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

November 16, 2023, 1:00 – 2:30 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through September 30, 2023

- Report on decision goals for 4th Quarter FY 2023
- Status of Paused IVD Submissions
- De Novo

Guidance Development

Registration and Listing

Qualitative Update on Finances – 4th Quarter FY 2023

- User fee receipts through the 4th Quarter FY 2023

Annual Hiring Goals Update

Reviewer to Manager Ratio

TAP pilot progress

Quality Management Update

- Summary of FY 2023 audits conducted
- Planning for FY 2024 audits

Independent Assessments of MDUFA Workforce Metrics

Summary of Training Courses

Return on Investment

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 30 September 2023

Table of Contents

Acronyms and Abbreviations

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

Office Organizations

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

OHT2: Office of Cardiovascular Devices

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

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

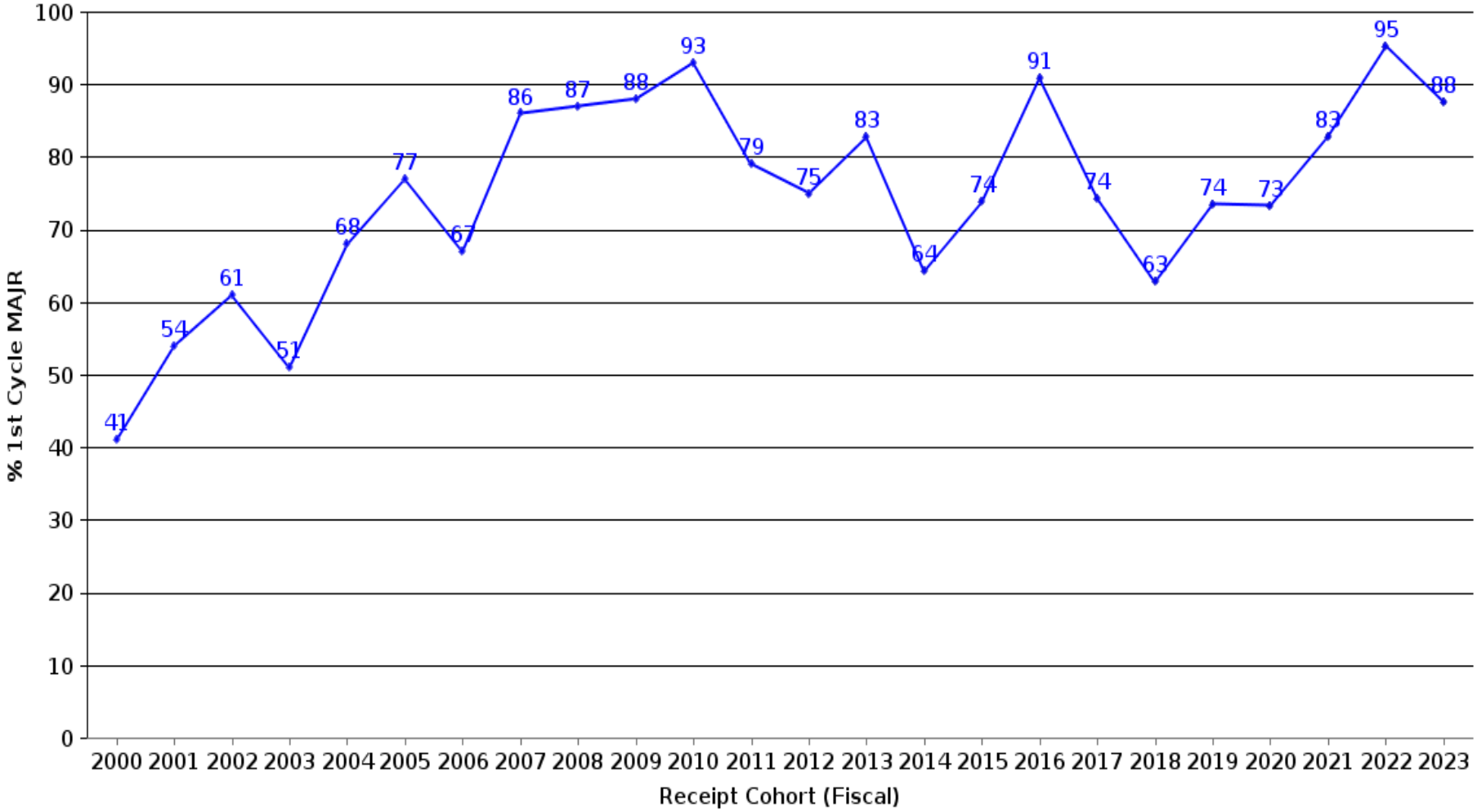
OHT8: Office of Radiological Health

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

PMAs

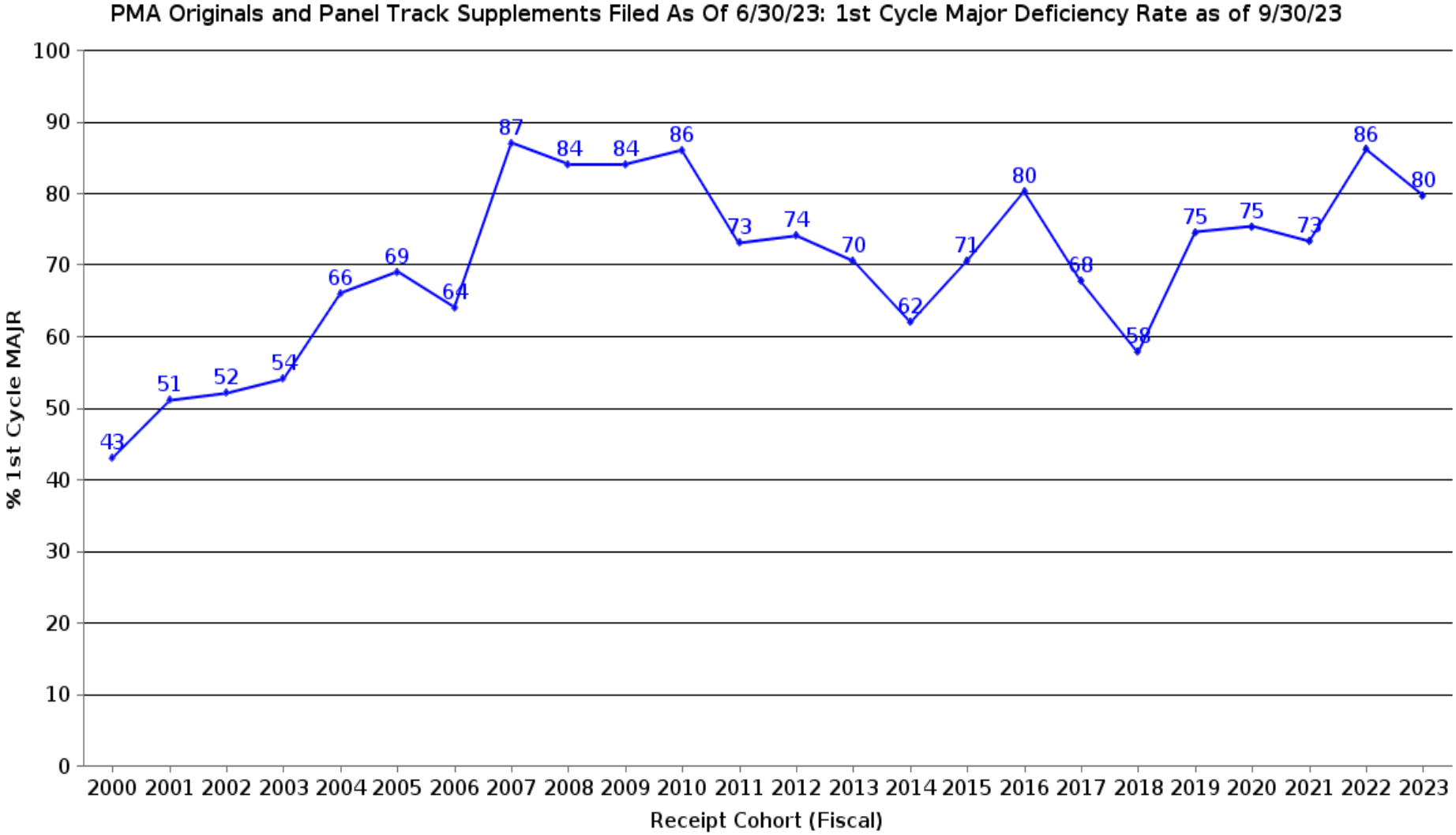
Q4FY2023

PMA Originals Filed As Of 6/30/23: 1st Cycle Major Deficiency Rate as of 9/30/23



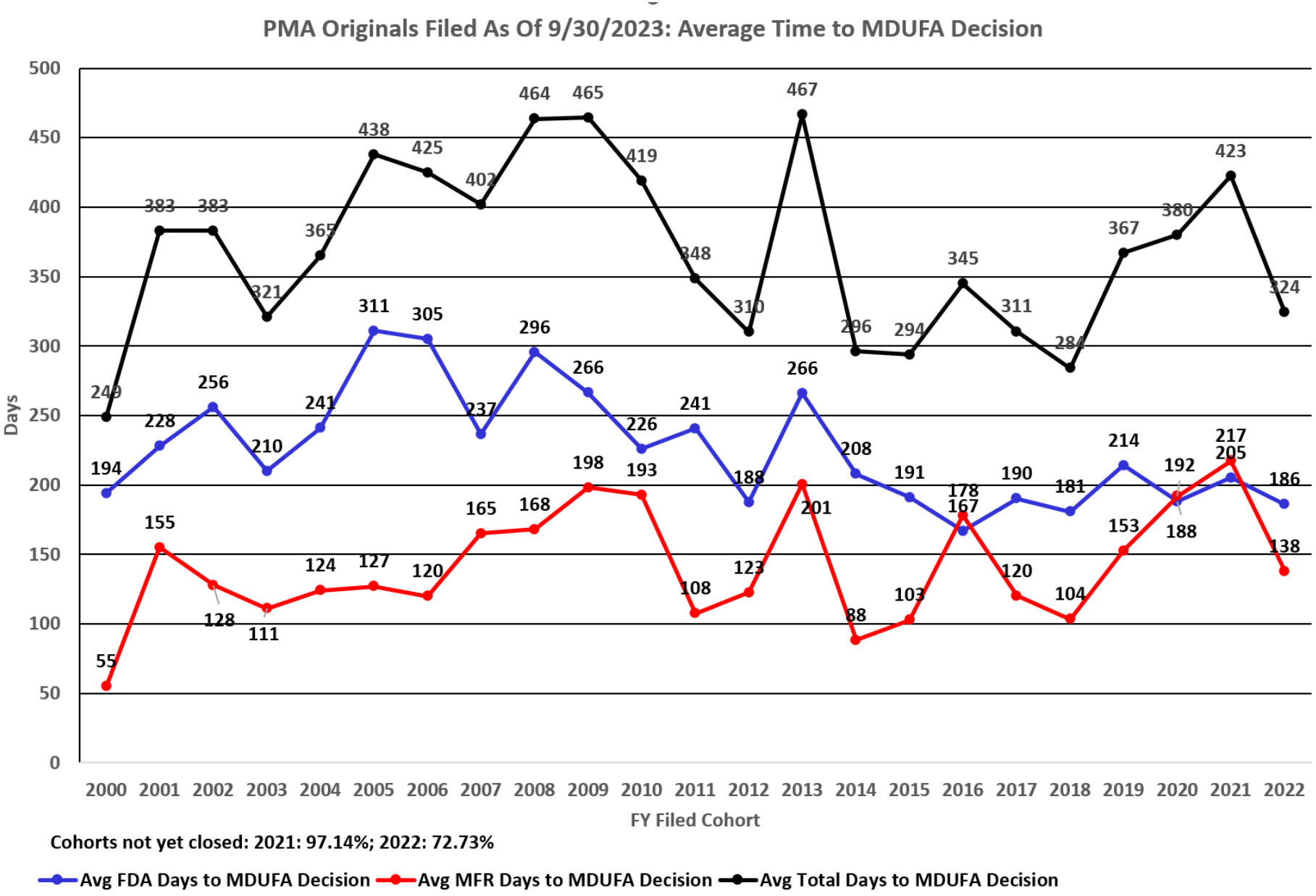
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/23.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

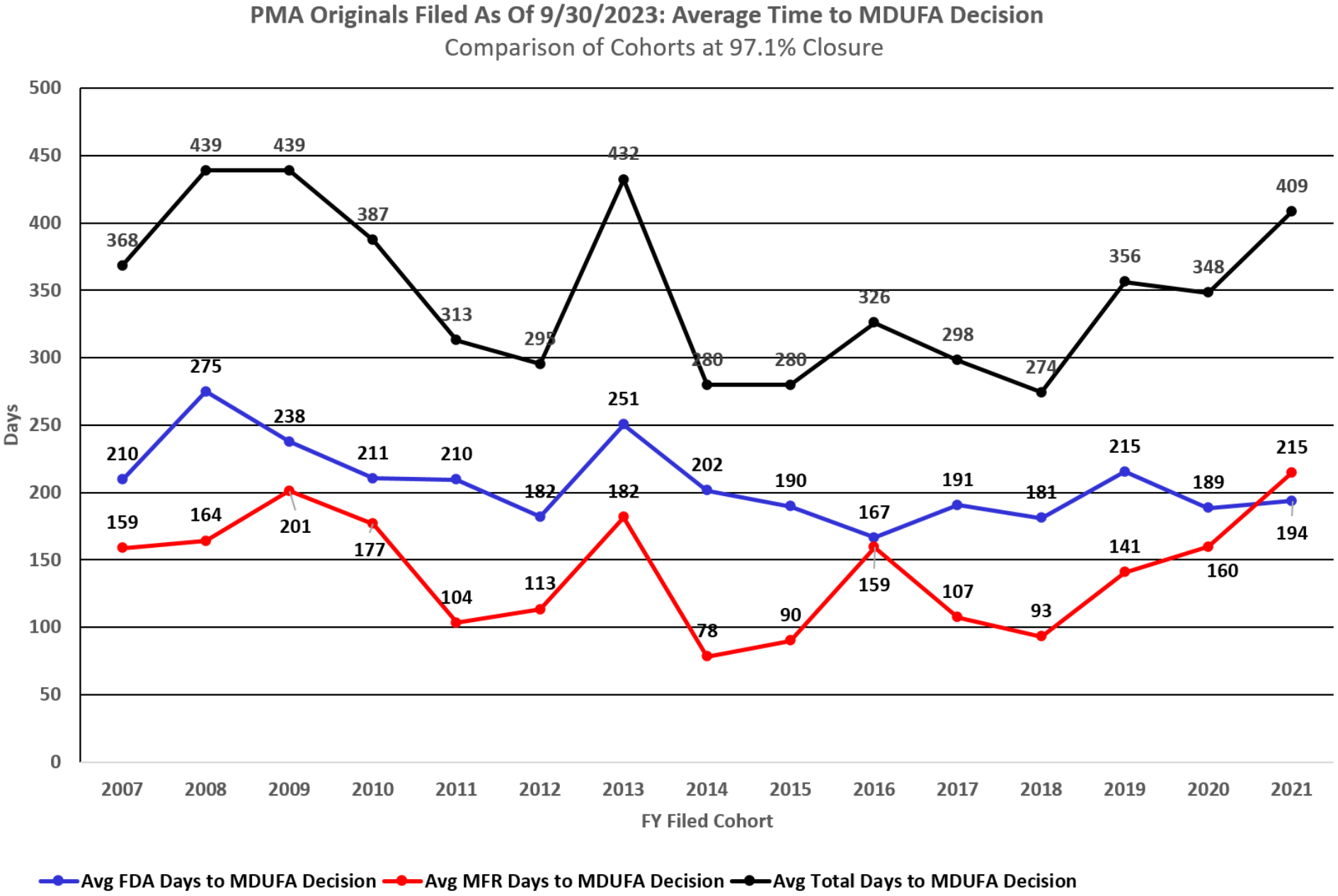
◆ % 1st Cycle MAJR PMAO

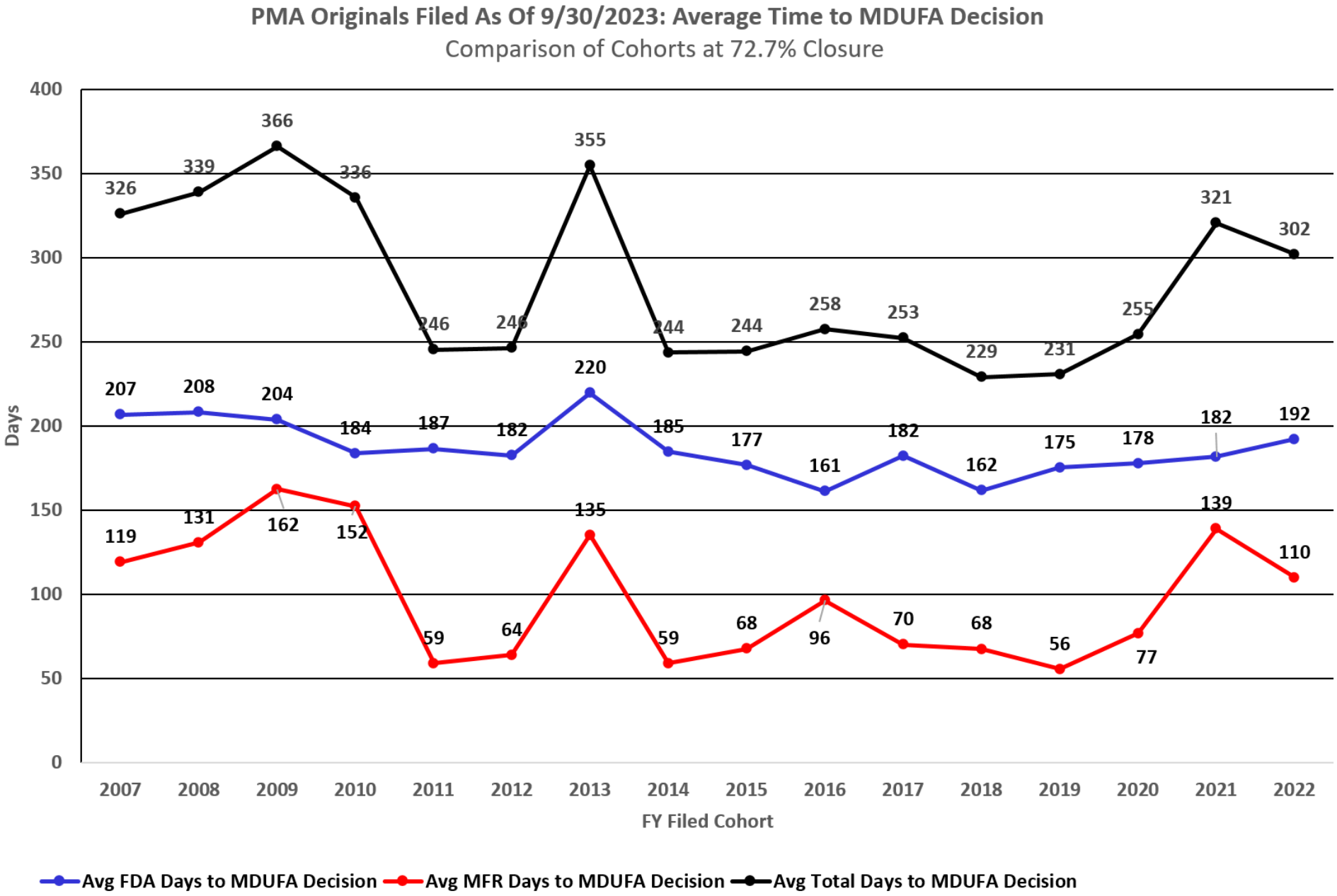


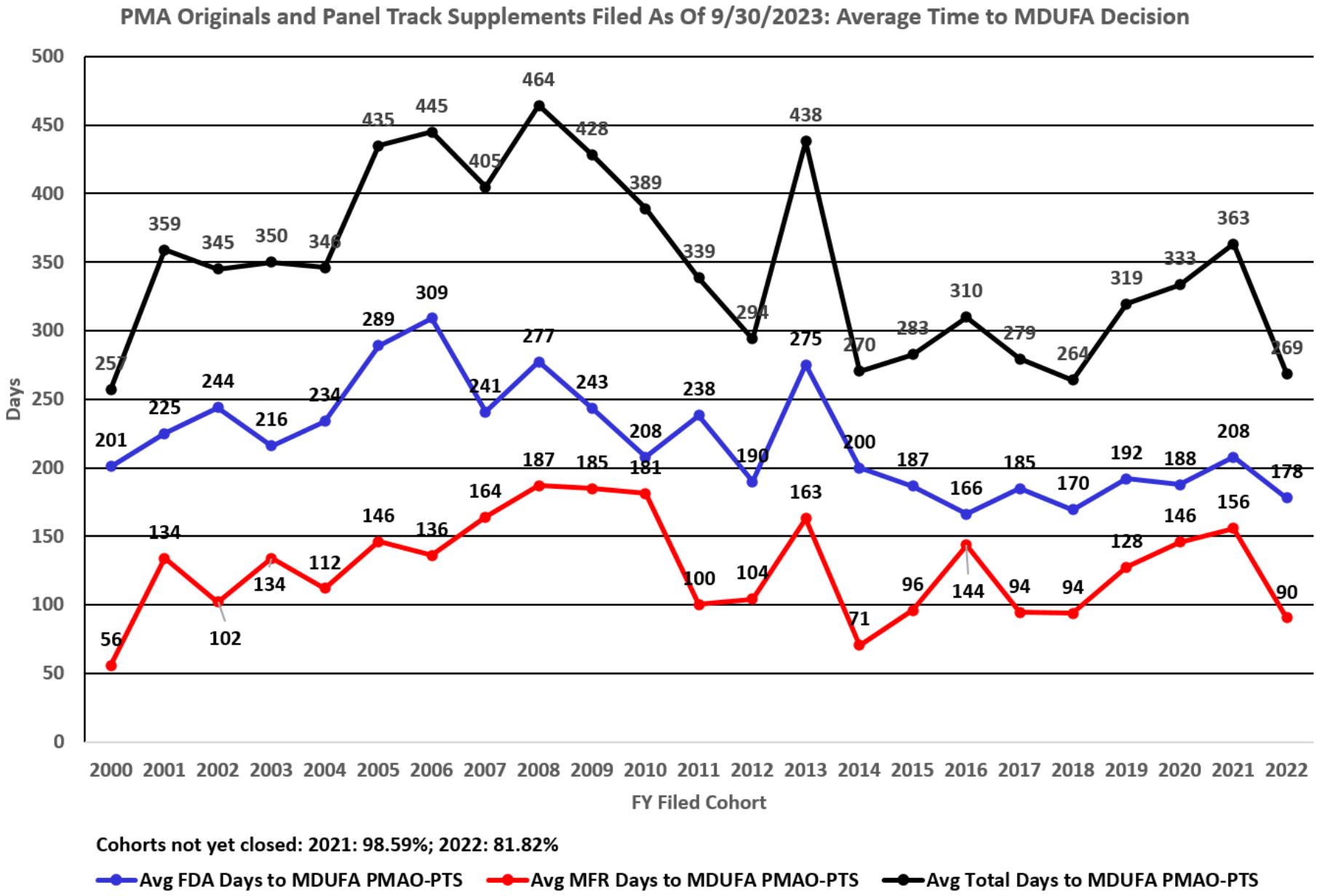
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/23. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

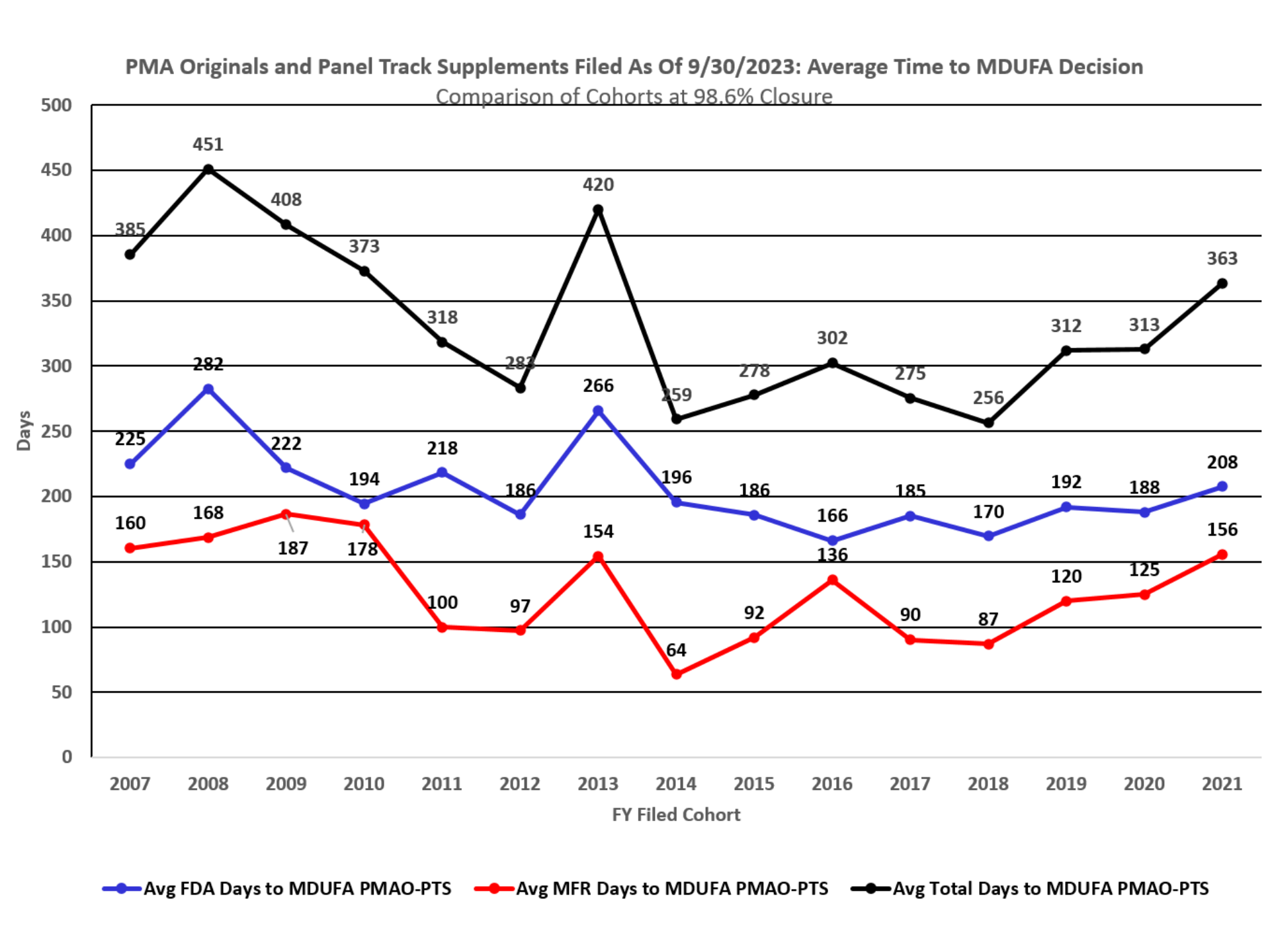
◆ % 1st Cycle MAJR PMAO/PTS

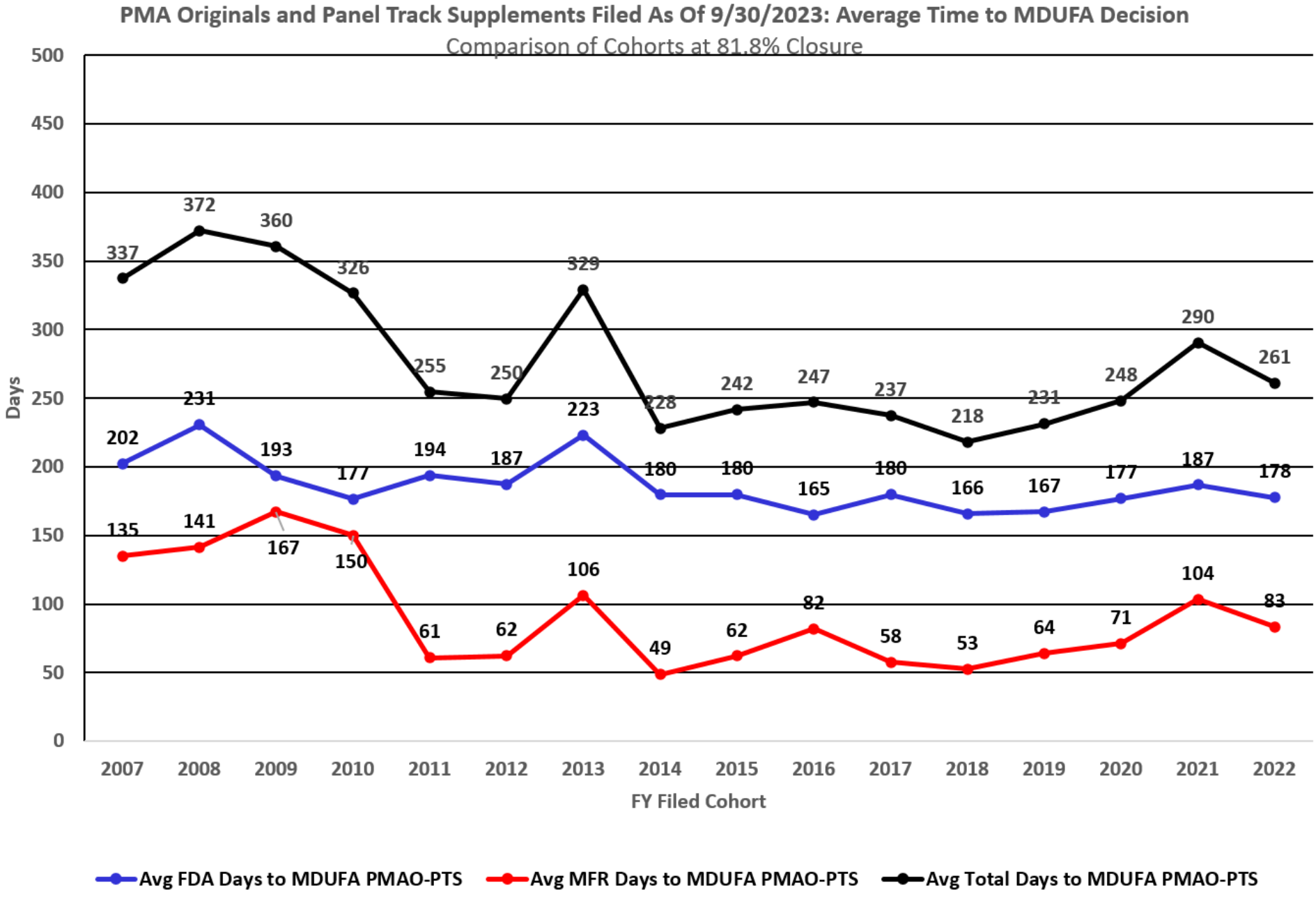

PMA Originals Filed As Of 9/30/2023: Average Time to MDUFA Decision
Days
FY Filed Cohort
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
Cohorts not yet closed: 2021: 97.14%; 2022: 72.73%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

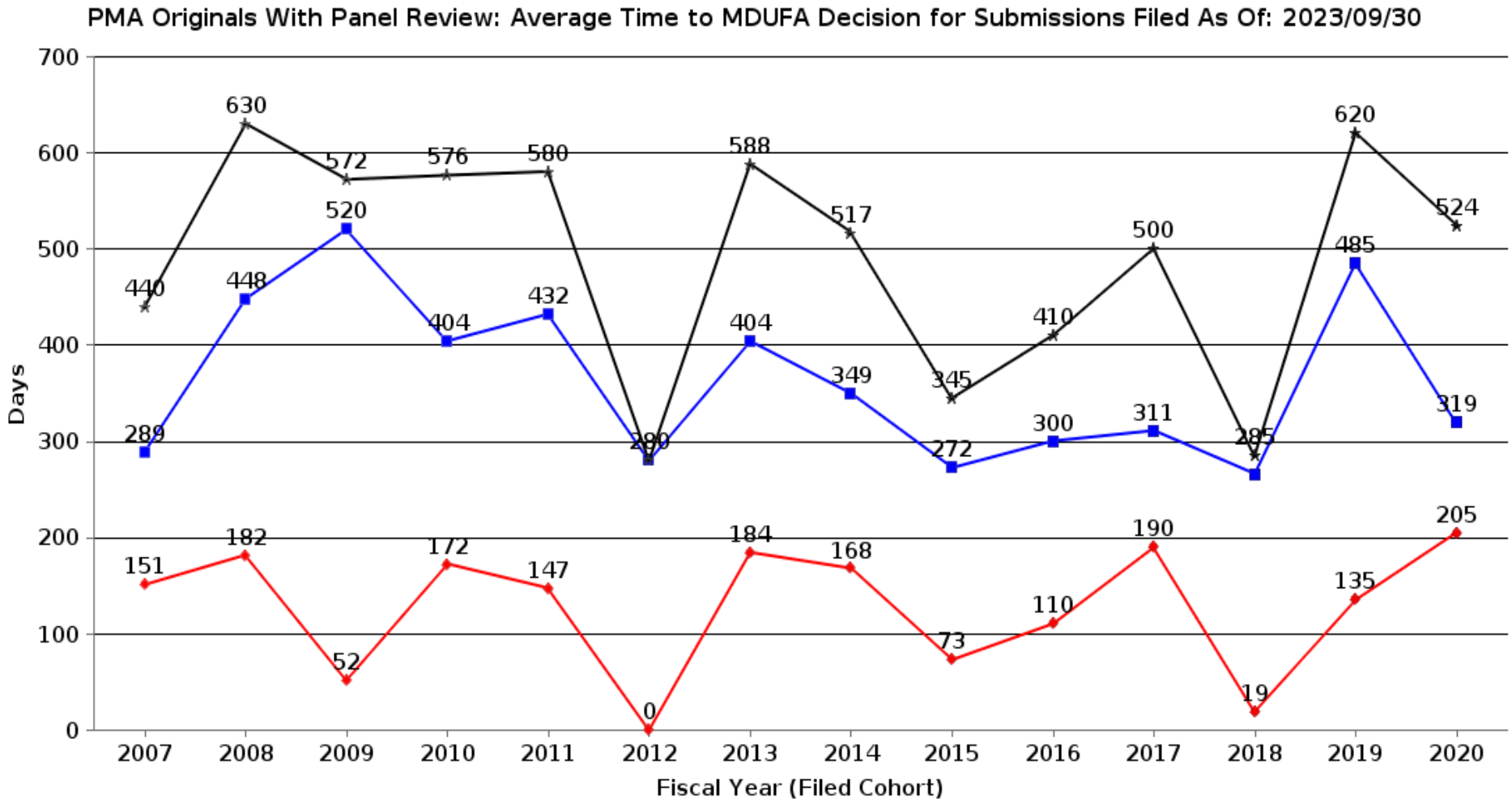

PMA Originals Filed As Of 9/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 97.1% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY Filed Cohort
368
439
439
387
313
295
432
280
280
326
298
274
356
348
409
210
275
238
211
210
182
251
202
190
167
191
181
215
189
194
159
164
201
177
104
113
182
78
90
159
107
93
141
160
215
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 9/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 72.7% Closure
Days
400
350
300
250
200
150
100
50
0
326
339
366
336
246
246
355
244
244
258
253
229
231
255
321
302
207
208
204
184
187
182
220
185
177
161
182
162
175
178
182
192
119
131
162
152
59
64
135
59
68
96
70
68
56
77
139
110
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed As Of 9/30/2023: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
FY Filed Cohort
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 188 208 178
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 94 128 146 156 90
257 359 345 350 348 435 445 405 464 428 389 339 294 438 270 283 310 279 264 319 333 363 269
Cohorts not yet closed: 2021: 98.59%; 2022: 81.82%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

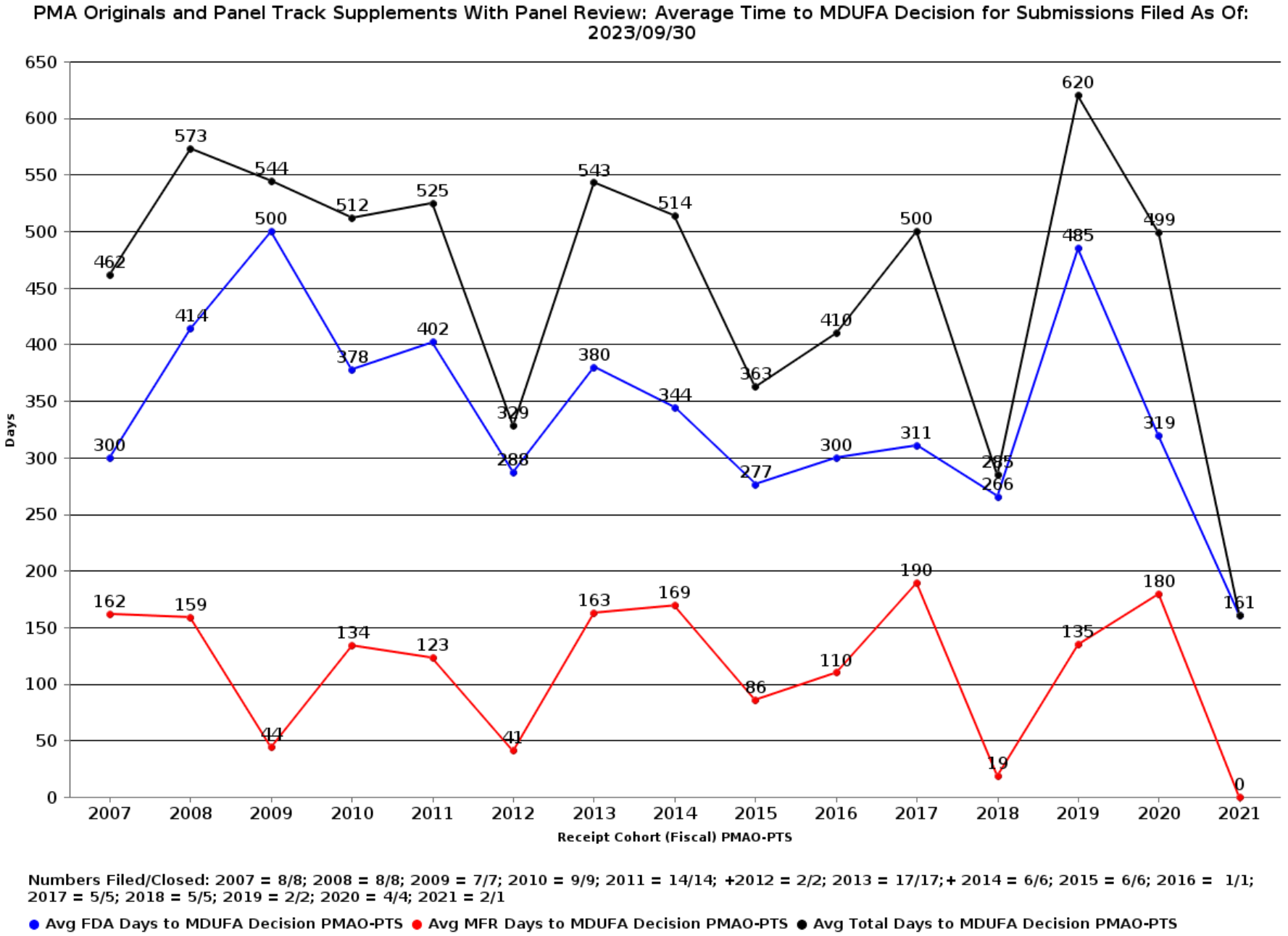

PMA Originals and Panel Track Supplements Filed As Of 9/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 98.6% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
385
451
408
373
318
283
420
259
278
302
275
256
312
313
363
225
282
222
194
218
186
266
196
186
166
185
170
192
188
208
160
168
187
178
100
97
154
64
92
136
90
87
120
125
156
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS


PMA Originals and Panel Track Supplements Filed As Of 9/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 81.8% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
337
372
360
326
255
250
329
228
242
247
237
218
231
248
290
261
202
231
193
177
194
187
223
180
180
165
180
166
167
177
187
178
135
141
167
150
61
62
106
49
62
82
58
53
64
71
104
83
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

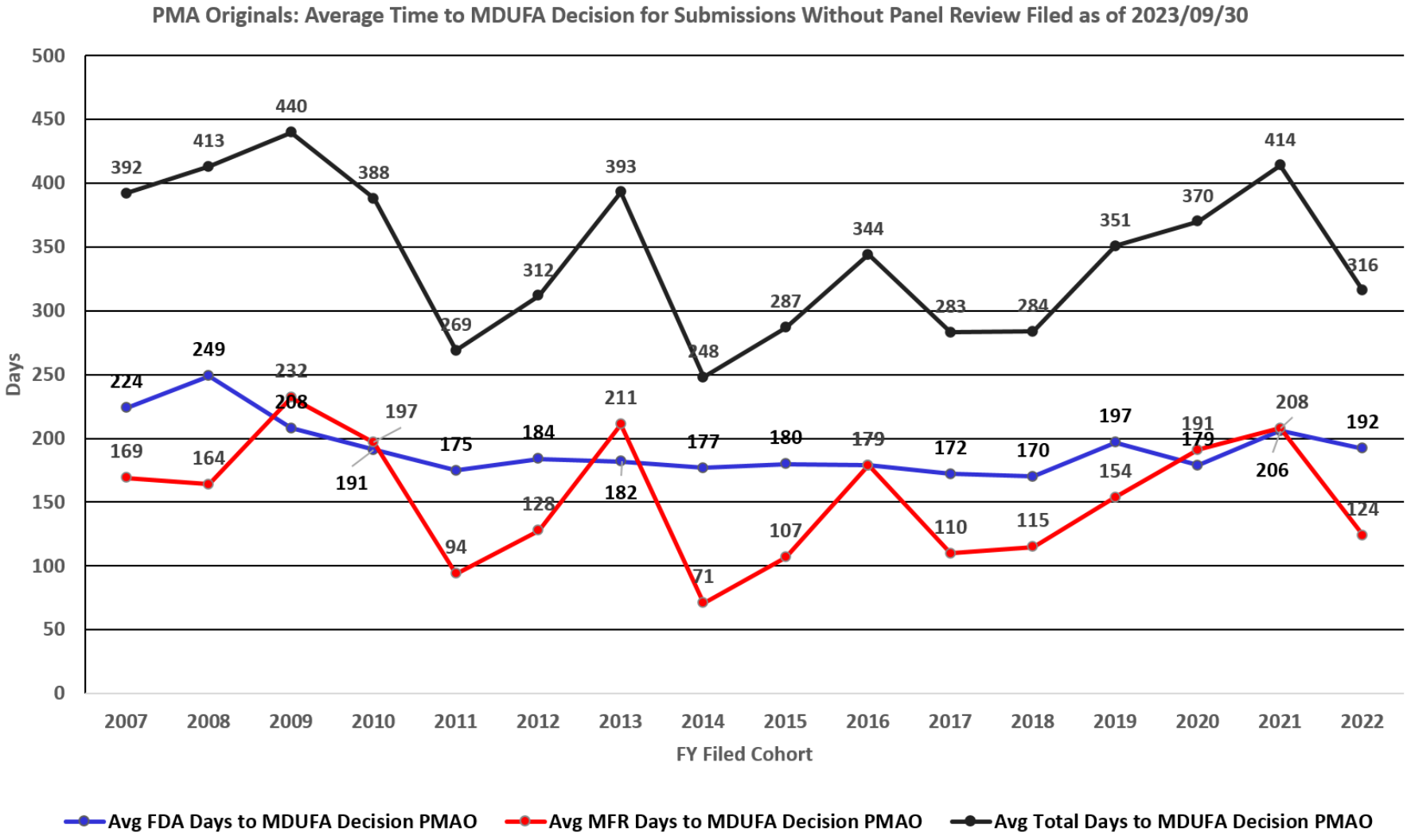


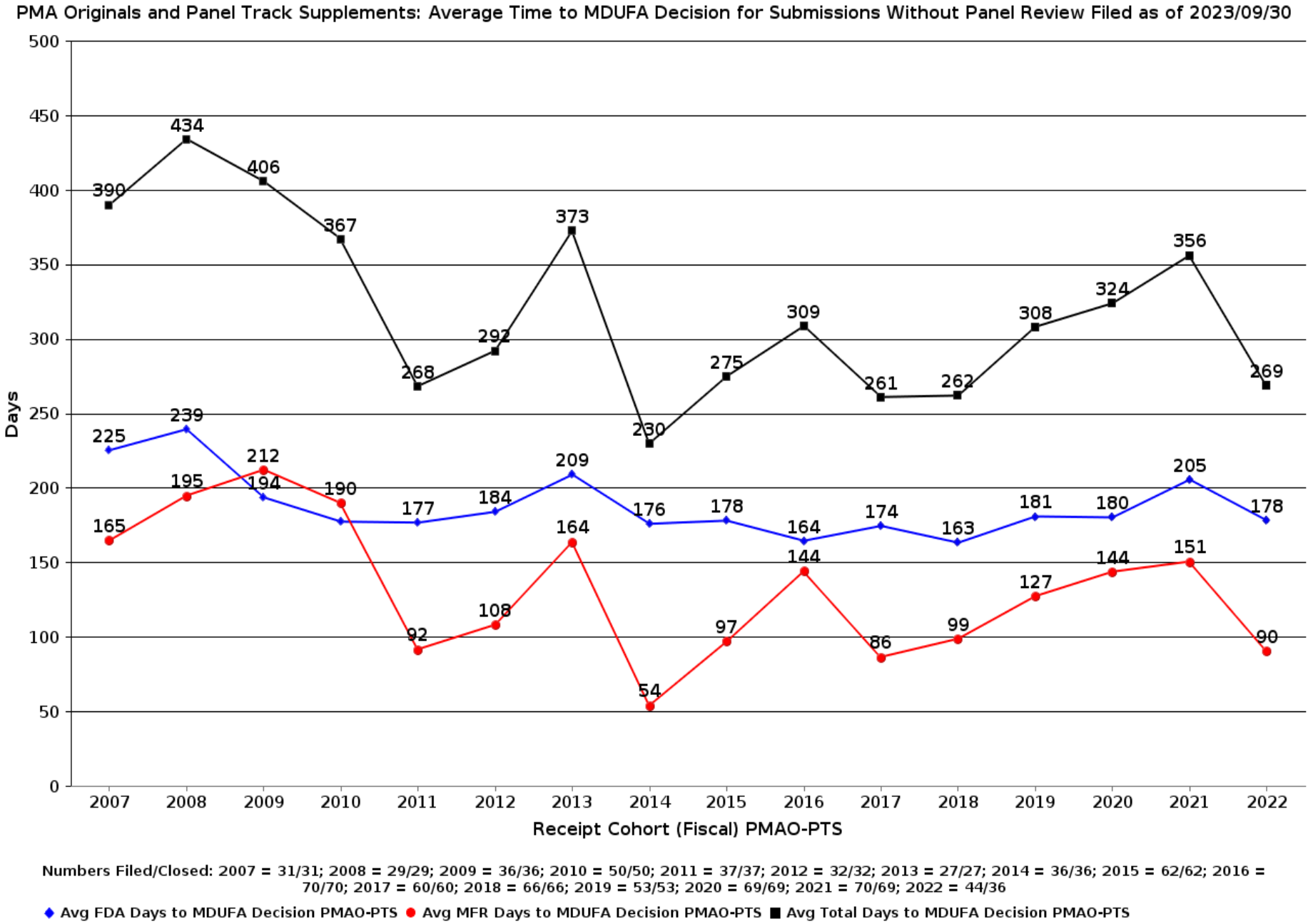
Numbers Filed/Closed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3

■ Avg FDA Days to MDUFA Decision PMAO ♦ Avg MFR Days to MDUFA Decision PMAO ★ Avg Total Days to MDUFA Decision PMAO



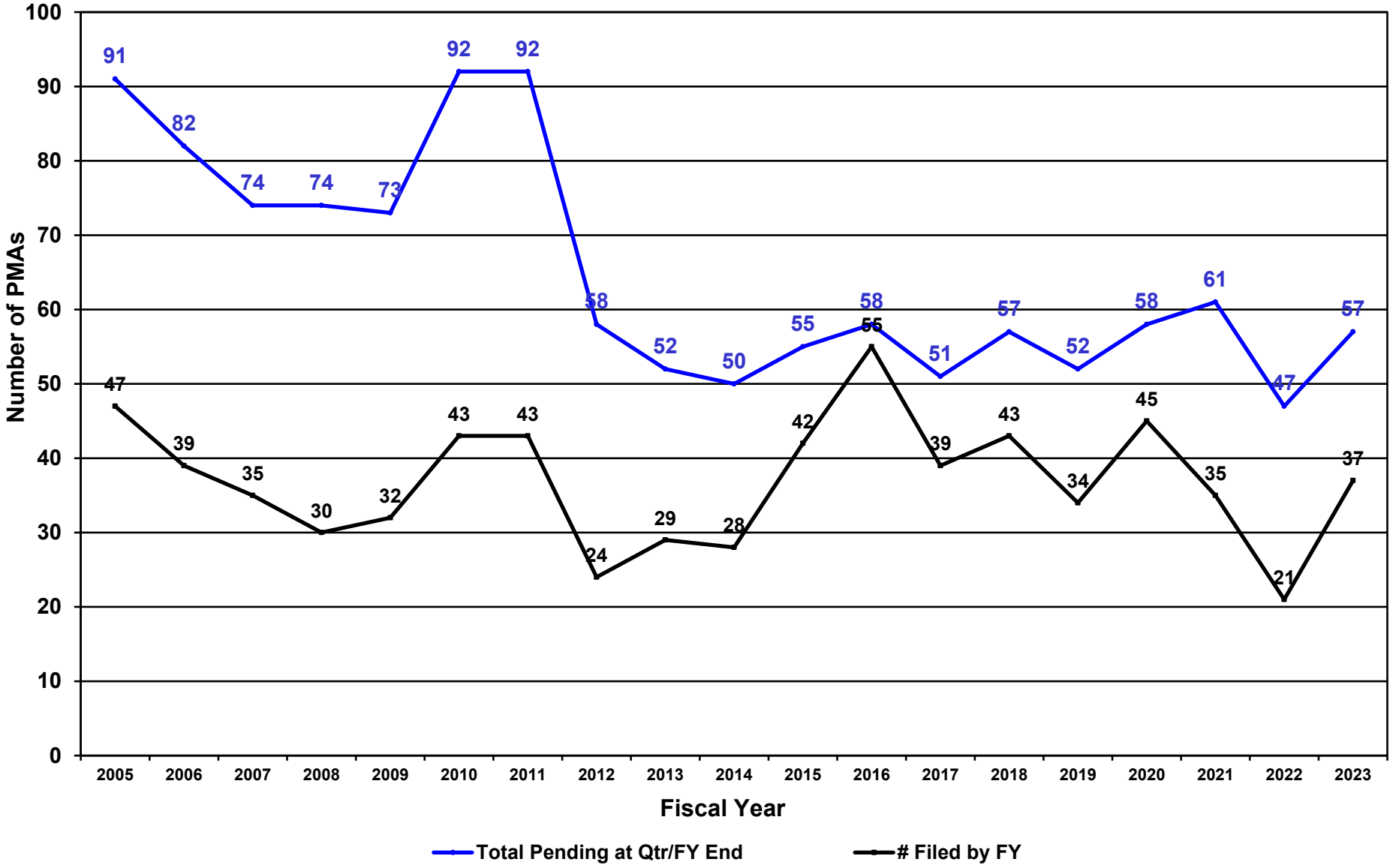
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.


PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2023/09/30
Days
500
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY Filed Cohort
392
413
440
388
269
312
393
248
287
344
283
284
351
370
414
316
224
249
191
175
184
177
180
179
172
170
197
179
206
192
169
164
208
197
94
128
211
182
71
107
110
115
154
191
208
124
Avg FDA Days to MDUFA Decision PMAO
Avg MFR Days to MDUFA Decision PMAO
Avg Total Days to MDUFA Decision PMAO



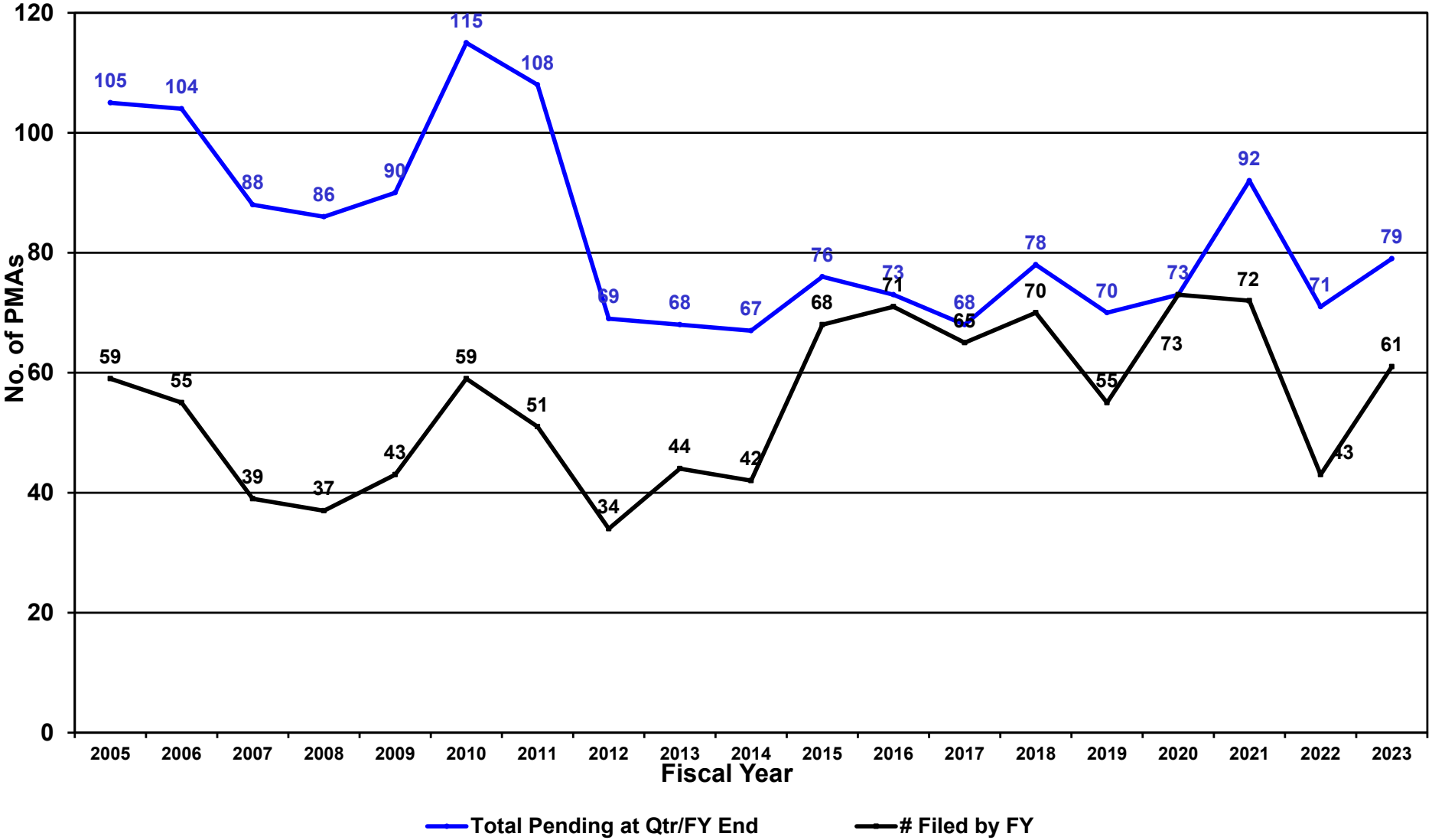
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

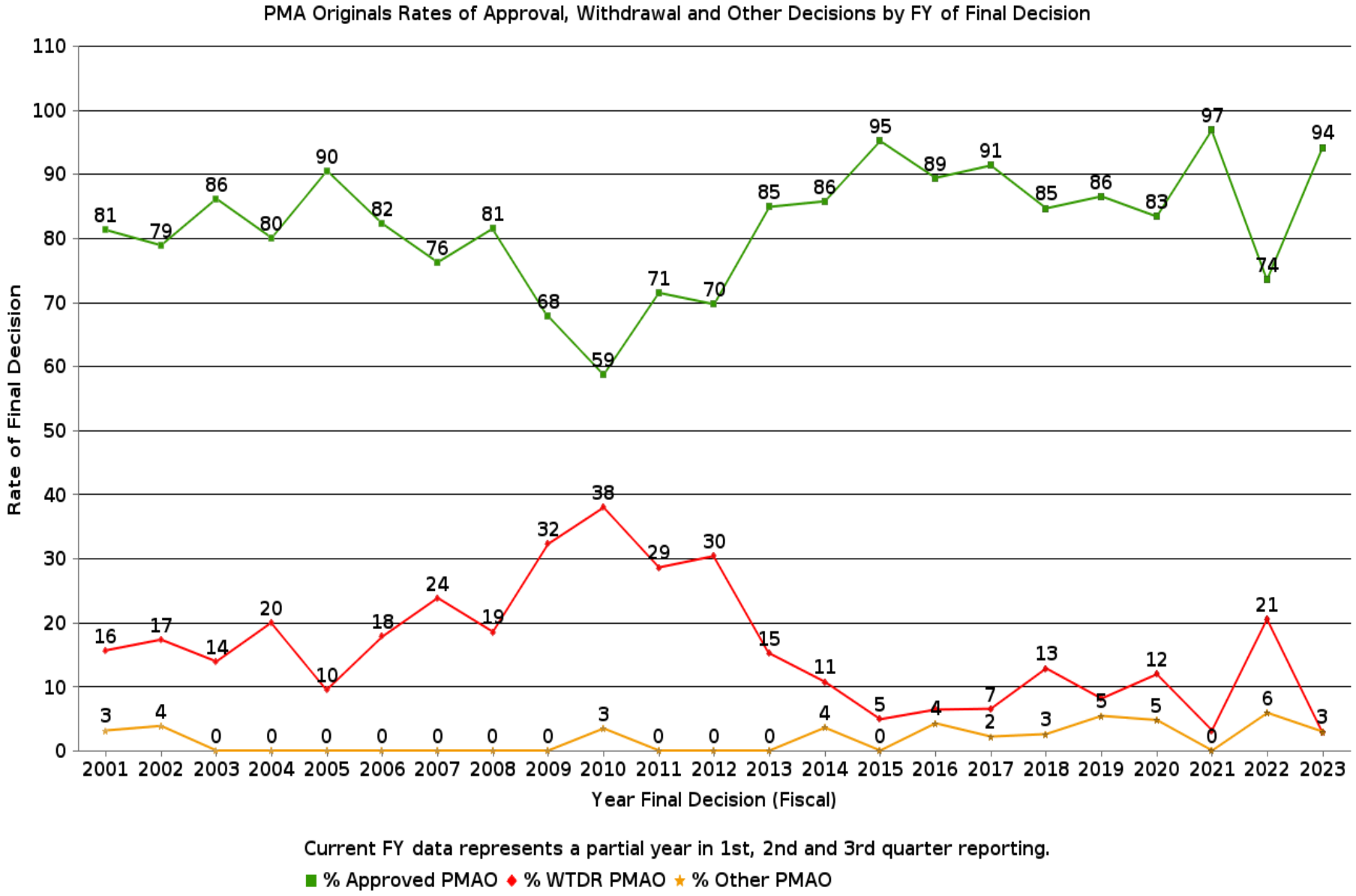


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

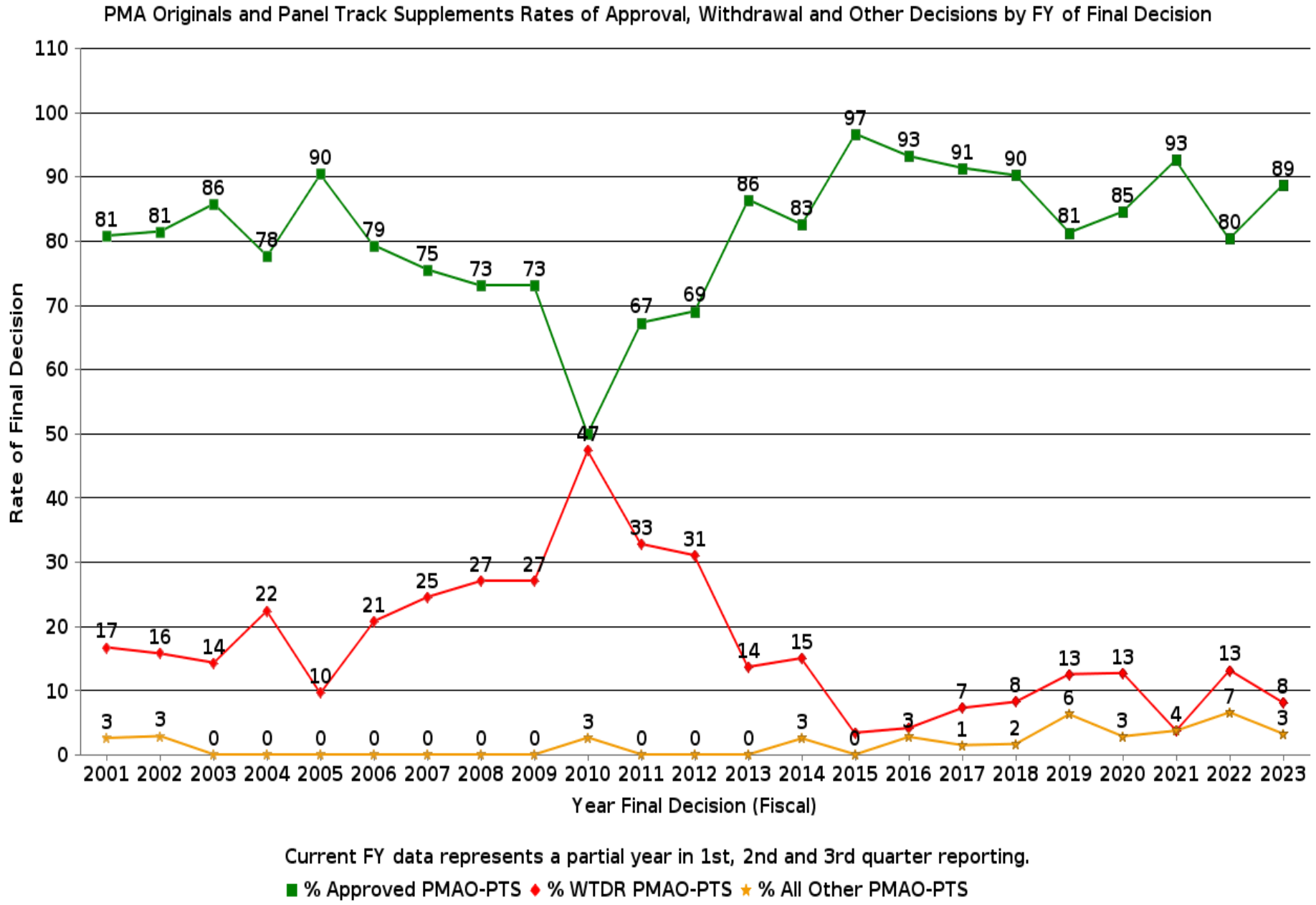
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



*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.

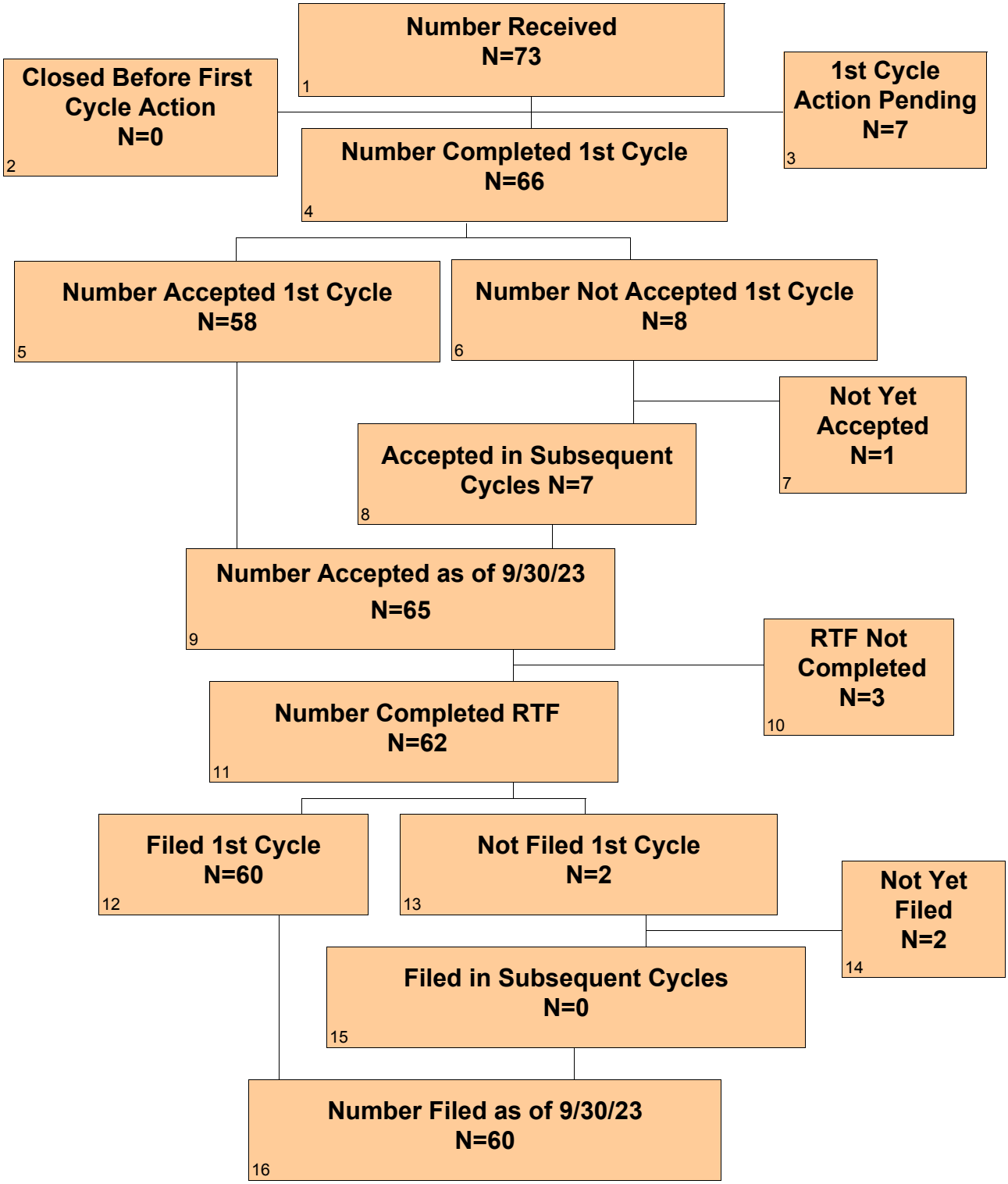


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

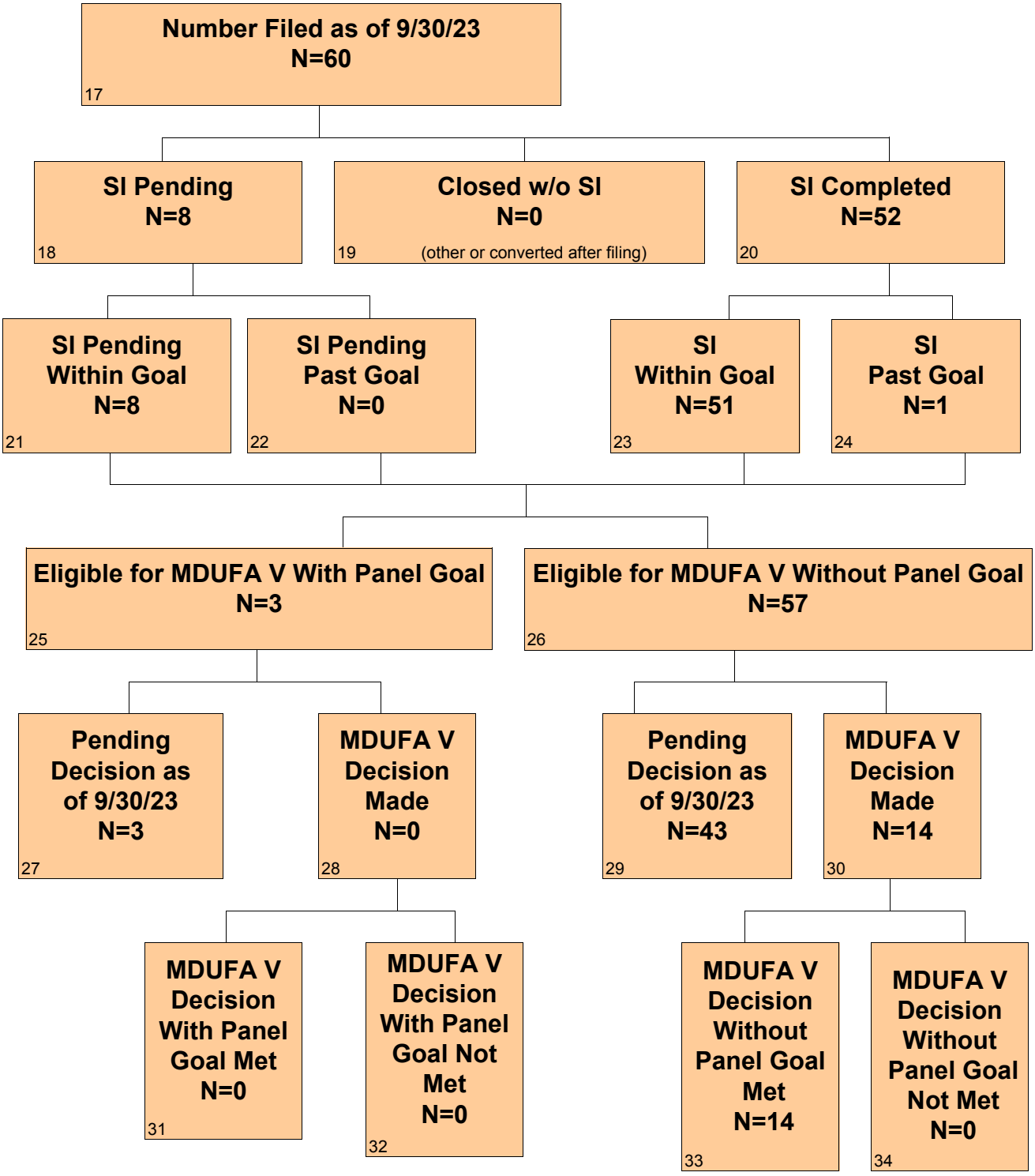


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

CDRH PMA Original and Panel Track Supplements - FY 2023 as of 9/30/23



CDRH PMA Original and Panel Track Supplements - FY 2023 as of 9/30/23 Continued



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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	58				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	7				
Number Not Accepted for Filing Review on First Cycle	8				
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.12%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73				
Number Accepted	58				
Completed RTF	62				
Number Not Filed	2				
Rate of Submissions Not Filed	3.23%				

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	61				
SI Goal Met	51				
SI Goal Not Met	1				
SI Pending Within Goal	9				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	98.08%				

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	52				
Average Number of FDA Days to Substantive Interaction	88.40				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	88				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	91				

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	57				
Non-MDUFA Decision	0				
MDUFA Decision	14				
MDUFA Decision Goal Met	14				
PMAs Pending MDUFA Decision	43				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	3				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	3				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	14				
Average FDA Days to MDUFA Decision	177.79				
20th Percentile FDA Days to MDUFA Decision	178				
40th Percentile FDA Days to MDUFA Decision	179				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	23.43				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	3				
60th Percentile Industry Days to MDUFA Decision	26				
80th Percentile Industry Days to MDUFA Decision	51				
Maximum Industry Days to MDUFA Decision	66				
Average Total Days to MDUFA Decision	201.21				
20th Percentile Total Days to MDUFA Decision	180				
40th Percentile Total Days to MDUFA Decision	182				
60th Percentile Total Days to MDUFA Decision	200				
80th Percentile Total Days to MDUFA Decision	231				
Maximum Total Days to MDUFA Decision	246				

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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	57				
Number with MDUFA Decision	14				
Number of Withdrawal	0				
Number of Not Approvable	1				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	7.14%				

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	3				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	5				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
PMAs Pending MDUFA Decision	3				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

***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	12				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	11				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	3				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted for Filing Review on First Cycle	5				
Rate of Submissions Not Accepted for Filing Review on First Cycle	62.50%				

***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				
Number Accepted	3				
Completed RTF	8				
Number Not Filed	1				
Rate of Submissions Not Filed	12.50%				

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	7				
SI Goal Met	5				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	5				
Average Number of FDA Days to Substantive Interaction	89.40				
20th Percentile FDA Days to Substantive Interaction	89				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	7				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	6				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	1				
Average FDA Days to MDUFA Decision	180.00				
20th Percentile FDA Days to MDUFA Decision	180				
40th Percentile FDA Days to MDUFA Decision	180				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	52.00				
20th Percentile Industry Days to MDUFA Decision	52				
40th Percentile Industry Days to MDUFA Decision	52				
60th Percentile Industry Days to MDUFA Decision	52				
80th Percentile Industry Days to MDUFA Decision	52				
Maximum Industry Days to MDUFA Decision	52				
Average Total Days to MDUFA Decision	232.00				
20th Percentile Total Days to MDUFA Decision	232				
40th Percentile Total Days to MDUFA Decision	232				
60th Percentile Total Days to MDUFA Decision	232				
80th Percentile Total Days to MDUFA Decision	232				
Maximum Total Days to MDUFA Decision	232				

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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	7				
Number with MDUFA Decision	1				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	18				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted for Filing Review on First Cycle	1				
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.26%				

***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				
Number Accepted	18				
Completed RTF	18				
Number Not Filed	0				
Rate of Submissions Not Filed	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	18				
SI Goal Met	15				
SI Goal Not Met	0				
SI Pending Within Goal	3				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	15				
Average Number of FDA Days to Substantive Interaction	88.27				
20th Percentile FDA Days to Substantive Interaction	86				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	16				
Non-MDUFA Decision	0				
MDUFA Decision	5				
MDUFA Decision Goal Met	5				
PMAs Pending MDUFA Decision	11				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	2				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	2				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	5				
Average FDA Days to MDUFA Decision	176.20				
20th Percentile FDA Days to MDUFA Decision	175				
40th Percentile FDA Days to MDUFA Decision	179				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	24.80				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	8				
60th Percentile Industry Days to MDUFA Decision	29				
80th Percentile Industry Days to MDUFA Decision	53				
Maximum Industry Days to MDUFA Decision	59				
Average Total Days to MDUFA Decision	201.00				
20th Percentile Total Days to MDUFA Decision	177				
40th Percentile Total Days to MDUFA Decision	187				
60th Percentile Total Days to MDUFA Decision	208				
80th Percentile Total Days to MDUFA Decision	233				
Maximum Total Days to MDUFA Decision	239				

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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	16				
Number with MDUFA Decision	5				
Number of Withdrawal	0				
Number of Not Approvable	1				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	20.00%				

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	2				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	3				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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				
Number Accepted	3				
Completed RTF	3				
Number Not Filed	0				
Rate of Submissions Not Filed	0.00%				

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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				
Average Number of FDA Days to Substantive Interaction	88.33				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	88				
60th Percentile FDA Days to Substantive Interaction	88				
80th Percentile FDA Days to Substantive Interaction	89				
Maximum FDA Days to Substantive Interaction	90				

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

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

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

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

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

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

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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	0				

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	8				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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				
Number Accepted	8				
Completed RTF	8				
Number Not Filed	0				
Rate of Submissions Not Filed	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	8				
SI Goal Met	8				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	8				
Average Number of FDA Days to Substantive Interaction	88.63				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	8				
Non-MDUFA Decision	0				
MDUFA Decision	3				
MDUFA Decision Goal Met	3				
PMAs Pending MDUFA Decision	5				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	3				
Average FDA Days to MDUFA Decision	179.33				
20th Percentile FDA Days to MDUFA Decision	179				
40th Percentile FDA Days to MDUFA Decision	180				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	35.33				
20th Percentile Industry Days to MDUFA Decision	16				
40th Percentile Industry Days to MDUFA Decision	32				
60th Percentile Industry Days to MDUFA Decision	45				
80th Percentile Industry Days to MDUFA Decision	56				
Maximum Industry Days to MDUFA Decision	66				
Average Total Days to MDUFA Decision	214.67				
20th Percentile Total Days to MDUFA Decision	195				
40th Percentile Total Days to MDUFA Decision	210				
60th Percentile Total Days to MDUFA Decision	224				
80th Percentile Total Days to MDUFA Decision	235				
Maximum Total Days to MDUFA Decision	246				

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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	8				
Number with MDUFA Decision	3				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	3				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	2				
Number Not Accepted for Filing Review on First Cycle	1				
Rate of Submissions Not Accepted for Filing Review on First Cycle	25.00%				

***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				
Number Accepted	3				
Completed RTF	3				
Number Not Filed	0				
Rate of Submissions Not Filed	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	3				
SI Goal Met	2				
SI Goal Not Met	1				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	66.67%				

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	3				
Average Number of FDA Days to Substantive Interaction	90.33				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	91				
Maximum FDA Days to Substantive Interaction	91				

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	3				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	3				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	3				
Number with MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	3				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted for Filing Review on First Cycle	1				
Rate of Submissions Not Accepted for Filing Review on First Cycle	25.00%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5				
Number Accepted	3				
Completed RTF	4				
Number Not Filed	0				
Rate of Submissions Not Filed	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	4				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	3				
Average Number of FDA Days to Substantive Interaction	87.67				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	88				
60th Percentile FDA Days to Substantive Interaction	88				
80th Percentile FDA Days to Substantive Interaction	88				
Maximum FDA Days to Substantive Interaction	88				

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	4				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	4				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	4				
Number with MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	20				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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				
Number Accepted	20				
Completed RTF	18				
Number Not Filed	1				
Rate of Submissions Not Filed	5.56%				

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	18				
SI Goal Met	15				
SI Goal Not Met	0				
SI Pending Within Goal	3				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	15				
Average Number of FDA Days to Substantive Interaction	87.87				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	87				
60th Percentile FDA Days to Substantive Interaction	89				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	17				
Non-MDUFA Decision	0				
MDUFA Decision	3				
MDUFA Decision Goal Met	3				
PMAs Pending MDUFA Decision	14				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	3				
Average FDA Days to MDUFA Decision	179.67				
20th Percentile FDA Days to MDUFA Decision	179				
40th Percentile FDA Days to MDUFA Decision	180				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	6.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	4				
80th Percentile Industry Days to MDUFA Decision	11				
Maximum Industry Days to MDUFA Decision	18				
Average Total Days to MDUFA Decision	185.67				
20th Percentile Total Days to MDUFA Decision	179				
40th Percentile Total Days to MDUFA Decision	180				
60th Percentile Total Days to MDUFA Decision	184				
80th Percentile Total Days to MDUFA Decision	191				
Maximum Total Days to MDUFA Decision	198				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	17				
Number with MDUFA Decision	3				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	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	0				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	5				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
PMAs Pending MDUFA Decision	3				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

***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	12				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	11				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	0				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	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				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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				
Average Number of FDA Days to Substantive Interaction	N/A				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Number with MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

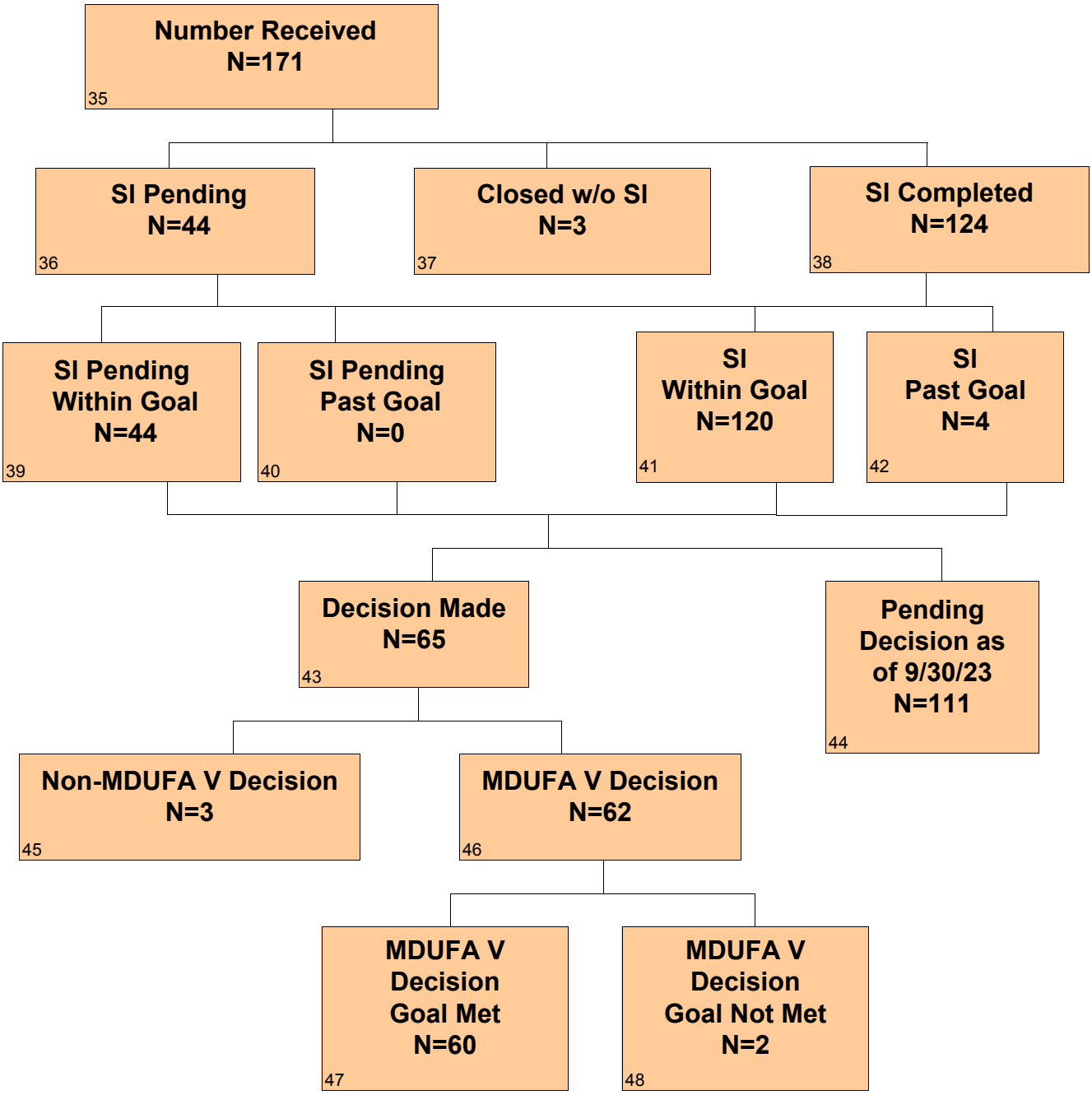
***Includes submission that went to panel**

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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

***Includes submission that went to panel**

CDRH PMA 180 Day Supplements - FY 2023 as of 9/30/23



Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	171				
SI Goal Met	120				
SI Goal Not Met	4				
SI Pending Within Goal	44				
SI Pending Past Goal	0				
Closed Without SI	3				
Current SI Performance Percent Goal Met	96.77%				

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	171				
Non-MDUFA Decision	3				
MDUFA Decision	62				
MDUFA Decision Goal Met	60				
Supplements Pending MDUFA Decision	106				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	96.77%				

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	171				
Number with MDUFA Decision	62				
Number of Not Approvable	2				
Rate of Not Approvable	3.23%				

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				
Mean FDA Days for Submissions that Missed the Goal	197.00				
Mean Industry Days for Submissions that Missed the Goal	77.00				

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	16				
SI Goal Met	11				
SI Goal Not Met	0				
SI Pending Within Goal	5				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	3				
MDUFA Decision Goal Met	3				
Supplements Pending MDUFA Decision	13				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number with MDUFA Decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
SI Goal Met	44				
SI Goal Not Met	0				
SI Pending Within Goal	12				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	56				
Non-MDUFA Decision	0				
MDUFA Decision	27				
MDUFA Decision Goal Met	27				
Supplements Pending MDUFA Decision	29				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number with MDUFA Decision	27				
Number of Not Approvable	1				
Rate of Not Approvable	3.70%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
SI Goal Met	14				
SI Goal Not Met	1				
SI Pending Within Goal	6				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	93.33%				

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				
Non-MDUFA Decision	0				
MDUFA Decision	6				
MDUFA Decision Goal Met	6				
Supplements Pending MDUFA Decision	15				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number with MDUFA Decision	6				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
SI Goal Met	6				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	8				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number with MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	24				
SI Goal Met	12				
SI Goal Not Met	3				
SI Pending Within Goal	9				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	80.00%				

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	24				
Non-MDUFA Decision	0				
MDUFA Decision	8				
MDUFA Decision Goal Met	6				
Supplements Pending MDUFA Decision	16				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	75.00%				

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	24				
Number with MDUFA Decision	8				
Number of Not Approvable	1				
Rate of Not Approvable	12.50%				

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				
Mean FDA Days for Submissions that Missed the Goal	197.00				
Mean Industry Days for Submissions that Missed the Goal	77.00				

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	7				
SI Goal Met	6				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	7				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Goal Met	4				
Supplements Pending MDUFA Decision	3				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	7				
Number with MDUFA Decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	38				
SI Goal Met	27				
SI Goal Not Met	0				
SI Pending Within Goal	8				
SI Pending Past Goal	0				
Closed Without SI	3				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	38				
Non-MDUFA Decision	3				
MDUFA Decision	14				
MDUFA Decision Goal Met	14				
Supplements Pending MDUFA Decision	21				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	38				
Number with MDUFA Decision	14				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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

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

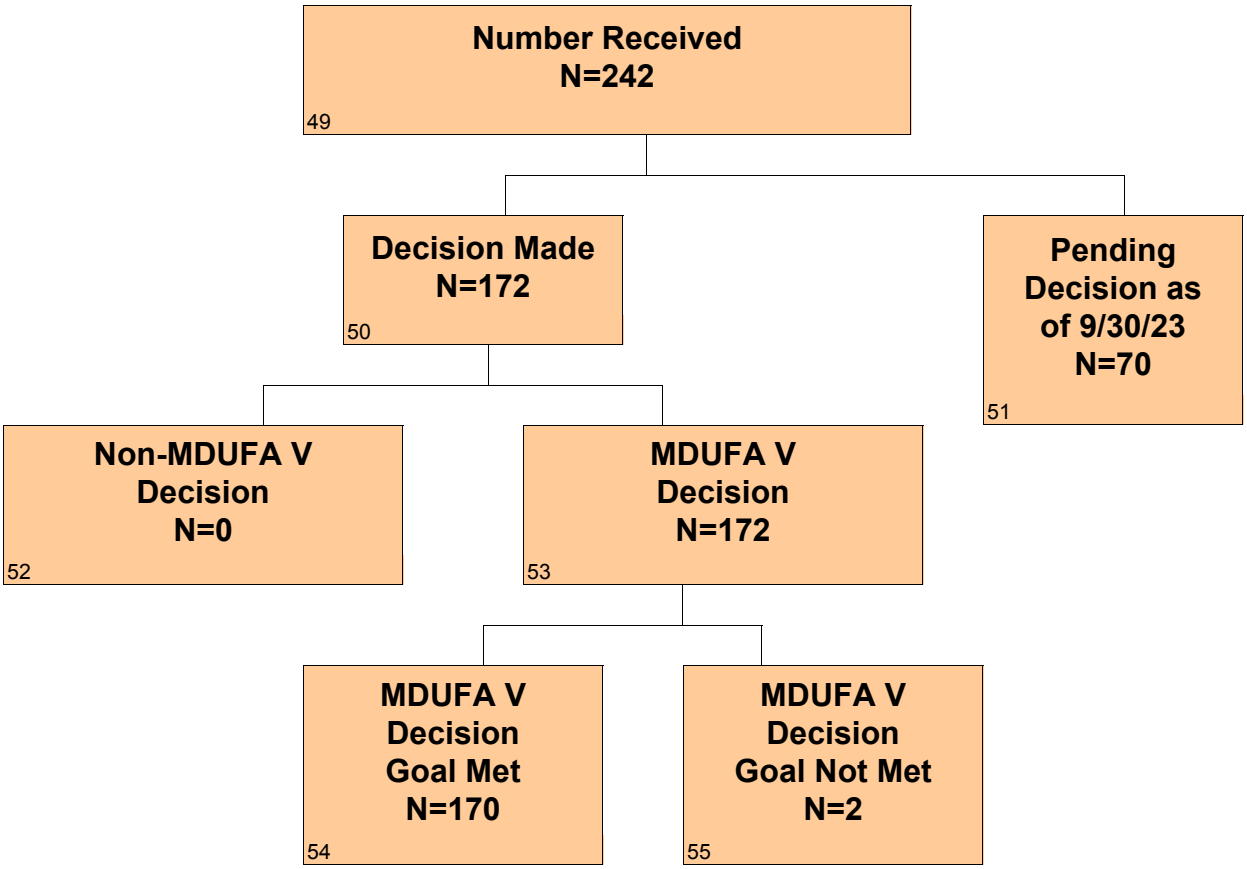
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1				
Number with MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	N/A				

CDRH PMA Real Time Supplements - FY 2023 as of 9/30/23



Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	242				
Non-MDUFA Decision	0				
MDUFA Decision	172				
MDUFA Decision Goal Met	170				
Supplements Pending MDUFA Decision	70				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	98.84%				

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	242				
Number With MDUFA Decision	172				
Number of Not Approvable	5				
Rate of Not Approvable	2.91%				

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				
Mean FDA Days for Submissions that Missed the Goal	109.50				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA Decision	0				
MDUFA Decision	17				
MDUFA Decision Goal Met	17				
Supplements Pending MDUFA Decision	7				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number With MDUFA Decision	17				
Number of Not Approvable	1				
Rate of Not Approvable	5.88%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	137				
Non-MDUFA Decision	0				
MDUFA Decision	111				
MDUFA Decision Goal Met	111				
Supplements Pending MDUFA Decision	26				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	137				
Number With MDUFA Decision	111				
Number of Not Approvable	2				
Rate of Not Approvable	1.80%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	0				
MDUFA Decision	12				
MDUFA Decision Goal Met	11				
Supplements Pending MDUFA Decision	7				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	91.67%				

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				
Number With MDUFA Decision	12				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

Table 3.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1				
Mean FDA Days for Submissions that Missed the Goal	92.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	6				
Non-MDUFA Decision	0				
MDUFA Decision	5				
MDUFA Decision Goal Met	5				
Supplements Pending MDUFA Decision	1				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	6				
Number With MDUFA Decision	5				
Number of Not Approvable	2				
Rate of Not Approvable	40.00%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	17				
Non-MDUFA Decision	0				
MDUFA Decision	6				
MDUFA Decision Goal Met	5				
Supplements Pending MDUFA Decision	11				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	83.33%				

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	17				
Number With MDUFA Decision	6				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

Table 3.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1				
Mean FDA Days for Submissions that Missed the Goal	127.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	5				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
Supplements Pending MDUFA Decision	3				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	5				
Number With MDUFA Decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	0				
MDUFA Decision	18				
MDUFA Decision Goal Met	18				
Supplements Pending MDUFA Decision	14				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Number With MDUFA Decision	18				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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

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

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

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

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

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2022 and September 30, 2023.

Section 5 PMA Annual General Metrics

Table 5.1 CDRH - PMAs (All Review Tracks) Annual General Metrics - PMAs Received by Type

PMA Submissions Received	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Premarket Report Submissions	0				
Original PMAs (Panel) - Breakthrough Device	3				
Original PMAs (No Panel) - Breakthrough Device	11				
Original PMAs (Panel) - Non-Breakthrough Device	0				
Original PMAs (No Panel) - Non-Breakthrough Device	30				
Panel-Tracked Supplements (Panel) - Breakthrough Device	0				
Panel-Tracked Supplements (No Panel) - Breakthrough Device	2				
Panel-Tracked Supplements (Panel) - Non-Breakthrough Device	0				
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	27				
PMA Modules	79				
180-Day Supplements	171				
Real-Time Supplements	242				

Table 5.2 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Percent Cohorts Closed

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	61				
Number With a Decision (MDUFA or Non-MDUFA)	14				
% of FY Closed	22.95%				

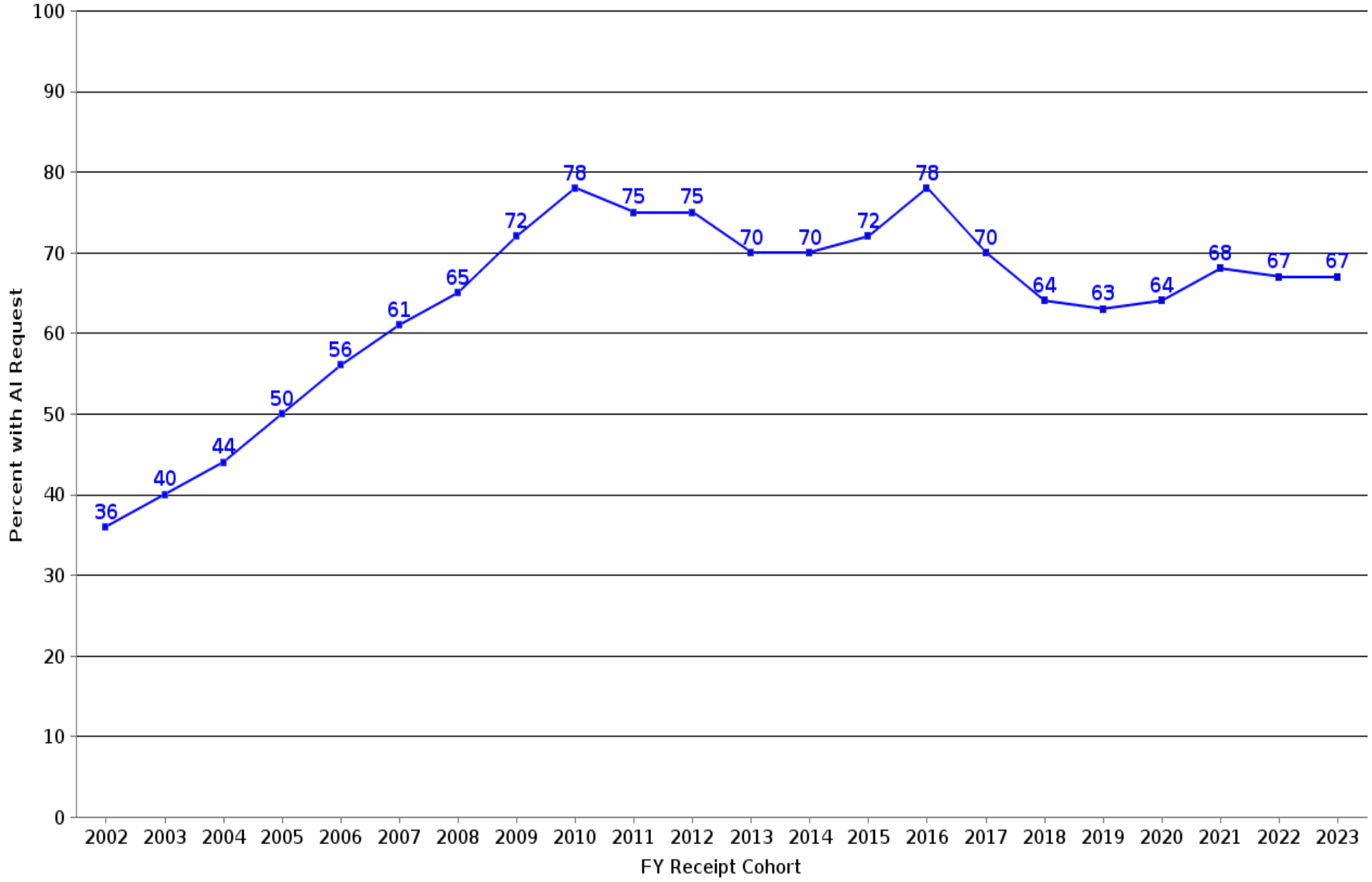
Table 5.3 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Three-Year Rolling Average Time to MDUFA IV Decision

Performance Metric	FY 2023 3 Year Cohort 290 FDA Days	FY 2024 3 Year Cohort 290 FDA Days	FY 2025 3 Year Cohort 285 FDA Days	FY 2026 3 Year Cohort 285 FDA Days	FY 2027 3 Year Cohort 285 FDA Days
Number With a MDUFA Decision	119				
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	101				
Three-year Rolling Average Total Time to MDUFA Decision	N/A				

510(k)s

Q4FY2023

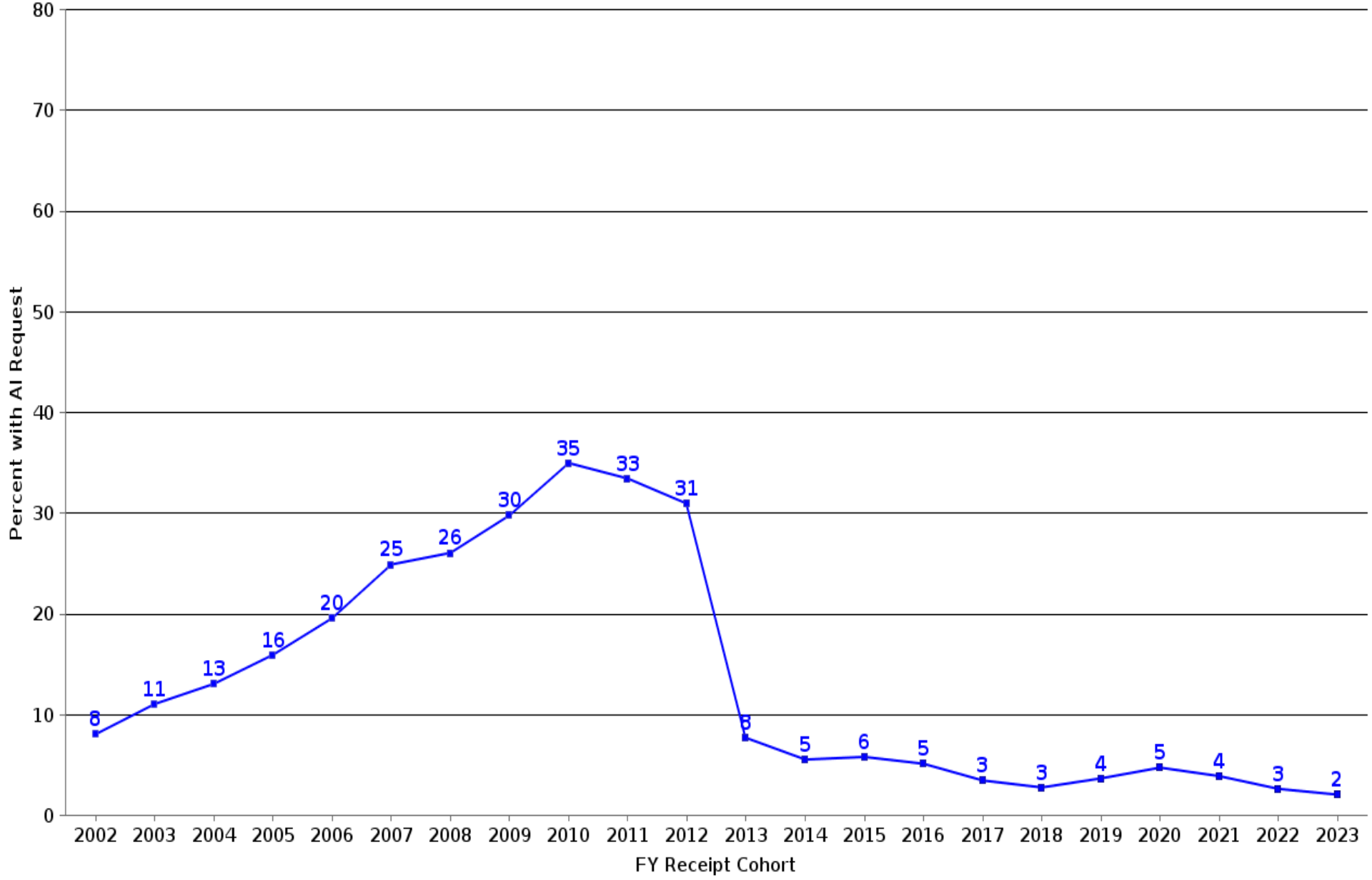
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/23

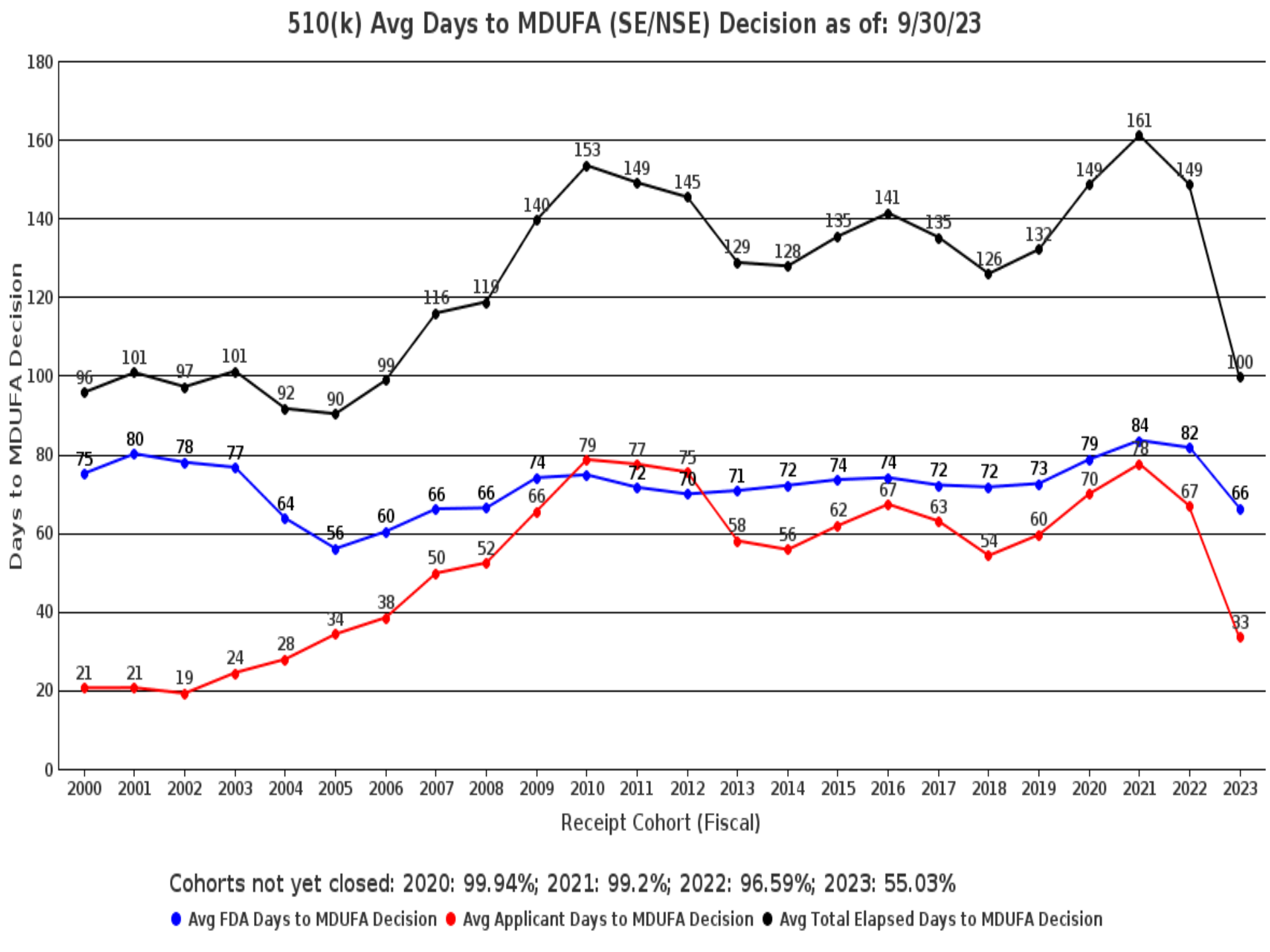
■ % with 1st Cycle AI Request

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



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 2/28/23

■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 9/30/23
Days to MDUFA Decision
Receipt Cohort (Fiscal)
0
20
40
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160
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149
145
129
128
135
141
135
126
132
149
161
149
100
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60
66
66
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72
73
79
84
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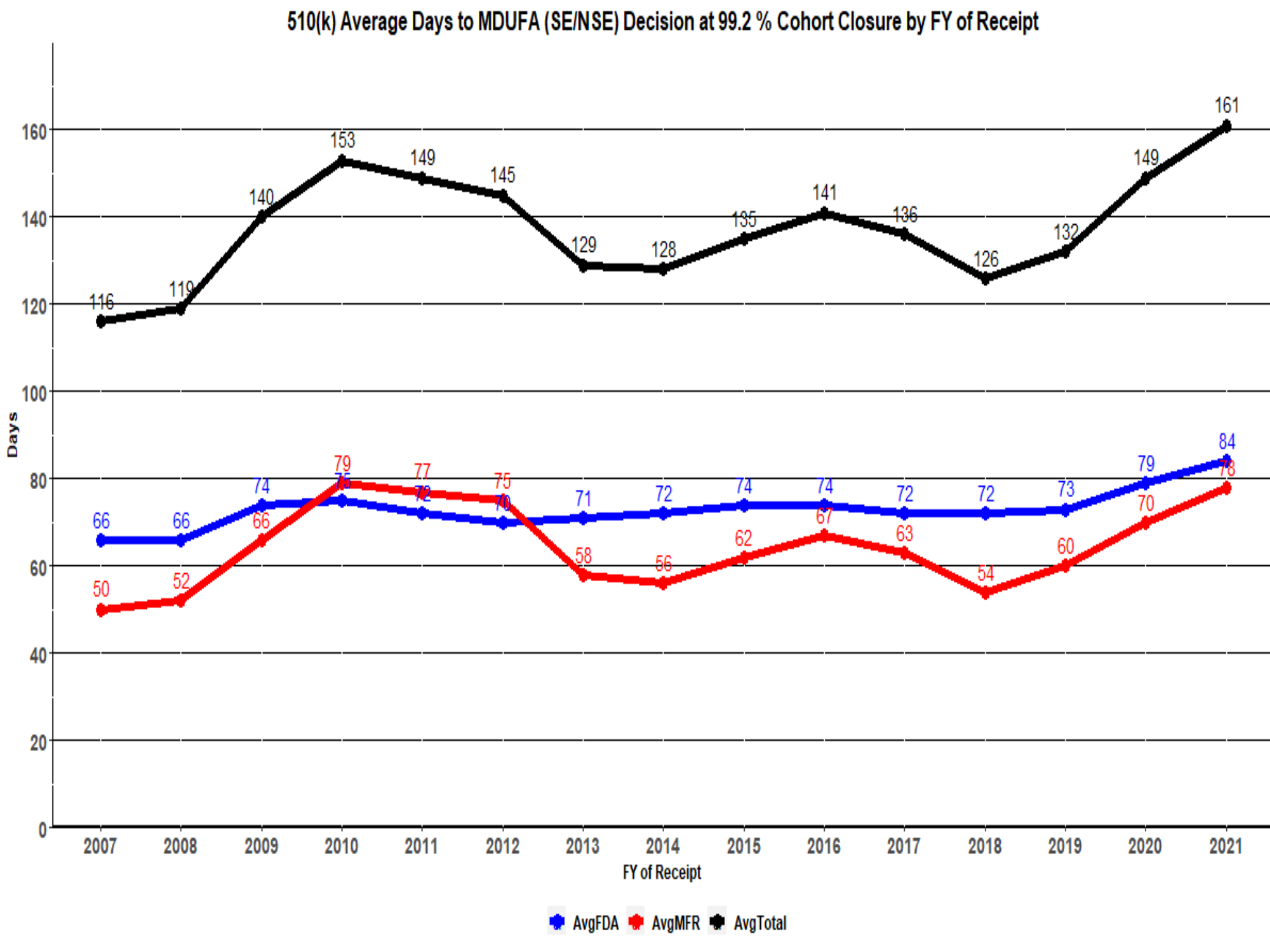
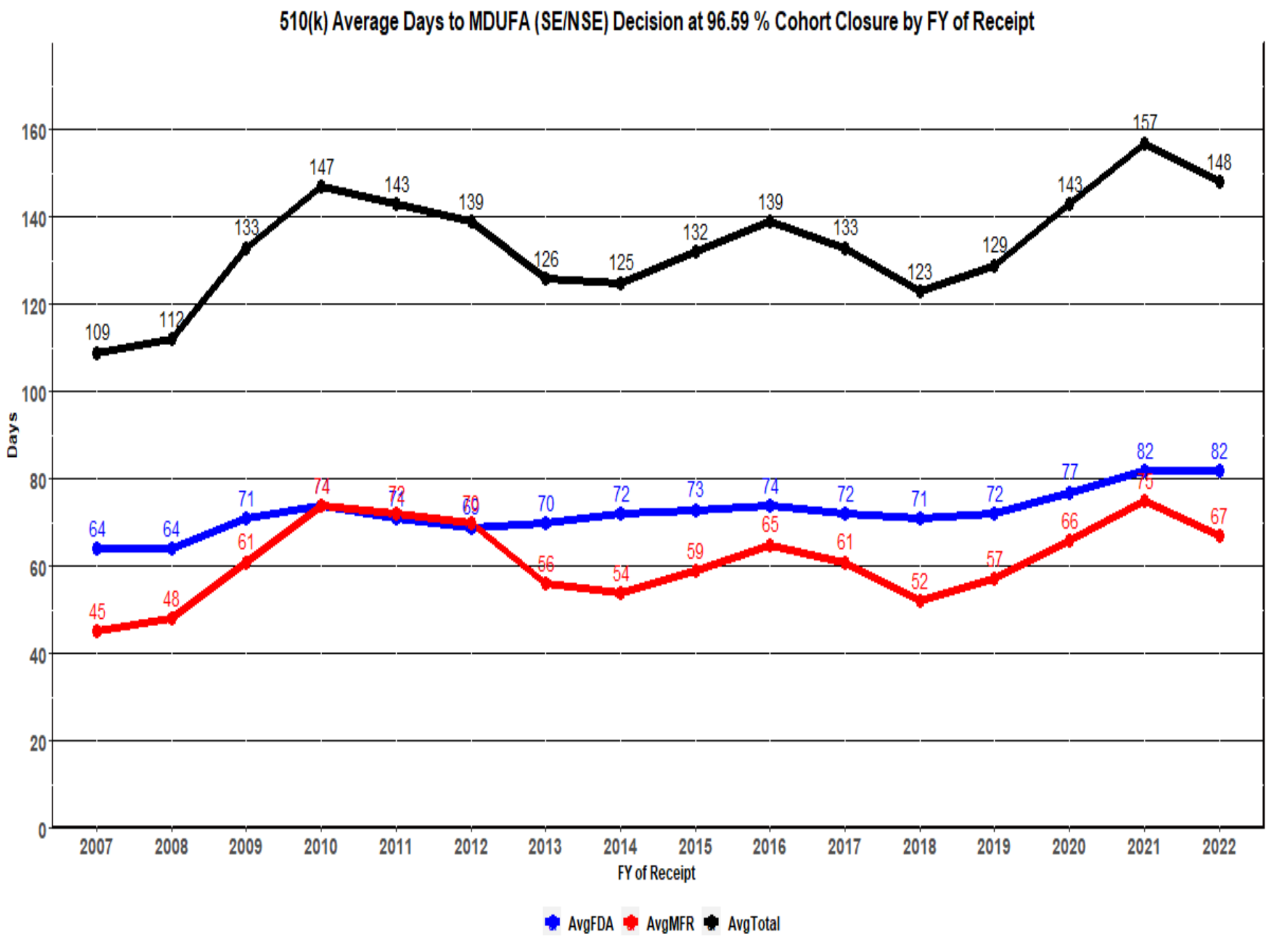
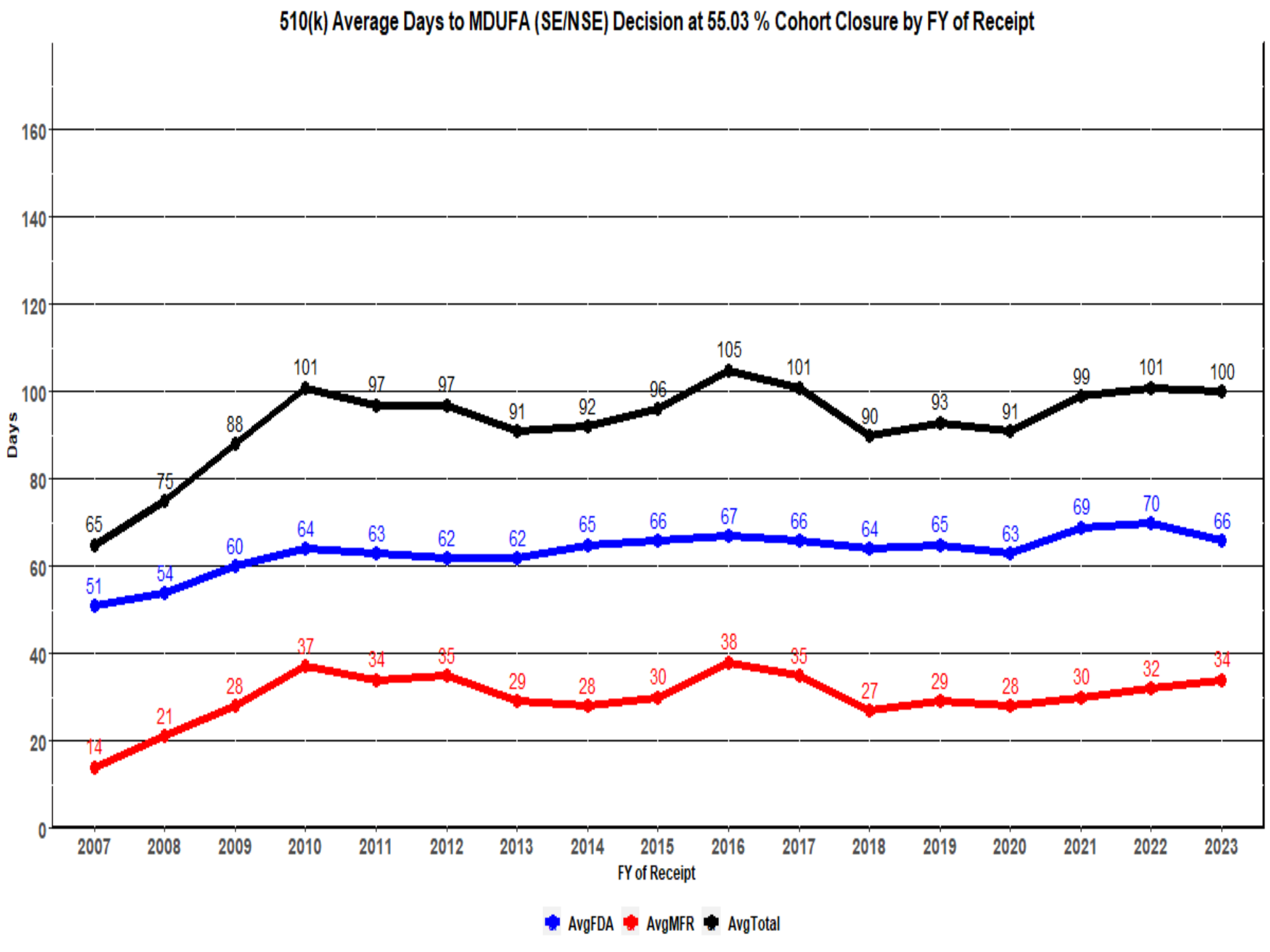
66
21
21
19
24
28
34
38
50
52
66
79
77
75
58
56
62
67
63
54
60
70
78
67
33
Cohorts not yet closed: 2020: 99.94%; 2021: 99.2%; 2022: 96.59%; 2023: 55.03%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision

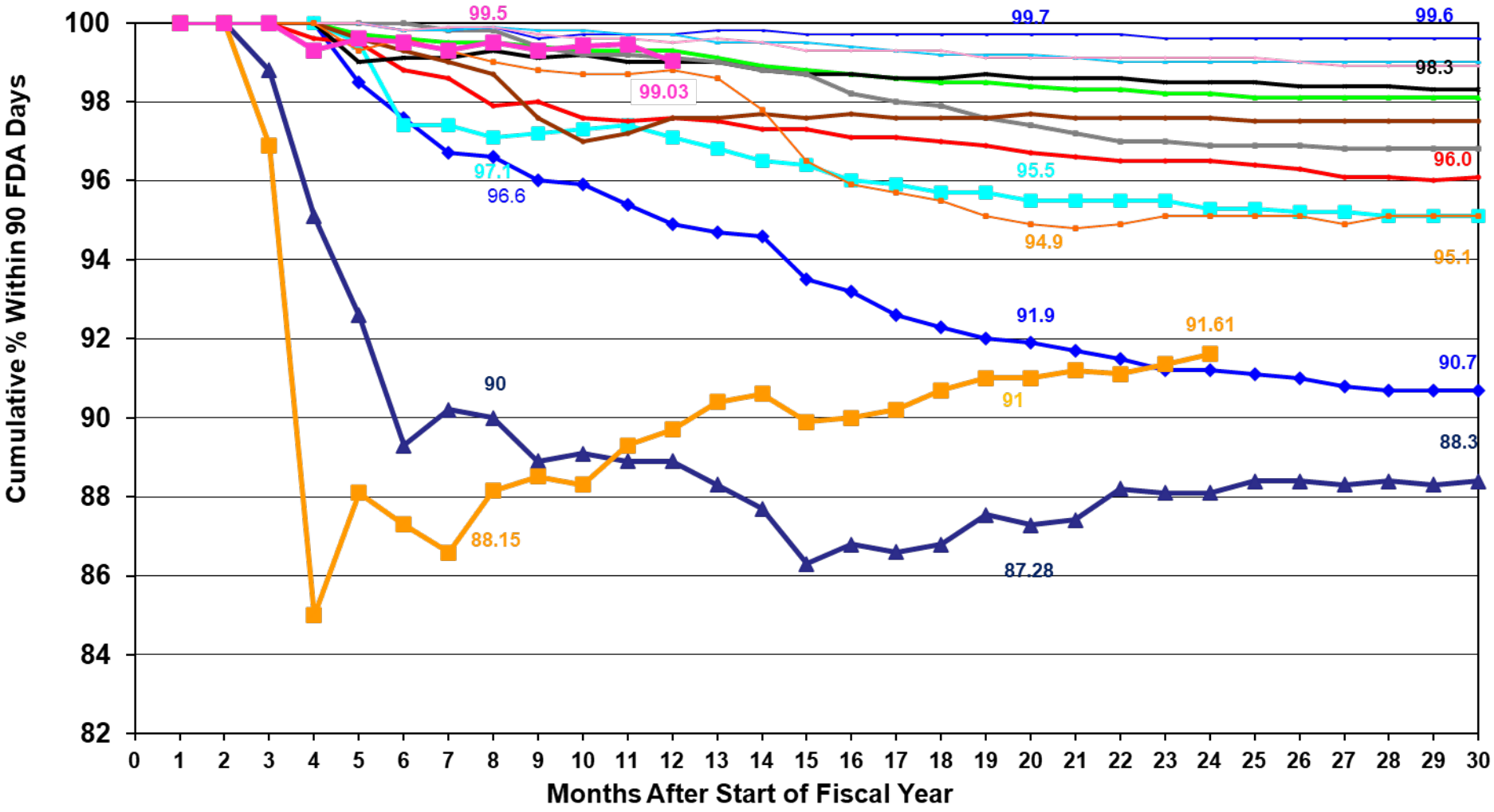

510(k) Average Days to MDUFA (SE/NSE) Decision at 99.2 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
AvgFDA
AvgMFR
AvgTotal
116
119
140
153
149
145
129
128
135
141
136
126
132
149
161
66
66
74
75
72
70
71
72
74
74
72
72
73
79
84
50
52
66
79
77
75
58
56
62
67
63
54
60
70
78


510(k) Average Days to MDUFA (SE/NSE) Decision at 96.59 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
AvgFDA
AvgMFR
AvgTotal

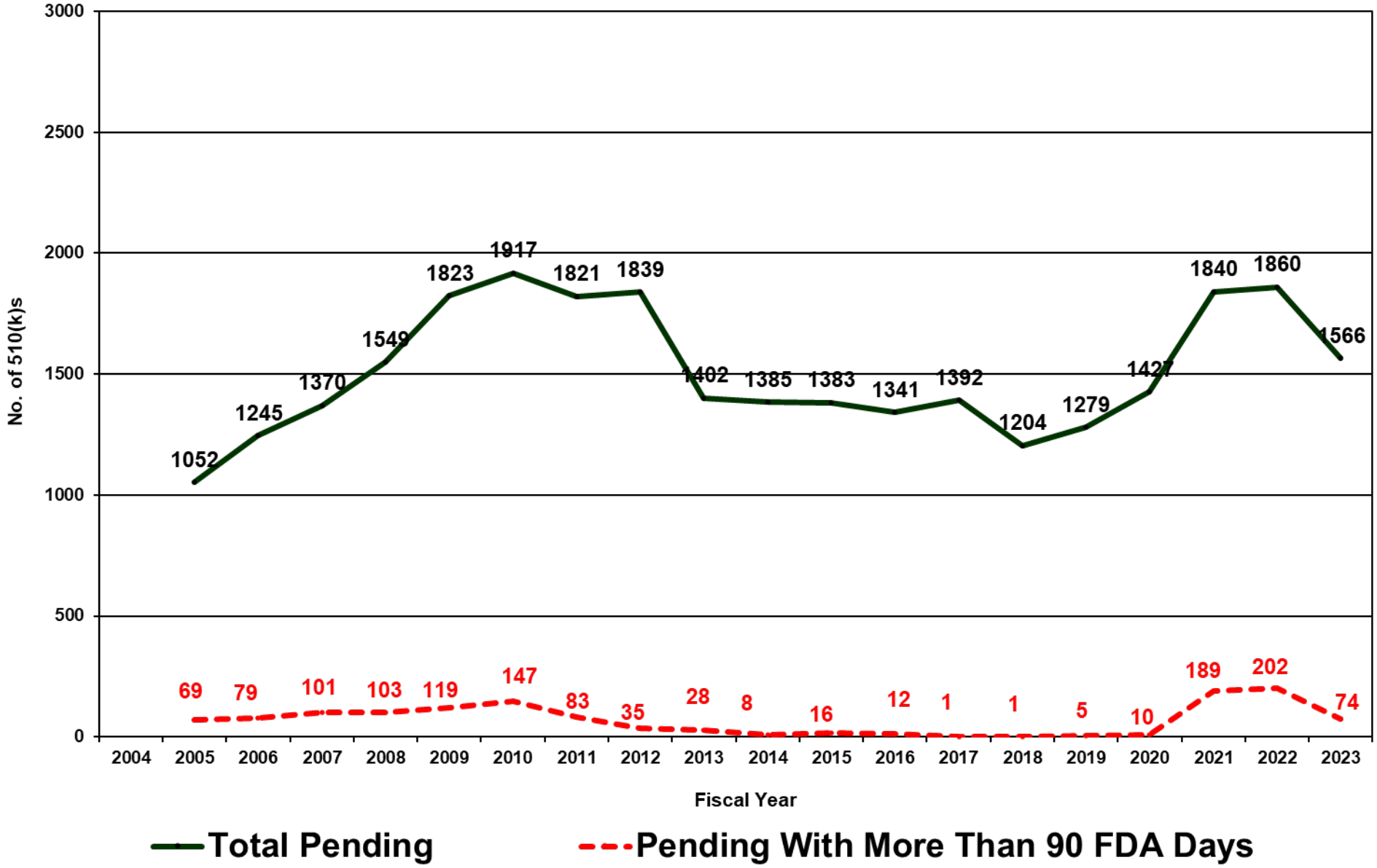

510(k) Average Days to MDUFA (SE/NSE) Decision at 55.03 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
FY of Receipt
65
75
88
101
97
97
91
92
96
105
101
90
93
91
99
101
100
51
54
60
64
63
62
62
65
66
67
66
64
65
63
69
70
66
14
21
28
37
34
35
29
28
30
38
35
27
29
28
30
32
34
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

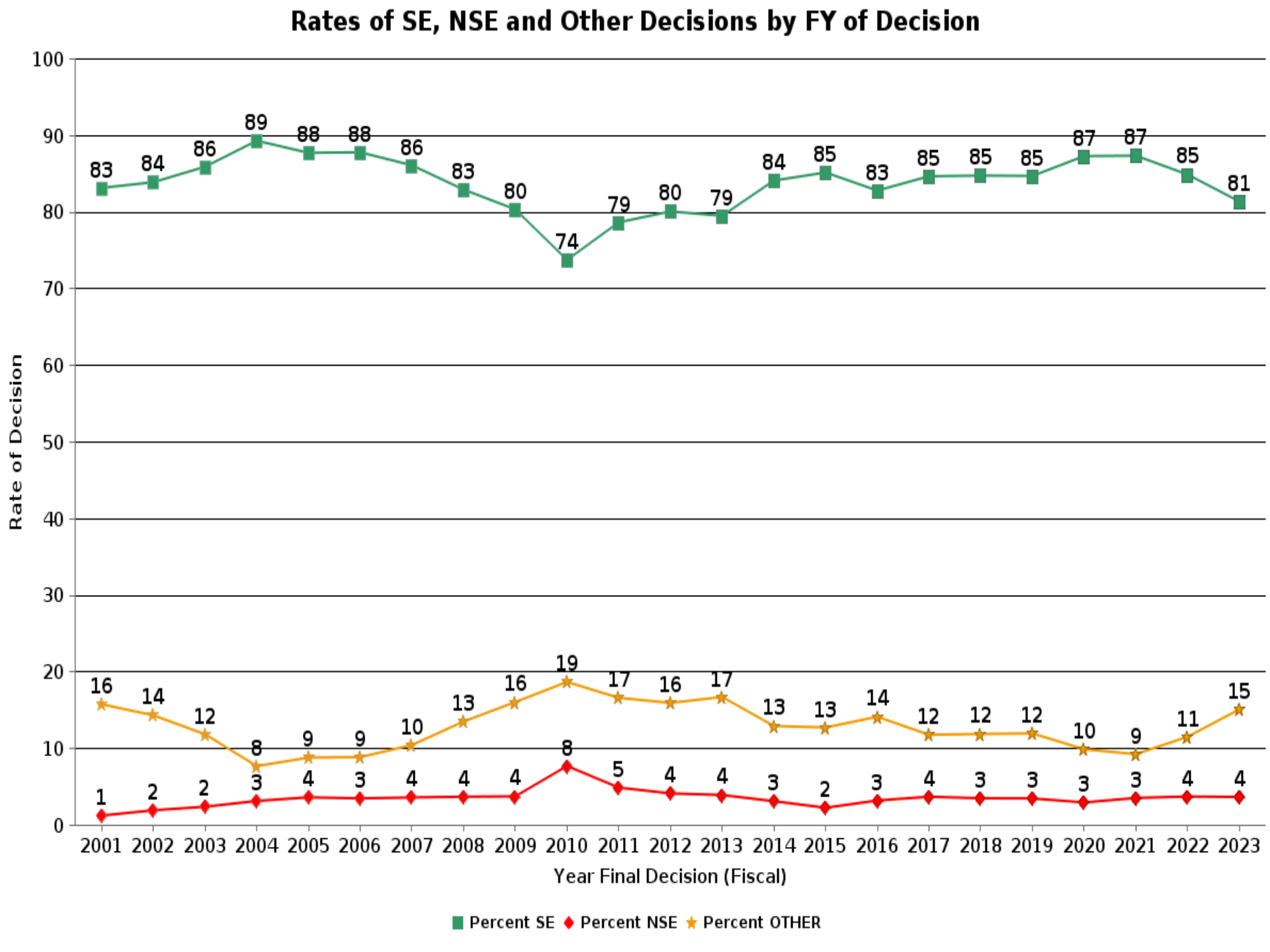
Comparison of FY10 – FY23 Receipt Cohorts



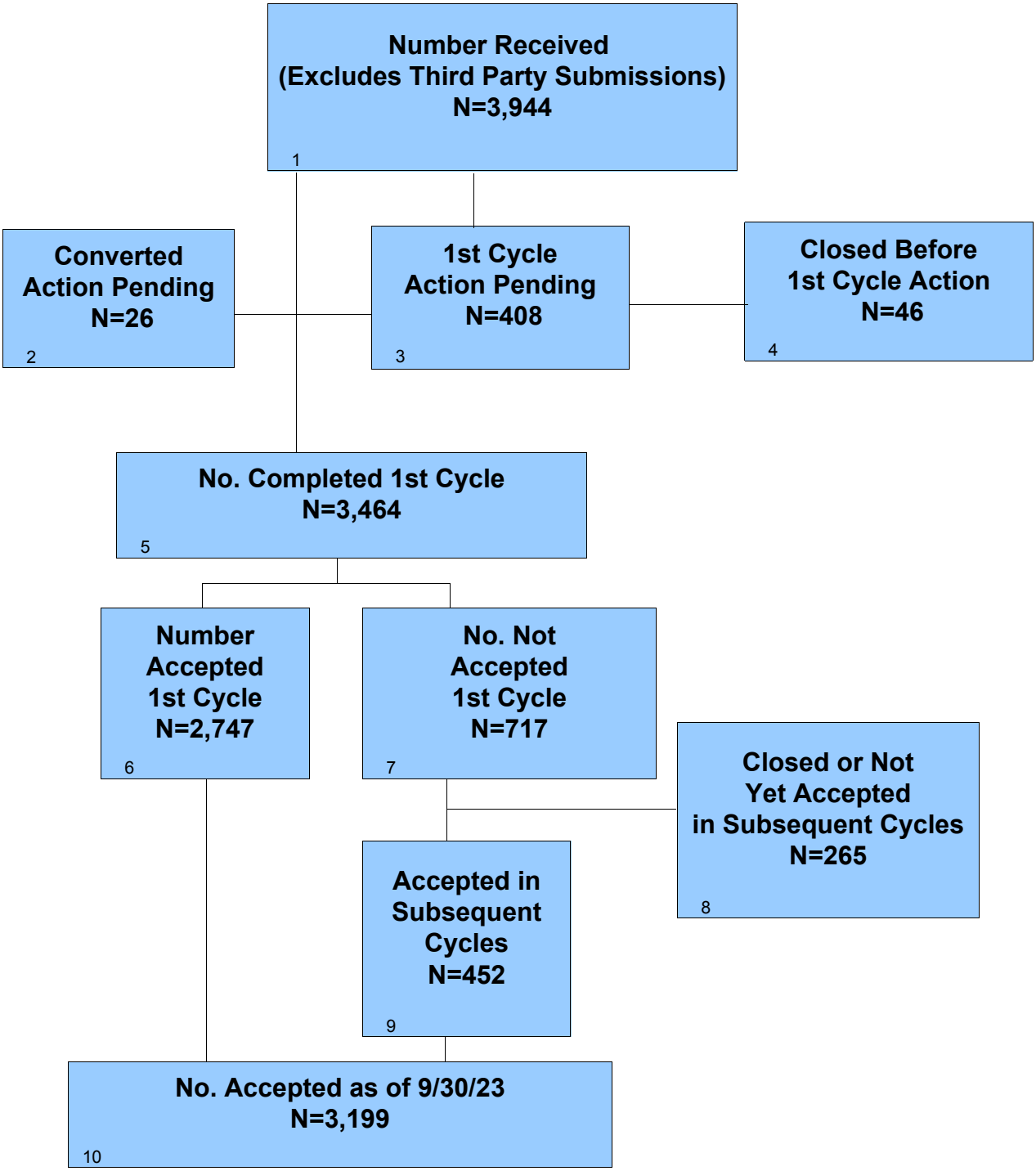
510(k)s Pending at End of Quarter/Year



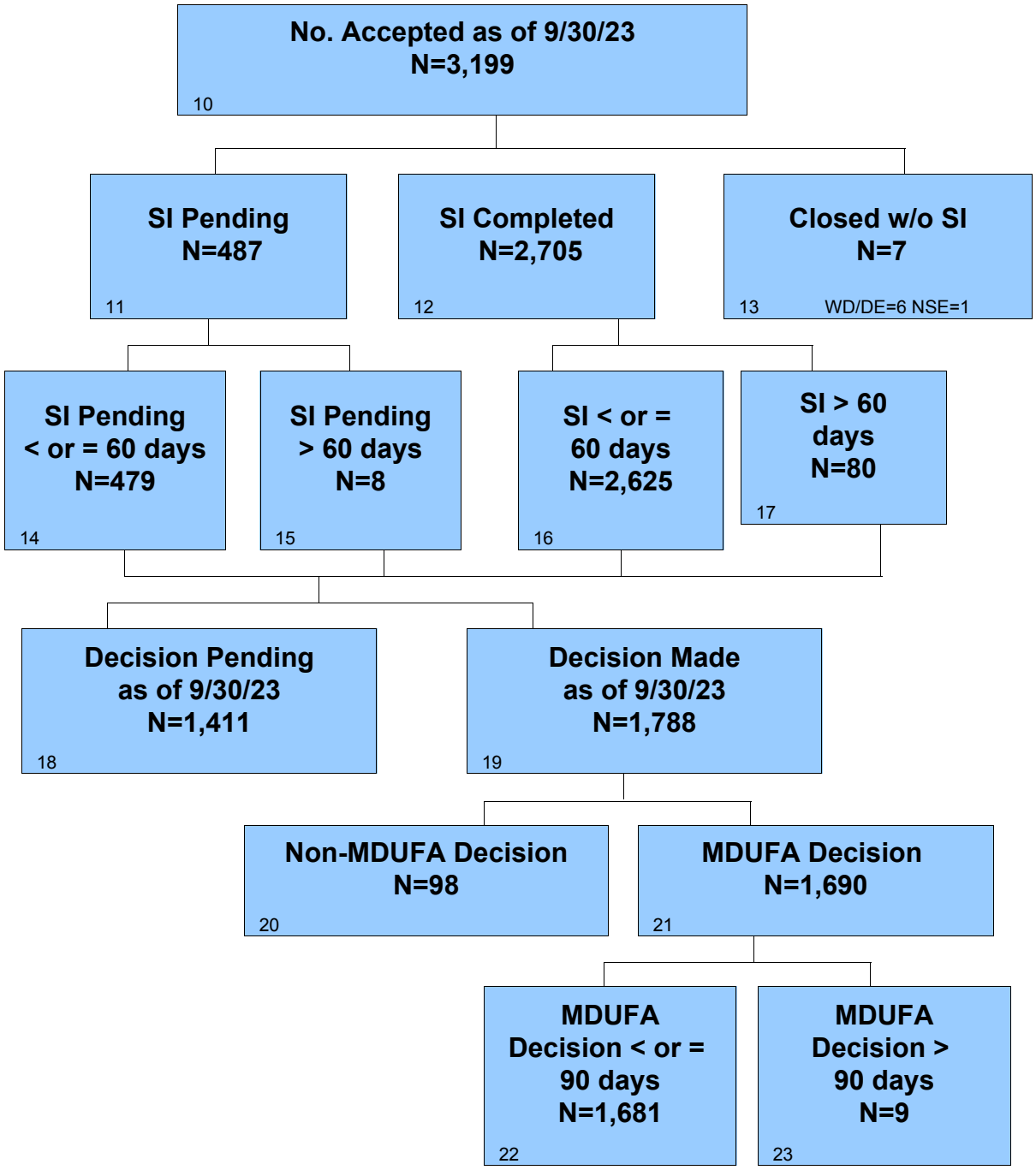
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 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
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

CDRH 510(k)s - FY 2023
as of 9/30/23



CDRH 510(k)s - FY 2023
as of 9/30/23 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,944				
Closed Before First RTA or TS Action [1]	46				
Number Accepted or Passed TS on First Cycle [2]	2,730				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	17				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	434				
Number Not Accepted or Failed TS on First Cycle [2]	717				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.70%				

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	3,199				
Deleted or Withdrawn Prior to SI	6				
SI Within 60 FDA Days	2,625				
SI Over 60 FDA Days	80				
SI Pending Within 60 FDA Days	479				
SI Pending Over 60 FDA Days	8				
510(k)s NSE Without SI	1				
Current SI Performance Percent Within 60 FDA Days	96.72%				

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	2,705				
Average Number of FDA Days to Substantive Interaction	51.90				
20th Percentile FDA Days to Substantive Interaction	45				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	212				

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	3,199				
Non-MDUFA V Decision	98				
MDUFA V Decision (SE/NSE)	1,690				
MDUFA V Decision Within 90 FDA Days	1,681				
510(k)s Pending MDUFA V Decision	1,411				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	5				
Current Performance Percent Within 90 FDA Days	99.17%				

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	1.49				
Number With MDUFA V Decision	1,690				
Average Number of FDA Days to MDUFA V Decision	67.57				
20th Percentile FDA Days to MDUFA V Decision	30				
40th Percentile FDA Days to MDUFA V Decision	60				
60th Percentile FDA Days to MDUFA V Decision	86				
80th Percentile FDA Days to MDUFA V Decision	89				
Maximum FDA Days to MDUFA V Decision	276				
Average Number of Industry Days to MDUFA V Decision	34.16				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	18				
80th Percentile Industry Days to MDUFA V Decision	71				
Maximum Industry Days to MDUFA V Decision	194				
Average Number of Total Days to MDUFA V Decision	101.68				
20th Percentile Total Days to MDUFA V Decision	30				
40th Percentile Total Days to MDUFA V Decision	72				
60th Percentile Total Days to MDUFA V Decision	100				
80th Percentile Total Days to MDUFA V Decision	156				
Maximum Total Days to MDUFA V Decision	323				

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	3,199				
Number With MDUFA V Decision	1,690				
Number of SE Decision	1,658				
Number of NSE Decision	32				
Number of Withdrawal	65				
Number of Deleted	28				
Rate of SE Decision	98.11%				
Rate of NSE Decision	1.89%				
Rate of Withdrawal	2.03%				
Rate of Deleted	0.88%				

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	9				
Mean FDA Days for Submissions that Missed the Goal	112.78				
Mean Industry Days for Submissions that Missed the Goal	103.78				

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

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	236				
Non-MDUFA V Decision	15				
MDUFA V Decision (SE/NSE)	93				
MDUFA V Decision Within 90 FDA Days	93				
510(k)s Pending MDUFA V Decision	128				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	600				
Closed Before First RTA or TS Action [1]	8				
Number Accepted or Passed TS on First Cycle [2]	287				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	69				
Number Not Accepted or Failed TS on First Cycle [2]	233				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.55%				

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

Table 6.2 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	426				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	296				
SI Over 60 FDA Days	55				
SI Pending Within 60 FDA Days	71				
SI Pending Over 60 FDA Days	2				
510(k)s NSE Without SI	1				
Current SI Performance Percent Within 60 FDA Days	83.62%				

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	351				
Average Number of FDA Days to Substantive Interaction	55.86				
20th Percentile FDA Days to Substantive Interaction	53				
40th Percentile FDA Days to Substantive Interaction	58				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	212				

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	426				
Non-MDUFA V Decision	13				
MDUFA V Decision (SE/NSE)	185				
MDUFA V Decision Within 90 FDA Days	181				
510(k)s Pending MDUFA V Decision	228				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	97.84%				

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	1.57				
Number With MDUFA V Decision	185				
Average Number of FDA Days to MDUFA V Decision	76.91				
20th Percentile FDA Days to MDUFA V Decision	59				
40th Percentile FDA Days to MDUFA V Decision	86				
60th Percentile FDA Days to MDUFA V Decision	89				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	276				
Average Number of Industry Days to MDUFA V Decision	35.73				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	27				
80th Percentile Industry Days to MDUFA V Decision	68				
Maximum Industry Days to MDUFA V Decision	181				
Average Number of Total Days to MDUFA V Decision	112.64				
20th Percentile Total Days to MDUFA V Decision	60				
40th Percentile Total Days to MDUFA V Decision	90				
60th Percentile Total Days to MDUFA V Decision	114				
80th Percentile Total Days to MDUFA V Decision	156				
Maximum Total Days to MDUFA V Decision	323				

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	426				
Number With MDUFA V Decision	185				
Number of SE Decision	178				
Number of NSE Decision	7				
Number of Withdrawal	8				
Number of Deleted	5				
Rate of SE Decision	96.22%				
Rate of NSE Decision	3.78%				
Rate of Withdrawal	1.88%				
Rate of Deleted	1.17%				

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	4				
Mean FDA Days for Submissions that Missed the Goal	137.75				
Mean Industry Days for Submissions that Missed the Goal	103.00				

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	395				
Closed Before First RTA or TS Action [1]	7				
Number Accepted or Passed TS on First Cycle [2]	309				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	38				
Number Not Accepted or Failed TS on First Cycle [2]	39				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	11.14%				

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

Table 6.2 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	336				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	278				
SI Over 60 FDA Days	7				
SI Pending Within 60 FDA Days	49				
SI Pending Over 60 FDA Days	2				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	96.86%				

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	285				
Average Number of FDA Days to Substantive Interaction	50.99				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	86				

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	336				
Non-MDUFA V Decision	4				
MDUFA V Decision (SE/NSE)	190				
MDUFA V Decision Within 90 FDA Days	186				
510(k)s Pending MDUFA V Decision	142				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2				
Current Performance Percent Within 90 FDA Days	96.88%				

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	1.57				
Number With MDUFA V Decision	190				
Average Number of FDA Days to MDUFA V Decision	67.38				
20th Percentile FDA Days to MDUFA V Decision	30				
40th Percentile FDA Days to MDUFA V Decision	60				
60th Percentile FDA Days to MDUFA V Decision	87				
80th Percentile FDA Days to MDUFA V Decision	89				
Maximum FDA Days to MDUFA V Decision	95				
Average Number of Industry Days to MDUFA V Decision	42.79				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	36				
80th Percentile Industry Days to MDUFA V Decision	85				
Maximum Industry Days to MDUFA V Decision	185				
Average Number of Total Days to MDUFA V Decision	110.17				
20th Percentile Total Days to MDUFA V Decision	30				
40th Percentile Total Days to MDUFA V Decision	86				
60th Percentile Total Days to MDUFA V Decision	121				
80th Percentile Total Days to MDUFA V Decision	169				
Maximum Total Days to MDUFA V Decision	280				

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	336				
Number With MDUFA V Decision	190				
Number of SE Decision	184				
Number of NSE Decision	6				
Number of Withdrawal	3				
Number of Deleted	1				
Rate of SE Decision	96.84%				
Rate of NSE Decision	3.16%				
Rate of Withdrawal	0.89%				
Rate of Deleted	0.30%				

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				
Mean FDA Days for Submissions that Missed the Goal	92.75				
Mean Industry Days for Submissions that Missed the Goal	82.50				

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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	495				
Closed Before First RTA or TS Action [1]	4				
Number Accepted or Passed TS on First Cycle [2]	352				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	56				
Number Not Accepted or Failed TS on First Cycle [2]	81				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	18.62%				

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 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	402				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	323				
SI Over 60 FDA Days	9				
SI Pending Within 60 FDA Days	66				
SI Pending Over 60 FDA Days	3				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	96.42%				

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	332				
Average Number of FDA Days to Substantive Interaction	54.39				
20th Percentile FDA Days to Substantive Interaction	54				
40th Percentile FDA Days to Substantive Interaction	58				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	77				

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	402				
Non-MDUFA V Decision	13				
MDUFA V Decision (SE/NSE)	180				
MDUFA V Decision Within 90 FDA Days	179				
510(k)s Pending MDUFA V Decision	209				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3				
Current Performance Percent Within 90 FDA Days	97.81%				

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	1.62				
Number With MDUFA V Decision	180				
Average Number of FDA Days to MDUFA V Decision	73.10				
20th Percentile FDA Days to MDUFA V Decision	57				
40th Percentile FDA Days to MDUFA V Decision	85				
60th Percentile FDA Days to MDUFA V Decision	88				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	93				
Average Number of Industry Days to MDUFA V Decision	49.44				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	4				
60th Percentile Industry Days to MDUFA V Decision	48				
80th Percentile Industry Days to MDUFA V Decision	103				
Maximum Industry Days to MDUFA V Decision	192				
Average Number of Total Days to MDUFA V Decision	122.54				
20th Percentile Total Days to MDUFA V Decision	59				
40th Percentile Total Days to MDUFA V Decision	90				
60th Percentile Total Days to MDUFA V Decision	130				
80th Percentile Total Days to MDUFA V Decision	190				
Maximum Total Days to MDUFA V Decision	285				

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	402				
Number With MDUFA V Decision	180				
Number of SE Decision	174				
Number of NSE Decision	6				
Number of Withdrawal	7				
Number of Deleted	5				
Rate of SE Decision	96.67%				
Rate of NSE Decision	3.33%				
Rate of Withdrawal	1.74%				
Rate of Deleted	1.24%				

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				
Mean FDA Days for Submissions that Missed the Goal	93.00				
Mean Industry Days for Submissions that Missed the Goal	192.00				

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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	666				
Closed Before First RTA or TS Action [1]	7				
Number Accepted or Passed TS on First Cycle [2]	456				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	87				
Number Not Accepted or Failed TS on First Cycle [2]	115				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.10%				

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	539				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	446				
SI Over 60 FDA Days	3				
SI Pending Within 60 FDA Days	89				
SI Pending Over 60 FDA Days	1				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	99.11%				

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	449				
Average Number of FDA Days to Substantive Interaction	51.86				
20th Percentile FDA Days to Substantive Interaction	46				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	71				

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	539				
Non-MDUFA V Decision	15				
MDUFA V Decision (SE/NSE)	305				
MDUFA V Decision Within 90 FDA Days	305				
510(k)s Pending MDUFA V Decision	219				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48				
Number With MDUFA V Decision	305				
Average Number of FDA Days to MDUFA V Decision	69.80				
20th Percentile FDA Days to MDUFA V Decision	55				
40th Percentile FDA Days to MDUFA V Decision	70				
60th Percentile FDA Days to MDUFA V Decision	85				
80th Percentile FDA Days to MDUFA V Decision	88				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	27.55				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	13				
80th Percentile Industry Days to MDUFA V Decision	56				
Maximum Industry Days to MDUFA V Decision	181				
Average Number of Total Days to MDUFA V Decision	97.08				
20th Percentile Total Days to MDUFA V Decision	56				
40th Percentile Total Days to MDUFA V Decision	79				
60th Percentile Total Days to MDUFA V Decision	90				
80th Percentile Total Days to MDUFA V Decision	133				
Maximum Total Days to MDUFA V Decision	270				

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	539				
Number With MDUFA V Decision	305				
Number of SE Decision	301				
Number of NSE Decision	4				
Number of Withdrawal	11				
Number of Deleted	4				
Rate of SE Decision	98.69%				
Rate of NSE Decision	1.31%				
Rate of Withdrawal	2.04%				
Rate of Deleted	0.74%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	328				
Closed Before First RTA or TS Action [1]	3				
Number Accepted or Passed TS on First Cycle [2]	191				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	55				
Number Not Accepted or Failed TS on First Cycle [2]	78				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	28.89%				

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	237				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	195				
SI Over 60 FDA Days	6				
SI Pending Within 60 FDA Days	36				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	97.01%				

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	201				
Average Number of FDA Days to Substantive Interaction	53.66				
20th Percentile FDA Days to Substantive Interaction	50				
40th Percentile FDA Days to Substantive Interaction	58				
60th Percentile FDA Days to Substantive Interaction	60				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	80				

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	237				
Non-MDUFA V Decision	6				
MDUFA V Decision (SE/NSE)	118				
MDUFA V Decision Within 90 FDA Days	118				
510(k)s Pending MDUFA V Decision	113				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.56				
Number With MDUFA V Decision	118				
Average Number of FDA Days to MDUFA V Decision	69.76				
20th Percentile FDA Days to MDUFA V Decision	47				
40th Percentile FDA Days to MDUFA V Decision	60				
60th Percentile FDA Days to MDUFA V Decision	88				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	45.19				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	40				
80th Percentile Industry Days to MDUFA V Decision	95				
Maximum Industry Days to MDUFA V Decision	194				
Average Number of Total Days to MDUFA V Decision	114.96				
20th Percentile Total Days to MDUFA V Decision	53				
40th Percentile Total Days to MDUFA V Decision	86				
60th Percentile Total Days to MDUFA V Decision	119				
80th Percentile Total Days to MDUFA V Decision	183				
Maximum Total Days to MDUFA V Decision	281				

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	237				
Number With MDUFA V Decision	118				
Number of SE Decision	112				
Number of NSE Decision	6				
Number of Withdrawal	1				
Number of Deleted	3				
Rate of SE Decision	94.92%				
Rate of NSE Decision	5.08%				
Rate of Withdrawal	0.42%				
Rate of Deleted	1.27%				

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

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

Table 6.8 OHT5 - Office of Neurological and Physical Medicine Devices
LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	678				
Closed Before First RTA or TS Action [1]	7				
Number Accepted or Passed TS on First Cycle [2]	509				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	58				
Number Not Accepted or Failed TS on First Cycle [2]	102				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	16.64%				

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	586				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	520				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	65				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	520				
Average Number of FDA Days to Substantive Interaction	49.60				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	586				
Non-MDUFA V Decision	21				
MDUFA V Decision (SE/NSE)	378				
MDUFA V Decision Within 90 FDA Days	378				
510(k)s Pending MDUFA V Decision	187				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.35				
Number With MDUFA V Decision	378				
Average Number of FDA Days to MDUFA V Decision	60.72				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	56				
60th Percentile FDA Days to MDUFA V Decision	76				
80th Percentile FDA Days to MDUFA V Decision	88				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	22.04				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	31				
Maximum Industry Days to MDUFA V Decision	180				
Average Number of Total Days to MDUFA V Decision	82.75				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	57				
60th Percentile Total Days to MDUFA V Decision	85				
80th Percentile Total Days to MDUFA V Decision	117				
Maximum Total Days to MDUFA V Decision	269				

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	586				
Number With MDUFA V Decision	378				
Number of SE Decision	377				
Number of NSE Decision	1				
Number of Withdrawal	18				
Number of Deleted	2				
Rate of SE Decision	99.74%				
Rate of NSE Decision	0.26%				
Rate of Withdrawal	3.07%				
Rate of Deleted	0.34%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	294				
Closed Before First RTA or TS Action [1]	7				
Number Accepted or Passed TS on First Cycle [2]	217				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	4				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	33				
Number Not Accepted or Failed TS on First Cycle [2]	33				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	12.99%				

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	237				
Deleted or Withdrawn Prior to SI	3				
SI Within 60 FDA Days	191				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	43				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	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	191				
Average Number of FDA Days to Substantive Interaction	52.50				
20th Percentile FDA Days to Substantive Interaction	48				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	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	237				
Non-MDUFA V Decision	15				
MDUFA V Decision (SE/NSE)	94				
MDUFA V Decision Within 90 FDA Days	94				
510(k)s Pending MDUFA V Decision	128				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.28				
Number With MDUFA V Decision	94				
Average Number of FDA Days to MDUFA V Decision	65.39				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	59				
60th Percentile FDA Days to MDUFA V Decision	87				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	31.86				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	75				
Maximum Industry Days to MDUFA V Decision	180				
Average Number of Total Days to MDUFA V Decision	97.26				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	60				
60th Percentile Total Days to MDUFA V Decision	89				
80th Percentile Total Days to MDUFA V Decision	153				
Maximum Total Days to MDUFA V Decision	270				

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	237				
Number With MDUFA V Decision	94				
Number of SE Decision	93				
Number of NSE Decision	1				
Number of Withdrawal	10				
Number of Deleted	5				
Rate of SE Decision	98.94%				
Rate of NSE Decision	1.06%				
Rate of Withdrawal	4.22%				
Rate of Deleted	2.11%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	1				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	1				
MDUFA V Decision Within 90 FDA Days	1				
510(k)s Pending MDUFA V Decision	0				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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	236				
Non-MDUFA V Decision	15				
MDUFA V Decision (SE/NSE)	93				
MDUFA V Decision Within 90 FDA Days	93				
510(k)s Pending MDUFA V Decision	128				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Closed Before First RTA or TS Action [1]	3				
Number Accepted or Passed TS on First Cycle [2]	409				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	38				
Number Not Accepted or Failed TS on First Cycle [2]	36				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.05%				

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	436				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	376				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	60				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	376				
Average Number of FDA Days to Substantive Interaction	48.70				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	53				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	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	436				
Non-MDUFA V Decision	11				
MDUFA V Decision (SE/NSE)	240				
MDUFA V Decision Within 90 FDA Days	240				
510(k)s Pending MDUFA V Decision	185				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.56				
Number With MDUFA V Decision	240				
Average Number of FDA Days to MDUFA V Decision	64.10				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	58				
60th Percentile FDA Days to MDUFA V Decision	84				
80th Percentile FDA Days to MDUFA V Decision	88				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	37.61				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	29				
80th Percentile Industry Days to MDUFA V Decision	71				
Maximum Industry Days to MDUFA V Decision	182				
Average Number of Total Days to MDUFA V Decision	101.70				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	60				
60th Percentile Total Days to MDUFA V Decision	111				
80th Percentile Total Days to MDUFA V Decision	153				
Maximum Total Days to MDUFA V Decision	272				

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	436				
Number With MDUFA V Decision	240				
Number of SE Decision	239				
Number of NSE Decision	1				
Number of Withdrawal	7				
Number of Deleted	3				
Rate of SE Decision	99.58%				
Rate of NSE Decision	0.42%				
Rate of Withdrawal	1.61%				
Rate of Deleted	0.69%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	N/A				

Section 7 510(k) Annual General Metrics

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

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted	3,276				
Number of Traditional Submissions	2,673				
Number of Special Submissions	482				
Number of Abbreviated Submissions	44				
Average Number of Days to Accept/Refuse to Accept	11.30				
Number of Third Party Submissions	77				

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

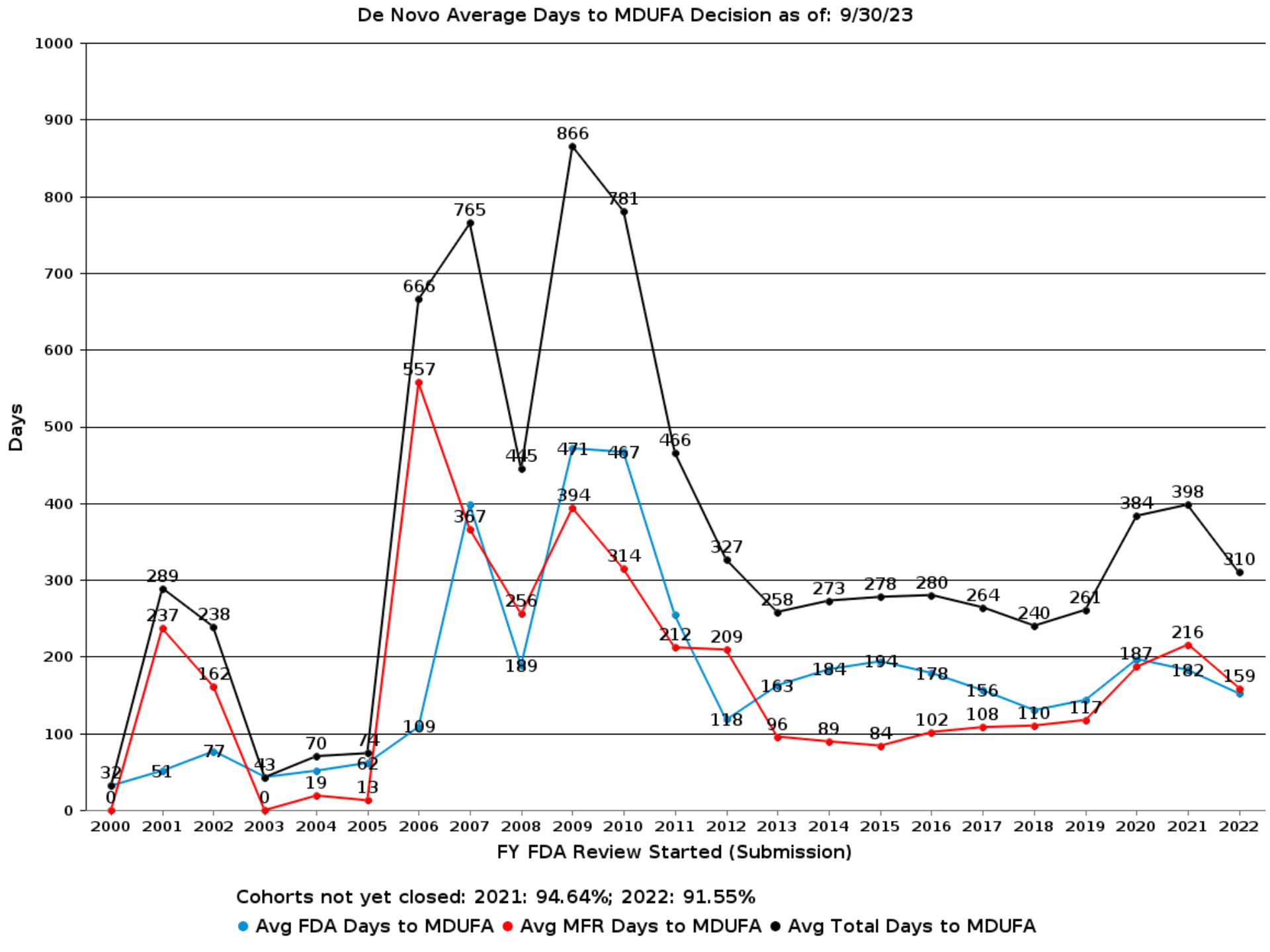
Performance Metrics	FY 2023 128 Days	FY 2024 124 Days	FY 2025 112 Days	FY 2026 112 Days	FY 2027 112 Days
Number Accepted	3,276				
Currently Under Review	1,427				
Number With Non-MDUFA V Decision	103				
Number With MDUFA IV Decision	1,746				
Percent of Cohort Closed	55.03%				
Number With MDUFA V Decision After Trimming the Upper and Lower 2%	1,794				
Average Total Time to MDUFA IV Decision	99.64				

Table 7.3 CDRH - 510(k) Third Party Performance

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Third Party Submissions	77				
90th Percentile FDA Days to MDUFA V Decision	30.00				

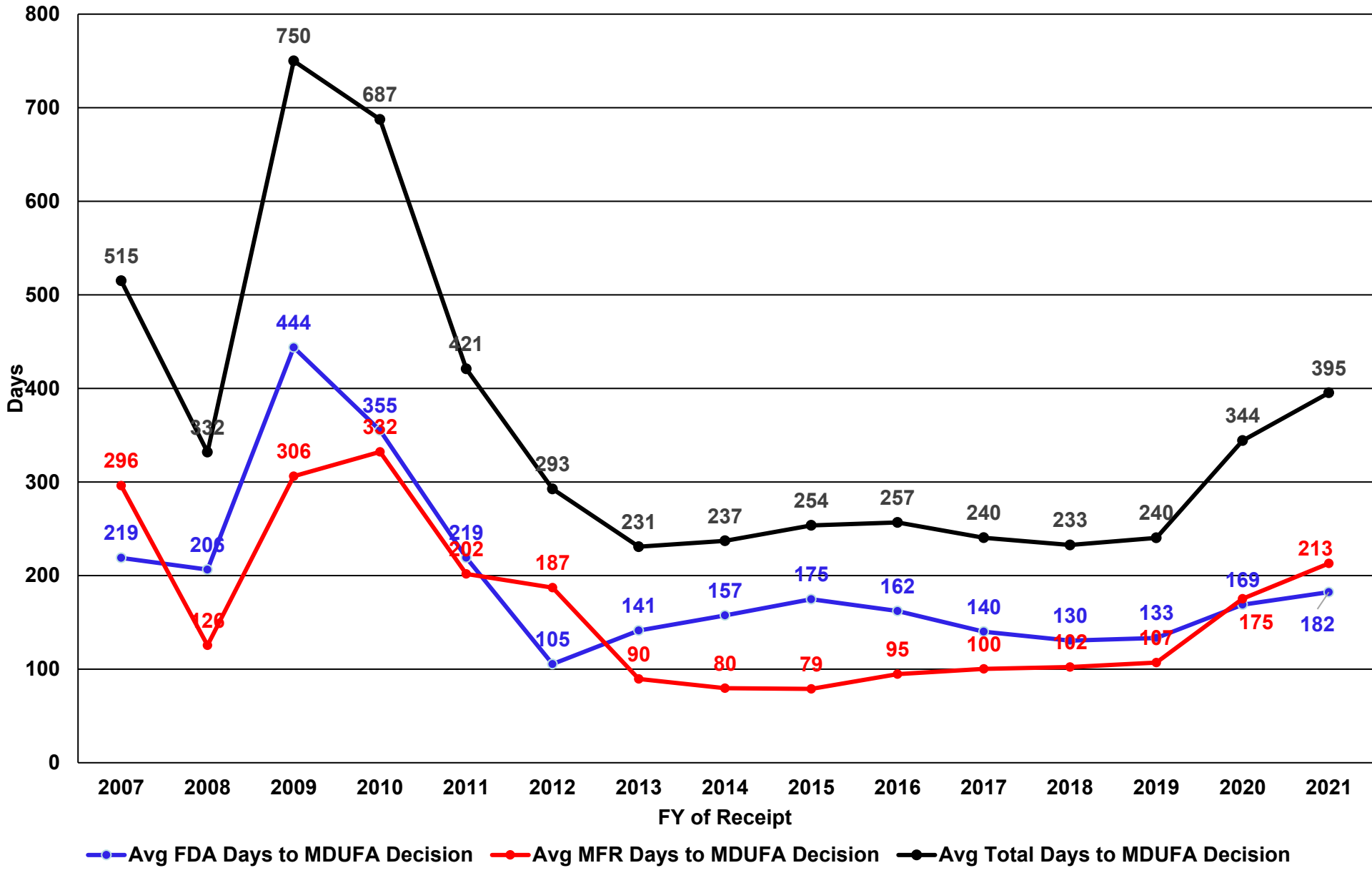
De Novos

Q4FY2023


De Novo Average Days to MDUFA Decision as of: 9/30/23
Days
1000
900
800
700
600
500
400
300
200
100
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
FY FDA Review Started (Submission)
Cohorts not yet closed: 2021: 94.64%; 2022: 91.55%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA
0 51 77 43 19 62 109 367 189 471 467 212 118 163 184 194 178 156 110 117 187 182 159
0 237 162 0 19 13 557 367 256 394 314 212 209 96 89 84 102 108 110 117 187 216 159
32 289 238 43 70 74 666 765 445 866 781 466 327 258 273 278 280 264 240 261 384 398 310

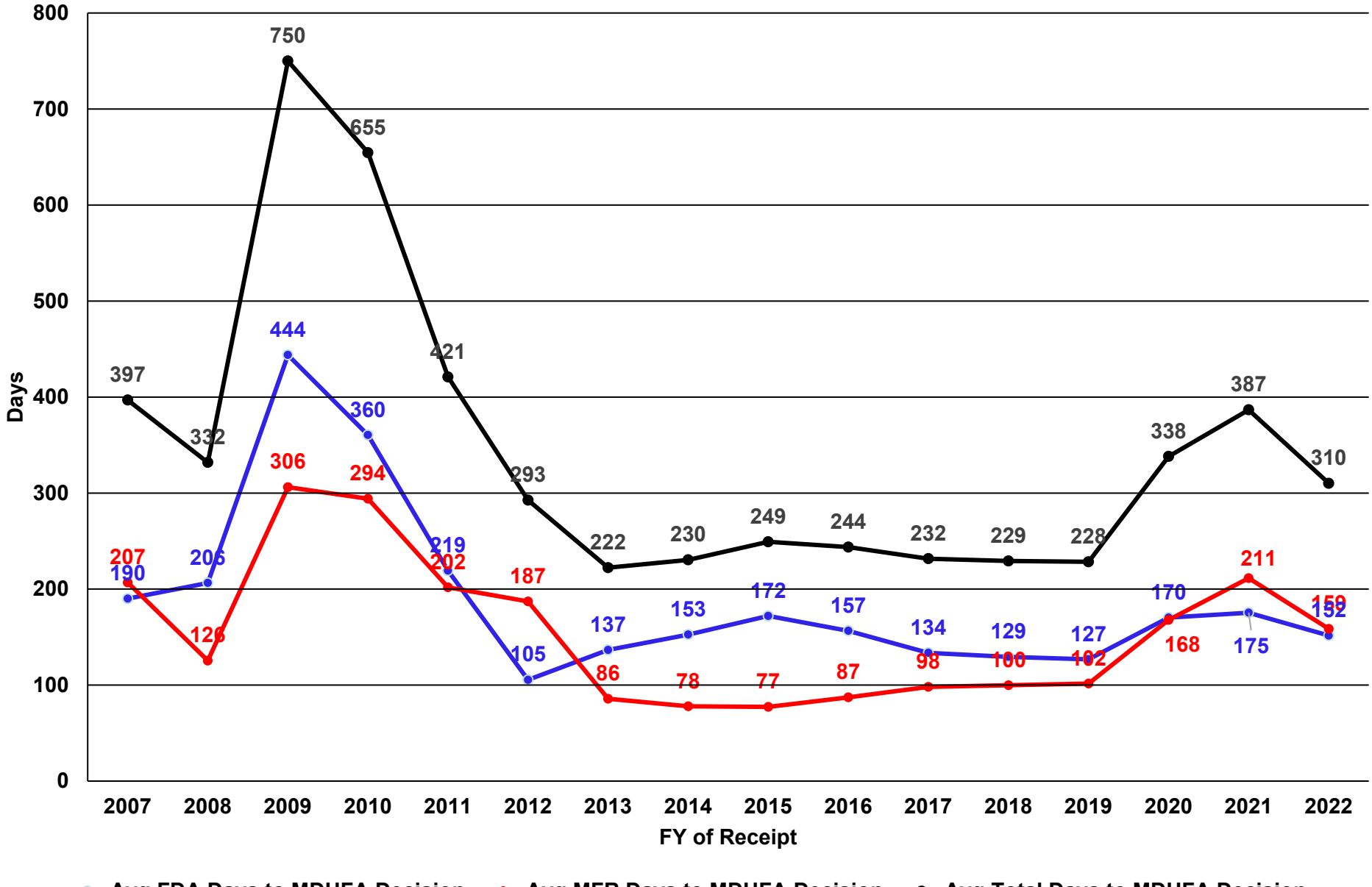
Average Time to MDUFA Decision: De Novos

(94.64% closure comparison)

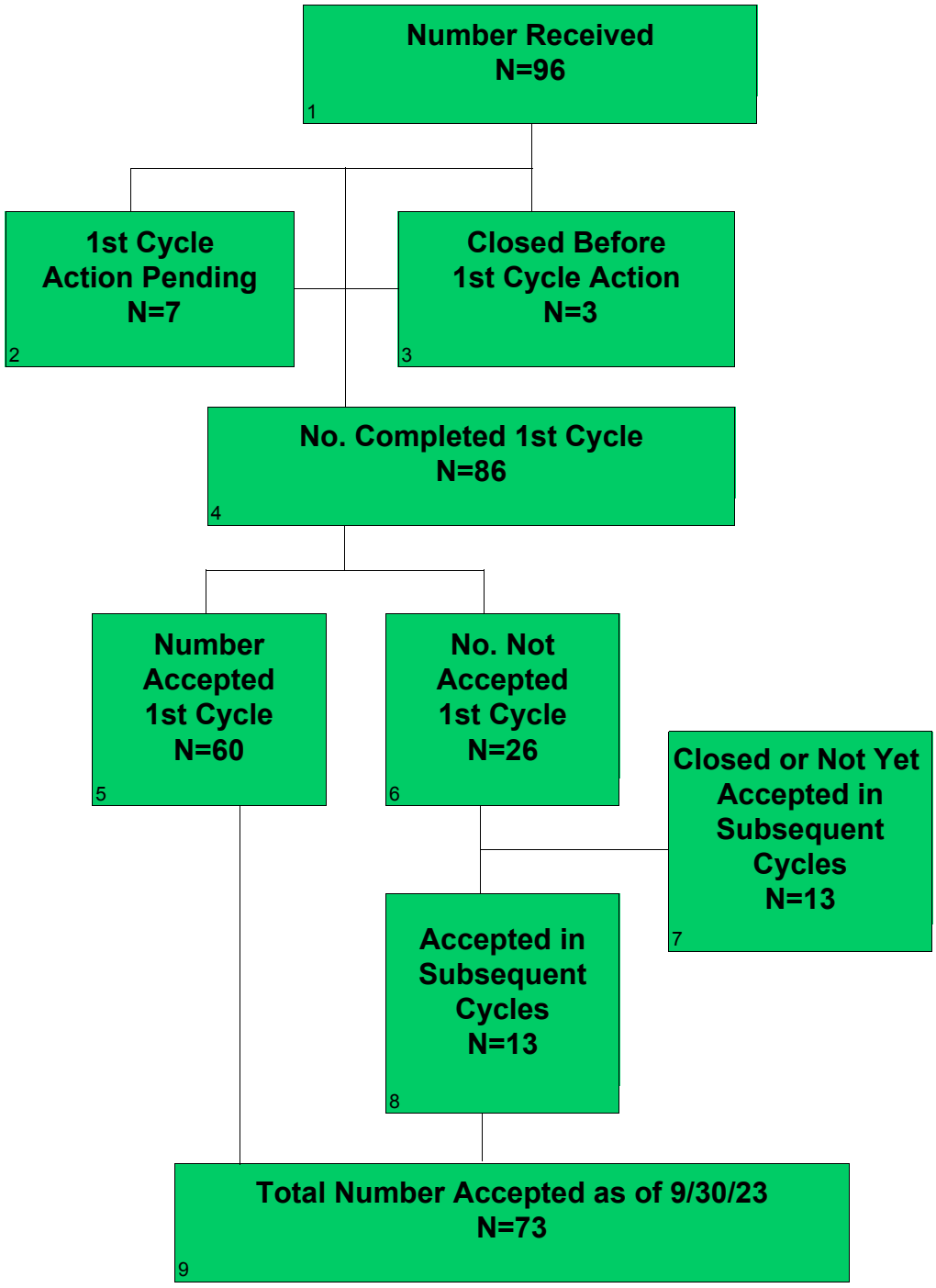


Average Time to MDUFA Decision: De Novos

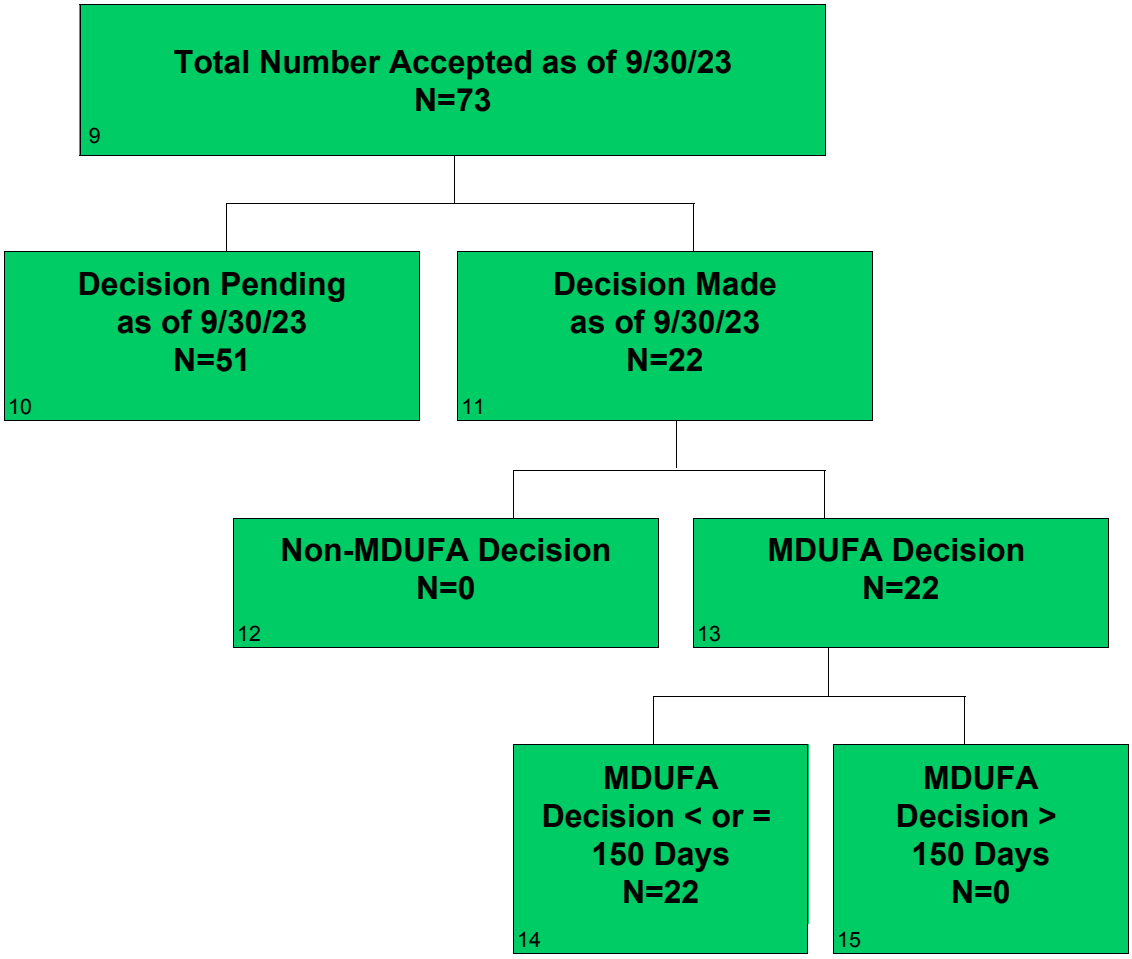
(91.55% closure comparison)



CDRH De Novo - FY 2023
as of 9/30/23



CDRH De Novo - FY 2023
as of 9/30/23 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96				
Closed Before First RTA or TS Action	3				
Number Accepted or Passed TS on First Cycle	60				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	7				
Number Not Accepted or Failed TS on First Cycle	26				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.23%				

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

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	73				
Non-MDUFA Decision	0				
MDUFA Decision	22				
MDUFA Decision Within 150 FDA Days	22				
De Novos Pending MDUFA Decision	51				
De Novos Pending MDUFA Decision Over 150 FDA Days	1				
Current Performance Percent Within 150 FDA Days	95.65%				

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	1.59				
Number With MDUFA Decision	22				
Average FDA Days to MDUFA Decision	131.64				
20th Percentile FDA Days to MDUFA Decision	109				
40th Percentile FDA Days to MDUFA Decision	147				
60th Percentile FDA Days to MDUFA Decision	150				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	90.77				
20th Percentile Industry Days to MDUFA Decision	3				
40th Percentile Industry Days to MDUFA Decision	59				
60th Percentile Industry Days to MDUFA Decision	142				
80th Percentile Industry Days to MDUFA Decision	177				
Maximum Industry Days to MDUFA Decision	183				
Average Total Days to MDUFA Decision	222.41				
20th Percentile Total Days to MDUFA Decision	148				
40th Percentile Total Days to MDUFA Decision	205				
60th Percentile Total Days to MDUFA Decision	244				
80th Percentile Total Days to MDUFA Decision	302				
Maximum Total Days to MDUFA Decision	330				

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	73				
Number With MDUFA Decision	22				
Number With Granted Decision	10				
Number With Declined Decision	6				
Number of Withdrawal	4				
Number of Deleted	2				
Rate of Granted Decision	45.45%				
Rate of Declined Decision	27.27%				
Rate of Withdrawal	18.18%				
Rate of Deleted	9.09%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	1				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	16				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Within 150 FDA Days	4				
De Novos Pending MDUFA Decision	12				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

Table 8.8 CDRH - De Novo Annual General Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	73				
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.10				

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

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Within 150 FDA Days	2				
De Novos Pending MDUFA Decision	9				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1.00				
Number With MDUFA Decision	2				
Average FDA Days to MDUFA Decision	74.00				
20th Percentile FDA Days to MDUFA Decision	73				
40th Percentile FDA Days to MDUFA Decision	74				
60th Percentile FDA Days to MDUFA Decision	74				
80th Percentile FDA Days to MDUFA Decision	75				
Maximum FDA Days to MDUFA Decision	75				
Average Industry Days to MDUFA Decision	156.50				
20th Percentile Industry Days to MDUFA Decision	141				
40th Percentile Industry Days to MDUFA Decision	151				
60th Percentile Industry Days to MDUFA Decision	162				
80th Percentile Industry Days to MDUFA Decision	172				
Maximum Industry Days to MDUFA Decision	182				
Average Total Days to MDUFA Decision	230.50				
20th Percentile Total Days to MDUFA Decision	216				
40th Percentile Total Days to MDUFA Decision	226				
60th Percentile Total Days to MDUFA Decision	235				
80th Percentile Total Days to MDUFA Decision	245				
Maximum Total Days to MDUFA Decision	255				

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

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	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	9				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	1				
Number Not Accepted or Failed TS on First Cycle	2				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%				

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

Table 8.2 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	9				
Non-MDUFA Decision	0				
MDUFA Decision	6				
MDUFA Decision Within 150 FDA Days	6				
De Novos Pending MDUFA Decision	3				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1.83				
Number With MDUFA Decision	6				
Average FDA Days to MDUFA Decision	128.67				
20th Percentile FDA Days to MDUFA Decision	103				
40th Percentile FDA Days to MDUFA Decision	149				
60th Percentile FDA Days to MDUFA Decision	150				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	113.50				
20th Percentile Industry Days to MDUFA Decision	55				
40th Percentile Industry Days to MDUFA Decision	66				
60th Percentile Industry Days to MDUFA Decision	180				
80th Percentile Industry Days to MDUFA Decision	180				
Maximum Industry Days to MDUFA Decision	183				
Average Total Days to MDUFA Decision	242.17				
20th Percentile Total Days to MDUFA Decision	205				
40th Percentile Total Days to MDUFA Decision	216				
60th Percentile Total Days to MDUFA Decision	253				
80th Percentile Total Days to MDUFA Decision	283				
Maximum Total Days to MDUFA Decision	329				

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	9				
Number With MDUFA Decision	6				
Number With Granted Decision	3				
Number With Declined Decision	2				
Number of Withdrawal	0				
Number of Deleted	1				
Rate of Granted Decision	50.00%				
Rate of Declined Decision	33.33%				
Rate of Withdrawal	0.00%				
Rate of Deleted	16.67%				

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				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	9				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	2				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%				

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

Table 8.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	10				
Non-MDUFA Decision	0				
MDUFA Decision	3				
MDUFA Decision Within 150 FDA Days	3				
De Novos Pending MDUFA Decision	7				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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	1.67				
Number With MDUFA Decision	3				
Average FDA Days to MDUFA Decision	147.33				
20th Percentile FDA Days to MDUFA Decision	146				
40th Percentile FDA Days to MDUFA Decision	147				
60th Percentile FDA Days to MDUFA Decision	148				
80th Percentile FDA Days to MDUFA Decision	149				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	82.00				
20th Percentile Industry Days to MDUFA Decision	33				
40th Percentile Industry Days to MDUFA Decision	66				
60th Percentile Industry Days to MDUFA Decision	99				
80th Percentile Industry Days to MDUFA Decision	131				
Maximum Industry Days to MDUFA Decision	163				
Average Total Days to MDUFA Decision	229.33				
20th Percentile Total Days to MDUFA Decision	179				
40th Percentile Total Days to MDUFA Decision	214				
60th Percentile Total Days to MDUFA Decision	247				
80th Percentile Total Days to MDUFA Decision	280				
Maximum Total Days to MDUFA Decision	313				

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	10				
Number With MDUFA Decision	3				
Number With Granted Decision	3				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	100.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	10				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	2				
Number Not Accepted or Failed TS on First Cycle	8				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%				

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

Table 8.2 OHT4 - Office of Surgical and Infection Control Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	13				
Non-MDUFA Decision	0				
MDUFA Decision	3				
MDUFA Decision Within 150 FDA Days	3				
De Novos Pending MDUFA Decision	10				
De Novos Pending MDUFA Decision Over 150 FDA Days	1				
Current Performance Percent Within 150 FDA Days	75.00%				

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	1.67				
Number With MDUFA Decision	3				
Average FDA Days to MDUFA Decision	149.33				
20th Percentile FDA Days to MDUFA Decision	149				
40th Percentile FDA Days to MDUFA Decision	150				
60th Percentile FDA Days to MDUFA Decision	150				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	81.33				
20th Percentile Industry Days to MDUFA Decision	26				
40th Percentile Industry Days to MDUFA Decision	51				
60th Percentile Industry Days to MDUFA Decision	87				
80th Percentile Industry Days to MDUFA Decision	134				
Maximum Industry Days to MDUFA Decision	180				
Average Total Days to MDUFA Decision	230.67				
20th Percentile Total Days to MDUFA Decision	175				
40th Percentile Total Days to MDUFA Decision	200				
60th Percentile Total Days to MDUFA Decision	236				
80th Percentile Total Days to MDUFA Decision	283				
Maximum Total Days to MDUFA Decision	330				

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	13				
Number With MDUFA Decision	3				
Number With Granted Decision	2				
Number With Declined Decision	1				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	66.67%				
Rate of Declined Decision	33.33%				
Rate of Withdrawal	0.00%				
Rate of Deleted	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	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	4				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	2				
Number Not Accepted or Failed TS on First Cycle	3				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	42.86%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	6				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Within 150 FDA Days	2				
De Novos Pending MDUFA Decision	4				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00				
Number With MDUFA Decision	2				
Average FDA Days to MDUFA Decision	150.00				
20th Percentile FDA Days to MDUFA Decision	150				
40th Percentile FDA Days to MDUFA Decision	150				
60th Percentile FDA Days to MDUFA Decision	150				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	84.50				
20th Percentile Industry Days to MDUFA Decision	45				
40th Percentile Industry Days to MDUFA Decision	71				
60th Percentile Industry Days to MDUFA Decision	98				
80th Percentile Industry Days to MDUFA Decision	124				
Maximum Industry Days to MDUFA Decision	150				
Average Total Days to MDUFA Decision	234.50				
20th Percentile Total Days to MDUFA Decision	195				
40th Percentile Total Days to MDUFA Decision	221				
60th Percentile Total Days to MDUFA Decision	248				
80th Percentile Total Days to MDUFA Decision	274				
Maximum Total Days to MDUFA Decision	300				

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	6				
Number With MDUFA Decision	2				
Number With Granted Decision	1				
Number With Declined Decision	1				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	50.00%				
Rate of Declined Decision	50.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	3				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	0				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	3				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	2				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	148.00				
20th Percentile FDA Days to MDUFA Decision	148				
40th Percentile FDA Days to MDUFA Decision	148				
60th Percentile FDA Days to MDUFA Decision	148				
80th Percentile FDA Days to MDUFA Decision	148				
Maximum FDA Days to MDUFA Decision	148				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	148.00				
20th Percentile Total Days to MDUFA Decision	148				
40th Percentile Total Days to MDUFA Decision	148				
60th Percentile Total Days to MDUFA Decision	148				
80th Percentile Total Days to MDUFA Decision	148				
Maximum Total Days to MDUFA Decision	148				

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				
Number With MDUFA Decision	1				
Number With Granted Decision	1				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	100.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	15				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	2				
Number Not Accepted or Failed TS on First Cycle	5				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	25.00%				

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

Table 8.2 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	17				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Within 150 FDA Days	4				
De Novos Pending MDUFA Decision	13				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.50				
Number With MDUFA Decision	4				
Average FDA Days to MDUFA Decision	143.75				
20th Percentile FDA Days to MDUFA Decision	141				
40th Percentile FDA Days to MDUFA Decision	147				
60th Percentile FDA Days to MDUFA Decision	147				
80th Percentile FDA Days to MDUFA Decision	148				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	79.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	31				
60th Percentile Industry Days to MDUFA Decision	124				
80th Percentile Industry Days to MDUFA Decision	157				
Maximum Industry Days to MDUFA Decision	161				
Average Total Days to MDUFA Decision	222.75				
20th Percentile Total Days to MDUFA Decision	141				
40th Percentile Total Days to MDUFA Decision	178				
60th Percentile Total Days to MDUFA Decision	271				
80th Percentile Total Days to MDUFA Decision	306				
Maximum Total Days to MDUFA Decision	311				

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	17				
Number With MDUFA Decision	4				
Number With Granted Decision	0				
Number With Declined Decision	2				
Number of Withdrawal	2				
Number of Deleted	0				
Rate of Granted Decision	0.00%				
Rate of Declined Decision	50.00%				
Rate of Withdrawal	50.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	16				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Within 150 FDA Days	4				
De Novos Pending MDUFA IV Decision	12				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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

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

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	4				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	3				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	63.00				
20th Percentile FDA Days to MDUFA Decision	63				
40th Percentile FDA Days to MDUFA Decision	63				
60th Percentile FDA Days to MDUFA Decision	63				
80th Percentile FDA Days to MDUFA Decision	63				
Maximum FDA Days to MDUFA Decision	63				
Average Industry Days to MDUFA Decision	28.00				
20th Percentile Industry Days to MDUFA Decision	28				
40th Percentile Industry Days to MDUFA Decision	28				
60th Percentile Industry Days to MDUFA Decision	28				
80th Percentile Industry Days to MDUFA Decision	28				
Maximum Industry Days to MDUFA Decision	28				
Average Total Days to MDUFA Decision	91.00				
20th Percentile Total Days to MDUFA Decision	91				
40th Percentile Total Days to MDUFA Decision	91				
60th Percentile Total Days to MDUFA Decision	91				
80th Percentile Total Days to MDUFA Decision	91				
Maximum Total Days to MDUFA Decision	91				

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				
Number With MDUFA Decision	1				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	1				
Number of Deleted	0				
Rate of Granted Decision	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	100.00%				
Rate of Deleted	0.00%				

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

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

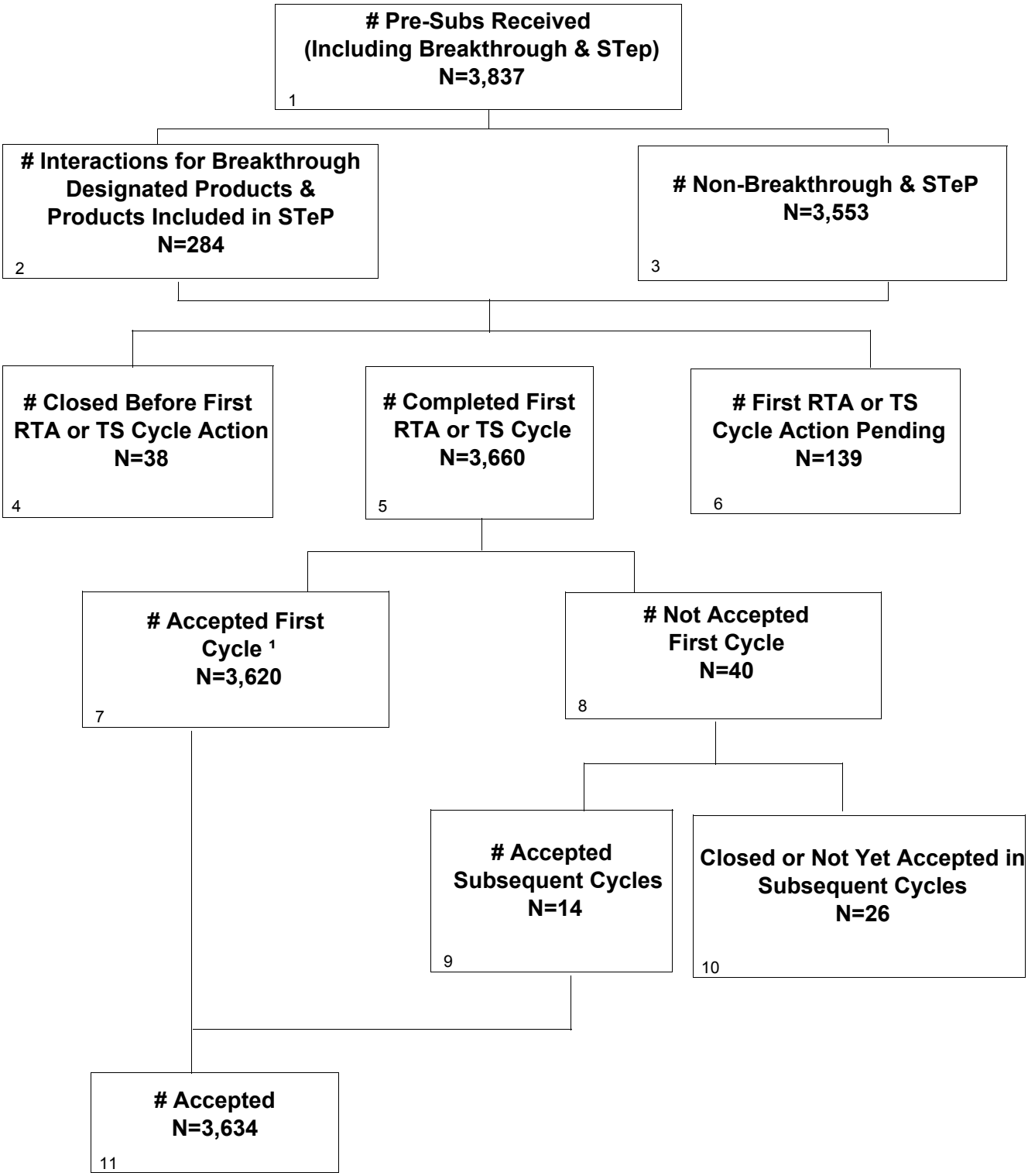
Table 8.7 OHT8 - Office of Radiological Health
Conventional V (non-LDT) De Novo MDUFA IV Decision Metrics

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

Table 8.8 CDRH - De Novo Annual General Metrics

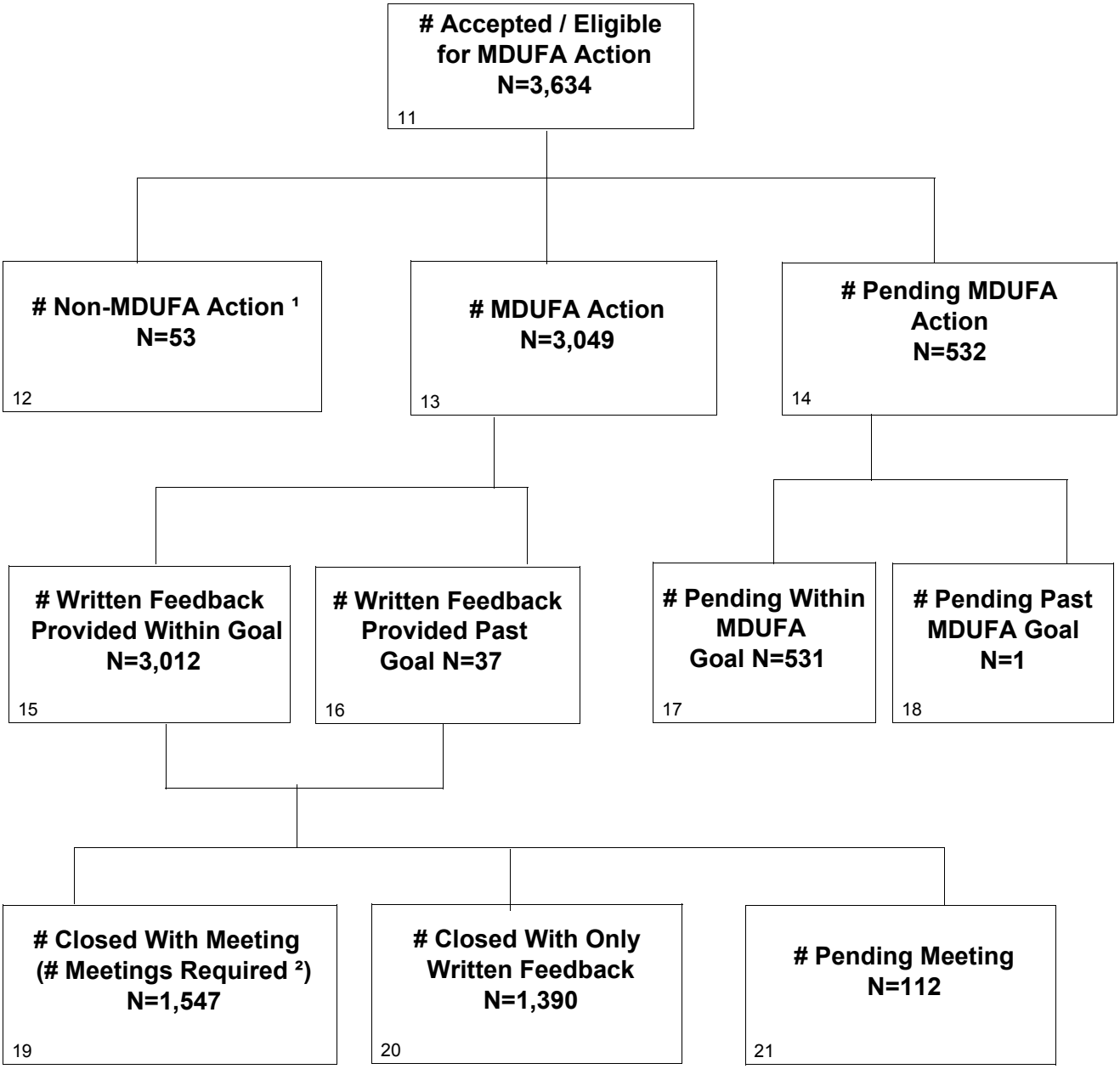
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	73				
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.10				

CDRH Pre-Sub - FY 2023
as of 9/30/23



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

CDRH Pre-Sub - FY 2023 as of 9/30/23 Continued



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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,837				
Interactions for Breakthrough Designated Products & Products Included in STeP	284				
Number Closed Before First RTA Action	38				
Number Accepted First RTA Cycle [1]	3,508				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	112				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	139				
Number Not Accepted First RTA Cycle	40				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.09%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	3,634				
Number with Non-MDUFA Action [3]	53				
Number with MDUFA Action	3,049				
Written Feedback Provided Within Goal	3,012				
Number Pending MDUFA Action	532				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	3,581				
Current Performance Percent Within Goal	98.75%				

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	3,049				
Average FDA Days to Written Feedback	61.78				
20th Percentile FDA Days to Written Feedback	56				
40th Percentile FDA Days to Written Feedback	64				
60th Percentile FDA Days to Written Feedback	67				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	141				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	118				
Average Days to Scheduling for Meetings Scheduled After Day 30	40.72				

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]	1,546				
Meeting Minutes Submitted Within 15 Days of Meeting	1,121				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	54				
Meeting Minutes Past 15 Days of Meeting	318				
Meeting Minutes Not Submitted and >15 Days Since Meeting	53				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.13%				

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

Section 9 Pre-Sub Office Level Metrics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	446				
Interactions for Breakthrough Designated Products & Products Included in STeP	20				
Number Closed Before First RTA Action	3				
Number Accepted First RTA Cycle [1]	402				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	19				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	14				
Number Not Accepted First RTA Cycle	8				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.86%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	422				
Number with Non-MDUFA Action [3]	11				
Number with MDUFA Action	343				
Written Feedback Provided Within Goal	333				
Number Pending MDUFA Action	68				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	411				
Current Performance Percent Within Goal	97.08%				

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	343				
Average FDA Days to Written Feedback	64.93				
20th Percentile FDA Days to Written Feedback	60				
40th Percentile FDA Days to Written Feedback	66				
60th Percentile FDA Days to Written Feedback	69				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	141				

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	23				
Average Days to Scheduling for Meetings Scheduled After Day 30	46.48				

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]	194				
Meeting Minutes Submitted Within 15 Days of Meeting	131				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	8				
Meeting Minutes Past 15 Days of Meeting	44				
Meeting Minutes Not Submitted and >15 Days Since Meeting	11				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	70.43%				

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	726				
Interactions for Breakthrough Designated Products & Products Included in STeP	72				
Number Closed Before First RTA Action	6				
Number Accepted First RTA Cycle [1]	678				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	11				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	26				
Number Not Accepted First RTA Cycle	5				
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.72%				

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

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

Table 9.2 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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	693				
Number with Non-MDUFA Action [3]	4				
Number with MDUFA Action	593				
Written Feedback Provided Within Goal	579				
Number Pending MDUFA Action	96				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	689				
Current Performance Percent Within Goal	97.47%				

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	593				
Average FDA Days to Written Feedback	58.93				
20th Percentile FDA Days to Written Feedback	49				
40th Percentile FDA Days to Written Feedback	60				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	87				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	32				
Average Days to Scheduling for Meetings Scheduled After Day 30	38.28				

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]	327				
Meeting Minutes Submitted Within 15 Days of Meeting	240				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	10				
Meeting Minutes Past 15 Days of Meeting	67				
Meeting Minutes Not Submitted and >15 Days Since Meeting	10				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.71%				

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				
Interactions for Breakthrough Designated Products & Products Included in STeP	42				
Number Closed Before First RTA Action	5				
Number Accepted First RTA Cycle [1]	418				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	22				
Number Not Accepted First RTA Cycle	6				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.38%				

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

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

Table 9.2 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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	431				
Number with Non-MDUFA Action [3]	10				
Number with MDUFA Action	347				
Written Feedback Provided Within Goal	343				
Number Pending MDUFA Action	74				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	421				
Current Performance Percent Within Goal	98.85%				

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	347				
Average FDA Days to Written Feedback	61.71				
20th Percentile FDA Days to Written Feedback	55				
40th Percentile FDA Days to Written Feedback	64				
60th Percentile FDA Days to Written Feedback	67				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	78				

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	10				
Average Days to Scheduling for Meetings Scheduled After Day 30	40.20				

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]	189				
Meeting Minutes Submitted Within 15 Days of Meeting	143				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	9				
Meeting Minutes Past 15 Days of Meeting	31				
Meeting Minutes Not Submitted and >15 Days Since Meeting	6				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	79.44%				

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	357				
Interactions for Breakthrough Designated Products & Products Included in STeP	21				
Number Closed Before First RTA Action	4				
Number Accepted First RTA Cycle [1]	329				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	7				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	12				
Number Not Accepted First RTA Cycle	5				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.47%				

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 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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	338				
Number with Non-MDUFA Action [3]	7				
Number with MDUFA Action	284				
Written Feedback Provided Within Goal	284				
Number Pending MDUFA Action	47				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	331				
Current Performance Percent Within Goal	100.00%				

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

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

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

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

Table 9.3 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	284				
Average FDA Days to Written Feedback	60.14				
20th Percentile FDA Days to Written Feedback	54				
40th Percentile FDA Days to Written Feedback	62				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	11				
Average Days to Scheduling for Meetings Scheduled After Day 30	36.18				

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]	149				
Meeting Minutes Submitted Within 15 Days of Meeting	115				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	25				
Meeting Minutes Not Submitted and >15 Days Since Meeting	8				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.70%				

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	395				
Interactions for Breakthrough Designated Products & Products Included in STeP	42				
Number Closed Before First RTA Action	5				
Number Accepted First RTA Cycle [1]	358				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	16				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	12				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.06%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	376				
Number with Non-MDUFA Action [3]	5				
Number with MDUFA Action	305				
Written Feedback Provided Within Goal	303				
Number Pending MDUFA Action	66				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	371				
Current Performance Percent Within Goal	99.34%				

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	305				
Average FDA Days to Written Feedback	65.92				
20th Percentile FDA Days to Written Feedback	64				
40th Percentile FDA Days to Written Feedback	68				
60th Percentile FDA Days to Written Feedback	70				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	108				

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	24				
Average Days to Scheduling for Meetings Scheduled After Day 30	39.25				

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]	187				
Meeting Minutes Submitted Within 15 Days of Meeting	121				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	5				
Meeting Minutes Past 15 Days of Meeting	56				
Meeting Minutes Not Submitted and >15 Days Since Meeting	5				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	66.48%				

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	301				
Interactions for Breakthrough Designated Products & Products Included in STeP	53				
Number Closed Before First RTA Action	5				
Number Accepted First RTA Cycle [1]	274				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	8				
Number Not Accepted First RTA Cycle	5				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.74%				

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

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

Table 9.2 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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	285				
Number with Non-MDUFA Action [3]	7				
Number with MDUFA Action	250				
Written Feedback Provided Within Goal	247				
Number Pending MDUFA Action	28				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	278				
Current Performance Percent Within Goal	98.80%				

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	250				
Average FDA Days to Written Feedback	58.59				
20th Percentile FDA Days to Written Feedback	47				
40th Percentile FDA Days to Written Feedback	58				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	97				

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	3				
Average Days to Scheduling for Meetings Scheduled After Day 30	49.67				

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]	105				
Meeting Minutes Submitted Within 15 Days of Meeting	80				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	19				
Meeting Minutes Not Submitted and >15 Days Since Meeting	4				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.67%				

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				
Interactions for Breakthrough Designated Products & Products Included in STeP	29				
Number Closed Before First RTA Action	9				
Number Accepted First RTA Cycle [1]	800				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	34				
Number Not Accepted First RTA Cycle	3				
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.36%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	835				
Number with Non-MDUFA Action [3]	6				
Number with MDUFA Action	708				
Written Feedback Provided Within Goal	704				
Number Pending MDUFA Action	121				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	829				
Current Performance Percent Within Goal	99.44%				

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	708				
Average FDA Days to Written Feedback	63.22				
20th Percentile FDA Days to Written Feedback	59				
40th Percentile FDA Days to Written Feedback	65				
60th Percentile FDA Days to Written Feedback	69				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	75				

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	10				
Average Days to Scheduling for Meetings Scheduled After Day 30	40.00				

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]	226				
Meeting Minutes Submitted Within 15 Days of Meeting	170				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	10				
Meeting Minutes Past 15 Days of Meeting	42				
Meeting Minutes Not Submitted and >15 Days Since Meeting	4				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.70%				

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				
Interactions for Breakthrough Designated Products & Products Included in STeP	5				
Number Closed Before First RTA Action	1				
Number Accepted First RTA Cycle [1]	249				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	11				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.55%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	254				
Number with Non-MDUFA Action [3]	3				
Number with MDUFA Action	219				
Written Feedback Provided Within Goal	219				
Number Pending MDUFA Action	32				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	251				
Current Performance Percent Within Goal	100.00%				

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	219				
Average FDA Days to Written Feedback	60.03				
20th Percentile FDA Days to Written Feedback	54				
40th Percentile FDA Days to Written Feedback	59				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	67				
Maximum FDA Days to Written Feedback	70				

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

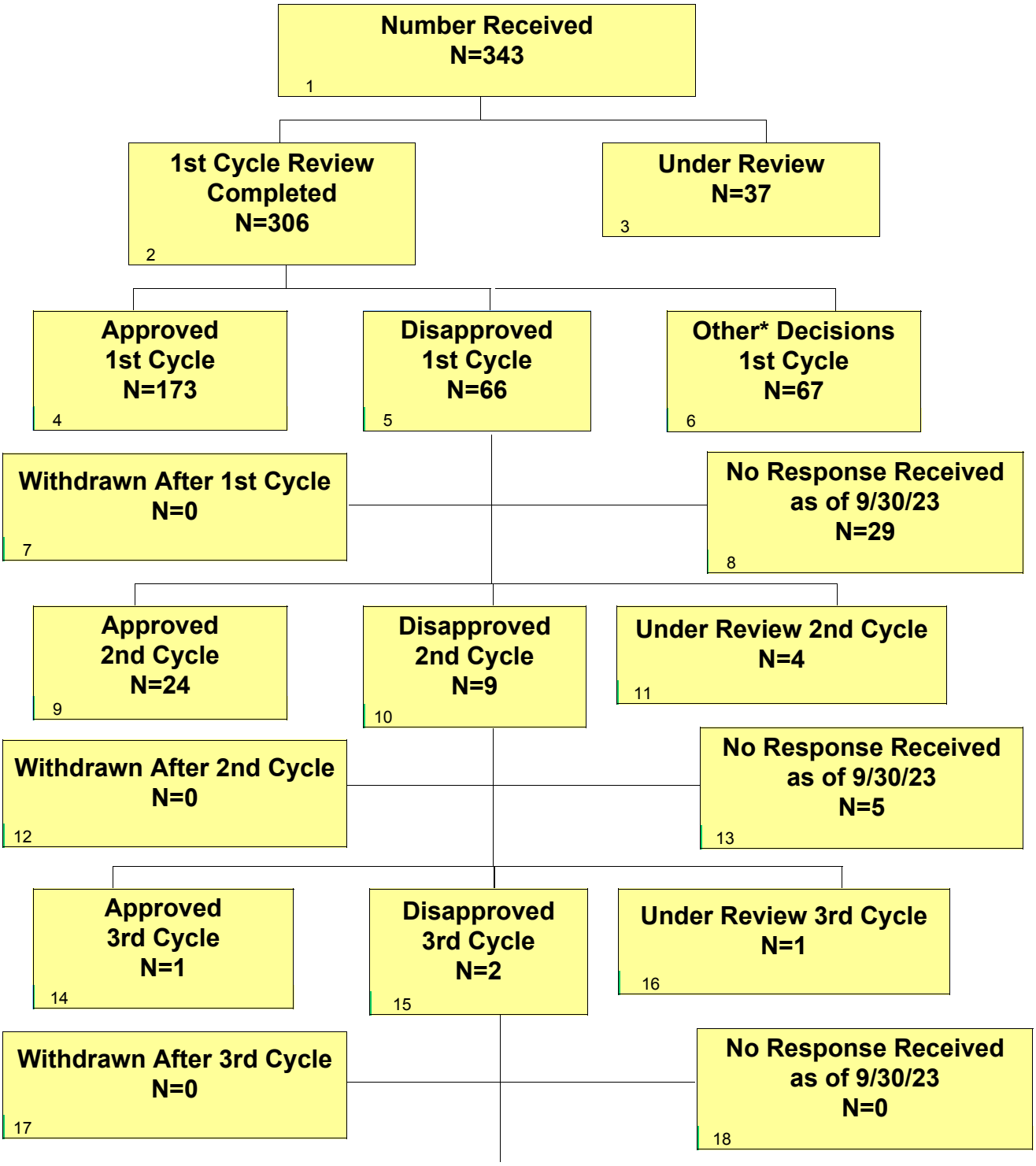
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5				
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00				

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]	169				
Meeting Minutes Submitted Within 15 Days of Meeting	121				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	9				
Meeting Minutes Past 15 Days of Meeting	34				
Meeting Minutes Not Submitted and >15 Days Since Meeting	5				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.63%				

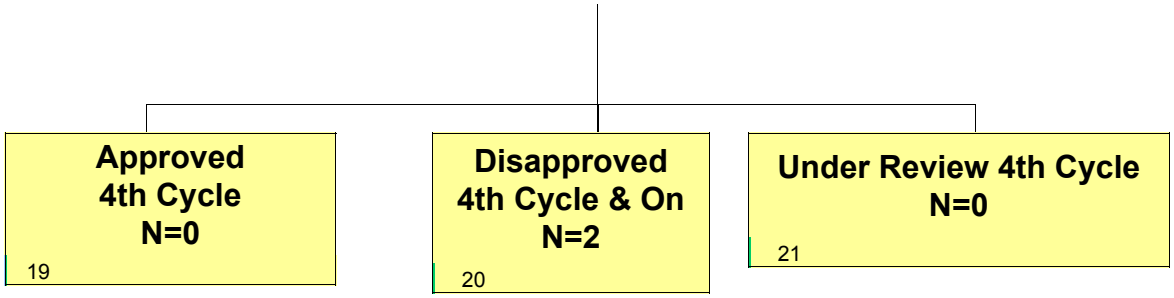
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 9/30/23



*** Other decisions include withdrawn (N=10), withdrawn and converted (N=47), RTA (N=0), nonsignificant risk device (N=8), 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 9/30/23



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343				
Average Number of Cycles to IDE Approval or Conditional Approval	1.17				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.17				

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				
Average Number of Cycles to IDE Approval or Conditional Approval	1.21				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.21				

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				
Average Number of Cycles to IDE Approval or Conditional Approval	1.27				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.27				

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				
Average Number of Cycles to IDE Approval or Conditional Approval	1.27				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.27				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	33				
Average Number of Cycles to IDE Approval or Conditional Approval	1.12				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.12				

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				
Average Number of Cycles to IDE Approval or Conditional Approval	1.08				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	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	29				
Average Number of Cycles to IDE Approval or Conditional Approval	1.33				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	9				
Average Number of Cycles to IDE Approval or Conditional Approval	1.40				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40				

Section 11 CLIA Waiver Annual Metrics

Table 11.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	3				
Withdrawn prior to SI	1				
SI within 90 FDA days	1				
SI over 90 FDA days	1				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Denial without SI	0				
Current SI Performance Percent within 90 FDA days	N/A*				

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.2.CDRH – CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	2				
Average number of FDA days to Substantive Interaction	60.50				
20th Percentile FDA days to Substantive Interaction	37				
40th Percentile FDA days to Substantive Interaction	53				
60th Percentile FDA days to Substantive Interaction	68				
80th Percentile FDA days to Substantive Interaction	84				
Maximum FDA days to Substantive Interaction	99				

Table 11.3.CDRH – CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	3				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	3				
MDUFA IV Decisions within 150 FDA Days	3				
CLIA Waiver Applications pending MDUFA IV Decision	0				
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0				
Current Performance Percent within 150 FDA Days	N/A*				

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.4.CDRH – CLIA Waiver with Panel Review MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decisions	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions within 320 FDA Days	0				
CLIA Waiver Applications pending MDUFA IV Decision	0				
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	N/A*				

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.5.CDRH – CLIA Waiver (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA decision	3				
Average FDA days to MDUFA IV decision	59.67				
20th Percentile FDA days to MDUFA IV decision	18				
40th Percentile FDA days to MDUFA IV decision	21				
60th Percentile FDA days to MDUFA IV decision	46				
80th Percentile FDA days to MDUFA IV decision	94				
Maximum FDA days to MDUFA IV decision	142				
Average Industry days to MDUFA IV decision	0.00				
20th Percentile Industry days to MDUFA IV decision	0				
40th Percentile Industry days to MDUFA IV decision	0				
60th Percentile Industry days to MDUFA IV decision	0				
80th Percentile Industry days to MDUFA IV decision	0				
Maximum Industry days to MDUFA IV decision	0				
Average Total days to MDUFA IV decision	59.67				
20th Percentile Total days to MDUFA IV decision	18				
40th Percentile Total days to MDUFA IV decision	21				
60th Percentile Total days to MDUFA IV decision	46				
80th Percentile Total days to MDUFA IV decision	94				
Maximum Total days to MDUFA IV decision	142				

Table 11.6.CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision

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

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

Table 12.1 CDRH – DUAL (510(k) and CLIA Waiver) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	14				
Withdrawn prior to SI	0				
SI within 90 FDA days	13				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Denial without SI	0				
Current SI Performance Percent within 90 FDA days	100.00%				

Table 12.2.CDRH –DUAL (510(k) and CLIA Waiver)Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	13				
Average number of FDA days to Substantive Interaction	83.15				
20th Percentile FDA days to Substantive Interaction	76				
40th Percentile FDA days to Substantive Interaction	89				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

Table 12.3.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Eligible for MDUFA IV Decision	14				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	4				
MDUFA IV Decisions within 180 FDA Days	4				
CLIA Waiver Applications pending MDUFA IV Decision	10				
CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100.00%				

Table 12.4.CDRH – DUAL (510(k) and CLIA Waiver) (with panel review) MDUFA Decision Performance Goals

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decision	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions with in 320 FDA Days	0				
CLIA Waiver Applications pending MDUFA IV Decision	0				
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	N/A*				

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.5.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA IV decision	4				
Average FDA days to MDUFA IV decision	130.50				
20th Percentile FDA days to MDUFA IV decision	90				
40th Percentile FDA days to MDUFA IV decision	105				
60th Percentile FDA days to MDUFA IV decision	150				
80th Percentile FDA days to MDUFA IV decision	170				
Maximum FDA days to MDUFA IV decision	177				
Average Industry days to MDUFA IV decision	132.00				
20th Percentile Industry days to MDUFA IV decision	92				
40th Percentile Industry days to MDUFA IV decision	125				
60th Percentile Industry days to MDUFA IV decision	163				
80th Percentile Industry days to MDUFA IV decision	177				
Maximum Industry days to MDUFA IV decision	179				
Average Total days to MDUFA IV decision	262.50				
20th Percentile Total days to MDUFA IV decision	224				
40th Percentile Total days to MDUFA IV decision	243				
60th Percentile Total days to MDUFA IV decision	260				
80th Percentile Total days to MDUFA IV decision	297				
Maximum Total days to MDUFA IV decision	344				

Table 12.6.CDRH – DUAL (510(k) and CLIA Waiver) (with Panel Review) Time to MDUFA Decision

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

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submissions that went to panel

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

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

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

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

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

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

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

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

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

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

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

Section 3 PMA Real Time Supplements

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

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

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

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

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

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

Section 5 PMA Annual Metrics and Goals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 De Novo MDUFA V Performance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

Section 9 Pre-Submissions

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

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

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

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

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

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

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

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

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

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 30 September 2023

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3				
Closed Before RTA Action	0				
Number with Accepted RTA Review	3				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	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				
Number Accepted	3				
Completed RTF	3				
Number Not Filed	0				
Rate of Submissions Not Filed	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				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	2				
Average Number of FDA Days to Substantive Interaction	89.00				
20th Percentile FDA Days to Substantive Interaction	88				
40th Percentile FDA Days to Substantive Interaction	89				
60th Percentile FDA Days to Substantive Interaction	89				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

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

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

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				
Non-MDUFA V Decision	0				
MDUFA V Decision	0				
MDUFA V Decision Goal Met	0				
PMAs Pending MDUFA V Decision	0				
PMAs Pending MDUFA V Decision Past Goal	0				
Current Performance Percent Goal Met	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	2				
Average FDA Days to MDUFA V Decision	179.50				
20th Percentile FDA Days to MDUFA V Decision	179				
40th Percentile FDA Days to MDUFA V Decision	179				
60th Percentile FDA Days to MDUFA V Decision	180				
80th Percentile FDA Days to MDUFA V Decision	180				
Maximum FDA Days to MDUFA V Decision	180				
Average Industry Days to MDUFA V Decision	0.00				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	0				
Maximum Industry Days to MDUFA V Decision	0				
Average Total Days to MDUFA V Decision	179.50				
20th Percentile Total Days to MDUFA V Decision	179				
40th Percentile Total Days to MDUFA V Decision	179				
60th Percentile Total Days to MDUFA V Decision	180				
80th Percentile Total Days to MDUFA V Decision	180				
Maximum Total Days to MDUFA V Decision	180				

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				
Average FDA Days to MDUFA V Decision	0.00				
20th Percentile FDA Days to MDUFA V Decision	0				
40th Percentile FDA Days to MDUFA V Decision	0				
60th Percentile FDA Days to MDUFA V Decision	0				
80th Percentile FDA Days to MDUFA V Decision	0				
Maximum FDA Days to MDUFA V Decision	0				
Average Industry Days to MDUFA V Decision	0.00				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	0.00				
Maximum Industry Days to MDUFA V Decision	0				
Average Total Days to MDUFA V Decision	0				
20th Percentile Total Days to MDUFA V Decision	0				
40th Percentile Total Days to MDUFA V Decision	0				
60th Percentile Total Days to MDUFA V Decision	0				
80th Percentile Total Days to MDUFA V Decision	0				
Maximum Total Days to MDUFA V Decision	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				
Number with MDUFA V Decision	2				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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				
Number With MDUFA V Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	0				
MDUFA V Decision	0				
MDUFA V Decision Goal Met	0				
PMAs Pending MDUFA V Decision	0				
PMAs Pending MDUFA V Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA V Decision	0				
MDUFA V Decision	0				
MDUFA V Decision Goal Met	0				
PMAs Pending MDUFA V Decision	0				
PMAs Pending MDUFA V Decision Past Goal	0				
Current Performance Percent Goal Met	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				
SI Goal Met	1				
SI Goal Not Met	2				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	33.33%				

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				
Non-MDUFA V Decision	0				
MDUFA V Decision	1				
MDUFA V Decision Goal Met	1				
Supplements Pending MDUFA V Decision	3				
Supplements Pending MDUFA V Decision Past Goal	1				
Current Performance Percent Goal Met	50.00%				

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

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

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

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

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

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

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

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

Section 5 PMA Annual Metrics and Goals

Table 5.1 CBER – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type

PMA Submissions Received	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Premarket Report Submissions	0				
Original PMAs (Panel) – Priority	0				
Original PMAs (No Panel) – Priority	1				
Original PMAs (Panel) – Non-Priority	0				
Original PMAs (No Panel) – Non-Priority	0				
Panel-Tracked Supplements (Panel) – Priority	0				
Panel-Tracked Supplements (No Panel) – Priority	1				
Panel-Tracked Supplements (Panel) – Non-Priority	0				
Panel-Tracked Supplements (No Panel) – Non-Priority	1				
PMA Modules	0				
180-Day Supplements	4				
Real-Time Supplements	3				

Table 5.2 CBER – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3				
Number with a decision (MDUFA or Non-MDUFA)	2				
% of FY closed	66.67%				

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

Performance Metric	FY 2023 3 year cohort 290 days	FY 2024 3 year cohort 290 days	FY 2025 3 year cohort 285 days	FY 2026 3 year cohort 285 days	FY 2027 3 year cohort 285 days
Number with a MDUFA decision	4				
Number with a MDUFA decision after trimming the upper and lower 5%	4				
Three-year Rolling Average Total Time to MDUFA decision	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	42				
Closed Before First RTA or TS Action [1]	0				
Number Accepted or Passed TS on First Cycle [2]	26				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	7				
Number Not Accepted or Failed TS on First Cycle [2]	9				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	25.71%				

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	31				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	26				
SI Over 60 FDA Days	2				
SI Pending Within 60 FDA Days	3				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	92.86%				

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	26				
Average Number of FDA Days to Substantive Interaction	51.85				
20th Percentile FDA Days to Substantive Interaction	49				
40th Percentile FDA Days to Substantive Interaction	55				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	31				
Non-MDUFA V Decision	1				
MDUFA V Decision (SE/NSE)	23				
MDUFA V Decision Within 90 FDA Days	23				
510(k)s Pending MDUFA V Decision	7				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.13				
Number With MDUFA V Decision	23				
Average Number of FDA Days to MDUFA V Decision	76.17				
20th Percentile FDA Days to MDUFA V Decision	76				
40th Percentile FDA Days to MDUFA V Decision	85				
60th Percentile FDA Days to MDUFA V Decision	88				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	8.91				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	0				
Maximum Industry Days to MDUFA V Decision	115				
Average Number of Total Days to MDUFA V Decision	85.09				
20th Percentile Total Days to MDUFA V Decision	80				
40th Percentile Total Days to MDUFA V Decision	85				
60th Percentile Total Days to MDUFA V Decision	89				
80th Percentile Total Days to MDUFA V Decision	90				
Maximum Total Days to MDUFA V Decision	196				

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	31				
Number With MDUFA V Decision	23				
Number of SE Decision	23				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	1				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	3.23%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	0				
MDUFA V Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA V Decision	0				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	N/A				

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	8				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	6				
MDUFA V Decision Within 90 FDA Days	6				
510(k)s Pending MDUFA V Decision	2				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

Section 7 510(k) Annual General Metrics

Table 7.1 CBER - 510(k) Annual General Metrics - 510(k)s Received by Type

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted	31				
Number of Traditional Submissions	27				
Number of Special Submissions	4				
Number of Abbreviated Submissions	0				
Average Number of Days to Accept/Refuse to Accept	12.71				
Number of Third Party Submissions	0				

Table 7.2 CBER - 510(k) Annual Shared Outcome Goal

Performance Metrics	FY 2023 128 Days	FY 2024 124 Days	FY 2025 112 Days	FY 2026 112 Days	FY 2027 112 Days
Number Accepted	31.00				
Currently Under Review	7.00				
Number With Non-MDUFA V Decision	1.00				
Number With MDUFA V Decision	23.00				
Percent of Cohort Closed	76.67%				
Number With MDUFA V Decision After Trimming the Upper and Lower 2%	23				
Average Total Time to MDUFA V Decision	85.09				

Table 7.3 CBER - 510(k) Third Party Performance

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Third Party Submissions	0.00				
90th Percentile FDA Days to MDUFA V Decision	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				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	0				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	1				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%				

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

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

Table 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00				
Number With MDUFA Decision	0				
Average FDA Days to MDUFA Decision	0.00				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	0.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	0.00				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Number With MDUFA Decision	0				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	N/A				
Rate of Declined Decision	N/A				
Rate of Withdrawal	N/A				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	0				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	0				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	67				
Interactions for Breakthrough Designated Products & Products Included in STeP	2				
Number Closed Before First RTA Action	7				
Number Accepted First RTA Cycle [1]	60				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	4				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted First RTA Cycle	0				
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%				

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

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

Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	60				
Number with Non-MDUFA Action [3]	2				
Number with MDUFA Action	51				
Written Feedback Provided Within Goal	48				
Number Pending MDUFA Action	7				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	58				
Current Performance Percent Within Goal	94.12%				

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	51				
Average FDA Days to Written Feedback	59.10				
20th Percentile FDA Days to Written Feedback	54				
40th Percentile FDA Days to Written Feedback	60				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	72				

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				
Average Days to Scheduling for Meetings Scheduled After Day 30	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]	23				
Meeting Minutes Submitted Within 15 Days of Meeting	19				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	3				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	86.36%				

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

BLA

CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard BLAs Filed	6				
Number of Standard BLA First Actions less than or equal to 10 months	0				
Number of Standard BLA Frist Actions greater than 10 months	0				
Number of Standard BLAs Pending	6				
Number of Priority BLA Filed	0				
Number of Priority BLA First Actions less than or equal to 6 months	0				
Number of Priority BLA Frist Actions greater than 6 months	0				
Number of Priority BLAs Pending	0				

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard Efficacy Supplements Filed	1				
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0				
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0				
Number of Standard Efficacy Supplements Pending	1				
Number of Priority Efficacy Supplements Filed	0				
Number of Priority Efficacy Supplements First Actions less than or equal to 6 months	0				
Number of Priority Efficacy Supplements Frist Actions greater than 6 months	0				
Number of Priority Efficacy Supplements Pending	0				

BLA Prior Approval Manufacturing Supplements

CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard PAS Supplements Filed	81				
Number of Standard PAS Supplements First Actions less than or equal to 4months	65				
Number of Standard PAS Supplements First Actions greater than 4 months	0				
Number of Standard PAS Supplements Pending	16				

BLA/BLA Resubmissions

CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Class 1 Resubmissions Received	0				
Number of Class 1 Resubmission Actions less than or equal to 2 months	0				
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0				
Number of Class 1 Resbumssions Pending	0				
Number of Class 2 Resubmissions Received	0				
Number of Class 2 Resubmission Actions less than or equal to 6 months	0				
Number of Class 2 Resubmission Actions greater than 6 months	0				
Number of Class 2 Resubmissions Pending	0				

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,[1] the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA V Commitment Letter are indicated as such.[2] The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List). [3]

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2023

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	[4]FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
2	Q1	[4]FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
3	Q1	[4]FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
4	Q1	[4]User Fees for 513(g) Requests for Information www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information	10/5/2022	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.
[3] www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023.
[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
5	Q1	[4]User Fees and Refunds for Premarket Notification Submissions (510(k)s) www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-notification-submissions-510ks	10/5/2022	Yes	No	N/A	No
6	Q1	[4]User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-approval-applications-and-device-biologics-license-applications	10/5/2022	Yes	No	N/A	No
7	Q1	[4]User Fees and Refunds for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests	10/5/2022	Yes	No	N/A	No
8	Q1	Procedures for Handling Post-Approval Studies Imposed by PMA Order www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-handling-post-approval-studies-imposed-pma-order	10/7/2022	Yes	No	N/A	A-List
9	Q1	Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act	10/7/2022	Yes	No	N/A	A-List
10	Q1	Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-breakthrough-devices-program-guidance-reducing-disparities-health-and-health-care	10/21/2022	Yes	No	N/A	A-List
11	Q1	[4]Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions	10/26/2022	Yes	Yes	MDUFA V Commitment Letter V.B.	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q1	Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents www.fda.gov/regulatory-information/search-fda-guidance-documents/referencing-definition-device-federal-food-drug-and-cosmetic-act-guidance-regulatory-documents	11/14/2022	No	No	N/A	No
13	Q1	Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-malfunction-summary-reporting-vmsr-program-manufacturers	12/9/2022	Yes	No	N/A	A-List
14	Q1	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	12/9/2022	Yes	No	N/A	B-List
15	Q1	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection (December 2022) www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection-december	12/16/2022	No	No	N/A	No
16	Q2	[4]Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests-revised	1/12/2023	No	No	N/A	No
17	Q2	[4]Policy for Coronavirus Disease-2019 Tests (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised	1/12/2023	No	No	N/A	No
18	Q2	Photobiomodulation (PBM) Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/photobiomodulation-pbm-devices-premarket-notification-510k-submissions	1/12/2023	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	Surveying, Leveling, and Alignment Laser Products www.fda.gov/regulatory-information/search-fda-guidance-documents/surveying-leveling-and-alignment-laser-products	1/31/2023	No	No	N/A	No
20	Q2	[4]Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-and-premarket-notification-510k-submissions-ultrasonic-diathermy-devices	2/21/2023	Yes	No	N/A	No
21	Q2	[4]Medical X-Ray Imaging Devices Conformance with IEC Standards www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards	2/21/2023	Yes	No	N/A	No
22	Q2	[4]Marketing Clearance of Diagnostic Ultrasound Systems and Transducers www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers	2/21/2023	Yes	No	N/A	No
23	Q2	[4]Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56) www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56	2/21/2023	No	No	N/A	No
24	Q2	[4]Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide www.fda.gov/regulatory-information/search-fda-guidance-documents/performance-standard-diagnostic-x-ray-systems-and-their-major-components-21cfr-102030-102031-102032	2/21/2023	No	No	N/A	No
25	Q2	[4]Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-food-and-drug-administration-staff-assemblers-guide-diagnostic-x-ray-equipment	2/21/2023	No	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
26	Q2	[4]Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-shields-surgical-masks-and-respirators-during-coronavirus-disease-covid-19	3/13/2023	Yes	No	N/A	No
27	Q2	[4]Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public	3/13/2023	Yes	No	N/A	No
28	Q2	Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-systems-electronic-records-and-electronic-signatures-clinical-investigations-questions	3/16/2023	No	No	N/A	No
29	Q2	Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease	3/27/2023	Yes	No	N/A	A-List
30	Q2	Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease	3/27/2023	Yes	No	N/A	A-List
31	Q2	Soft (Hydrophilic) Daily Wear Contact Lenses - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/soft-hydrophilic-daily-wear-contact-lenses-performance-criteria-safety-and-performance-based-pathway	3/28/2023	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
32	Q2	General Considerations for Animal Studies Intended to Evaluate Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/general-considerations-animal-studies-intended-evaluate-medical-devices	3/28/2023	Yes	No	N/A	No
33	Q2	Orthopedic Non-Spinal Bone Plates, Screws, and Washers - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions	3/29/2023	Yes	No	N/A	No
34	Q2	[5]Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-refuse-accept-policy-cyber-devices-and-related-systems-under-section	3/30/2023	Yes	No	N/A	No
35	Q3	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial	4/3/2023	Yes	Yes	MDUFA V Commitment Letter V.G.5	B-List
36	Q3	Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory	4/6/2023	Yes	Yes	Section 3002 of the 21st Century Cures Act	No
37	Q3	A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-based-approach-monitoring-clinical-investigations-questions-and-answers	4/12/2023	Yes	No	N/A	No

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

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
38	Q3	Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-percutaneous-transluminal-angioplasty-pta-and-specialty-catheters-premarket-notification	4/14/2023	Yes	No	N/A	No
39	Q3	[4]Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	4/28/2023	Yes	No	N/A	No
40	Q3	Decentralized Clinical Trials for Drugs, Biological Products, and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices	5/3/2023	Yes	Yes	Section 3606(a) of the Food and Drug Omnibus Reform Act (FDORA)	No
41	Q3	Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/use-whole-slide-imaging-nonclinical-toxicology-studies-questions-and-answers	5/25/2023	Yes	No	N/A	No
42	Q3	Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-performance-assessment-tissue-containment-systems-used-during-power-morcellation	5/26/2023	Yes	No	N/A	No
43	Q3	[4]Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program	6/2/2023	Yes	No	N/A	No
44	Q3	Content of Premarket Submissions for Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions	06/14/2023	Yes	Yes	MDUFA V Commitment Letter V.G.4.	A-List
45	Q3	Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/oncology-drug-products-used-certain-in-vitro-diagnostic-tests-pilot-program	6/20/2023	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
46	Q3	Patient-Matched Guides to Orthopedic Implants www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-matched-guides-orthopedic-implants	6/28/2023	Yes	No	N/A	No
47	Q4	[4]Qualification of Medical Device Development Tools www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-medical-device-development-tools	7/17/2023	Yes	No	N/A	No
48	Q4	Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations – Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/hydrogen-peroxide-based-contact-lens-care-products-consumer-labeling-recommendations-premarket	7/27/2023	Yes	No	N/A	B-List
49	Q4	Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-considerations-studies-devices-intended-treat-opioid-use-disorder	7/28/2023	Yes	No	N/A	A-List
50	Q4	[4]Off-The-Shelf Software Use in Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices	8/11/2023	Yes	No	N/A	No
51	Q4	Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent	8/16/2023	No	No	N/A	No
52	Q4	[4]Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public	9/5/2023	Yes	No	N/A	No
53	Q4	Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-use-clinical-data-premarket-notification-510k-submissions	9/7/2023	Yes	No	N/A	No

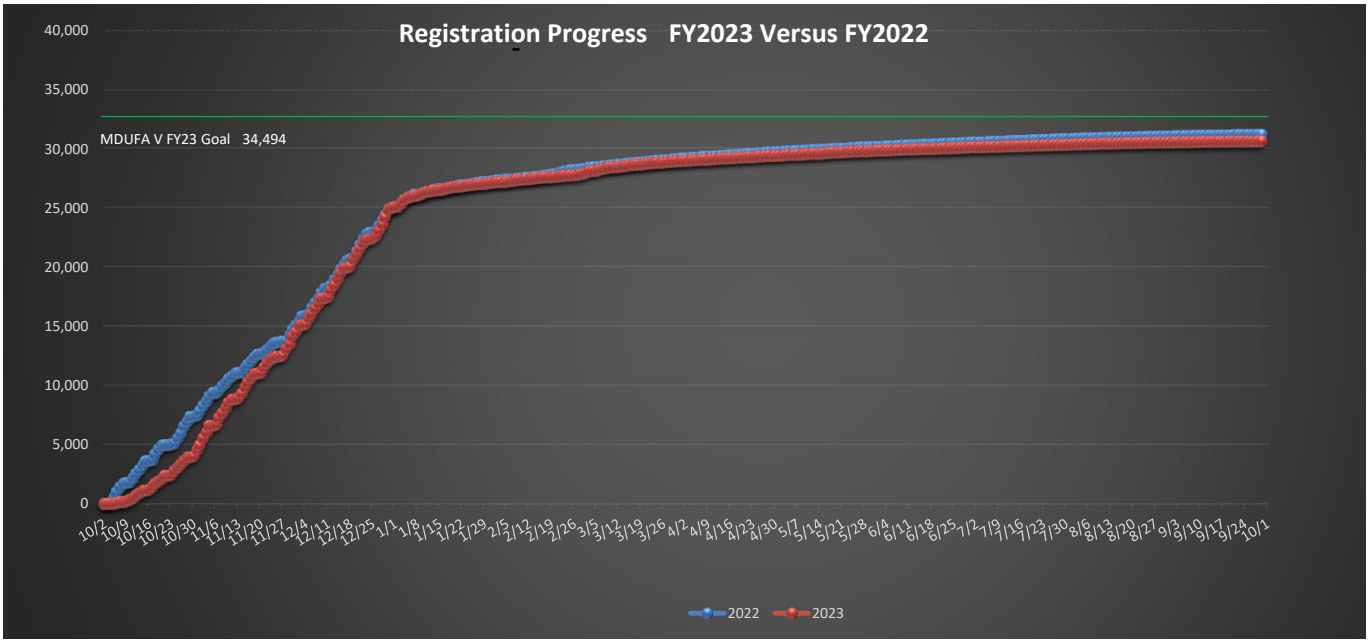
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
54	Q4	Evidentiary Expectations for 510(k) Implant Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/evidentiary-expectations-510k-implant-devices	9/7/2023	Yes	No	N/A	No
55	Q4	Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-selecting-predicate-device-support-premarket-notification-510k-submission	9/7/2023	Yes	No	N/A	No
56	Q4	Application of Human Factors Engineering Principles for Combination Products: Questions and Answers **www.fda.gov/regulatory-information/search-fda-guidance-documents/application-human-factors-engineering-principles-combination-products-questions-and-answers**	9/7/2023	Yes	No	N/A	No
57	Q4	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and	9/8/2023	Yes	No	N/A	No
58	Q4	Breakthrough Devices Program www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program	9/14/2023	Yes	No	No	A-List
59	Q4	Medical Devices with Indications Associated with Weight Loss – Non-Clinical Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-indications-associated-weight-loss-non-clinical-recommendations	9/15/2023	Yes	No	N/A	No
60	Q4	Medical Devices with Indications Associated with Weight Loss – Clinical Study and Benefit-Risk Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-indications-associated-weight-loss-clinical-study-and-benefit-risk-considerations	9/15/2023	Yes	No	N/A	No

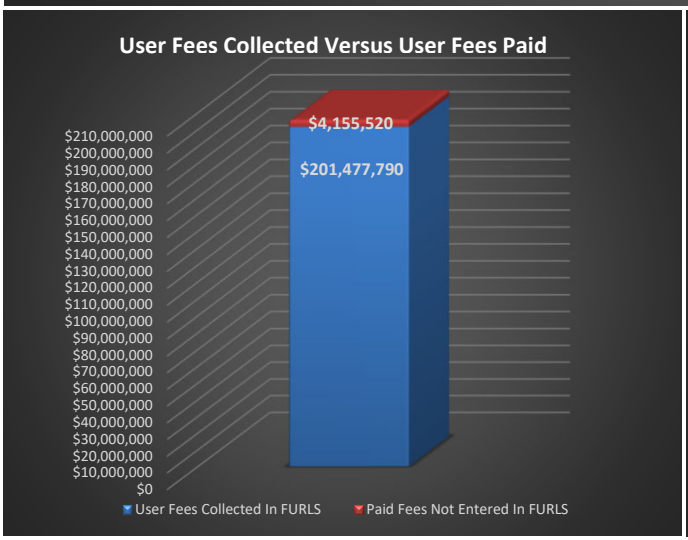
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
61	Q4	Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program www.fda.gov/regulatory-information/search-fda-guidance-documents/fostering-medical-device-improvement-fda-activities-and-engagement-voluntary-improvement-program	9/15/2023	No	No	N/A	A-List
62	Q4	Regulatory Considerations for Prescription Drug Use-Related Software www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-prescription-drug-use-related-software	9/19/2023	Yes	No	N/A	No
63	Q4	Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-conduct-clinical-trials-medical-products-during-major-disruptions-due-disasters-and	9/21/2023	Yes	No	N/A	No
64	Q4	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions	9/27/2023	Yes	No	N/A	A-List
65	Q4	Electronic Submission Template for Medical Device De Novo Request www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-de-novo-requests	9/29/2023	Yes	Yes	745A(b) of the FD&C Act	No
66	Q4	Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-medical-devices-physiologic-closed-loop-control-technology	9/29/2023	Yes	No	No	No
67	Q4	Antimicrobial Susceptibility Test (AST) System Devices – Updating Breakpoints in Device Labeling www.fda.gov/regulatory-information/search-fda-guidance-documents/antimicrobial-susceptibility-test-ast-system-devices-updating-breakpoints-device-labeling	9/29/2023	Yes	No	N/A	No

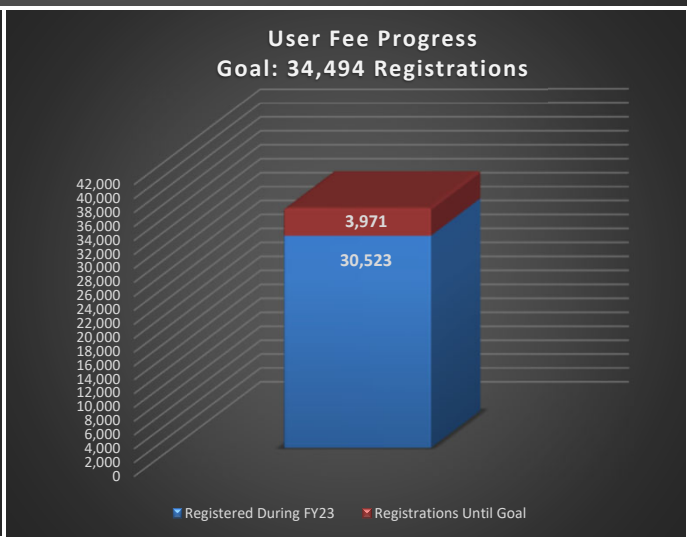
MDUFA V Registrations - 4th Quarter Summary FY2023*

Current Active Registrations by Type	FY23 Q4			FY22 Year End Active Totals			FY23 vs End FY22
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,677	12,332	19,009	6,848	12,892	19,738	96.31%
Contract Manufacturer	1,243	1,893	3,136	1,234	1,798	3,032	103.43%
Contract Sterilizer	76	169	245	68	166	234	104.70%
Specification Developer	1,668	557	2,225	1,768	573	2,341	95.04%
Reprocessor of Single Use Devices	34	3	37	25	5	30	123.33%
U.S. Manufacturer of Export Only Devices	127	0	127	138	0	138	92.03%
Repackager/Relabeler	1,116	221	1,337	1,178	209	1,387	96.40%
Remanufacturer	14	9	23	22	10	32	71.88%
Foreign Exporter/Private Label Distributor		1,132	1,132		1,156	1,156	97.92%
Initial Importer	3,357		3,357	3,640		3,640	92.23%
Unknown	6	11	17	6	12	18	94.44%
Total:	**14,318**	**16,327**	**30,645**	**14,927**	**16,821**	**31,748**	**96.53%**

*Note: This data is current as of 9/29/2023







FY 2023 Medical Device User Fee Collections as of September 30, 2023 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$201,890,717	-$565,353	$201,325,365		
Application Fees	$101,937,821	-$2,297,352	$99,640,469		
Total	**$303,828,539**	**-$2,862,705**	**$300,965,834**	**$324,777,000**	**93%**

Medical Device User Fee Collection History Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,738,775	$34,425,417	$28,031,569
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,794,823	$56,962,602	$63,699,312	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,306,430	$122,346,416	$136,098,825	$147,157,165	$137,771,541
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,892,253	$208,655,559	$214,598,068	$274,869,614	$265,585,641
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$300,965,834				

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

CDRH and CBER Combined Data 4th Quarter FY 2023 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	7	1
PMA	7	1
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
Panel Track Supplements	2	5
De Novo Classification	3	68
180-Day Supplements	2	12
Real-Time Supplements	2	30
510(k)s	57	2,035
30-day Notices	14	55
513(g)s	0	59
PMA Annual Report	0	18
Total	**87**	**2,283**

[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. CBER counts are included in PMA's (1 reduced), Panel Track Supplements (2 reduced) DeNovo Classifiation (1 reduced), 180 Day Supplements (1 reduced), Real-Time Supplements (1 reduced), 510(k)s (13 reduced), and 30-day Notices (4 reduced).

A. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2023 Summary meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[1]:

> *"VII. Performance Reports…4. In addition, the Agency will provide the following information on an annual basis… 4.12. Report on QMOE program… 4.13. Summary of QMOE audits, including annual audit of Deficiency Letters…"*

B. CDRH Quality Management Program

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[2]:

> *"IV.A… The CDRH Quality Management and Organizational Excellence (QMOE) Program is comprised of a team of certified quality management staff who report to the Center Director…"*

C. Quality Management Unit Expertise

C.1. The CDRH (QM Unit) resides at the Office of the Center Director. Additional QM staff resides in CDRH Offices, including the OPEQ QM Staff.

C.2. ISO 9001:2015 Quality Management Systems. All CDRH QMOE Program Staff at the Office of the Center Director satisfactorily completed training associated with quality auditing under an ISO 9001:2015 Quality Management Systems (QMS).

C.3. ISO and Quality Credentials. Collectively, CDRH QM staff hold one or more of the following quality-related credentials: ASQ Certified Quality Improvement Associate (CQIA), ASQ Certified Quality Auditor (CQA), ASQ Certified Quality Engineer (CQE), ASQ Certified Software Quality Engineer (CSQE), ASQ Certified Manager of Quality and Operational Excellence (CMQOE), ASQ Certified Lean Six Sigma Yellow Belt (CLSSYB), ASQ Certified Lean Six Sigma Green Belt (CLSSGB), Lean Six Sigma Master Black Belt (LSSMBB), ISO 13485:2013 Lead Auditor, ISO 9001:2015 Lead Auditor, Project Management Professional (PMP), PMI Agile Certified Practitioner (PMI-ACP)®, and Bronze Level Kirkpatrick Evaluation Certification.

[1] MDUFA V Agreement page 28
[2] MDUFA V Agreement page 12

C.4. Quality Management Training

To support the adoption of quality management across CDRH, the following training was provided in FY 2023:

- ISO 9001:2015 Requirements from A-Z
- ASQ Certified Quality Auditor Training
- ASQ Six Sigma Yellow Belt Training
- ASQ Certified Manager of Quality and Organizational Excellence Training
- How to Write SOPs for Human Error Reduction
- How to Measure Anything: Principles of Applied Information Economics
- NVivo Training
- Agile Ways Fundamentals

D. CDRH Quality Management System (QMS)

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 requirement[3]:

> *"…The QMOE Program establishes and leads the CDRH Quality Management System (QMS) activities, facilitates process improvements, independently audits CDRH processes and activities, and assesses the effectiveness of actions taken to prevent potential (risk management) and resolve existing issues (nonconformity management)…"*

D.1. ISO 9001:2015 Certification

The FY 2023 surveillance audit will take place November 2023.

D.2. Voice of the Customer (VOC). The CDRH customer satisfaction survey is available through FDA.gov and is included in all CDRH staff email correspondence. Overall, industry continued to be highly satisfied with CDRH. Industry's customer service satisfaction rate with CDRH was 96 percent (554/578) in FY 2023. Industry respondents continued to comment positively about their satisfaction with the premarket review process.

D.3. Feedback✓CDRH. Feedback✓CDRH is the internal system used to collect internal staff input. The input is assigned to offices who determine whether actions need to be taken. After feedback is addressed, a summary of actions taken is made available to all CDRH staff. In FY 2023, 59 percent of the feedback received referenced OPEQ processes and procedures, with 69 percent of that feedback related to premarket review. All feedback was examined and addressed within the established CDRH timelines.

[3] MDUFA V Agreement page 12

E. Document Control

E.1. Document Control System (DCS) – FY 2023 Improvements. The system continues to be CDRH repository for all controlled documents.

E.2. CDRH's QMS Documentation. All documents related to the CDRH QMS are controlled using the CDRH DCS.

E.3. Conforming Offices Documentation. All documents related to the management and execution of the premarket review program processes are controlled using the CDRH DCS. The system houses 1016 operating procedures, work instructions, forms and templates. At the time of this report, 67 percent (683/1016) of the CDRH controlled documentation pertains to OPEQ core processes. Of those, 51 percent (346/683) are associated with premarket review.

F. Internal Audits

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement[4]:

> *"…At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan with the QMOE Program. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's nonconformity management process. FDA will continue to expand the scope of its annual audits as it implements and builds up its auditing capability, as resources permit. At a minimum, FDA audits in the following areas will be completed: Pre-Submissions and Third Party Review Program…"*

F.1. Audit Schedule FY 2024. The FY 2024 data call for audit topics was submitted in Q3 FY 2023 and the audit schedule will be finalized in Q1 FY 2024.

FY 2024 Audit Schedule (Tentative)*
ISO Required Audits of all QMS Functions
MDUFA V Required Audit of Deficiency Letters
***Additional programmatic audits under consideration. Final Schedule to be reported Q1 2024**

F.2.

F.3. Audit Schedule FY 2023. The following internal audits were conducted in FY 2023. Nine QMS core processes were examined during 3 internal audits:

Title	Purpose	Findings
AF-2023-00075	FY 23 MDUFA V Required audit of Deficiency Letters	N/A - Analyzing results As required, results will be presented at the FY 2024 Q1 meeting.
AF-2022-00075	Deficiency Letter Baseline	Process Audits, no findings
AF-2023-00077	Regulatory Science Products Internal Audit	Internal audit, 4 findings
AF-2023-00078	TSR, Risk, and DDVV	Internal audit, 2 findings
AF-2023-00079	QMR, DCS, Training	Internal audit, no findings
AF-2023-00080	VOC, NCR, Audit Program	Internal audit, no findings

[4] MDUFA V Agreement page 12

F.4. CDRH QMS Audits (AF-2023-00077, AF-2023-00078, AF-2023-00079, and AF-2023-00080).

AF-2023-00077. An internal audit for Regulatory Science Products was conducted in FY23. The internal audit reported four (4) findings (minor nonconformances) addressing the CDRH QMS Scope, QMS enabling processes and improvements to the Quality Management Review template.

AF-2023-00078, AF-2023-00079, and AF-2023-00080. Nine QMS core processes were examined during 3 internal audits. The internal audits reported two (2) findings (minor nonconformances) related to the operations supporting the QMS process for the development and delivery of services.

F.5. AF-2022-00075: Deficiency Letters Baseline

Purpose: Assess the rate with which CDRH conforms to Part 3A of 4-Part Harmony, specifically to determine whether deficiencies include a complete "statement of basis for the deficiency," i.e., with an "impact on decision" statement.

Findings: Baseline audit conducted using a sample of FY 2022 deficiency letters to assess current state. Fifty-nine percent of the deficiencies examined contained a statement of basis for the deficiency that aligned to the clarified requirements. The audit fulfilled its goal to assess current state. No additional actions were necessary.

F.6. Audit Findings Next Steps. Where nonconformities were found, the auditee is working to address them. Additional information will be provided as the nonconformities are addressed.

G. Continual Improvement.

G.1. Business Process Improvement (BPI; ongoing).

CDRH's Simplicity Strategic Priority and Digital Transformation initiatives continued through FY 2023. CDRH continues to lean CDRH core businesses processes. BPI objectives include:

- Simplifying processes to improve process efficiency, repeatability, and effectiveness,
- Supporting process harmonization to increase standardization, and
- Improving clarity of process and supporting documents (e.g., Standard Operating Procedures, Work Instructions, etc.).

G.2. Audit Program Improvements

CDRH continued to expand the Audit Program to support a planned expansion of the CDRH QMS scope and MDUFA V commitments, including the MDUFA V commitment to use audits to assess performance (deficiency letters). QMOE:

- Increased the number of auditors dedicated to premarket review processes and
- Streamlined internal audit processes

As a result of these actions, QMOE increased the Audit Program's ability to execute audits and assessments and reduced time to deliver results.

G.3. Deficiency Letter Assessments

QMOE conducted additional assessments to support OPEQ's implementation of the MDUFA V deficiency letters performance commitment. Conducted by the QMOE deficiency letter auditors, these assessments:

- Additional Assessment 1: Reviewed over 400 additional deficiency letters (approximately 1900 deficiencies) to provide earlier identification of best practices and areas of focus.
- Additional Assessment 2: Reviewed approximately 120 SMART template "stock deficiencies" to provide earlier identification of best practices and areas of focus.

G.4. Innovative Technological Improvements: eSTAR Submission Tool

In 2023, CDRH continued to advance innovative technologies and meet the MDUFA V commitment to develop electronic submission templates to improve the sponsor submission process through the electronic Submission Template and Resource (eSTAR) pilot. eSTAR is a method for industry to submit submissions in an effort to develop resources to aid sponsors in providing structured electronic submissions.

With the publication of the guidance "Electronic Submission Template for Medical Device 510(k) Submissions" on September 22, 2022, 510(k) submissions prepared as eSTARs are required as of October 1, 2023. No notable issues have occurred with this transition.

The use of eSTAR by Health Canada in our International Pilot began on January 10, 2023 and is ongoing. We've begun incorporating feedback by those applicants with devices authorized in both jurisdictions. The pilot will end when a final decision is rendered for the last submission.

We released the Early Submission Requests eSTAR (PreSTAR) on June 9, 2023 with both types of Pre-Submissions enabled. We expect that the 513(g) content will be enabled early in 2024.

We are expecting to enable PMA content in the nIVD and IVD eSTARs by the end of CY2023.

As of 10/30/2023, CDRH received 1,922 eSTARs; 805 are under review.

Development on the IDE eSTAR content will begin in the first half of CY 2024.

H. Independent Assessment of Review Process

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 requirement[5]:

"*…FDA and the industry will participate in a targeted assessment of the process for the review of device applications. The assessment will include consultation with both FDA*

[5] MDUFA V Agreement page 27

and industry at the start of the assessment and prior to issuance of the final report. The assessment shall be conducted under contract to FDA by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment scope described below within the budget provided under this user fee agreement.

The contractor will:

1. *Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V;*
2. *Assess the alignment of resource needs with the training and expertise of hires;*
3. *Identify and share best practices across OHTs in OPEQ;*
4. *Assess the effectiveness of program areas targeted for improvement under this agreement, including the following:*
    a. *Implementation and impact of changes to the guidance "Developing and Responding to the Deficiencies in Accordance with the Least Burdensome Provisions,*
    b. *Implementation and impact of changes to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The QSubmission Program,"*
    c. *Third Party Review program (continued reduction of routine re-review by FDA of Third Party reviews)*
    d. *Digital Health program,*
    e. *Patient Engagement program,*
    f. *Real World Evidence program;*
    g. *International Harmonization*
5. *Assess other key areas identified by FDA and industry as resources permit*

FDA will award the contract no later than March 31, 2025. However, the contractor would not begin the audit of Pre-Submissions before October 1, 2025. The contractor will publish comprehensive findings and recommendations within 1 year, after reviews with FDA and industry and opportunities to provide feedback for the contractor's consideration prior to finalizing the final report. For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable.

FDA will incorporate findings and recommendations, as appropriate, into its management of the process for the review of device applications. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness.

H.1. Reporting Status. N/A

Center for Devices and Radiological Health Internal Training Summary Report

FY'23: October 2022 – September 2023

Prepared by: The Division of Employee Training and Development (DETD)

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Introduction:

The FDA continues to invest in internal and external training opportunities supporting medical device regulation. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, leadership training, career development programs, and customized learning opportunities. We help further the Center's mission by championing employee growth across the Center's seven offices. Our approach to improving performance combines classroom, experiential, and online learning with mentoring, self-study initiatives, and specialty programs. We are committed to providing CDRH employees with the knowledge and skills needed to maximize their organizational and individual potential.

Table X provides a summary of internal training conducted in CDRH between October 1, 2022 and September 30, 2023. DETD offered 789 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. The training was designed to support the Medical Device User Fee Amendment (MDUFA) goals and program activities.

Table X – FY'23 CDRH Internal Training Conducted by DETD:

October 1, 2022 and September 30, 2023

Category	Program	# of Learning Events	Total # of Completions
Regulatory and Law (LAW) Training	ELP	9	162
	MDUFA V	4	7531
	Other LAW	386	29883
	LAW Subtotal:	*399*	*37576*
Leadership Development Training (LED)	LEAD: Leadership for Managers	39	611
	Leadership for Non-Managers	9	115
	Other LED	20	293
	LED Subtotal:	*68*	*1019*
Professional Development (PRO) Training	New Employee Orientation	6	35
	Other PRO	129	2815
	PRO Subtotal:	*135*	*2850*
Center-Specific Information Technology (CIT) Training	All CIT	7	551
	CIT Subtotal:	*7*	*551*
Science (SCI) Training	All SCI	180	8509
	SCI Subtotal:	*180*	*8509*
		789	**50505**

Reviewer Training

Reviewer Certification Program (RCP):

The RCP curriculum is a 39-hour program consisting of online and classroom courses essential to new reviewers during their first 60 days of hire. The condensed course design results in reviewers receiving the most salient knowledge in a timely fashion. After completion of the RCP, reviewers enroll in advanced courses designed to further enhance their knowledge and skills. The curriculum consists of the following components:

- 14 classroom courses, including a program Orientation and Capstone, totaling 17.5 hours of training
- 16 online courses, totaling 21.5 hours
- 8 Advanced courses, totaling 43.5 hours, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

RCP Training by Cohort: October 1, 2022 and September 30, 2023

Cohort	# of Classroom Learning Events	# of Online Learning Events	# of Participants	# of Completions	# of Training Hours
Fall 1 2022 Cohort	**14**	**16**	***55***	***1016***	***1313***
Fall 2 2022 Cohort	**14**	**16**	***31***	***672***	***838***
Spring 1 2023 Cohort	**14**	**16**	***39***	***707***	***909***
Spring 2 2023 Cohort	**14**	**16**	***55***	***1074***	***1349***
Summer 1 2023 Cohort	**14**	**16**	***34***	***561***	***710***
Summer 2 2023 Cohort	**14**	**16**	***43***	***1513***	***1974***
Total:	**84**	**96**	***257***	***5543***	**7093**

Experiential Learning Program (ELP):

The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the review of resulting medical devices. The Program fosters an understanding of how medical devices are developed, clinically tested, manufactured, and utilized. Staff involved in medical device regulation visit ELP sites identified by training need and selected through a formalized proposal submission process.

In FY23, CDRH conducted 9 site visits for 162 attendees. Participants received a total of 1,633 hours of training in the areas of innovation, digital health, biocompatibility, reprocessing, and sterilization.

CDRH Informal Training

CDRH Informal Training:

Informal training targets specific audiences and addresses specialized training topics. It is offered at the Office, Division and Branch levels and is conducted as on-the-job training, All-Hands meetings, small group sessions and classroom and remote training. Formal and informal training is necessary to meet the mission-critical training needs of Center staff. Examples of informal training content include:

- Additional instruction provided following formal training (e.g. Medical Device Regulation training)
- Policy change updates (e.g. New technology, MDUFA, new guidance)
- Best practices used in a specific product area

In FY23 CDRH offered 78 Informal Events for a total of 16,637 participants

MDUFA ROI Reporting

Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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Outline

- Background Information
  - Language in Commitment Letter
  - Definition of ROI in the private vs. public sector
  - Overall strategic framework
- Key MDUFA V Enhancements
  - We hit the ground running to meet MDUFA V commitments
  - We are promoting innovation and patient access
  - We are transforming customer digital experience
- Next Steps
- Main ROI Takeaways

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BACKGROUND INFORMATION

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ROI Reporting Language in MDUFA V Commitment Letter

"The Agency will provide the following information on an annual basis: (…) The return on investment, which may include process improvements, improved performance, and other enhancements, under MDUFA V." (MDUFA V Commitment Letter, Section VII, Item 4.15)

- During and after MDUFA V negotiations, we received clarification from Industry regarding their vision and expectations for this commitment.
- This represents our initial response. We will refine ROI reporting over the course of MDUFA V as we receive Industry's feedback and acquire more data.

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Definition of ROI

- *Traditionally*, return on investment (ROI) is a financial performance measure used to evaluate the efficiency or profitability of an investment or to compare the efficiency of different investments. ROI measures the amount of return on a particular investment, relative to the investment's cost:

$$\text{ROI} = \frac{Return}{Investment} = \frac{Net\ Income}{Expenses} \approx \frac{Value\ of\ Benefits}{Costs}$$

- *In the public sector*, some types of returns cannot be easily monetized, so we adopted a broader framework that captures a wide range of returns, including qualitative benefits that go beyond the purely quantitative financial measures typically used in business.

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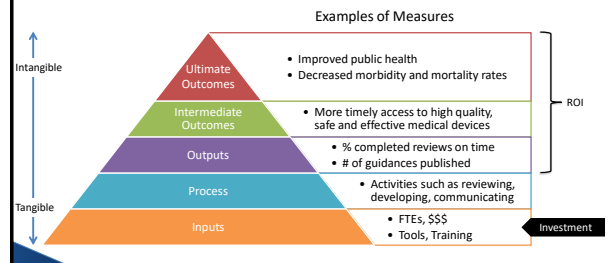
ROI in the Public Sector



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Overall Strategic Framework

- We aim at capturing **monetized, quantified, and intangible benefits**. Whenever possible, we are trying to monetize (or at least quantify) returns, using sound and defensible values and procedures. We are also looking beyond quantifiable benefits and capturing other benefits that we may not be able to quantify at this time, but that are important when assessing value.
- We are looking at benefits for a **variety of stakeholders** at macro level (public, patients, providers, industry sector, FDA, medical device ecosystem) and micro level (individual company/product, individual patient).
- We are taking a **multi-year approach.** Each year we will improve the methodology and build upon previous feedback. For this year, we will present benefits, enhancements, and improvements in a more qualitative way.
- As MDUFA V unfolds, we aspire to add financial ROI reporting.

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Key MDUFA V Enhancements

WE HIT THE GROUND RUNNING TO MEET MDUFA V COMMITMENTS

WE ARE PROMOTING INNOVATION AND PATIENT ACCESS

WE ARE TRANSFORMING CUSTOMER DIGITAL EXPERIENCE

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We Are Currently Meeting FY23 Review Goals

Submission Type	Review-Time Goal	FY23 Target Performance	FY23 Current Performance*
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports			
Substantive Interaction	90 calendar days	95%	
Decision with No Advisory Committee Input	180 FDA days	90%	
Decision with Advisory Committee Input	320 FDA days	90%	
180-Day PMA Supplements			
Substantive Interaction	90 calendar days	95%	
Decision	180 FDA days	95%	
Real-Time PMA Supplements			
Decision	90 FDA days	95%	
De Novo Classification Requests			
Decision	150 FDA days	70%	
510(k) Premarket Notifications			
Substantive Interaction	60 calendar days	95%	
Decision	90 FDA days	95%	
Pre-Submissions			
Provide Written Feedback	70 calendar days or 5 days prior to meeting	90% if < 3,585 or 75% up to 4,300	

* CDRH data only; data are as of 09/30/23 and may change until cohorts are closed.

= Performance TBD
= Currently meeting goal

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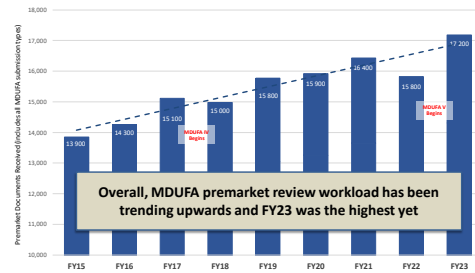
...Even in the Presence of Increasing Workload



Received = All applicable eCopy and user fee requirements met; excludes Compassionate Use requests and some CUA; CDRH only
MDUFA submission types = 510(k), PMA, De Novo, Q-Sub, 513(g), and IDE; does not include EUA or Pre-EUA

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Other MDUFA V Accomplishments

SUBMISSION REVIEW PERFORMANCE	PROGRAM AND PROCESS IMPROVEMENTS	PERFORMANCE ACCOUNTABILITY	FINANCIAL TRANSPARENCY AND HIRING
• Deficiency Letters: Updated 2017 guidance and provided training • 3PR Program: Hosted 2-day workshop; Completed audit on recognized ROs; Published performance of individual accredited Third Parties • CDRH Portal: Added upload capability; Progress tracker available for 510(k)s and Pre-Subs • eSTAR: Completed electronic templates for De Novos, Pre-Subs, and 510(k)s; Deployed Health Canada International Pilot eSTAR with PMA content	• TAP: Launched pilot and established expansion plan • RWE: Published document requesting public comment • ASCA: Transitioned to permanent program • Digital Health: Published final guidance on premarket software and draft guidance on PCCP • International Harmonization: Published draft strategic plan • PSE: Published COA draft guidance; Obtained public feedback on proposed revisions to PPI guidance; Launched PS FPP	• Published MDUFA Quarterly Performance Reports and held MDUFA Quarterly Meetings on time • Conducted FY23 Deficiency Letter Audit and 5 additional audits • Established tentative schedule for FY24 audits	• Published FY23 MDUFA V Five-Year Financial Plan, including MDUFA V annual hiring targets • Filled 141 MDUFA V positions

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Key MDUFA V Enhancements

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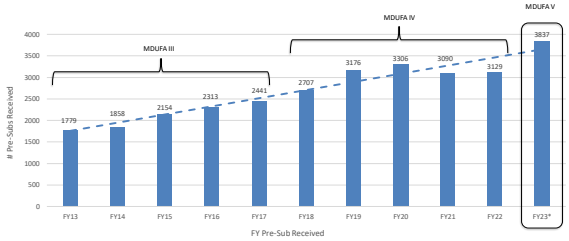
Pre-Submission Program Continues to Grow



* Data are as of 09/30/23 and may change until cohort is closed.

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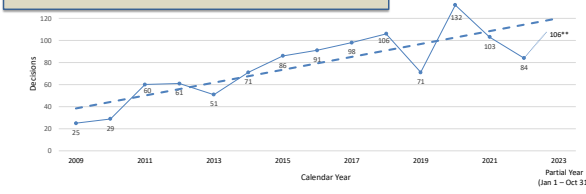
Sustained Increase in Novel Device Authorizations

> 3-fold Increase in # of Novel Device* Authorizations



* Novel devices include original PMAs, panel track supplement PMAs, De Novos, HDEs, breakthrough 510(k)s, and specific EUAs deemed novel.

** Partial year data not included in the trendline. Data are as of October 31, 2023. Data are not complete, since CY23 will end December 31, 2023.

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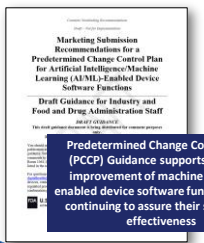
FDA Promotes Development of Safe and Effective AI/ML-Enabled Devices


Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

Predetermined Change Control Plan (PCCP) Guidance supports iterative improvement of machine learning enabled device software functions while continuing to assure their safety and effectiveness

- Helps enable personalized medical care & increases pace of medical device innovation
- Facilitates more rapid and continuous improvement of AI/ML enabled device performance across diverse populations
- Ensures crucial performance considerations (race, ethnicity, disease severity gender age, geography) are addressed throughout the total product lifecycle

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Key MDUFA V Enhancements

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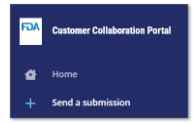
FDA Transforms Customer Digital Experience

Premarket Progress Tracker

Firms can access the site and view status of their:
- Traditional, Special, and Abbreviated 510(k)s
- Pre-Submissions

Submission Upload Capability

- Firms can upload eCopy and eSTAR premarket submissions
- eSTAR available for De Novos, Pre-Submissions, and 510(k)s; PMA Pilot underway
- Starting Oct.1, 2023, eSTAR mandatory for all 510(k) submissions, unless exempt [see Section VI.A of the Final eSTAR 510(k) guidance]



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Benefits Include:

TIME SAVINGS	COST SAVINGS	RISK REDUCTION	IMPROVED USER EXPERIENCE
• For industry: immediate delivery vs. waiting for mail couriers to deliver packages • For FDA: less time spent on archiving, scanning, searching for documents	• For industry: cut costs, including costs for: - printing - handling - logistics - mailing • For FDA: cut costs, including costs for storage and retrieval	• Minimizes risk of lost and misrouted submission • Reduces risk of human error • Ability to access submissions remotely reduces risk of work disruptions	• Improved internal user experience for FDA reviewers (more streamlined workflows) • Improved external user experience for companies (more efficient, predictable, and consistent review process)

A better information technology environment for the exchange, review, and management of submissions will help drive a more efficient device review process

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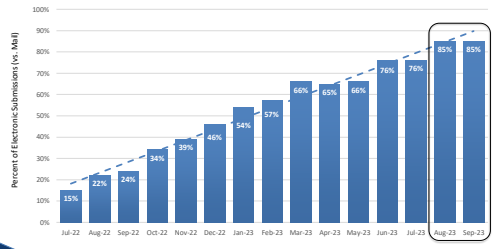
Use of CDRH Portal Has Steadily Increased and Is Now Used for 85% of Submissions



Based on data captured on the 15th of every month.

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Highlights of User Comments on CDRH Portal

- ✓ *Thanks for this easy submission process - I love it!!*
- ✓ *So far, it has been fantastic. The portal is user friendly, and the upload was fast. I have no complaints.*
- ✓ *Excellent!! I am having a great experience using CCP. I really appreciate the efficiency of submitting regulatory submissions and love the dashboard features that gives me the status of my files.*
- ✓ *My experience was entirely positive. The portal is a game-changer and is much appreciated. I would ordinarily offer suggestions for improvement, but the process went smoothly, flawlessly, and successfully.*
- ✓ *I will start my email by saying FDA's CCP is terrific! Thank you for all of the work that has gone into making this such a simple way to upload and check on the status of FDA submissions!*
- ✓ ***This is the best change FDA has made in the 37 years that I have been working in the industry.***

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Digital Transformation: Current Plan

- Enhance the CDRH Portal to provide greater capabilities to our stakeholders:
  - Allow for **visibility** into the progress of De Novo, IDE, and PMA reviews
  - Enable enhanced **collaboration** with CDRH within the Portal
  - Provide **education** for patients to learn how CDRH evaluates clinical trials, regulatory applications, and supporting evidence
- Continue modernization of data and legacy systems to allow CDRH staff to:
  - Spend more **time** on regulatory review and less time on administrative or redundant activities
  - Gain better **insight** into device performance through enhanced connections across CDRH data

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NEXT STEPS

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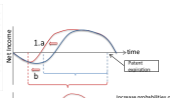
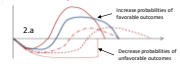
Goal: Improve Ability to Measure ROI

- Key components of MDUFA may be amenable to more rigorous quantitative measures of ROI, using related concepts of internal rate of return (IRR) and net present value (NPV)
- Measuring financial ROI of the pre-market review program can be distilled down to three categories:

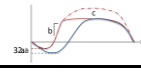
1. Value of Reduction in Development and Review Time
   a) Faster to the market
   b) Longer time on the market



2. Value from Increasing Predictability of FDA Marketing Authorization
   a) Reduced uncertainty / volatility of expected returns ⇒ higher expected NPV
   b) Reduced technical risk ⇒ reduced cost of capital



3. Value of Strategic Planning
   a) Earlier identification, characterization, and management of technical and financial risks
   b) Faster market growth due to faster reimbursement coding, coverage, and payment
   c) Higher revenues due to broader market penetration from expanded indications



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Main ROI Takeaways

- We adopted a broad ROI framework to capture a wide range of benefits, returns, and impacts on a variety of stakeholders.
  - We are strengthening our foundation; we are "**back to basics**" and we met or are on track to meet MDUFA V Commitments for FY23.
  - We are accelerating the **innovation** pipeline, especially by providing increased support at the Pre-Submission stage and improving clarity through guidances.
  - We are transforming the customer **digital** experience, continuing to build a robust, agile IT infrastructure to support a more efficient device review process, increase our readiness for future needs, and improve communication with all stakeholders.
- We will continue working on making ROI more quantitative and collaborating with our partners in the medical device ecosystem to maximize the impact of the investments and improve business and public health outcomes.

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Expected MDUFA V Impacts on FDA Staff, Industry, and Patients

FDA Staff

- Enhanced hiring and retention of world-class technical and scientific staff
- Increased capacity to handle continually increasing workload
- Improved operational efficiency

Industry

- Improved review experience (more efficient, predictable, and consistent)
- Improved clarity of FDA expectations and decision making
- More frequent and transparent interactions with Industry

Patients

- Faster, and more widespread access to innovative devices that are safe and effective
- Increased patient engagement and incorporation of diverse perspectives
- Increased transparency and accountability mechanisms

It is an agreement that will ultimately have positive impacts on all our stakeholders

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List of Abbreviations

3PR	Third Party Review	**IDE**	Investigational Device Exemption
510(k)	Medical Device Premarket Notification	**IRR**	Internal Rate of Return
AI/ML	Artificial Intelligence/Machine Learning	**MDUFA**	Medical Device User Fee Amendments
ASCA	Accreditation Scheme for Conformity Assessment	**NPV**	Net Present Value
CCP	Customer Collaboration Portal	**PCCP**	Predetermined Change Control Plan
CDRH	Center for Devices and Radiological Health	**PDP**	Product Development Protocol
CLIA	Clinical Laboratory Improvement Amendments	**PMA**	Premarket Approval
COA	Clinical Outcome Assessment	**PPI**	Patient Preference Information
CY	Calendar Year	**PS FPP**	Patient Science Focal Point Program
eSTAR	Electronic Submission Template and Resource	**PSE**	Patient Science and Engagement
EUA	Emergency Use Authorization	**ROI**	Return On Investment
FDA	Food and Drug Administration	**ROs**	Review Organizations
FTE	Full-Time Equivalent	**RWE**	Real-World Evidence
FY	Fiscal Year	**TAP**	Total Product Life Cycle Advisory Program
HDE	Humanitarian Device Exemption	**TBD**	To Be Determined

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FDA U.S. FOOD & DRUG ADMINISTRATION

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