		
Enrollment Requests Not Accepted			0		
Enrollment Requests Pending			1		

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					
Closed before Teleconference					
Teleconferences Held					
Teleconferences Held Within 14 Days					
Teleconferences Pending					
Teleconferences Pending Over 14 Days					
Current Performance Percent Within 14 Days					

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					
Closed before Written Feedback					
Written Feedback Provided					
Written Feedback Provided Within 21 Days					
Written Feedback Pending					
Written Feedback Pending Over 21 Days					
Current Performance Percent Within 21 Days					

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					
Closed before Written Feedback					
Written Feedback Provided					
Written Feedback Provided Within 40 Days					
Written Feedback Pending					
Written Feedback Pending Over 40 Days					
Current Performance Percent Within 40 Days					

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

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

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			1		
Closed before Teleconference			0		
Teleconferences Held			1		
Teleconferences Held Within 14 Days			1		
Teleconferences Pending			0		
Teleconferences Pending Over 14 Days			0		
Current Performance Percent Within 14 Days			100.00%		

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received			7		
Enrollment Requests Accepted			5		
Enrollment Requests Not Accepted			1		
Enrollment Requests Pending			1		

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 (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for FDA days, Industry days, and Total days to MDUFA decision.

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

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

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

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

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

Section 9 Pre-Submissions

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

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

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

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

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

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

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

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

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

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 13 Total 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.

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Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 30 June 2025

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	1		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	3	0	1		
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	0.00%		

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	1		
Number Accepted	3	0	1		
Completed RTF	3	0	1		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	N/A	0.00%		

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	1		
SI Goal Met	3	0	1		
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	100.00%		

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	1		
Average Number of FDA Days to Substantive Interaction	88.33	0.00	90.00		
20th Percentile FDA Days to Substantive Interaction	87	0	90		
40th Percentile FDA Days to Substantive Interaction	88	0	90		
60th Percentile FDA Days to Substantive Interaction	88	0	90		
80th Percentile FDA Days to Substantive Interaction	89	0	90		
Maximum FDA Days to Substantive Interaction	90	0	90		

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	1		
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	1		
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		
Maximum Industry Days to MDUFA V Decision	0	0	0		
Average Total Days to MDUFA V Decision	0	0	0.00		
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	1		
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	6		
SI Goal Met	2	5	3		
SI Goal Not Met	2	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	1		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	50.00%	100.00%	75.00%		

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	4	5	6		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	4	5	2		
MDUFA V Decision Goal Met	3	5	2		
Supplements Pending MDUFA V Decision	0	0	4		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	75.00%	100.00%	100.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	6		
Number with MDUFA V Decision	4	5	2		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	25.00%	20.00%	0.00%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	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	2		
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	1		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	2		
Number With MDUFA V Decision	3	2	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	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	33	35		
Closed Before First RTA or TS Action [1]	0	3	0		
Number Accepted or Passed TS on First Cycle [2]	30	25	30		
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	5	4		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	16.67%	11.76%		

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	29	31		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	37	29	24		
SI Over 60 FDA Days	2	0	0		
SI Pending Within 60 FDA Days	0	0	7		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	1	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	29	24		
Average Number of FDA Days to Substantive Interaction	55.53	56.79	49.83		
20th Percentile FDA Days to Substantive Interaction	51	56	29		
40th Percentile FDA Days to Substantive Interaction	56	57	58		
60th Percentile FDA Days to Substantive Interaction	59	58	59		
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	29	31		
Non-MDUFA V Decision	3	1	1		
MDUFA V Decision (SE/NSE)	36	25	13		
MDUFA V Decision Within 90 FDA Days	36	25	13		
510(k)s Pending MDUFA V Decision	0	3	17		
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 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	1.52	1.15		
Number With MDUFA V Decision	36	25	13		
Average Number of FDA Days to MDUFA V Decision	77.33	80.00	63.00		
20th Percentile FDA Days to MDUFA V Decision	69	72	27		
40th Percentile FDA Days to MDUFA V Decision	84	86	66		
60th Percentile FDA Days to MDUFA V Decision	89	87	88		
80th Percentile FDA Days to MDUFA V Decision	90	89	88		
Maximum FDA Days to MDUFA V Decision	90	90	88		
Average Number of Industry Days to MDUFA V Decision	48.92	77.76	4.23		
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	95	0		
80th Percentile Industry Days to MDUFA V Decision	115	179	0		
Maximum Industry Days to MDUFA V Decision	315	207	34		
Average Number of Total Days to MDUFA V Decision	126.25	157.76	67.23		
20th Percentile Total Days to MDUFA V Decision	81	78	27		
40th Percentile Total Days to MDUFA V Decision	88	90	66		
60th Percentile Total Days to MDUFA V Decision	90	184	88		
80th Percentile Total Days to MDUFA V Decision	90	265	88		
Maximum Total Days to MDUFA V Decision	375	288	122		

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	29	31		
Number With MDUFA V Decision	36	25	13		
Number of SE Decision	35	20	11		
Number of NSE Decision	1	5	2		
Number of Withdrawal	2	0	1		
Number of Deleted	1	1	0		
Rate of SE Decision	97.22%	80.00%	84.62%		
Rate of NSE Decision	2.78%	20.00%	15.38%		
Rate of Withdrawal	5.13%	0.00%	3.23%		
Rate of Deleted	2.56%	3.45%	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	2		
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	2		
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	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 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00	0.00	0.00		
Number With MDUFA Decision	1	0	0		
Average FDA Days to MDUFA Decision	75.00	0.00	0.00		
20th Percentile FDA Days to MDUFA Decision	75	0			
40th Percentile FDA Days to MDUFA Decision	75	0	0		
60th Percentile FDA Days to MDUFA Decision	75	0	0		
80th Percentile FDA Days to MDUFA Decision	75	0	0		
Maximum FDA Days to MDUFA Decision	75	0	0		
Average Industry Days to MDUFA Decision	177.00	0.00	0.00		
20th Percentile Industry Days to MDUFA Decision	177	0	0		
40th Percentile Industry Days to MDUFA Decision	177	0	0		
60th Percentile Industry Days to MDUFA Decision	177	0	0		
80th Percentile Industry Days to MDUFA Decision	177	0	0		
Maximum Industry Days to MDUFA Decision	177	0	0		
Average Total Days to MDUFA Decision	252.00	0.00	0.00		
20th Percentile Total Days to MDUFA Decision	252	0	0		
40th Percentile Total Days to MDUFA Decision	252	0	0		
60th Percentile Total Days to MDUFA Decision	252	0	0		
80th Percentile Total Days to MDUFA Decision	252	0	0		
Maximum Total Days to MDUFA Decision	252	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	1	0	0		
Number With Granted Decision	0	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	0.00%	N/A	N/A		
Rate of Declined Decision	100.00%	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 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	54		
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	2		
Number Closed Before First RTA Action	7	1	1		
Number Accepted First RTA Cycle [1]	59	60	53		
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	53		
Number with Non-MDUFA Action [3]	3	0	0		
Number with MDUFA Action	58	61	43		
Written Feedback Provided Within Goal	55	61	43		
Number Pending MDUFA Action	0	0	10		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300)[4]	58	61	53		
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	43		
Average FDA Days to Written Feedback	59.38	60.79	60.49		
20th Percentile FDA Days to Written Feedback	55	54	55		
40th Percentile FDA Days to Written Feedback	60	61	61		
60th Percentile FDA Days to Written Feedback	64	65	66		
80th Percentile FDA Days to Written Feedback	69	69	68		
Maximum FDA Days to Written Feedback	72	70	70		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0	0	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	14		
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	12		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0		
Meeting Minutes Past 15 Days of Meeting	3	5	2		
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%	85.71%		

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	10		
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.07	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.06	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
10	Q2	Study of Sex Differences in the Clinical Evaluation of Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products	01/07/2025	Yes	No	N/A	No
11	Q2	Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency	01/07/2025	No	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).

#	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
12	Q2	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses	01/07/2025	No	No	N/A	No
13	Q2	Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological	01/07/2025	Yes	No	N/A	No
14	Q2	Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing	01/07/2025	Yes	No	N/A	A-List
15	Q2	Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and	01/07/2025	Yes	No	N/A	A-List
16	Q2	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	01/07/2025	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act	No
17	Q2	Developing Drugs for Optical Imaging www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging	01/08/2025	Yes	No	N/A	No
18	Q2	[4]Premarket Approval Application and Humanitarian Device Exemption Modular Review www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review	01/13/2025	Yes	No	N/A	No

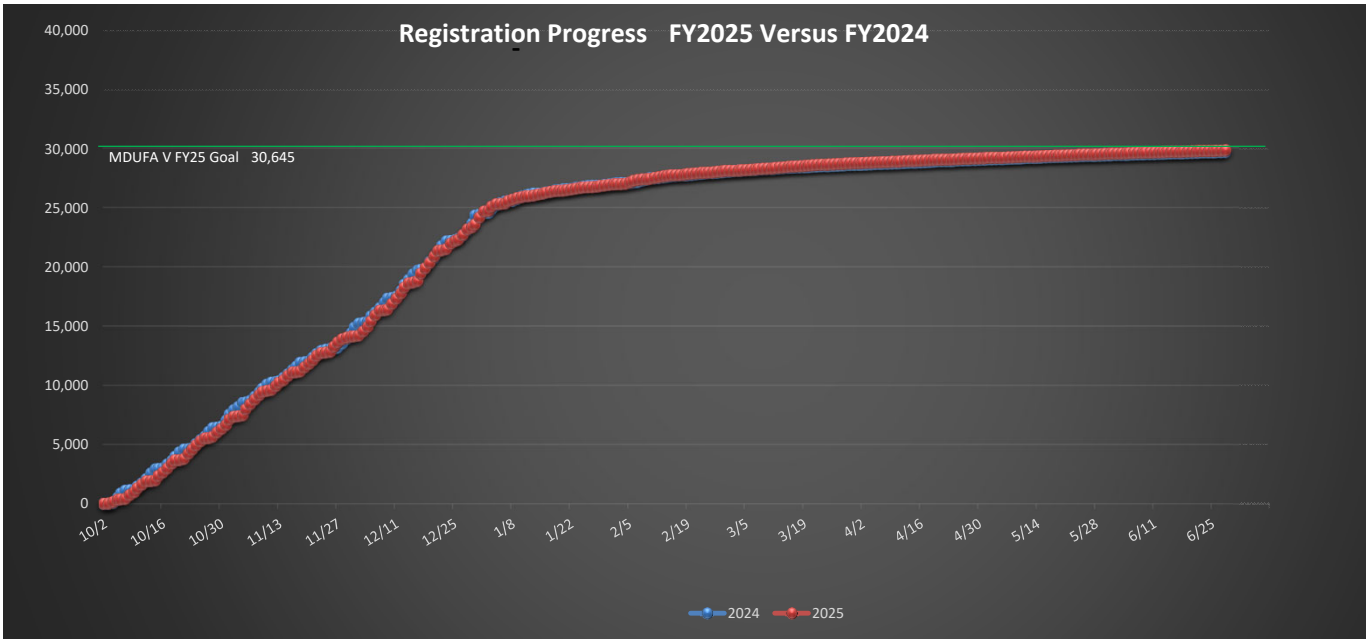
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	[4]Institutional Review Board (IRB) Written Procedures www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures	02/05/2025	No	No	N/A	No
20	Q2	[4]Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	03/24/2025	Yes	No	N/A	No
21	Q2	[4]Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug	03/31/2025	Yes	No	N/A	No
22	Q3	Electronic Submission Template for Medical Device Q-Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions	05/29/2025	Yes	Yes	745A(b) of the FD&C Act	No
23	Q3	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program	05/29/2025	Yes	Yes	MDUFA V Commitment Letter II.A.	A-List
24	Q3	Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/transfer-premarket-notification-510k-clearance-questions-and-answers	06/05/2025	Yes	No	N/A	No
25	Q3	Hernia Mesh – Package Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/hernia-mesh-package-labeling-recommendations	06/06/2025	Yes	No	N/A	No
26	Q3	Conducting Remote Regulatory Assessments Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers	06/26/2025	Yes	No	N/A	No

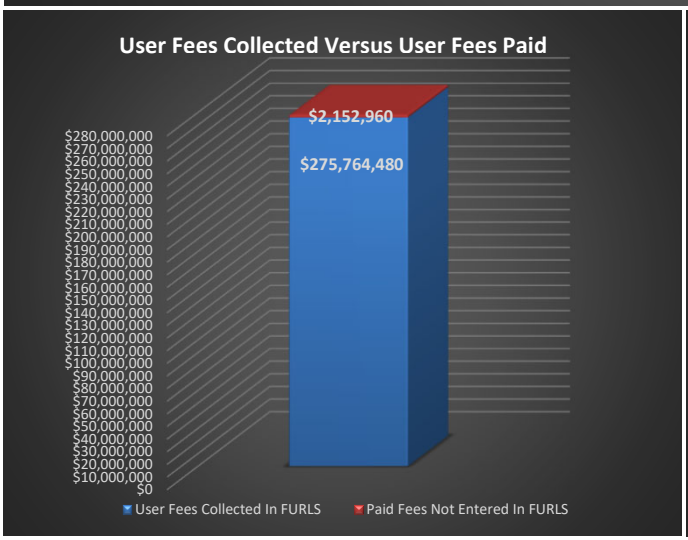
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
27	Q3	Unique Device Identifier Requirements for Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products	06/26/2025	Yes	No	N/A	No
28	Q3	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions	06/27/2025	Yes	No	N/A	A-List

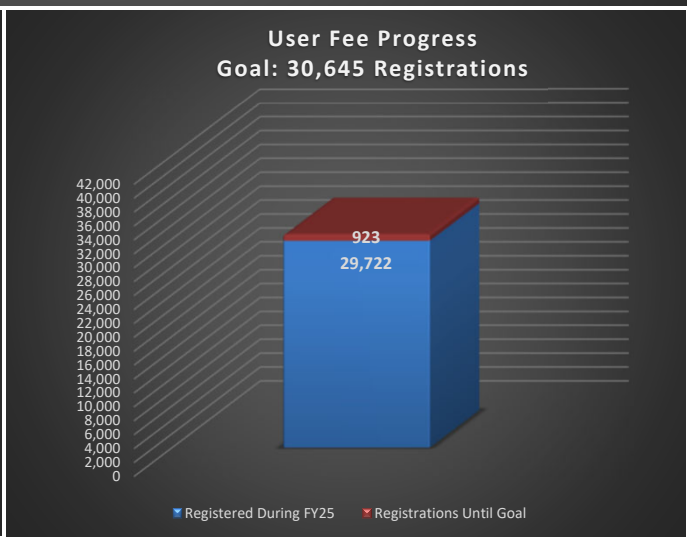
MDUFA V Registrations - 3rd Quarter Summary FY2025*

Current Active Registrations by Type	FY25 Q3			FY24 Year End Active Totals			FY25 vs End FY24
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,419	11,865	18,284	6,677	12,332	19,009	96.19%
Contract Manufacturer	1,260	2,058	3,318	1,243	1,893	3,136	105.80%
Contract Sterilizer	76	176	252	76	169	245	102.86%
Specification Developer	1,567	551	2,118	1,668	557	2,225	95.19%
Reprocessor of Single Use Devices	22	4	26	34	3	37	70.27%
U.S. Manufacturer of Export Only Devices	115	0	115	127	0	127	90.55%
Repackager/Relabeler	1,035	181	1,216	1,116	221	1,337	90.95%
Remanufacturer	15	9	24	14	9	23	104.35%
Foreign Exporter/Private Label Distributor		1,048	1,048		1,132	1,132	92.58%
Initial Importer	3,032		3,032	3,357		3,357	90.32%
Unknown	6	12	18	6	11	17	105.88%
Total:	**13,547**	**15,904**	**29,451**	**14,318**	**16,327**	**30,645**	**96.10%**

*Note: This data is current as of 06/28/2025







Q3 FY 2025 Medical Device User Fee Collections as of June 30, 2025 Excludes Unearned Revenue					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$276,728,318	-$1,037,733	$275,690,585		
Application Fees	$90,882,480	-$1,469,863	$89,412,616		
Total	**$367,610,798**	**-$2,507,596**	**$365,103,202**	**$393,710,000**	**93%**
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	$365,103,202		

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

CDRH Data 3rd Quarter FY 2025 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	6	0
PMA	6	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	1	0
De Novo Classification	6	32
180-Day Supplements	3	10
Real-Time Supplements	2	29
510(k)s	36	1,437
30-day Notices /135 day supplements*	8	35
513(g)s	0	37
PMA Annual Report		
Total	**62**	**1,580**

[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**