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

August 25, 2026, 1:00 – 2:00 pm
Teams

Welcome –

FDA MDUFA Performance — Actions through June 30, 2026

- Report on performance goals for 3rd Quarter FY 2026

Guidance Development

Registration and Listing

Qualitative Update on Finances – 3rd Quarter FY 2026

- User fee receipts through the 3rd Quarter FY 2026

Annual Hiring Goals Update

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 30 June 2026

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 (as identified by the submitter)
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

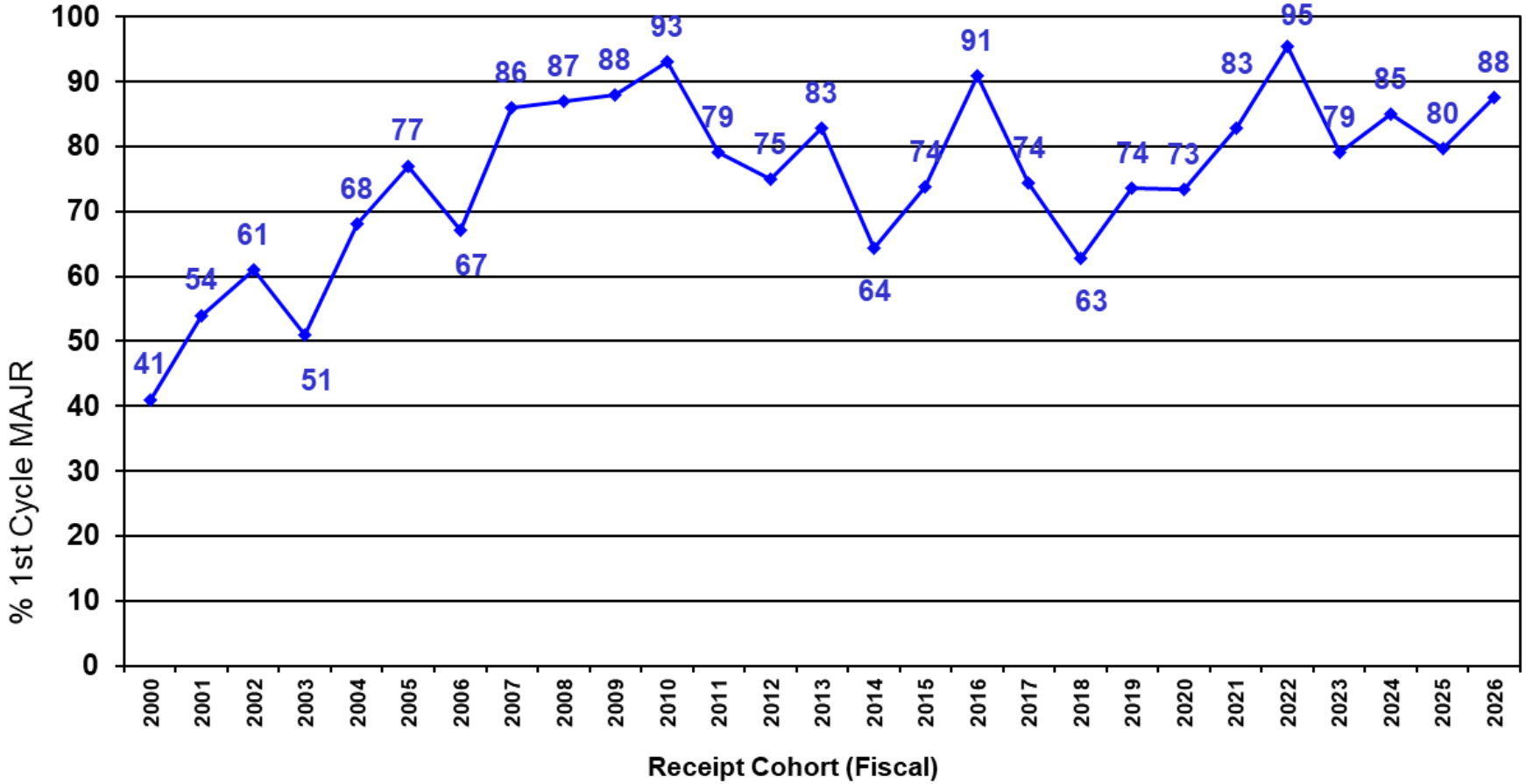
OHT8: Office of Radiological Health

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

PMAs

Q3FY2026

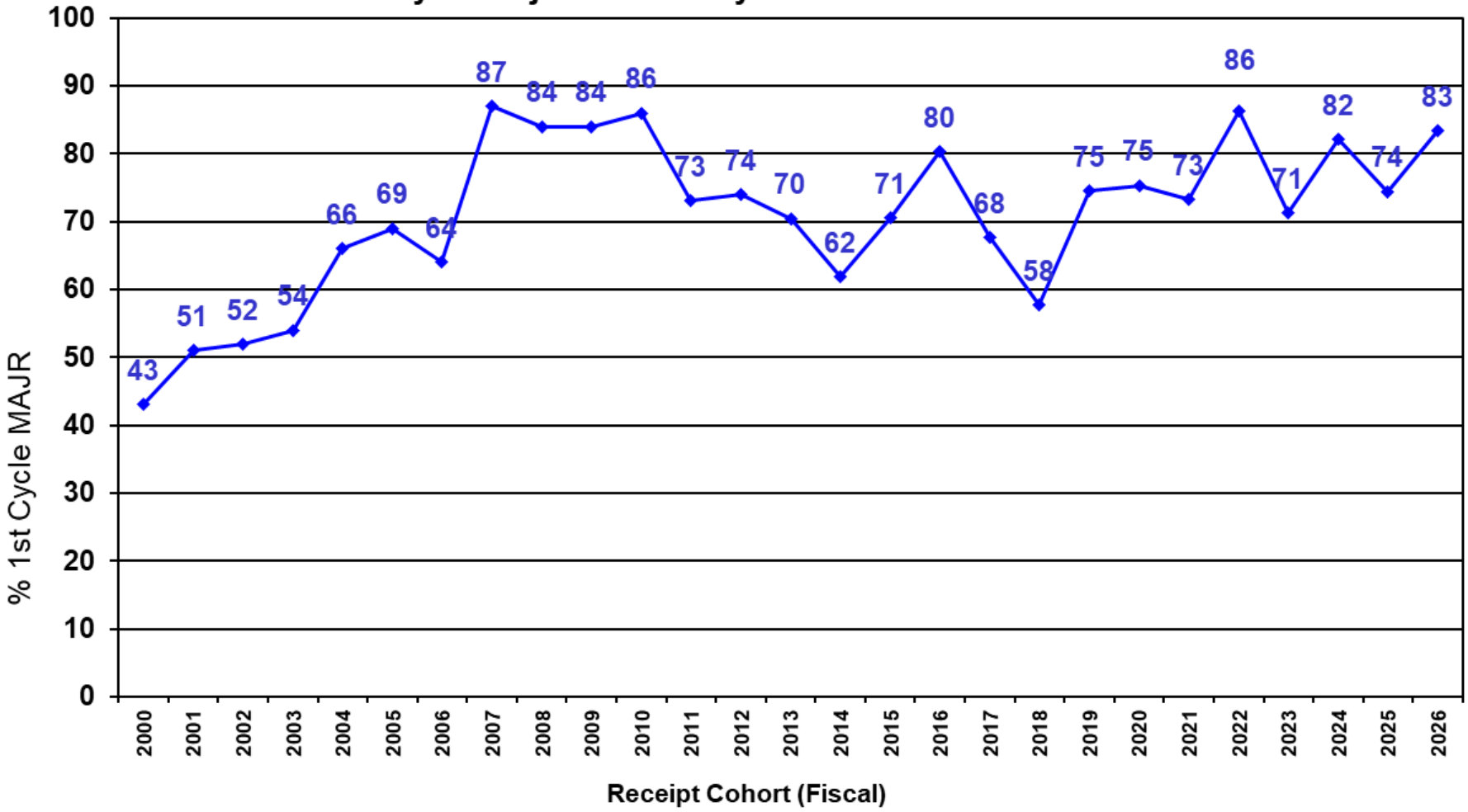
PMA Originals Filed as of 03/31/2026: 1st Cycle Major Deficiency Rate as of 06/30/2026



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 3/31/2026.
Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

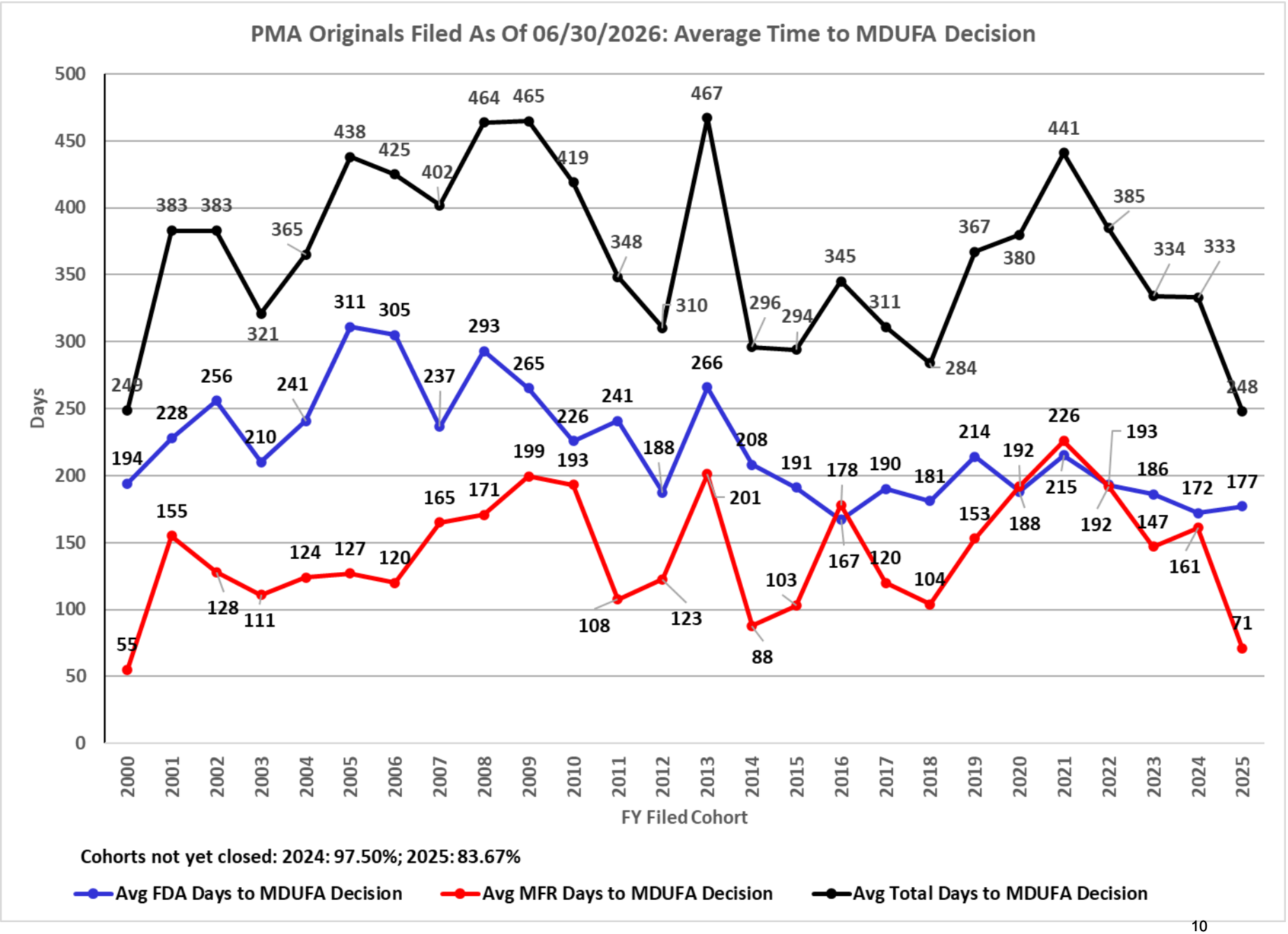
% 1st Cycle MAJR PMAO/PTS

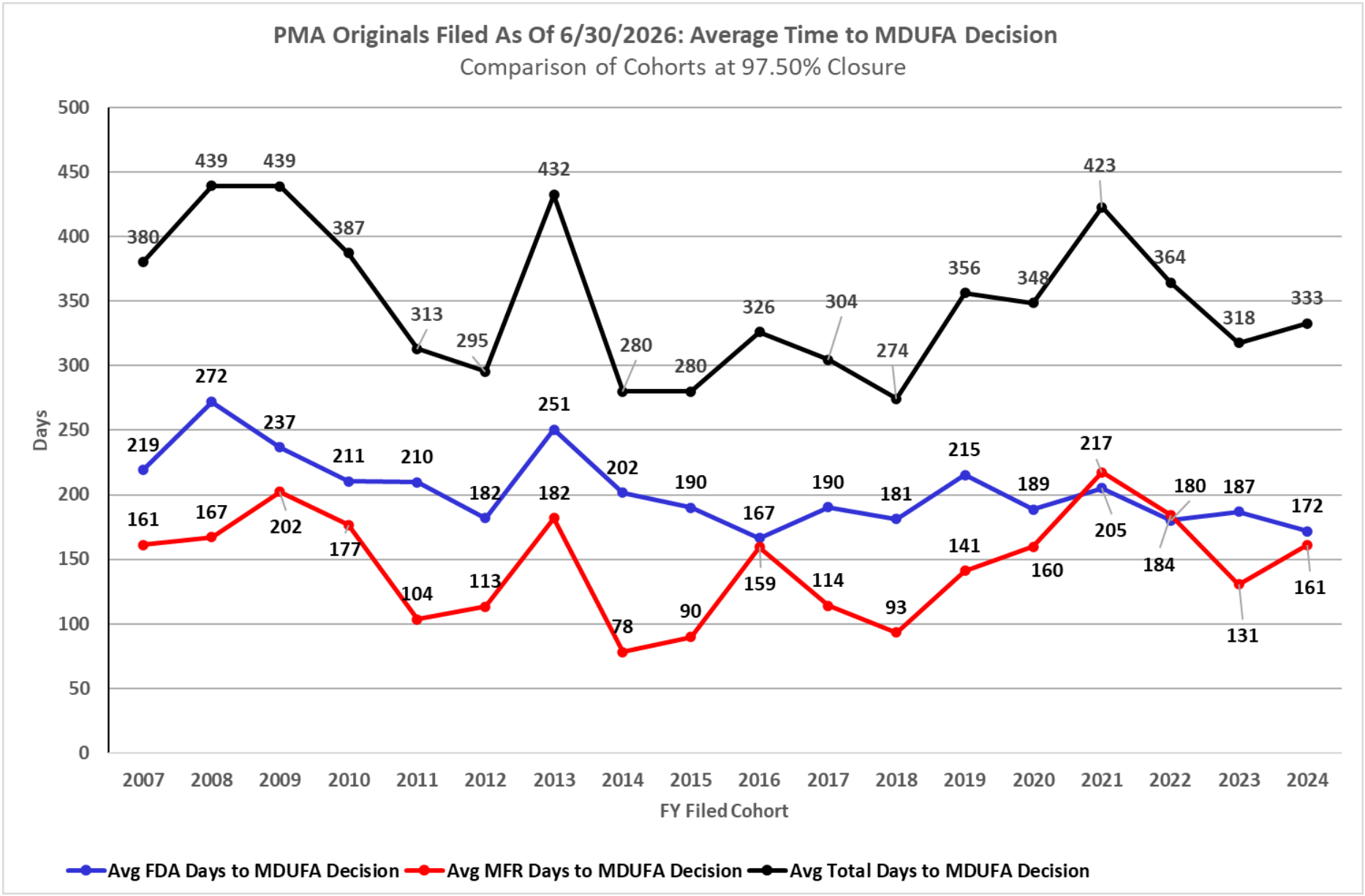
PMA Originals and Panel track Supplements Filed as of 03/31/2026: 1st Cycle Major Deficiency Rate as of 06/30/2026

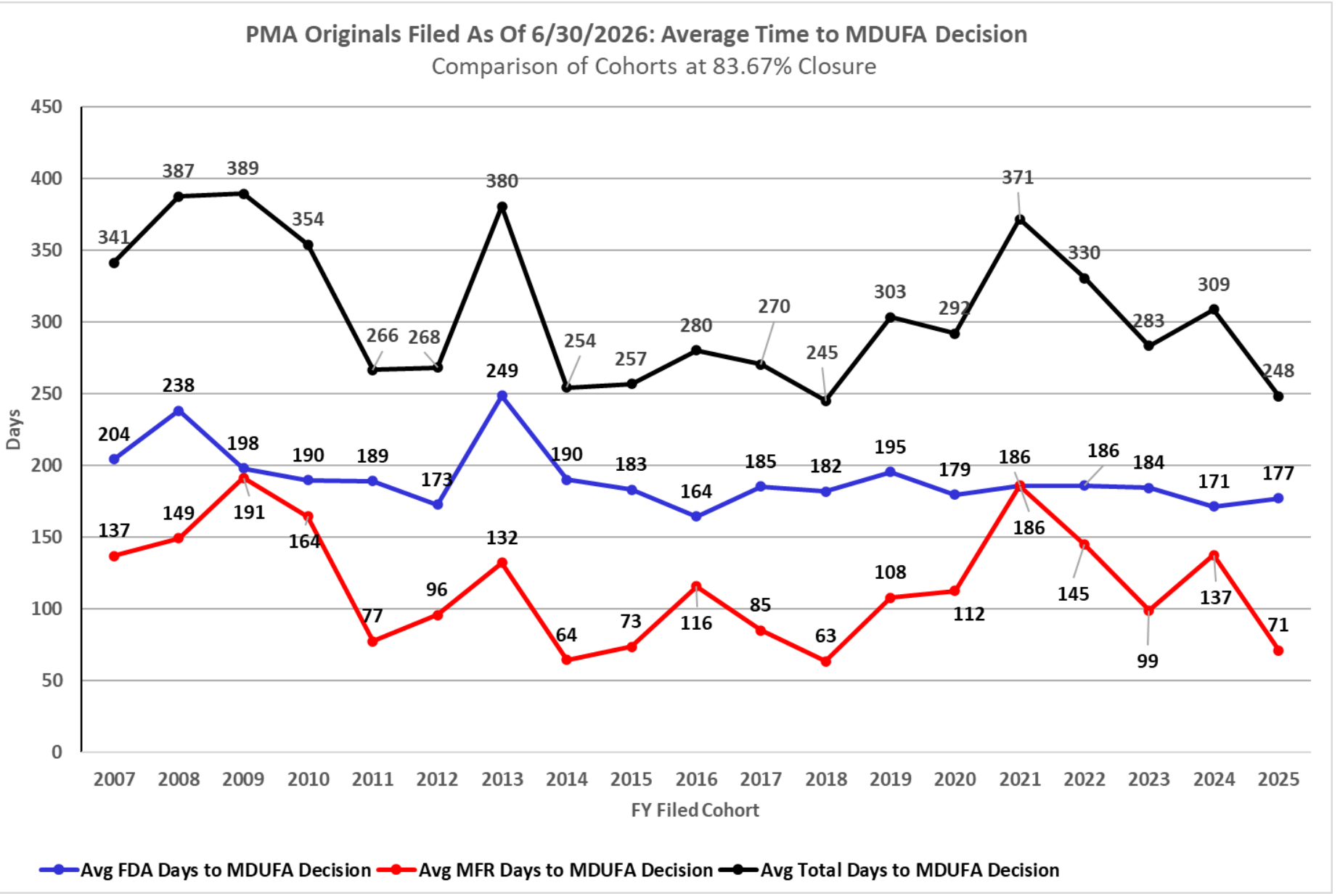


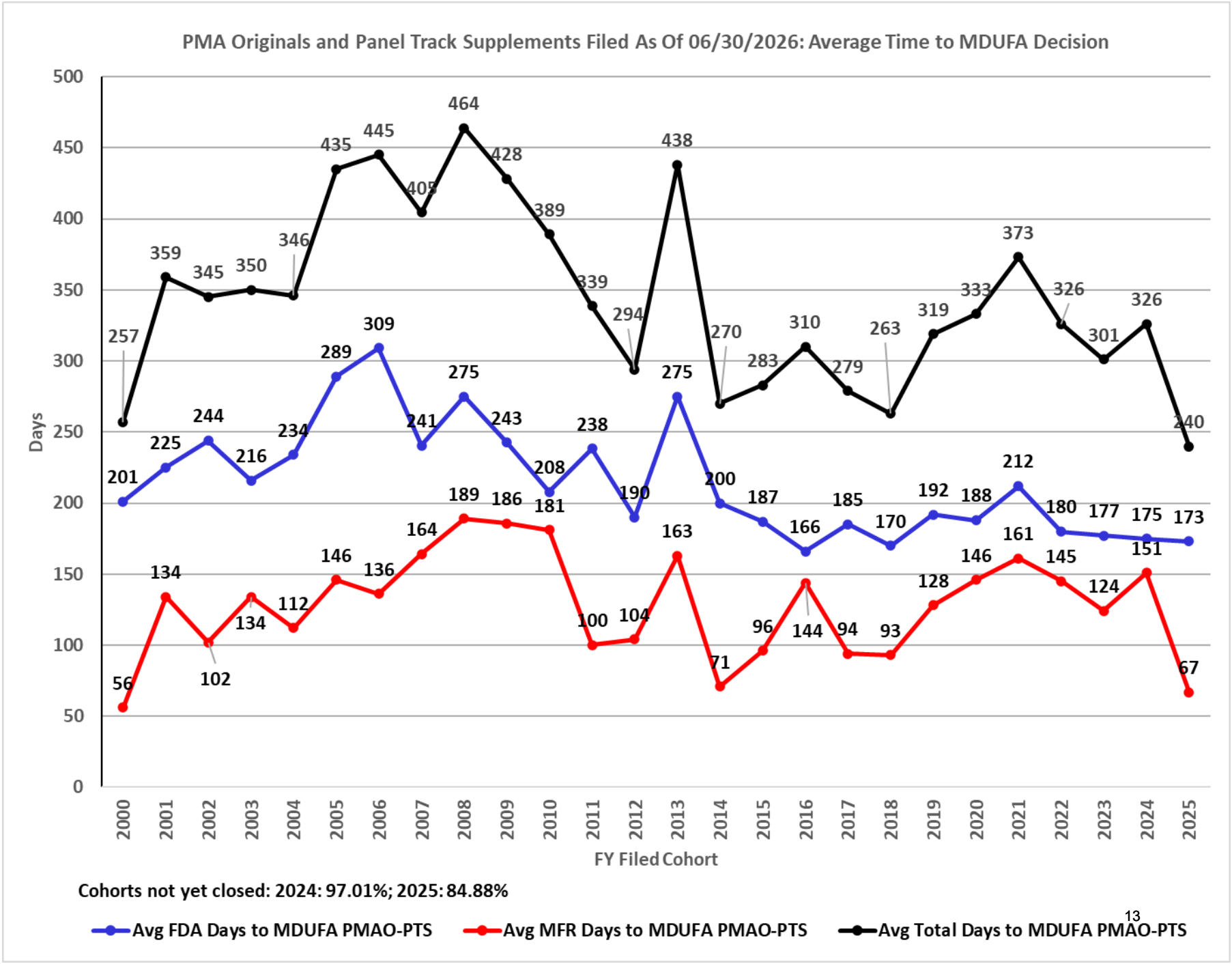
Data are based upon the number of submissions that received a major deficienecy letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 3/31/2026.
Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

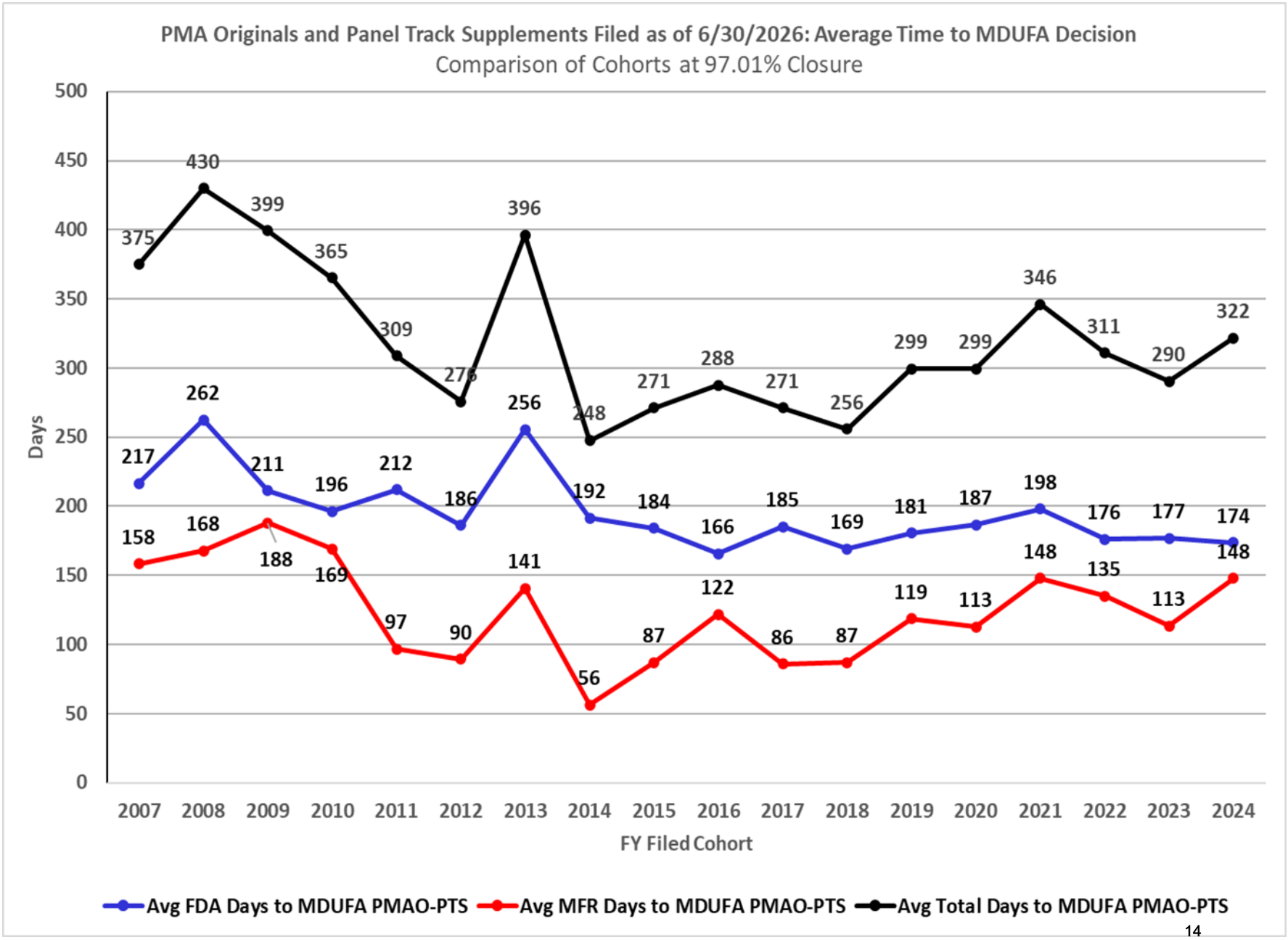
% 1st Cycle MAJR PMAO/PTS

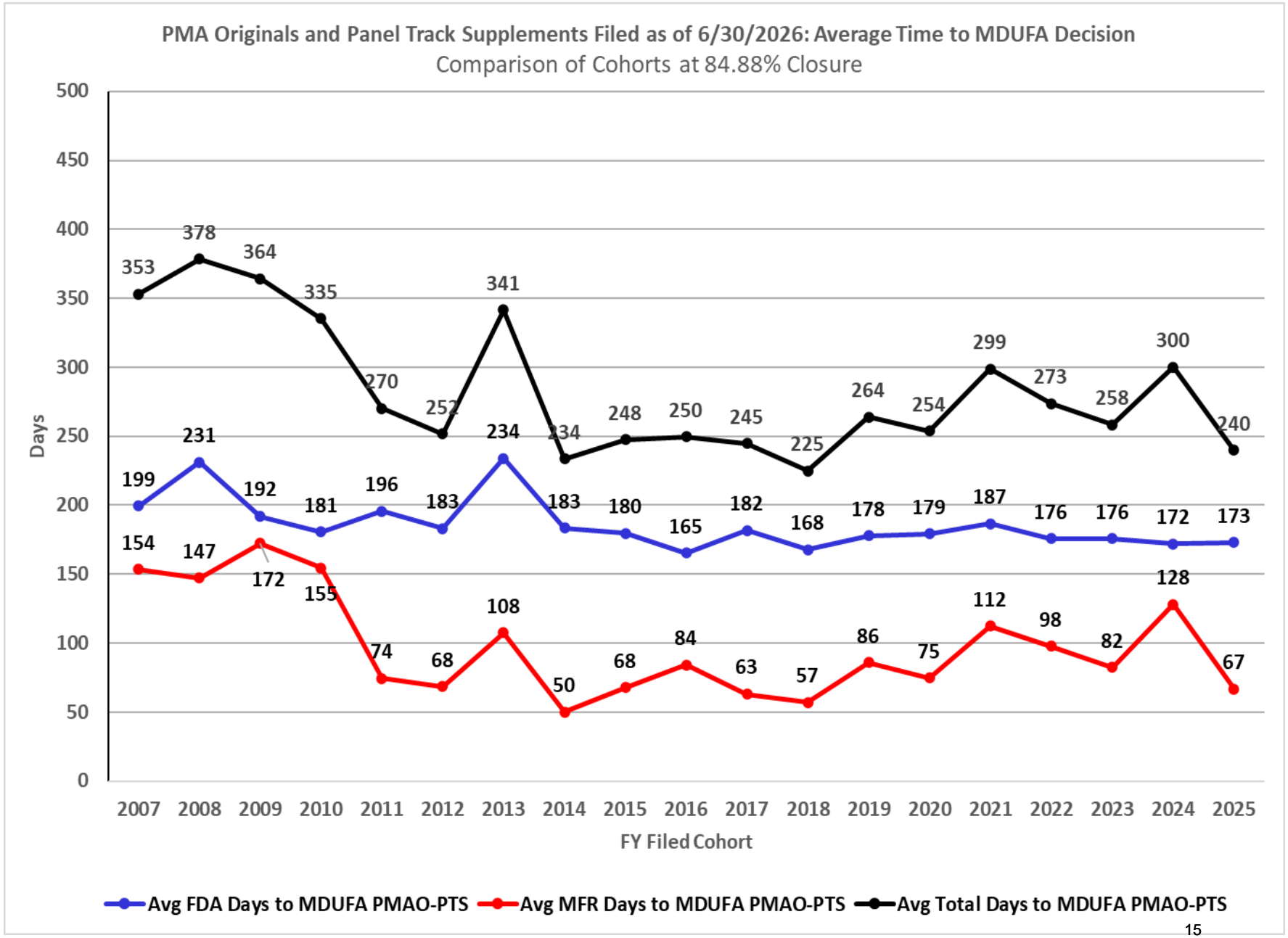

PMA Originals Filed As Of 06/30/2026: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2024: 97.50%; 2025: 83.67%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 6/30/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 97.50% 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 2024
FY Filed Cohort
380 439 439 387 313 295 432 280 280 326 304 274 356 348 423 364 318 333
219 272 237 211 210 182 251 202 190 167 190 181 215 189 205 184 187 172
161 167 202 177 104 113 182 78 90 159 114 93 141 160 217 180 131 161
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

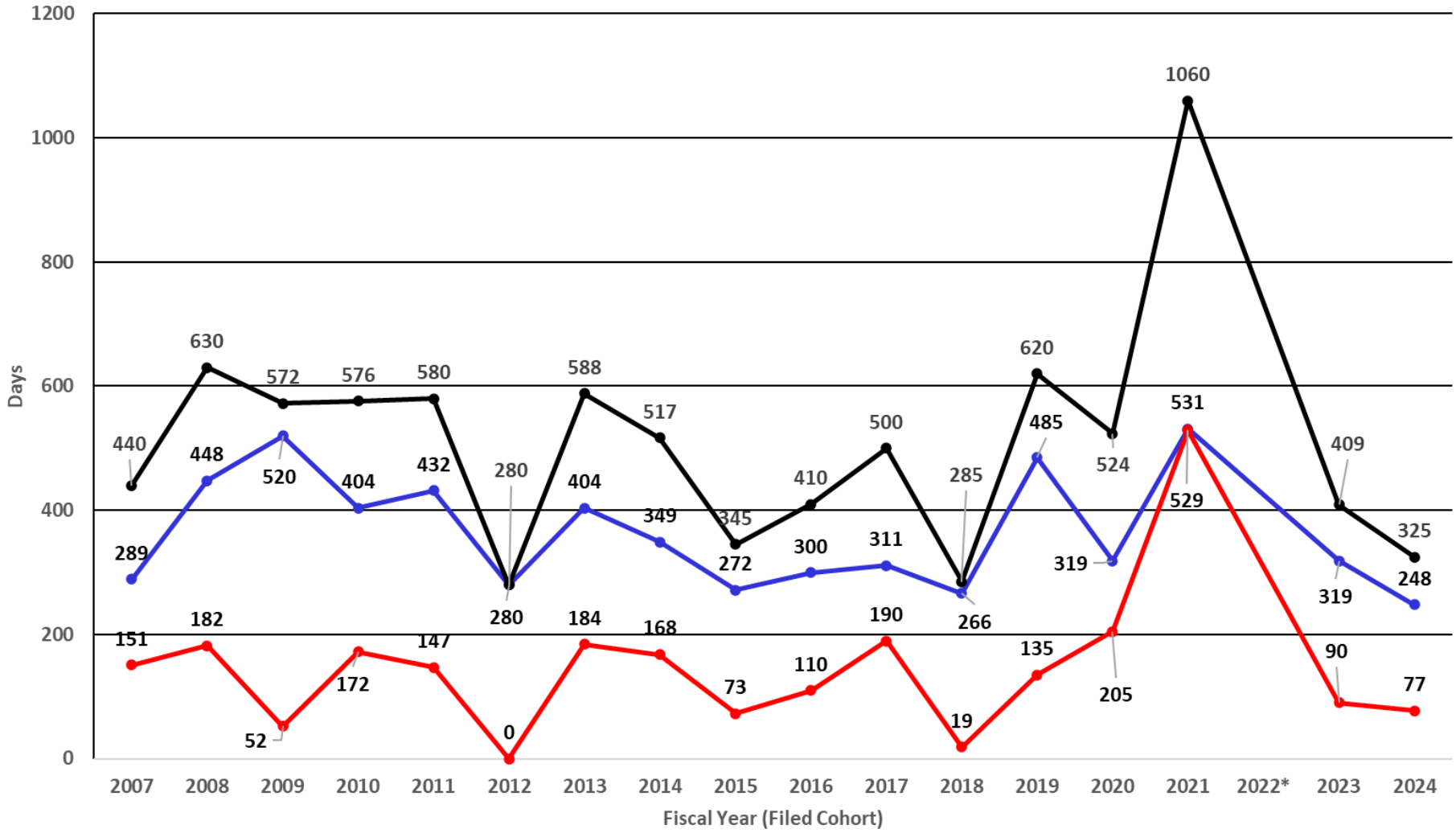

PMA Originals Filed As Of 6/30/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 83.67% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed As Of 06/30/2026: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2024: 97.01%; 2025: 84.88%
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 6/30/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 97.01% 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 2024
FY Filed Cohort
375 430 399 365 309 276 396 248 271 288 271 256 299 299 346 311 290 322
217 262 211 196 212 186 256 192 184 166 185 169 181 187 198 176 177 174
158 168 188 169 97 90 141 56 87 122 86 87 119 113 148 135 113 148
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 6/30/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 84.88% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
353 378 364 335 270 252 341 234 248 250 245 225 264 254 299 273 258 300 240
199 231 192 181 196 183 234 183 180 165 182 168 178 179 187 176 176 172 173
154 147 172 155 74 68 108 50 68 84 63 57 86 75 112 98 82 128 67
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

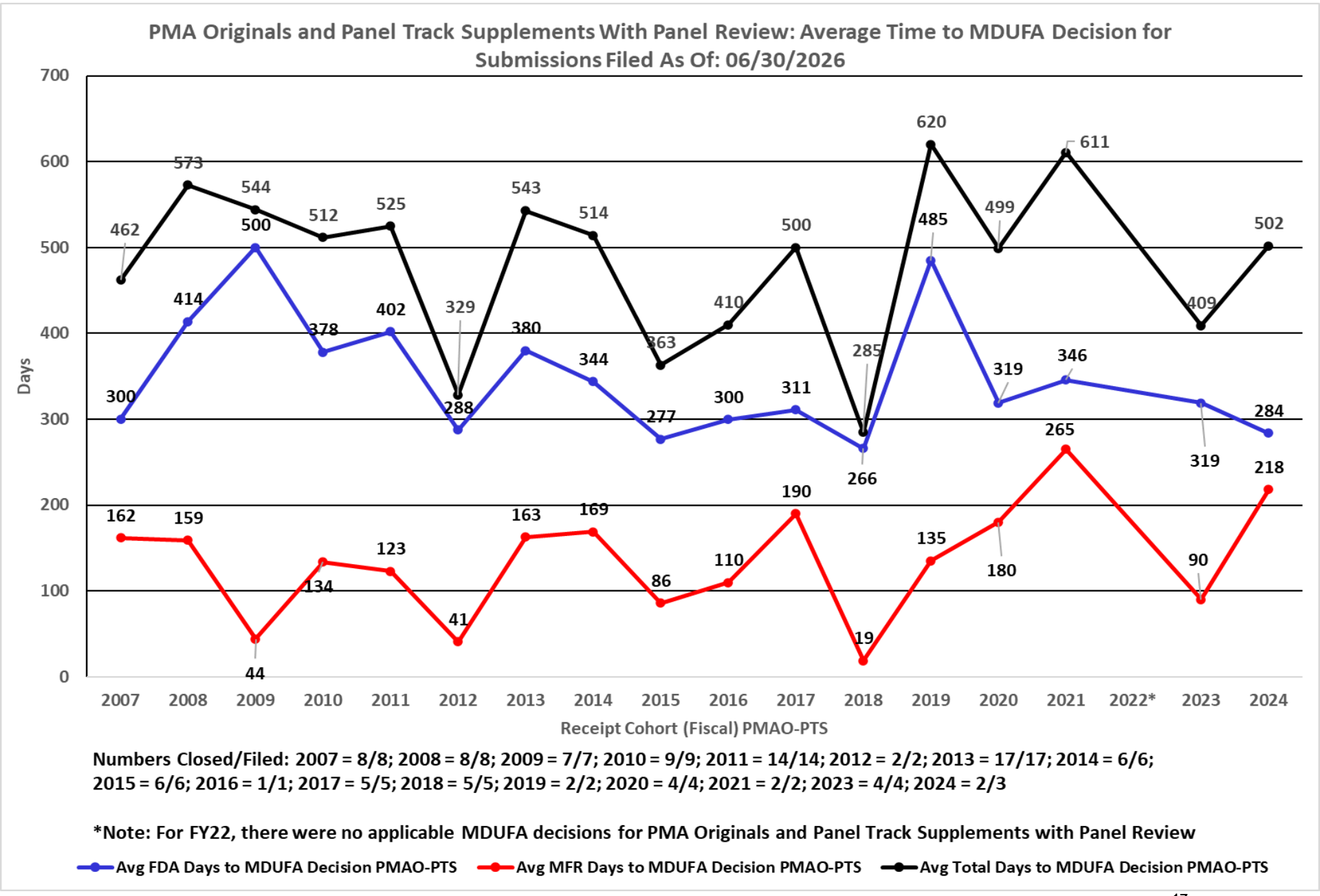
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 06/30/2026



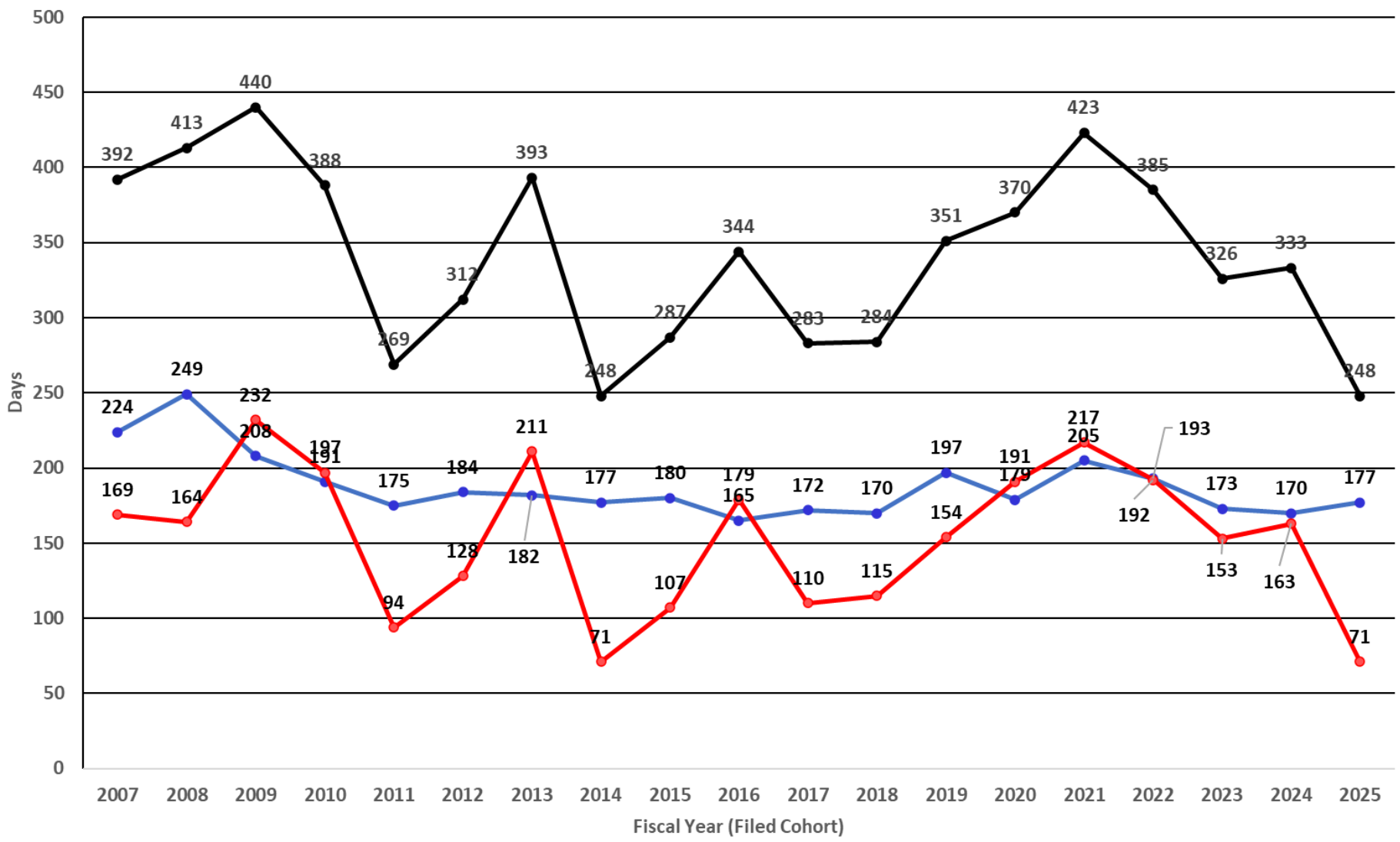
Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2021 = 1/1; 2023 = 4/4; 2024 = 1/1

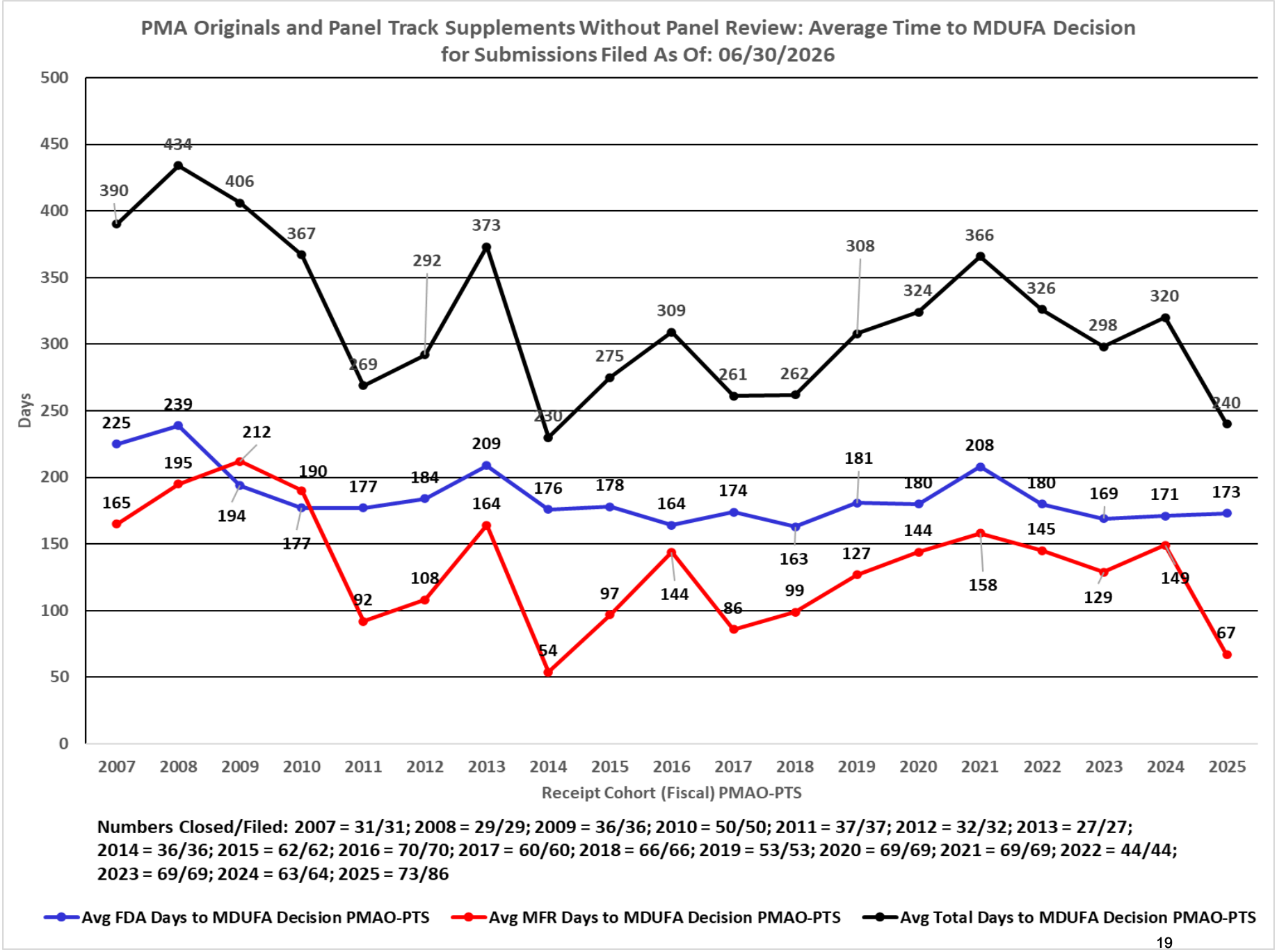
*Note: For FY22, there were no applicable MDUFA decisions for PMA Originals with Panel Review

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



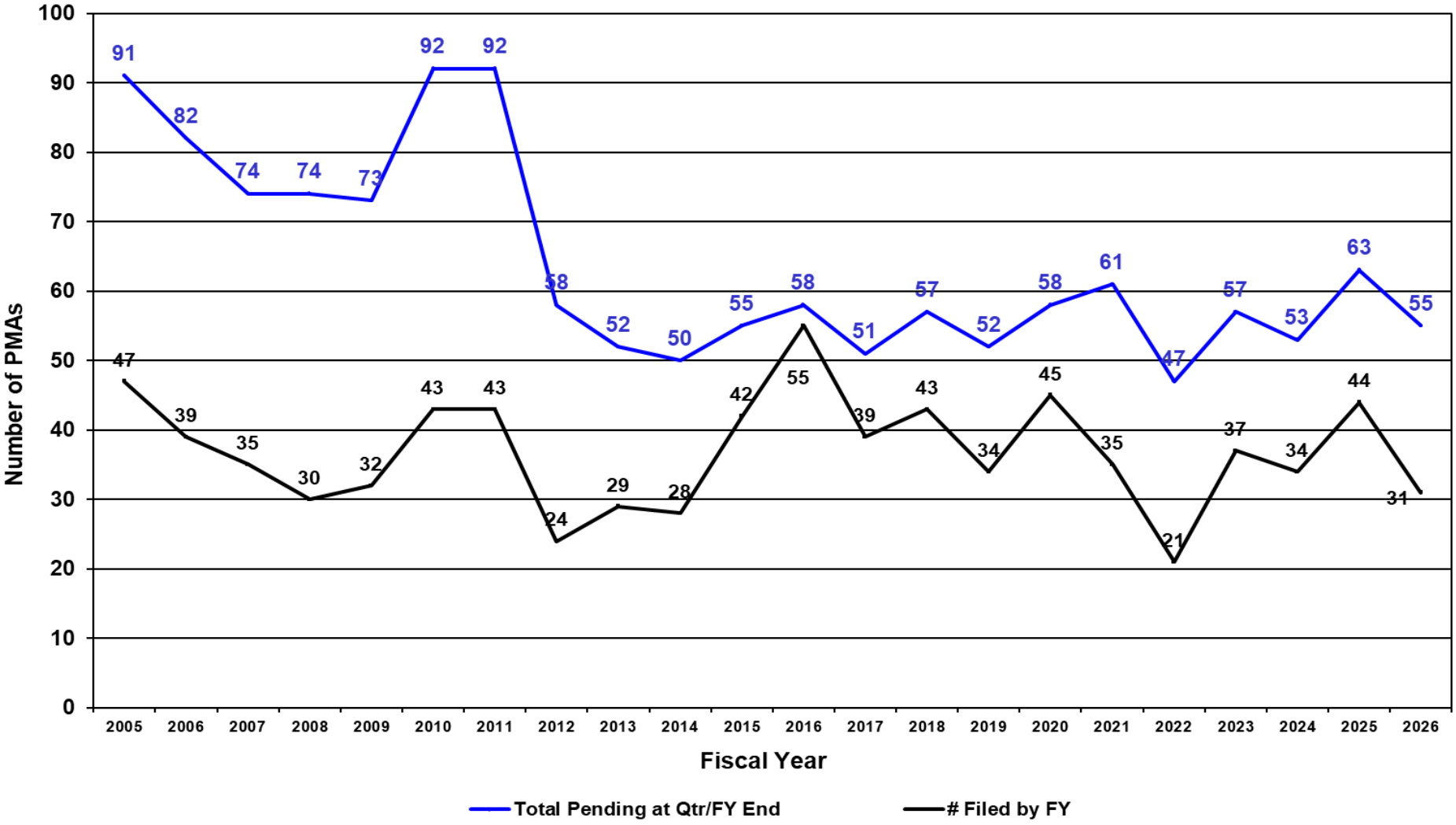
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.


PMA Originals Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 06/30/2026
Days
Fiscal Year (Filed Cohort)
0
50
100
150
200
250
300
350
400
450
500
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025
392
413
440
388
269
312
393
248
287
344
283
284
351
370
423
385
326
333
248
224
249
208
191
175
184
182
177
180
165
172
170
197
179
205
192
173
170
177
169
164
232
197
94
128
211
71
107
110
115
154
191
217
193
153
163
71
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 = 39/39; 2024 = 38/39; 2025 = 41/49
Avg FDA Days to MDUFA Decision PMAO
Avg MFR Days to MDUFA Decision PMAO
Avg Total Days to MDUFA Decision PMAO



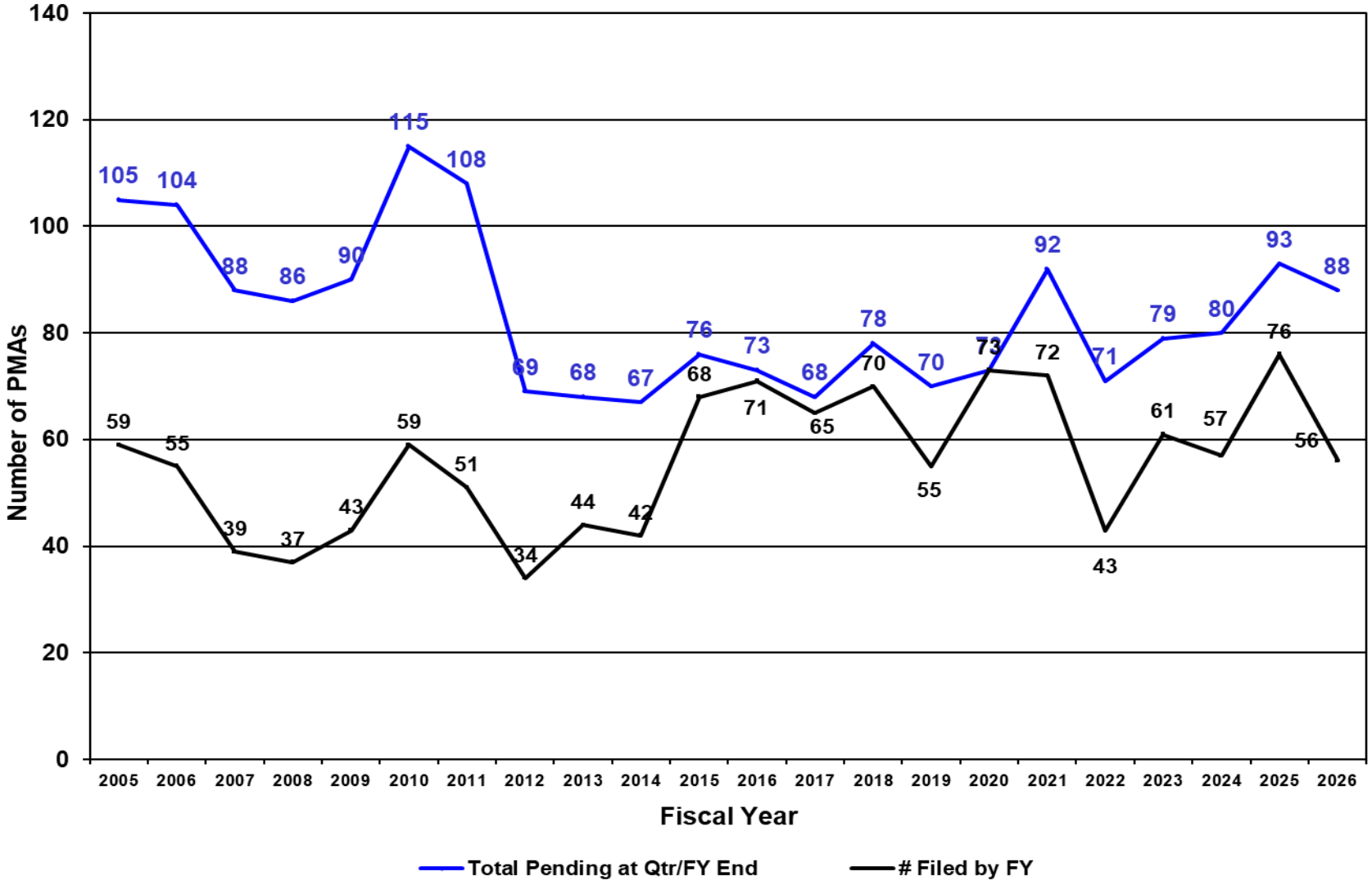
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

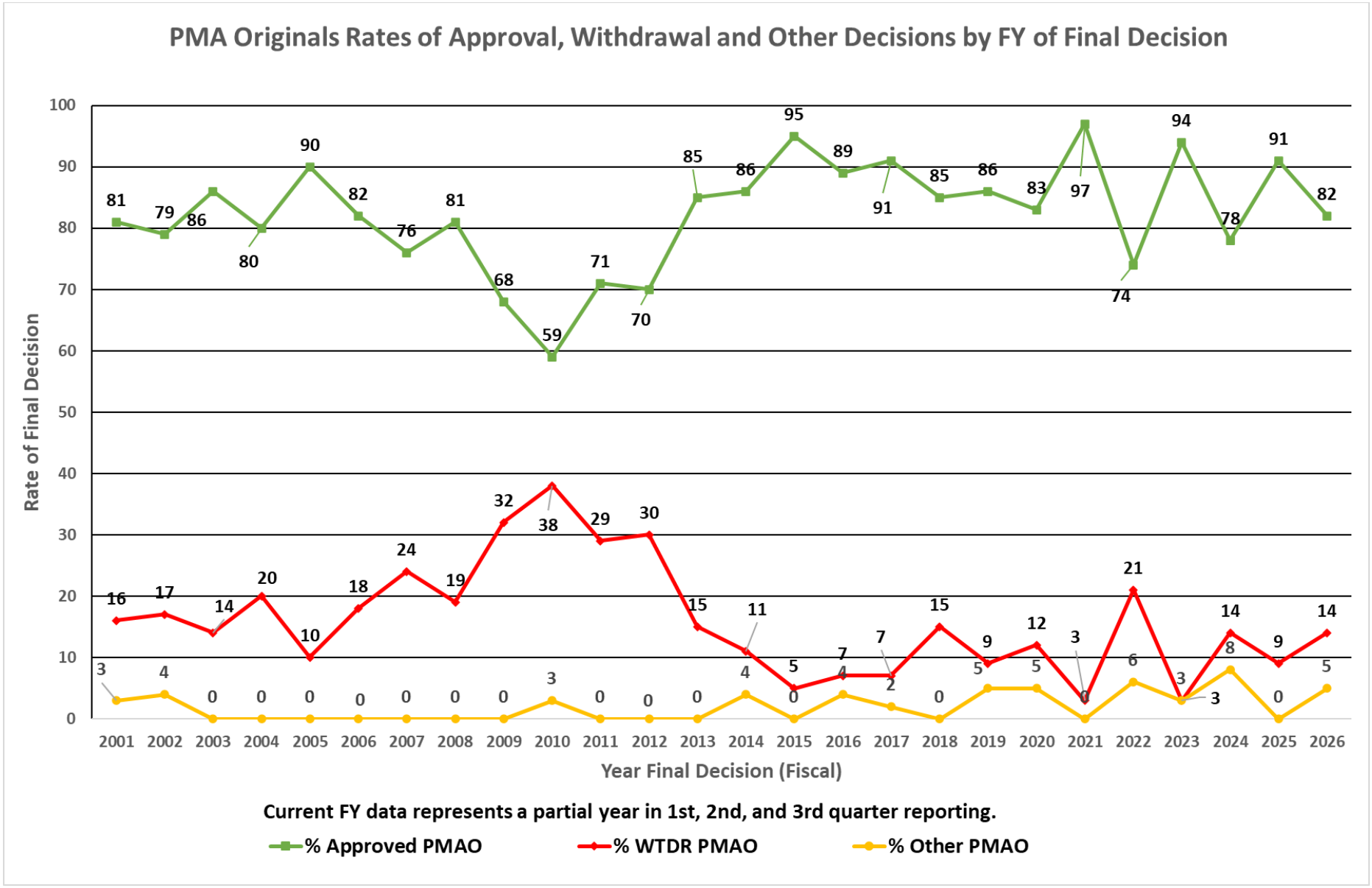


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

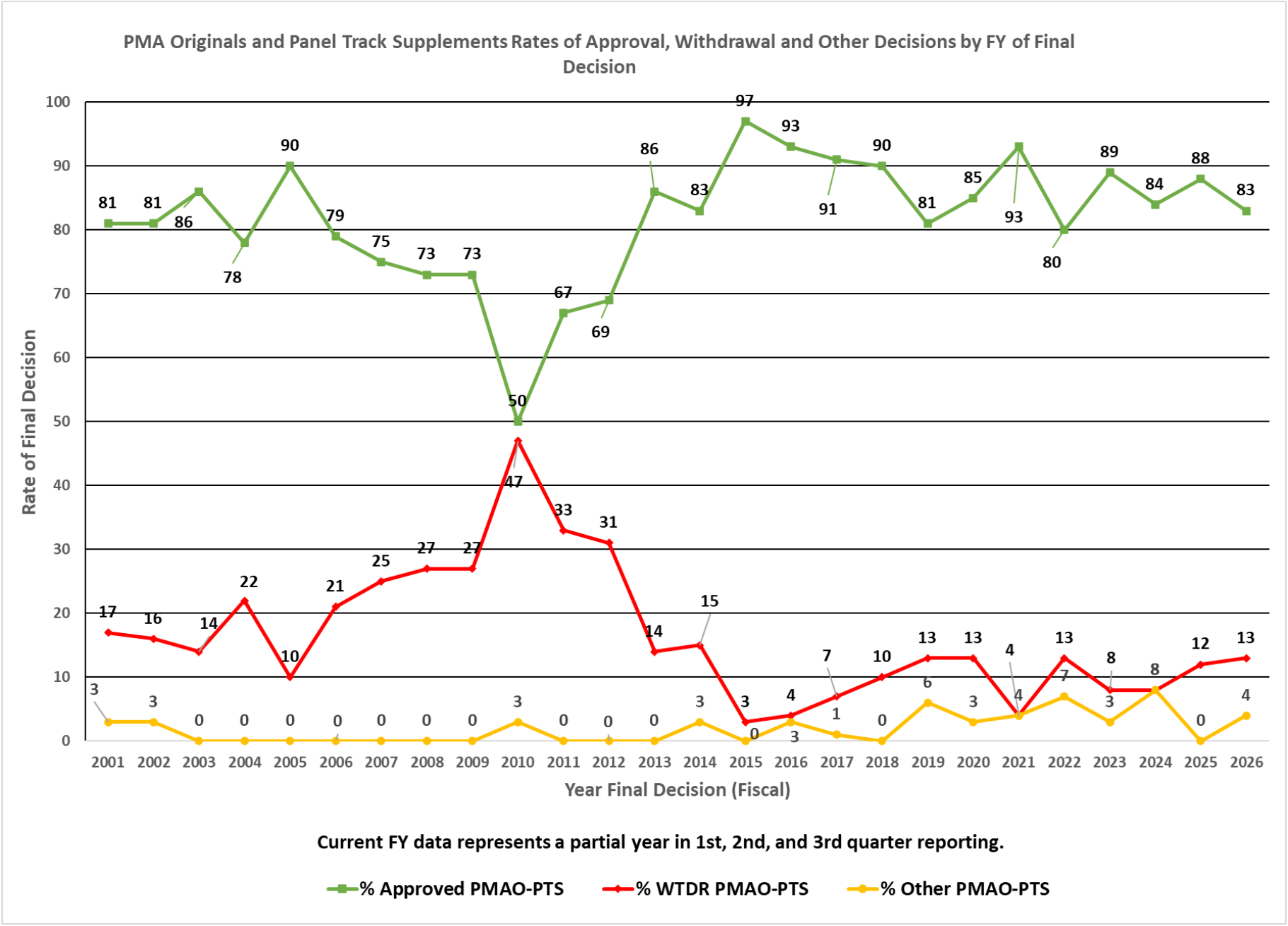
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



*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.

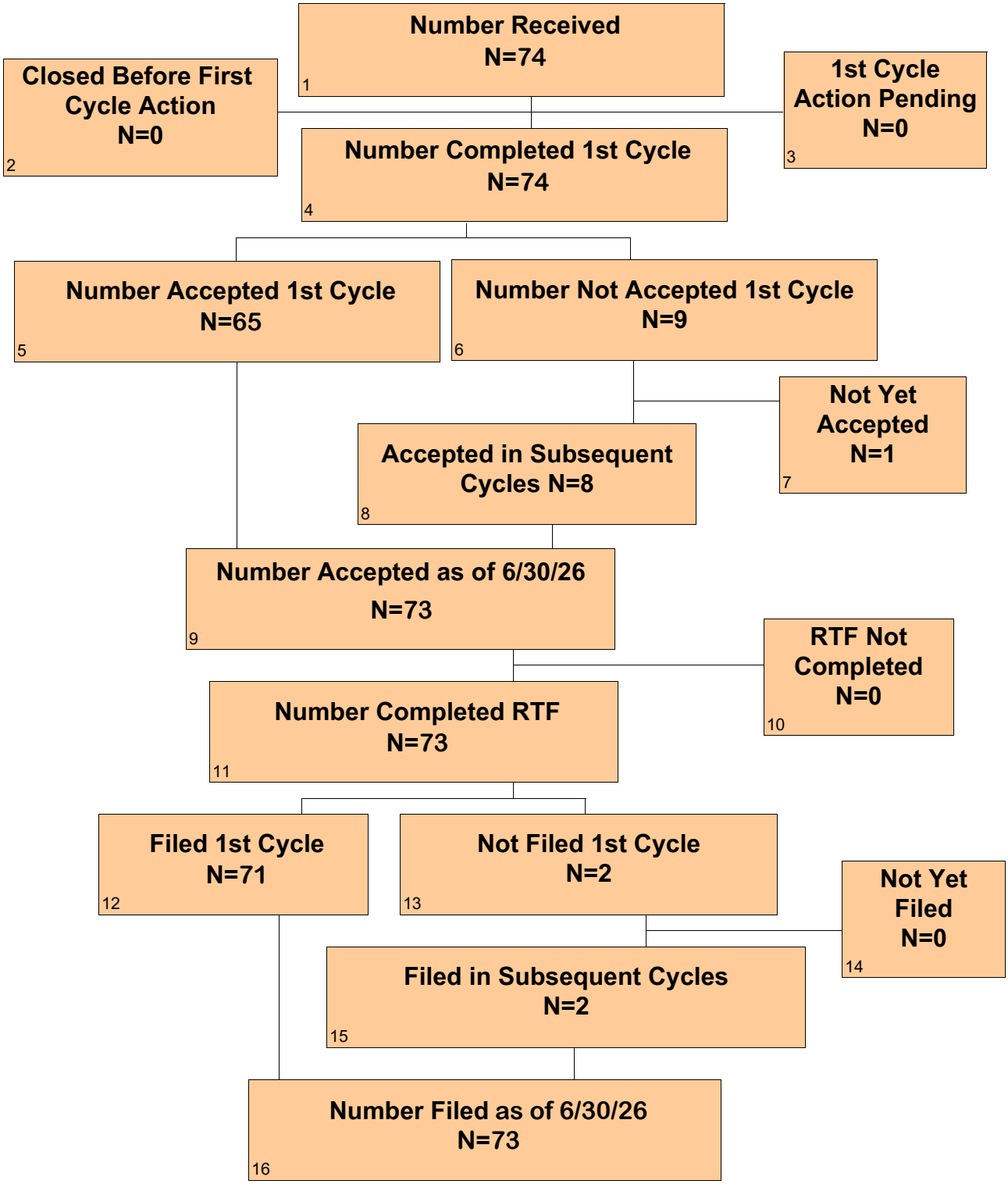


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

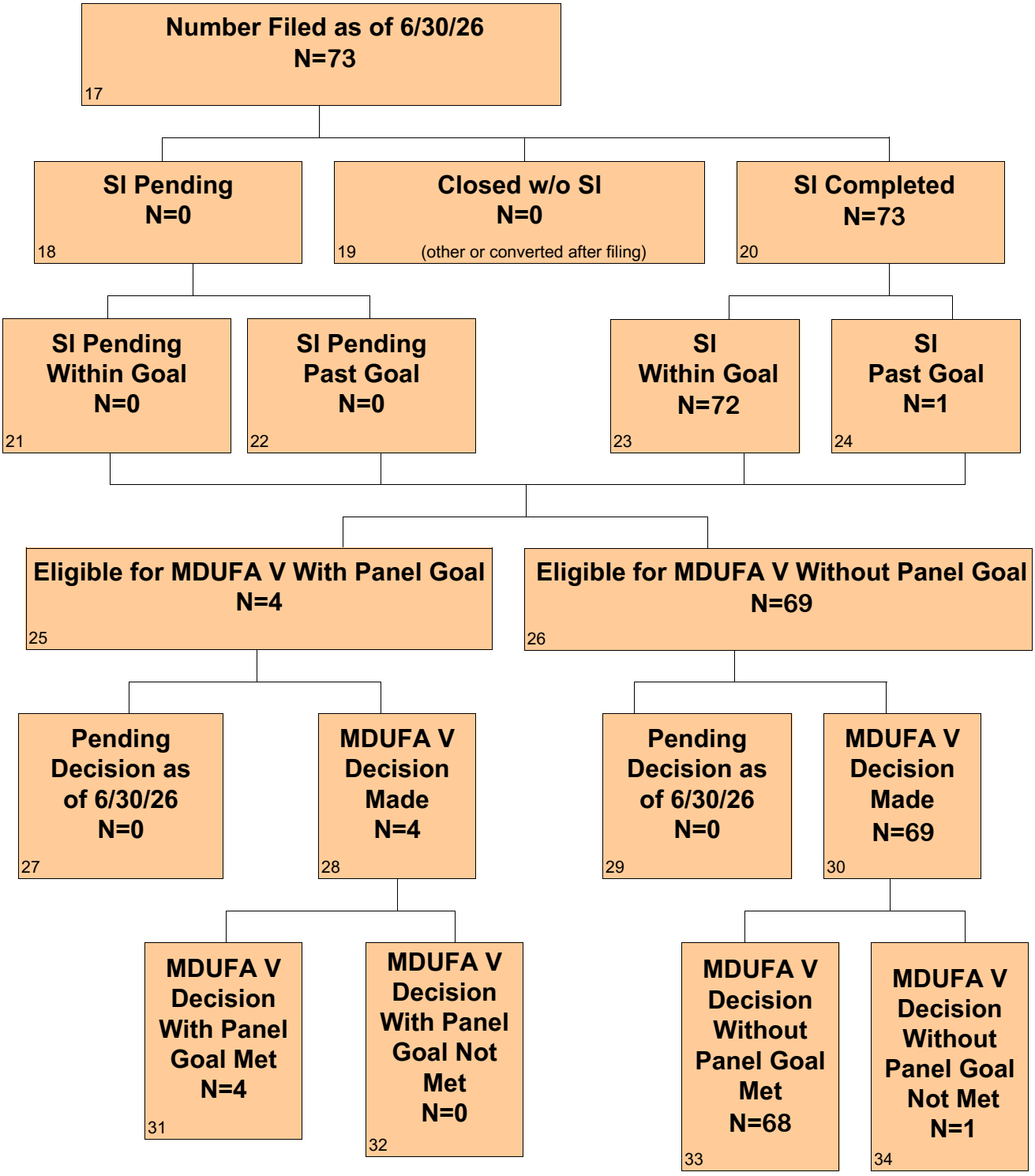


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

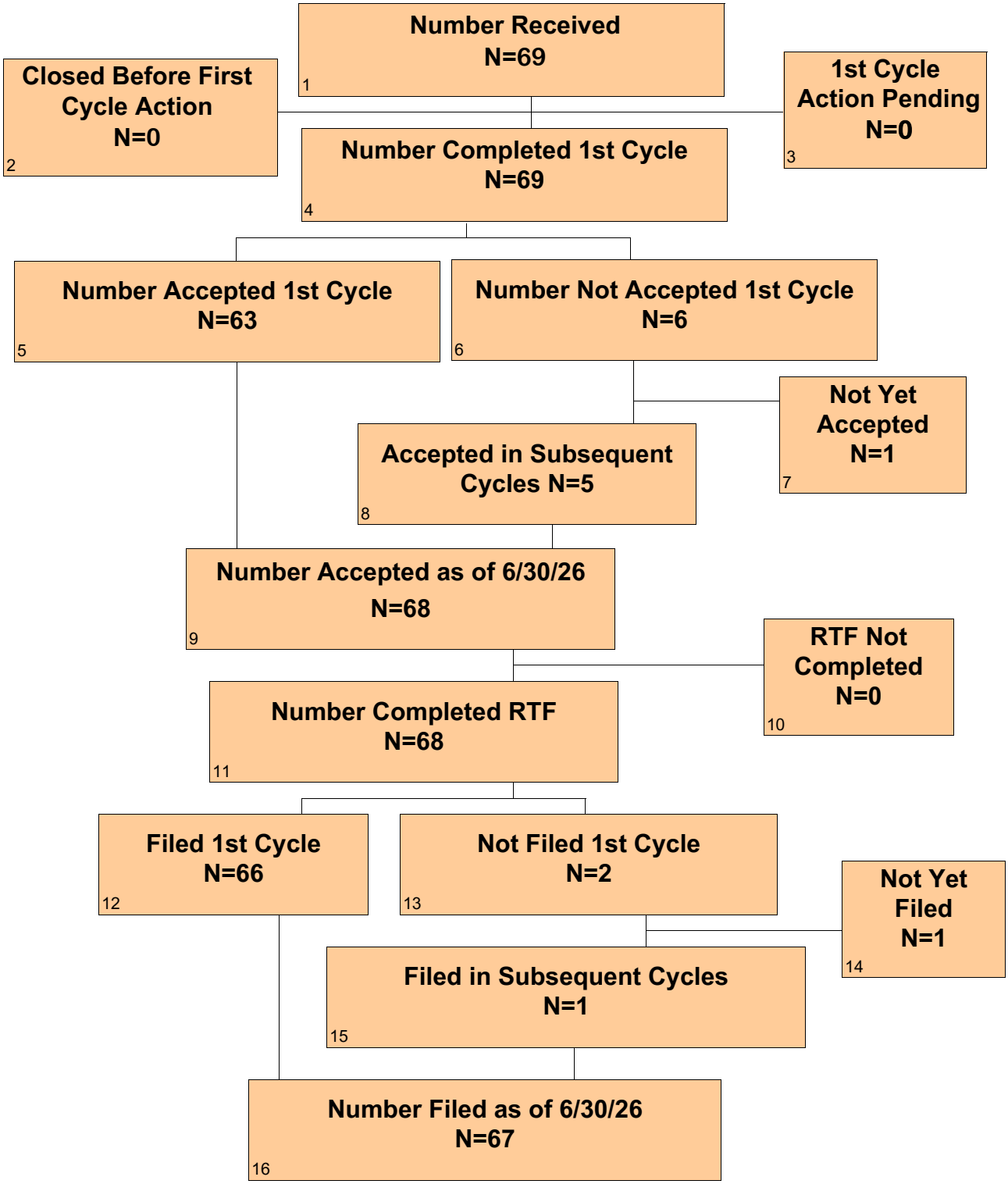
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/26



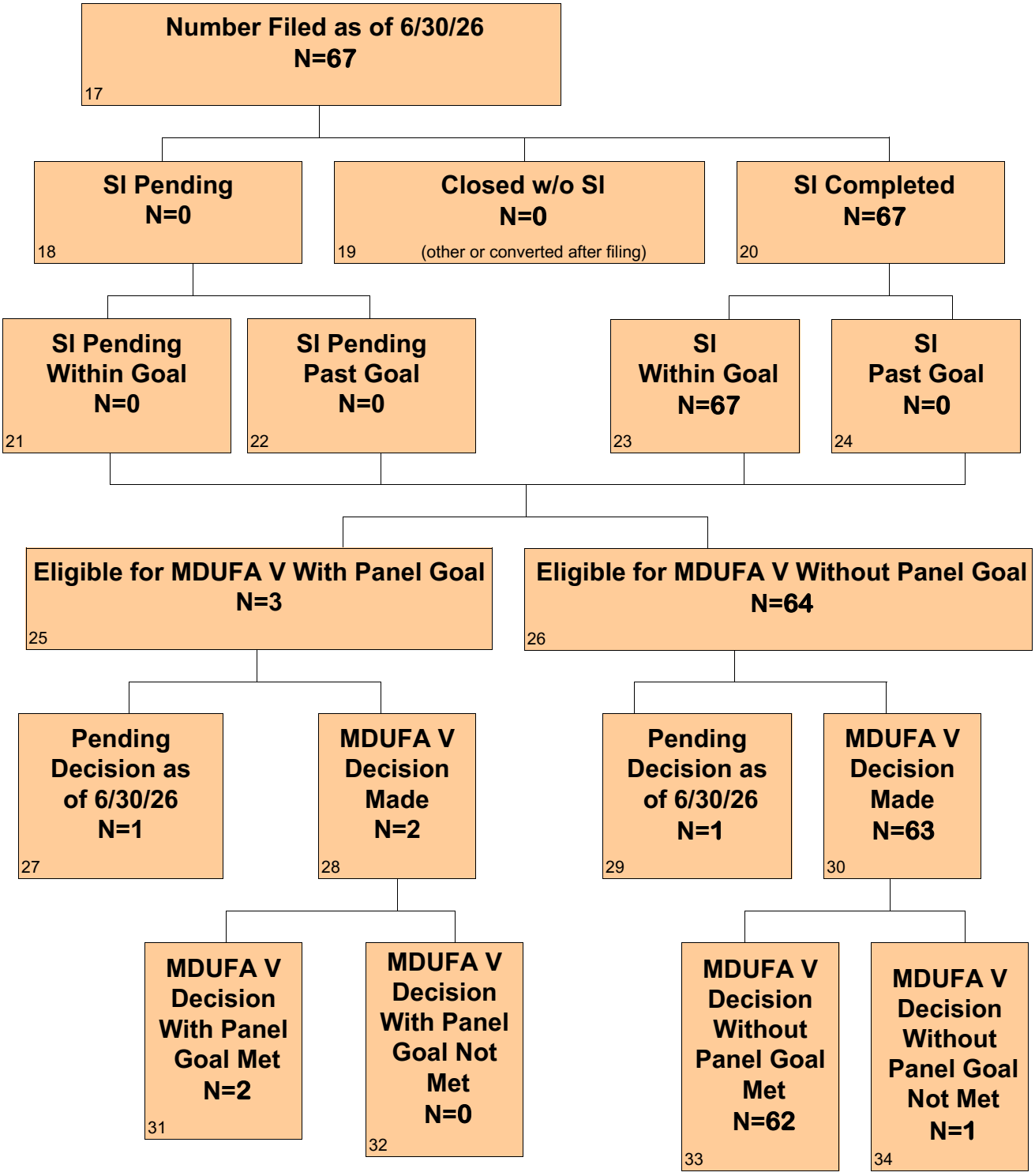
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/26 Con't



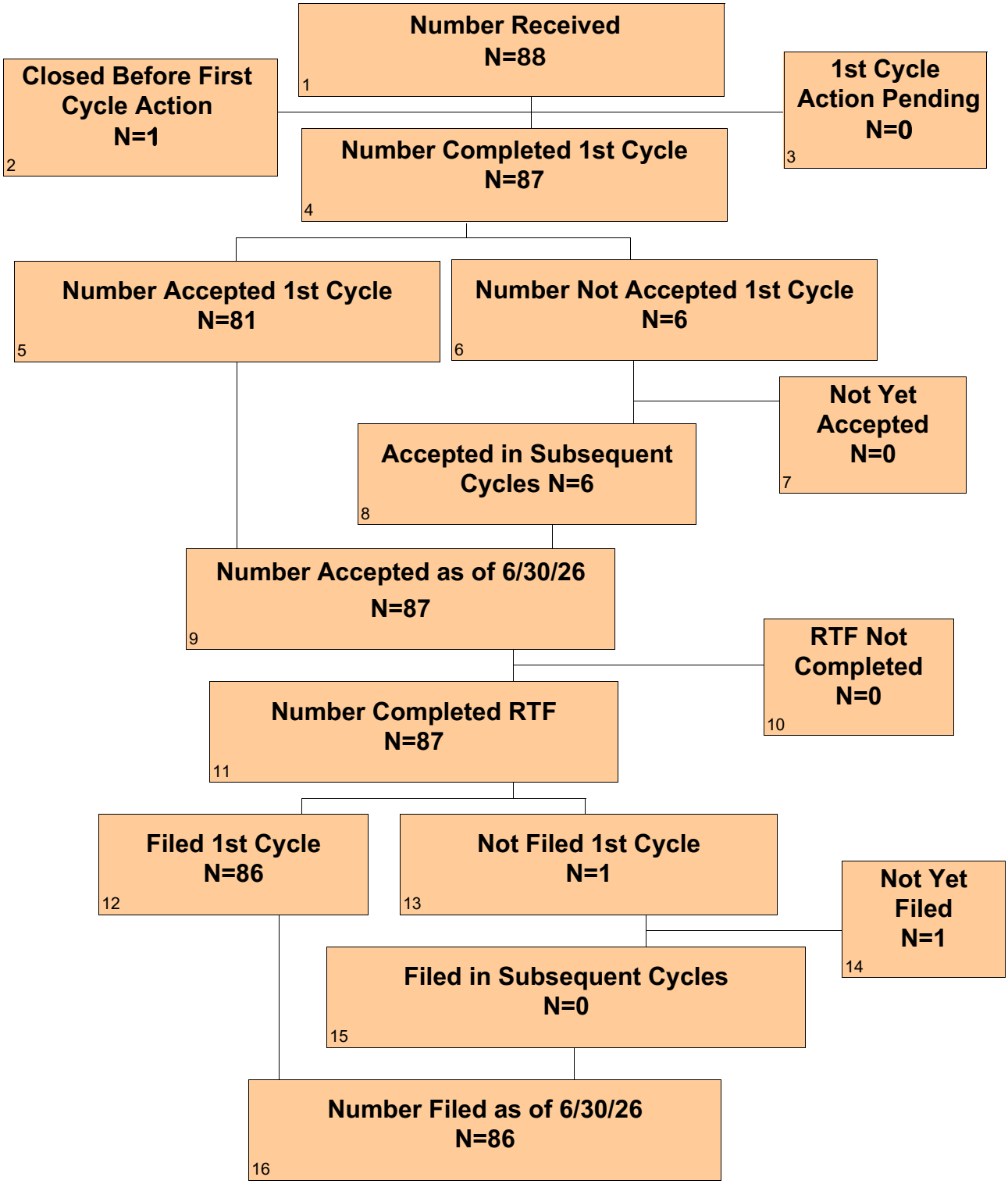
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 6/30/26



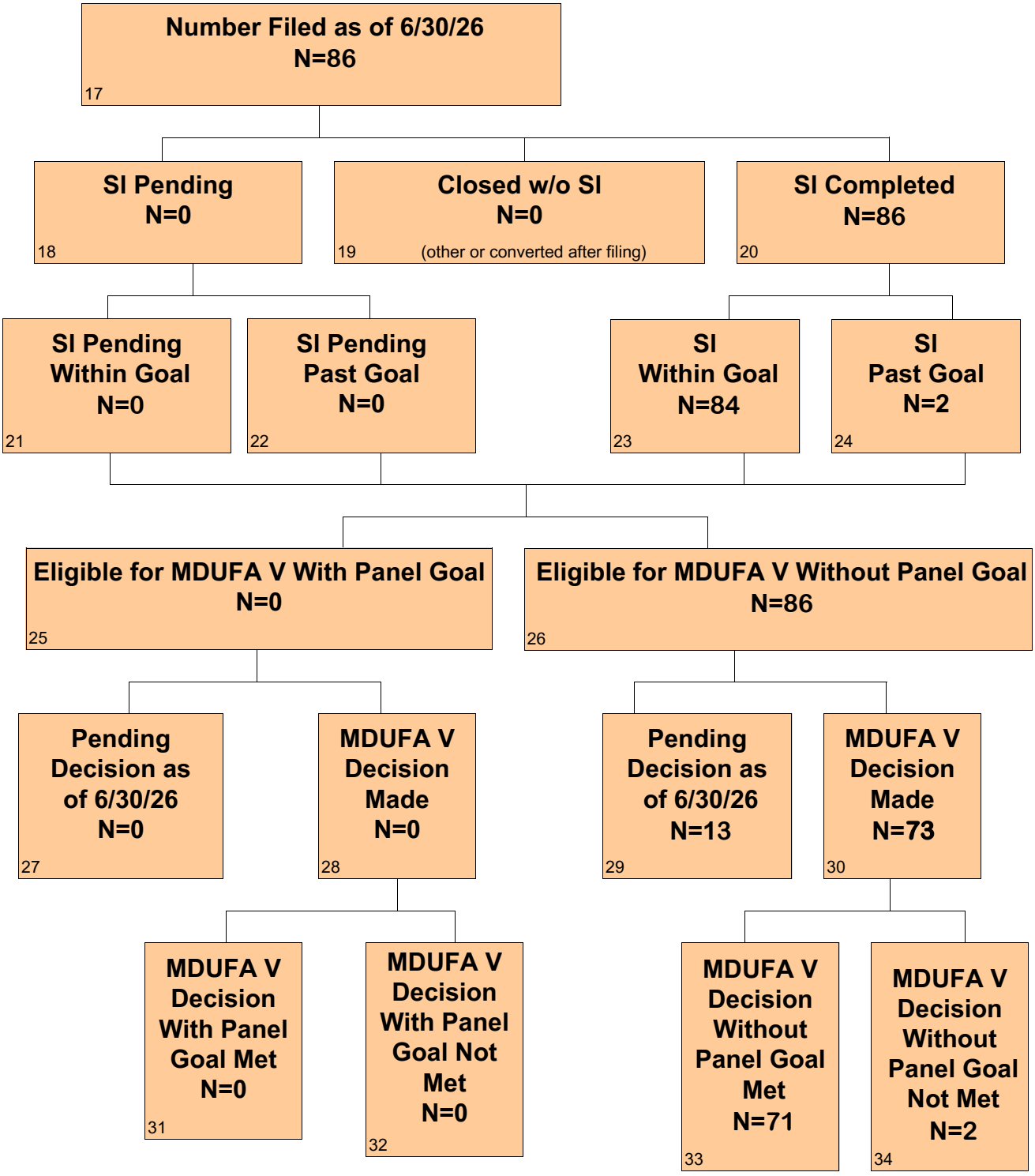
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 6/30/26 Con't



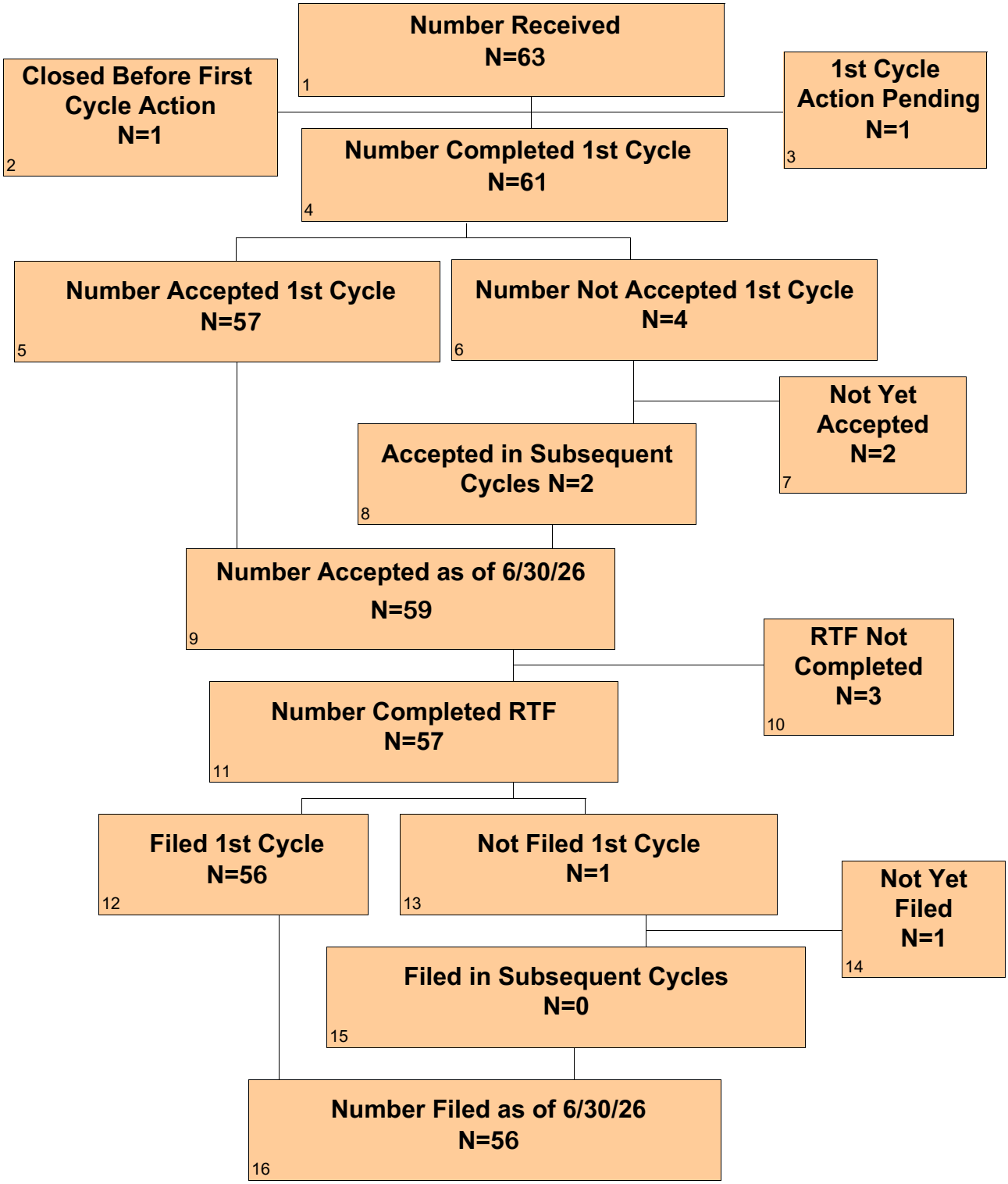
CDRH PMA Original and Panel Track Supplements - FY 2025 as of 6/30/26



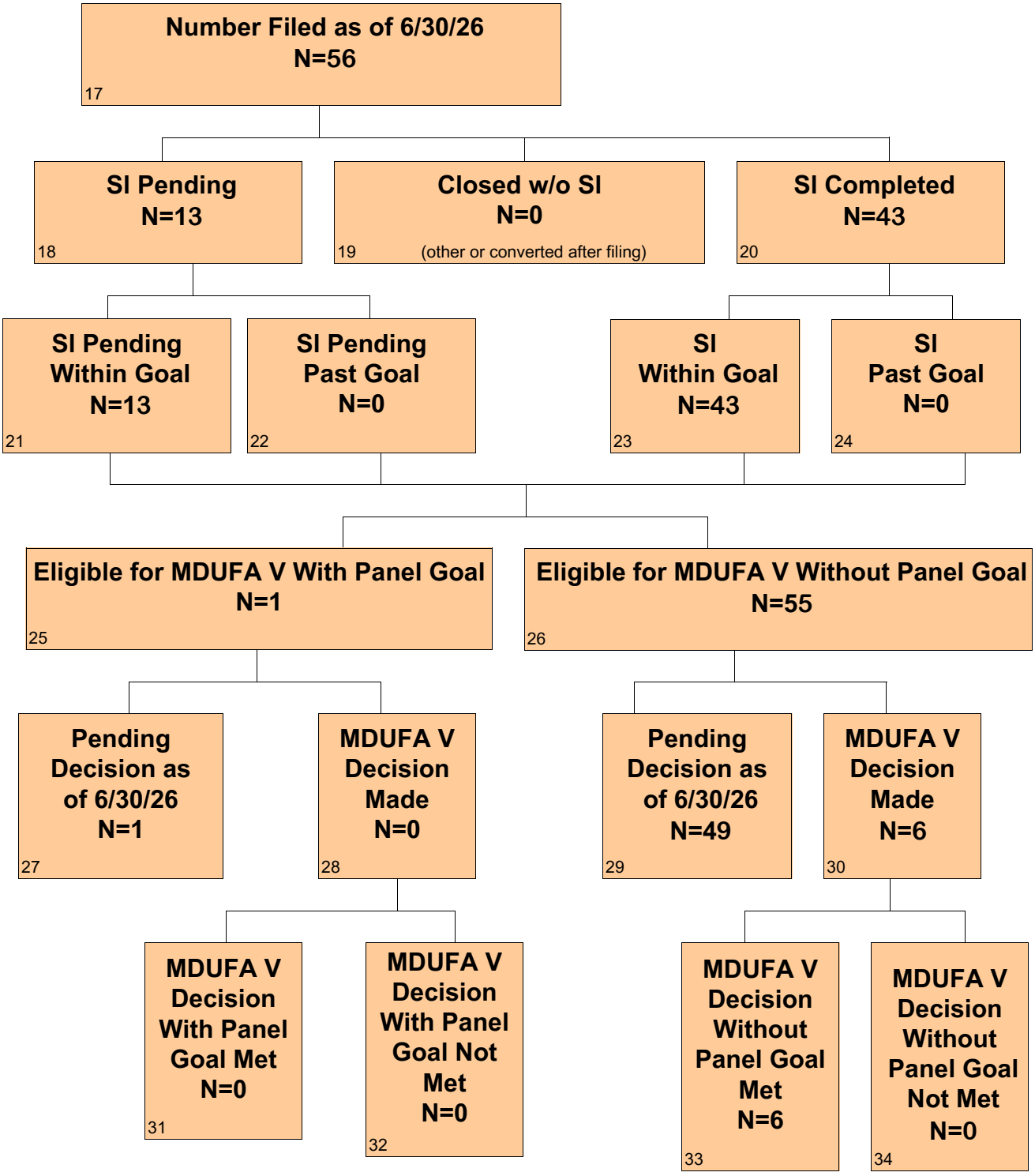
CDRH PMA Original and Panel Track Supplements - FY 2025 as of 6/30/26 Con't



CDRH PMA Original and Panel Track Supplements - FY 2026 as of 6/30/26



CDRH PMA Original and Panel Track Supplements - FY 2026 as of 6/30/26 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	74	69	88	63	
Number Closed Before First RTA Action	0	0	1	1	
Number Accepted First RTA Review	65	61	79	56	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	2	1	
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	9	6	6	4	
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.16%	8.70%	6.90%	6.56%	

***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	74	69	88	63	
Number Accepted	65	63	81	57	
Completed RTF	73	68	87	57	
Number Not Filed	2	2	1	1	
Rate of Submissions Not Filed	2.74%	2.94%	1.15%	1.75%	

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	73	67	86	56	
SI Goal Met	72	67	84	43	
SI Goal Not Met	1	0	2	0	
SI Pending Within Goal	0	0	0	13	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	98.63%	100.00%	97.67%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	73	67	86	43	
Average Number of FDA Days to Substantive Interaction	87.40	89.13	87.42	88.93	
20th Percentile FDA Days to Substantive Interaction	86	88	86	88	
40th Percentile FDA Days to Substantive Interaction	88	89	88	89	
60th Percentile FDA Days to Substantive Interaction	90	90	89	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	91	153	151	90	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	69	64	86	55	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	69	63	73	6	
MDUFA Decision Goal Met	68	62	71	6	
PMAs Pending MDUFA Decision	0	1	13	49	
PMAs Pending MDUFA Decision Past Goal	0	1	0	0	
Current Performance Percent Goal Met	98.55%	96.88%	97.26%	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	3	0	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	2	0	0	
MDUFA Decision Goal Met	4	2	0	0	
PMAs Pending MDUFA Decision	0	1	0	1	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	69	63	73	6	
Average FDA Days to MDUFA Decision	168.77	171.38	173.07	167.00	
20th Percentile FDA Days to MDUFA Decision	171	175	176	177	
40th Percentile FDA Days to MDUFA Decision	178	178	178	179	
60th Percentile FDA Days to MDUFA Decision	180	180	180	180	
80th Percentile FDA Days to MDUFA Decision	180	180	180	180	
Maximum FDA Days to MDUFA Decision	271	243	311	180	
Average Industry Days to MDUFA Decision	129.17	148.97	67.07	13.83	
20th Percentile Industry Days to MDUFA Decision	0	13	0	0	
40th Percentile Industry Days to MDUFA Decision	40	59	34	0	
60th Percentile Industry Days to MDUFA Decision	101	149	81	0	
80th Percentile Industry Days to MDUFA Decision	288	340	115	31	
Maximum Industry Days to MDUFA Decision	629	368	241	52	
Average Total Days to MDUFA Decision	297.94	320.35	240.14	180.83	
20th Percentile Total Days to MDUFA Decision	179	196	179	177	
40th Percentile Total Days to MDUFA Decision	220	236	206	179	
60th Percentile Total Days to MDUFA Decision	293	327	257	180	
80th Percentile Total Days to MDUFA Decision	454	463	291	211	
Maximum Total Days to MDUFA Decision	809	591	419	232	

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	2	0	0	
Average FDA Days to MDUFA Decision	319.00	284.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	318	262	0	0	
40th Percentile FDA Days to MDUFA Decision	318	277	0	0	
60th Percentile FDA Days to MDUFA Decision	320	291	0	0	
80th Percentile FDA Days to MDUFA Decision	320	306	0	0	
Maximum FDA Days to MDUFA Decision	320	320	0	0	
Average Industry Days to MDUFA Decision	90.00	217.50	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	51	133	0	0	
40th Percentile Industry Days to MDUFA Decision	61	189	0	0	
60th Percentile Industry Days to MDUFA Decision	72	246	0	0	
80th Percentile Industry Days to MDUFA Decision	120	302	0	0	
Maximum Industry Days to MDUFA Decision	186	358	0	0	
Average Total Days to MDUFA Decision	409.00	501.50	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	370	396	0	0	
40th Percentile Total Days to MDUFA Decision	381	466	0	0	
60th Percentile Total Days to MDUFA Decision	392	537	0	0	
80th Percentile Total Days to MDUFA Decision	439	607	0	0	
Maximum Total Days to MDUFA Decision	504	678	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	69	64	86	55	
Number with MDUFA Decision	69	63	73	6	
Number of Withdrawal	3	2	2	0	
Number of Not Approvable	14	8	6	0	
Number of Deleted	1	4	0	0	
Rate of Withdrawal	4.35%	3.17%	2.74%	0.00%	
Rate of Not Approvable	20.29%	12.70%	8.22%	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	3	0	1	
Number With MDUFA Decision	4	2	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	N/A	N/A	
Rate of Not Approvable	0.00%	50.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	2	2	0	
Mean FDA Days for Submissions that Missed the Goal	191.00	253.00	255.50	N/A	
Mean Industry Days for Submissions that Missed the Goal	28.00	180.00	108.50	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	4	4	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	4	4	0	
MDUFA Decision Goal Met	6	4	4	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	11	20	18	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	11	17	1	
MDUFA Decision Goal Met	15	11	17	1	
PMAs Pending MDUFA Decision	0	0	3	17	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	7	5	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	3	6	6	2	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	6	1	1	3	
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%	14.29%	60.00%	

***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	7	5	
Number Accepted	3	6	6	2	
Completed RTF	8	7	7	4	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	12.50%	0.00%	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	7	4	
SI Goal Met	8	7	7	3	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	7	3	
Average Number of FDA Days to Substantive Interaction	82.00	89.43	88.71	89.33	
20th Percentile FDA Days to Substantive Interaction	87	88	87	89	
40th Percentile FDA Days to Substantive Interaction	90	90	89	90	
60th Percentile FDA Days to Substantive Interaction	90	90	90	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	90	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	7	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	8	7	6	0	
MDUFA Decision Goal Met	8	7	6	0	
PMAs Pending MDUFA Decision	0	0	1	4	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	6	0	
Average FDA Days to MDUFA Decision	138.00	180.00	179.17	N/A	
20th Percentile FDA Days to MDUFA Decision	90	180	179	0	
40th Percentile FDA Days to MDUFA Decision	157	180	180	0	
60th Percentile FDA Days to MDUFA Decision	179	180	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	217.75	145.43	79.83	N/A	
20th Percentile Industry Days to MDUFA Decision	65	65	26	0	
40th Percentile Industry Days to MDUFA Decision	247	102	48	0	
60th Percentile Industry Days to MDUFA Decision	295	148	107	0	
80th Percentile Industry Days to MDUFA Decision	337	236	136	0	
Maximum Industry Days to MDUFA Decision	362	311	147	0	
Average Total Days to MDUFA Decision	355.75	325.43	259.00	N/A	
20th Percentile Total Days to MDUFA Decision	245	245	206	0	
40th Percentile Total Days to MDUFA Decision	354	282	224	0	
60th Percentile Total Days to MDUFA Decision	456	328	287	0	
80th Percentile Total Days to MDUFA Decision	478	416	315	0	
Maximum Total Days to MDUFA Decision	536	491	327	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	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	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	7	4	
Number with MDUFA Decision	8	7	6	0	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	0	1	1	0	
Number of Deleted	1	0	0	0	
Rate of Withdrawal	12.50%	0.00%	0.00%	N/A	
Rate of Not Approvable	0.00%	14.29%	16.67%	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	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	28	24	
Number Closed Before First RTA Action	0	0	1	1	
Number Accepted First RTA Review	19	17	24	20	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	2	1	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	1	1	1	1	
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%	3.70%	4.55%	

***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	28	24	
Number Accepted	19	19	26	21	
Completed RTF	20	20	27	20	
Number Not Filed	0	1	1	0	
Rate of Submissions Not Filed	0.00%	5.00%	3.70%	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	20	26	20	
SI Goal Met	20	20	25	12	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	8	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	96.15%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	20	20	26	12	
Average Number of FDA Days to Substantive Interaction	88.25	88.20	88.35	89.08	
20th Percentile FDA Days to Substantive Interaction	86	87	88	88	
40th Percentile FDA Days to Substantive Interaction	90	89	89	89	
60th Percentile FDA Days to Substantive Interaction	90	90	90	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	90	90	102	90	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	17	19	26	20	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	17	19	23	4	
MDUFA Decision Goal Met	17	18	22	4	
PMAs Pending MDUFA Decision	0	0	3	16	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	94.74%	95.65%	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	1	0	0	
MDUFA Decision Goal Met	3	1	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	19	23	4	
Average FDA Days to MDUFA Decision	177.65	174.37	182.57	179.75	
20th Percentile FDA Days to MDUFA Decision	172	177	177	180	
40th Percentile FDA Days to MDUFA Decision	177	178	179	180	
60th Percentile FDA Days to MDUFA Decision	180	180	180	180	
80th Percentile FDA Days to MDUFA Decision	180	180	180	180	
Maximum FDA Days to MDUFA Decision	271	228	311	180	
Average Industry Days to MDUFA Decision	64.29	70.00	41.61	20.75	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	23	2	0	6	
60th Percentile Industry Days to MDUFA Decision	47	30	31	25	
80th Percentile Industry Days to MDUFA Decision	113	81	78	39	
Maximum Industry Days to MDUFA Decision	271	362	232	52	
Average Total Days to MDUFA Decision	241.94	244.37	224.17	200.50	
20th Percentile Total Days to MDUFA Decision	176	179	179	180	
40th Percentile Total Days to MDUFA Decision	201	191	180	186	
60th Percentile Total Days to MDUFA Decision	236	222	205	205	
80th Percentile Total Days to MDUFA Decision	305	259	262	219	
Maximum Total Days to MDUFA Decision	442	537	411	232	

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	0	
Average FDA Days to MDUFA Decision	319.33	248.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	319	248	0	0	
40th Percentile FDA Days to MDUFA Decision	320	248	0	0	
60th Percentile FDA Days to MDUFA Decision	320	248	0	0	
80th Percentile FDA Days to MDUFA Decision	320	248	0	0	
Maximum FDA Days to MDUFA Decision	320	248	0	0	
Average Industry Days to MDUFA Decision	58.00	77.00	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	47	77	0	0	
40th Percentile Industry Days to MDUFA Decision	54	77	0	0	
60th Percentile Industry Days to MDUFA Decision	61	77	0	0	
80th Percentile Industry Days to MDUFA Decision	68	77	0	0	
Maximum Industry Days to MDUFA Decision	76	77	0	0	
Average Total Days to MDUFA Decision	377.33	325.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	366	325	0	0	
40th Percentile Total Days to MDUFA Decision	373	325	0	0	
60th Percentile Total Days to MDUFA Decision	381	325	0	0	
80th Percentile Total Days to MDUFA Decision	388	325	0	0	
Maximum Total Days to MDUFA Decision	396	325	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	17	19	26	20	
Number with MDUFA Decision	17	19	23	4	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	3	0	4	0	
Number of Deleted	0	1	0	0	
Rate of Withdrawal	5.88%	0.00%	0.00%	0.00%	
Rate of Not Approvable	17.65%	0.00%	17.39%	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	0	
Number With MDUFA Decision	3	1	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	N/A	N/A	
Rate of Not Approvable	0.00%	100.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	1	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	228.00	311.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	66.00	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	5	5	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	3	6	5	5	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	1	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	14.29%	0.00%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	5	5	
Number Accepted	3	6	5	5	
Completed RTF	3	7	5	4	
Number Not Filed	0	1	0	1	
Rate of Submissions Not Filed	0.00%	14.29%	0.00%	25.00%	

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	5	3	
SI Goal Met	3	6	5	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	5	2	
Average Number of FDA Days to Substantive Interaction	88.33	96.67	87.80	90.00	
20th Percentile FDA Days to Substantive Interaction	87	88	87	90	
40th Percentile FDA Days to Substantive Interaction	88	88	88	90	
60th Percentile FDA Days to Substantive Interaction	88	90	88	90	
80th Percentile FDA Days to Substantive Interaction	89	90	88	90	
Maximum FDA Days to Substantive Interaction	90	153	90	90	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	6	5	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	6	3	0	
MDUFA Decision Goal Met	2	6	3	0	
PMAs Pending MDUFA Decision	0	0	2	3	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	66.67%	100.00%	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	6	3	0	
Average FDA Days to MDUFA Decision	180.67	188.17	178.67	N/A	
20th Percentile FDA Days to MDUFA Decision	175	178	178	0	
40th Percentile FDA Days to MDUFA Decision	178	179	179	0	
60th Percentile FDA Days to MDUFA Decision	181	180	180	0	
80th Percentile FDA Days to MDUFA Decision	186	180	180	0	
Maximum FDA Days to MDUFA Decision	191	243	180	0	
Average Industry Days to MDUFA Decision	18.67	249.83	74.67	N/A	
20th Percentile Industry Days to MDUFA Decision	11	189	64	0	
40th Percentile Industry Days to MDUFA Decision	22	217	69	0	
60th Percentile Industry Days to MDUFA Decision	28	304	76	0	
80th Percentile Industry Days to MDUFA Decision	28	348	85	0	
Maximum Industry Days to MDUFA Decision	28	354	94	0	
Average Total Days to MDUFA Decision	199.33	438.00	253.33	N/A	
20th Percentile Total Days to MDUFA Decision	187	358	241	0	
40th Percentile Total Days to MDUFA Decision	196	396	248	0	
60th Percentile Total Days to MDUFA Decision	204	484	256	0	
80th Percentile Total Days to MDUFA Decision	211	532	265	0	
Maximum Total Days to MDUFA Decision	219	591	274	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	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	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	5	3	
Number with MDUFA Decision	3	6	3	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	1	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	33.33%	16.67%	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	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	191.00	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	28.00	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	14	4	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	9	6	11	4	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	0	3	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%	21.43%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6	14	4	
Number Accepted	9	6	11	4	
Completed RTF	9	6	14	4	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	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	14	4	
SI Goal Met	9	6	13	2	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	92.86%	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	14	2	
Average Number of FDA Days to Substantive Interaction	88.78	89.33	92.64	88.50	
20th Percentile FDA Days to Substantive Interaction	88	89	87	88	
40th Percentile FDA Days to Substantive Interaction	90	89	89	88	
60th Percentile FDA Days to Substantive Interaction	90	90	90	89	
80th Percentile FDA Days to Substantive Interaction	90	90	90	89	
Maximum FDA Days to Substantive Interaction	90	90	151	90	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	9	4	14	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	9	4	11	1	
MDUFA Decision Goal Met	9	4	10	1	
PMAs Pending MDUFA Decision	0	0	3	3	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	90.91%	100.00%	

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	2	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	1	0	0	
MDUFA Decision Goal Met	0	1	0	0	
PMAs Pending MDUFA Decision	0	1	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	100.00%	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	9	4	11	1	
Average FDA Days to MDUFA Decision	179.11	156.25	173.18	177.00	
20th Percentile FDA Days to MDUFA Decision	178	141	178	177	
40th Percentile FDA Days to MDUFA Decision	179	177	180	177	
60th Percentile FDA Days to MDUFA Decision	180	179	180	177	
80th Percentile FDA Days to MDUFA Decision	180	180	180	177	
Maximum FDA Days to MDUFA Decision	180	180	200	177	
Average Industry Days to MDUFA Decision	123.56	281.50	105.82	N/A	
20th Percentile Industry Days to MDUFA Decision	0	233	55	0	
40th Percentile Industry Days to MDUFA Decision	42	351	98	0	
60th Percentile Industry Days to MDUFA Decision	60	353	119	0	
80th Percentile Industry Days to MDUFA Decision	145	358	151	0	
Maximum Industry Days to MDUFA Decision	629	365	214	0	
Average Total Days to MDUFA Decision	302.67	437.75	279.00	177.00	
20th Percentile Total Days to MDUFA Decision	180	367	233	177	
40th Percentile Total Days to MDUFA Decision	221	469	256	177	
60th Percentile Total Days to MDUFA Decision	238	515	290	177	
80th Percentile Total Days to MDUFA Decision	325	530	351	177	
Maximum Total Days to MDUFA Decision	809	530	394	177	

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	1	0	0	
Average FDA Days to MDUFA Decision	N/A	320.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	320	0	0	
40th Percentile FDA Days to MDUFA Decision	0	320	0	0	
60th Percentile FDA Days to MDUFA Decision	0	320	0	0	
80th Percentile FDA Days to MDUFA Decision	0	320	0	0	
Maximum FDA Days to MDUFA Decision	0	320	0	0	
Average Industry Days to MDUFA Decision	N/A	358.00	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	358	0	0	
40th Percentile Industry Days to MDUFA Decision	0	358	0	0	
60th Percentile Industry Days to MDUFA Decision	0	358	0	0	
80th Percentile Industry Days to MDUFA Decision	0	358	0	0	
Maximum Industry Days to MDUFA Decision	0	358	0	0	
Average Total Days to MDUFA Decision	N/A	678.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	678	0	0	
40th Percentile Total Days to MDUFA Decision	0	678	0	0	
60th Percentile Total Days to MDUFA Decision	0	678	0	0	
80th Percentile Total Days to MDUFA Decision	0	678	0	0	
Maximum Total Days to MDUFA Decision	0	678	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	4	14	4	
Number with MDUFA Decision	9	4	11	1	
Number of Withdrawal	0	0	1	0	
Number of Not Approvable	2	1	0	0	
Number of Deleted	0	1	0	0	
Rate of Withdrawal	0.00%	0.00%	9.09%	0.00%	
Rate of Not Approvable	22.22%	25.00%	0.00%	0.00%	

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	2	0	0	
Number With MDUFA Decision	0	1	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	0.00%	N/A	N/A	
Rate of Not Approvable	N/A	0.00%	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	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	200.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	151.00	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	6	6	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	5	6	5	6	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	1	1	1	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	14.29%	16.67%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	6	6	
Number Accepted	5	6	5	6	
Completed RTF	6	7	6	6	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	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	6	6	
SI Goal Met	5	7	6	5	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	83.33%	100.00%	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	6	5	
Average Number of FDA Days to Substantive Interaction	88.50	86.43	89.00	88.00	
20th Percentile FDA Days to Substantive Interaction	88	86	88	87	
40th Percentile FDA Days to Substantive Interaction	90	89	89	88	
60th Percentile FDA Days to Substantive Interaction	90	90	89	89	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	91	90	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	6	6	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	7	5	0	
MDUFA Decision Goal Met	6	7	5	0	
PMAs Pending MDUFA Decision	0	0	1	6	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	7	5	0	
Average FDA Days to MDUFA Decision	175.33	165.14	179.60	N/A	
20th Percentile FDA Days to MDUFA Decision	179	176	179	0	
40th Percentile FDA Days to MDUFA Decision	180	177	180	0	
60th Percentile FDA Days to MDUFA Decision	180	178	180	0	
80th Percentile FDA Days to MDUFA Decision	180	179	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	55.17	133.57	140.00	N/A	
20th Percentile Industry Days to MDUFA Decision	0	43	98	0	
40th Percentile Industry Days to MDUFA Decision	37	84	121	0	
60th Percentile Industry Days to MDUFA Decision	71	114	136	0	
80th Percentile Industry Days to MDUFA Decision	101	223	157	0	
Maximum Industry Days to MDUFA Decision	122	355	239	0	
Average Total Days to MDUFA Decision	230.50	298.71	319.60	N/A	
20th Percentile Total Days to MDUFA Decision	180	221	278	0	
40th Percentile Total Days to MDUFA Decision	217	261	301	0	
60th Percentile Total Days to MDUFA Decision	251	292	315	0	
80th Percentile Total Days to MDUFA Decision	281	330	337	0	
Maximum Total Days to MDUFA Decision	301	534	419	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	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	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	6	6	
Number with MDUFA Decision	6	7	5	0	
Number of Withdrawal	0	1	0	0	
Number of Not Approvable	1	2	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	14.29%	0.00%	N/A	
Rate of Not Approvable	16.67%	28.57%	0.00%	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	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	6	3	4	1	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	5	3	4	1	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	1	0	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	0.00%	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	6	3	4	1	
Number Accepted	5	3	4	1	
Completed RTF	6	3	4	1	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	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	6	3	4	1	
SI Goal Met	6	3	4	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	6	3	4	1	
Average Number of FDA Days to Substantive Interaction	85.50	88.00	84.00	89.00	
20th Percentile FDA Days to Substantive Interaction	85	87	81	89	
40th Percentile FDA Days to Substantive Interaction	86	87	84	89	
60th Percentile FDA Days to Substantive Interaction	87	88	85	89	
80th Percentile FDA Days to Substantive Interaction	88	89	87	89	
Maximum FDA Days to Substantive Interaction	88	90	88	89	

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	6	3	4	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	3	4	0	
MDUFA Decision Goal Met	6	3	4	0	
PMAs Pending MDUFA Decision	0	0	0	1	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	6	3	4	0	
Average FDA Days to MDUFA Decision	174.83	179.33	159.50	N/A	
20th Percentile FDA Days to MDUFA Decision	171	179	148	0	
40th Percentile FDA Days to MDUFA Decision	178	180	176	0	
60th Percentile FDA Days to MDUFA Decision	179	180	177	0	
80th Percentile FDA Days to MDUFA Decision	180	180	178	0	
Maximum FDA Days to MDUFA Decision	180	180	178	0	
Average Industry Days to MDUFA Decision	222.33	169.00	56.50	N/A	
20th Percentile Industry Days to MDUFA Decision	96	144	0	0	
40th Percentile Industry Days to MDUFA Decision	172	145	7	0	
60th Percentile Industry Days to MDUFA Decision	350	160	28	0	
80th Percentile Industry Days to MDUFA Decision	356	189	97	0	
Maximum Industry Days to MDUFA Decision	360	218	191	0	
Average Total Days to MDUFA Decision	397.17	348.33	216.00	N/A	
20th Percentile Total Days to MDUFA Decision	257	323	150	0	
40th Percentile Total Days to MDUFA Decision	343	324	184	0	
60th Percentile Total Days to MDUFA Decision	529	340	204	0	
80th Percentile Total Days to MDUFA Decision	536	369	274	0	
Maximum Total Days to MDUFA Decision	540	398	369	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	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	6	3	4	1	
Number with MDUFA Decision	6	3	4	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	4	2	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	66.67%	66.67%	0.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	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	24	18	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	21	14	24	18	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	2	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	12.50%	0.00%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	24	18	
Number Accepted	21	14	24	18	
Completed RTF	21	15	24	18	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	4.76%	0.00%	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	24	18	
SI Goal Met	21	15	24	18	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	24	18	
Average Number of FDA Days to Substantive Interaction	88.14	88.60	83.08	88.94	
20th Percentile FDA Days to Substantive Interaction	87	88	82	89	
40th Percentile FDA Days to Substantive Interaction	87	89	86	90	
60th Percentile FDA Days to Substantive Interaction	89	89	89	90	
80th Percentile FDA Days to Substantive Interaction	90	90	89	90	
Maximum FDA Days to Substantive Interaction	90	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	24	17	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	20	15	21	1	
MDUFA Decision Goal Met	20	15	21	1	
PMAs Pending MDUFA Decision	0	0	3	16	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Goal Met	1	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	1	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	N/A	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	15	21	1	
Average FDA Days to MDUFA Decision	163.30	161.40	161.10	106.00	
20th Percentile FDA Days to MDUFA Decision	136	150	160	106	
40th Percentile FDA Days to MDUFA Decision	178	177	176	106	
60th Percentile FDA Days to MDUFA Decision	179	180	178	106	
80th Percentile FDA Days to MDUFA Decision	180	180	180	106	
Maximum FDA Days to MDUFA Decision	180	180	180	106	
Average Industry Days to MDUFA Decision	162.25	152.33	54.57	N/A	
20th Percentile Industry Days to MDUFA Decision	0	23	0	0	
40th Percentile Industry Days to MDUFA Decision	68	59	0	0	
60th Percentile Industry Days to MDUFA Decision	236	138	66	0	
80th Percentile Industry Days to MDUFA Decision	322	352	99	0	
Maximum Industry Days to MDUFA Decision	354	368	241	0	
Average Total Days to MDUFA Decision	325.55	313.73	215.67	106.00	
20th Percentile Total Days to MDUFA Decision	179	202	176	106	
40th Percentile Total Days to MDUFA Decision	247	226	180	106	
60th Percentile Total Days to MDUFA Decision	364	318	232	106	
80th Percentile Total Days to MDUFA Decision	502	459	271	106	
Maximum Total Days to MDUFA Decision	534	532	297	106	

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	0	
Average FDA Days to MDUFA Decision	318.00	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	318	0	0	0	
40th Percentile FDA Days to MDUFA Decision	318	0	0	0	
60th Percentile FDA Days to MDUFA Decision	318	0	0	0	
80th Percentile FDA Days to MDUFA Decision	318	0	0	0	
Maximum FDA Days to MDUFA Decision	318	0	0	0	
Average Industry Days to MDUFA Decision	186.00	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	186	0	0	0	
40th Percentile Industry Days to MDUFA Decision	186	0	0	0	
60th Percentile Industry Days to MDUFA Decision	186	0	0	0	
80th Percentile Industry Days to MDUFA Decision	186	0	0	0	
Maximum Industry Days to MDUFA Decision	186	0	0	0	
Average Total Days to MDUFA Decision	504.00	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	504	0	0	0	
40th Percentile Total Days to MDUFA Decision	504	0	0	0	
60th Percentile Total Days to MDUFA Decision	504	0	0	0	
80th Percentile Total Days to MDUFA Decision	504	0	0	0	
Maximum Total Days to MDUFA Decision	504	0	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	24	17	
Number with MDUFA Decision	20	15	21	1	
Number of Withdrawal	1	1	1	0	
Number of Not Approvable	3	1	1	0	
Number of Deleted	0	2	0	0	
Rate of Withdrawal	5.00%	6.67%	4.76%	0.00%	
Rate of Not Approvable	15.00%	6.67%	4.76%	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	1	
Number With MDUFA Decision	1	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	N/A	N/A	N/A	
Rate of Not Approvable	0.00%	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	4	4	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	4	4	0	
MDUFA Decision Goal Met	6	4	4	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	11	20	18	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	11	17	1	
MDUFA Decision Goal Met	15	11	17	1	
PMAs Pending MDUFA Decision	0	0	3	17	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	0	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	0	3	0	0	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	0	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	N/A	0.00%	N/A	N/A	

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

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

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

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

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

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

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

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	3	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	2	0	0	
MDUFA Decision Goal Met	0	2	0	0	
PMAs Pending MDUFA Decision	0	1	0	0	
PMAs Pending MDUFA Decision Past Goal	0	1	0	0	
Current Performance Percent Goal Met	N/A	66.67%	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	2	0	0	
Average FDA Days to MDUFA Decision	N/A	177.50	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	176	0	0	
40th Percentile FDA Days to MDUFA Decision	0	177	0	0	
60th Percentile FDA Days to MDUFA Decision	0	178	0	0	
80th Percentile FDA Days to MDUFA Decision	0	179	0	0	
Maximum FDA Days to MDUFA Decision	0	180	0	0	
Average Industry Days to MDUFA Decision	N/A	342.50	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	334	0	0	
40th Percentile Industry Days to MDUFA Decision	0	340	0	0	
60th Percentile Industry Days to MDUFA Decision	0	345	0	0	
80th Percentile Industry Days to MDUFA Decision	0	351	0	0	
Maximum Industry Days to MDUFA Decision	0	357	0	0	
Average Total Days to MDUFA Decision	N/A	520.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	513	0	0	
40th Percentile Total Days to MDUFA Decision	0	518	0	0	
60th Percentile Total Days to MDUFA Decision	0	522	0	0	
80th Percentile Total Days to MDUFA Decision	0	527	0	0	
Maximum Total Days to MDUFA Decision	0	532	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	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	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	0	
Number with MDUFA Decision	0	2	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	0.00%	N/A	N/A	
Rate of Not Approvable	N/A	0.00%	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	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	1	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	278.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	360.00	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

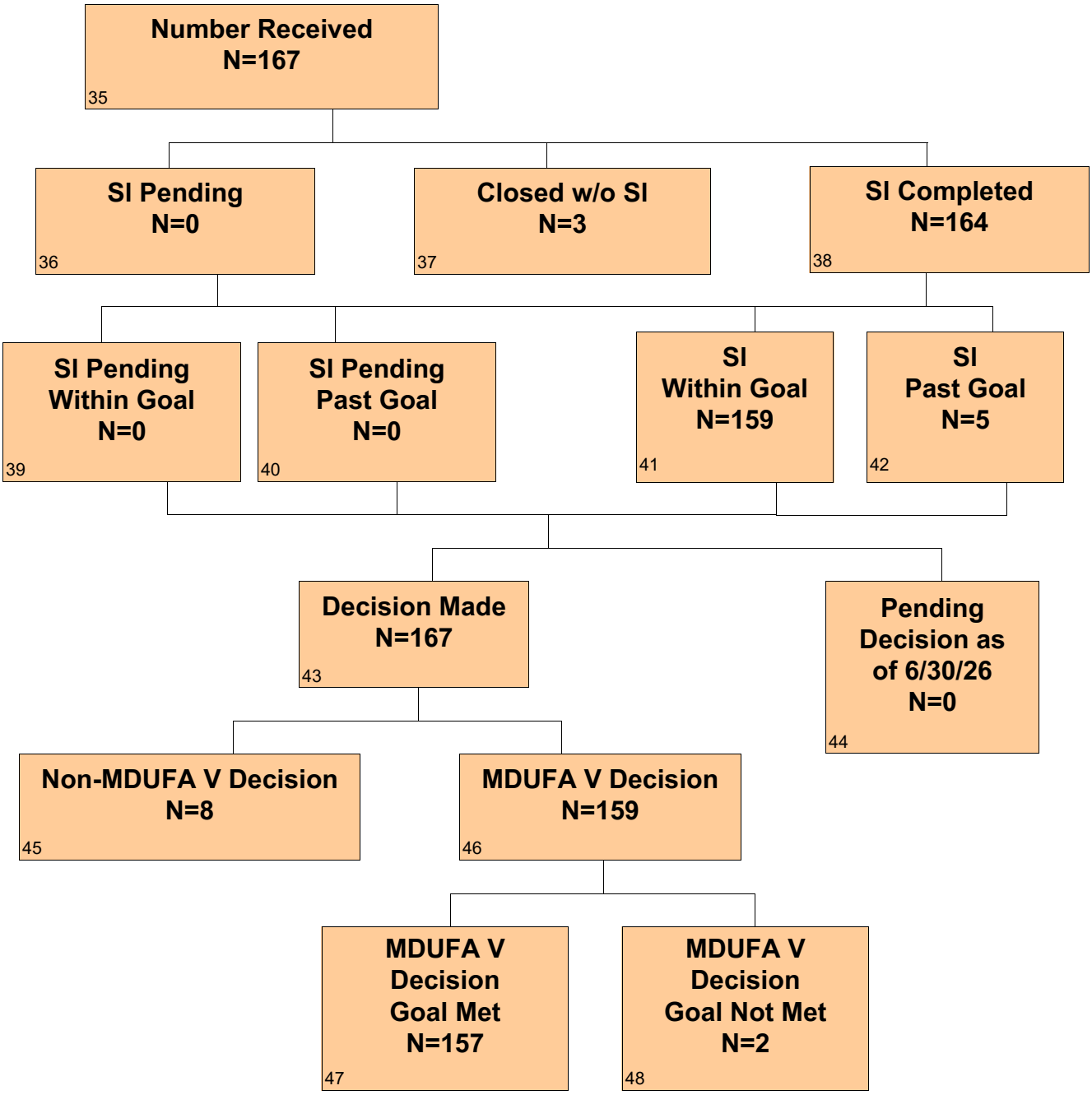
***Includes submission that went to panel**

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

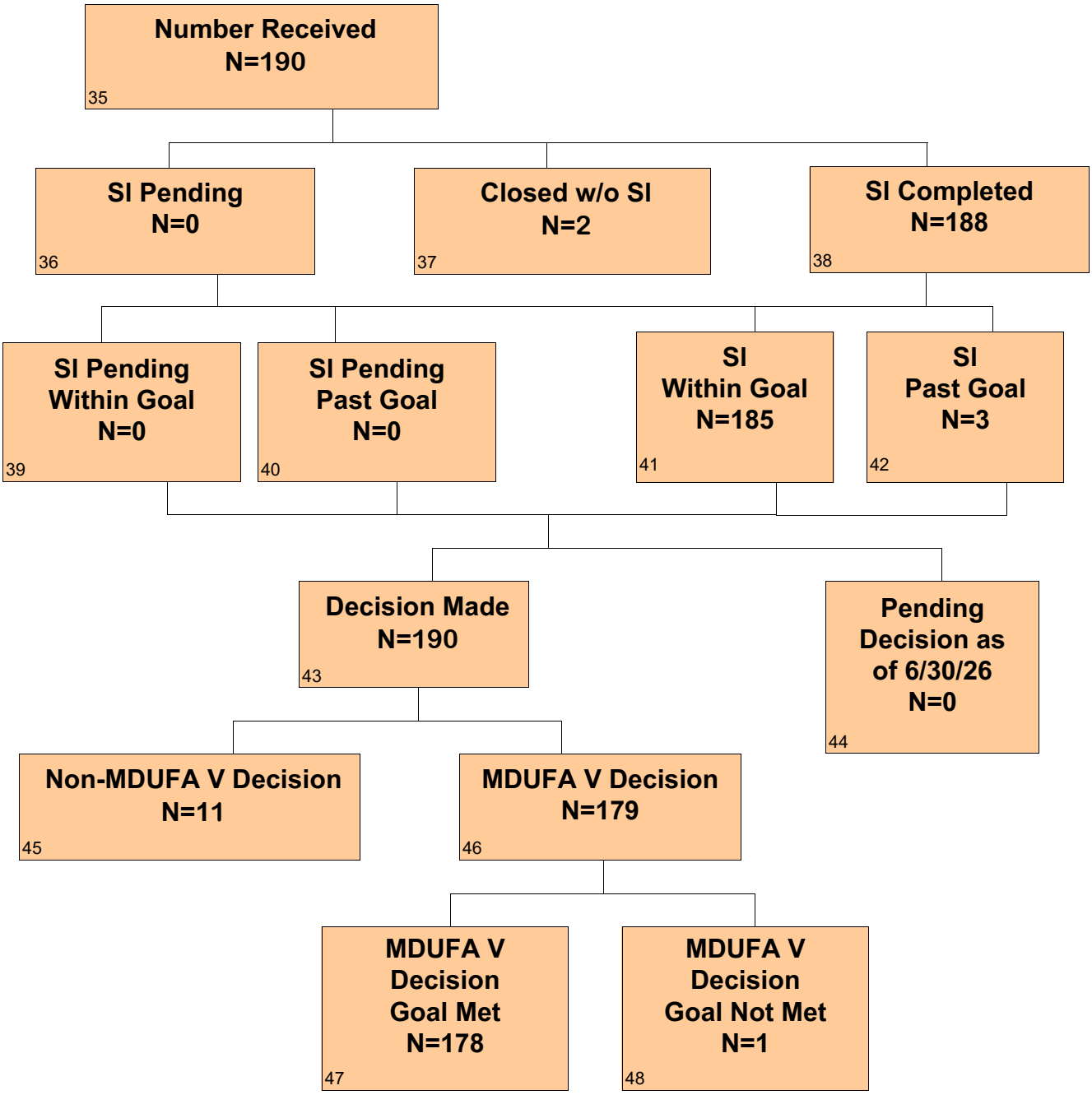
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal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

***Includes submission that went to panel**

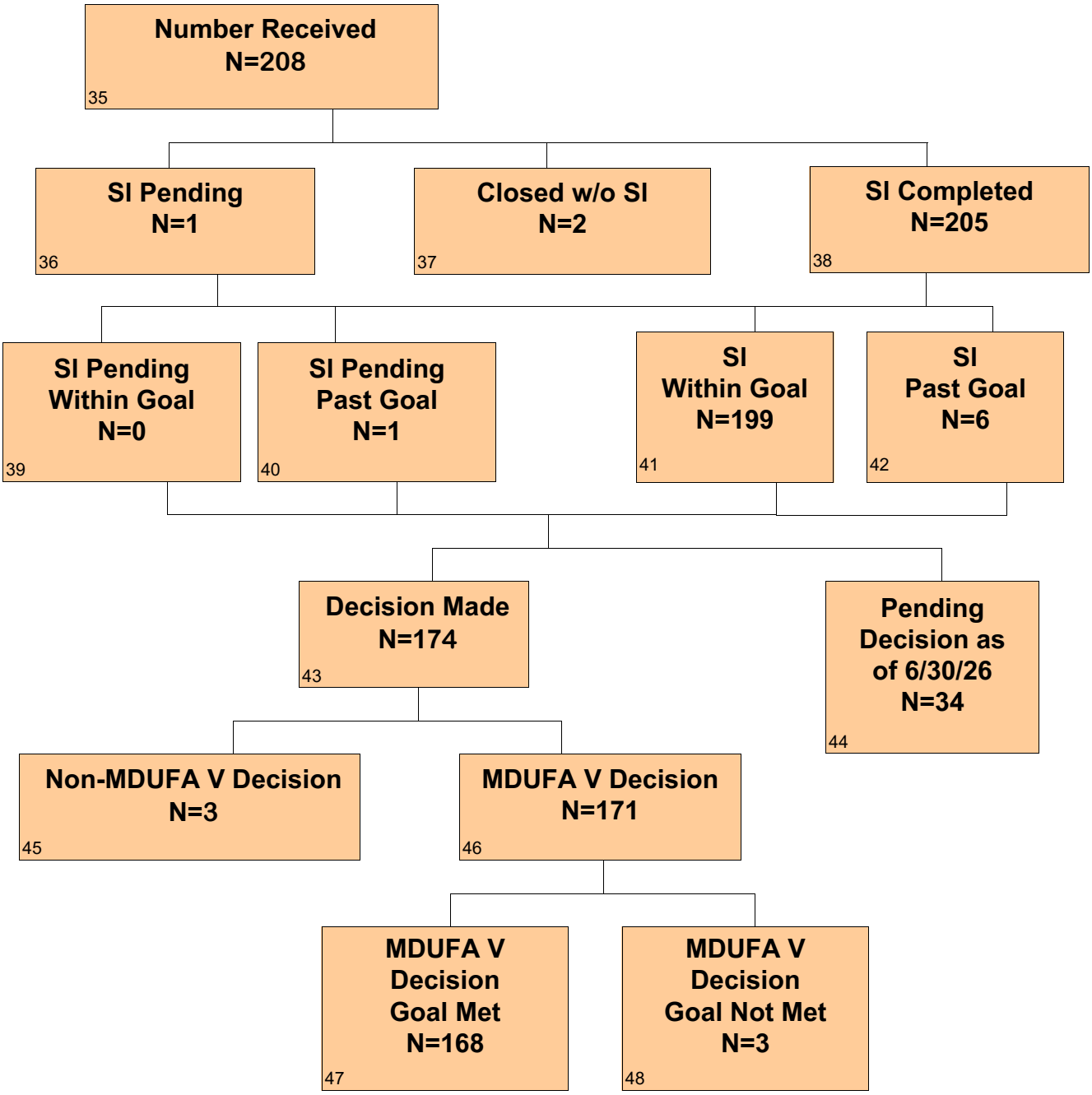
CDRH PMA 180 Day Supplements - FY 2023 as of 6/30/26



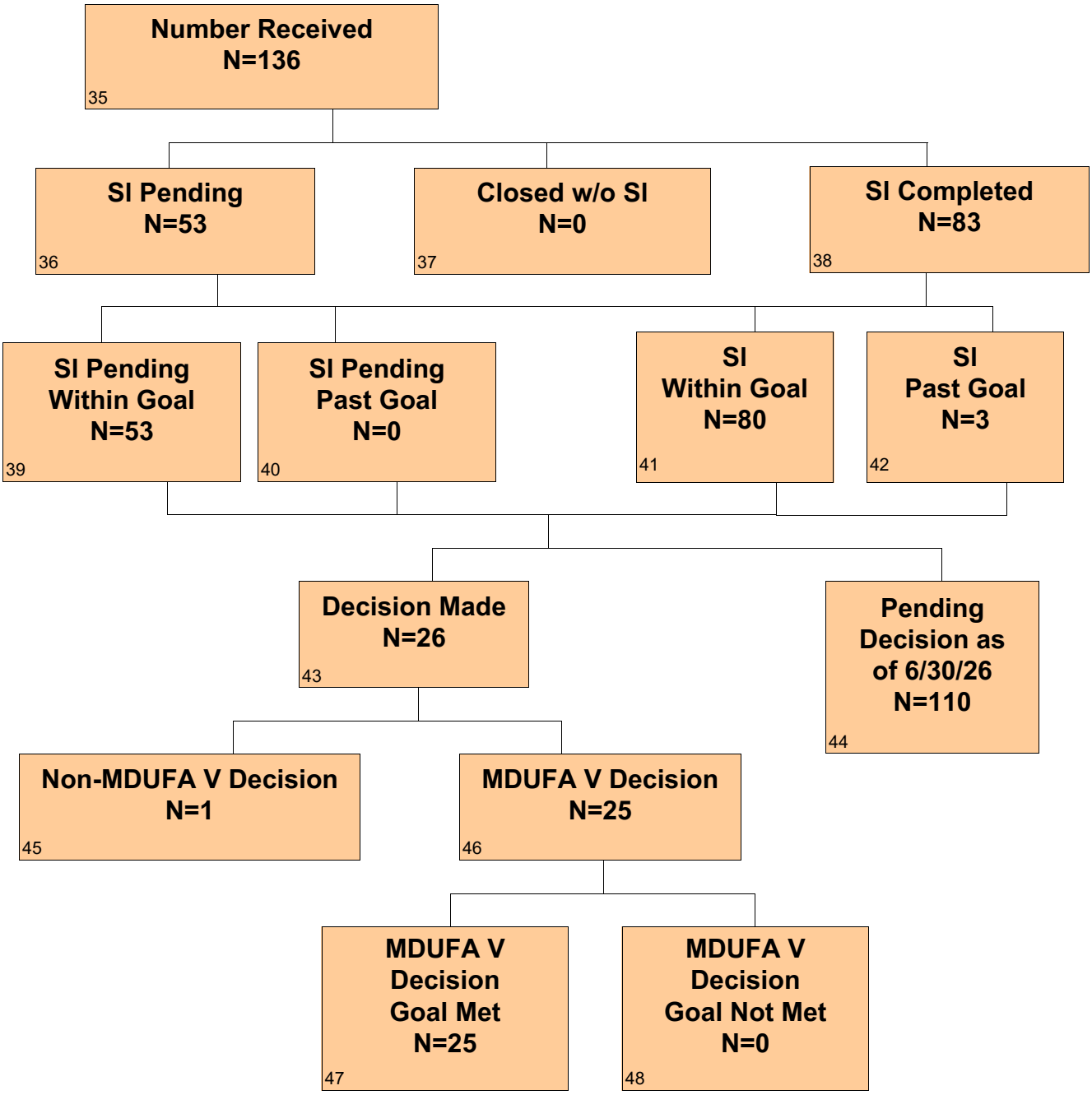
CDRH PMA 180 Day Supplements - FY 2024 as of 6/30/26



CDRH PMA 180 Day Supplements - FY 2025 as of 6/30/26



CDRH PMA 180 Day Supplements - FY 2026 as of 6/30/26



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	208	136	
SI Goal Met	159	185	199	80	
SI Goal Not Met	5	3	6	3	
SI Pending Within Goal	0	0	0	53	
SI Pending Past Goal	0	0	1	0	
Closed Without SI	3	2	2	0	
Current SI Performance Percent Goal Met	96.95%	98.40%	96.60%	96.39%	

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	208	136	
Non-MDUFA Decision	8	11	3	1	
MDUFA Decision	159	179	171	25	
MDUFA Decision Goal Met	157	178	168	25	
Supplements Pending MDUFA Decision	0	0	34	110	
Supplements Pending MDUFA Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	98.74%	99.44%	97.67%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	167	190	208	136	
Number with MDUFA Decision	159	179	171	25	
Number of Not Approvable	7	15	10	0	
Rate of Not Approvable	4.40%	8.38%	5.85%	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	3	0	
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	185.33	N/A	
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	58.67	N/A	

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	16	15	21	17	
SI Goal Met	16	15	11	11	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	6	6	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	21	17	
Non-MDUFA Decision	1	2	0	0	
MDUFA Decision	15	13	14	4	
MDUFA Decision Goal Met	15	13	14	4	
Supplements Pending MDUFA Decision	0	0	7	13	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	21	17	
Number with MDUFA Decision	15	13	14	4	
Number of Not Approvable	1	1	2	0	
Rate of Not Approvable	6.67%	7.69%	14.29%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	77	56	
SI Goal Met	55	80	71	38	
SI Goal Not Met	0	0	3	2	
SI Pending Within Goal	0	0	0	16	
SI Pending Past Goal	0	0	1	0	
Closed Without SI	1	1	2	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	94.67%	95.00%	

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	56	81	77	56	
Non-MDUFA Decision	3	6	2	0	
MDUFA Decision	53	75	67	14	
MDUFA Decision Goal Met	53	75	65	14	
Supplements Pending MDUFA Decision	0	0	8	42	
Supplements Pending MDUFA Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	100.00%	100.00%	95.59%	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	77	56	
Number with MDUFA Decision	53	75	67	14	
Number of Not Approvable	1	12	1	0	
Rate of Not Approvable	1.89%	16.00%	1.49%	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	2	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	187.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	88.00	N/A	

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	17	19	12	
SI Goal Met	20	17	18	7	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	95.24%	100.00%	94.74%	100.00%	

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	21	17	19	12	
Non-MDUFA Decision	0	0	0	1	
MDUFA Decision	21	17	17	2	
MDUFA Decision Goal Met	21	17	16	2	
Supplements Pending MDUFA Decision	0	0	2	9	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	94.12%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	17	19	12	
Number with MDUFA Decision	21	17	17	2	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	182.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	N/A	

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	12	13	6	
SI Goal Met	8	12	13	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	4	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	13	6	
Non-MDUFA Decision	0	1	0	0	
MDUFA Decision	8	11	8	0	
MDUFA Decision Goal Met	8	11	8	0	
Supplements Pending MDUFA Decision	0	0	5	6	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8	12	13	6	
Number with MDUFA Decision	8	11	8	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	31	19	
SI Goal Met	20	17	30	6	
SI Goal Not Met	3	3	1	0	
SI Pending Within Goal	0	0	0	13	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	86.96%	85.00%	96.77%	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	31	19	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	23	20	27	1	
MDUFA Decision Goal Met	21	19	27	1	
Supplements Pending MDUFA Decision	0	0	3	18	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	91.30%	95.00%	100.00%	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	31	19	
Number with MDUFA Decision	23	20	27	1	
Number of Not Approvable	3	1	5	0	
Rate of Not Approvable	13.04%	5.00%	18.52%	0.00%	

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	6	5	11	5	
SI Goal Met	6	5	11	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	3	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	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	11	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	8	2	
MDUFA Decision Goal Met	6	5	8	2	
Supplements Pending MDUFA Decision	0	0	3	3	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	11	5	
Number with MDUFA Decision	6	5	8	2	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	35	19	
SI Goal Met	33	37	34	13	
SI Goal Not Met	1	0	1	1	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	2	1	0	0	
Current SI Performance Percent Goal Met	97.06%	100.00%	97.14%	92.86%	

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	35	19	
Non-MDUFA Decision	4	2	0	0	
MDUFA Decision	32	36	29	2	
MDUFA Decision Goal Met	32	36	29	2	
Supplements Pending MDUFA Decision	0	0	6	17	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	35	19	
Number with MDUFA Decision	32	36	29	2	
Number of Not Approvable	2	1	2	0	
Rate of Not Approvable	6.25%	2.78%	6.90%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	2	
SI Goal Met	1	2	1	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

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

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

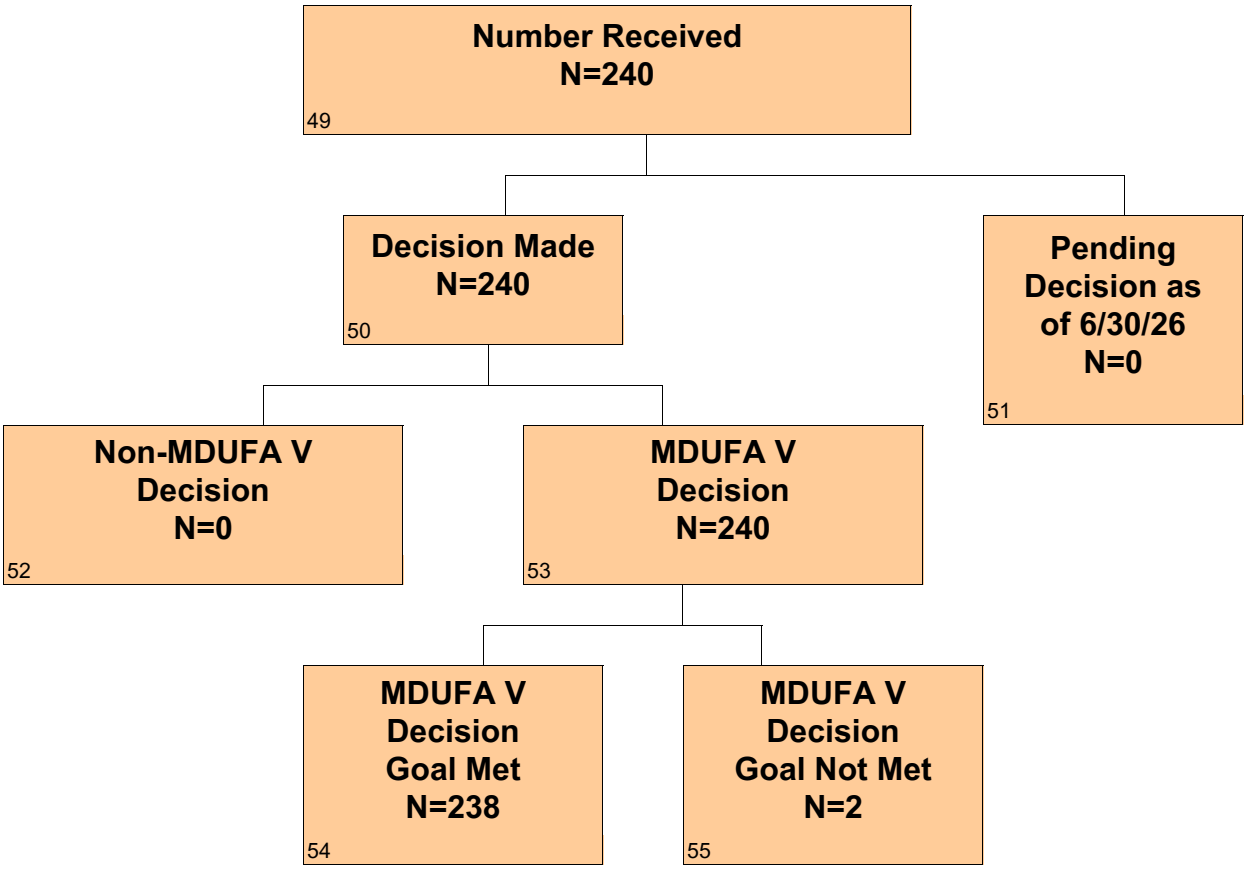
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

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

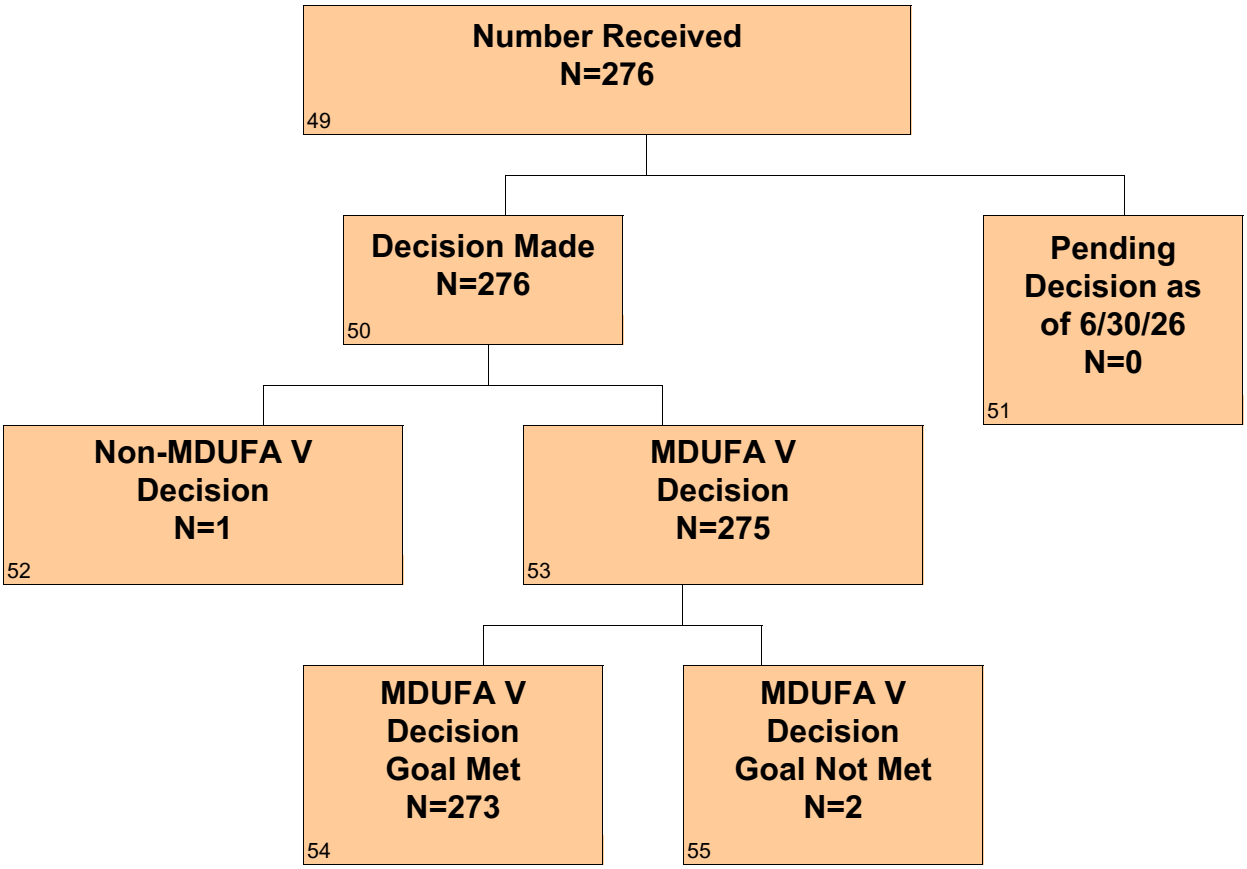
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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

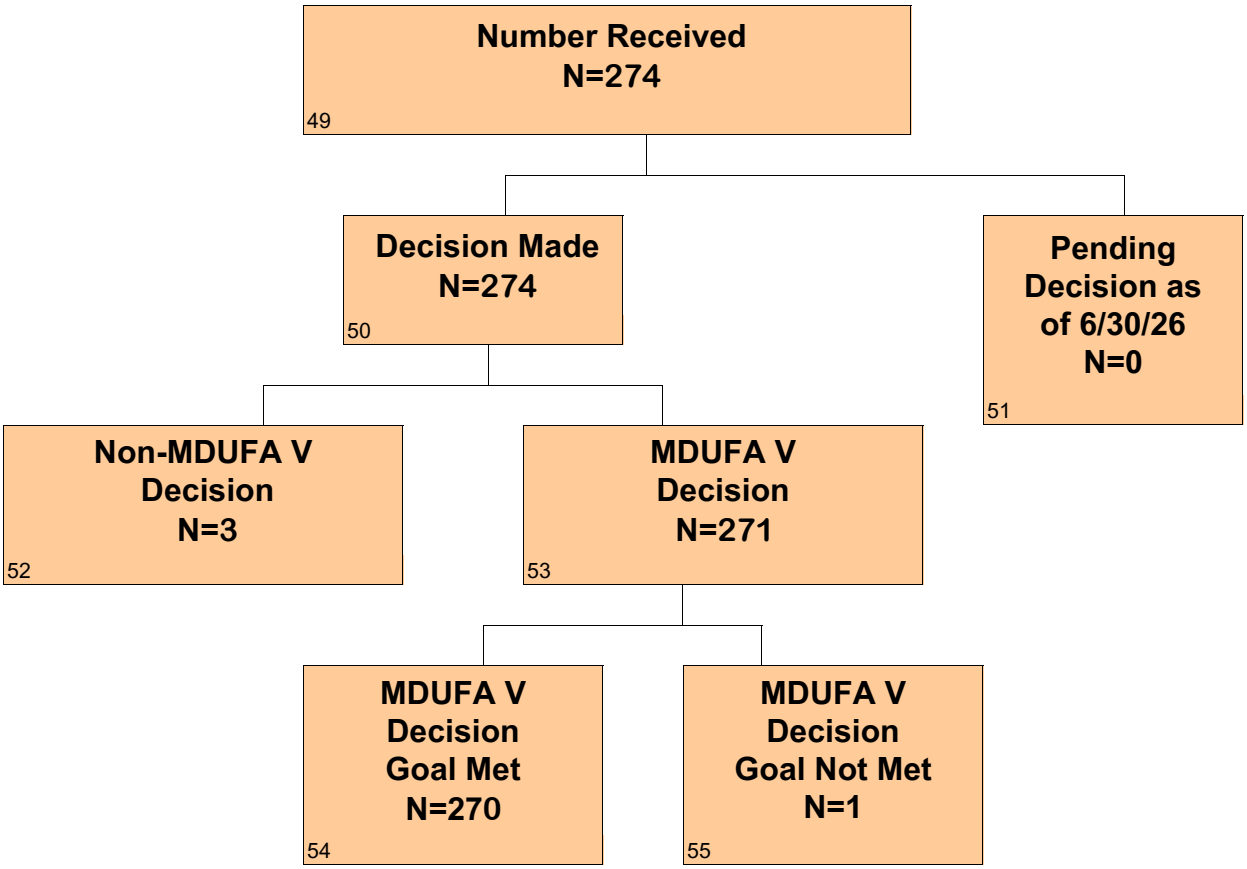
CDRH PMA Real Time Supplements - FY 2023 as of 6/30/26



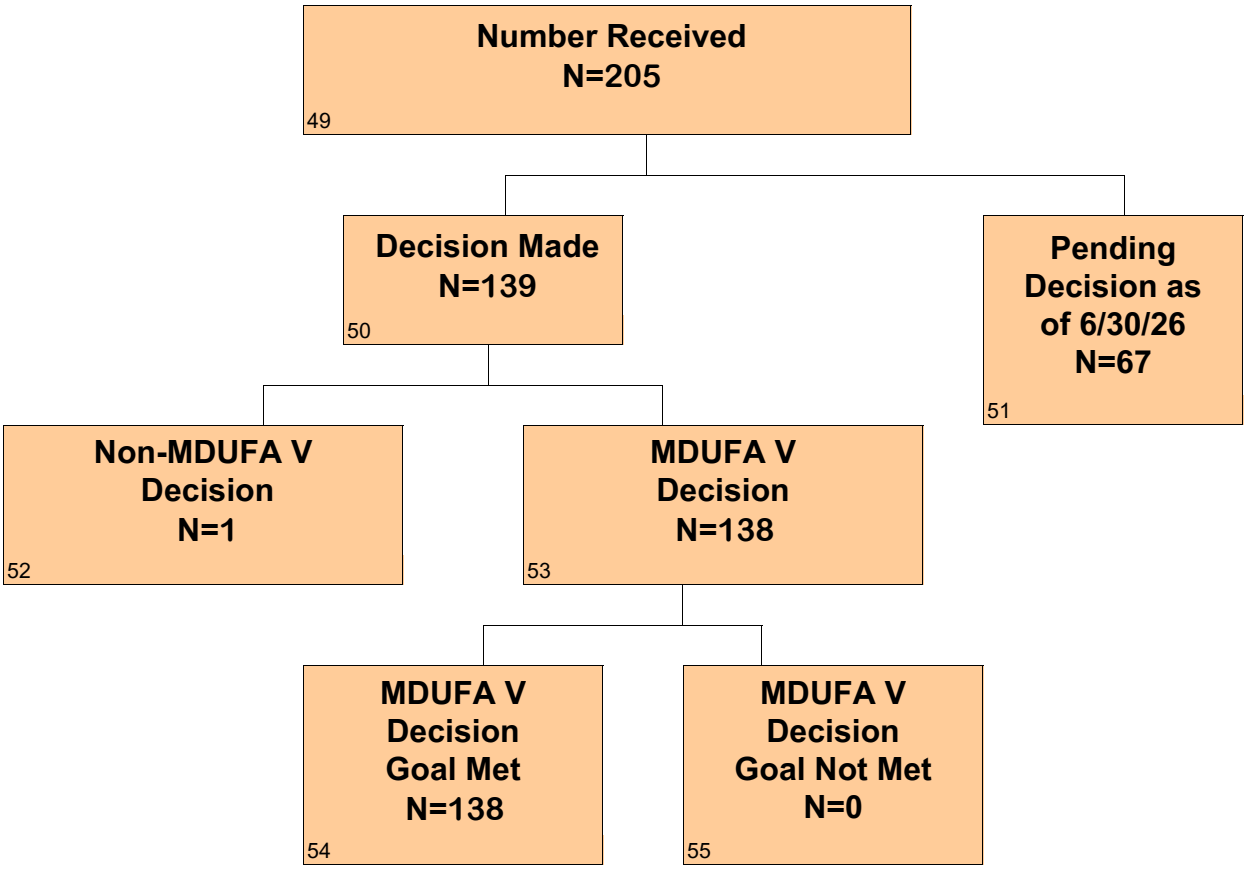
CDRH PMA Real Time Supplements - FY 2024 as of 6/30/26



CDRH PMA Real Time Supplements - FY 2025 as of 6/30/26



CDRH PMA Real Time Supplements - FY 2026 as of 6/30/26



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	274	205	
Non-MDUFA Decision	0	1	3	1	
MDUFA Decision	240	275	271	138	
MDUFA Decision Goal Met	238	273	270	138	
Supplements Pending MDUFA Decision	0	0	0	66	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	99.17%	99.27%	99.63%	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	274	205	
Number With MDUFA Decision	240	275	271	138	
Number of Not Approvable	11	10	20	12	
Rate of Not Approvable	4.58%	3.64%	7.38%	8.70%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	2	1	0	
Mean FDA Days for Submissions that Missed the Goal	109.50	119.50	102.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	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	27	16	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	24	19	26	11	
MDUFA Decision Goal Met	24	19	26	11	
Supplements Pending MDUFA Decision	0	0	0	5	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	27	16	
Number With MDUFA Decision	24	19	26	11	
Number of Not Approvable	3	2	1	1	
Rate of Not Approvable	12.50%	10.53%	3.85%	9.09%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	125	117	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	136	142	124	79	
MDUFA Decision Goal Met	136	142	123	79	
Supplements Pending MDUFA Decision	0	0	0	38	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	99.19%	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	125	117	
Number With MDUFA Decision	136	142	124	79	
Number of Not Approvable	4	1	12	5	
Rate of Not Approvable	2.94%	0.70%	9.68%	6.33%	

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	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	102.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	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	17	15	
Non-MDUFA Decision	0	1	0	0	
MDUFA Decision	19	22	17	9	
MDUFA Decision Goal Met	18	21	17	9	
Supplements Pending MDUFA Decision	0	0	0	6	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	94.74%	95.45%	100.00%	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	17	15	
Number With MDUFA Decision	19	22	17	9	
Number of Not Approvable	2	4	2	2	
Rate of Not Approvable	10.53%	18.18%	11.76%	22.22%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	92.00	91.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A	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	10	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	7	10	10	3	
MDUFA Decision Goal Met	7	10	10	3	
Supplements Pending MDUFA Decision	0	0	0	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	10	5	
Number With MDUFA Decision	7	10	10	3	
Number of Not Approvable	2	1	3	0	
Rate of Not Approvable	28.57%	10.00%	30.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	50	25	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	16	37	50	15	
MDUFA Decision Goal Met	15	36	50	15	
Supplements Pending MDUFA Decision	0	0	0	10	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	93.75%	97.30%	100.00%	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	50	25	
Number With MDUFA Decision	16	37	50	15	
Number of Not Approvable	0	1	2	1	
Rate of Not Approvable	0.00%	2.70%	4.00%	6.67%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A	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	4	
Non-MDUFA Decision	0	0	0	1	
MDUFA Decision	4	11	0	2	
MDUFA Decision Goal Met	4	11	0	2	
Supplements Pending MDUFA Decision	0	0	0	1	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	11	0	4	
Number With MDUFA Decision	4	11	0	2	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	N/A	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	45	23	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	32	33	44	19	
MDUFA Decision Goal Met	32	33	44	19	
Supplements Pending MDUFA Decision	0	0	0	4	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	45	23	
Number With MDUFA Decision	32	33	44	19	
Number of Not Approvable	0	1	0	3	
Rate of Not Approvable	0.00%	3.03%	0.00%	15.79%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	2	1	0	0	
MDUFA Decision Goal Met	2	1	0	0	
Supplements Pending MDUFA Decision	0	0	0	0	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	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	0	
Number With MDUFA Decision	2	1	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between April 1, 2026 and June 30, 2026.

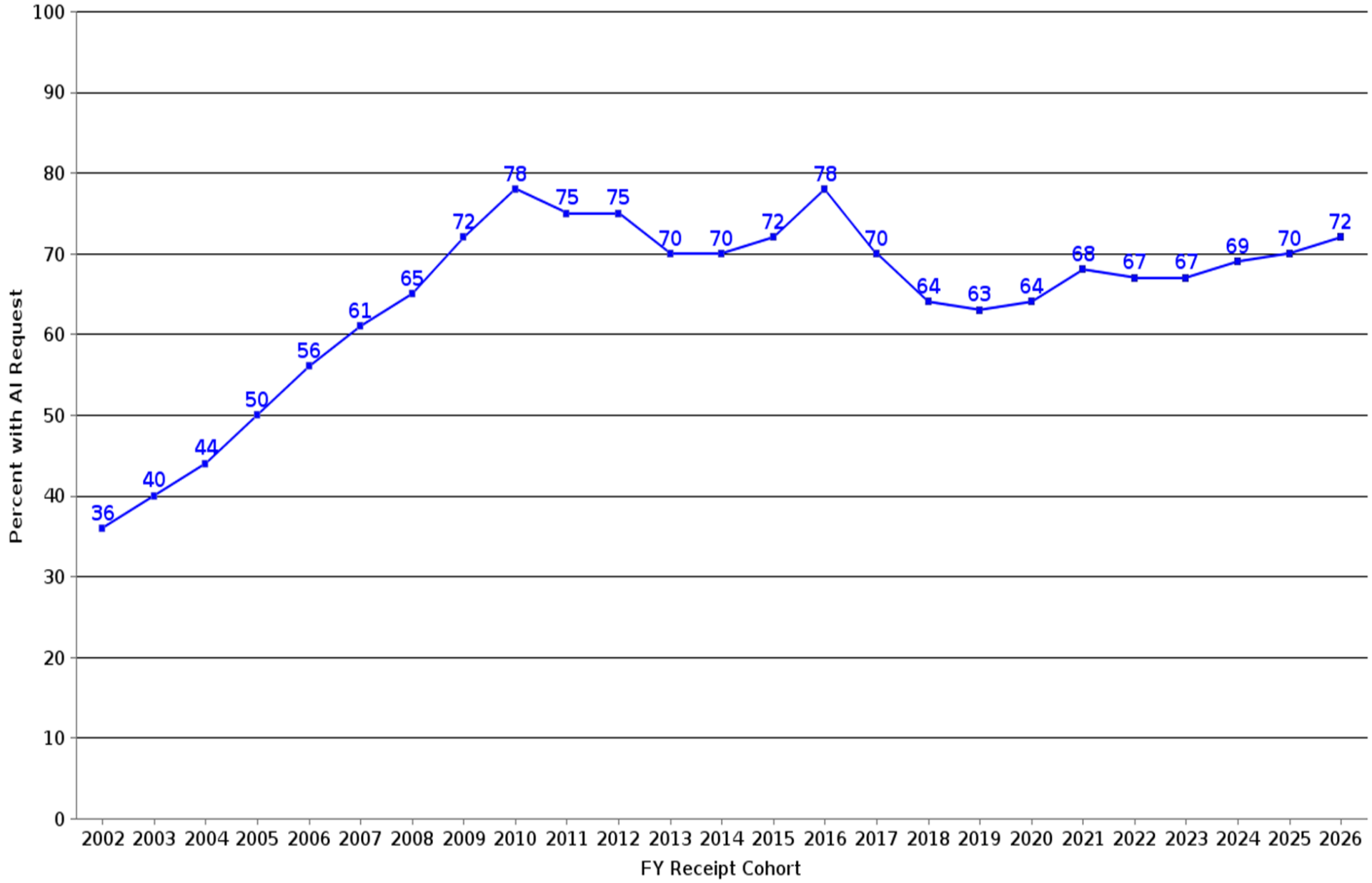
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q3FY2026

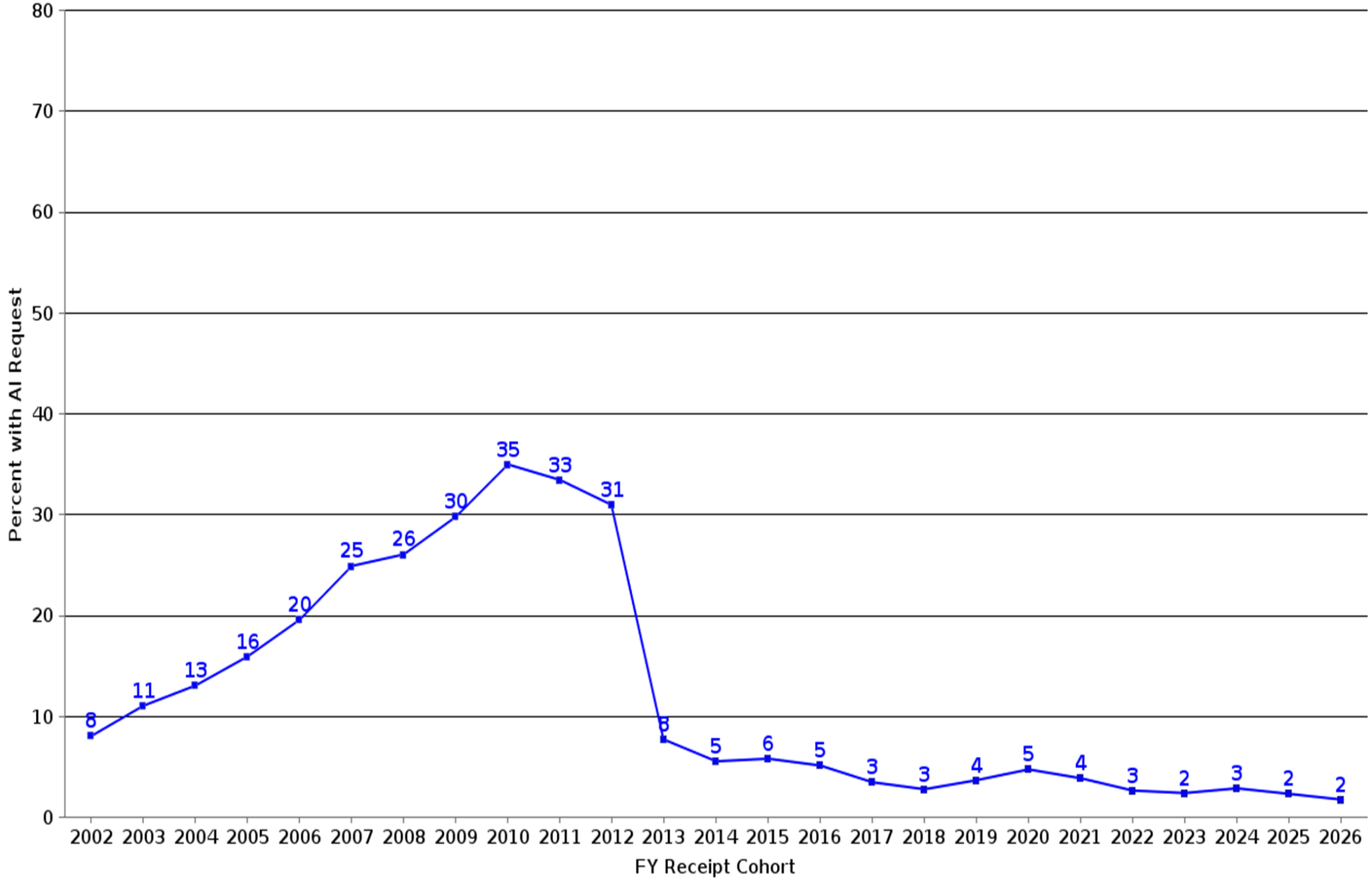
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 4/30/26

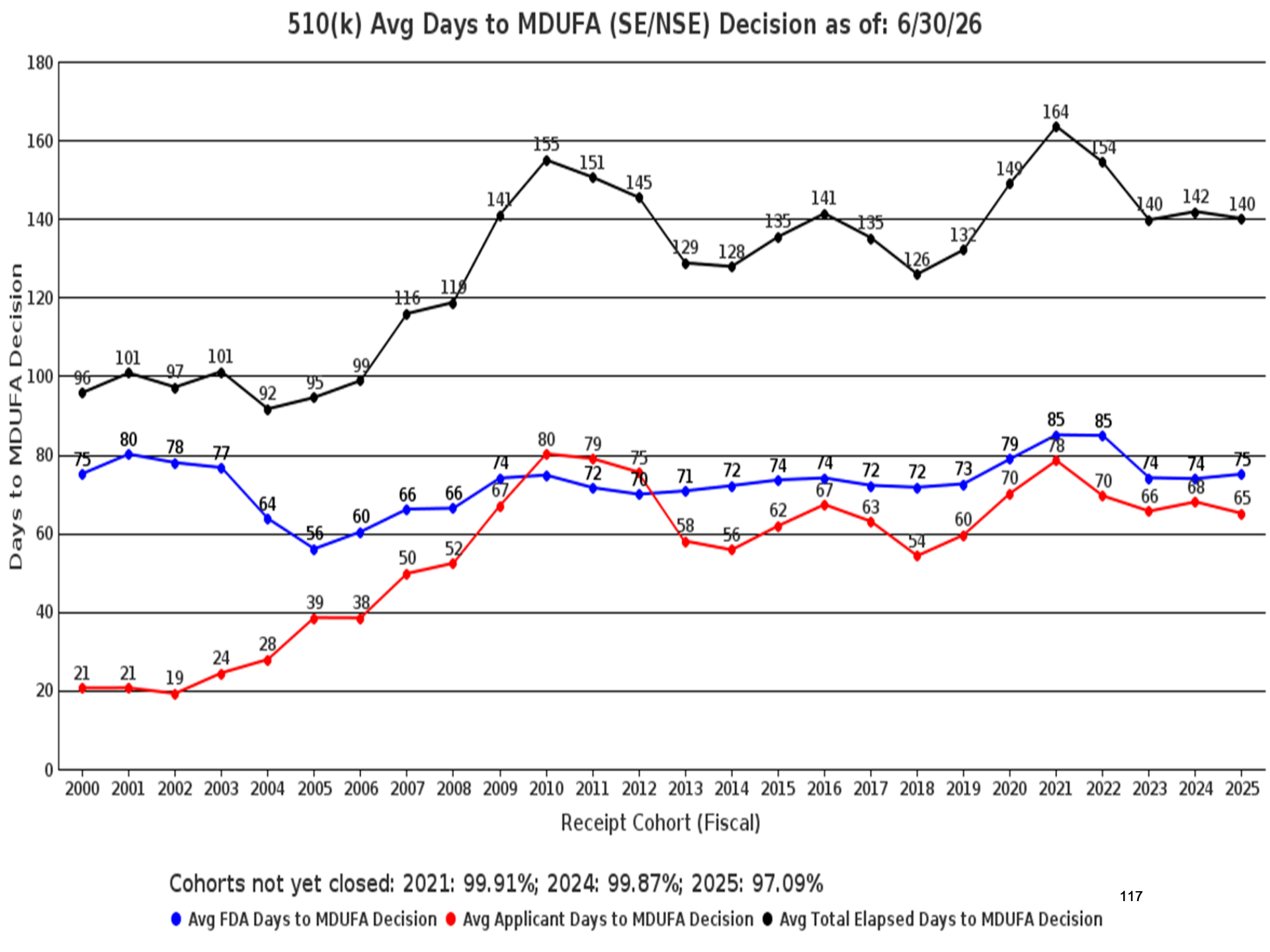
■ % with 1st Cycle AI Request

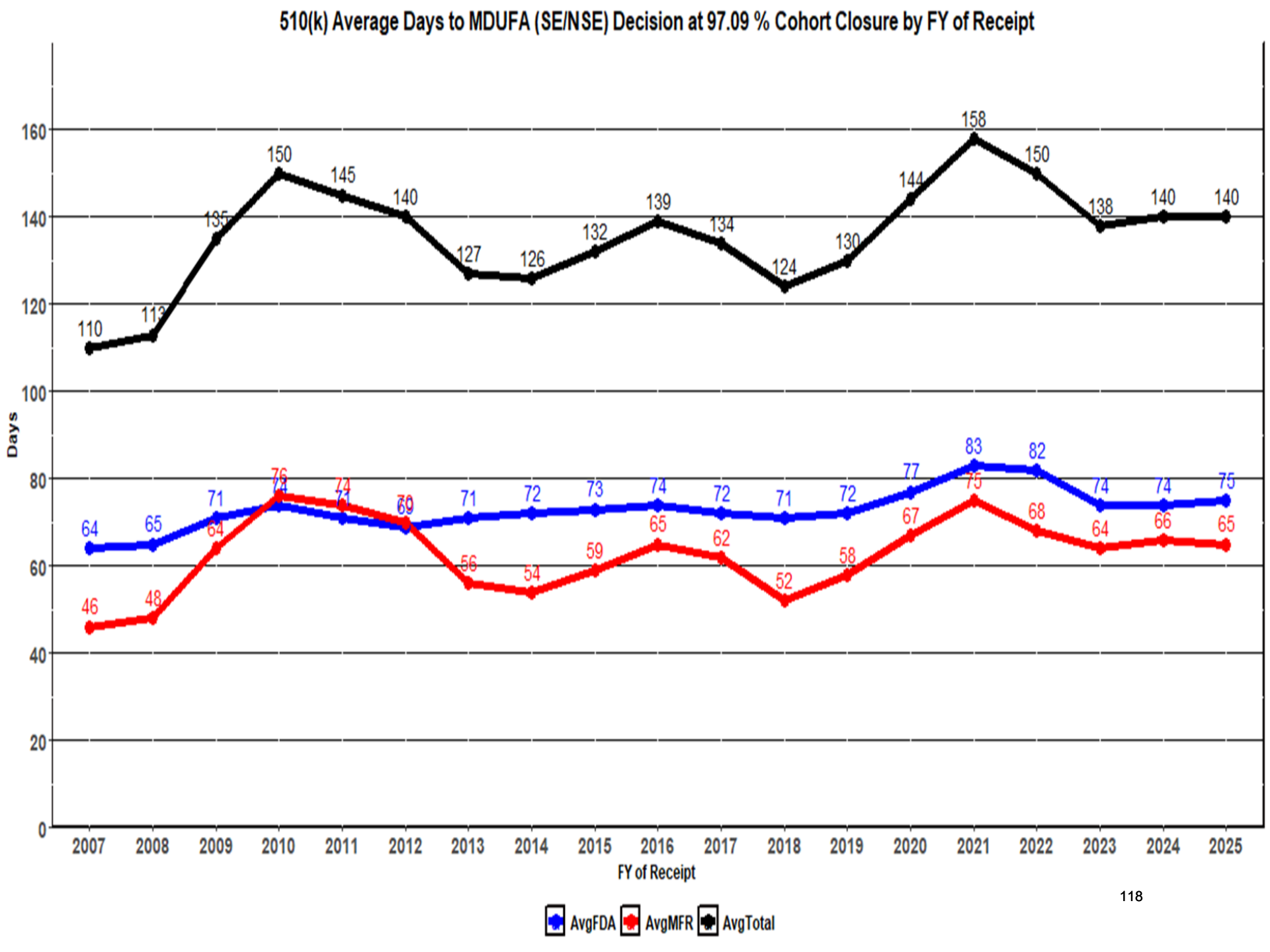
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 11/30/25

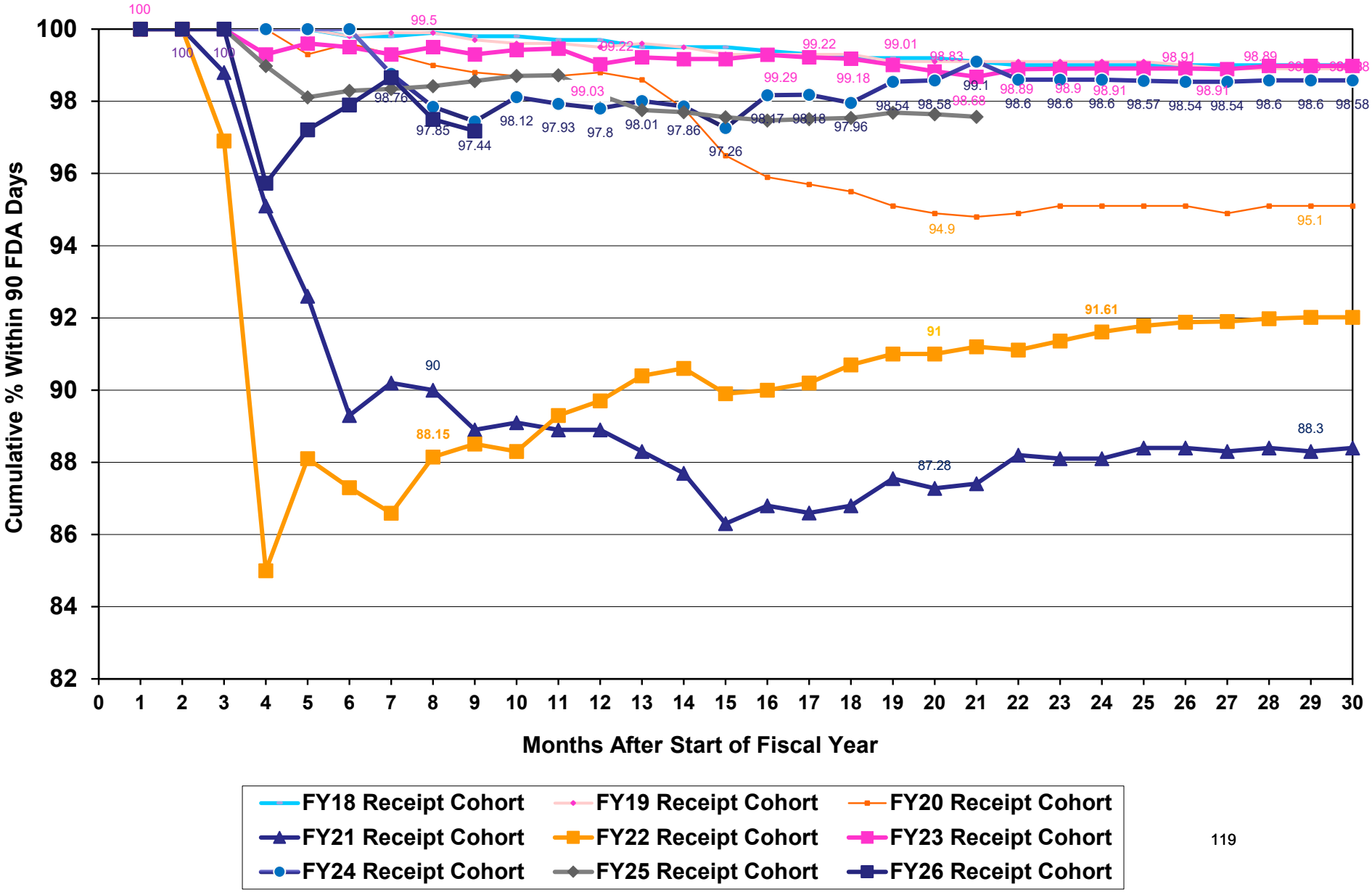
■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 6/30/26
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2021: 99.91%; 2024: 99.87%; 2025: 97.09%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision

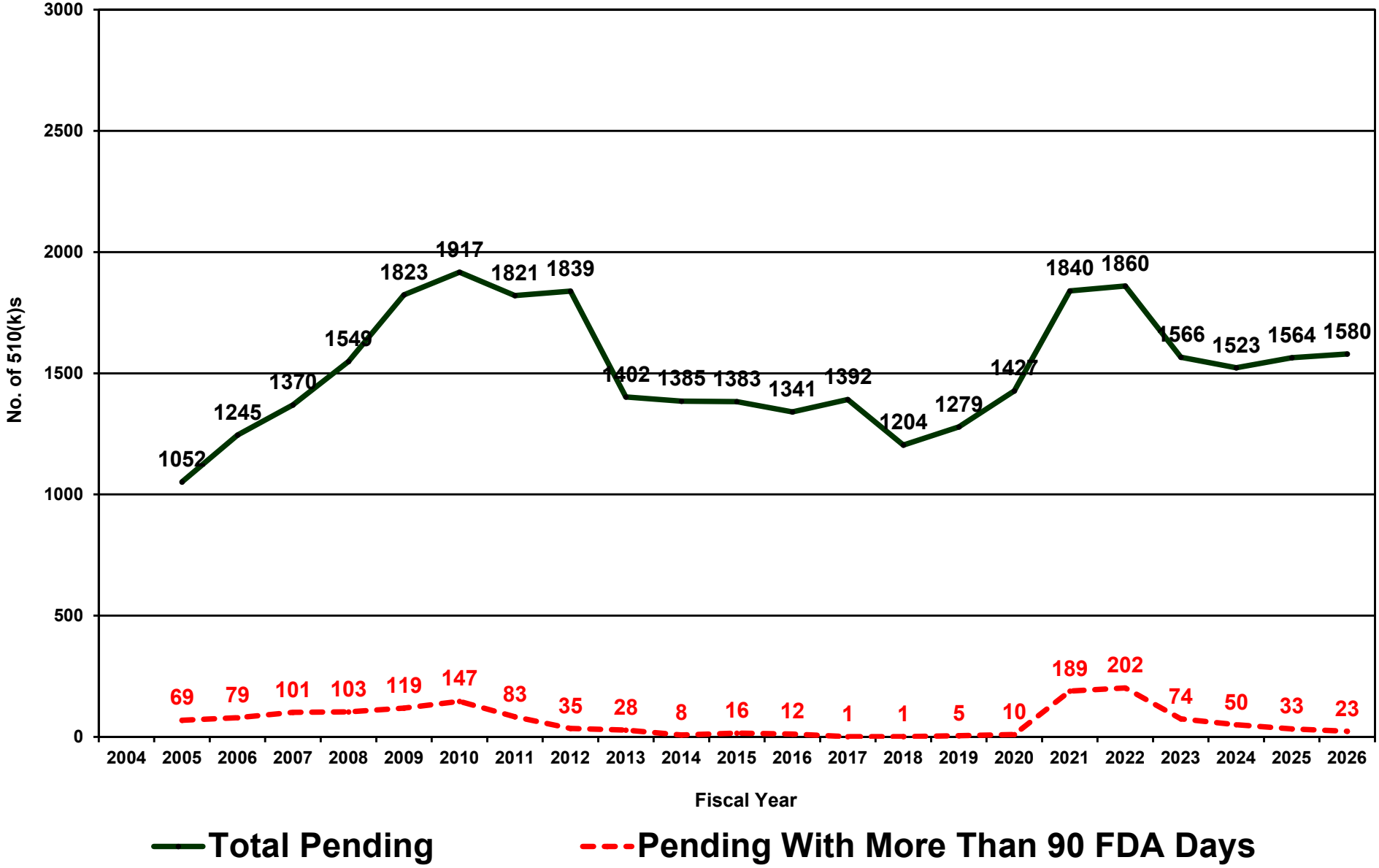

510(k) Average Days to MDUFA (SE/NSE) Decision at 97.09 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
0 20 40 60 80 100 120 140 160
110 113 135 150 145 140 127 126 132 139 134 124 130 144 158 150 138 140 140
64 65 71 74 71 69 71 72 73 74 72 71 72 77 83 82 74 74 75
46 48 64 76 74 70 56 54 59 65 62 52 58 67 75 68 64 66 65
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

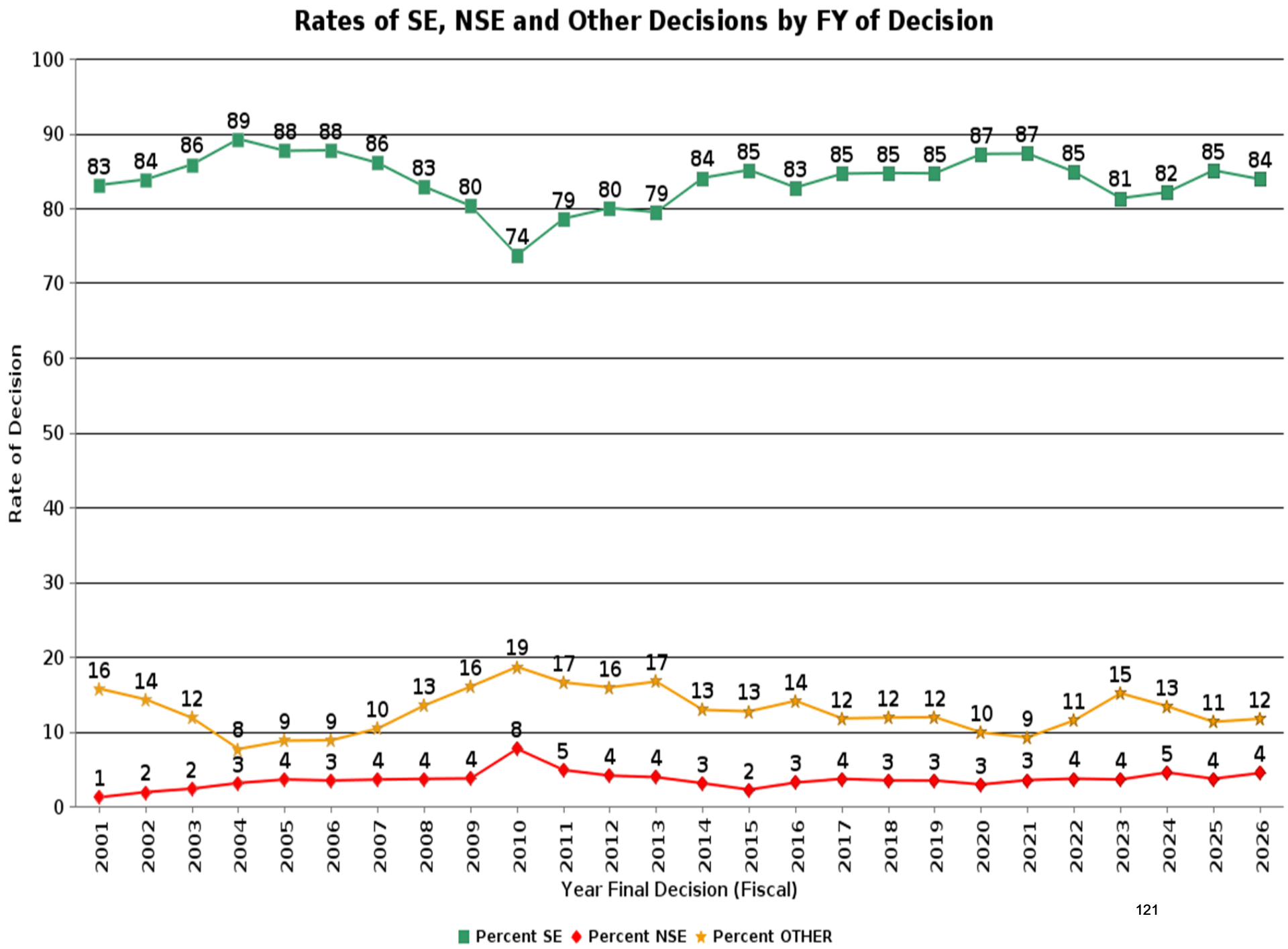
Comparison of FY18 – FY26 Receipt Cohorts



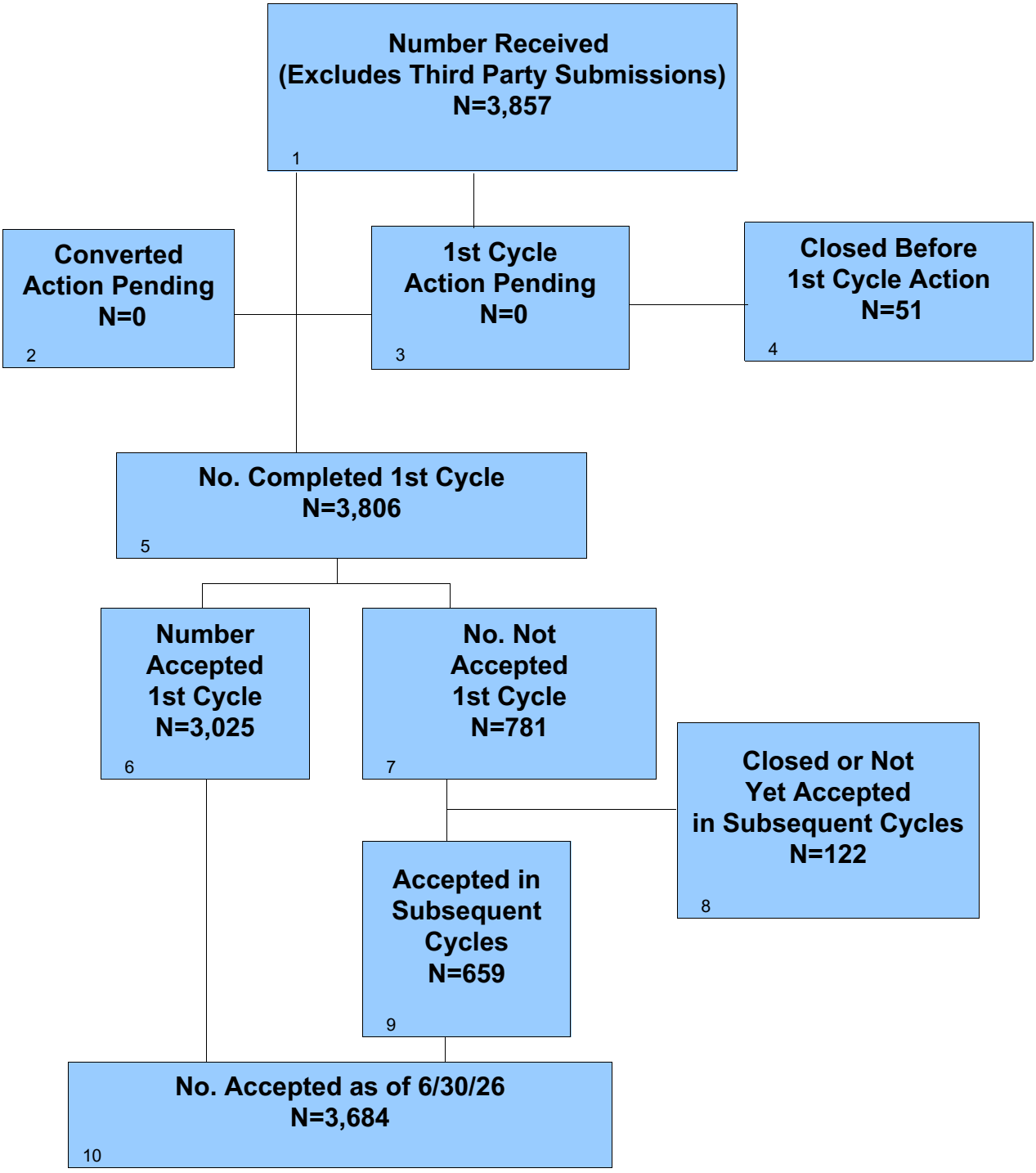
510(k)s Pending at End of Quarter/Year



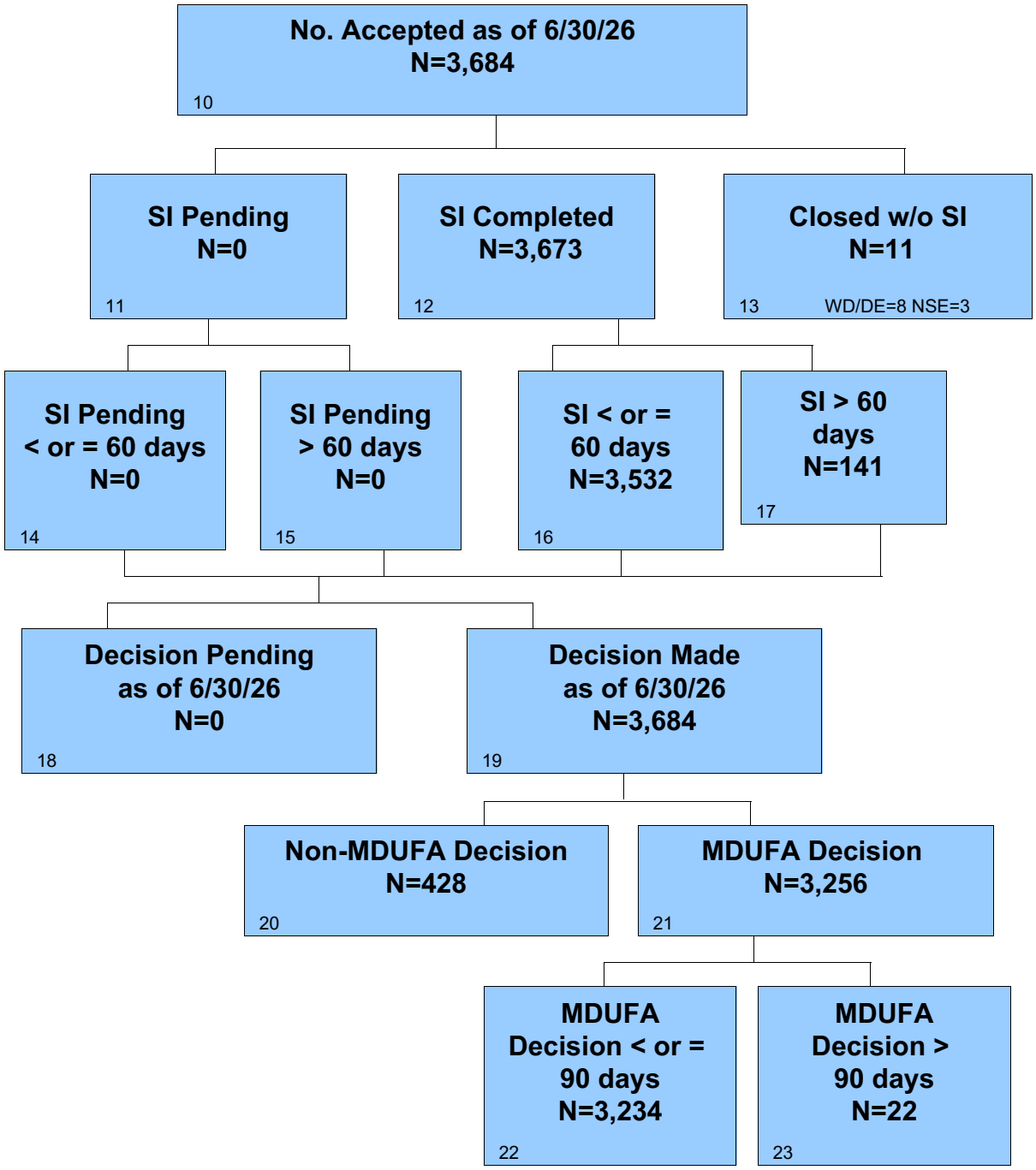
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


Rates of SE, NSE and Other Decisions by FY of Decision
Rate of Decision
100
90
80
70
60
50
40
30
20
10
0
83 84 86 89 88 88 86 83 80 74 79 80 79 84 85 83 85 85 85 87 87 85 81 82 85 84
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15 13 11 12
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4 4 4 5 4 4
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

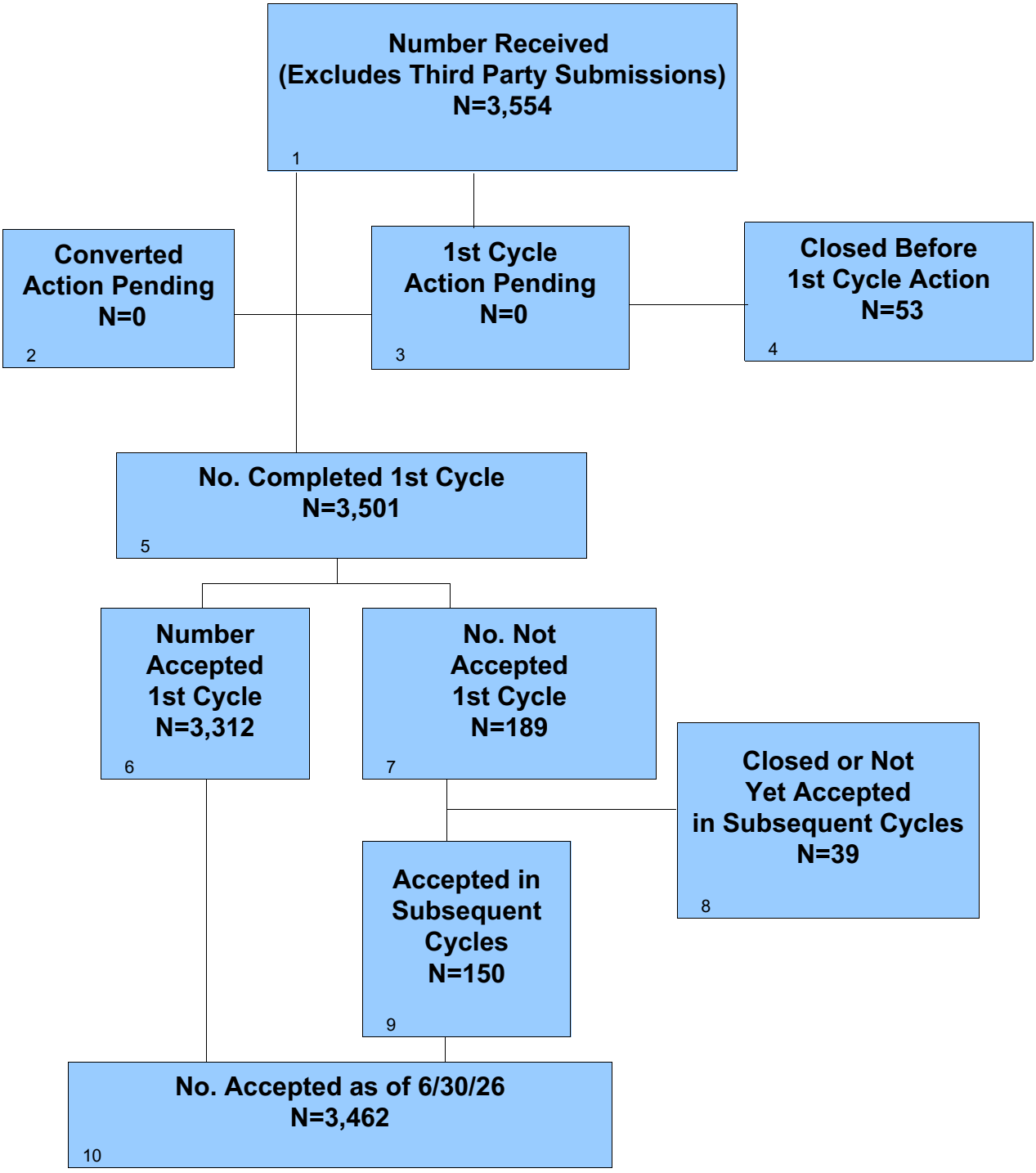
CDRH 510(k)s - FY 2023
as of 6/30/26



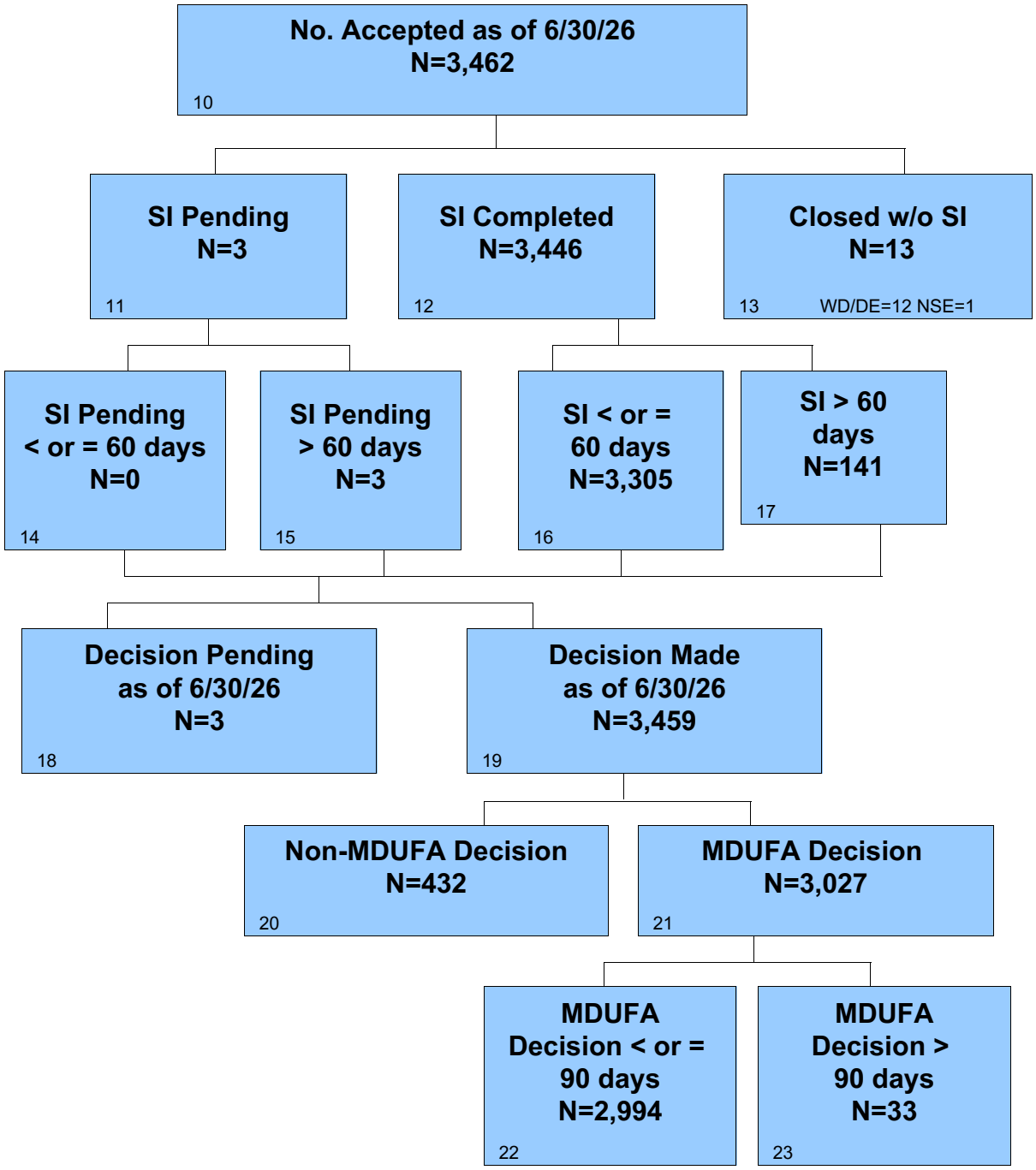
CDRH 510(k)s - FY 2023
as of 6/30/26 Continued



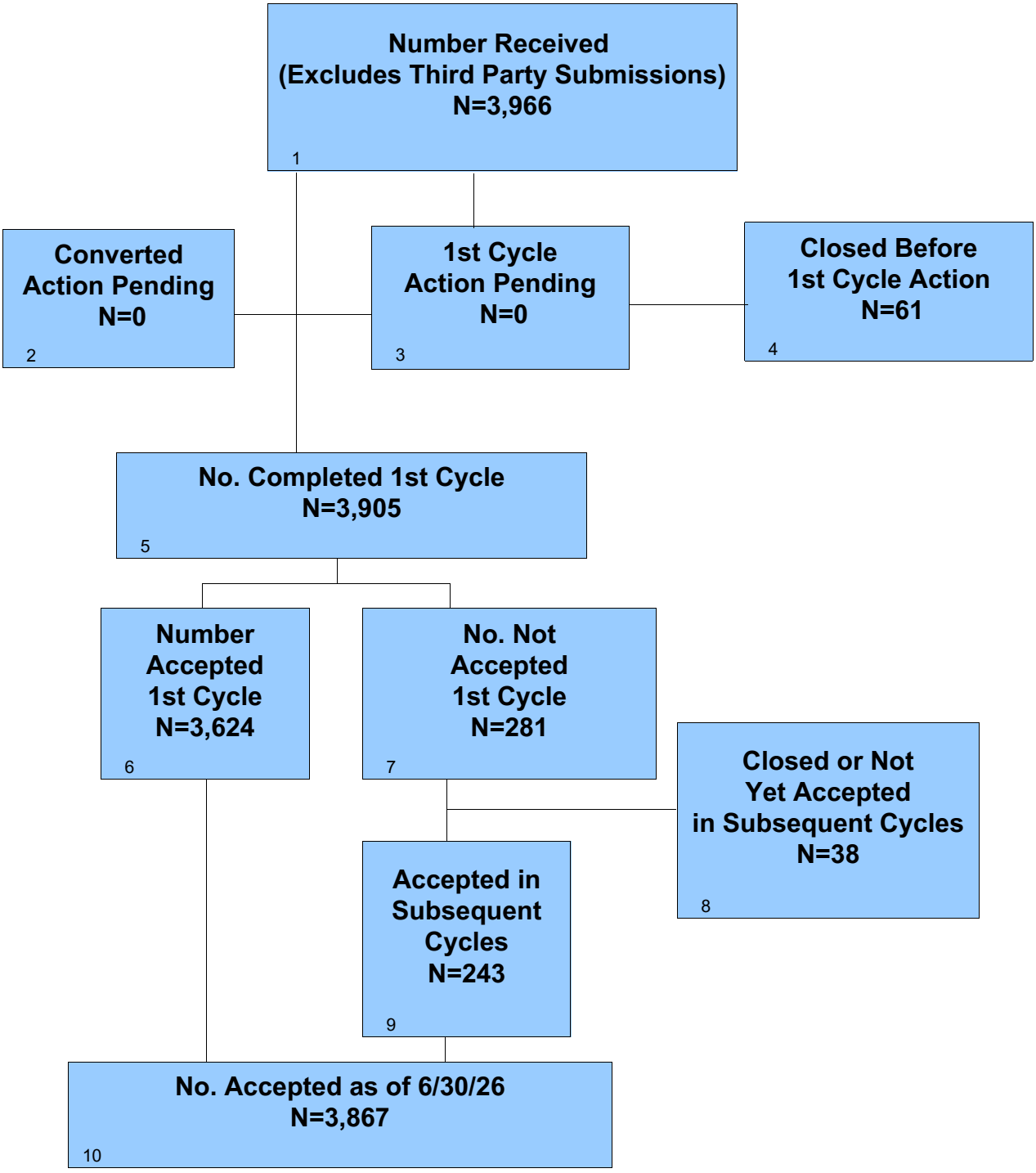
CDRH 510(k)s - FY 2024
as of 6/30/26



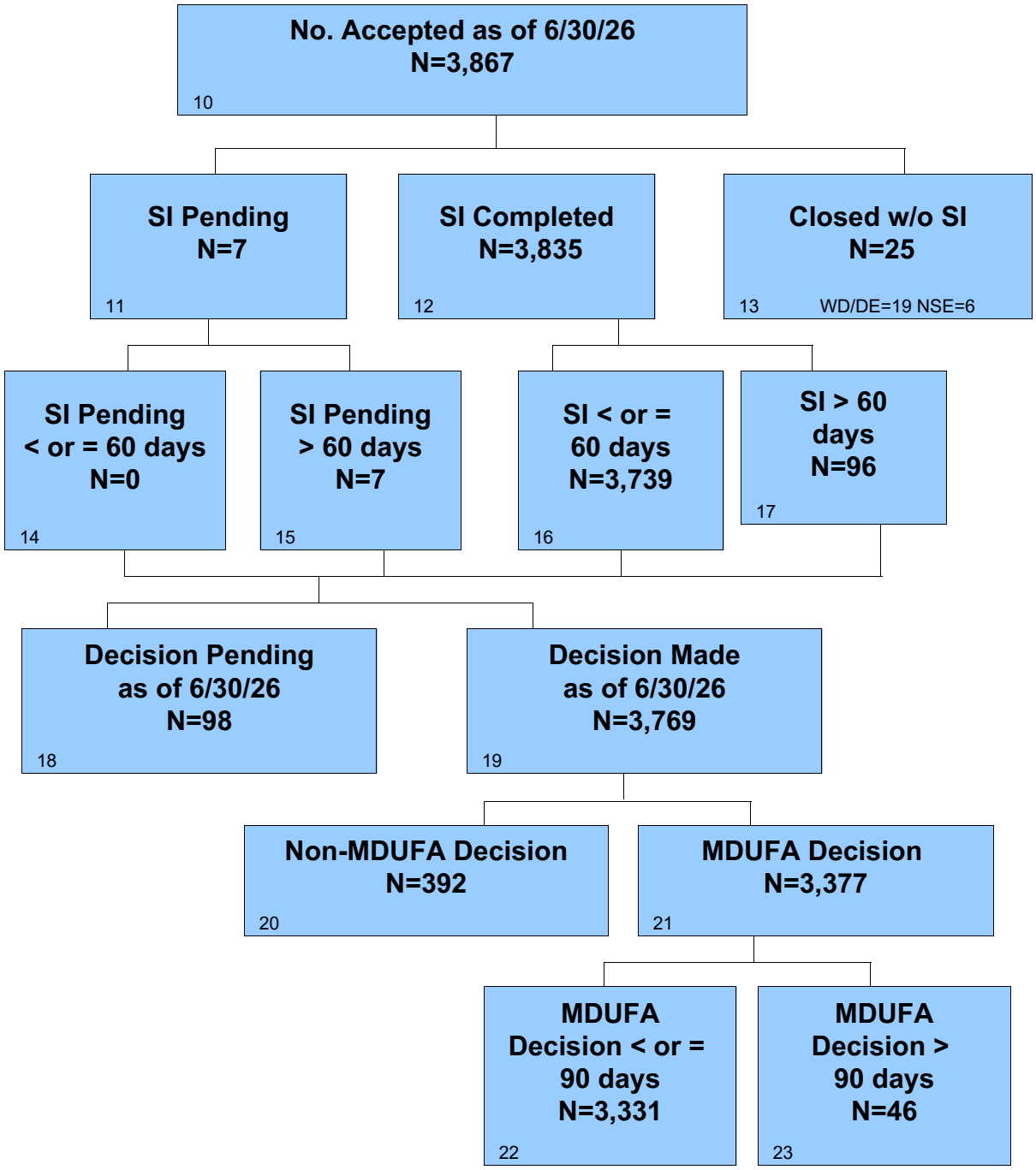
CDRH 510(k)s - FY 2024
as of 6/30/26 Continued



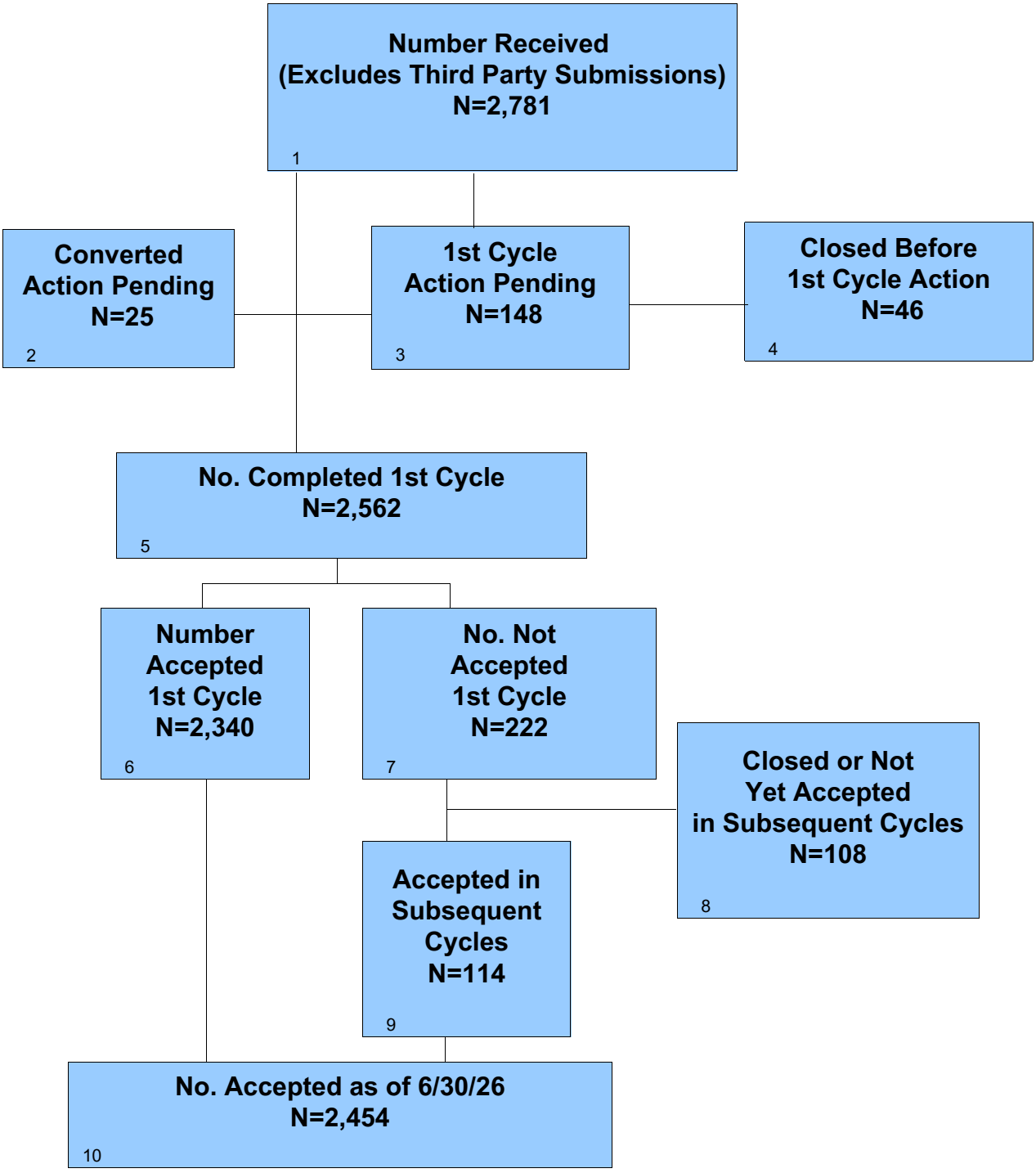
CDRH 510(k)s - FY 2025
as of 6/30/26



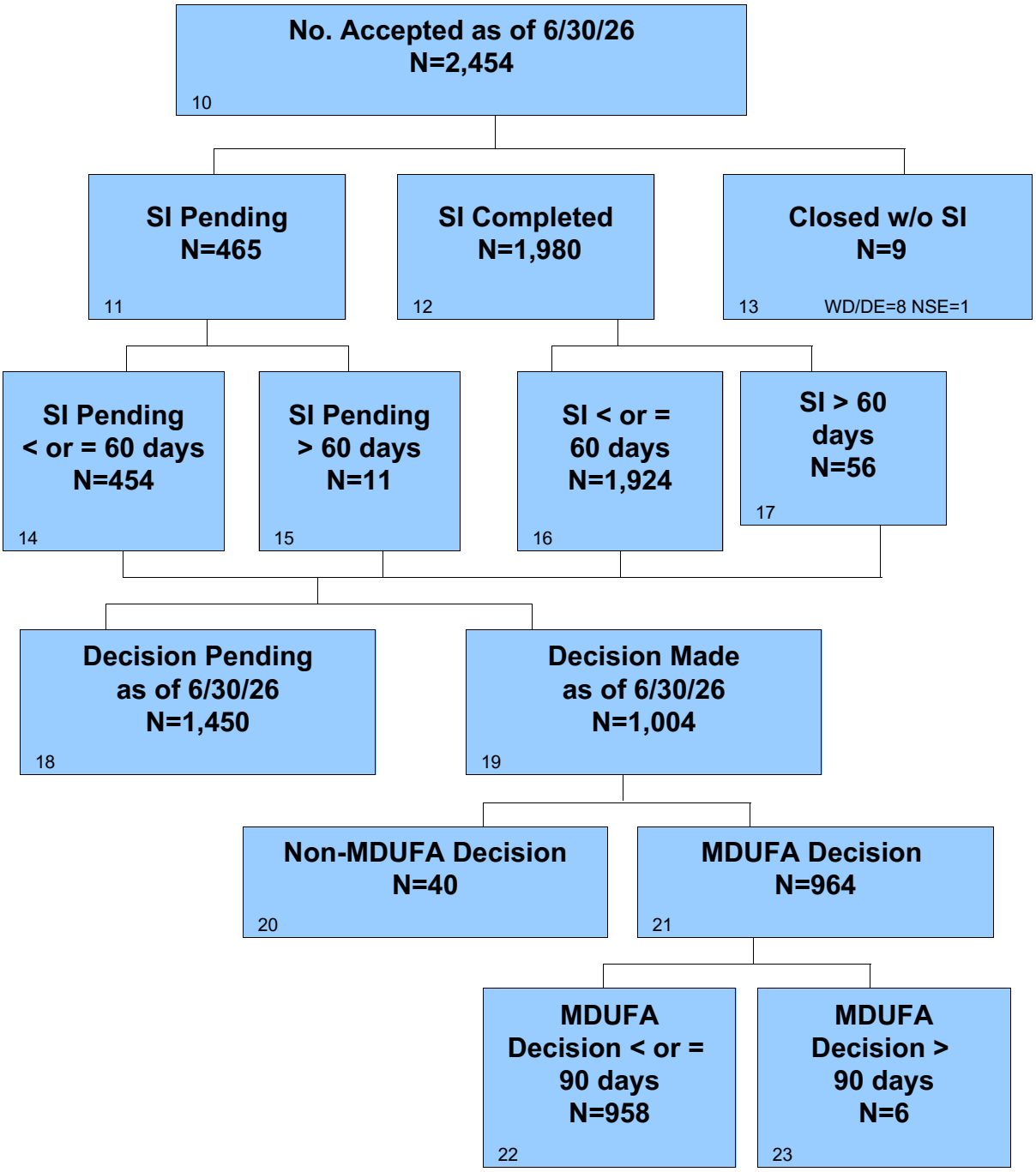
CDRH 510(k)s - FY 2025 as of 6/30/26 Continued



CDRH 510(k)s - FY 2026
as of 6/30/26



CDRH 510(k)s - FY 2026
as of 6/30/26 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	3,857	3,554	3,966	2,781	
Closed Before First RTA or TS Action [1]	51	53	61	46	
Number Accepted or Passed TS on First Cycle [2]	3,007	3,284	3,584	2,309	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	18	28	40	31	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	173	
Number Not Accepted or Failed TS on First Cycle [2]	781	189	281	222	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.52%	5.40%	7.20%	8.67%	

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	3,462	3,867	2,454	
Deleted or Withdrawn Prior to SI	8	12	19	8	
SI Within 60 FDA Days	3,532	3,305	3,739	1,924	
SI Over 60 FDA Days	141	141	96	56	
SI Pending Within 60 FDA Days	0	0	0	454	
SI Pending Over 60 FDA Days	0	3	7	11	
510(k)s NSE Without SI	3	1	6	1	
Current SI Performance Percent Within 60 FDA Days	96.08%	95.80%	97.17%	96.59%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	3,673	3,446	3,835	1,980	
Average Number of FDA Days to Substantive Interaction	52.70	52.47	52.48	52.57	
20th Percentile FDA Days to Substantive Interaction	48	48	48	48	
40th Percentile FDA Days to Substantive Interaction	57	57	57	57	
60th Percentile FDA Days to Substantive Interaction	59	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	212	95	175	173	

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	3,462	3,867	2,454	
Non-MDUFA V Decision	428	432	392	40	
MDUFA V Decision (SE/NSE)	3,256	3,027	3,377	964	
MDUFA V Decision Within 90 FDA Days	3,234	2,994	3,331	958	
510(k)s Pending MDUFA V Decision	0	3	98	1,450	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	3	24	18	
Current Performance Percent Within 90 FDA Days	99.32%	98.81%	97.94%	97.56%	

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	1.69	1.69	1.46	
Number With MDUFA V Decision	3,256	3,027	3,377	962	
Average Number of FDA Days to MDUFA V Decision	75.02	74.79	75.60	67.21	
20th Percentile FDA Days to MDUFA V Decision	57	57	57	30	
40th Percentile FDA Days to MDUFA V Decision	84	85	85	63	
60th Percentile FDA Days to MDUFA V Decision	88	88	88	86	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	89	
Maximum FDA Days to MDUFA V Decision	448	349	375	132	
Average Number of Industry Days to MDUFA V Decision	66.44	68.85	65.65	19.39	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	14	18	18	0	
60th Percentile Industry Days to MDUFA V Decision	70	73	68	11	
80th Percentile Industry Days to MDUFA V Decision	152	157	150	41	
Maximum Industry Days to MDUFA V Decision	417	392	362	145	
Average Number of Total Days to MDUFA V Decision	141.46	143.64	141.24	86.60	
20th Percentile Total Days to MDUFA V Decision	59	58	60	30	
40th Percentile Total Days to MDUFA V Decision	97	101	102	71	
60th Percentile Total Days to MDUFA V Decision	155	158	153	91	
80th Percentile Total Days to MDUFA V Decision	238	243	237	126	
Maximum Total Days to MDUFA V Decision	865	525	529	223	

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	3,462	3,867	2,454	
Number With MDUFA V Decision	3,256	3,027	3,377	964	
Number of SE Decision	3,108	2,886	3,234	951	
Number of NSE Decision	148	141	143	13	
Number of Withdrawal	225	230	229	38	
Number of Deleted	194	195	157	0	
Rate of SE Decision	95.45%	95.34%	95.77%	98.65%	
Rate of NSE Decision	4.55%	4.66%	4.23%	1.35%	
Rate of Withdrawal	6.11%	6.64%	5.92%	1.55%	
Rate of Deleted	5.27%	5.63%	4.06%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	22	33	46	6	
Mean FDA Days for Submissions that Missed the Goal	150.86	115.94	127.61	100.17	
Mean Industry Days for Submissions that Missed the Goal	152.27	146.24	120.41	28.00	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	1	2	
Non-MDUFA V Decision	0	0	1	0	
MDUFA V Decision (SE/NSE)	2	4	0	0	
MDUFA V Decision Within 90 FDA Days	2	4	0	0	
510(k)s Pending MDUFA V Decision	0	0	0	2	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A	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	274	180	
Non-MDUFA V Decision	51	45	43	7	
MDUFA V Decision (SE/NSE)	218	191	226	65	
MDUFA V Decision Within 90 FDA Days	218	191	226	65	
510(k)s Pending MDUFA V Decision	0	0	5	108	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	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	576	529	574	399	
Closed Before First RTA or TS Action [1]	8	8	6	4	
Number Accepted or Passed TS on First Cycle [2]	313	467	491	304	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	4	3	7	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	24	
Number Not Accepted or Failed TS on First Cycle [2]	252	50	74	60	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.37%	9.60%	13.03%	16.17%	

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	513	560	340	
Deleted or Withdrawn Prior to SI	2	2	4	2	
SI Within 60 FDA Days	425	427	537	266	
SI Over 60 FDA Days	105	84	18	12	
SI Pending Within 60 FDA Days	0	0	0	59	
SI Pending Over 60 FDA Days	0	0	0	1	
510(k)s NSE Without SI	1	0	1	0	
Current SI Performance Percent Within 60 FDA Days	80.04%	83.56%	96.58%	95.34%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	530	511	555	278	
Average Number of FDA Days to Substantive Interaction	56.90	55.87	54.15	54.22	
20th Percentile FDA Days to Substantive Interaction	55	53	50	52	
40th Percentile FDA Days to Substantive Interaction	58	57	56	57	
60th Percentile FDA Days to Substantive Interaction	60	59	58	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	212	80	79	96	

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	513	560	340	
Non-MDUFA V Decision	84	69	74	8	
MDUFA V Decision (SE/NSE)	449	444	465	106	
MDUFA V Decision Within 90 FDA Days	439	438	455	106	
510(k)s Pending MDUFA V Decision	0	0	21	226	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1	2	
Current Performance Percent Within 90 FDA Days	97.77%	98.65%	97.64%	98.15%	

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	1.79	1.80	1.46	
Number With MDUFA V Decision	449	444	465	105	
Average Number of FDA Days to MDUFA V Decision	83.61	82.28	80.86	69.73	
20th Percentile FDA Days to MDUFA V Decision	82	83	79	43	
40th Percentile FDA Days to MDUFA V Decision	88	87	87	78	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	87	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	90	
Maximum FDA Days to MDUFA V Decision	448	120	127	90	
Average Number of Industry Days to MDUFA V Decision	77.09	85.89	78.87	21.25	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	39	42	39	0	
60th Percentile Industry Days to MDUFA V Decision	88	106	94	13	
80th Percentile Industry Days to MDUFA V Decision	162	174	165	45	
Maximum Industry Days to MDUFA V Decision	417	392	322	120	
Average Number of Total Days to MDUFA V Decision	160.69	168.17	159.73	90.98	
20th Percentile Total Days to MDUFA V Decision	87	89	88	43	
40th Percentile Total Days to MDUFA V Decision	126	128	126	85	
60th Percentile Total Days to MDUFA V Decision	178	192	179	98	
80th Percentile Total Days to MDUFA V Decision	252	261	254	128	
Maximum Total Days to MDUFA V Decision	865	482	421	205	

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	513	560	340	
Number With MDUFA V Decision	449	444	465	106	
Number of SE Decision	413	413	438	106	
Number of NSE Decision	36	31	27	0	
Number of Withdrawal	41	31	37	7	
Number of Deleted	42	37	36	0	
Rate of SE Decision	91.98%	93.02%	94.19%	100.00%	
Rate of NSE Decision	8.02%	6.98%	5.81%	0.00%	
Rate of Withdrawal	7.69%	6.04%	6.61%	2.06%	
Rate of Deleted	7.88%	7.21%	6.43%	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	10	6	10	0	
Mean FDA Days for Submissions that Missed the Goal	178.70	102.67	101.50	N/A	
Mean Industry Days for Submissions that Missed the Goal	150.40	165.83	132.40	N/A	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	416	318	
Closed Before First RTA or TS Action [1]	8	6	7	7	
Number Accepted or Passed TS on First Cycle [2]	332	354	365	254	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	6	5	4	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	18	
Number Not Accepted or Failed TS on First Cycle [2]	38	12	39	35	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.24%	3.23%	9.54%	11.95%	

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	404	283	
Deleted or Withdrawn Prior to SI	0	0	1	0	
SI Within 60 FDA Days	355	345	372	202	
SI Over 60 FDA Days	10	22	25	27	
SI Pending Within 60 FDA Days	0	0	0	53	
SI Pending Over 60 FDA Days	0	3	3	1	
510(k)s NSE Without SI	0	0	3	0	
Current SI Performance Percent Within 60 FDA Days	97.26%	93.24%	92.31%	87.83%	

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	397	229	
Average Number of FDA Days to Substantive Interaction	51.40	51.09	52.79	52.82	
20th Percentile FDA Days to Substantive Interaction	44	30	44	31	
40th Percentile FDA Days to Substantive Interaction	56	56	57	57	
60th Percentile FDA Days to Substantive Interaction	59	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	86	85	86	173	

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	404	283	
Non-MDUFA V Decision	34	46	34	2	
MDUFA V Decision (SE/NSE)	331	321	356	100	
MDUFA V Decision Within 90 FDA Days	327	310	336	97	
510(k)s Pending MDUFA V Decision	0	3	14	181	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	3	4	4	
Current Performance Percent Within 90 FDA Days	98.79%	95.68%	93.33%	93.27%	

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	1.77	1.78	1.47	
Number With MDUFA V Decision	331	321	356	100	
Average Number of FDA Days to MDUFA V Decision	73.39	73.88	77.46	60.68	
20th Percentile FDA Days to MDUFA V Decision	55	52	58	30	
40th Percentile FDA Days to MDUFA V Decision	84	83	86	55	
60th Percentile FDA Days to MDUFA V Decision	88	89	89	73	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	88	
Maximum FDA Days to MDUFA V Decision	95	349	301	132	
Average Number of Industry Days to MDUFA V Decision	71.75	79.21	76.79	18.12	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	27	35	35	0	
60th Percentile Industry Days to MDUFA V Decision	78	93	82	9	
80th Percentile Industry Days to MDUFA V Decision	155	171	167	38	
Maximum Industry Days to MDUFA V Decision	360	360	362	109	
Average Number of Total Days to MDUFA V Decision	145.14	153.09	154.25	78.80	
20th Percentile Total Days to MDUFA V Decision	57	56	64	30	
40th Percentile Total Days to MDUFA V Decision	107	113	120	56	
60th Percentile Total Days to MDUFA V Decision	162	177	168	90	
80th Percentile Total Days to MDUFA V Decision	238	260	256	126	
Maximum Total Days to MDUFA V Decision	448	525	452	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	404	283	
Number With MDUFA V Decision	331	321	356	100	
Number of SE Decision	308	295	308	98	
Number of NSE Decision	23	26	48	2	
Number of Withdrawal	17	27	14	2	
Number of Deleted	17	17	20	0	
Rate of SE Decision	93.05%	91.90%	86.52%	98.00%	
Rate of NSE Decision	6.95%	8.10%	13.48%	2.00%	
Rate of Withdrawal	4.66%	7.30%	3.47%	0.71%	
Rate of Deleted	4.66%	4.59%	4.95%	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	11	20	3	
Mean FDA Days for Submissions that Missed the Goal	92.75	142.73	120.00	105.67	
Mean Industry Days for Submissions that Missed the Goal	82.50	182.36	131.35	26.67	

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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	445	545	347	
Closed Before First RTA or TS Action [1]	5	11	8	6	
Number Accepted or Passed TS on First Cycle [2]	389	417	504	300	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	1	4	4	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	18	
Number Not Accepted or Failed TS on First Cycle [2]	81	16	29	19	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	17.16%	3.69%	5.40%	5.88%	

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	533	311	
Deleted or Withdrawn Prior to SI	1	0	4	1	
SI Within 60 FDA Days	448	430	518	243	
SI Over 60 FDA Days	10	0	11	1	
SI Pending Within 60 FDA Days	0	0	0	64	
SI Pending Over 60 FDA Days	0	0	0	2	
510(k)s NSE Without SI	0	1	0	0	
Current SI Performance Percent Within 60 FDA Days	97.82%	99.77%	97.92%	98.78%	

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	430	529	244	
Average Number of FDA Days to Substantive Interaction	54.93	52.87	53.30	54.26	
20th Percentile FDA Days to Substantive Interaction	55	49	49	55	
40th Percentile FDA Days to Substantive Interaction	58	57	57	58	
60th Percentile FDA Days to Substantive Interaction	59	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	77	60	175	63	

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	533	311	
Non-MDUFA V Decision	54	70	66	5	
MDUFA V Decision (SE/NSE)	405	361	450	85	
MDUFA V Decision Within 90 FDA Days	404	359	444	84	
510(k)s Pending MDUFA V Decision	0	0	17	221	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	6	4	
Current Performance Percent Within 90 FDA Days	99.75%	99.45%	97.37%	94.38%	

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	1.73	1.51	
Number With MDUFA V Decision	405	361	450	85	
Average Number of FDA Days to MDUFA V Decision	79.93	76.58	78.04	72.54	
20th Percentile FDA Days to MDUFA V Decision	79	58	59	51	
40th Percentile FDA Days to MDUFA V Decision	88	87	87	83	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	88	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	90	
Maximum FDA Days to MDUFA V Decision	93	160	375	91	
Average Number of Industry Days to MDUFA V Decision	85.37	82.91	77.07	22.09	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	48	41	31	0	
60th Percentile Industry Days to MDUFA V Decision	106	106	94	18	
80th Percentile Industry Days to MDUFA V Decision	172	171	171	50	
Maximum Industry Days to MDUFA V Decision	354	349	331	123	
Average Number of Total Days to MDUFA V Decision	165.30	159.48	155.11	94.64	
20th Percentile Total Days to MDUFA V Decision	87	67	67	52	
40th Percentile Total Days to MDUFA V Decision	133	124	119	86	
60th Percentile Total Days to MDUFA V Decision	193	193	181	107	
80th Percentile Total Days to MDUFA V Decision	260	258	257	134	
Maximum Total Days to MDUFA V Decision	443	438	529	199	

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	533	311	
Number With MDUFA V Decision	405	361	450	85	
Number of SE Decision	377	332	431	84	
Number of NSE Decision	28	29	19	1	
Number of Withdrawal	24	38	34	5	
Number of Deleted	29	30	29	0	
Rate of SE Decision	93.09%	91.97%	95.78%	98.82%	
Rate of NSE Decision	6.91%	8.03%	4.22%	1.18%	
Rate of Withdrawal	5.23%	8.82%	6.38%	1.61%	
Rate of Deleted	6.32%	6.96%	5.44%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	2	6	1	
Mean FDA Days for Submissions that Missed the Goal	93.00	125.50	203.67	91.00	
Mean Industry Days for Submissions that Missed the Goal	192.00	51.50	95.00	0.00	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	638	440	
Closed Before First RTA or TS Action [1]	10	6	8	8	
Number Accepted or Passed TS on First Cycle [2]	558	561	565	362	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	12	22	10	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	28	
Number Not Accepted or Failed TS on First Cycle [2]	140	35	43	32	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.03%	5.76%	6.83%	7.92%	

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	599	618	386	
Deleted or Withdrawn Prior to SI	1	5	3	2	
SI Within 60 FDA Days	671	580	592	289	
SI Over 60 FDA Days	5	14	22	7	
SI Pending Within 60 FDA Days	0	0	0	84	
SI Pending Over 60 FDA Days	0	0	0	4	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	99.26%	97.64%	96.26%	96.33%	

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	594	614	296	
Average Number of FDA Days to Substantive Interaction	52.62	52.84	53.07	51.00	
20th Percentile FDA Days to Substantive Interaction	49	50	49	45	
40th Percentile FDA Days to Substantive Interaction	56	57	57	56	
60th Percentile FDA Days to Substantive Interaction	58	58	59	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	122	66	121	63	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	677	599	618	386	
Non-MDUFA V Decision	89	83	62	7	
MDUFA V Decision (SE/NSE)	588	516	544	162	
MDUFA V Decision Within 90 FDA Days	586	511	540	162	
510(k)s Pending MDUFA V Decision	0	0	12	217	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	4	6	
Current Performance Percent Within 90 FDA Days	99.66%	99.03%	98.54%	96.43%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.62	1.61	1.60	1.36	
Number With MDUFA V Decision	588	516	544	162	
Average Number of FDA Days to MDUFA V Decision	75.12	74.50	75.10	64.64	
20th Percentile FDA Days to MDUFA V Decision	58	57	58	29	
40th Percentile FDA Days to MDUFA V Decision	83	84	84	60	
60th Percentile FDA Days to MDUFA V Decision	87	88	88	85	
80th Percentile FDA Days to MDUFA V Decision	89	90	89	88	
Maximum FDA Days to MDUFA V Decision	101	95	234	90	
Average Number of Industry Days to MDUFA V Decision	56.52	53.43	55.32	15.44	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	47	40	44	0	
80th Percentile Industry Days to MDUFA V Decision	124	121	125	23	
Maximum Industry Days to MDUFA V Decision	359	360	321	145	
Average Number of Total Days to MDUFA V Decision	131.64	127.92	130.43	80.08	
20th Percentile Total Days to MDUFA V Decision	60	58	58	29	
40th Percentile Total Days to MDUFA V Decision	88	90	90	63	
60th Percentile Total Days to MDUFA V Decision	128	125	132	89	
80th Percentile Total Days to MDUFA V Decision	211	207	213	105	
Maximum Total Days to MDUFA V Decision	449	448	410	223	

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	599	618	386	
Number With MDUFA V Decision	588	516	544	162	
Number of SE Decision	571	509	533	161	
Number of NSE Decision	17	7	11	1	
Number of Withdrawal	52	40	40	6	
Number of Deleted	36	42	21	0	
Rate of SE Decision	97.11%	98.64%	97.98%	99.38%	
Rate of NSE Decision	2.89%	1.36%	2.02%	0.62%	
Rate of Withdrawal	7.68%	6.68%	6.47%	1.55%	
Rate of Deleted	5.32%	7.01%	3.40%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	5	4	0	
Mean FDA Days for Submissions that Missed the Goal	96.50	92.20	157.25	N/A	
Mean Industry Days for Submissions that Missed the Goal	59.50	118.60	14.00	N/A	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	389	304	
Closed Before First RTA or TS Action [1]	3	3	10	6	
Number Accepted or Passed TS on First Cycle [2]	214	275	338	249	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	1	5	1	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	14	
Number Not Accepted or Failed TS on First Cycle [2]	96	27	36	34	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	30.87%	8.91%	9.50%	11.97%	

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

Table 6.2 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	376	265	
Deleted or Withdrawn Prior to SI	0	0	2	0	
SI Within 60 FDA Days	287	281	356	206	
SI Over 60 FDA Days	11	19	13	8	
SI Pending Within 60 FDA Days	0	0	0	49	
SI Pending Over 60 FDA Days	0	0	4	2	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	96.31%	93.67%	95.19%	95.37%	

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	369	214	
Average Number of FDA Days to Substantive Interaction	54.67	54.90	52.85	54.90	
20th Percentile FDA Days to Substantive Interaction	56	53	48	56	
40th Percentile FDA Days to Substantive Interaction	58	58	57	58	
60th Percentile FDA Days to Substantive Interaction	60	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	80	95	104	64	

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	376	265	
Non-MDUFA V Decision	34	32	31	1	
MDUFA V Decision (SE/NSE)	264	268	329	104	
MDUFA V Decision Within 90 FDA Days	259	259	324	102	
510(k)s Pending MDUFA V Decision	0	0	16	160	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	8	2	
Current Performance Percent Within 90 FDA Days	98.11%	96.64%	96.14%	96.23%	

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	1.79	1.75	1.66	
Number With MDUFA V Decision	264	268	329	104	
Average Number of FDA Days to MDUFA V Decision	79.01	78.52	76.64	76.37	
20th Percentile FDA Days to MDUFA V Decision	59	61	57	60	
40th Percentile FDA Days to MDUFA V Decision	87	87	87	86	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	89	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	90	
Maximum FDA Days to MDUFA V Decision	382	126	118	99	
Average Number of Industry Days to MDUFA V Decision	77.26	77.13	64.87	25.86	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	35	37	22	3	
60th Percentile Industry Days to MDUFA V Decision	91	91	72	27	
80th Percentile Industry Days to MDUFA V Decision	168	157	140	49	
Maximum Industry Days to MDUFA V Decision	367	268	342	125	
Average Number of Total Days to MDUFA V Decision	156.27	155.65	141.50	102.22	
20th Percentile Total Days to MDUFA V Decision	62	83	70	69	
40th Percentile Total Days to MDUFA V Decision	118	124	108	91	
60th Percentile Total Days to MDUFA V Decision	177	181	154	114	
80th Percentile Total Days to MDUFA V Decision	255	240	228	132	
Maximum Total Days to MDUFA V Decision	732	356	460	214	

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	376	265	
Number With MDUFA V Decision	264	268	329	104	
Number of SE Decision	246	247	308	100	
Number of NSE Decision	18	21	21	4	
Number of Withdrawal	10	10	16	1	
Number of Deleted	21	21	15	0	
Rate of SE Decision	93.18%	92.16%	93.62%	96.15%	
Rate of NSE Decision	6.82%	7.84%	6.38%	3.85%	
Rate of Withdrawal	3.36%	3.33%	4.26%	0.38%	
Rate of Deleted	7.05%	7.00%	3.99%	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	5	9	5	2	
Mean FDA Days for Submissions that Missed the Goal	175.00	103.11	101.40	96.50	
Mean Industry Days for Submissions that Missed the Goal	241.00	125.44	177.20	44.00	

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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	613	393	
Closed Before First RTA or TS Action [1]	6	4	7	4	
Number Accepted or Passed TS on First Cycle [2]	517	535	575	331	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	0	1	5	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	33	
Number Not Accepted or Failed TS on First Cycle [2]	93	24	30	20	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.17%	4.29%	4.95%	5.62%	

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	554	604	348	
Deleted or Withdrawn Prior to SI	1	2	1	0	
SI Within 60 FDA Days	604	552	601	296	
SI Over 60 FDA Days	0	0	2	1	
SI Pending Within 60 FDA Days	0	0	0	51	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	99.67%	99.66%	

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	552	603	297	
Average Number of FDA Days to Substantive Interaction	49.84	50.07	49.67	50.96	
20th Percentile FDA Days to Substantive Interaction	30	30	30	30	
40th Percentile FDA Days to Substantive Interaction	56	56	56	57	
60th Percentile FDA Days to Substantive Interaction	58	58	58	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	60	60	61	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	554	604	348	
Non-MDUFA V Decision	51	54	52	7	
MDUFA V Decision (SE/NSE)	554	500	546	190	
MDUFA V Decision Within 90 FDA Days	554	500	545	190	
510(k)s Pending MDUFA V Decision	0	0	6	151	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	99.82%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48	1.48	1.50	1.32	
Number With MDUFA V Decision	554	500	546	190	
Average Number of FDA Days to MDUFA V Decision	65.77	65.73	66.06	62.58	
20th Percentile FDA Days to MDUFA V Decision	30	30	30	29	
40th Percentile FDA Days to MDUFA V Decision	59	60	60	58	
60th Percentile FDA Days to MDUFA V Decision	85	85	86	82	
80th Percentile FDA Days to MDUFA V Decision	89	89	89	88	
Maximum FDA Days to MDUFA V Decision	90	90	97	90	
Average Number of Industry Days to MDUFA V Decision	42.82	44.81	43.01	12.67	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	18	12	19	0	
80th Percentile Industry Days to MDUFA V Decision	92	110	100	21	
Maximum Industry Days to MDUFA V Decision	354	349	248	109	
Average Number of Total Days to MDUFA V Decision	108.59	110.53	109.08	75.26	
20th Percentile Total Days to MDUFA V Decision	30	30	30	29	
40th Percentile Total Days to MDUFA V Decision	60	60	65	58	
60th Percentile Total Days to MDUFA V Decision	98	99	104	87	
80th Percentile Total Days to MDUFA V Decision	179	193	182	108	
Maximum Total Days to MDUFA V Decision	443	439	336	199	

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	554	604	348	
Number With MDUFA V Decision	554	500	546	190	
Number of SE Decision	544	492	539	188	
Number of NSE Decision	10	8	7	2	
Number of Withdrawal	37	38	38	7	
Number of Deleted	12	16	13	0	
Rate of SE Decision	98.19%	98.40%	98.72%	98.95%	
Rate of NSE Decision	1.81%	1.60%	1.28%	1.05%	
Rate of Withdrawal	6.12%	6.86%	6.29%	2.01%	
Rate of Deleted	1.98%	2.89%	2.15%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	97.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	76.00	N/A	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	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	285	208	
Closed Before First RTA or TS Action [1]	7	13	8	5	
Number Accepted or Passed TS on First Cycle [2]	243	228	264	178	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	5	4	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	19	
Number Not Accepted or Failed TS on First Cycle [2]	40	13	13	6	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.89%	5.31%	4.69%	3.26%	

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	275	182	
Deleted or Withdrawn Prior to SI	3	0	3	1	
SI Within 60 FDA Days	266	239	270	151	
SI Over 60 FDA Days	0	1	2	0	
SI Pending Within 60 FDA Days	0	0	0	30	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	2	0	0	0	
Current SI Performance Percent Within 60 FDA Days	99.25%	99.58%	99.26%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	266	240	272	151	
Average Number of FDA Days to Substantive Interaction	52.54	51.18	51.74	51.90	
20th Percentile FDA Days to Substantive Interaction	47	43	45	45	
40th Percentile FDA Days to Substantive Interaction	56	55	56	56	
60th Percentile FDA Days to Substantive Interaction	58	58	58	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	60	81	67	60	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	271	240	275	182	
Non-MDUFA V Decision	51	45	44	7	
MDUFA V Decision (SE/NSE)	220	195	226	65	
MDUFA V Decision Within 90 FDA Days	220	195	226	65	
510(k)s Pending MDUFA V Decision	0	0	5	110	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	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	1.64	1.51	1.27	
Number With MDUFA V Decision	220	195	226	64	
Average Number of FDA Days to MDUFA V Decision	76.25	74.90	74.96	69.53	
20th Percentile FDA Days to MDUFA V Decision	59	54	55	44	
40th Percentile FDA Days to MDUFA V Decision	87	87	86	71	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	87	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	90	
Maximum FDA Days to MDUFA V Decision	90	90	90	90	
Average Number of Industry Days to MDUFA V Decision	80.81	81.69	66.04	12.19	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	8	0	0	
60th Percentile Industry Days to MDUFA V Decision	119	110	69	0	
80th Percentile Industry Days to MDUFA V Decision	177	174	172	25	
Maximum Industry Days to MDUFA V Decision	361	361	222	84	
Average Number of Total Days to MDUFA V Decision	157.05	156.58	141.00	81.72	
20th Percentile Total Days to MDUFA V Decision	60	60	56	44	
40th Percentile Total Days to MDUFA V Decision	90	90	89	75	
60th Percentile Total Days to MDUFA V Decision	205	200	158	88	
80th Percentile Total Days to MDUFA V Decision	265	260	256	109	
Maximum Total Days to MDUFA V Decision	451	451	312	174	

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	275	182	
Number With MDUFA V Decision	220	195	226	65	
Number of SE Decision	211	187	221	65	
Number of NSE Decision	9	8	5	0	
Number of Withdrawal	28	22	32	7	
Number of Deleted	23	23	12	0	
Rate of SE Decision	95.91%	95.90%	97.79%	100.00%	
Rate of NSE Decision	4.09%	4.10%	2.21%	0.00%	
Rate of Withdrawal	10.33%	9.17%	11.64%	3.85%	
Rate of Deleted	8.49%	9.58%	4.36%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	2	
Non-MDUFA V Decision	0	0	1	0	
MDUFA V Decision (SE/NSE)	2	4	0	0	
MDUFA V Decision Within 90 FDA Days	2	4	0	0	
510(k)s Pending MDUFA V Decision	0	0	0	2	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A	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	274	180	
Non-MDUFA V Decision	51	45	43	7	
MDUFA V Decision (SE/NSE)	218	191	226	65	
MDUFA V Decision Within 90 FDA Days	218	191	226	65	
510(k)s Pending MDUFA V Decision	0	0	5	108	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	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	506	372	
Closed Before First RTA or TS Action [1]	4	2	7	6	
Number Accepted or Passed TS on First Cycle [2]	441	447	482	331	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	19	
Number Not Accepted or Failed TS on First Cycle [2]	41	12	17	16	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.47%	2.61%	3.41%	4.61%	

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	497	339	
Deleted or Withdrawn Prior to SI	0	3	1	2	
SI Within 60 FDA Days	476	451	493	271	
SI Over 60 FDA Days	0	1	3	0	
SI Pending Within 60 FDA Days	0	0	0	64	
SI Pending Over 60 FDA Days	0	0	0	1	
510(k)s NSE Without SI	0	0	0	1	
Current SI Performance Percent Within 60 FDA Days	100.00%	99.78%	99.40%	99.27%	

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	496	271	
Average Number of FDA Days to Substantive Interaction	49.51	50.89	52.32	51.13	
20th Percentile FDA Days to Substantive Interaction	35	46	49	44	
40th Percentile FDA Days to Substantive Interaction	53	55	56	55	
60th Percentile FDA Days to Substantive Interaction	57	58	58	58	
80th Percentile FDA Days to Substantive Interaction	59	59	60	60	
Maximum FDA Days to Substantive Interaction	60	61	67	60	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	476	455	497	339	
Non-MDUFA V Decision	31	33	29	3	
MDUFA V Decision (SE/NSE)	445	422	461	152	
MDUFA V Decision Within 90 FDA Days	445	422	461	152	
510(k)s Pending MDUFA V Decision	0	0	7	184	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	99.78%	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	1.82	1.67	
Number With MDUFA V Decision	445	422	461	152	
Average Number of FDA Days to MDUFA V Decision	71.52	74.77	77.89	68.09	
20th Percentile FDA Days to MDUFA V Decision	52	57	72	41	
40th Percentile FDA Days to MDUFA V Decision	79	84	85	72	
60th Percentile FDA Days to MDUFA V Decision	86	88	88	86	
80th Percentile FDA Days to MDUFA V Decision	89	89	89	89	
Maximum FDA Days to MDUFA V Decision	90	90	90	90	
Average Number of Industry Days to MDUFA V Decision	63.50	67.15	71.93	28.61	
20th Percentile Industry Days to MDUFA V Decision	0	0	8	0	
40th Percentile Industry Days to MDUFA V Decision	24	31	36	9	
60th Percentile Industry Days to MDUFA V Decision	62	71	80	32	
80th Percentile Industry Days to MDUFA V Decision	138	144	147	52	
Maximum Industry Days to MDUFA V Decision	182	215	185	141	
Average Number of Total Days to MDUFA V Decision	135.03	141.93	149.82	96.70	
20th Percentile Total Days to MDUFA V Decision	56	66	86	44	
40th Percentile Total Days to MDUFA V Decision	107	114	122	89	
60th Percentile Total Days to MDUFA V Decision	146	156	166	114	
80th Percentile Total Days to MDUFA V Decision	222	219	231	135	
Maximum Total Days to MDUFA V Decision	272	304	275	217	

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	497	339	
Number With MDUFA V Decision	445	422	461	152	
Number of SE Decision	438	411	456	149	
Number of NSE Decision	7	11	5	3	
Number of Withdrawal	16	24	18	3	
Number of Deleted	14	9	11	0	
Rate of SE Decision	98.43%	97.39%	98.92%	98.03%	
Rate of NSE Decision	1.57%	2.61%	1.08%	1.97%	
Rate of Withdrawal	3.36%	5.27%	3.62%	0.88%	
Rate of Deleted	2.94%	1.98%	2.21%	0.00%	

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

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

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

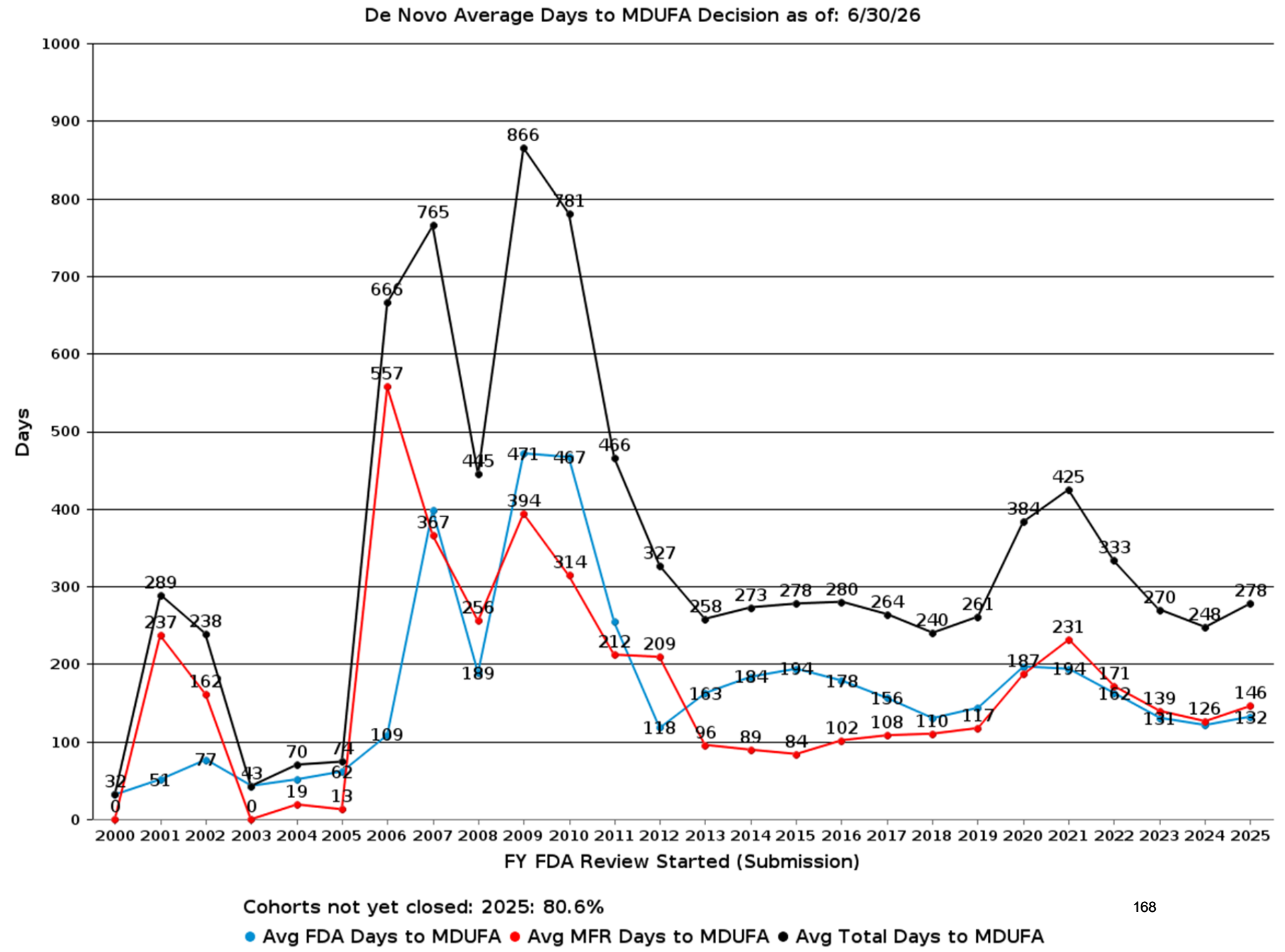
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V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

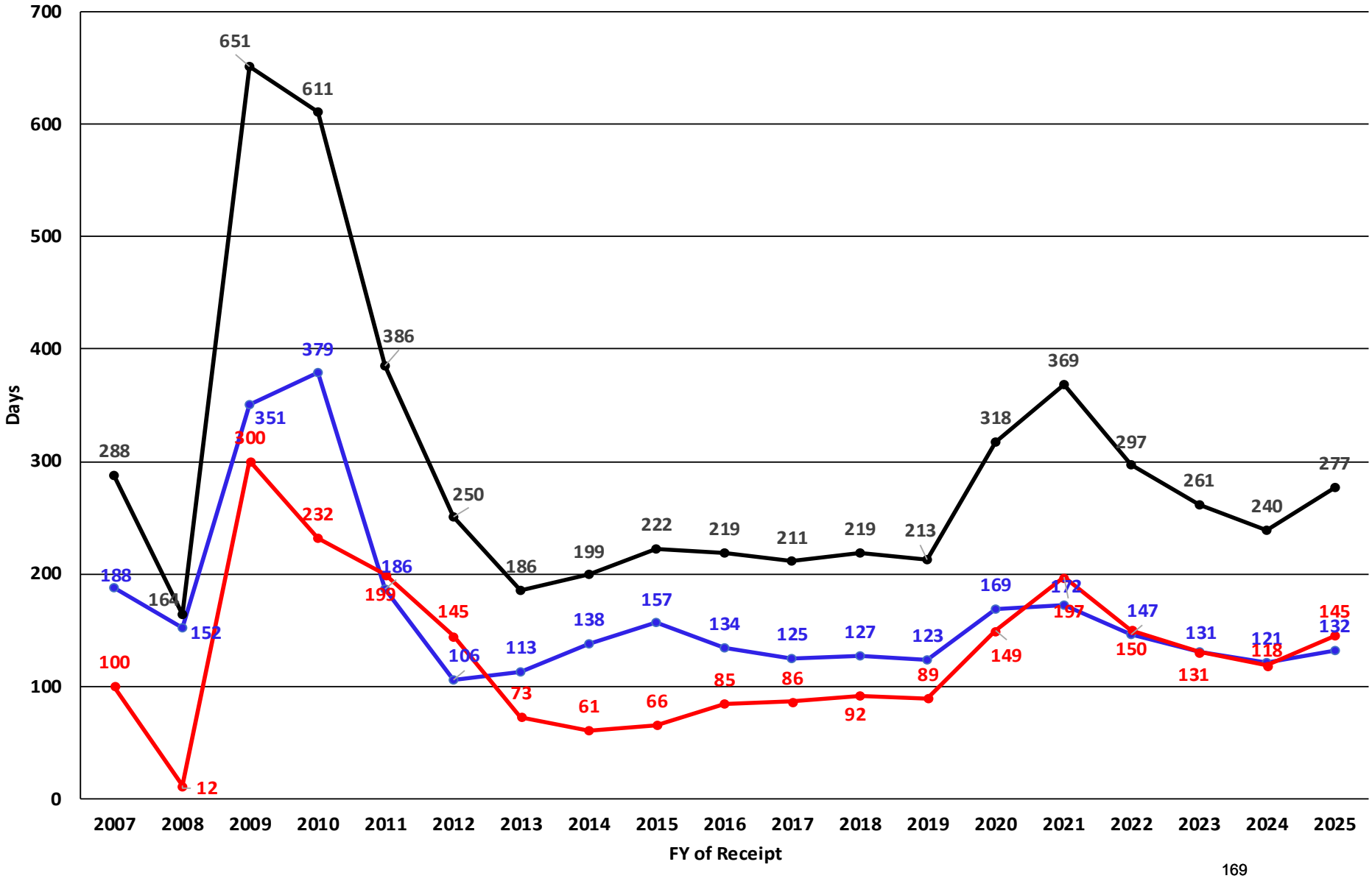
De Novos

Q3FY2026

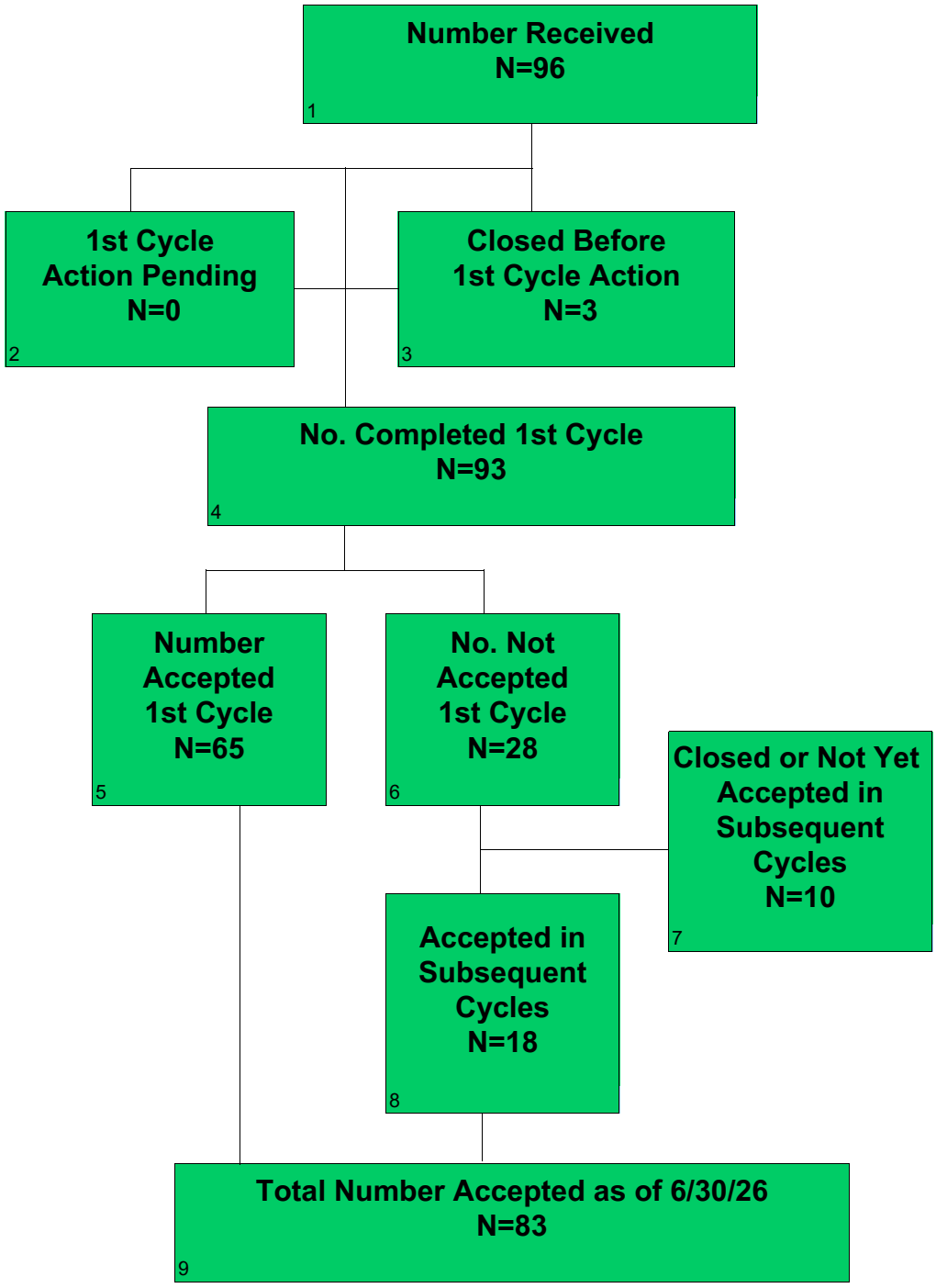

De Novo Average Days to MDUFA Decision as of: 6/30/26
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2025: 80.6%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos

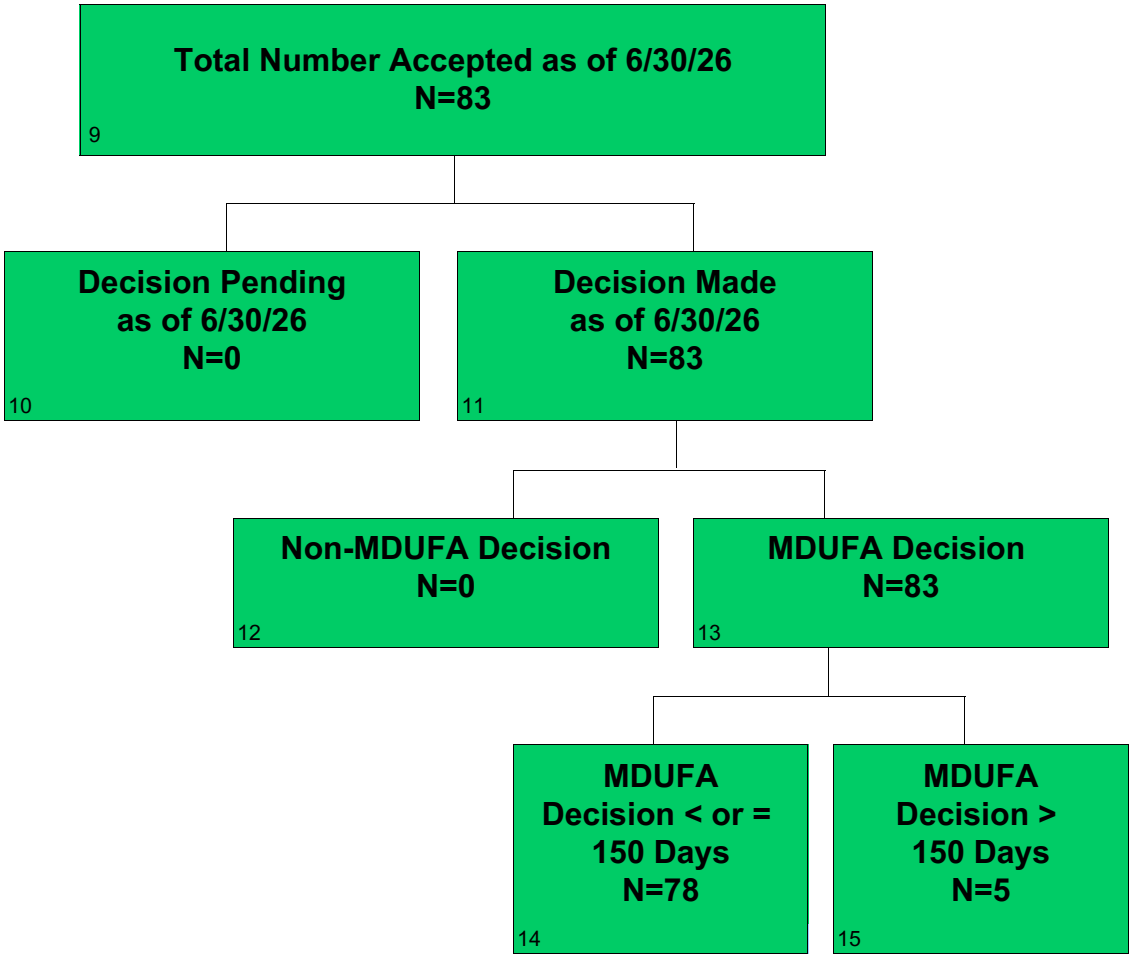
(80.6% closure comparison)



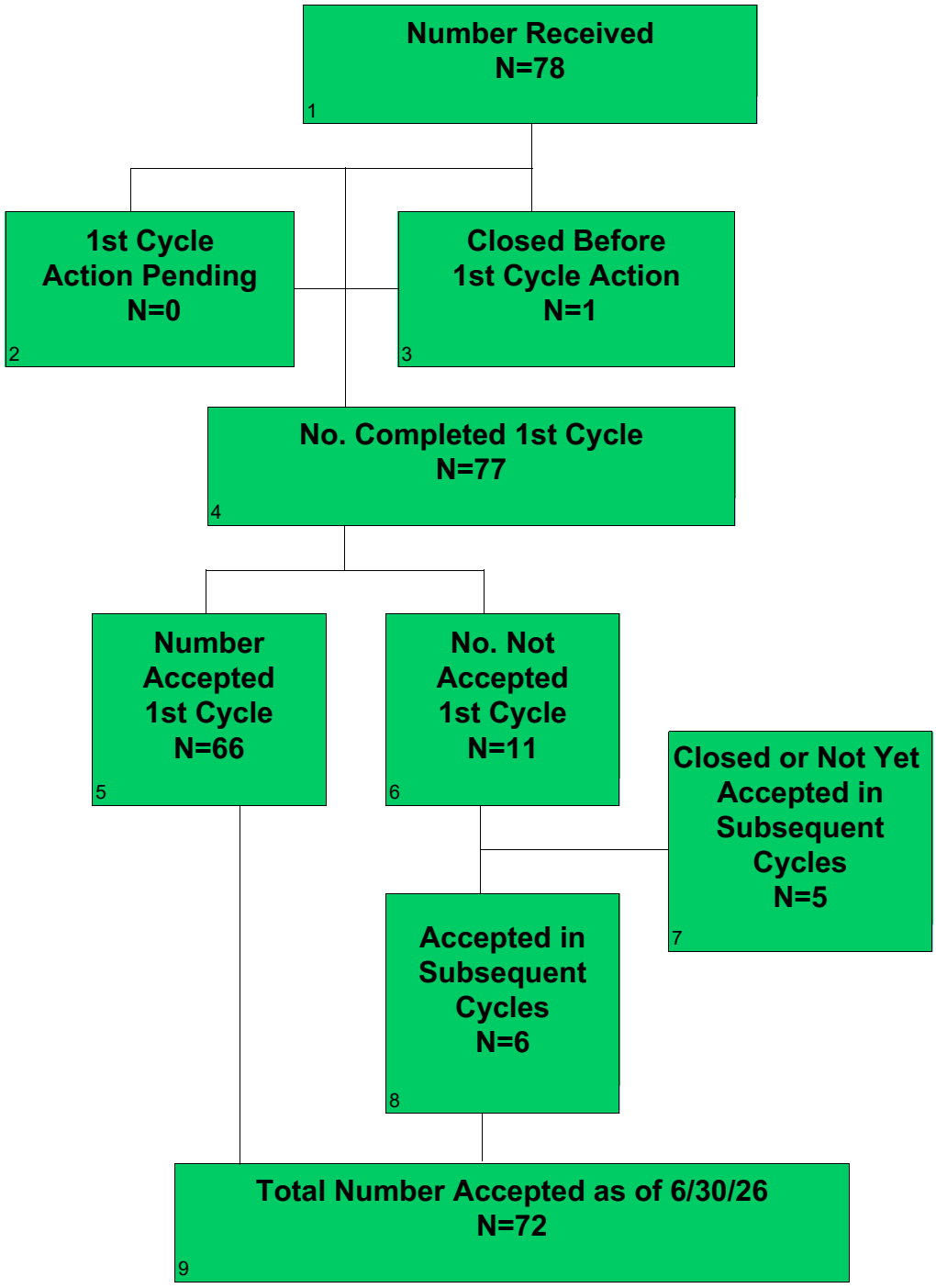
CDRH De Novo - FY 2023
as of 6/30/26



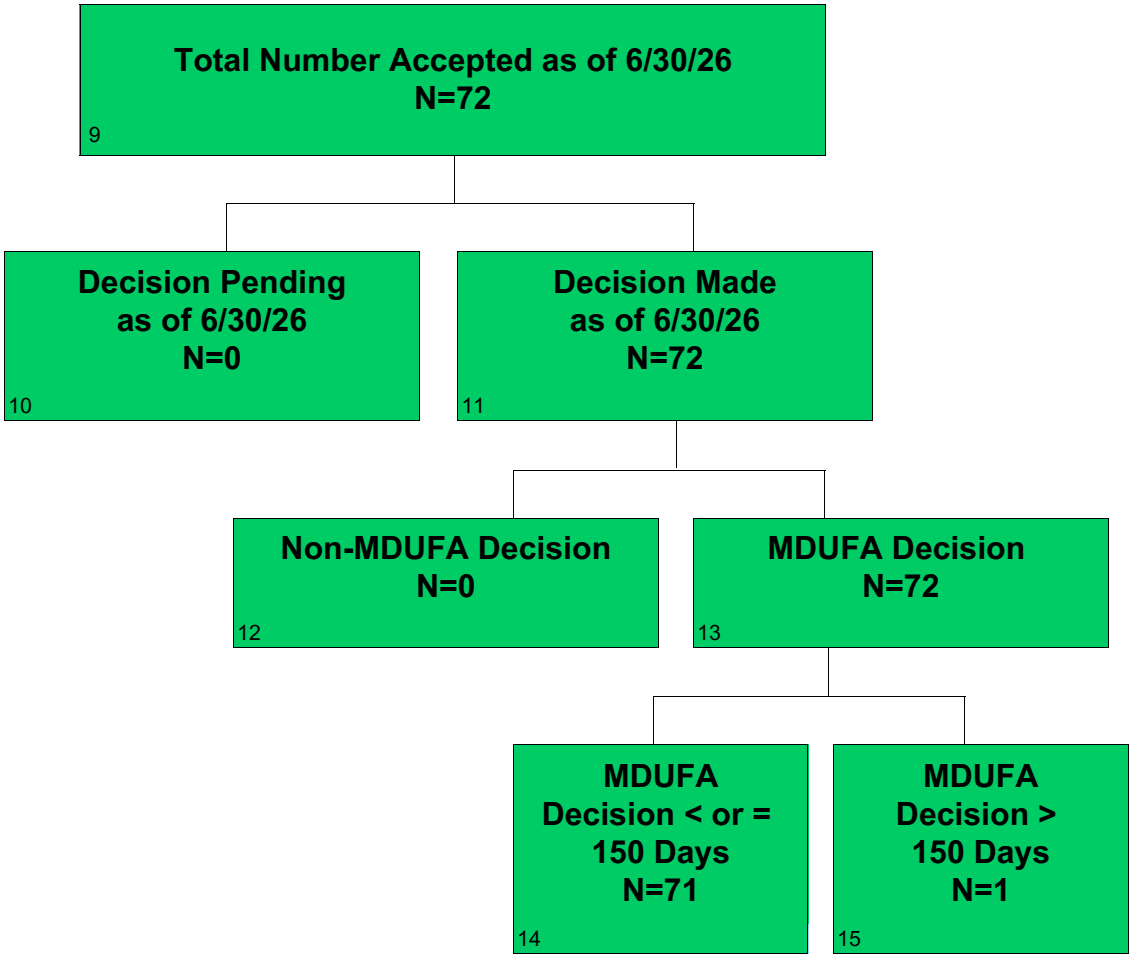
CDRH De Novo - FY 2023
as of 6/30/26 Continued



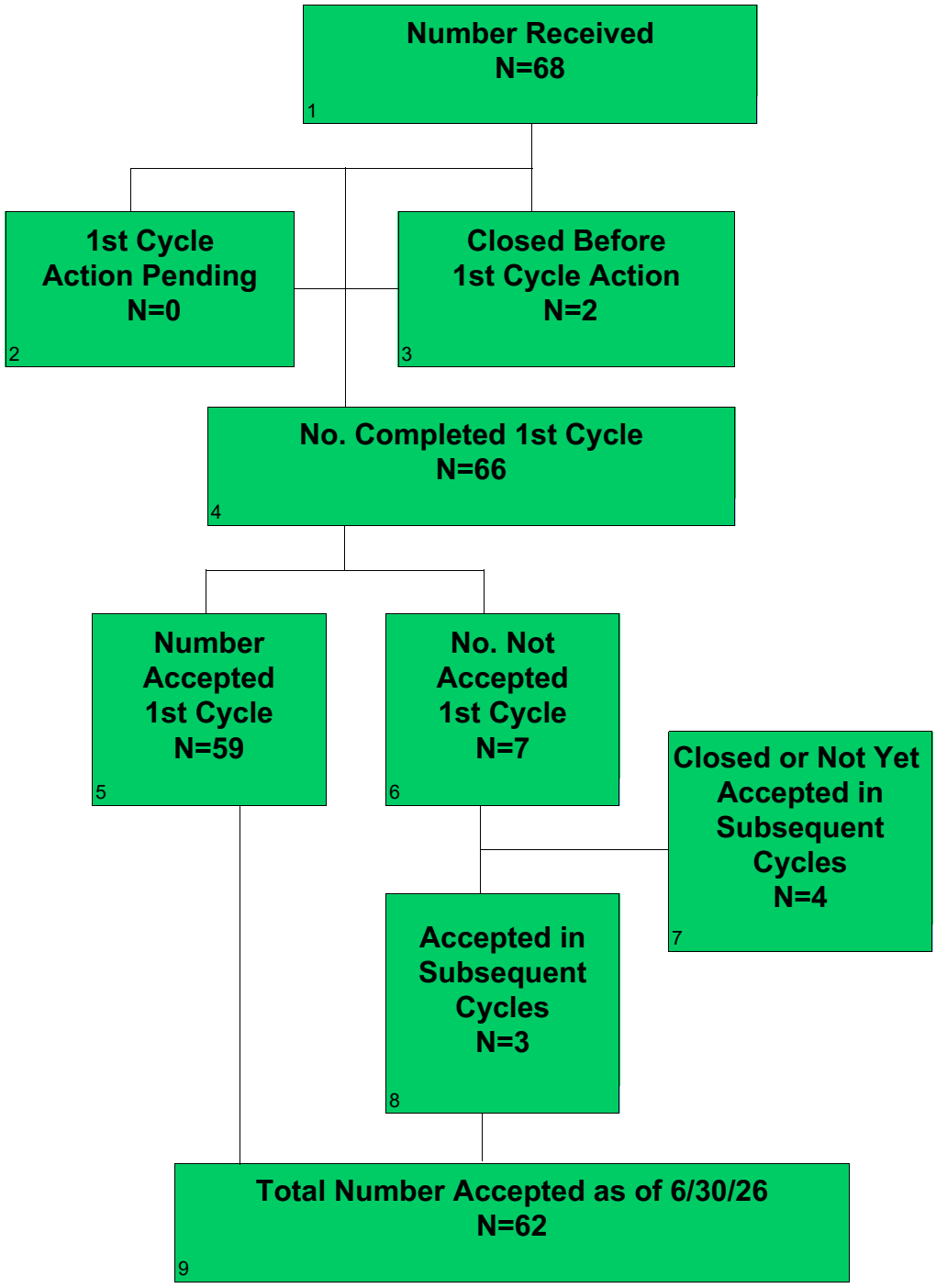
CDRH De Novo - FY 2024
as of 6/30/26



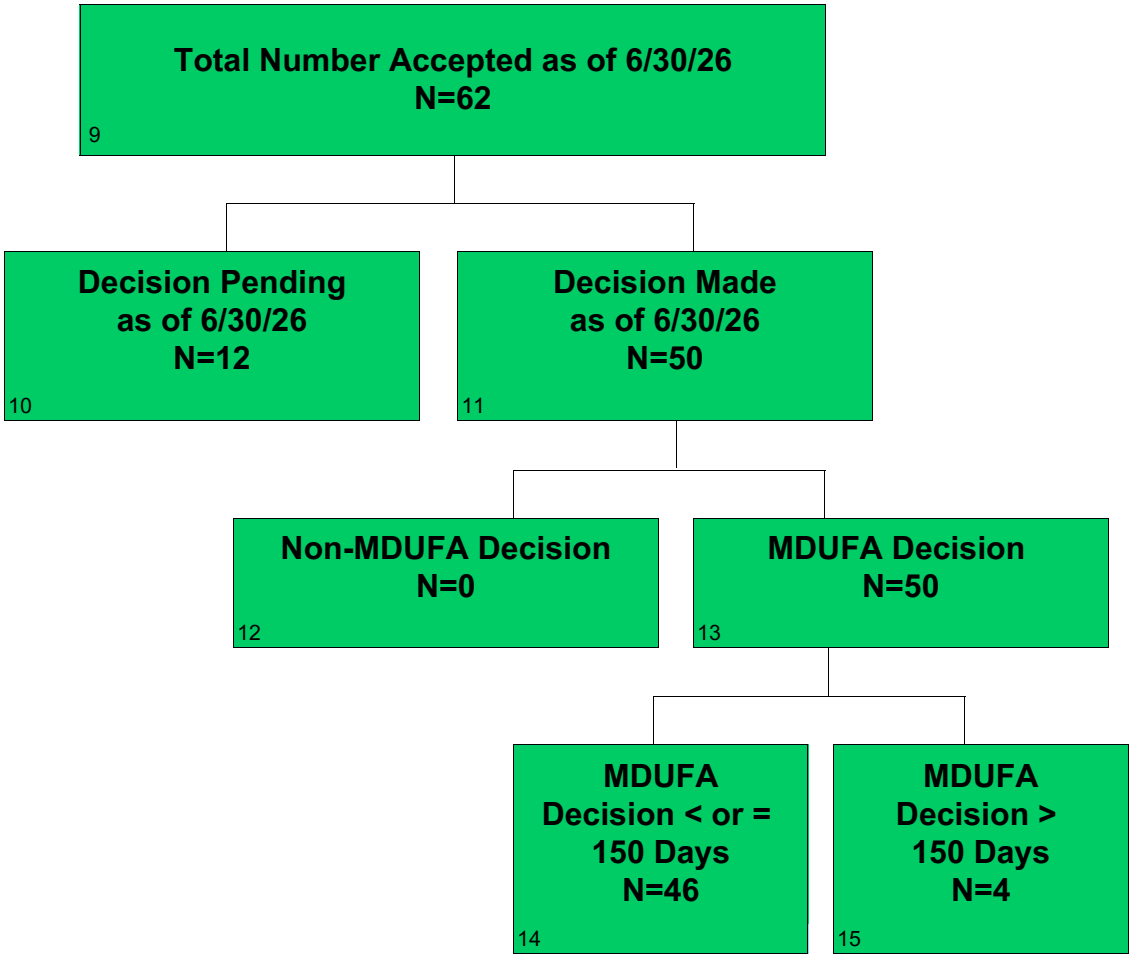
CDRH De Novo - FY 2024
as of 6/30/26 Continued



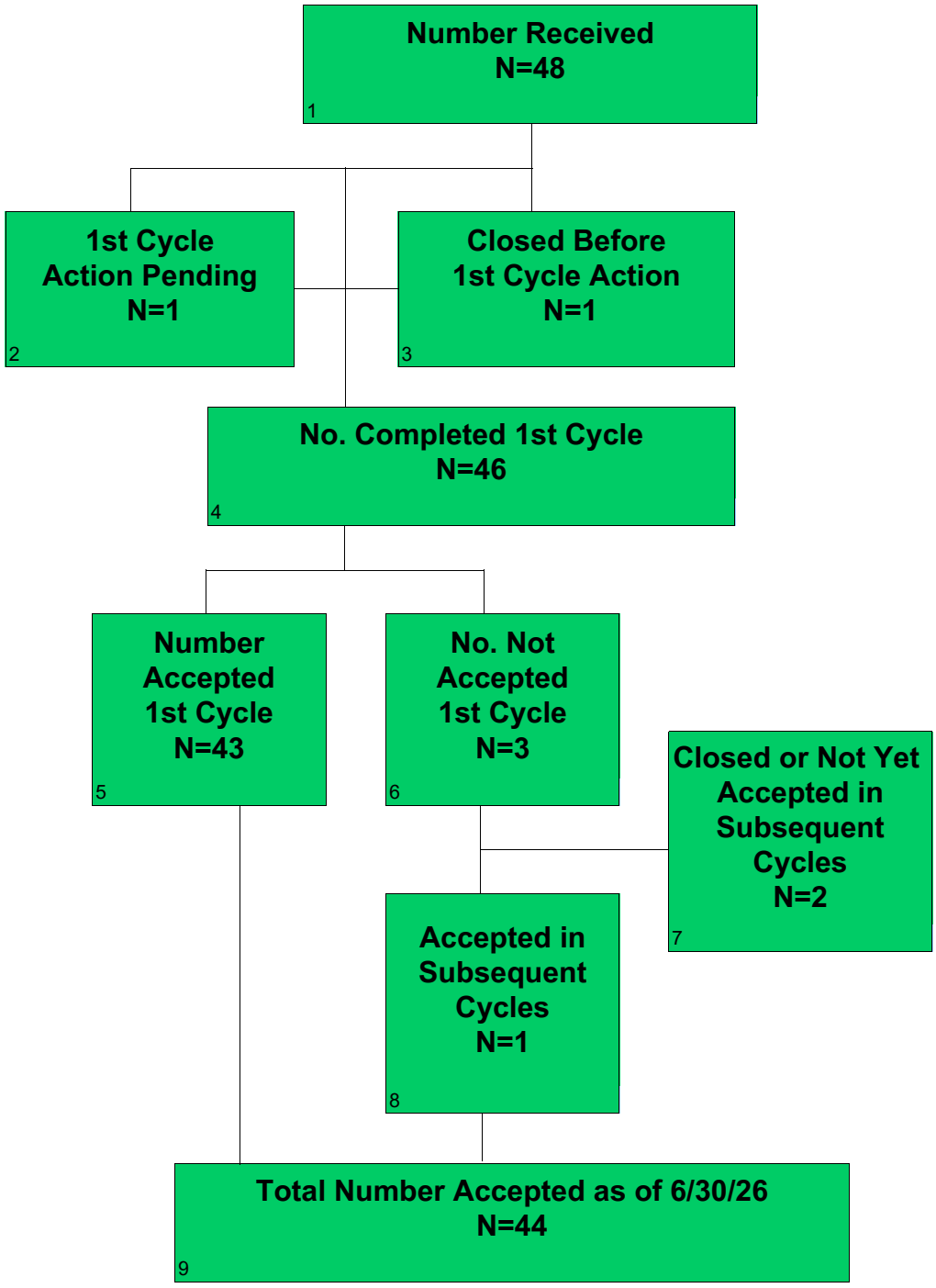
CDRH De Novo - FY 2025
as of 6/30/26



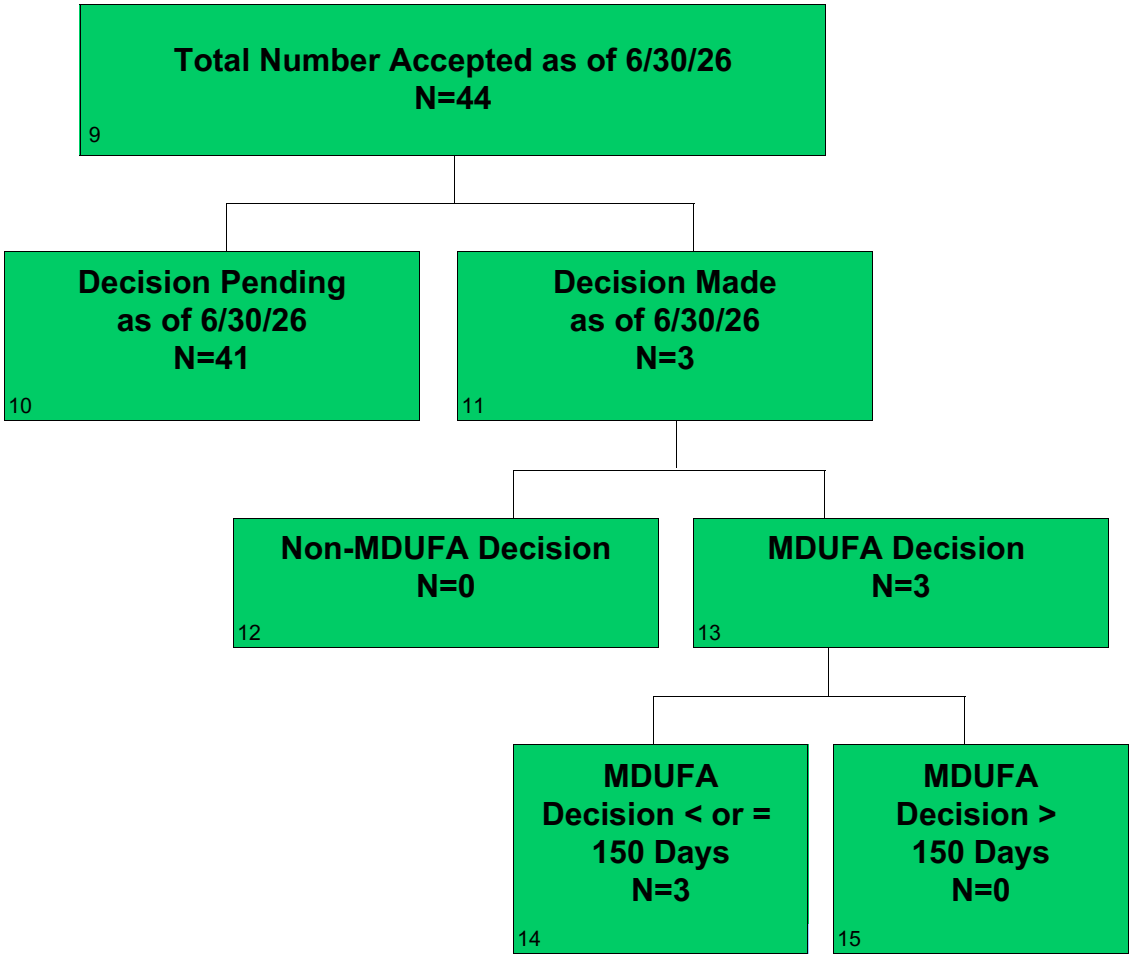
CDRH De Novo - FY 2025 as of 6/30/26 Continued



CDRH De Novo - FY 2026
as of 6/30/26



CDRH De Novo - FY 2026
as of 6/30/26 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96	78	68	48	
Closed Before First RTA or TS Action	3	1	2	1	
Number Accepted or Passed TS on First Cycle	65	66	59	43	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted or Failed TS on First Cycle	28	11	7	3	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	10.61%	6.52%	

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 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	83	72	62	44	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	83	72	50	3	
MDUFA Decision Within 150 FDA Days	78	71	46	3	
De Novos Pending MDUFA Decision	0	0	12	41	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	93.98%	98.61%	92.00%	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	1.61	1.68	1.33	
Number With MDUFA Decision	83	72	50	3	
Average FDA Days to MDUFA Decision	130.60	121.26	132.16	98.33	
20th Percentile FDA Days to MDUFA Decision	75	75	75	74	
40th Percentile FDA Days to MDUFA Decision	148	134	148	75	
60th Percentile FDA Days to MDUFA Decision	150	149	150	89	
80th Percentile FDA Days to MDUFA Decision	150	150	150	118	
Maximum FDA Days to MDUFA Decision	251	151	326	147	
Average Industry Days to MDUFA Decision	139.47	126.25	145.96	12.00	
20th Percentile Industry Days to MDUFA Decision	72	34	94	0	
40th Percentile Industry Days to MDUFA Decision	152	143	166	0	
60th Percentile Industry Days to MDUFA Decision	178	177	178	7	
80th Percentile Industry Days to MDUFA Decision	181	181	181	22	
Maximum Industry Days to MDUFA Decision	350	185	306	36	
Average Total Days to MDUFA Decision	270.07	247.51	278.12	110.33	
20th Percentile Total Days to MDUFA Decision	214	178	236	74	
40th Percentile Total Days to MDUFA Decision	256	255	256	75	
60th Percentile Total Days to MDUFA Decision	303	284	300	97	
80th Percentile Total Days to MDUFA Decision	329	327	328	140	
Maximum Total Days to MDUFA Decision	437	330	505	183	

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	62	44	
Number With MDUFA Decision	83	72	50	3	
Number With Granted Decision	37	29	28	1	
Number With Declined Decision	18	18	7	1	
Number of Withdrawal	17	13	5	1	
Number of Deleted	11	12	10	0	
Rate of Granted Decision	44.58%	40.28%	56.00%	33.33%	
Rate of Declined Decision	21.69%	25.00%	14.00%	33.33%	
Rate of Withdrawal	20.48%	18.06%	10.00%	33.33%	
Rate of Deleted	13.25%	16.67%	20.00%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	5	1	4	0	
Mean FDA Days for Submissions that Missed the Goal	194.80	151.00	207.25	N/A	
Mean Industry Days for Submissions that Missed the Goal	111.20	150.00	209.75	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	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Within 150 FDA Days	1	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	1	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	N/A	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	11	11	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	19	18	8	0	
MDUFA Decision Within 150 FDA Days	19	18	8	0	
De Novos Pending MDUFA Decision	0	0	3	11	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

Section 8 - De Novo Office Level Metrics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	13	10	3	
Closed Before First RTA or TS Action	0	0	1	0	
Number Accepted or Passed TS on First Cycle	6	10	5	3	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	6	3	4	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	23.08%	44.44%	0.00%	

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

Table 8.2 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	11	12	7	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	11	12	7	1	
MDUFA Decision Within 150 FDA Days	8	11	6	1	
De Novos Pending MDUFA Decision	0	0	0	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	72.73%	91.67%	85.71%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.67	1.57	1.00	
Number With MDUFA Decision	11	12	7	1	
Average FDA Days to MDUFA Decision	130.82	118.42	131.00	73.00	
20th Percentile FDA Days to MDUFA Decision	73	73	99	73	
40th Percentile FDA Days to MDUFA Decision	75	109	149	73	
60th Percentile FDA Days to MDUFA Decision	150	148	150	73	
80th Percentile FDA Days to MDUFA Decision	178	150	150	73	
Maximum FDA Days to MDUFA Decision	251	151	159	73	
Average Industry Days to MDUFA Decision	137.45	131.75	153.00	N/A	
20th Percentile Industry Days to MDUFA Decision	81	125	175	0	
40th Percentile Industry Days to MDUFA Decision	152	137	178	0	
60th Percentile Industry Days to MDUFA Decision	178	166	180	0	
80th Percentile Industry Days to MDUFA Decision	182	181	180	0	
Maximum Industry Days to MDUFA Decision	189	181	181	0	
Average Total Days to MDUFA Decision	268.27	250.17	284.00	73.00	
20th Percentile Total Days to MDUFA Decision	231	222	251	73	
40th Percentile Total Days to MDUFA Decision	255	261	292	73	
60th Percentile Total Days to MDUFA Decision	262	284	328	73	
80th Percentile Total Days to MDUFA Decision	328	321	330	73	
Maximum Total Days to MDUFA Decision	343	328	338	73	

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	7	3	
Number With MDUFA Decision	11	12	7	1	
Number With Granted Decision	5	3	5	0	
Number With Declined Decision	1	4	0	0	
Number of Withdrawal	1	3	1	1	
Number of Deleted	4	2	1	0	
Rate of Granted Decision	45.45%	25.00%	71.43%	0.00%	
Rate of Declined Decision	9.09%	33.33%	0.00%	0.00%	
Rate of Withdrawal	9.09%	25.00%	14.29%	100.00%	
Rate of Deleted	36.36%	16.67%	14.29%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	3	1	1	0	
Mean FDA Days for Submissions That Missed the Goal	206.67	151.00	159.00	N/A	
Mean Industry Days for Submissions That Missed the Goal	122.33	150.00	179.00	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	4	4	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	10	4	4	4	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	2	0	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	16.67%	0.00%	0.00%	0.00%	

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

Table 8.2 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	10	4	4	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	10	4	3	1	
MDUFA Decision Within 150 FDA Days	10	4	3	1	
De Novos Pending MDUFA Decision	0	0	1	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.75	1.67	2.00	
Number With MDUFA Decision	10	4	3	1	
Average FDA Days to MDUFA Decision	137.10	149.75	119.33	147.00	
20th Percentile FDA Days to MDUFA Decision	140	150	95	147	
40th Percentile FDA Days to MDUFA Decision	150	150	130	147	
60th Percentile FDA Days to MDUFA Decision	150	150	148	147	
80th Percentile FDA Days to MDUFA Decision	150	150	149	147	
Maximum FDA Days to MDUFA Decision	150	150	150	147	
Average Industry Days to MDUFA Decision	114.40	114.50	118.67	36.00	
20th Percentile Industry Days to MDUFA Decision	47	61	83	36	
40th Percentile Industry Days to MDUFA Decision	90	116	98	36	
60th Percentile Industry Days to MDUFA Decision	178	162	120	36	
80th Percentile Industry Days to MDUFA Decision	180	178	151	36	
Maximum Industry Days to MDUFA Decision	183	180	182	36	
Average Total Days to MDUFA Decision	251.50	264.25	238.00	183.00	
20th Percentile Total Days to MDUFA Decision	197	210	228	183	
40th Percentile Total Days to MDUFA Decision	238	266	237	183	
60th Percentile Total Days to MDUFA Decision	267	312	244	183	
80th Percentile Total Days to MDUFA Decision	328	328	249	183	
Maximum Total Days to MDUFA Decision	329	330	253	183	

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	4	4	
Number With MDUFA Decision	10	4	3	1	
Number With Granted Decision	6	3	1	1	
Number With Declined Decision	3	1	1	0	
Number of Withdrawal	0	0	0	0	
Number of Deleted	1	0	1	0	
Rate of Granted Decision	60.00%	75.00%	33.33%	100.00%	
Rate of Declined Decision	30.00%	25.00%	33.33%	0.00%	
Rate of Withdrawal	0.00%	0.00%	0.00%	0.00%	
Rate of Deleted	10.00%	0.00%	33.33%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	12	5	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	9	7	11	4	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted or Failed TS on First Cycle	2	1	1	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	12.50%	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 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	11	8	12	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	11	8	8	0	
MDUFA Decision Within 150 FDA Days	11	8	8	0	
De Novos Pending MDUFA Decision	0	0	4	4	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	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	1.88	1.63	N/A	
Number With MDUFA Decision	11	8	8	0	
Average FDA Days to MDUFA Decision	128.45	131.50	121.13	N/A	
20th Percentile FDA Days to MDUFA Decision	74	114	74	0	
40th Percentile FDA Days to MDUFA Decision	148	143	134	0	
60th Percentile FDA Days to MDUFA Decision	150	148	149	0	
80th Percentile FDA Days to MDUFA Decision	150	149	150	0	
Maximum FDA Days to MDUFA Decision	150	150	150	0	
Average Industry Days to MDUFA Decision	122.73	160.50	165.75	N/A	
20th Percentile Industry Days to MDUFA Decision	83	156	146	0	
40th Percentile Industry Days to MDUFA Decision	124	179	173	0	
60th Percentile Industry Days to MDUFA Decision	163	180	180	0	
80th Percentile Industry Days to MDUFA Decision	180	182	183	0	
Maximum Industry Days to MDUFA Decision	214	183	184	0	
Average Total Days to MDUFA Decision	251.18	292.00	286.88	N/A	
20th Percentile Total Days to MDUFA Decision	231	264	255	0	
40th Percentile Total Days to MDUFA Decision	247	288	270	0	
60th Percentile Total Days to MDUFA Decision	274	324	293	0	
80th Percentile Total Days to MDUFA Decision	293	327	318	0	
Maximum Total Days to MDUFA Decision	330	329	334	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	12	4	
Number With MDUFA Decision	11	8	8	0	
Number With Granted Decision	7	2	3	0	
Number With Declined Decision	1	2	2	0	
Number of Withdrawal	1	3	1	0	
Number of Deleted	2	1	2	0	
Rate of Granted Decision	63.64%	25.00%	37.50%	N/A	
Rate of Declined Decision	9.09%	25.00%	25.00%	N/A	
Rate of Withdrawal	9.09%	37.50%	12.50%	N/A	
Rate of Deleted	18.18%	12.50%	25.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	7	
Closed Before First RTA or TS Action	1	0	0	0	
Number Accepted or Passed TS on First Cycle	11	11	5	7	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	9	3	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	21.43%	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 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	15	12	5	7	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	12	5	1	
MDUFA Decision Within 150 FDA Days	13	12	3	1	
De Novos Pending MDUFA Decision	0	0	0	6	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	86.67%	100.00%	60.00%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.50	1.80	1.00	
Number With MDUFA Decision	15	12	5	1	
Average FDA Days to MDUFA Decision	126.87	119.92	172.80	75.00	
20th Percentile FDA Days to MDUFA Decision	75	74	134	75	
40th Percentile FDA Days to MDUFA Decision	143	117	150	75	
60th Percentile FDA Days to MDUFA Decision	148	150	156	75	
80th Percentile FDA Days to MDUFA Decision	150	150	197	75	
Maximum FDA Days to MDUFA Decision	203	150	326	75	
Average Industry Days to MDUFA Decision	134.87	129.00	179.80	N/A	
20th Percentile Industry Days to MDUFA Decision	80	29	177	0	
40th Percentile Industry Days to MDUFA Decision	156	165	178	0	
60th Percentile Industry Days to MDUFA Decision	180	174	178	0	
80th Percentile Industry Days to MDUFA Decision	181	179	181	0	
Maximum Industry Days to MDUFA Decision	198	185	189	0	
Average Total Days to MDUFA Decision	261.73	248.92	352.60	75.00	
20th Percentile Total Days to MDUFA Decision	228	164	314	75	
40th Percentile Total Days to MDUFA Decision	254	247	328	75	
60th Percentile Total Days to MDUFA Decision	302	319	333	75	
80th Percentile Total Days to MDUFA Decision	329	326	373	75	
Maximum Total Days to MDUFA Decision	346	330	505	75	

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	5	7	
Number With MDUFA Decision	15	12	5	1	
Number With Granted Decision	7	7	4	0	
Number With Declined Decision	2	2	0	1	
Number of Withdrawal	5	2	0	0	
Number of Deleted	1	1	1	0	
Rate of Granted Decision	46.67%	58.33%	80.00%	0.00%	
Rate of Declined Decision	13.33%	16.67%	0.00%	100.00%	
Rate of Withdrawal	33.33%	16.67%	0.00%	0.00%	
Rate of Deleted	6.67%	8.33%	20.00%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	0	2	0	
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A	245.50	N/A	
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A	177.00	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	15	6	
Closed Before First RTA or TS Action	1	0	0	0	
Number Accepted or Passed TS on First Cycle	5	11	15	6	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	4	1	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	8.33%	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 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	9	12	15	6	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	9	12	13	0	
MDUFA Decision Within 150 FDA Days	9	12	12	0	
De Novos Pending MDUFA Decision	0	0	2	6	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	92.31%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.11	1.67	1.85	N/A	
Number With MDUFA Decision	9	12	13	0	
Average FDA Days to MDUFA Decision	141.44	118.92	140.46	N/A	
20th Percentile FDA Days to MDUFA Decision	149	76	147	0	
40th Percentile FDA Days to MDUFA Decision	150	109	150	0	
60th Percentile FDA Days to MDUFA Decision	150	148	150	0	
80th Percentile FDA Days to MDUFA Decision	150	150	150	0	
Maximum FDA Days to MDUFA Decision	150	150	179	0	
Average Industry Days to MDUFA Decision	145.56	110.58	117.92	N/A	
20th Percentile Industry Days to MDUFA Decision	112	6	41	0	
40th Percentile Industry Days to MDUFA Decision	154	111	75	0	
60th Percentile Industry Days to MDUFA Decision	172	176	154	0	
80th Percentile Industry Days to MDUFA Decision	182	179	183	0	
Maximum Industry Days to MDUFA Decision	231	183	306	0	
Average Total Days to MDUFA Decision	287.00	229.50	258.38	N/A	
20th Percentile Total Days to MDUFA Decision	237	105	190	0	
40th Percentile Total Days to MDUFA Decision	300	255	224	0	
60th Percentile Total Days to MDUFA Decision	313	263	260	0	
80th Percentile Total Days to MDUFA Decision	326	326	311	0	
Maximum Total Days to MDUFA Decision	381	328	485	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	12	15	6	
Number With MDUFA Decision	9	12	13	0	
Number With Granted Decision	3	3	9	0	
Number With Declined Decision	5	6	2	0	
Number of Withdrawal	0	1	0	0	
Number of Deleted	1	2	2	0	
Rate of Granted Decision	33.33%	25.00%	69.23%	N/A	
Rate of Declined Decision	55.56%	50.00%	15.38%	N/A	
Rate of Withdrawal	0.00%	8.33%	0.00%	N/A	
Rate of Deleted	11.11%	16.67%	15.38%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	1	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	179.00	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	306.00	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	6	5	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	3	2	5	5	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	0	0	1	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	0.00%	16.67%	0.00%	

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

Table 8.2 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	3	2	5	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	2	3	0	
MDUFA Decision Within 150 FDA Days	3	2	3	0	
De Novos Pending MDUFA Decision	0	0	2	5	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.50	1.33	N/A	
Number With MDUFA Decision	3	2	3	0	
Average FDA Days to MDUFA Decision	149.00	111.50	89.67	N/A	
20th Percentile FDA Days to MDUFA Decision	148	88	63	0	
40th Percentile FDA Days to MDUFA Decision	149	104	68	0	
60th Percentile FDA Days to MDUFA Decision	149	119	85	0	
80th Percentile FDA Days to MDUFA Decision	150	135	113	0	
Maximum FDA Days to MDUFA Decision	150	150	141	0	
Average Industry Days to MDUFA Decision	119.33	180.00	179.67	N/A	
20th Percentile Industry Days to MDUFA Decision	71	179	176	0	
40th Percentile Industry Days to MDUFA Decision	142	180	179	0	
60th Percentile Industry Days to MDUFA Decision	178	180	182	0	
80th Percentile Industry Days to MDUFA Decision	179	181	183	0	
Maximum Industry Days to MDUFA Decision	180	181	185	0	
Average Total Days to MDUFA Decision	268.33	291.50	269.33	N/A	
20th Percentile Total Days to MDUFA Decision	220	269	240	0	
40th Percentile Total Days to MDUFA Decision	292	284	243	0	
60th Percentile Total Days to MDUFA Decision	328	299	260	0	
80th Percentile Total Days to MDUFA Decision	329	314	293	0	
Maximum Total Days to MDUFA Decision	329	329	326	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	3	2	5	5	
Number With MDUFA Decision	3	2	3	0	
Number With Granted Decision	2	1	0	0	
Number With Declined Decision	1	0	1	0	
Number of Withdrawal	0	0	1	0	
Number of Deleted	0	1	1	0	
Rate of Granted Decision	66.67%	50.00%	0.00%	N/A	
Rate of Declined Decision	33.33%	0.00%	33.33%	N/A	
Rate of Withdrawal	0.00%	0.00%	33.33%	N/A	
Rate of Deleted	0.00%	50.00%	33.33%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	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	13	14	
Closed Before First RTA or TS Action	1	1	1	1	
Number Accepted or Passed TS on First Cycle	17	17	11	11	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	5	2	1	2	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	8.33%	15.38%	

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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	20	18	11	12	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	20	18	8	0	
MDUFA Decision Within 150 FDA Days	20	18	8	0	
De Novos Pending MDUFA Decision	0	0	3	12	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	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	1.63	N/A	
Number With MDUFA Decision	20	18	8	0	
Average FDA Days to MDUFA Decision	127.95	116.61	129.38	N/A	
20th Percentile FDA Days to MDUFA Decision	85	73	103	0	
40th Percentile FDA Days to MDUFA Decision	140	113	146	0	
60th Percentile FDA Days to MDUFA Decision	149	148	149	0	
80th Percentile FDA Days to MDUFA Decision	150	150	150	0	
Maximum FDA Days to MDUFA Decision	150	150	150	0	
Average Industry Days to MDUFA Decision	167.85	114.33	130.25	N/A	
20th Percentile Industry Days to MDUFA Decision	139	16	107	0	
40th Percentile Industry Days to MDUFA Decision	175	101	145	0	
60th Percentile Industry Days to MDUFA Decision	179	175	153	0	
80th Percentile Industry Days to MDUFA Decision	182	181	171	0	
Maximum Industry Days to MDUFA Decision	350	185	182	0	
Average Total Days to MDUFA Decision	295.80	230.94	259.63	N/A	
20th Percentile Total Days to MDUFA Decision	252	155	250	0	
40th Percentile Total Days to MDUFA Decision	299	235	256	0	
60th Percentile Total Days to MDUFA Decision	328	256	276	0	
80th Percentile Total Days to MDUFA Decision	330	322	301	0	
Maximum Total Days to MDUFA Decision	437	329	301	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	11	12	
Number With MDUFA Decision	20	18	8	0	
Number With Granted Decision	5	9	4	0	
Number With Declined Decision	5	2	1	0	
Number of Withdrawal	9	3	1	0	
Number of Deleted	1	4	2	0	
Rate of Granted Decision	25.00%	50.00%	50.00%	N/A	
Rate of Declined Decision	25.00%	11.11%	12.50%	N/A	
Rate of Withdrawal	45.00%	16.67%	12.50%	N/A	
Rate of Deleted	5.00%	22.22%	25.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	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	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Within 150 FDA Days	1	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	1	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	N/A	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	11	11	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	19	18	8	0	
MDUFA Decision Within 150 FDA Days	19	18	8	0	
De Novos Pending MDUFA Decision	0	0	3	11	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	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	4	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	4	4	3	3	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	0	1	0	1	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	20.00%	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 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	4	4	3	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	4	3	0	
MDUFA Decision Within 150 FDA Days	4	4	3	0	
De Novos Pending MDUFA Decision	0	0	0	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	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	1.67	N/A	
Number With MDUFA Decision	4	4	3	0	
Average FDA Days to MDUFA Decision	108.75	117.75	123.33	N/A	
20th Percentile FDA Days to MDUFA Decision	70	95	102	0	
40th Percentile FDA Days to MDUFA Decision	89	115	133	0	
60th Percentile FDA Days to MDUFA Decision	133	133	149	0	
80th Percentile FDA Days to MDUFA Decision	149	143	150	0	
Maximum FDA Days to MDUFA Decision	150	149	150	0	
Average Industry Days to MDUFA Decision	130.50	118.50	177.33	N/A	
20th Percentile Industry Days to MDUFA Decision	83	70	175	0	
40th Percentile Industry Days to MDUFA Decision	132	129	176	0	
60th Percentile Industry Days to MDUFA Decision	169	164	177	0	
80th Percentile Industry Days to MDUFA Decision	186	178	179	0	
Maximum Industry Days to MDUFA Decision	193	181	181	0	
Average Total Days to MDUFA Decision	239.25	236.25	300.67	N/A	
20th Percentile Total Days to MDUFA Decision	190	197	278	0	
40th Percentile Total Days to MDUFA Decision	258	257	309	0	
60th Percentile Total Days to MDUFA Decision	265	264	325	0	
80th Percentile Total Days to MDUFA Decision	297	286	328	0	
Maximum Total Days to MDUFA Decision	343	315	331	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	3	
Number With MDUFA Decision	4	4	3	0	
Number With Granted Decision	2	1	2	0	
Number With Declined Decision	0	1	0	0	
Number of Withdrawal	1	1	1	0	
Number of Deleted	1	1	0	0	
Rate of Granted Decision	50.00%	25.00%	66.67%	N/A	
Rate of Declined Decision	0.00%	25.00%	0.00%	N/A	
Rate of Withdrawal	25.00%	25.00%	33.33%	N/A	
Rate of Deleted	25.00%	25.00%	0.00%	N/A	

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

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

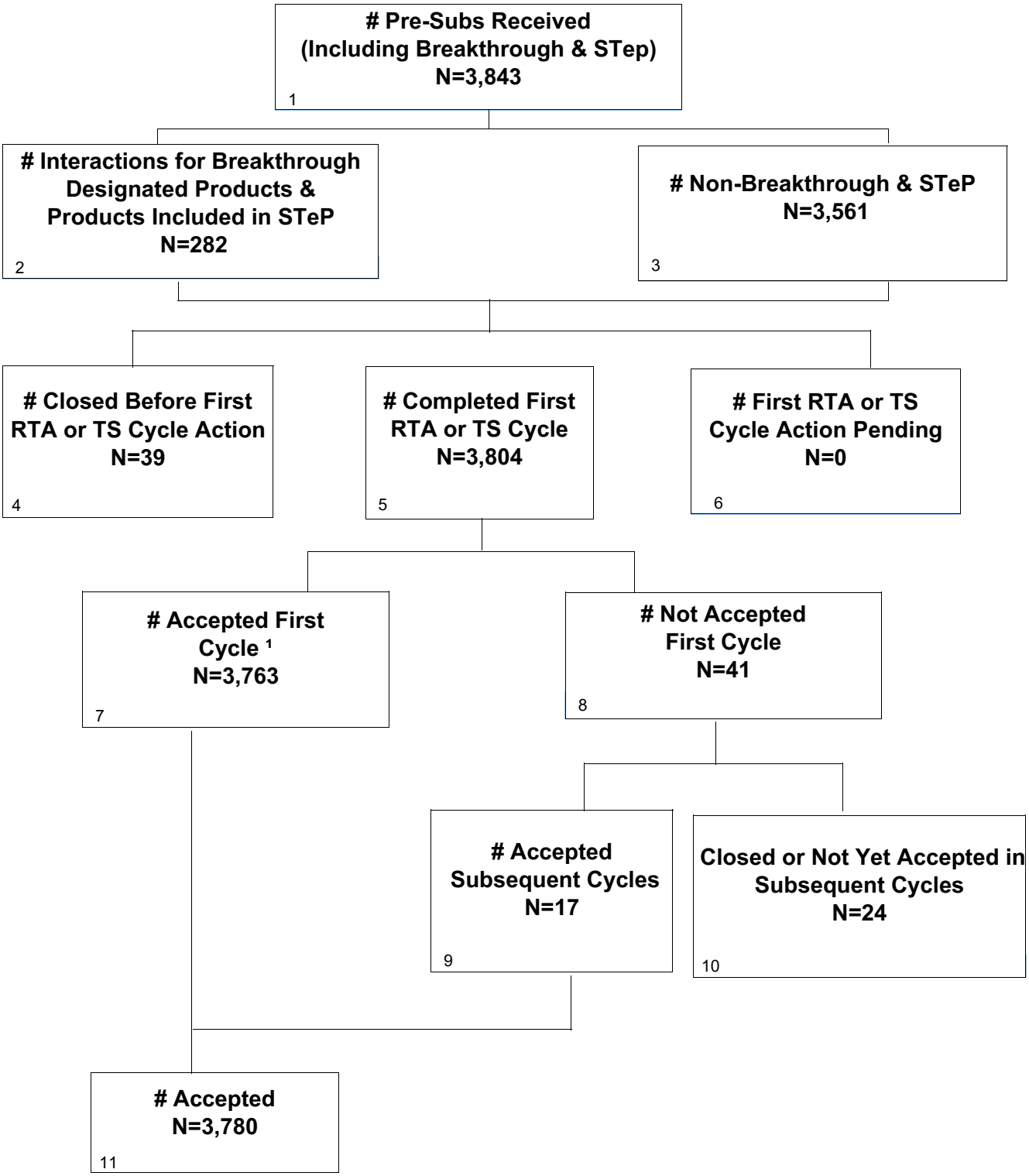
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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

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

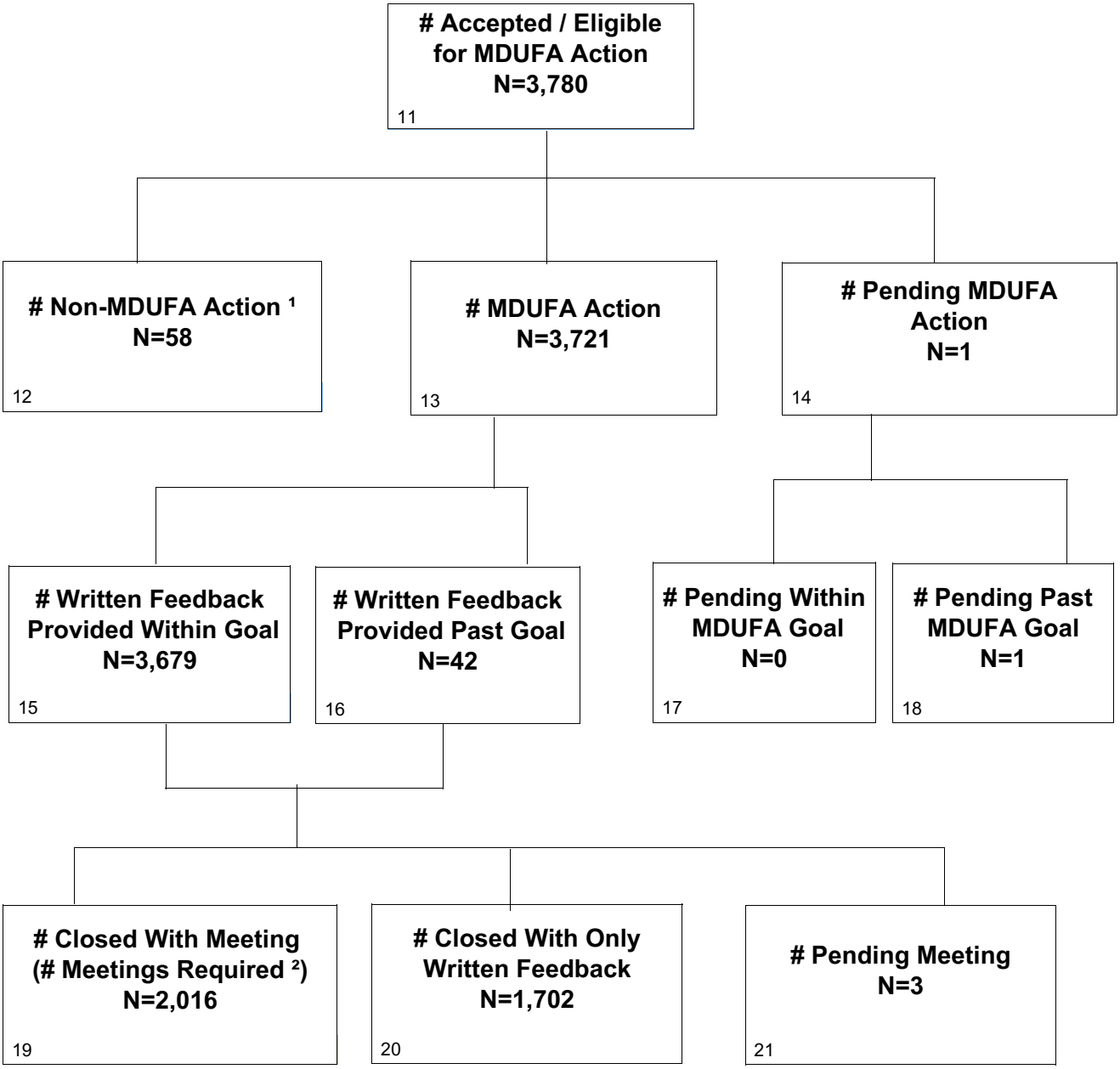
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150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

CDRH Pre-Sub - FY 2023
as of 6/30/26



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.

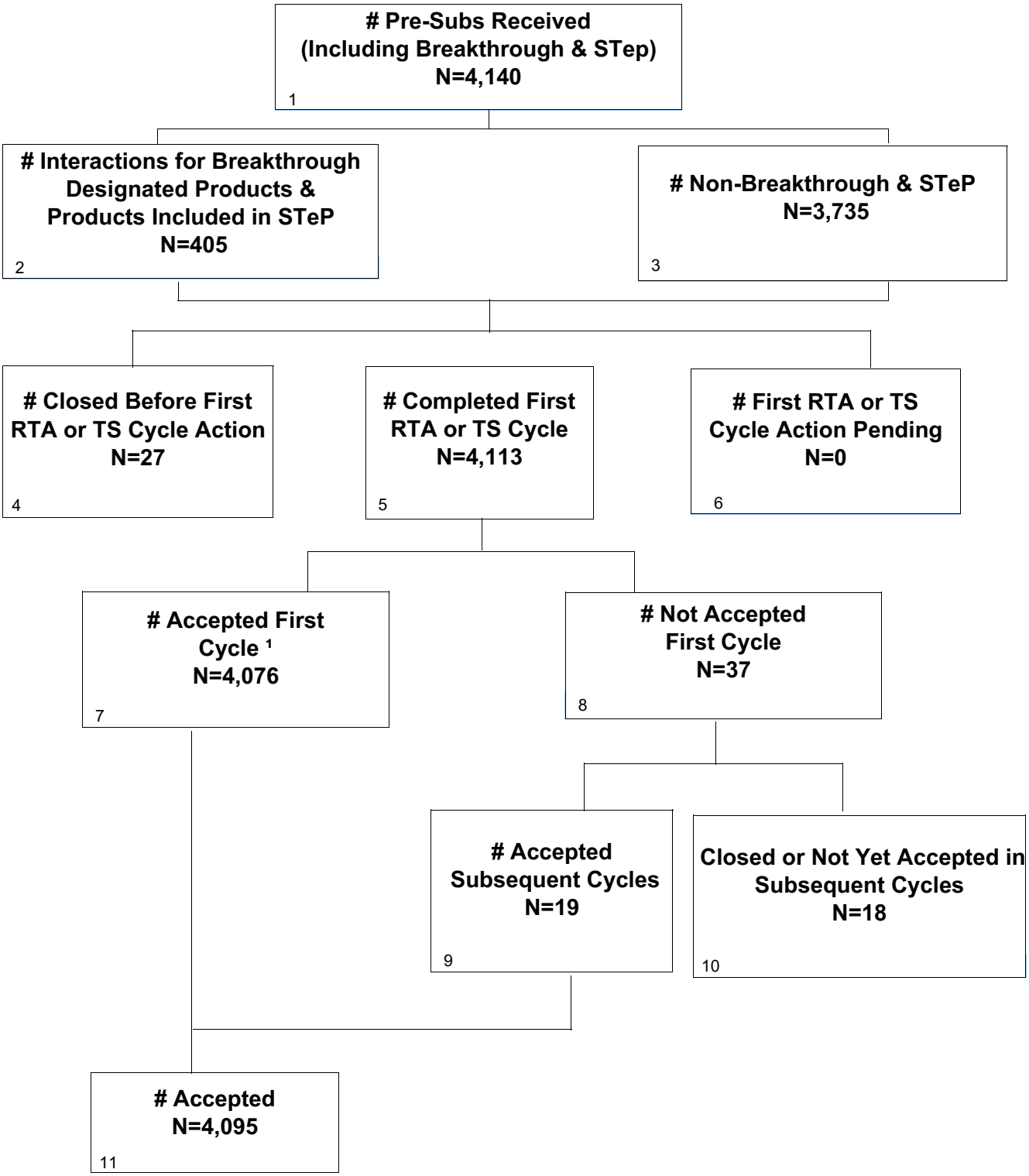
CDRH Pre-Sub - FY 2023
as of 6/30/26 Continued



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.

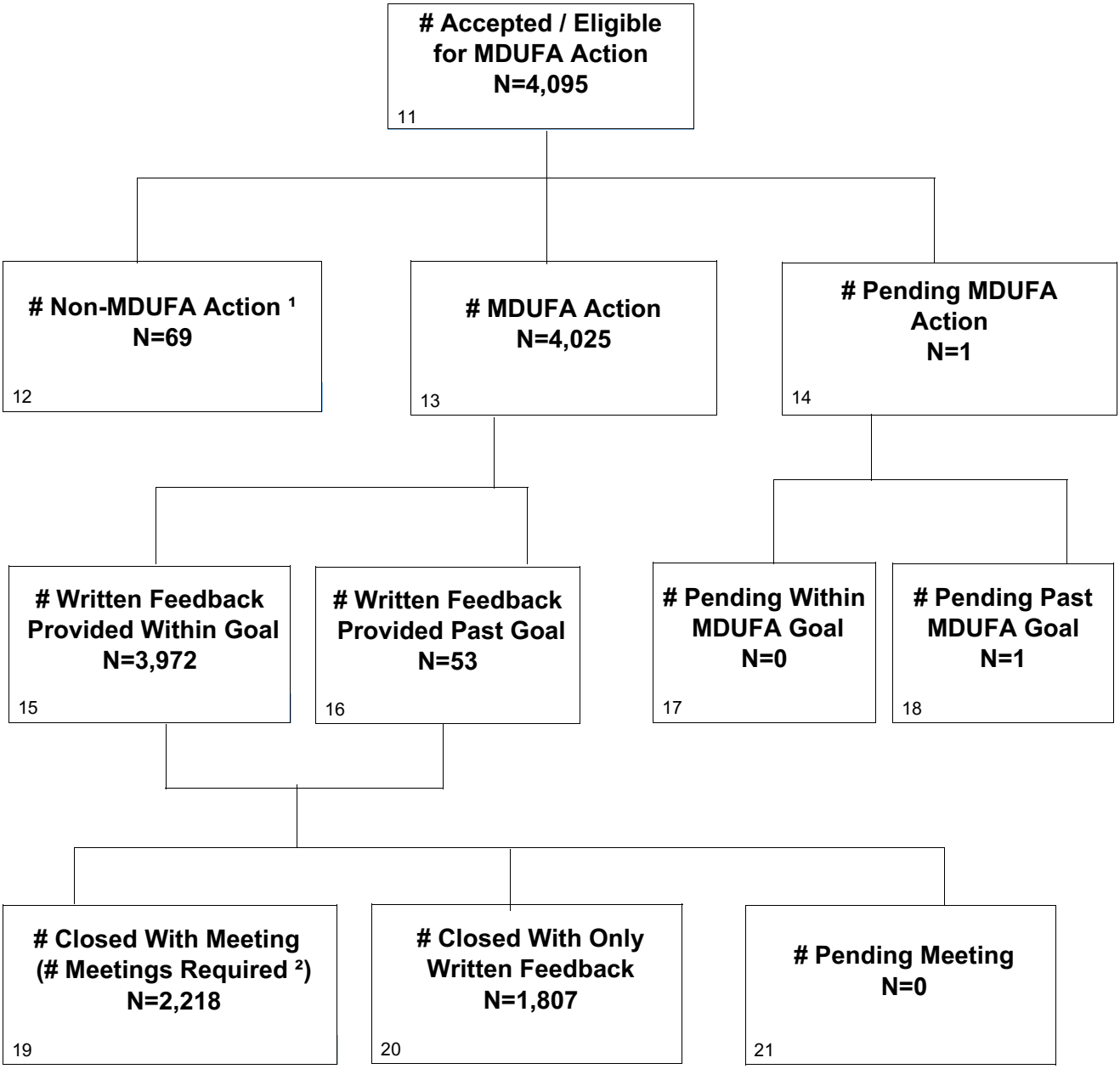
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 6/30/26



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.

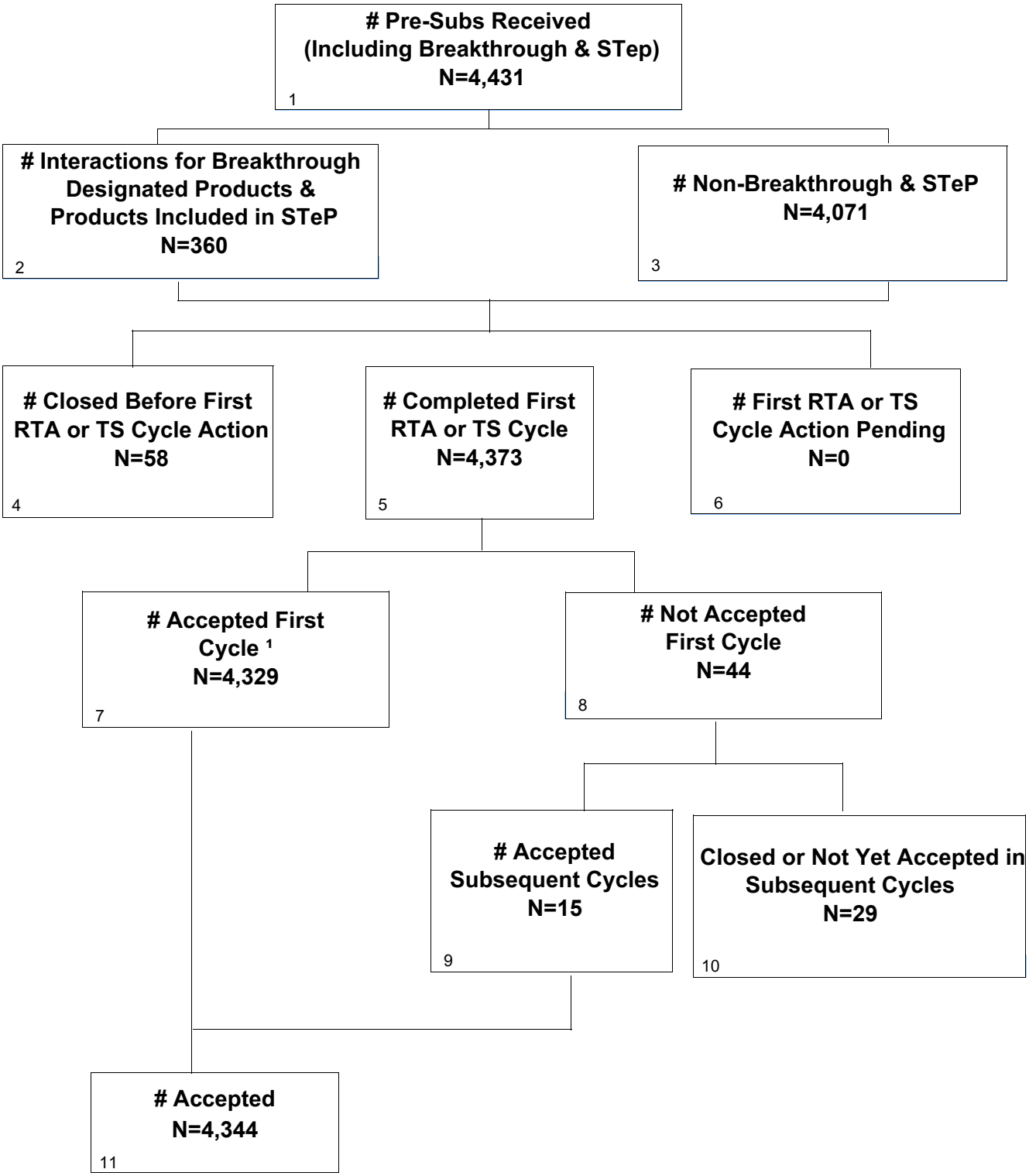
CDRH Pre-Sub - FY 2024 as of 6/30/26 Continued



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.

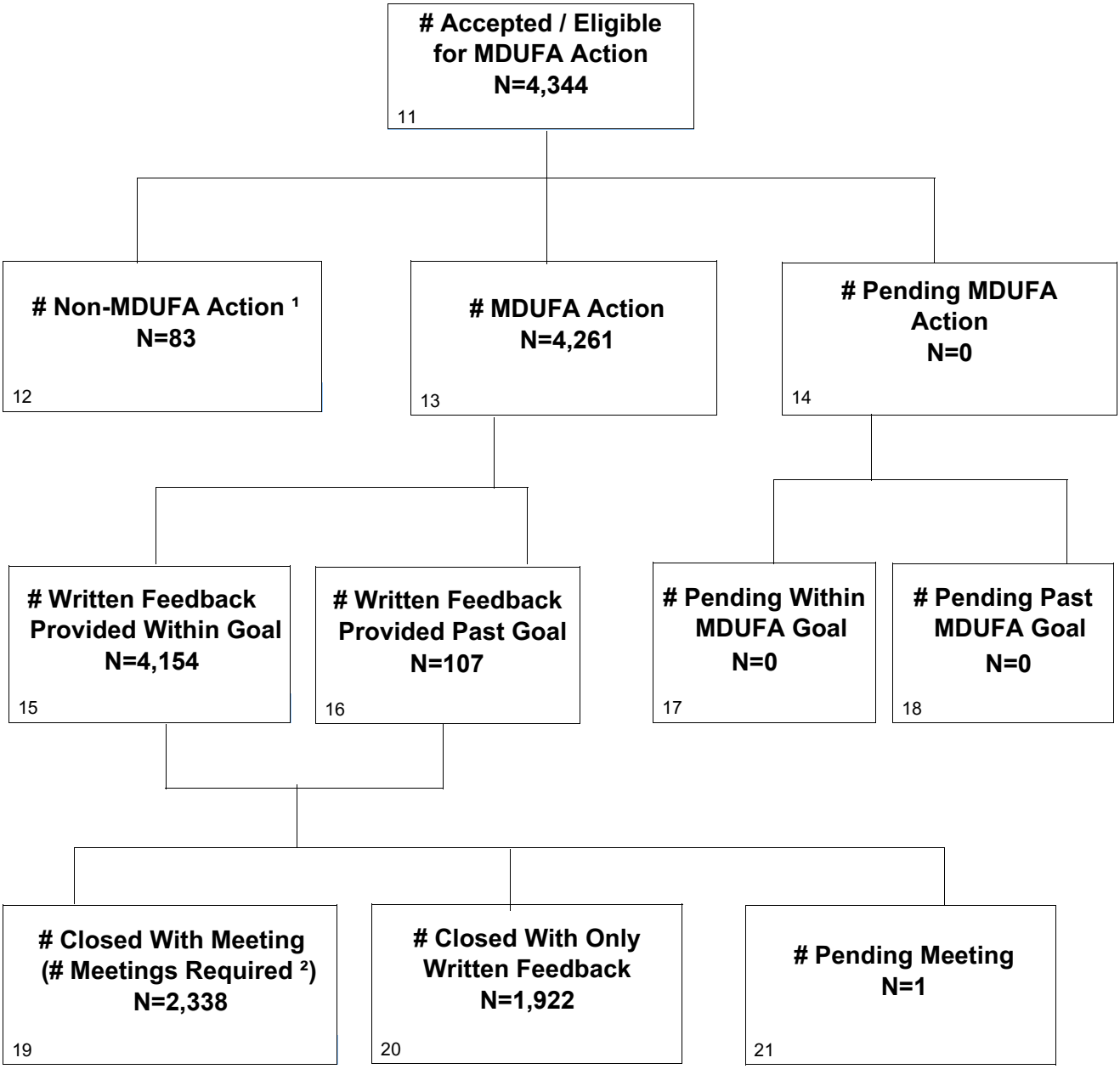
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2025
as of 6/30/26



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.

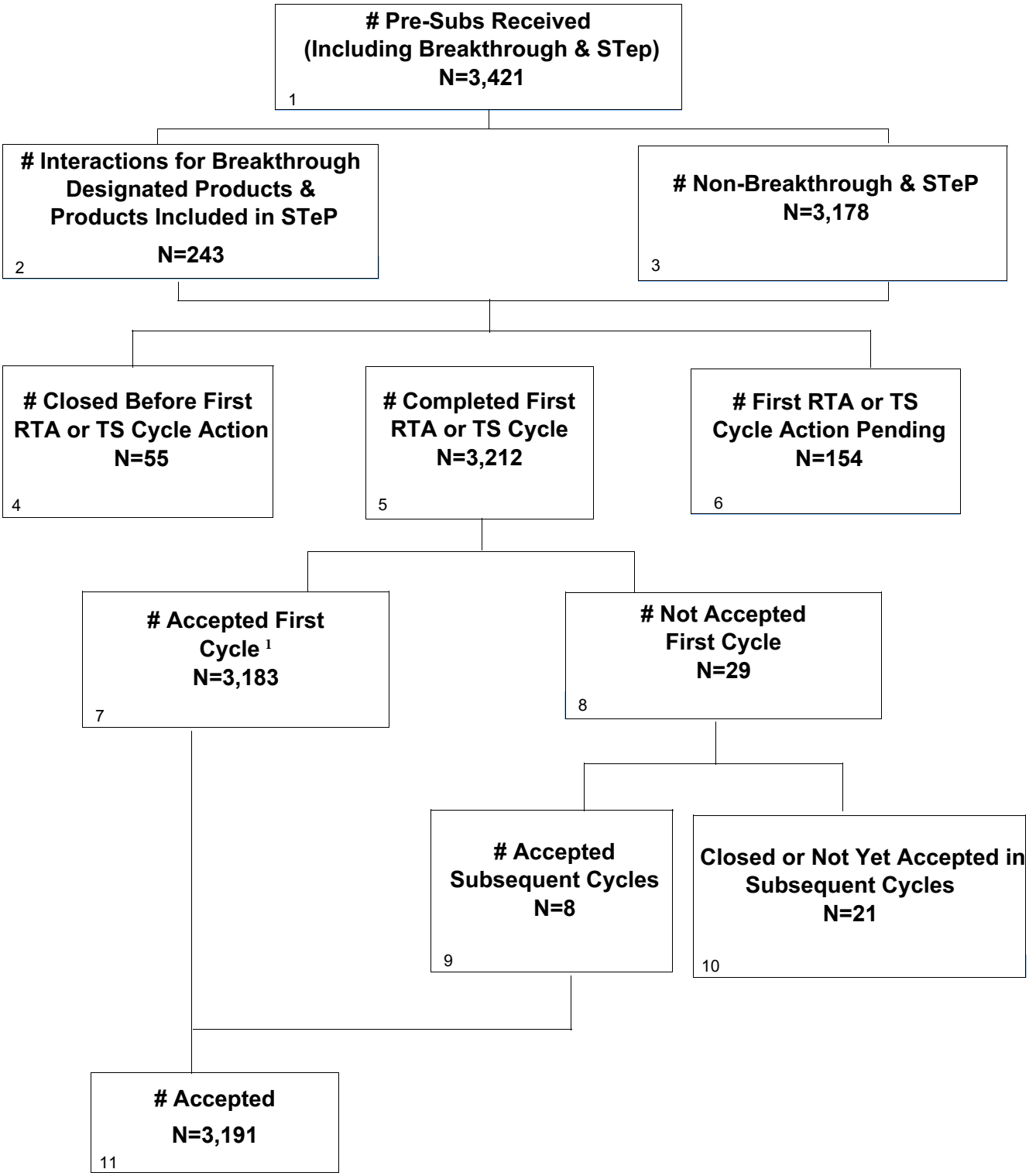
CDRH Pre-Sub - FY 2025 as of 6/30/26 Continued



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.

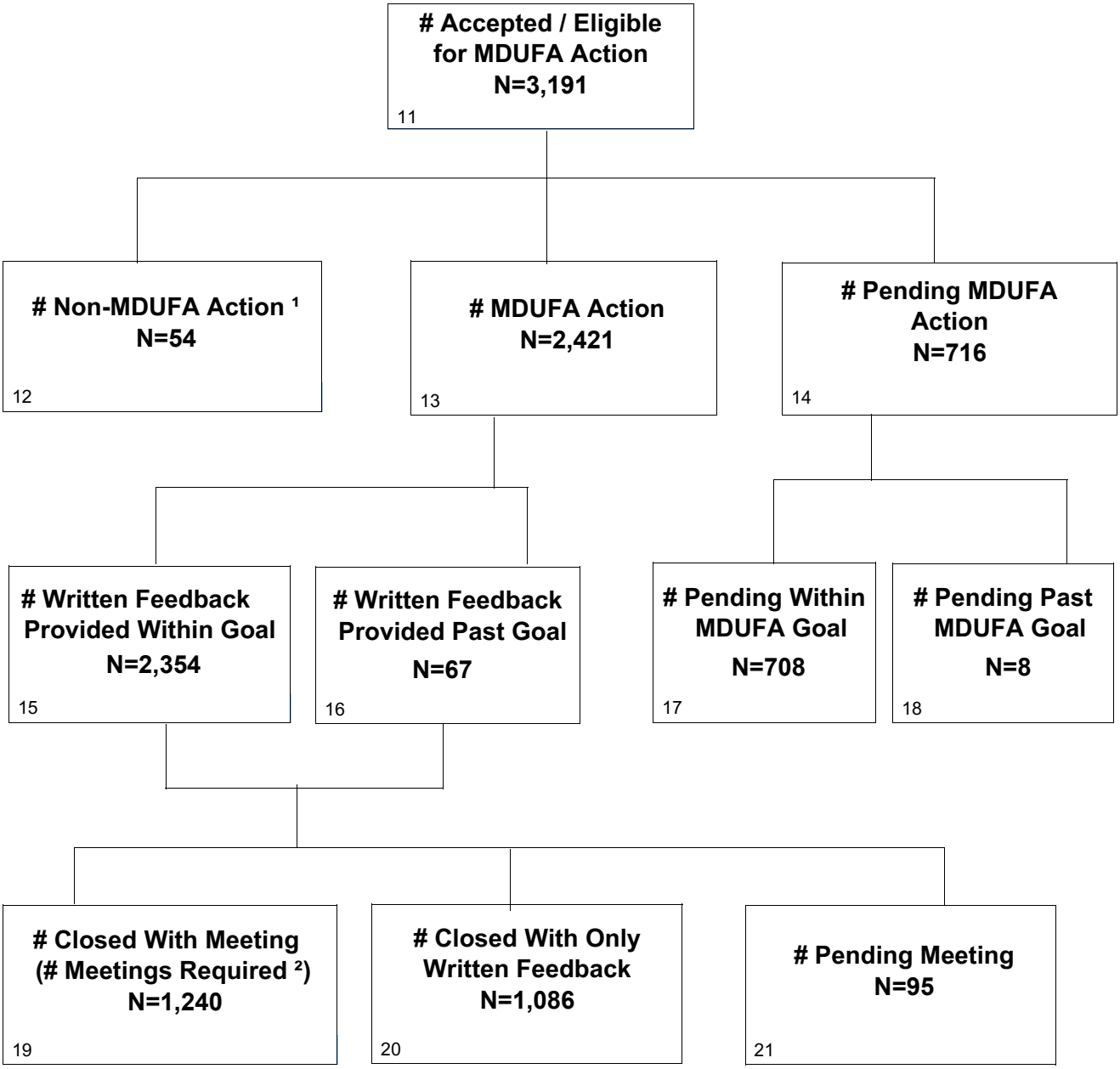
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2026
as of 6/30/26



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 2026 as of 6/30/26 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	4,431	3,421	
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	360	243	
Number Closed Before First RTA Action	39	27	58	55	
Number Accepted First RTA Cycle [1]	3,642	3,979	4,175	3,080	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	97	154	103	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	154	
Number Not Accepted First RTA Cycle	41	37	44	29	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	1.01%	0.90%	

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	4,344	3,191	
Number with Non-MDUFA Action [3]	58	69	83	54	
Number with MDUFA Action	3,721	4,025	4,261	2,421	
Written Feedback Provided Within Goal	3,679	3,972	4,154	2,354	
Number Pending MDUFA Action	1	1	0	716	
Pending MDUFA Action Past Goal	1	1	0	8	
Number in MDUFA Cohort (up to max 4300)[4]	3,722	4,026	4,261	3,137	
Current Performance Percent Within Goal	98.84%	98.66%	97.49%	96.91%	

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	4,261	2,421	
Average FDA Days to Written Feedback	62.20	62.25	61.89	61.74	
20th Percentile FDA Days to Written Feedback	56	56	56	55	
40th Percentile FDA Days to Written Feedback	64	64	64	64	
60th Percentile FDA Days to Written Feedback	68	67	67	68	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	141	245	307	157	

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	153	130	
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	40.50	40.06	

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	2,218	2,338	1,240	
Meeting Minutes Submitted Within 15 Days of Meeting	1,531	1,787	1,888	940	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	69	
Meeting Minutes Past 15 Days of Meeting	434	369	380	173	
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	62	70	58	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.98%	80.57%	80.75%	80.27%	

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	443	491	523	388	
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	23	17	
Number Closed Before First RTA Action	4	6	10	10	
Number Accepted First RTA Cycle [1]	410	460	491	346	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	20	10	13	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	16	
Number Not Accepted First RTA Cycle	9	5	12	3	
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.34%	0.83%	

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	434	484	507	359	
Number with Non-MDUFA Action [3]	12	12	15	8	
Number with MDUFA Action	422	472	492	256	
Written Feedback Provided Within Goal	409	459	473	245	
Number Pending MDUFA Action	0	0	0	95	
Pending MDUFA Action Past Goal	0	0	0	1	
Number in MDUFA Cohort (up to max 4300)[4]	422	472	492	351	
Current Performance Percent Within Goal	96.92%	97.25%	96.14%	95.33%	

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	422	472	492	256	
Average FDA Days to Written Feedback	65.35	65.26	65.23	65.48	
20th Percentile FDA Days to Written Feedback	62	62	62	63	
40th Percentile FDA Days to Written Feedback	66	66	66	67	
60th Percentile FDA Days to Written Feedback	69	69	69	69	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	141	101	107	102	

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	21	10	
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	41.57	46.40	

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]	248	274	283	138	
Meeting Minutes Submitted Within 15 Days of Meeting	178	225	227	105	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	4	
Meeting Minutes Past 15 Days of Meeting	59	40	42	22	
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	9	14	7	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.77%	82.12%	80.21%	78.36%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	724	745	800	585	
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	78	46	
Number Closed Before First RTA Action	6	2	3	9	
Number Accepted First RTA Cycle [1]	701	726	760	535	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	14	36	13	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	23	
Number Not Accepted First RTA Cycle	4	3	1	5	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.13%	0.90%	

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

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

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

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	717	741	796	550	
Number with Non-MDUFA Action [3]	4	4	4	2	
Number with MDUFA Action	712	736	792	425	
Written Feedback Provided Within Goal	697	715	752	391	
Number Pending MDUFA Action	1	1	0	123	
Pending MDUFA Action Past Goal	1	1	0	3	
Number in MDUFA Cohort (up to max 4300)[4]	713	737	792	548	
Current Performance Percent Within Goal	97.76%	97.01%	94.95%	91.36%	

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

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

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

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

Table 9.3 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	712	736	792	425	
Average FDA Days to Written Feedback	59.32	59.61	61.60	63.42	
20th Percentile FDA Days to Written Feedback	50	51	55	57	
40th Percentile FDA Days to Written Feedback	60	61	63	65	
60th Percentile FDA Days to Written Feedback	66	65	67	68	
80th Percentile FDA Days to Written Feedback	69	69	70	70	
Maximum FDA Days to Written Feedback	103	113	119	157	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	33	21	39	39	
Average Days to Scheduling for Meetings Scheduled After Day 30	38.09	36.90	39.38	38.59	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	406	423	430	225	
Meeting Minutes Submitted Within 15 Days of Meeting	308	317	315	165	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	14	
Meeting Minutes Past 15 Days of Meeting	91	90	99	37	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	16	16	9	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.86%	74.94%	73.26%	78.20%	

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	510	561	495	
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	54	41	
Number Closed Before First RTA Action	5	4	10	6	
Number Accepted First RTA Cycle [1]	438	484	522	449	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	11	15	8	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	20	
Number Not Accepted First RTA Cycle	6	11	14	12	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.17%	2.54%	2.56%	

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	499	541	459	
Number with Non-MDUFA Action [3]	10	11	8	8	
Number with MDUFA Action	443	488	533	334	
Written Feedback Provided Within Goal	439	485	527	330	
Number Pending MDUFA Action	0	0	0	117	
Pending MDUFA Action Past Goal	0	0	0	1	
Number in MDUFA Cohort (up to max 4300)[4]	443	488	533	451	
Current Performance Percent Within Goal	99.10%	99.39%	98.87%	98.51%	

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

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

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

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

Table 9.3 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	488	533	334	
Average FDA Days to Written Feedback	62.13	61.74	61.44	63.53	
20th Percentile FDA Days to Written Feedback	56	56	56	59	
40th Percentile FDA Days to Written Feedback	64	63	63	65	
60th Percentile FDA Days to Written Feedback	67	67	67	69	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	78	78	79	104	

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	12	12	15	3	
Average Days to Scheduling for Meetings Scheduled After Day 30	42.67	43.50	39.93	47.00	

Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	254	268	295	169	
Meeting Minutes Submitted Within 15 Days of Meeting	200	222	245	129	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	12	
Meeting Minutes Past 15 Days of Meeting	48	39	41	20	
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	7	9	8	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.74%	82.84%	83.05%	82.17%	

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	376	462	530	420	
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	32	22	
Number Closed Before First RTA Action	4	5	13	15	
Number Accepted First RTA Cycle [1]	356	435	482	373	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	14	32	18	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	13	
Number Not Accepted First RTA Cycle	7	8	3	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.88%	1.75%	0.58%	0.26%	

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

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

Table 9.2 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	368	454	516	392	
Number with Non-MDUFA Action [3]	11	18	18	16	
Number with MDUFA Action	357	436	498	291	
Written Feedback Provided Within Goal	357	434	480	285	
Number Pending MDUFA Action	0	0	0	85	
Pending MDUFA Action Past Goal	0	0	0	1	
Number in MDUFA Cohort (up to max 4300)[4]	357	436	498	376	
Current Performance Percent Within Goal	100.00%	99.54%	96.39%	97.60%	

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	357	436	498	291	
Average FDA Days to Written Feedback	60.46	61.99	60.44	60.86	
20th Percentile FDA Days to Written Feedback	54	56	54	54	
40th Percentile FDA Days to Written Feedback	62	63	63	63	
60th Percentile FDA Days to Written Feedback	65	67	67	67	
80th Percentile FDA Days to Written Feedback	69	70	70	70	
Maximum FDA Days to Written Feedback	70	70	141	73	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	14	15	15	26	
Average Days to Scheduling for Meetings Scheduled After Day 30	37.71	40.00	41.73	36.35	

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]	203	233	280	163	
Meeting Minutes Submitted Within 15 Days of Meeting	156	183	222	117	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	6	
Meeting Minutes Past 15 Days of Meeting	39	46	47	29	
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	4	11	11	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.85%	78.54%	79.29%	74.52%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	397	429	468	426	
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	37	37	
Number Closed Before First RTA Action	5	3	2	4	
Number Accepted First RTA Cycle [1]	371	407	433	370	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	10	23	28	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	19	
Number Not Accepted First RTA Cycle	4	9	10	5	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.11%	2.15%	1.24%	

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

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

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

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	390	422	458	400	
Number with Non-MDUFA Action [3]	5	5	11	9	
Number with MDUFA Action	385	417	447	309	
Written Feedback Provided Within Goal	383	409	427	303	
Number Pending MDUFA Action	0	0	0	82	
Pending MDUFA Action Past Goal	0	0	0	2	
Number in MDUFA Cohort (up to max 4300)[4]	385	417	447	391	
Current Performance Percent Within Goal	99.48%	98.08%	95.53%	97.43%	

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	385	417	447	309	
Average FDA Days to Written Feedback	66.14	67.22	67.05	64.95	
20th Percentile FDA Days to Written Feedback	64	65	63	63	
40th Percentile FDA Days to Written Feedback	68	69	69	68	
60th Percentile FDA Days to Written Feedback	70	70	70	70	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	108	245	307	82	

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	26	39	36	43	
Average Days to Scheduling for Meetings Scheduled After Day 30	39.04	39.26	39.00	41.65	

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]	250	261	275	158	
Meeting Minutes Submitted Within 15 Days of Meeting	178	208	213	117	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	12	
Meeting Minutes Past 15 Days of Meeting	65	45	53	18	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	8	9	11	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.20%	79.69%	77.45%	80.14%	

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	291	294	300	227	
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	57	30	
Number Closed Before First RTA Action	5	1	2	1	
Number Accepted First RTA Cycle [1]	272	286	289	204	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	7	7	6	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	15	
Number Not Accepted First RTA Cycle	4	0	2	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.40%	0.00%	0.67%	0.47%	

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	284	293	297	211	
Number with Non-MDUFA Action [3]	6	8	11	3	
Number with MDUFA Action	278	285	286	161	
Written Feedback Provided Within Goal	274	280	286	159	
Number Pending MDUFA Action	0	0	0	47	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	278	285	286	208	
Current Performance Percent Within Goal	98.56%	98.25%	100.00%	98.76%	

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	278	285	286	161	
Average FDA Days to Written Feedback	58.51	56.93	58.61	58.02	
20th Percentile FDA Days to Written Feedback	45	43	45	44	
40th Percentile FDA Days to Written Feedback	58	57	60	61	
60th Percentile FDA Days to Written Feedback	65	64	65	65	
80th Percentile FDA Days to Written Feedback	69	68	69	69	
Maximum FDA Days to Written Feedback	97	92	70	76	

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	5	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	39.40	31.00	

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]	126	129	140	74	
Meeting Minutes Submitted Within 15 Days of Meeting	93	103	118	56	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	29	17	20	12	
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	9	2	5	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.81%	79.84%	84.29%	76.71%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	881	922	909	611	
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	67	43	
Number Closed Before First RTA Action	9	5	15	7	
Number Accepted First RTA Cycle [1]	834	901	866	565	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	15	28	12	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	26	
Number Not Accepted First RTA Cycle	3	1	0	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%	0.00%	0.17%	

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	869	916	894	577	
Number with Non-MDUFA Action [3]	7	11	9	6	
Number with MDUFA Action	862	905	885	461	
Written Feedback Provided Within Goal	858	904	883	458	
Number Pending MDUFA Action	0	0	0	110	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	862	905	885	571	
Current Performance Percent Within Goal	99.54%	99.89%	99.77%	99.35%	

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	862	905	885	461	
Average FDA Days to Written Feedback	63.70	63.10	60.23	56.48	
20th Percentile FDA Days to Written Feedback	60	59	54	45	
40th Percentile FDA Days to Written Feedback	66	65	63	58	
60th Percentile FDA Days to Written Feedback	69	68	66	65	
80th Percentile FDA Days to Written Feedback	70	70	69	69	
Maximum FDA Days to Written Feedback	75	71	89	71	

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	20	7	
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	42.05	42.00	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	321	415	421	197	
Meeting Minutes Submitted Within 15 Days of Meeting	258	355	360	161	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	12	
Meeting Minutes Past 15 Days of Meeting	59	54	53	19	
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6	8	5	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.37%	85.54%	85.51%	87.03%	

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	270	287	340	269	
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	12	7	
Number Closed Before First RTA Action	1	1	3	3	
Number Accepted First RTA Cycle [1]	260	280	332	238	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	6	3	5	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	22	
Number Not Accepted First RTA Cycle	4	0	2	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.49%	0.00%	0.59%	0.41%	

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

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

Table 9.2 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	265	286	335	243	
Number with Non-MDUFA Action [3]	3	0	7	2	
Number with MDUFA Action	262	286	328	184	
Written Feedback Provided Within Goal	262	286	326	183	
Number Pending MDUFA Action	0	0	0	57	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	262	286	328	241	
Current Performance Percent Within Goal	100.00%	100.00%	99.39%	99.46%	

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	262	286	328	184	
Average FDA Days to Written Feedback	60.58	60.70	60.74	61.83	
20th Percentile FDA Days to Written Feedback	55	55	55	56	
40th Percentile FDA Days to Written Feedback	60	62	62	63	
60th Percentile FDA Days to Written Feedback	64	65	65	66	
80th Percentile FDA Days to Written Feedback	67	69	69	69	
Maximum FDA Days to Written Feedback	70	70	85	71	

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

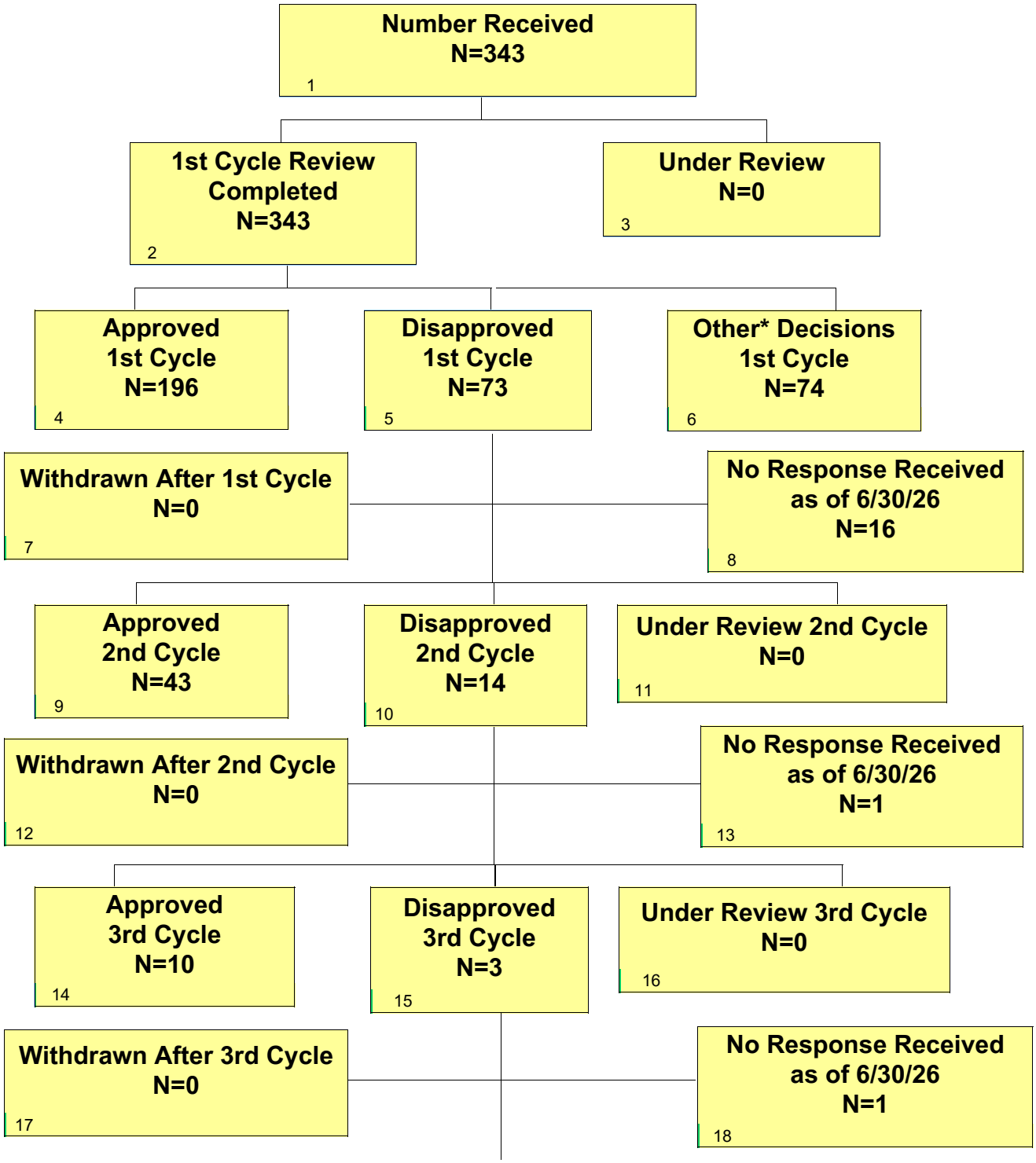
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4	2	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	60.50	37.00	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	207	215	214	116	
Meeting Minutes Submitted Within 15 Days of Meeting	160	174	188	90	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	8	
Meeting Minutes Past 15 Days of Meeting	44	38	25	16	
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3	1	2	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.29%	80.93%	87.85%	83.33%	

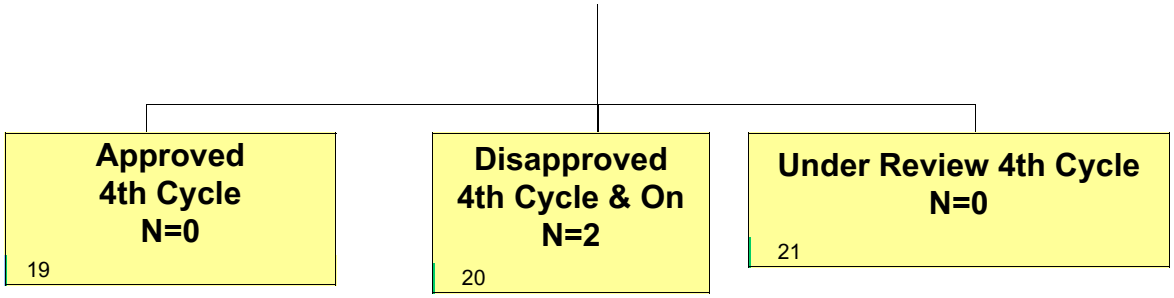
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 6/30/26

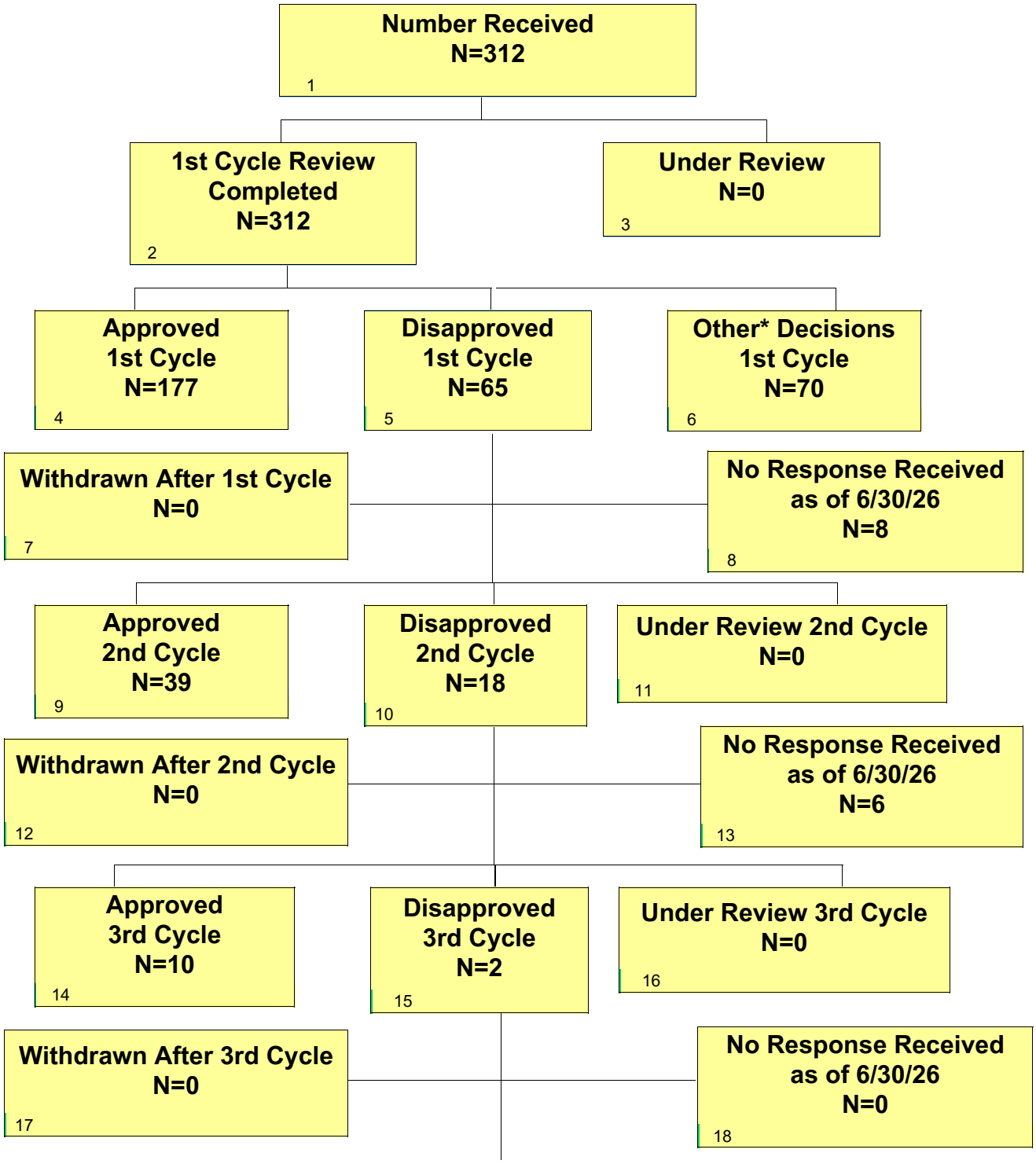


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 6/30/26

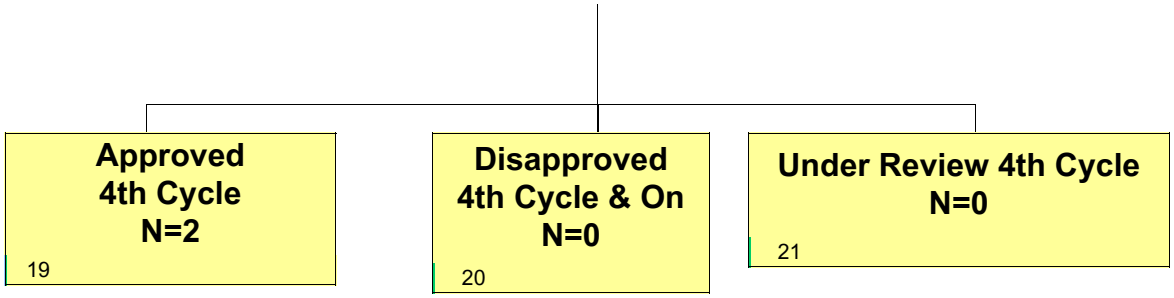


CDRH IDEs - FY 2024
as of 6/30/26

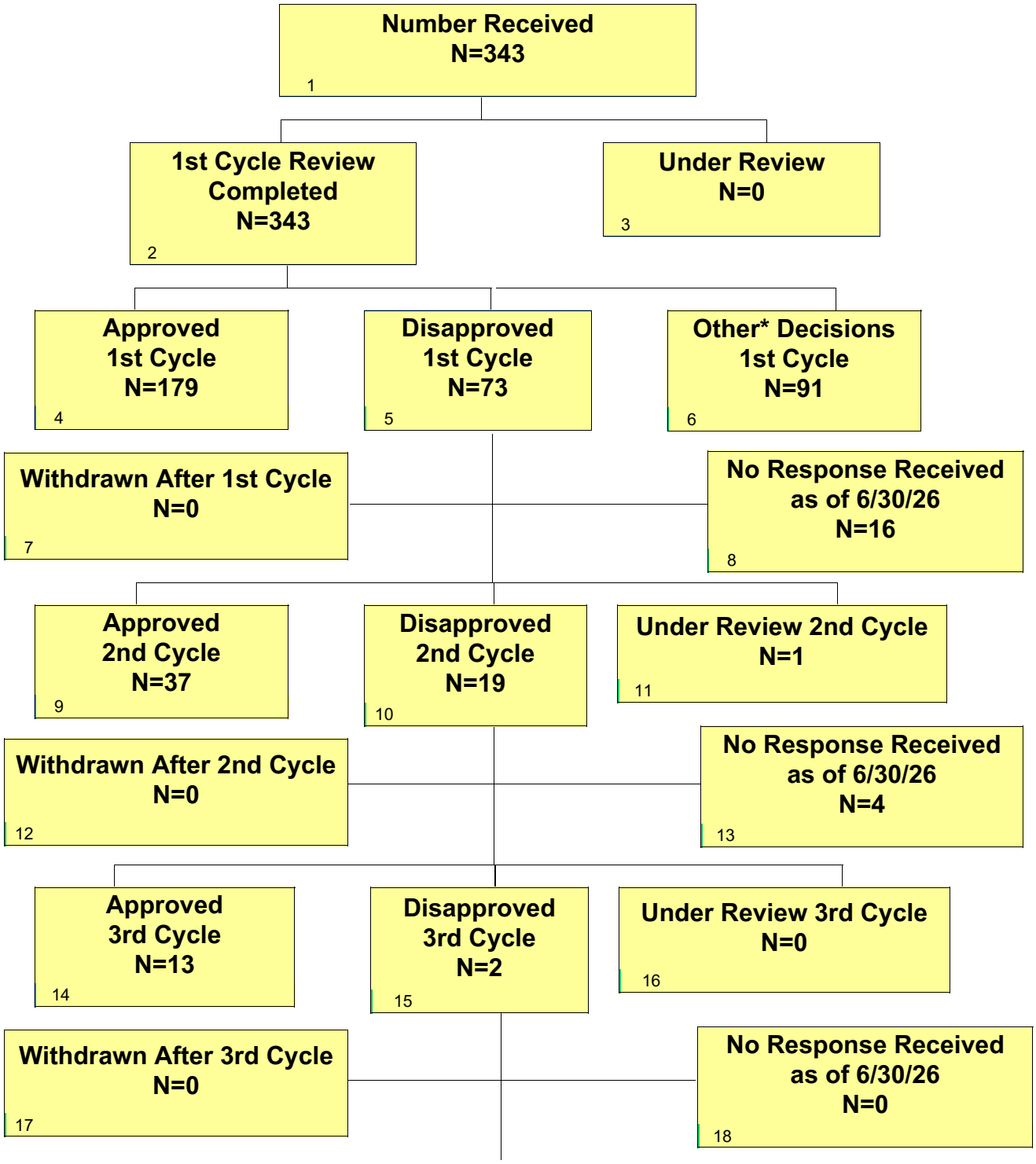


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 6/30/26

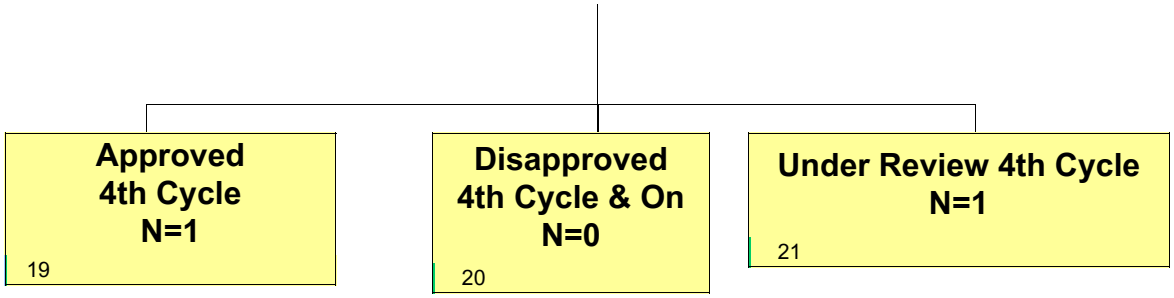


CDRH IDEs - FY 2025
as of 6/30/26

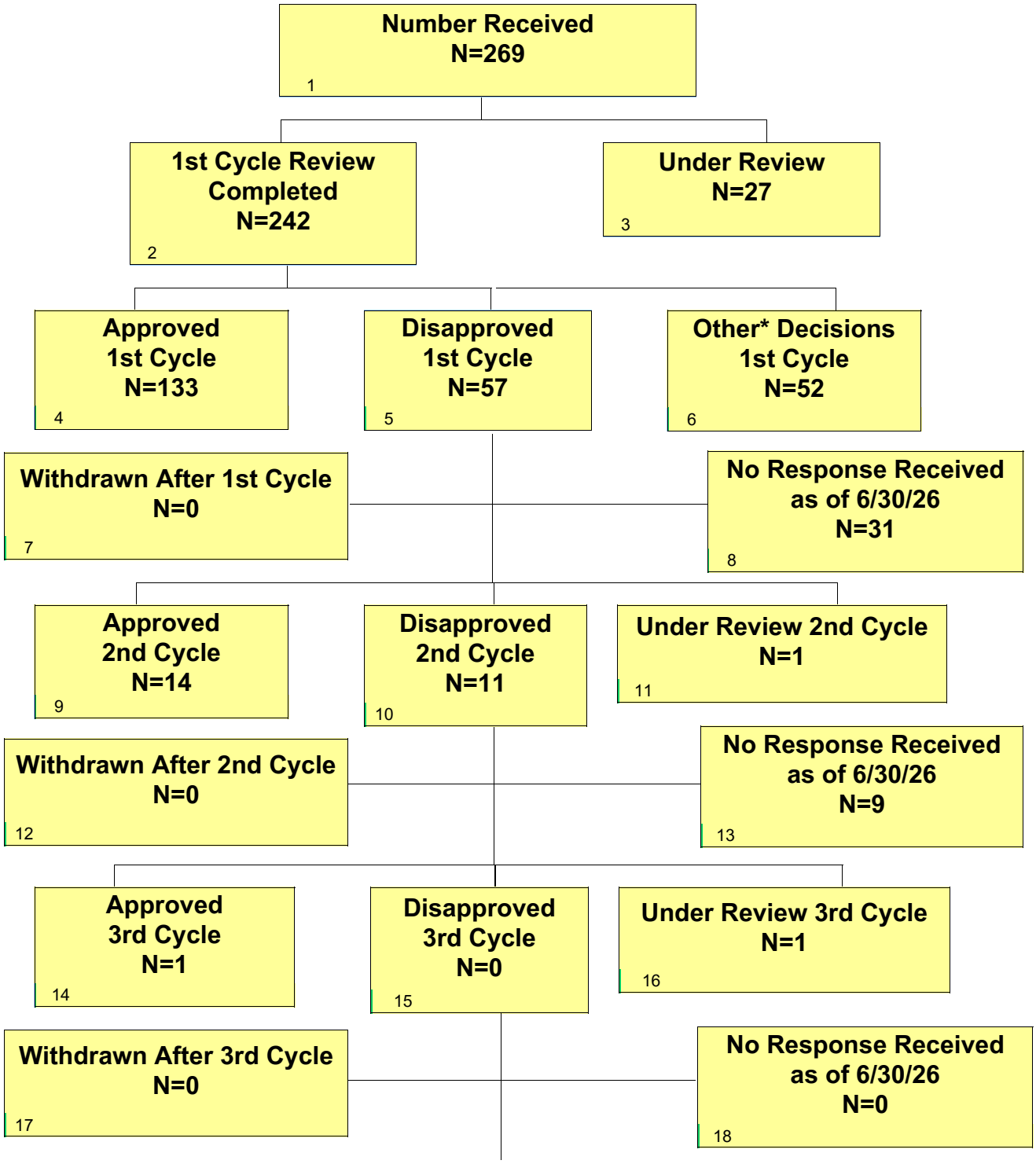


*** Other decisions include withdrawn (N=13), withdrawn and converted (N=46), RTA (N=0), nonsignificant risk device (N=24), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=7), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2025
as of 6/30/26

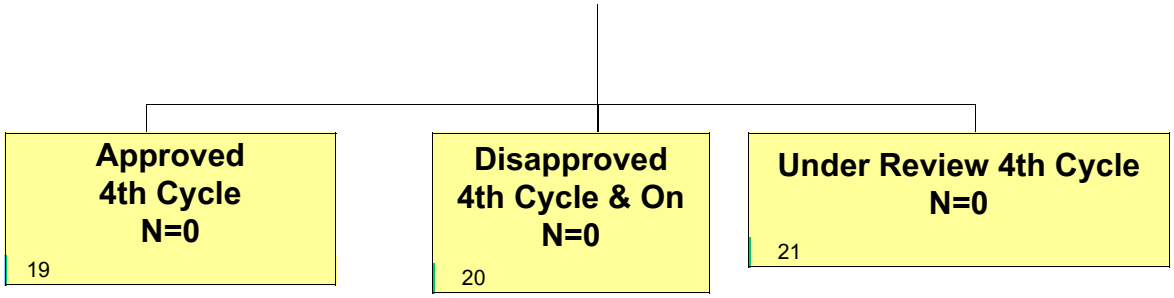


CDRH IDEs - FY 2026
as of 6/30/26



*** Other decisions include withdrawn (N=11), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=8), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2026
as of 6/30/26



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343	312	343	269	
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.29	1.29	1.11	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.29	0.29	0.11	

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	25	25	
Average Number of Cycles to IDE Approval or Conditional Approval	1.39	1.21	1.63	1.11	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.39	0.21	0.63	0.11	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	82	69	66	
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.40	1.44	1.33	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.40	0.44	0.33	

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	45	32	
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.31	1.19	1.16	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.31	0.19	0.16	

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	44	24	
Average Number of Cycles to IDE Approval or Conditional Approval	1.13	1.00	1.04	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.13	0.00	0.04	0.00	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	63	85	53	
Average Number of Cycles to IDE Approval or Conditional Approval	1.24	1.43	1.37	1.08	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.24	0.43	0.37	0.08	

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	17	13	
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.67	1.11	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	0.67	0.11	

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	51	47	
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	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	7	9	
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.25	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.25	0.00	0.00	

Section 11 CLIA Waiver Annual Metrics

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

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

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

Section 13 TAP Center Level Metrics

Table 13.1 CDRH - TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		31	81	58	
Closed before Teleconference		0	0	2	
Teleconferences Held		31	81	52	
Teleconferences Held Within 14 Days		30	78	44	
Teleconferences Pending		0	0	4	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		96.77%	96.30%	84.62%	

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

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	12	12	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		3	12	9	
Written Feedback Provided Within 21 Days		3	10	6	
Written Feedback Pending		0	0	3	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		100.00%	83.33%	66.67%	

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

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		44	67	68	
Closed before Written Feedback		0	1	1	
Written Feedback Provided		44	66	61	
Written Feedback Provided Within 40 Days		44	64	56	
Written Feedback Pending		0	0	6	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	96.97%	91.80%	

TAP Pilot Enrollment Data

Table 13.4 - TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		47	54	50	
Enrollment Requests Accepted		40	49	33	
Enrollment Requests Not Accepted		7	4	15	
Enrollment Requests Withdrawn Before Decision		0	1	0	
Enrollment Requests Pending		0	0	2	

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	2	1	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	2	1	
Teleconferences Held Within 14 Days		0	2	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	0.00%	

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

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	4	
Written Feedback Provided Within 21 Days		0	0	2	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	50.00%	

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

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

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

Table 13.4 - TAP Pilot Enrollment Data	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	2	1	
Enrollment Requests Accepted		0	2	1	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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	34	22	
Closed before Teleconference		0	0	1	
Teleconferences Held		21	34	17	
Teleconferences Held Within 14 Days		20	32	13	
Teleconferences Pending		0	0	4	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		95.24%	94.12%	76.47%	

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	6	5	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		3	6	4	
Written Feedback Provided Within 21 Days		3	4	2	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		100.00%	66.67%	50.00%	

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

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		34	39	32	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		34	39	28	
Written Feedback Provided Within 40 Days		34	39	24	
Written Feedback Pending		0	0	4	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	100.00%	85.71%	

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		21	14	15	
Enrollment Requests Accepted		16	13	10	
Enrollment Requests Not Accepted		5	1	5	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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

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

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

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

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

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

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		1	2	5	
Enrollment Requests Accepted		0	0	2	
Enrollment Requests Not Accepted		1	2	3	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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

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

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

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

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

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

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	0	0	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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	35	22	
Closed before Teleconference		0	0	1	
Teleconferences Held		10	35	21	
Teleconferences Held Within 14 Days		10	34	19	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		100.00%	97.14%	90.48%	

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	6	3	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	6	2	
Written Feedback Provided Within 21 Days		0	6	1	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	100.00%	50.00%	

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	21	18	
Closed before Written Feedback		0	1	1	
Written Feedback Provided		10	20	17	
Written Feedback Provided Within 40 Days		10	18	16	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	90.00%	94.12%	

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		25	12	10	
Enrollment Requests Accepted		24	12	6	
Enrollment Requests Not Accepted		1	0	3	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	1	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	9	9	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	9	9	
Teleconferences Held Within 14 Days		0	9	9	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	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	0	4	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	3	
Written Feedback Provided Within 21 Days		0	0	3	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	100.00%	

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

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	4	14	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	4	12	
Written Feedback Provided Within 40 Days		0	4	12	
Written Feedback Pending		0	0	2	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	100.00%	100.00%	

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	15	10	
Enrollment Requests Accepted		0	15	7	
Enrollment Requests Not Accepted		0	0	2	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	1	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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

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

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

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

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

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

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	0	0	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	1	4	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	1	4	
Teleconferences Held Within 14 Days		0	1	3	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	75.00%	

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

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

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

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

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	9	9	
Enrollment Requests Accepted		0	7	7	
Enrollment Requests Not Accepted		0	1	2	
Enrollment Requests Withdrawn Before Decision		0	1	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submissions that went to panel

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

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

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

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

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

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

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

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

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

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

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

Section 3 PMA Real Time Supplements

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

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

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

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

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

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

Section 5 PMA Annual Metrics and Goals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 De Novo MDUFA V Performance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

Section 9 Pre-Submissions

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

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

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

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

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

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

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

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

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

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 13 Total Product Life Cycle Advisory Program (TAP)

Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions

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

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

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

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

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

Table 13.4 TAP Pilot Enrollment Data– Definitions

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

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 30 June 2026

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	2	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	3	0	1	2	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	0.00%	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	2	
Number Accepted	3	0	1	2	
Completed RTF	3	0	1	2	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	N/A	0.00%	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	2	
SI Goal Met	3	0	1	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	N/A	100.00%	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	1	
Average Number of FDA Days to Substantive Interaction	88.33	0.00	90.00	90.00	
20th Percentile FDA Days to Substantive Interaction	87	0	90	90.00	
40th Percentile FDA Days to Substantive Interaction	88	0	90	90.00	
60th Percentile FDA Days to Substantive Interaction	88	0	90	90.00	
80th Percentile FDA Days to Substantive Interaction	89	0	90	90.00	
Maximum FDA Days to Substantive Interaction	90	0	90	90.00	

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

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

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	0	0	0	0	
MDUFA V Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA V Decision	0	0	0	0	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	1	0	
Average FDA Days to MDUFA V Decision	177.00	0.00	142.00	0.00	
20th Percentile FDA Days to MDUFA V Decision	175	0	142	0	
40th Percentile FDA Days to MDUFA V Decision	178	0	142	0	
60th Percentile FDA Days to MDUFA V Decision	179	0	142	0	
80th Percentile FDA Days to MDUFA V Decision	180	0	142	0	
Maximum FDA Days to MDUFA V Decision	180	0	142	0	
Average Industry Days to MDUFA V Decision	0.00	0.00	62.00	0.00	
20th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
60th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
80th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
Maximum Industry Days to MDUFA V Decision	0	0	62	0	
Average Total Days to MDUFA V Decision	177.00	0.00	204.00	0.00	
20th Percentile Total Days to MDUFA V Decision	175	0	204	0	
40th Percentile Total Days to MDUFA V Decision	178	0	204	0	
60th Percentile Total Days to MDUFA V Decision	179	0	204	0	
80th Percentile Total Days to MDUFA V Decision	180	0	204	0	
Maximum Total Days to MDUFA V Decision	180	0	204	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	0	
Average FDA Days to MDUFA V Decision	0.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
Maximum FDA Days to MDUFA V Decision	0	0	0	0	
Average Industry Days to MDUFA V Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
Maximum Industry Days to MDUFA V Decision	0	0	0	0	
Average Total Days to MDUFA V Decision	0.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA V Decision	0	0	0	0	
40th Percentile Total Days to MDUFA V Decision	0	0	0	0	
60th Percentile Total Days to MDUFA V Decision	0	0	0	0	
80th Percentile Total Days to MDUFA V Decision	0	0	0	0	
Maximum Total Days to MDUFA V Decision	0	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	2	
Number with MDUFA V Decision	3	0	1	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	N/A	0.00%	N/A	
Rate of Not Approvable	0.00%	N/A	0.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA V Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	0	0	0	0	
MDUFA V Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA V Decision	0	0	0	0	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	0	0	0	0	
MDUFA V Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA V Decision	0	0	0	0	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	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	8	5	
SI Goal Met	2	5	8	2	
SI Goal Not Met	2	0	0	0	
SI Pending Within Goal	0	0	0	3	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	4	5	8	5	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	4	5	6	0	
MDUFA V Decision Goal Met	3	5	6	0	
Supplements Pending MDUFA V Decision	0	0	2	5	
Supplements Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	75.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	8	5	
Number with MDUFA V Decision	4	5	6	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	25.00%	20.00%	0.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	121.00	N/A	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	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	3	2	2	0	
MDUFA V Decision Goal Met	3	2	2	0	
Supplements Pending MDUFA V Decision	0	0	0	0	
Supplements Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	52	31	
Closed Before First RTA or TS Action [1]	0	4	2	0	
Number Accepted or Passed TS on First Cycle [2]	30	25	40	24	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0	0	1	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle [2]	11	4	9	7	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	13.79%	18.00%	22.58%	

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.

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	46	30	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	37	29	45	25	
SI Over 60 FDA Days	2	0	1	1	
SI Pending Within 60 FDA Days	0	0	0	4	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	94.87%	100.00%	97.83%	96.15%	

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	46	26	
Average Number of FDA Days to Substantive Interaction	55.53	56.79	51.83	55.19	
20th Percentile FDA Days to Substantive Interaction	51	56	48	54	
40th Percentile FDA Days to Substantive Interaction	56	57	57	58	
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	90	60	62	73	

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	46	30	
Non-MDUFA V Decision	3	3	4	4	
MDUFA V Decision (SE/NSE)	36	26	40	16	
MDUFA V Decision Within 90 FDA Days	36	26	40	16	
510(k)s Pending MDUFA V Decision	0	0	2	10	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	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	1.54	1.58	1.25	
Number With MDUFA V Decision	36	26	40	16	
Average Number of FDA Days to MDUFA V Decision	77.33	80.08	73.03	75.19	
20th Percentile FDA Days to MDUFA V Decision	69	73	64	71	
40th Percentile FDA Days to MDUFA V Decision	84	86	81	81	
60th Percentile FDA Days to MDUFA V Decision	89	87	88	82	
80th Percentile FDA Days to MDUFA V Decision	90	89	89	89	
Maximum FDA Days to MDUFA V Decision	90	90	90	90	
Average Number of Industry Days to MDUFA V Decision	48.92	82.12	67.60	5.81	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	0	102	63	0	
80th Percentile Industry Days to MDUFA V Decision	115	180	179	9	
Maximum Industry Days to MDUFA V Decision	315	207	193	42	
Average Number of Total Days to MDUFA V Decision	126.25	162.19	140.63	81.00	
20th Percentile Total Days to MDUFA V Decision	81	79	70	75	
40th Percentile Total Days to MDUFA V Decision	88	90	87	81	
60th Percentile Total Days to MDUFA V Decision	90	188	139	89	
80th Percentile Total Days to MDUFA V Decision	90	266	267	91	
Maximum Total Days to MDUFA V Decision	375	288	271	113	

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	46	30	
Number With MDUFA V Decision	36	26	40	16	
Number of SE Decision	35	20	32	16	
Number of NSE Decision	1	6	8	0	
Number of Withdrawal	2	1	2	4	
Number of Deleted	1	2	2	0	
Rate of SE Decision	97.22%	76.92%	80.00%	100.00%	
Rate of NSE Decision	2.78%	23.08%	20.00%	0.00%	
Rate of Withdrawal	5.13%	3.45%	4.35%	13.33%	
Rate of Deleted	2.56%	6.90%	4.35%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	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	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision (SE/NSE)	0	0	0	0	
MDUFA V Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	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	7	4	3	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision (SE/NSE)	7	4	3	0	
MDUFA V Decision Within 90 FDA Days	7	4	3	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	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	1	0	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	0	0	1	0	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	1	0	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A	0.00%	N/A	

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

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

Table 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00	0.00	0.00	0.00	
Number With MDUFA Decision	1	0	0	0	
Average FDA Days to MDUFA Decision	75.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA Decision	75	0	0	0	
40th Percentile FDA Days to MDUFA Decision	75	0	0	0	
60th Percentile FDA Days to MDUFA Decision	75	0	0	0	
80th Percentile FDA Days to MDUFA Decision	75	0	0	0	
Maximum FDA Days to MDUFA Decision	75	0	0	0	
Average Industry Days to MDUFA Decision	177.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA Decision	177	0	0	0	
40th Percentile Industry Days to MDUFA Decision	177	0	0	0	
60th Percentile Industry Days to MDUFA Decision	177	0	0	0	
80th Percentile Industry Days to MDUFA Decision	177	0	0	0	
Maximum Industry Days to MDUFA Decision	177	0	0	0	
Average Total Days to MDUFA Decision	252.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA Decision	252	0	0	0	
40th Percentile Total Days to MDUFA Decision	252	0	0	0	
60th Percentile Total Days to MDUFA Decision	252	0	0	0	
80th Percentile Total Days to MDUFA Decision	252	0	0	0	
Maximum Total Days to MDUFA Decision	252	0	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	1	0	
Number With MDUFA Decision	1	0	0	0	
Number With Granted Decision	0	0	0	0	
Number With Declined Decision	1	0	0	0	
Number of Withdrawal	0	0	1	0	
Number of Deleted	0	0	0	0	
Rate of Granted Decision	0.00%	N/A	0.00%	N/A	
Rate of Declined Decision	100.00%	N/A	0.00%	N/A	
Rate of Withdrawal	0.00%	N/A	100.00%	N/A	
Rate of Deleted	0.00%	N/A	0.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	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	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	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	75	66	
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	4	3	
Number Closed Before First RTA Action	7	1	1	1	
Number Accepted First RTA Cycle [1]	59	60	74	65	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted First RTA Cycle	0	1	0	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.64%	0.00%	0.00%	

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

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

Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	61	61	74	65	
Number with Non-MDUFA Action [3]	3	0	0	0	
Number with MDUFA Action	58	61	74	49	
Written Feedback Provided Within Goal	55	61	74	49	
Number Pending MDUFA Action	0	0	0	16	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	58	61	74	65	
Current Performance Percent Within Goal	94.83%	100.00%	100.00%	100.00%	

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

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

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

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

Table 9.3 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	74	49	
Average FDA Days to Written Feedback	59.38	60.79	60.49	60.16	
20th Percentile FDA Days to Written Feedback	55	54	55	56	
40th Percentile FDA Days to Written Feedback	60	61	60	61	
60th Percentile FDA Days to Written Feedback	64	65	65	65	
80th Percentile FDA Days to Written Feedback	69	69	68	67	
Maximum FDA Days to Written Feedback	72	70	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	0	
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	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	23	18	
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	20	16	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	
Meeting Minutes Past 15 Days of Meeting	3	5	3	2	
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0	0	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	83.87%	86.96%	88.89%	

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	9	
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.07	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.06	0.00	0.00	

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

Medical Devices

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,[1] the table below includes all FDA guidance documents issued in FY 2026 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] Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2026.

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2026

#	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	Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome	10/22/2025	Yes	Yes	Section 3002 of the 21st Century Cures Act	No
2	Q1	Quality Management System Information for Certain Premarket Submission Reviews www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-management-system-information-certain-premarket-submission-reviews	10/27/2025	Yes	No	N/A	A-List
3	Q1	Menstrual Products - Performance Testing and Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/menstrual-products-performance-testing-and-labeling-recommendations	10/28/2025	Yes	No	No	A-List
4	Q1	Cross-Center Master Files: Where to Submit www.fda.gov/regulatory-information/search-fda-guidance-documents/cross-center-master-files-where-submit	11/25/2025	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]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions	12/03/2025	Yes	No	N/A	No
6	Q1	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	12/15/2025	Yes	No	N/A	No
7	Q1	Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	12/15/2025	Yes	No	N/A	No
8	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/18/2025	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
9	Q1	Processes and Practices Applicable to Bioresearch Monitoring Inspections www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	12/19/2025	Yes	Yes	Section 3612 of the Food and Drug Omnibus Reform Act (FDORA)	No
10	Q2	[4]General Wellness: Policy for Low Risk Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices	01/06/2026	Yes	No	N/A	No
11	Q2	Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval www.fda.gov/regulatory-information/search-fda-guidance-documents/minimal-residual-disease-and-complete-response-multiple-myeloma-use-endpoints-support-accelerated	01/21/2026	Yes	No	N/A	No
12	Q2	Cuffless Non-invasive Blood Pressure Measuring Devices – Clinical Performance Testing and Evaluation	01/23/2026	Yes	No	N/A	No

[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
		www.fda.gov/regulatory-information/search-fda-guidance-documents/cuffless-non-invasive-blood-pressure-measuring-devices-clinical-performance-testing-and-evaluation					
13	Q2	[4]Clinical Decision Support Software www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software	01/29/2026	Yes	No	N/A	No
14	Q2	[4]Computer Software Assurance for Production and Quality Management System Software www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software	02/03/2026	No	No	N/A	No
15	Q2	[4]Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket	02/03/2026	Yes	No	N/A	No
16	Q2	Medical Devices with Indications Associated with Weight Loss - Premarket Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-indications-associated-weight-loss-premarket-considerations	03/13/2026	Yes	No	N/A	B-List
17	Q2	[4]Pyrogen and Endotoxins Testing: Questions and Answers[4] www.fda.gov/regulatory-information/search-fda-guidance-documents/pyrogen-and-endotoxins-testing-questions-and-answers	03/18/2026	Yes	No	N/A	No
18	Q2	Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle-0	03/30/2026	Yes	Yes	MDUFA V Commitment Letter V.E.	A-List
19	Q3	Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-regarding-premarket-and-other-requirements-certain-niosh-approved-air-purifying	04/20/2026	Yes	No	N/A	A-List

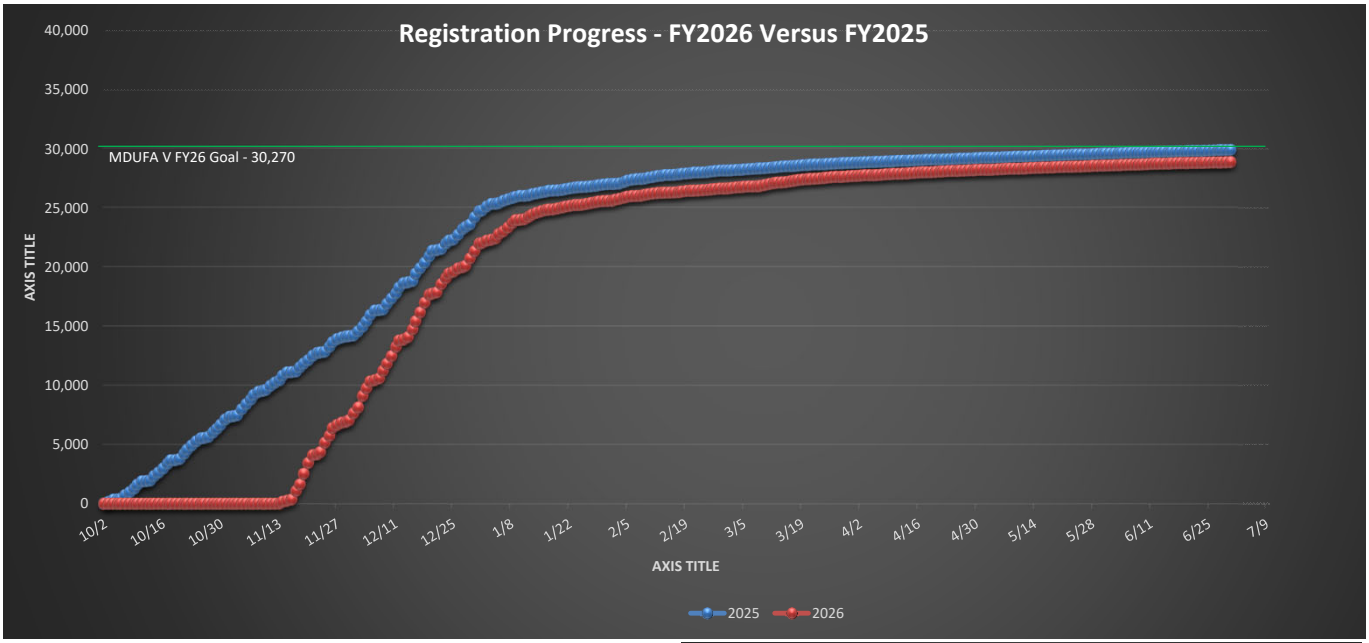
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
20	Q3	Patient-Matched Guides for Orthopedic Implants www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-matched-guides-orthopedic-implants	05/07/2026	Yes	No	N/A	No
21	Q3	Content of Human Factors Information in Medical Device Marketing Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions	05/29/2026	Yes	No	N/A	B-List
22	Q3	Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-and-device-manufacturer-communications-payors-formulary-committees-and-similar-entities	06/03/2026	No	No	N/A	No
23	Q3	Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements www.fda.gov/regulatory-information/search-fda-guidance-documents/intent-exempt-certain-unclassified-medical-devices-premarket-notification-requirements	06/05/2026	Yes	No	N/A	No

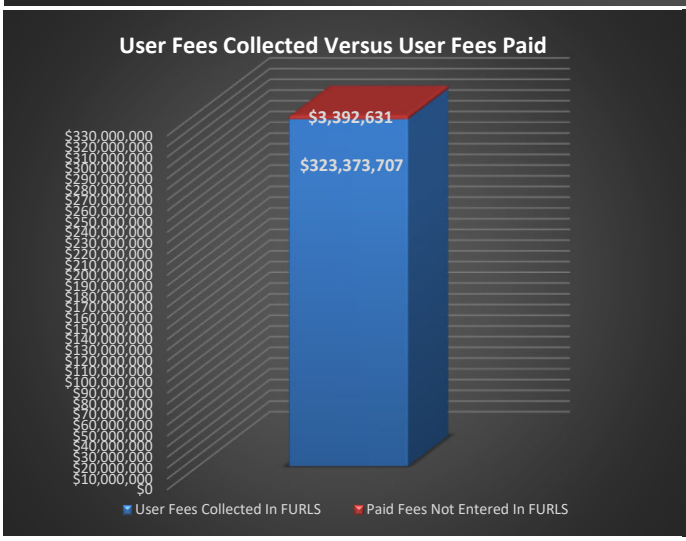
Registrations and Listings

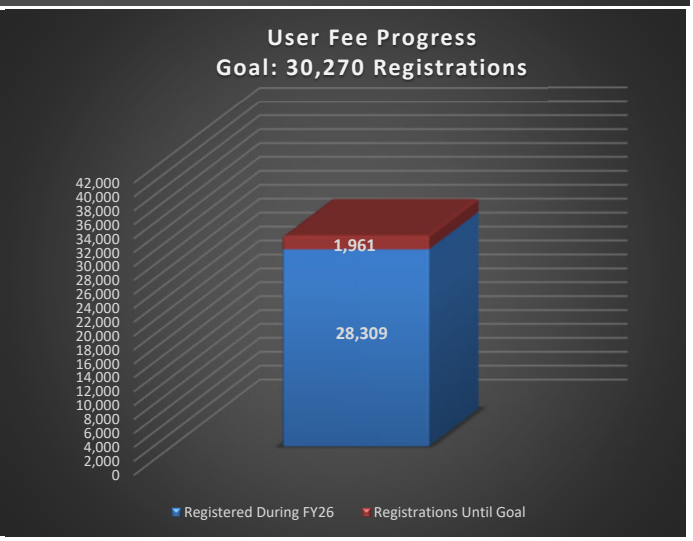
MDUFA V Registrations - 3rd Quarter Summary FY2026*

Current Active Registrations by Type	FY26 Q3			FY25 Year End Active Totals			FY26 vs End of FY25
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,311	11,416	17,727	6,499	12,045	18,544	95.59%
Contract Manufacturer	1,224	2,115	3,339	1,267	2,101	3,368	99.14%
Contract Sterilizer	75	178	253	77	181	258	98.06%
Specification Developer	1,477	529	2,006	1,579	551	2,130	94.18%
Reprocessor of Single Use Devices	22	4	26	23	4	27	96.30%
U.S. Manufacturer of Export Only Devices	88	0	88	113	0	113	77.88%
Repackager/Relabeler	975	172	1,147	1,057	189	1,246	92.05%
Remanufacturer	8	4	12	15	8	23	52.17%
Foreign Exporter/Private Label Distributor	0	913	913		1,064	1,064	85.81%
Initial Importer	2,806	0	2,806	3,063		3,063	91.61%
Unknown	0	0	0	0	0	0	0.00%
Total:	**12,986**	**15,331**	**28,317**	**13,693**	**16,143**	**29,836**	94.91%

*Data is current as of 06/30/2026







Medical Device User Fee Collections

Q3 FY 2026 Medical Device User Fee Collections as of June 30, 2026 Excludes Unearned Revenue					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$326,660,050	-$616,842	$326,043,208		
Application Fees	$97,947,112	-$1,513,641	$96,433,471		
Total	**$424,607,163**	**-$2,130,483**	**$422,476,680**	**$478,165,880**	**88%**

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	$411,483,643	$422,476,680	

Number of Discretionary Fee Waivers or Reductions

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 2026 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	7	2
PMA	7	2
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	6	0
De Novo Classification	3	32
180-Day Supplements	16	2
Real-Time Supplements	0	30
510(k)s	39	1,570
30-day Notices /135 day supplements*	9	67
513(g)s	0	40
PMA Annual Report	0	0
Total	**80**	**1,743**

[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**