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

March 1, 2023, 2:00 – 3:00 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through December 31, 2022

- Report on decision goals for 1st Quarter FY 2023
- Status of Paused IVD Submissions

Guidance Development

Registration and Listing

Qualitative Update on Finances – 1st Quarter FY 2023

- User fee receipts through the 1st Quarter FY 2023
- Funding for Non-NEST Organizations (if applicable)

Annual Hiring Goals Update

Quality Management Update

- FY 2023 Performance Goal Deficiency Audit Plan

TAP pilot progress

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Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 31 December 2022

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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.

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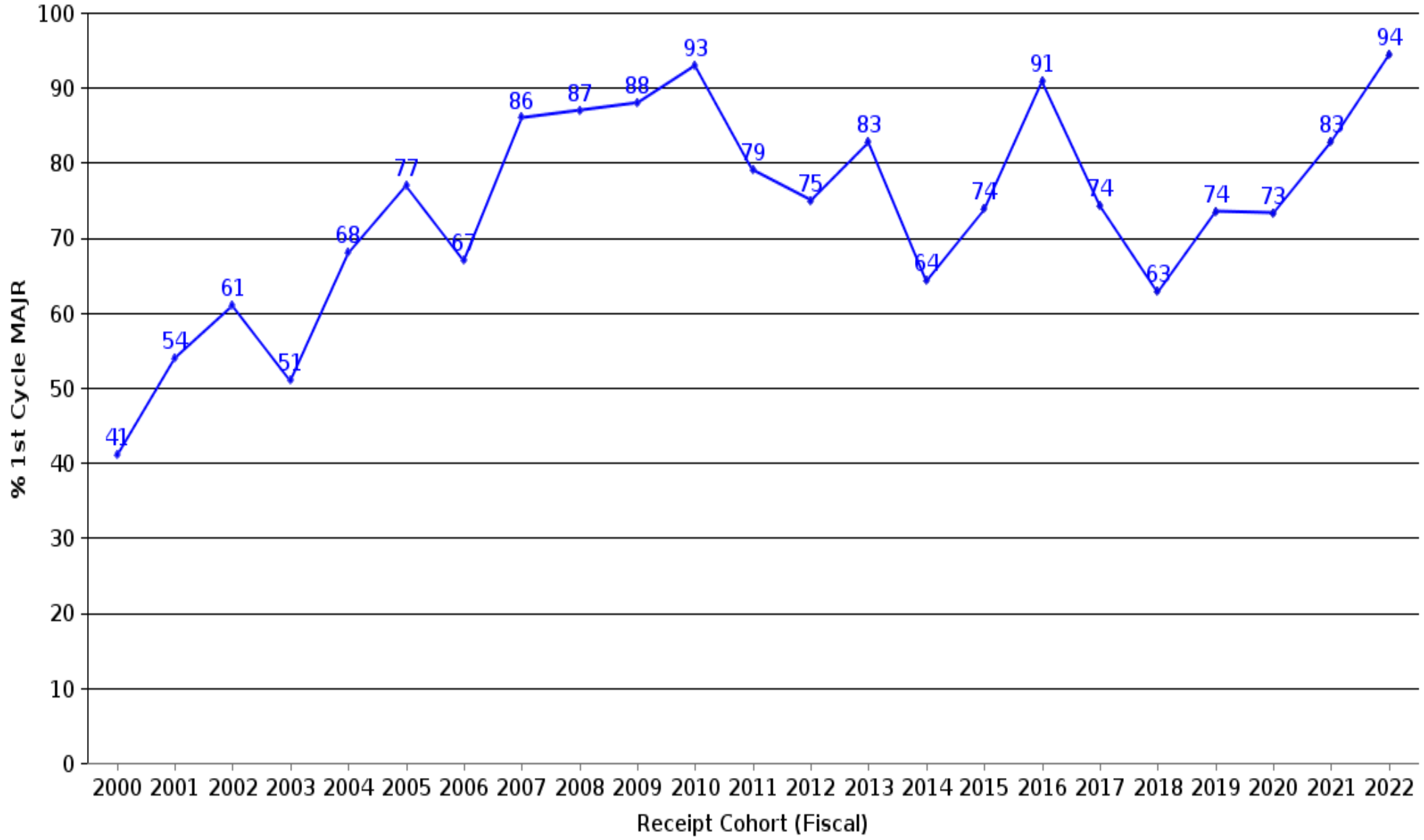
PMAs

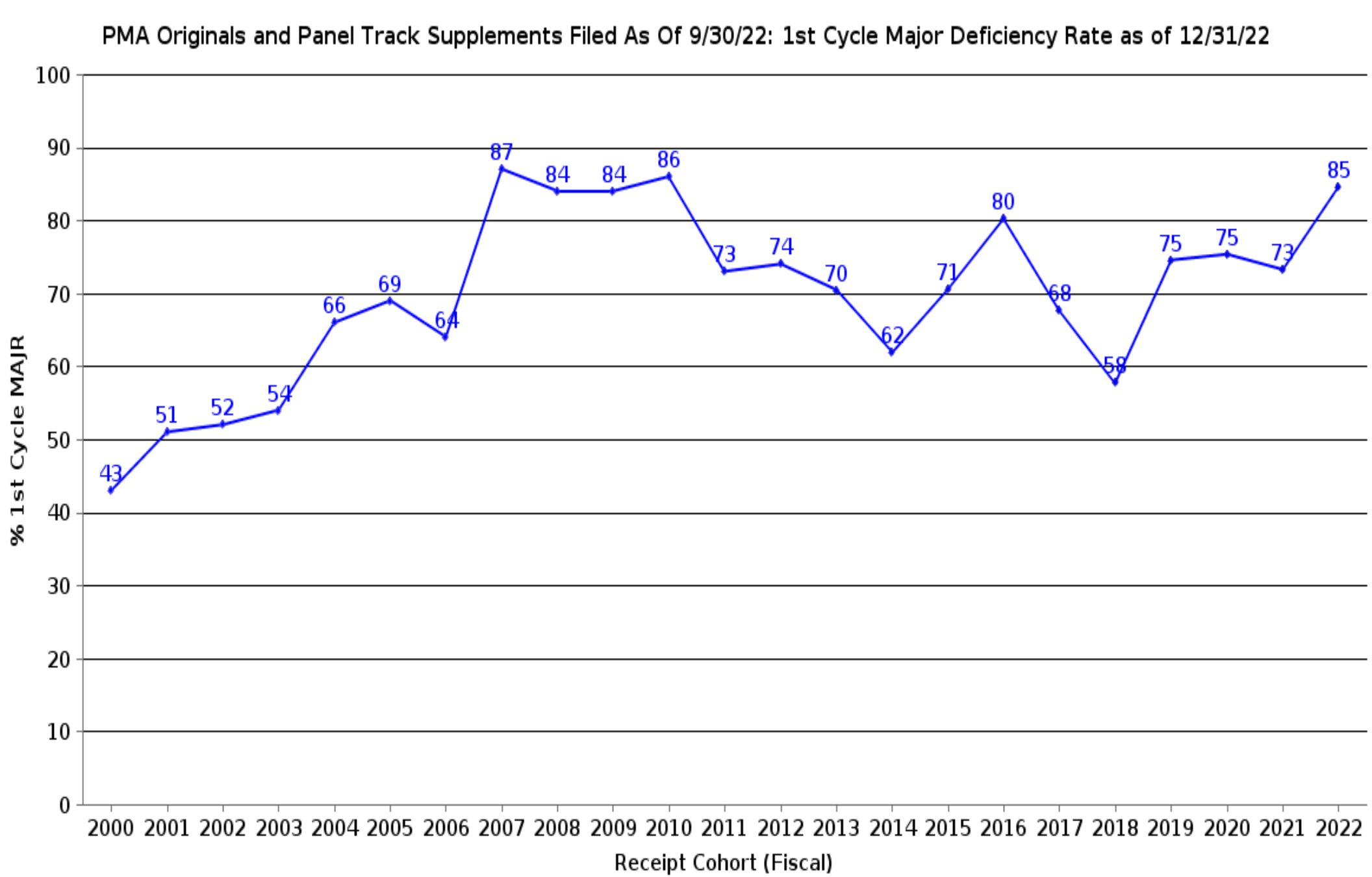
Q1FY2023

PMA Originals Filed As Of 9/30/22: 1st Cycle Major Deficiency Rate as of 12/31/22



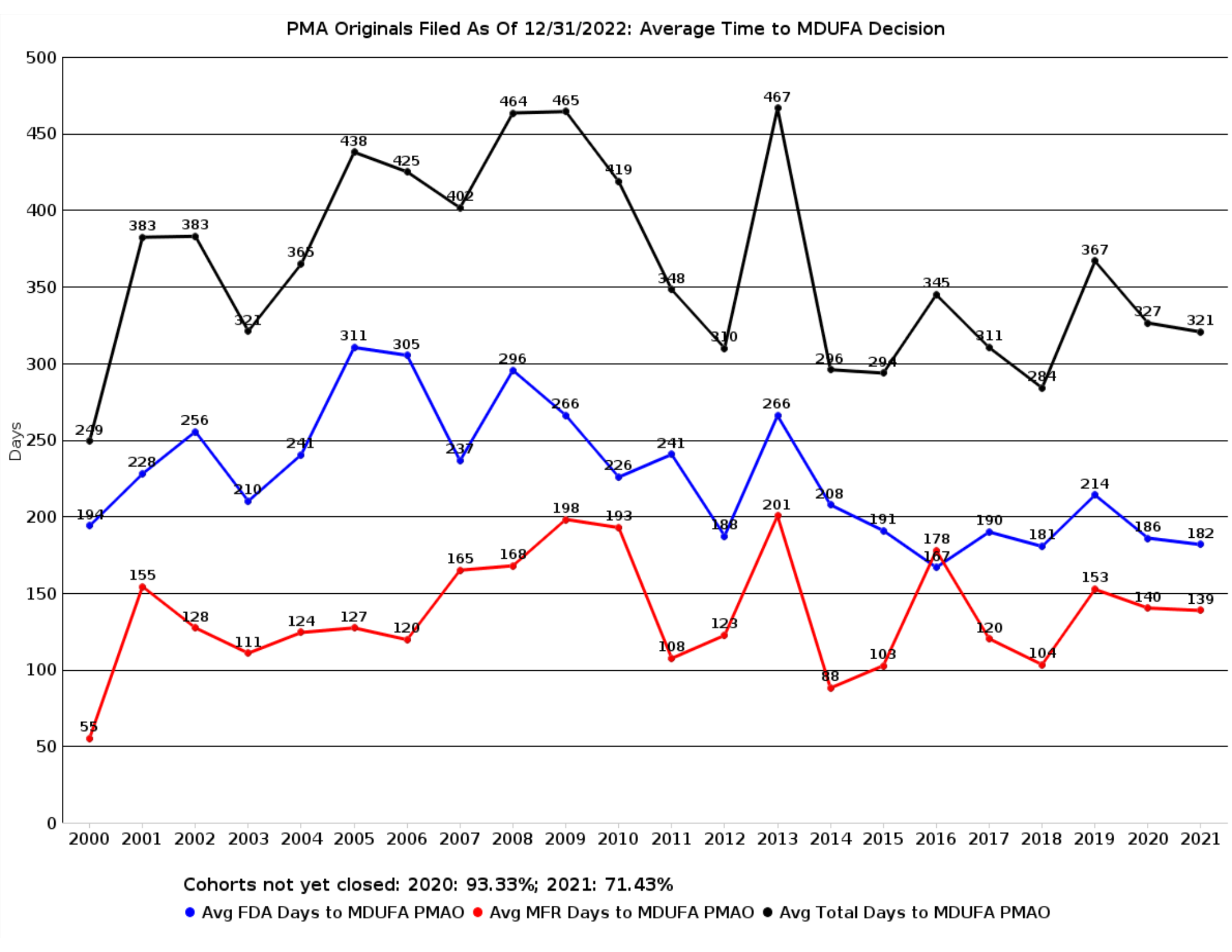
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 9/30/22.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO

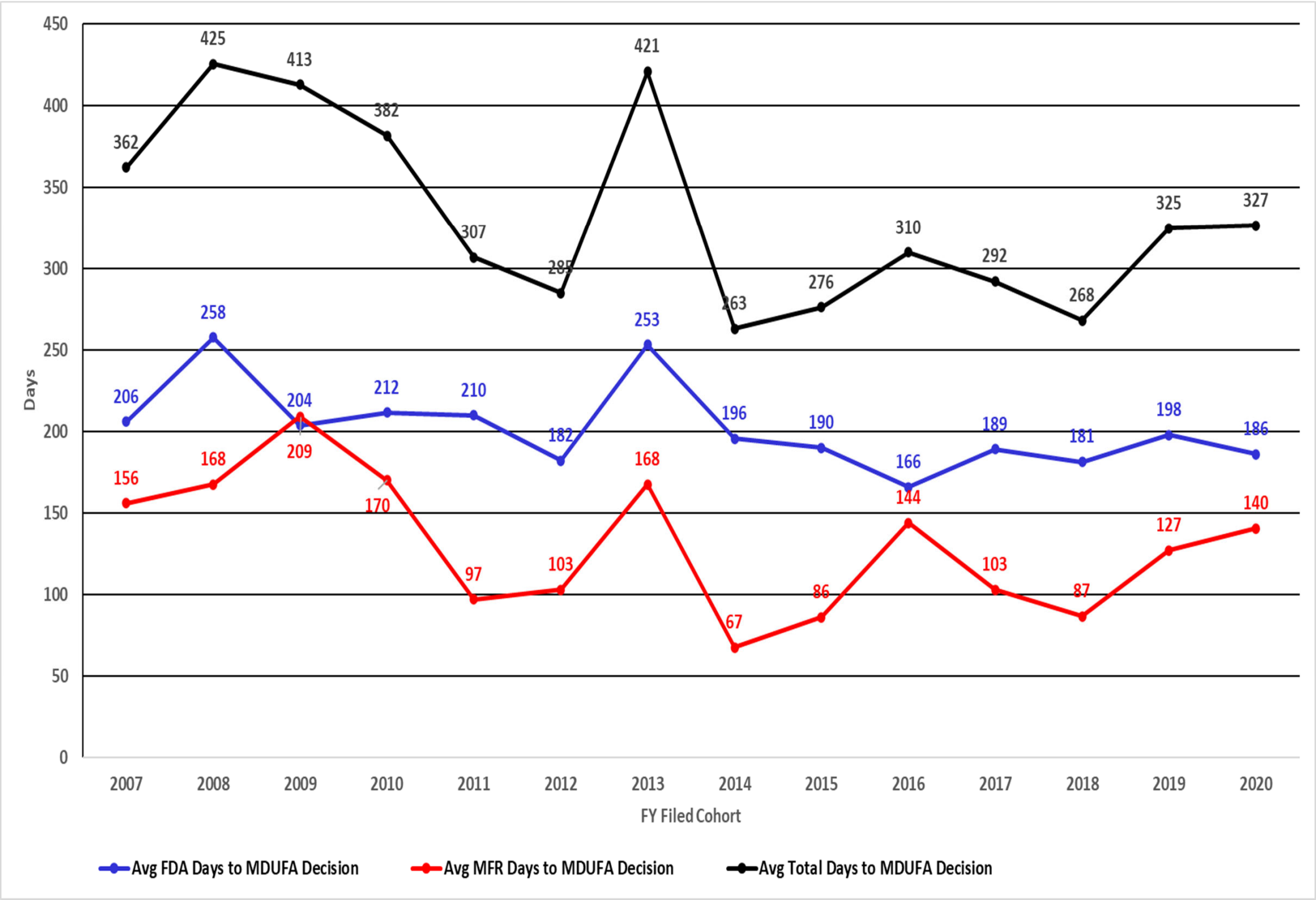


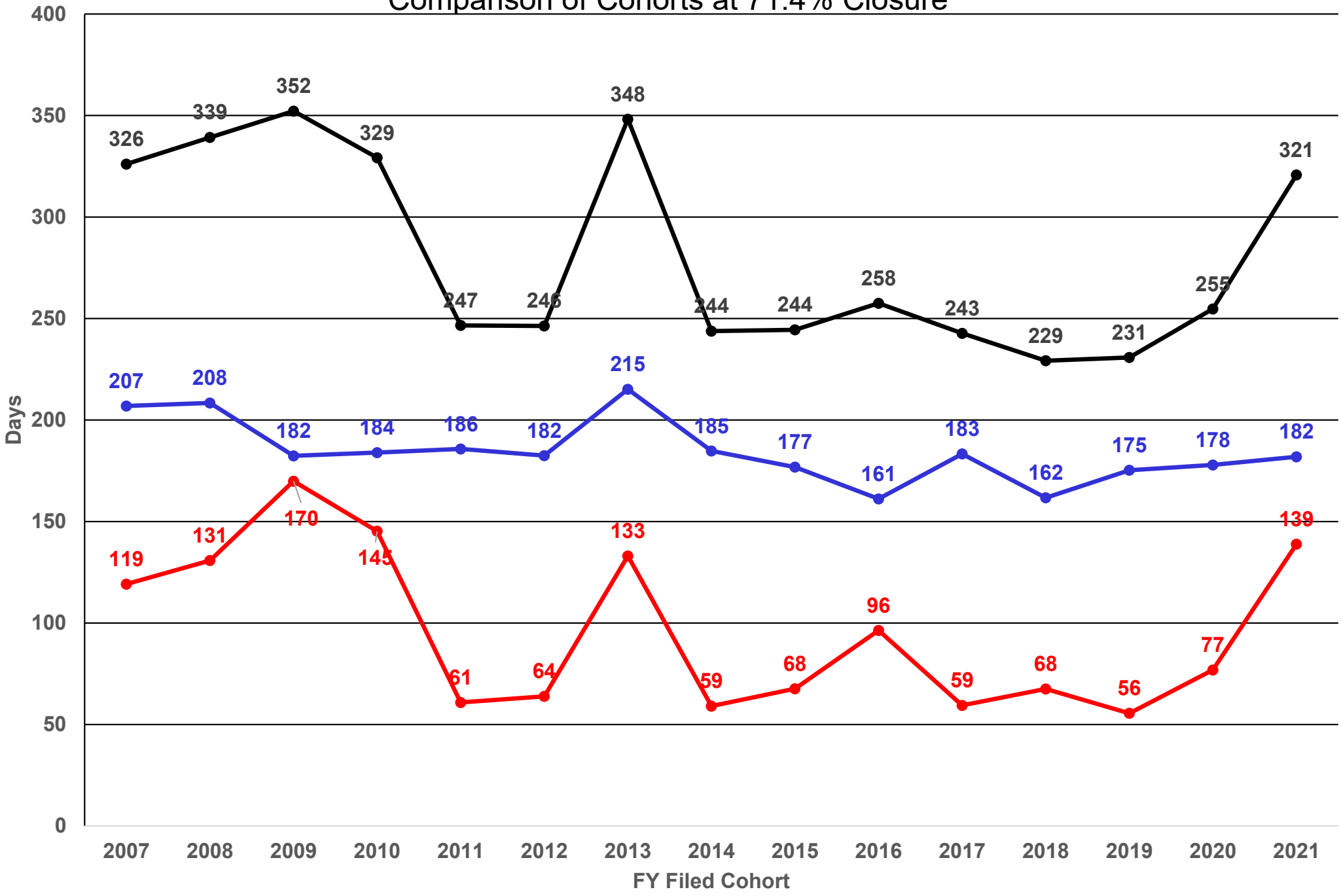
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 9/30/22. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

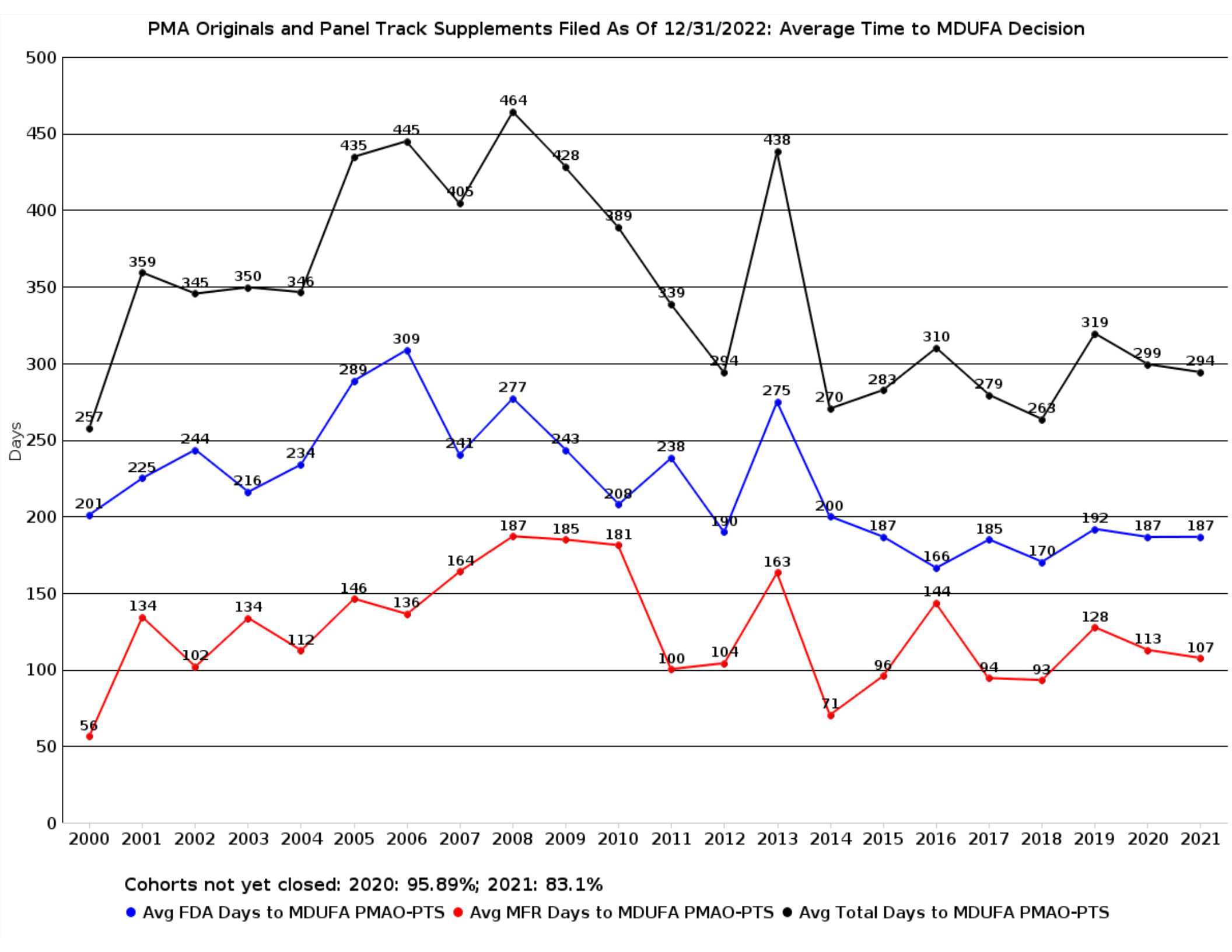
♦ % 1st Cycle MAJR PMAO/PTS


PMA Originals Filed As Of 12/31/2022: 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
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 327 321
194 228 256 210 241 311 305 237 296 266 226 241 188 266 208 191 178 190 181 214 186 182
55 155 128 111 124 127 120 165 168 198 193 108 123 201 88 103 167 120 104 153 140 139
Cohorts not yet closed: 2020: 93.33%; 2021: 71.43%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO

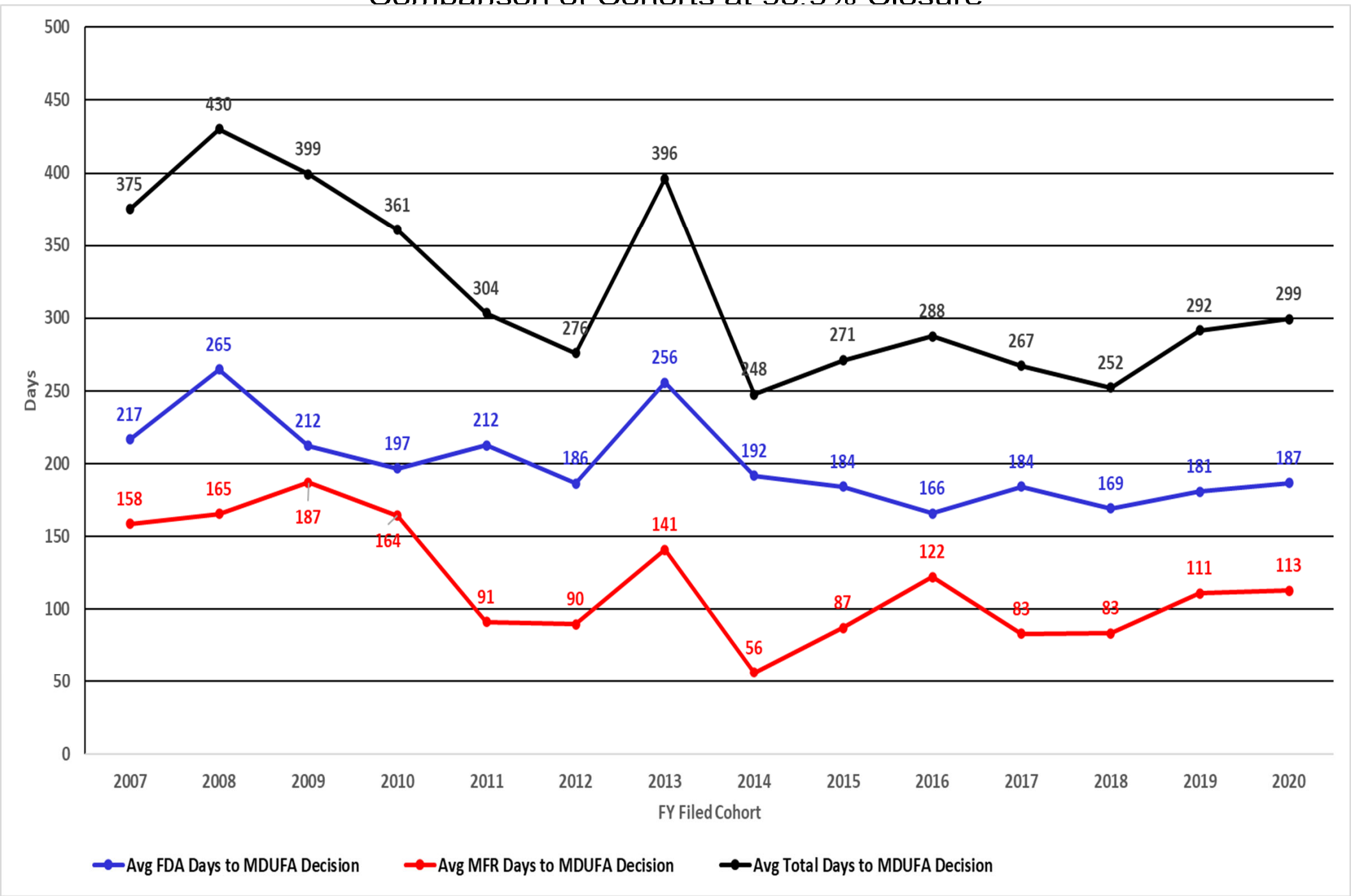
PMA Originals Filed as of 12/31/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 93.3% Closure



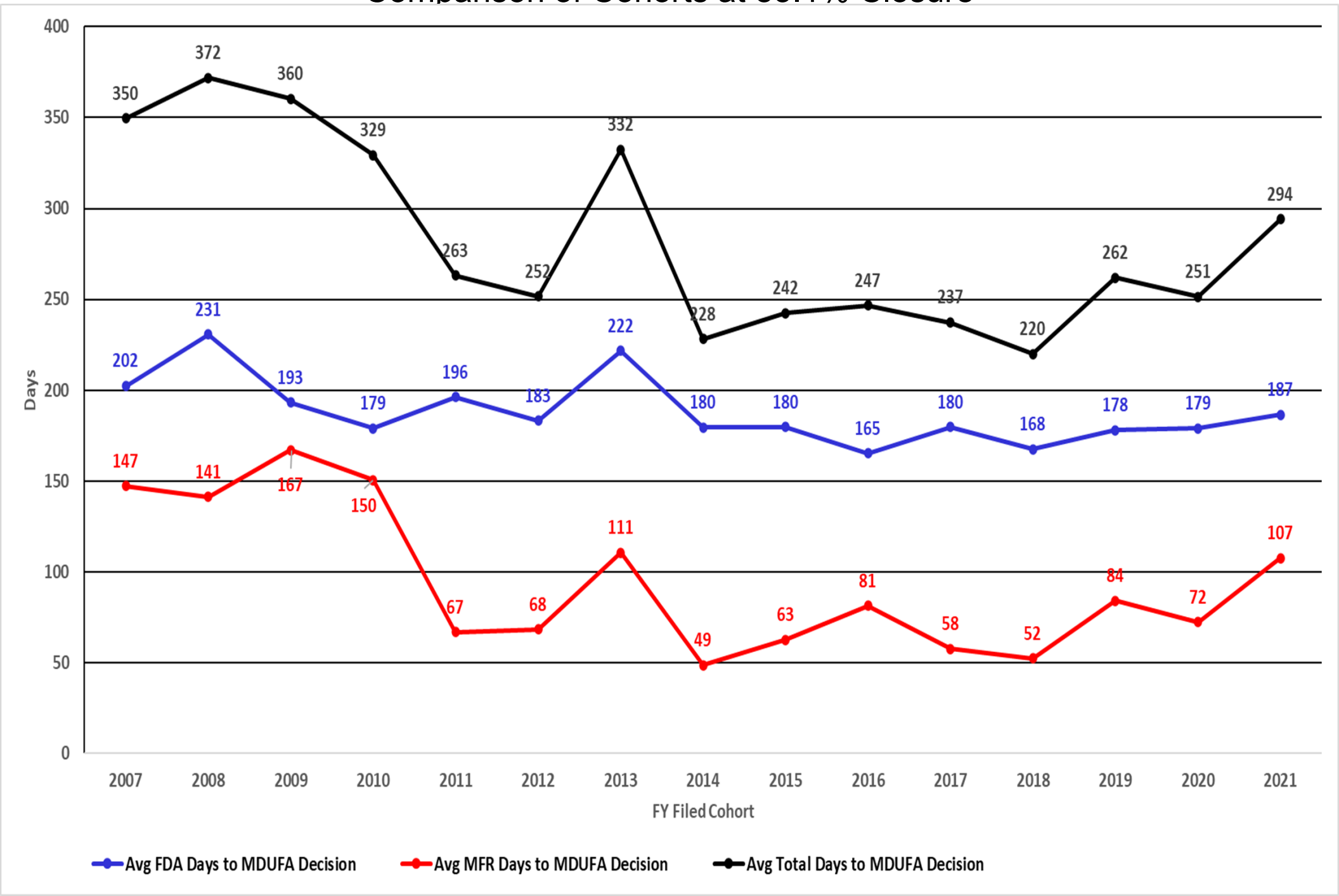

PMA Originals Filed as of 12/31/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 71.4% Closure
Days
400
350
300
250
200
150
100
50
0
326
339
352
329
247
246
348
244
244
258
243
229
231
255
321
207
208
182
184
186
182
215
185
177
161
183
162
175
178
182
119
131
170
145
61
64
133
59
68
96
59
68
56
77
139
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY Filed Cohort
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

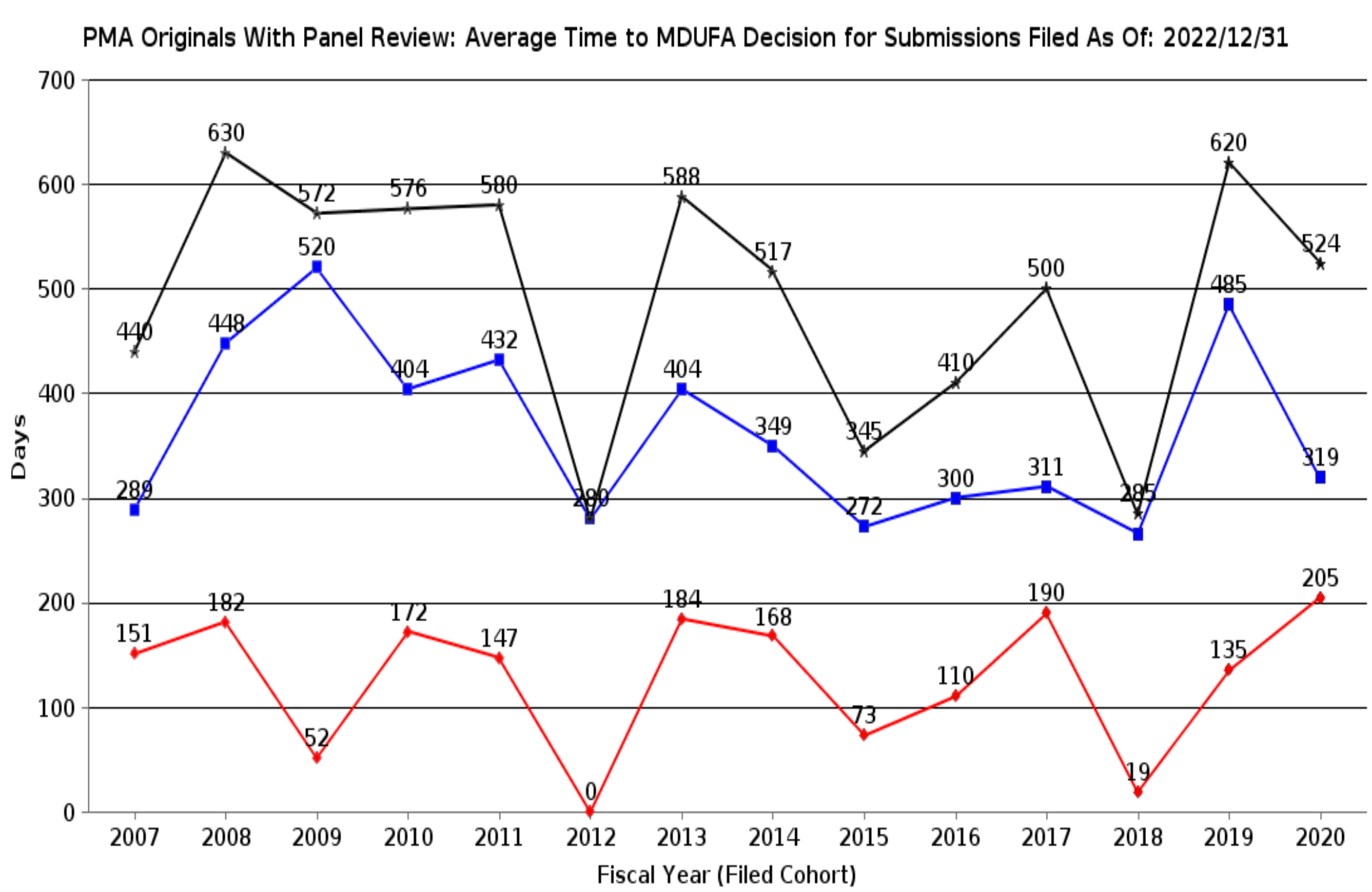

PMA Originals and Panel Track Supplements Filed As Of 12/31/2022: Average Time to MDUFA Decision
Days
0
50
100
150
200
250
300
350
400
450
500
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 268 319 299 294
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 187 187
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 93 128 113 107
Cohorts not yet closed: 2020: 95.89%; 2021: 83.1%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

PMA Originals and Panel Track Supplements Filed as of 12/31/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 95.9% Closure



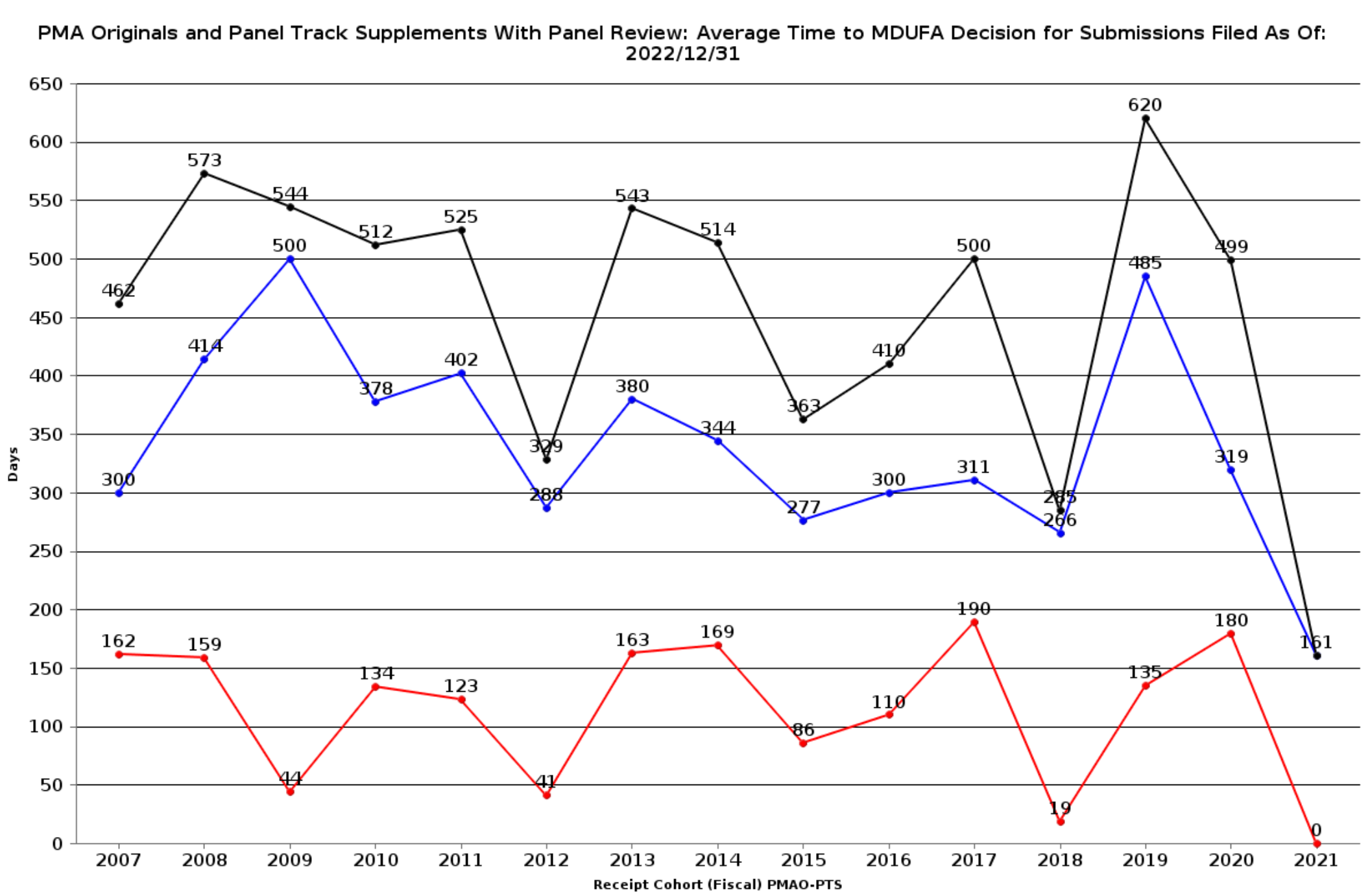
PMA Originals and Panel Track Supplements Filed as of 12/31/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 83.1% Closure



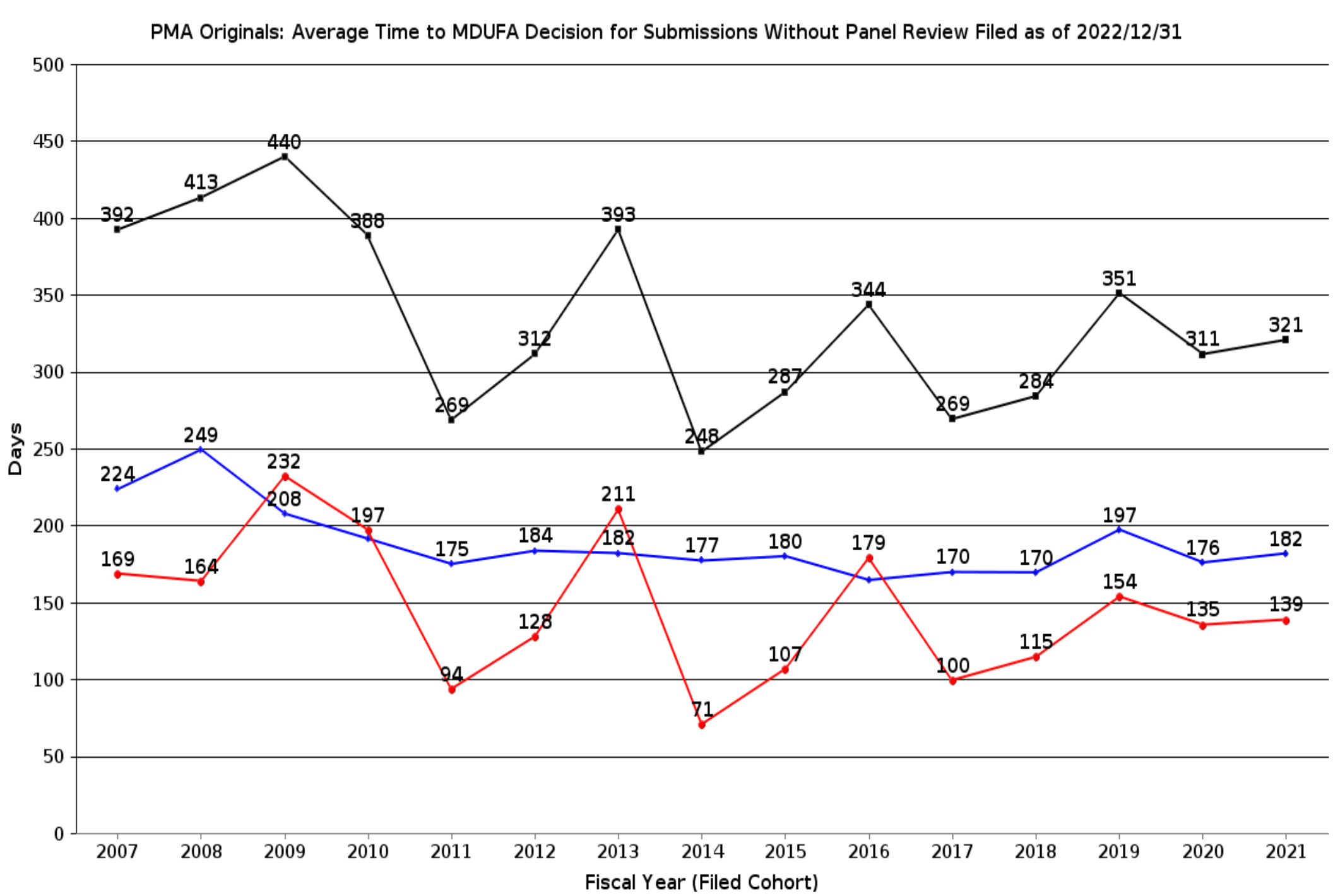


Numbers Filed/Closed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3

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

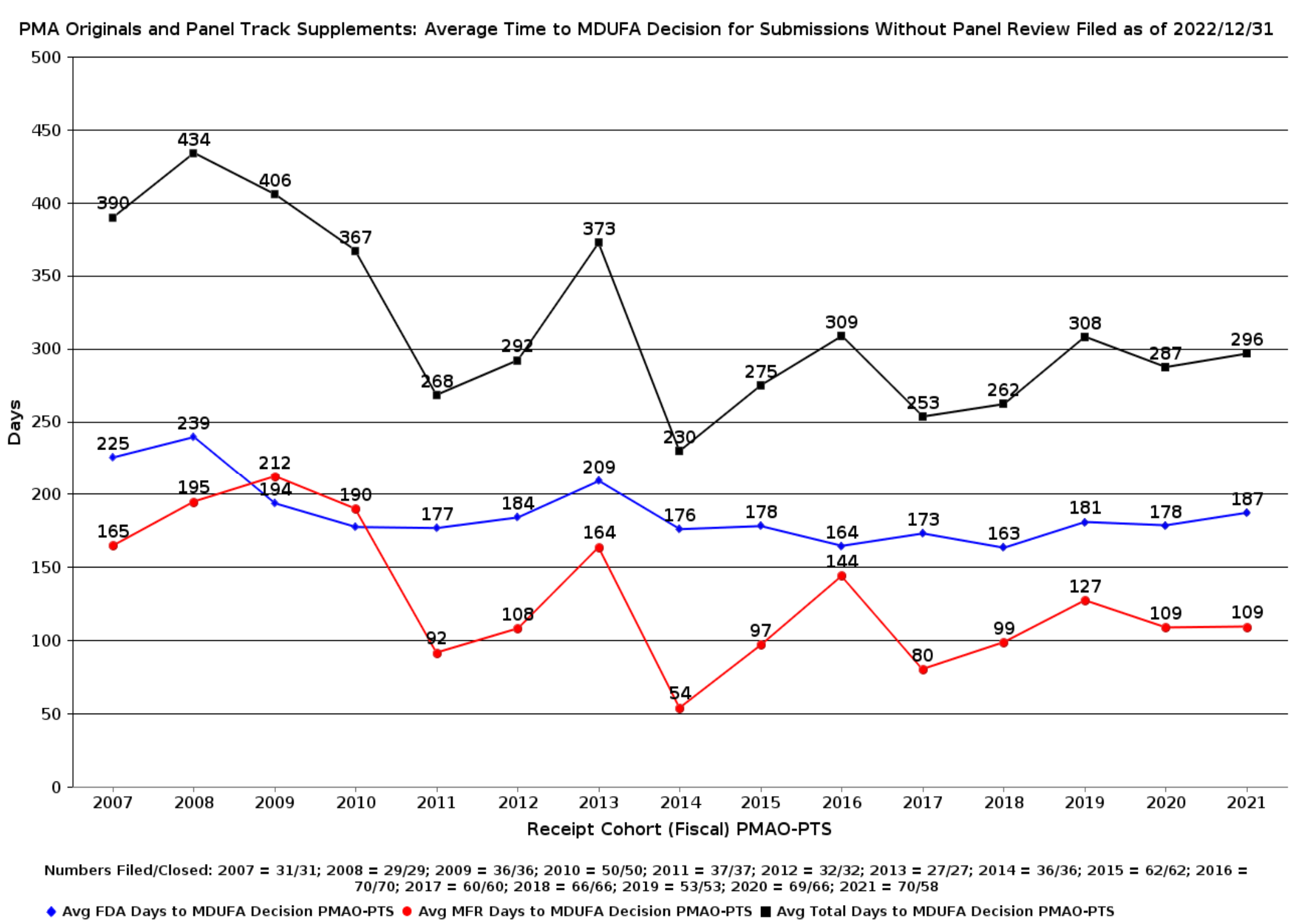


Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.



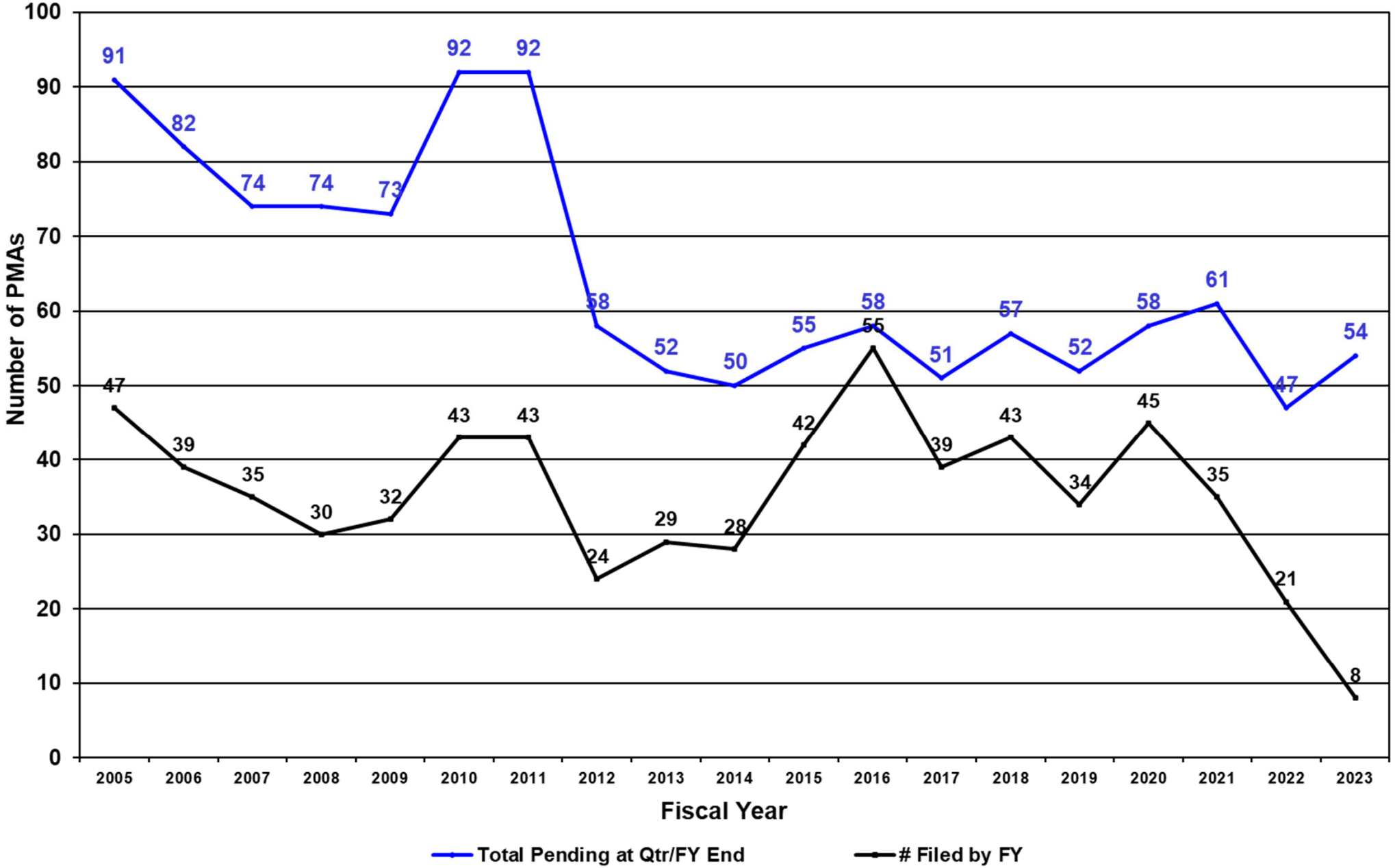
Numbers Filed/Closed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/39; 2021 = 42/25

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



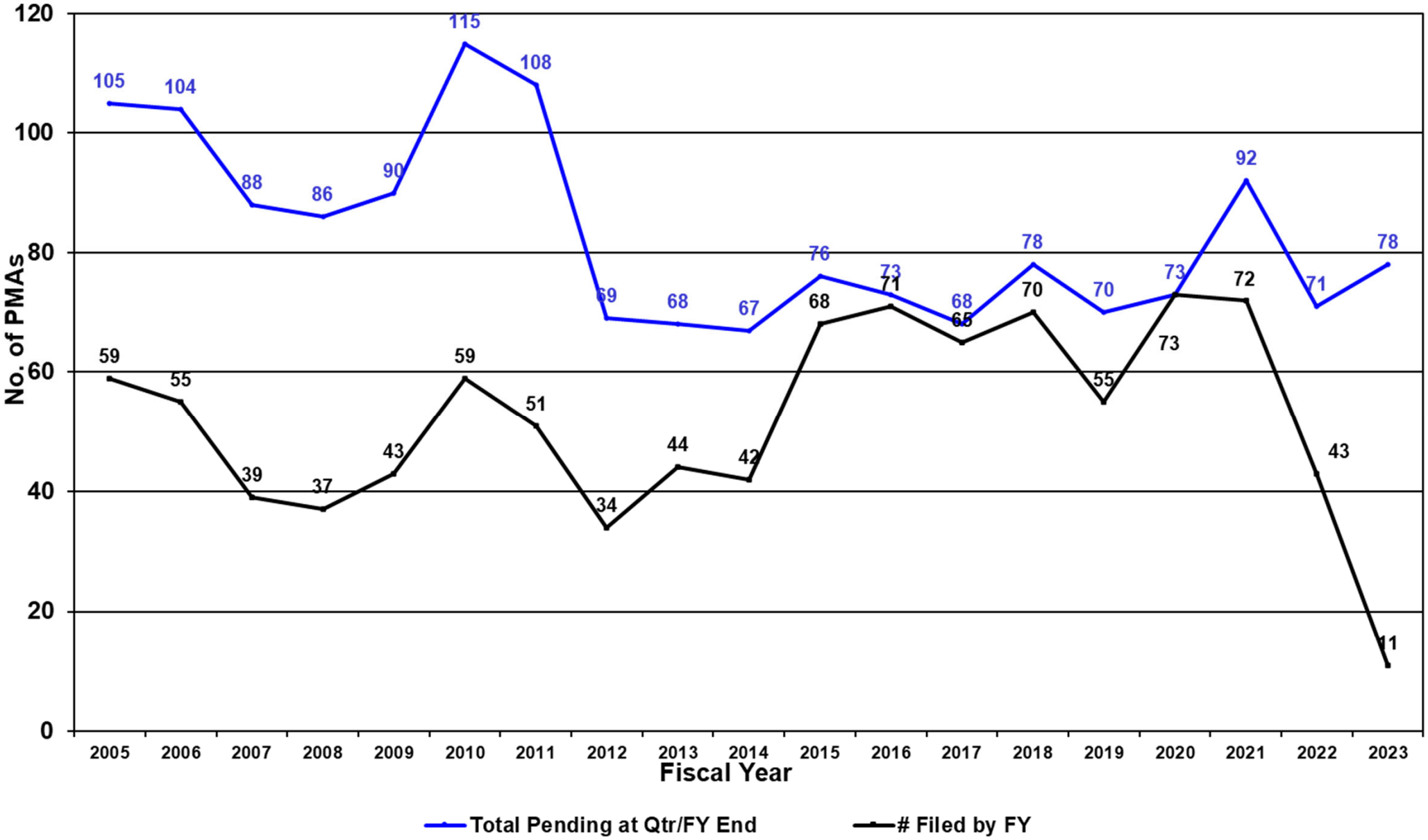
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

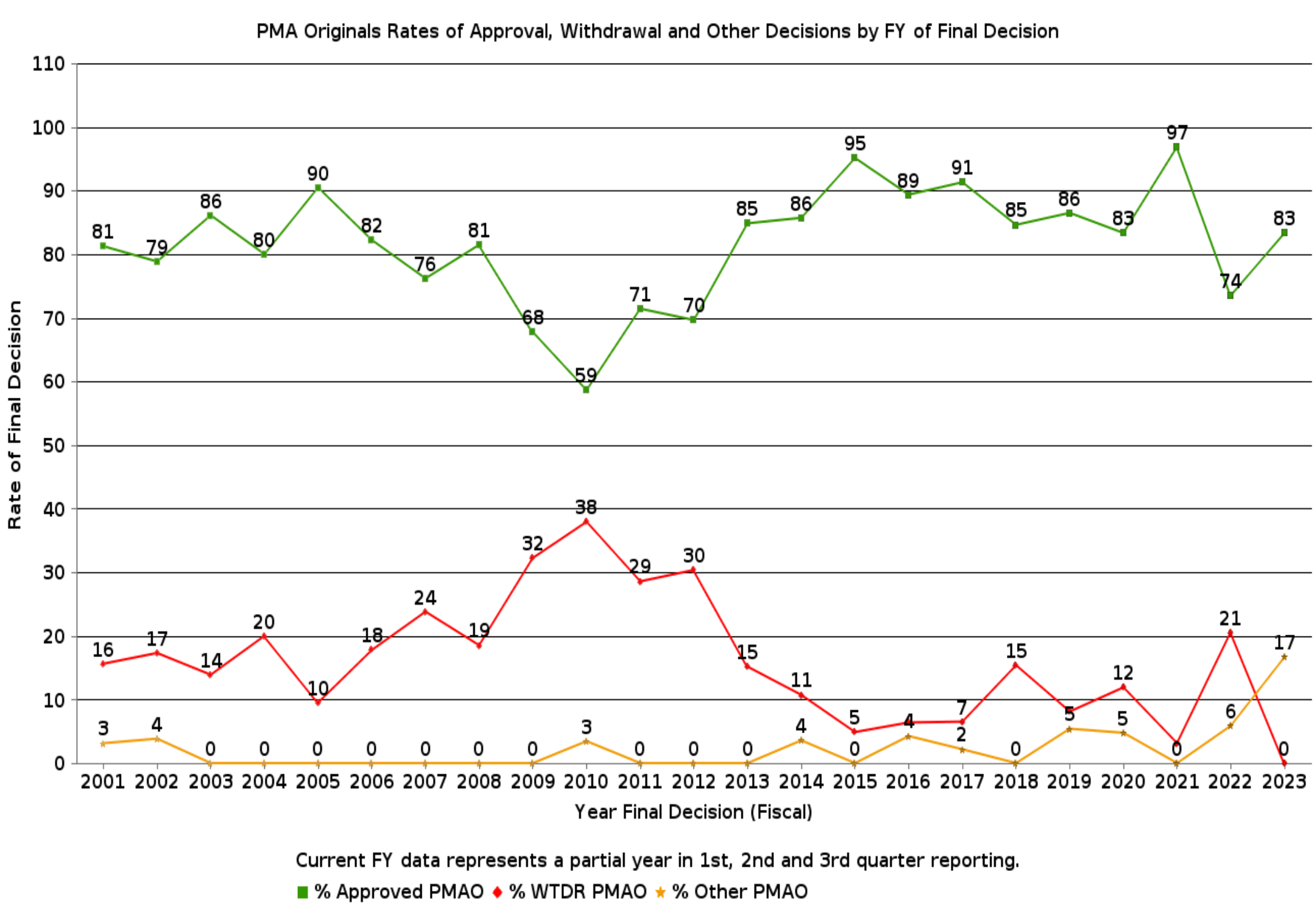


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

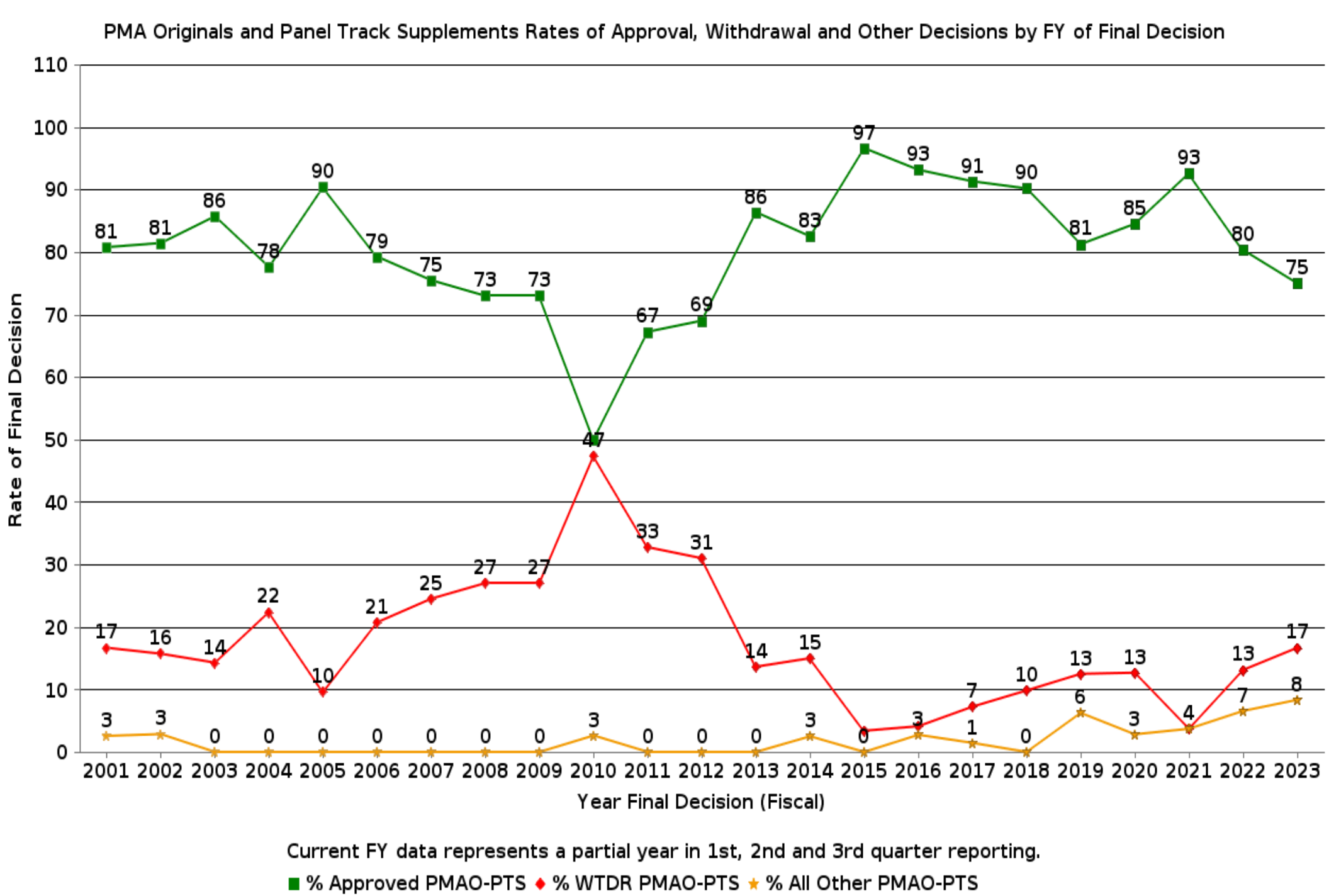
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



***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

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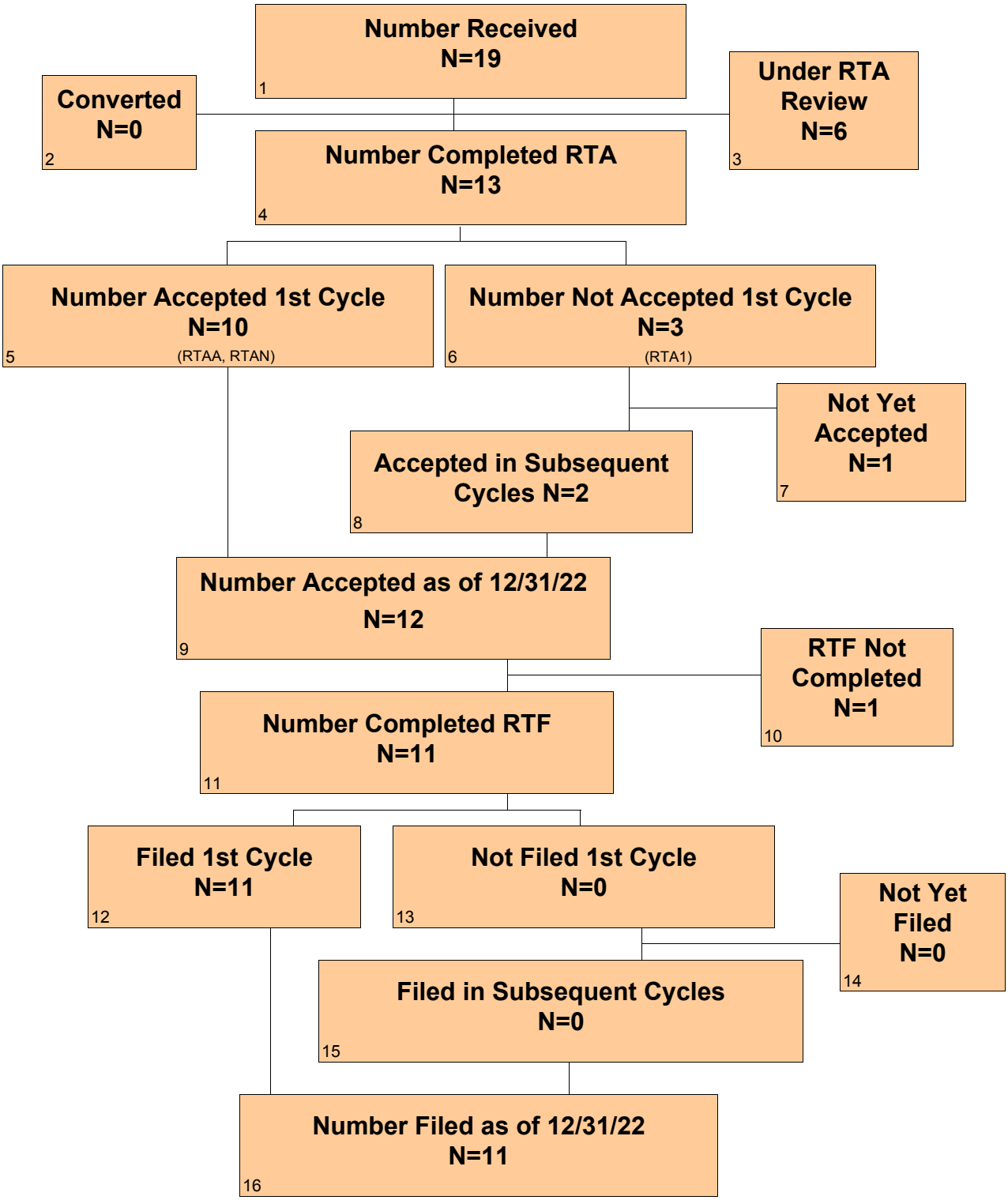
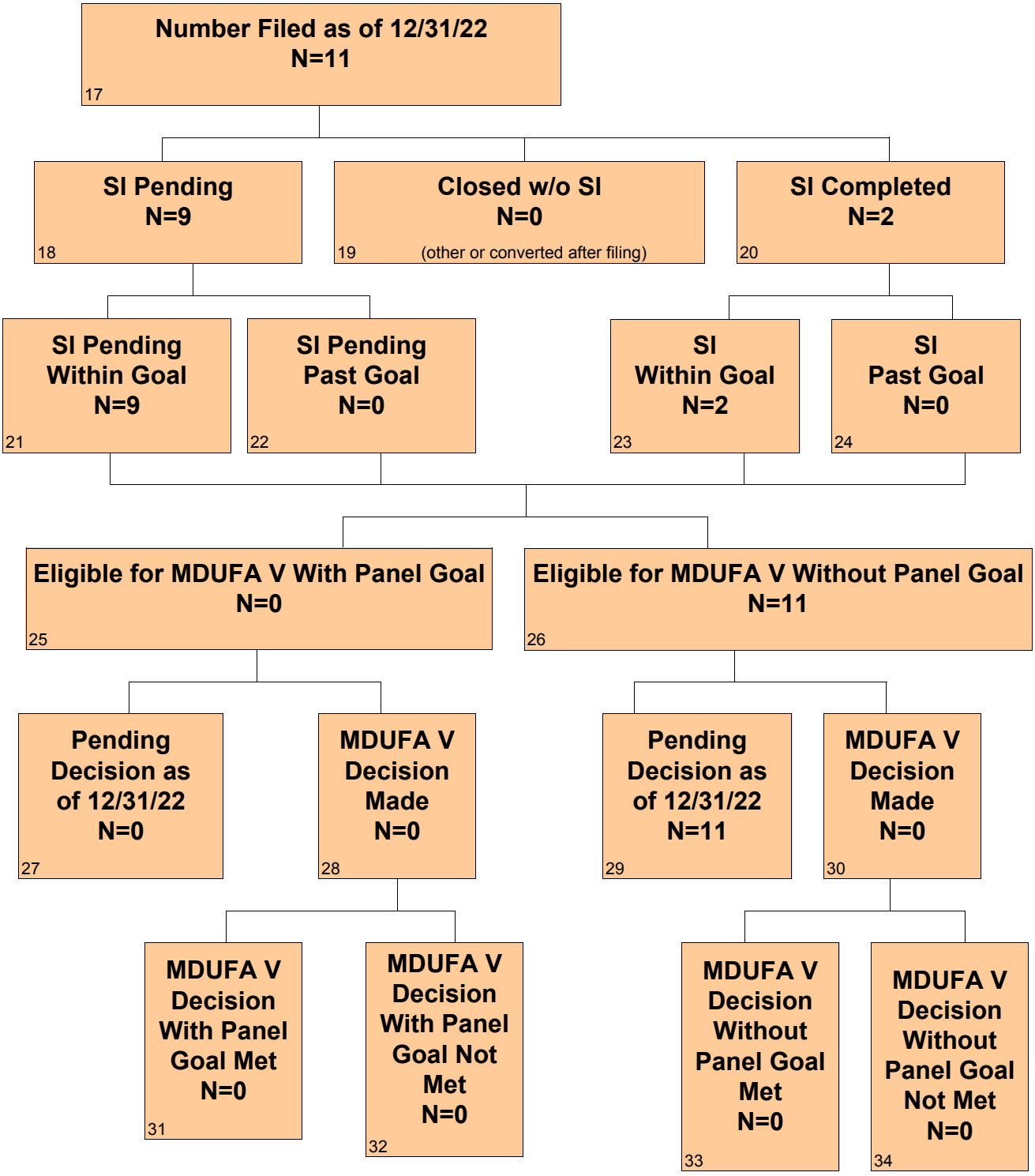
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/22



CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/22 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	19				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	10				
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)	6				
Number Not Accepted for Filing Review on First Cycle	3				
Rate of Submissions Not Accepted for Filing Review on First Cycle	23.08%				

***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	19				
Number Accepted	10				
Completed RTF	11				
Number Not Filed	0				
Rate of Submissions Not Filed	0.00%				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	11				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	9				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	2				
Average Number of FDA Days to Substantive Interaction	85.00				
20th Percentile FDA Days to Substantive Interaction	84				
40th Percentile FDA Days to Substantive Interaction	85				
60th Percentile FDA Days to Substantive Interaction	85				
80th Percentile FDA Days to Substantive Interaction	86				
Maximum FDA Days to Substantive Interaction	86				

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

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
Number of PMAs Filed	11				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	11				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

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
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 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	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 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	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 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	11				
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 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	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 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

Table 1.13 CDRH - LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

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
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				

***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	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
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				

***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	3				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	1				
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	2				
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%				

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

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

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

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2				
SI Goal Met	0				
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	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 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	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
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 1.6 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	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
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	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 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	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 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	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 1.10 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	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
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	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
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	8				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	5				
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	16.67%				

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

Table 1.2 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	8				
Number Accepted	5				
Completed RTF	6				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	6				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	4				
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	2				
Average Number of FDA Days to Substantive Interaction	85.00				
20th Percentile FDA Days to Substantive Interaction	84				
40th Percentile FDA Days to Substantive Interaction	85				
60th Percentile FDA Days to Substantive Interaction	85				
80th Percentile FDA Days to Substantive Interaction	86				
Maximum FDA Days to Substantive Interaction	86				

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	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
Number of PMAs Filed	6				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	6				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

Performance Metric	FY 2023	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
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 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	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 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	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 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	6				
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 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	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 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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

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
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	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
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	1				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	1				
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	1				
Number Accepted	1				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 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	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
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 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	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
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 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	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 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	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 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	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 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	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
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	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
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	2				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	2				
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 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	2				
Number Accepted	2				
Completed RTF	2				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2				
SI Goal Met	0				
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	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 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	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
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 1.6 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	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
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	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 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	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 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	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 1.10 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	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
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	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
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	1				
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)	1				
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 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	1				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 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	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
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 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	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
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	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 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	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 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	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 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	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
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	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
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	1				
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)	1				
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 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	1				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

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

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
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	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 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	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 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	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 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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

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
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	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
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	3				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	1				
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	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	3				
Number Accepted	1				
Completed RTF	1				
Number Not Filed	0				
Rate of Submissions Not Filed	0.00%				

Table 1.3 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

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

Performance Metric	FY 2023	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
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	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 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	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 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	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 1.10 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

Table 1.13 OHT7 - Office of In Vitro Diagnostics
LDT PMA Original and Panel-Track Supplements MDUFA V Metric*

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
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				

***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	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
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 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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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	0.00				
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	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
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	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
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	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 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	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 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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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

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
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				

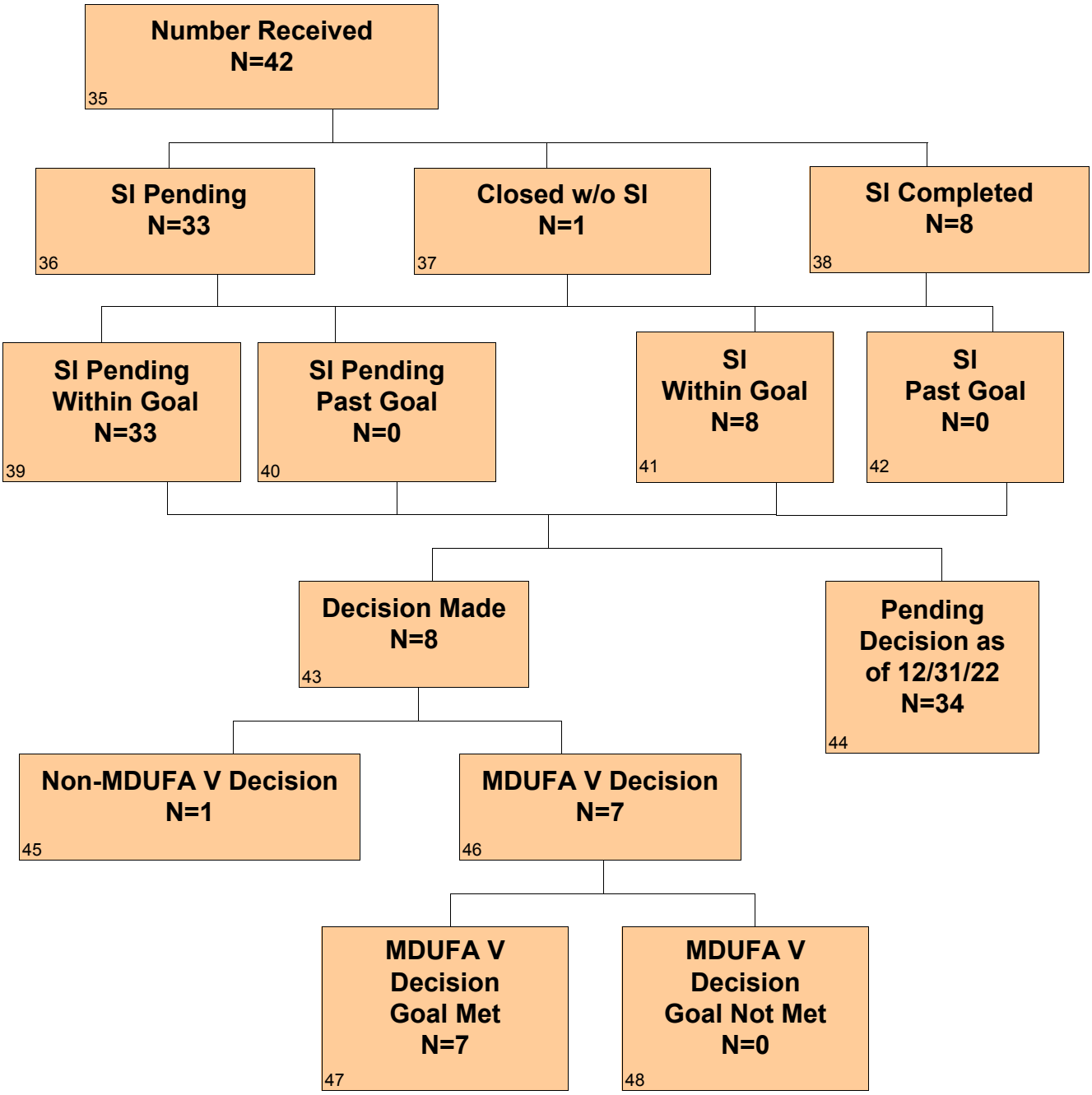
***Includes submission that went to panel**

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	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
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 12/31/22



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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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	42				
SI Goal Met	8				
SI Goal Not Met	0				
SI Pending Within Goal	33				
SI Pending Past Goal	0				
Closed Without SI	1				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	42				
Non-MDUFA Decision	1				
MDUFA Decision	7				
MDUFA Decision Goal Met	7				
Supplements Pending MDUFA Decision	34				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	42				
Number with MDUFA Decision	7				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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

Section 2 PMA 180-Day Supplements - Office Level Metric

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

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

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

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

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

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

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

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

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	19				
SI Goal Met	7				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	19				
Non-MDUFA Decision	0				
MDUFA Decision	7				
MDUFA Decision Goal Met	7				
Supplements Pending MDUFA Decision	12				
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	19				
Number with MDUFA Decision	7				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	5				
SI Goal Met	0				
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	N/A				

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

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

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	5				
Number with MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 2.2 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	0				
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	0				
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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6				
Number with MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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

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

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 2.2 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA V Decision

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

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

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

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

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

Table 2.1 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	6				
SI Pending Past Goal	0				
Closed Without SI	1				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	8				
Non-MDUFA Decision	1				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	7				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

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

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

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

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	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 2.2 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	0				
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	0				
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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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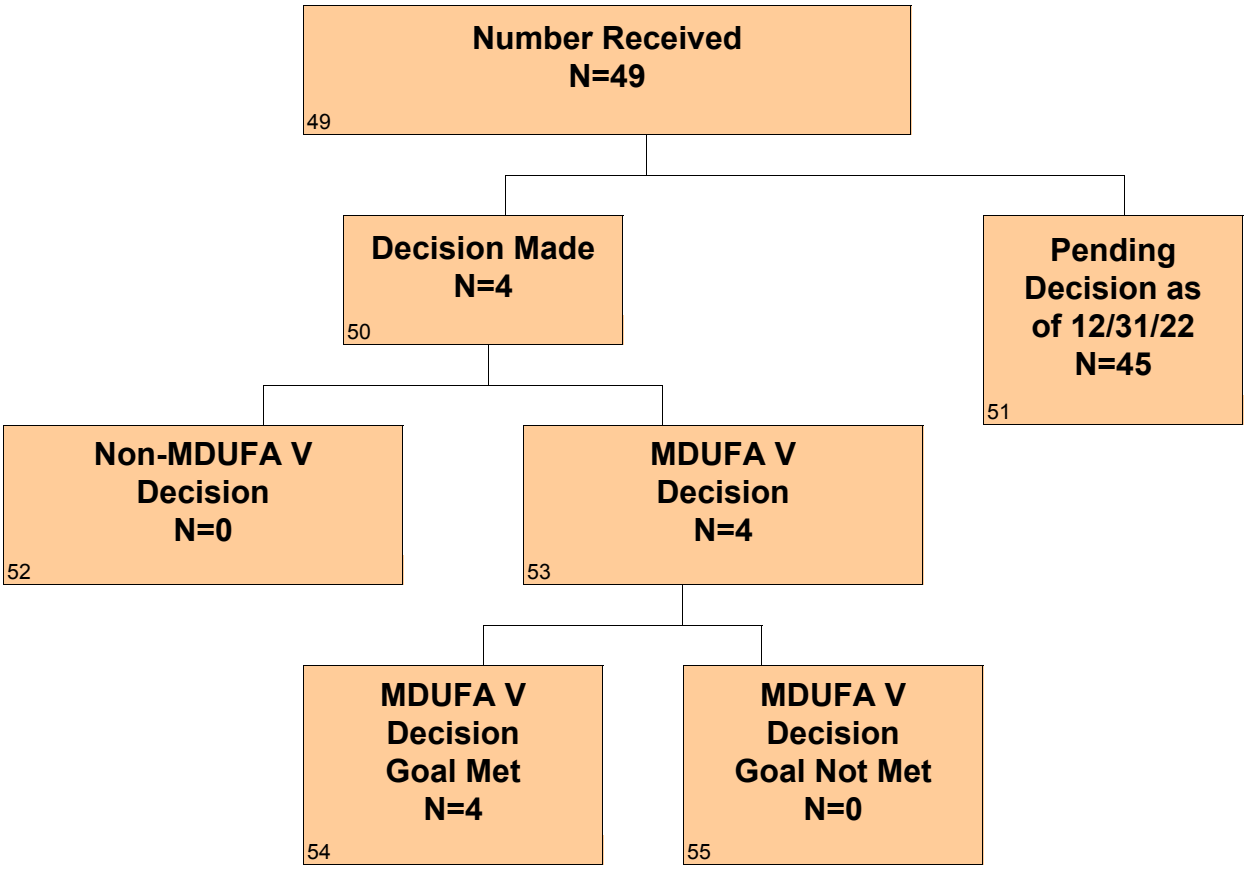
CDRH PMA Real Time Supplements - FY 2023 as of 12/31/22



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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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	49				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Goal Met	4				
Supplements Pending MDUFA Decision	45				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	49				
Number With MDUFA Decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	3				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	3				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

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	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	33				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Goal Met	4				
Supplements Pending MDUFA Decision	29				
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	33				
Number With MDUFA Decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

Table 3.3 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

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

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	3				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	3				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% 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 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	1				
Number With MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% 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 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	1				
Number With MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	0				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7				
Number With MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% 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 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	1				
Number With MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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

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

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Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2022 and December 31, 2022.

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Section 5 PMA Annual Metrics and Goals

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

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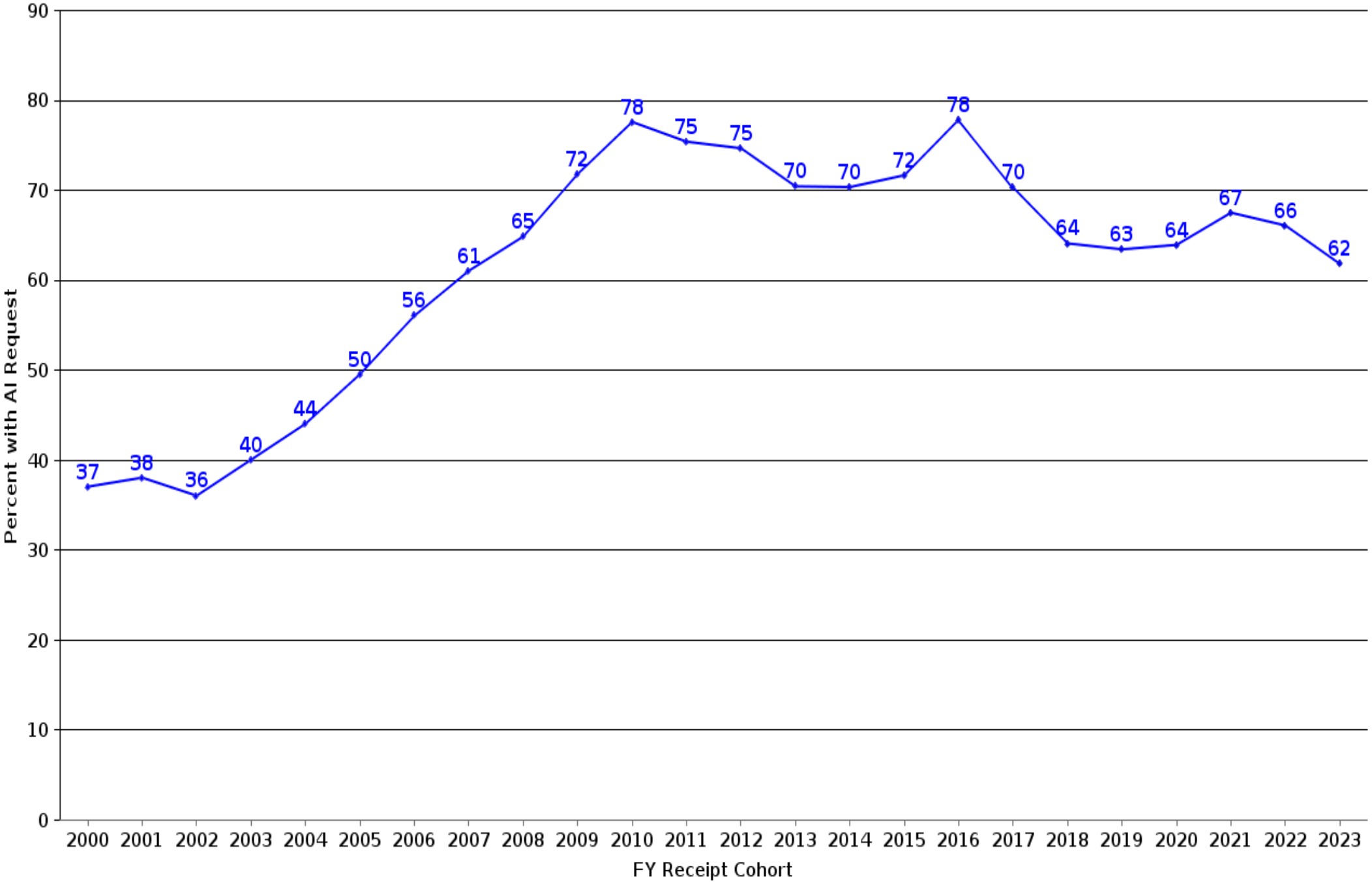
510(k)s

Q1FY2023

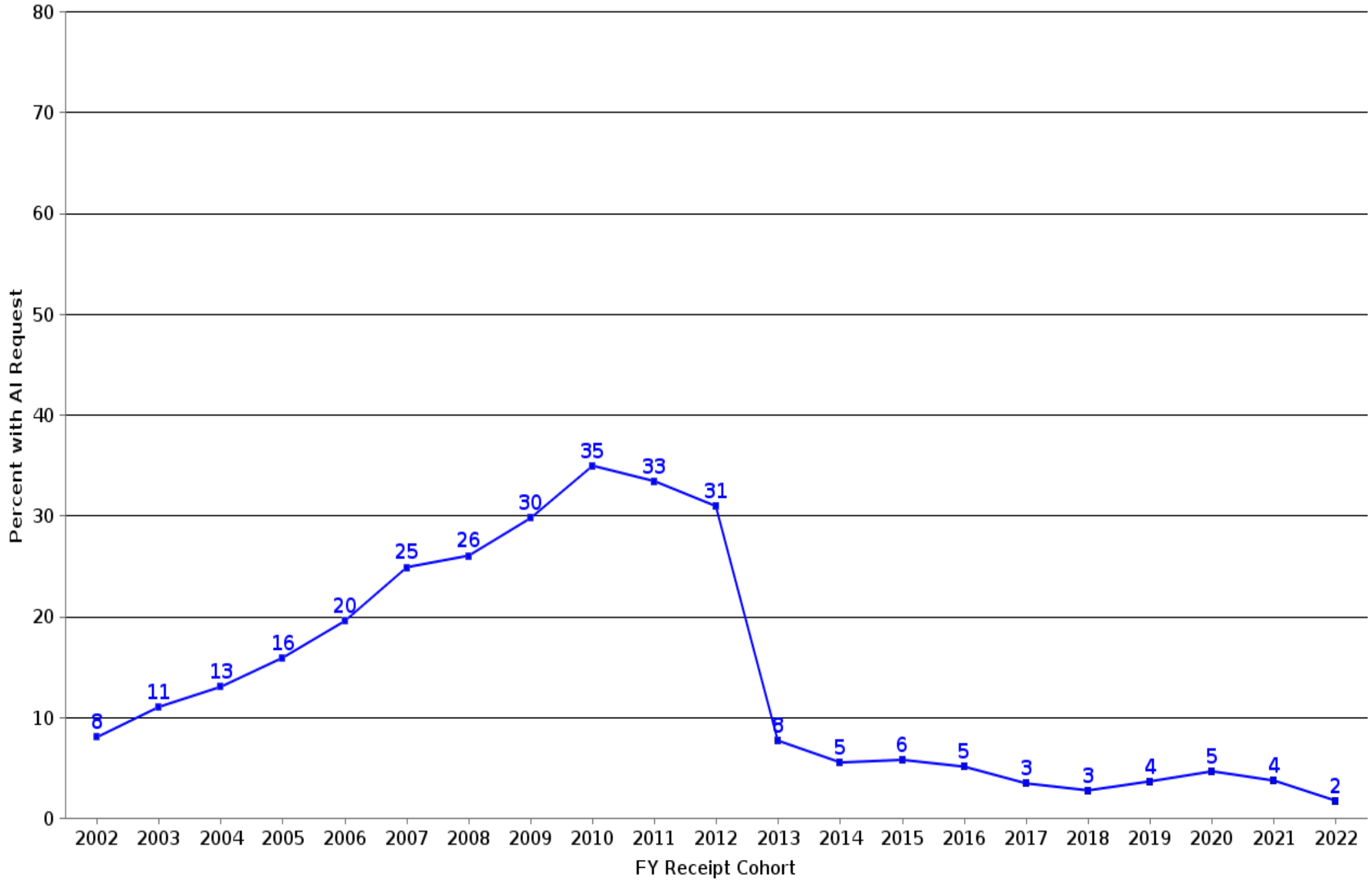
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 10/31/22

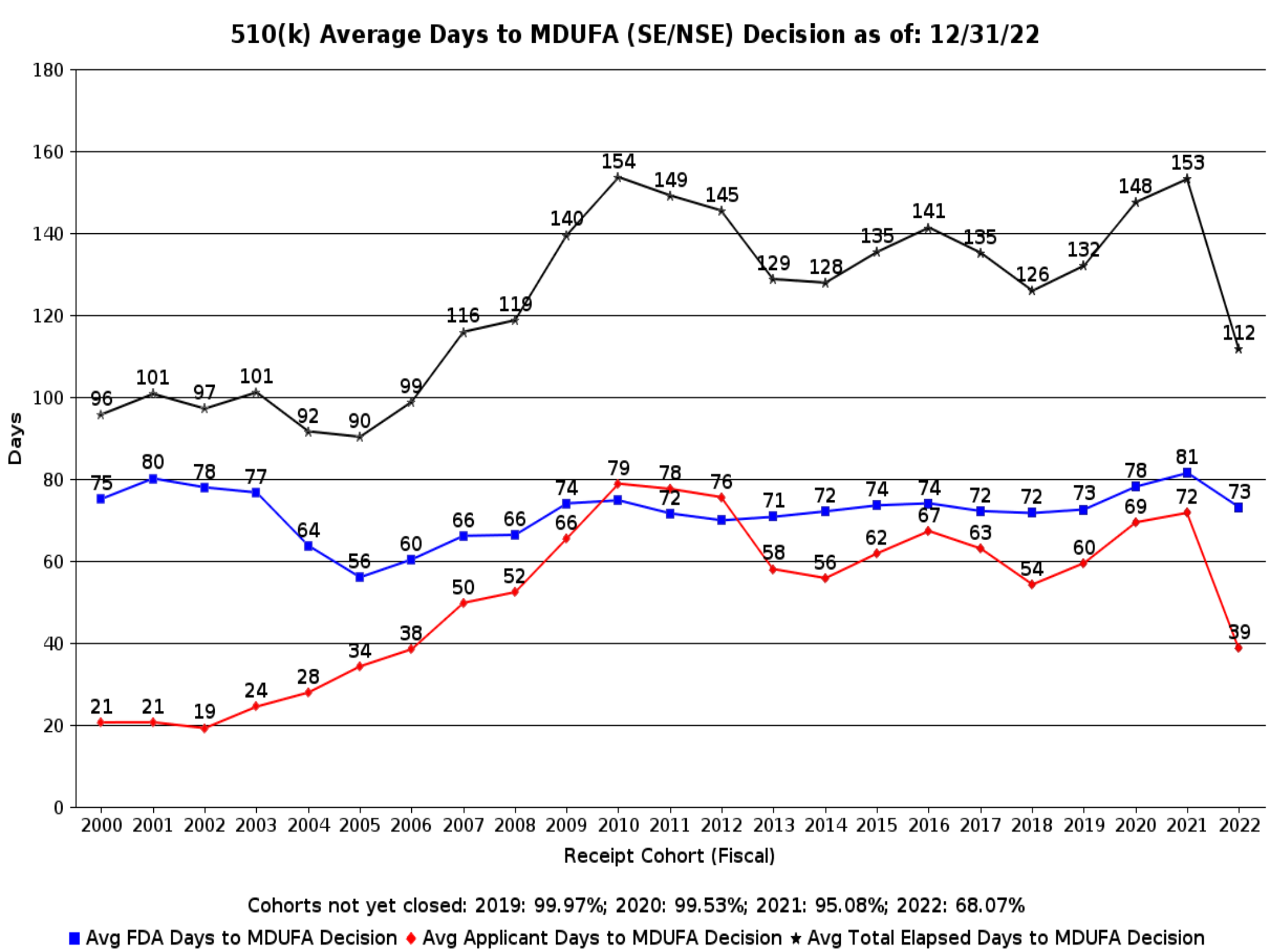
♦ % with 1st Cycle AI Request

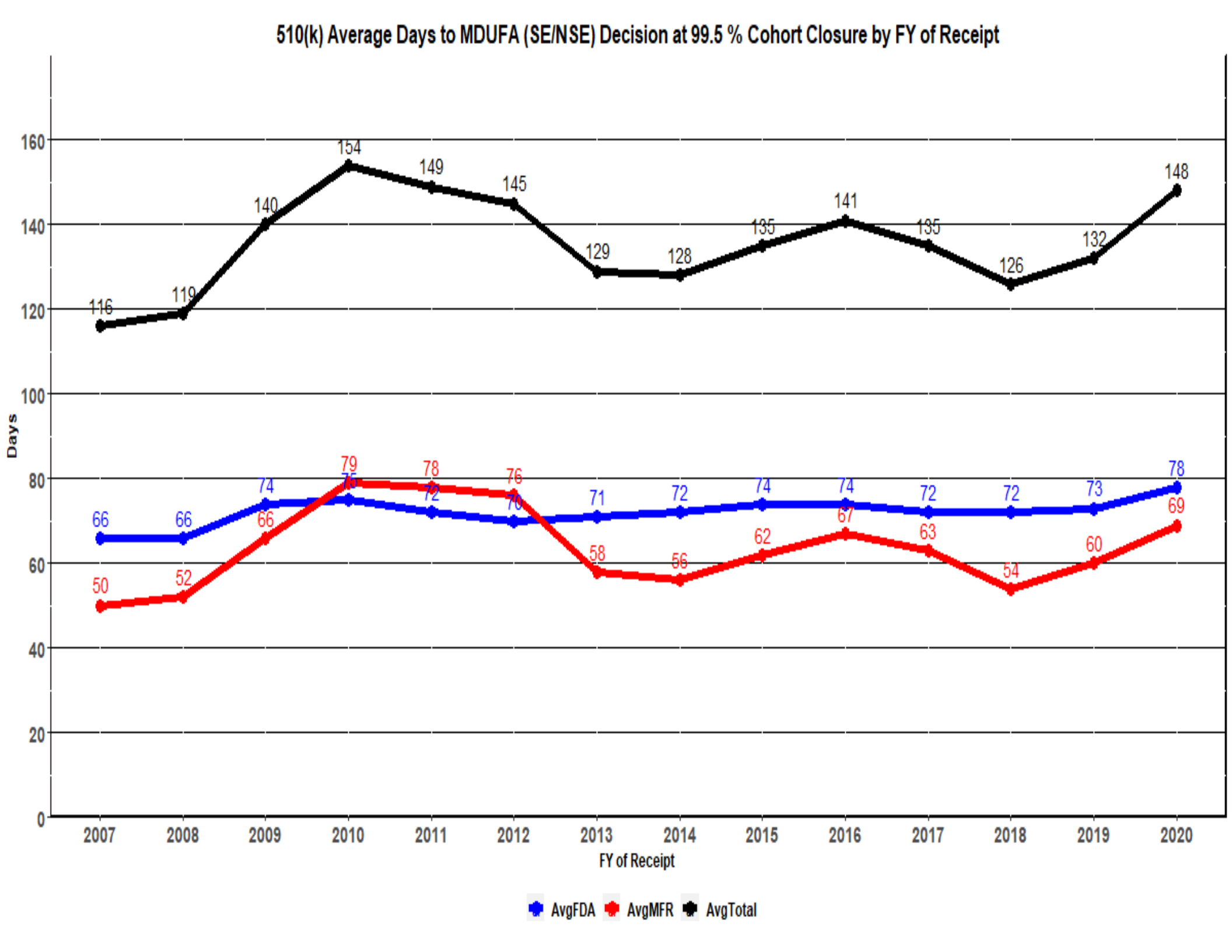
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 5/31/22

■ % with 2nd Cycle AI Request


510(k) Average Days to MDUFA (SE/NSE) Decision as of: 12/31/22
Days
Receipt Cohort (Fiscal)
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
96 101 97 101 92 90 99 116 119 140 154 149 145 129 128 135 141 135 126 132 148 153 112
75 80 78 77 64 56 60 66 66 74 79 78 76 71 72 74 74 72 72 73 78 81 73
21 21 19 24 28 34 38 50 52 66 72 58 56 62 67 63 54 60 69 72 39
Cohorts not yet closed: 2019: 99.97%; 2020: 99.53%; 2021: 95.08%; 2022: 68.07%
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 99.5 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
AvgFDA
AvgMFR
AvgTotal
116
119
140
154
149
145
129
128
135
141
135
126
132
148
66
66
74
75
72
70
71
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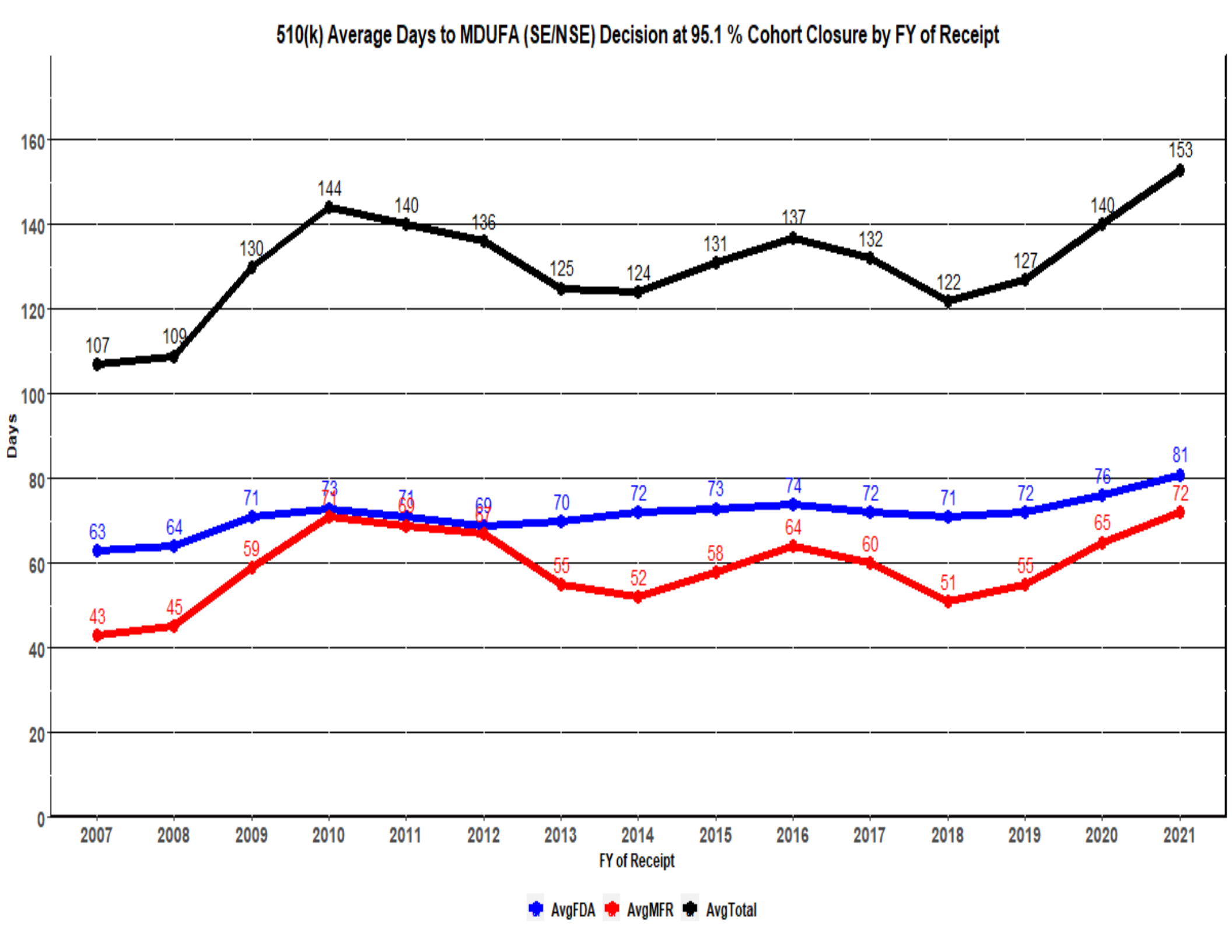
510(k) Average Days to MDUFA (SE/NSE) Decision at 95.1 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
AvgFDA
AvgMFR
AvgTotal
107
109
130
144
140
136
125
124
131
137
132
122
127
140
153
63
64
71
73
71
69
70
72
73
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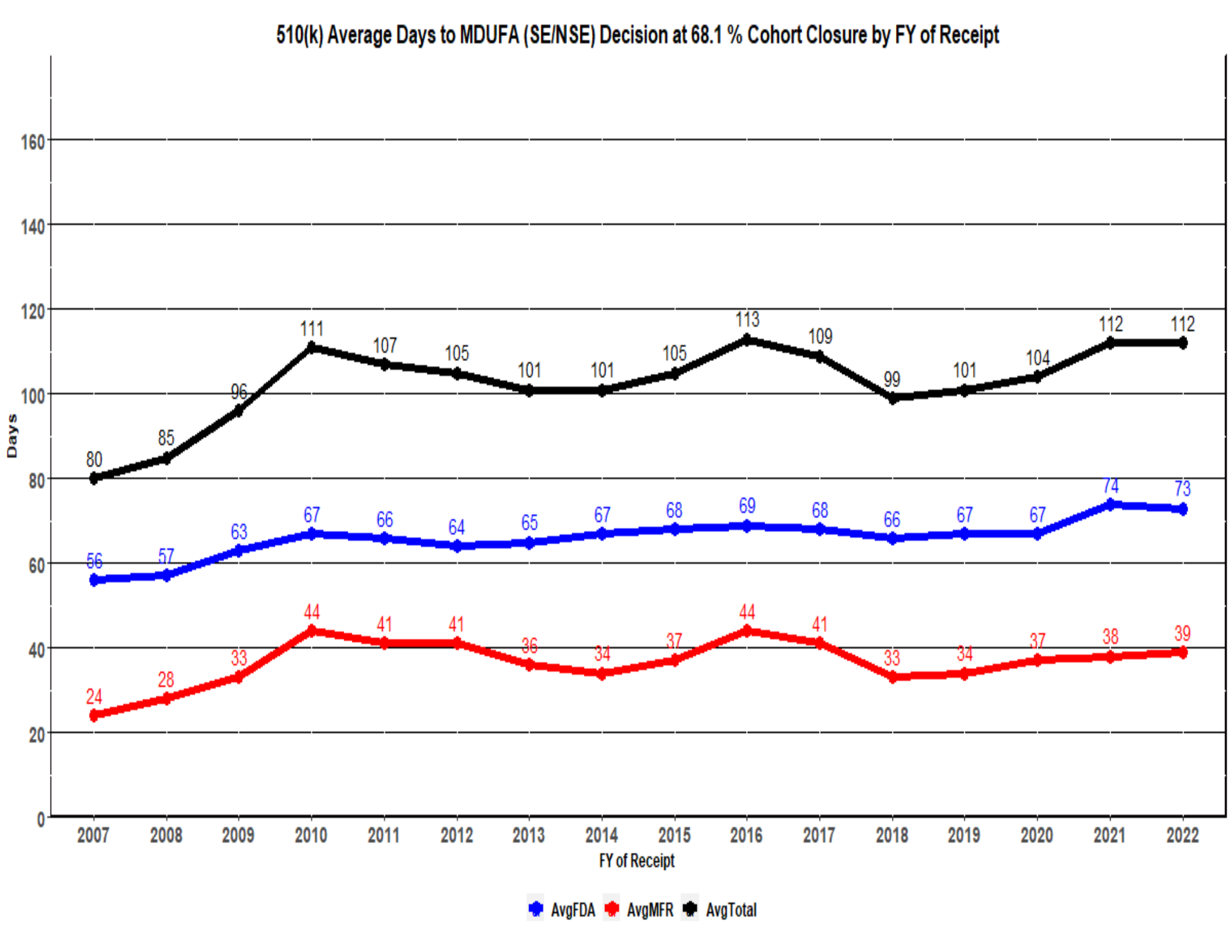
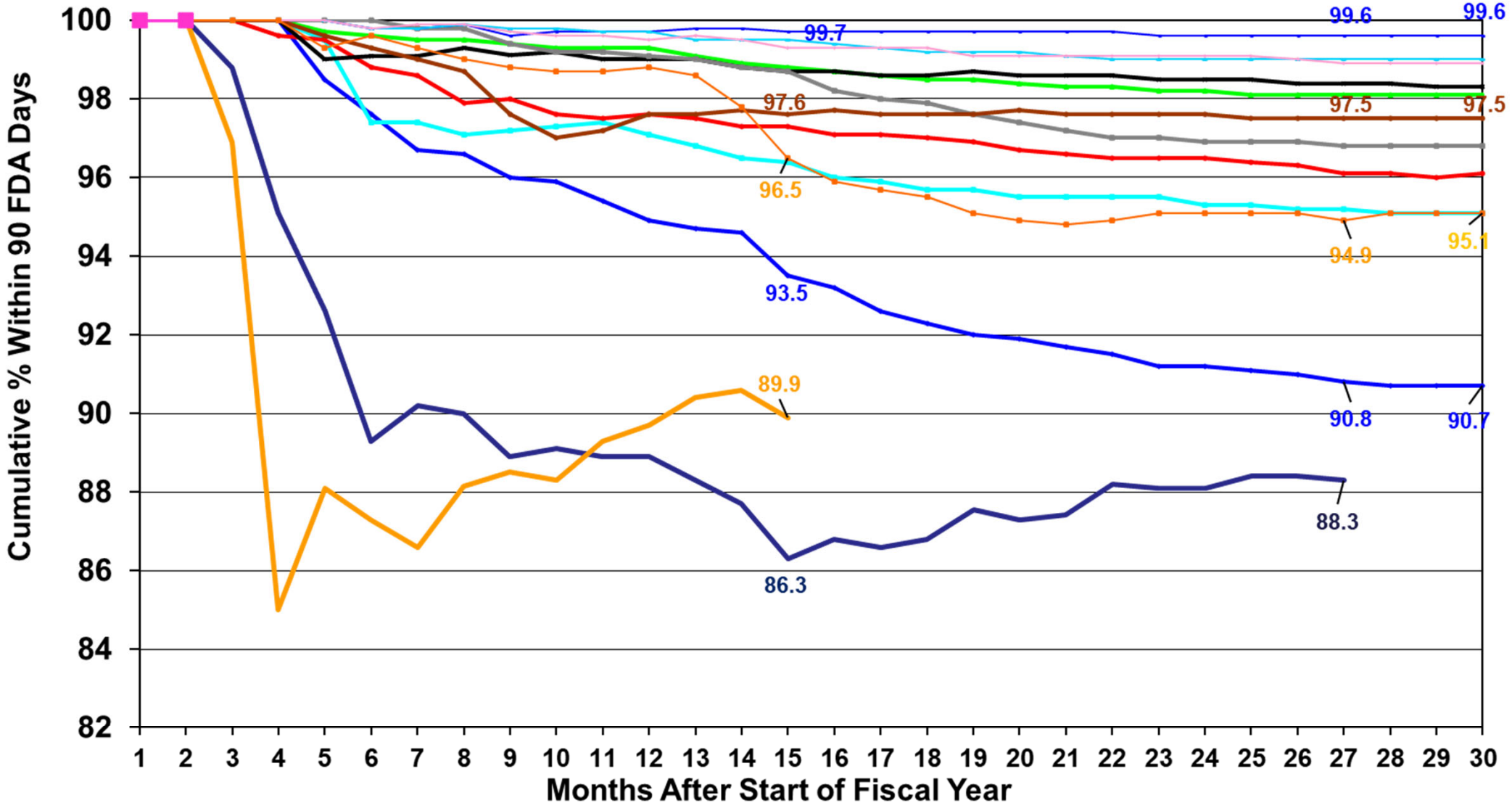
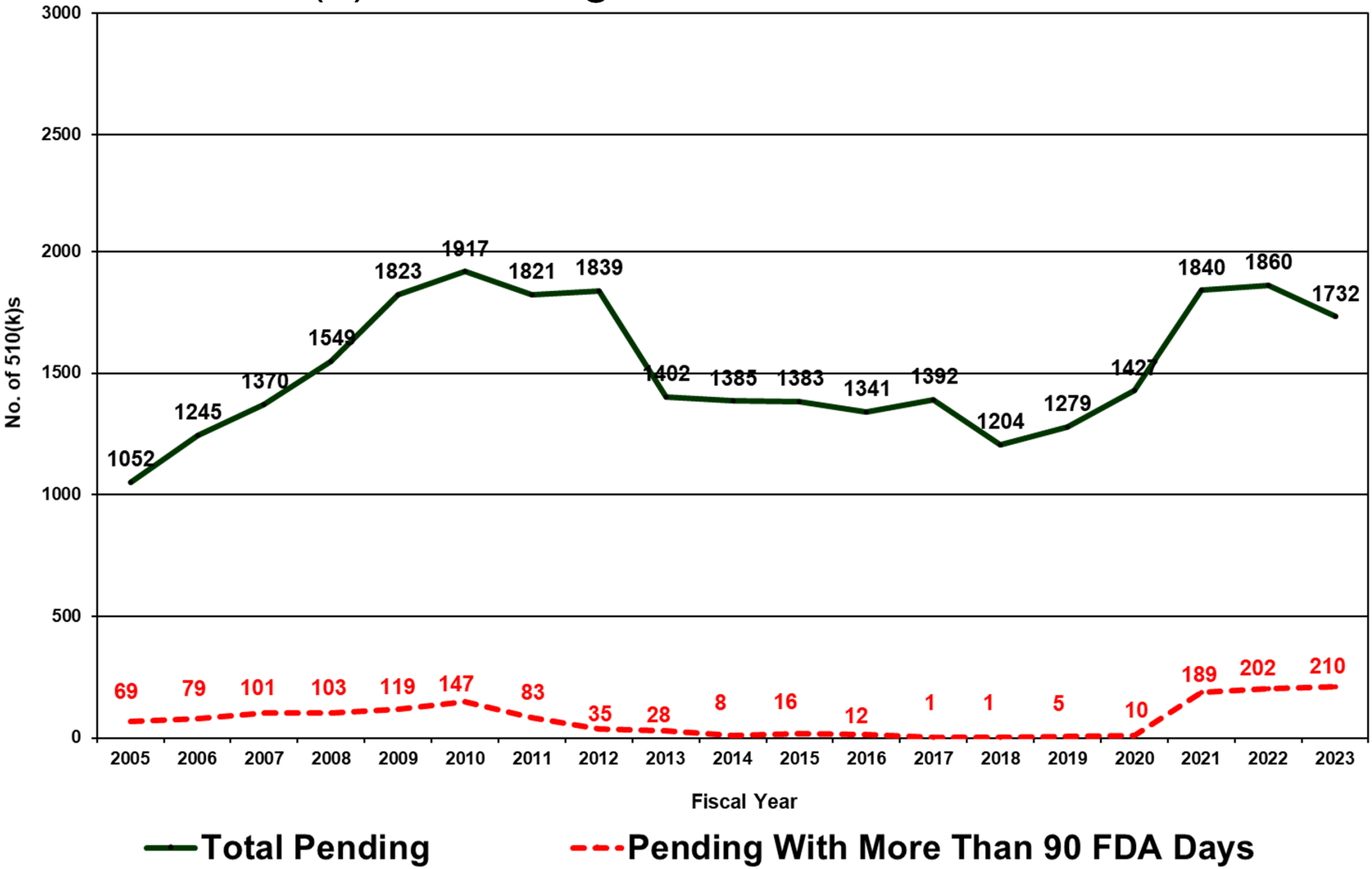

510(k) Average Days to MDUFA (SE/NSE) Decision at 68.1 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY of Receipt
80
85
96
111
107
105
101
101
105
113
109
99
101
104
112
112
56
57
63
67
66
64
65
67
68
69
68
66
67
67
74
73
24
28
33
44
41
41
36
34
37
44
41
33
34
37
38
39
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

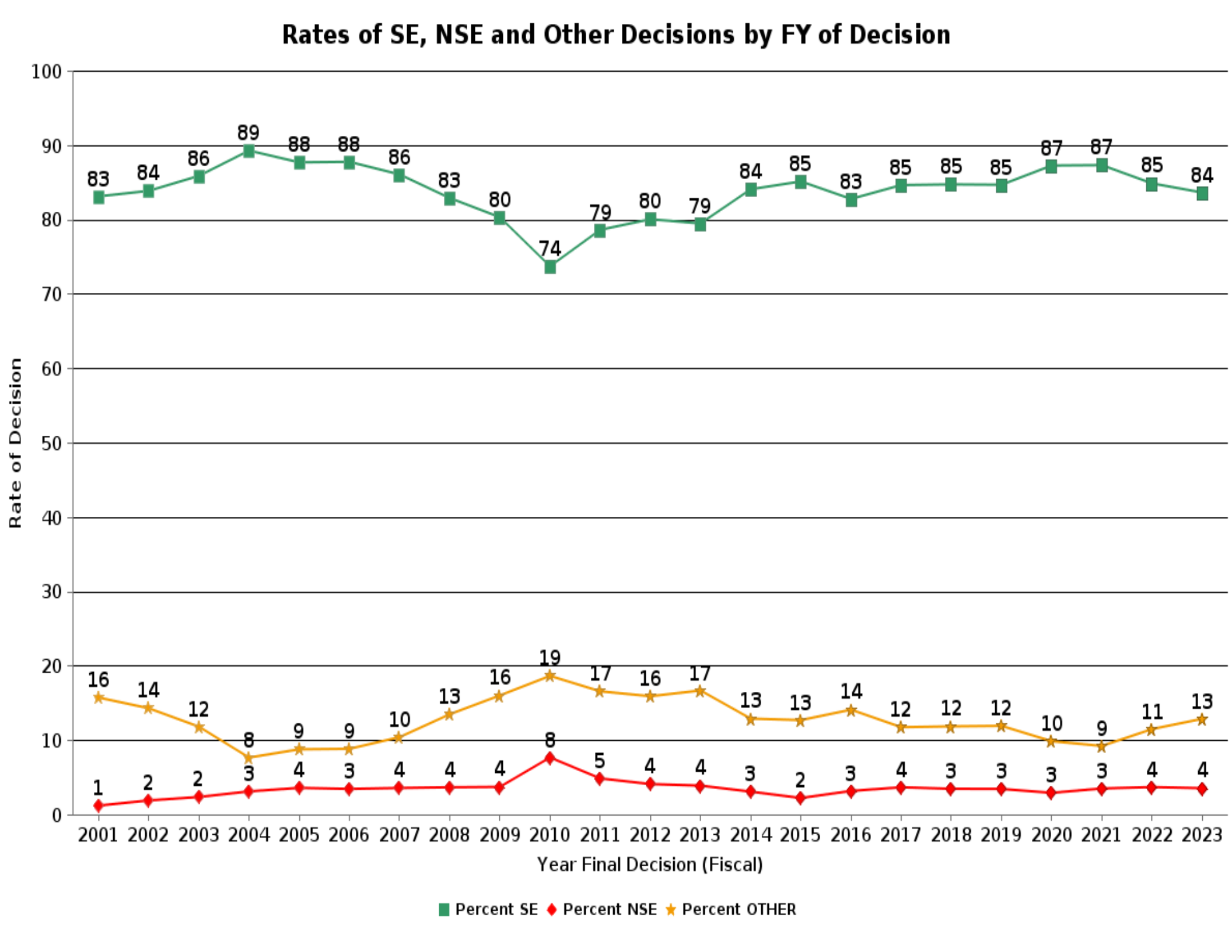
Comparison of FY10 – FY23 Receipt Cohorts



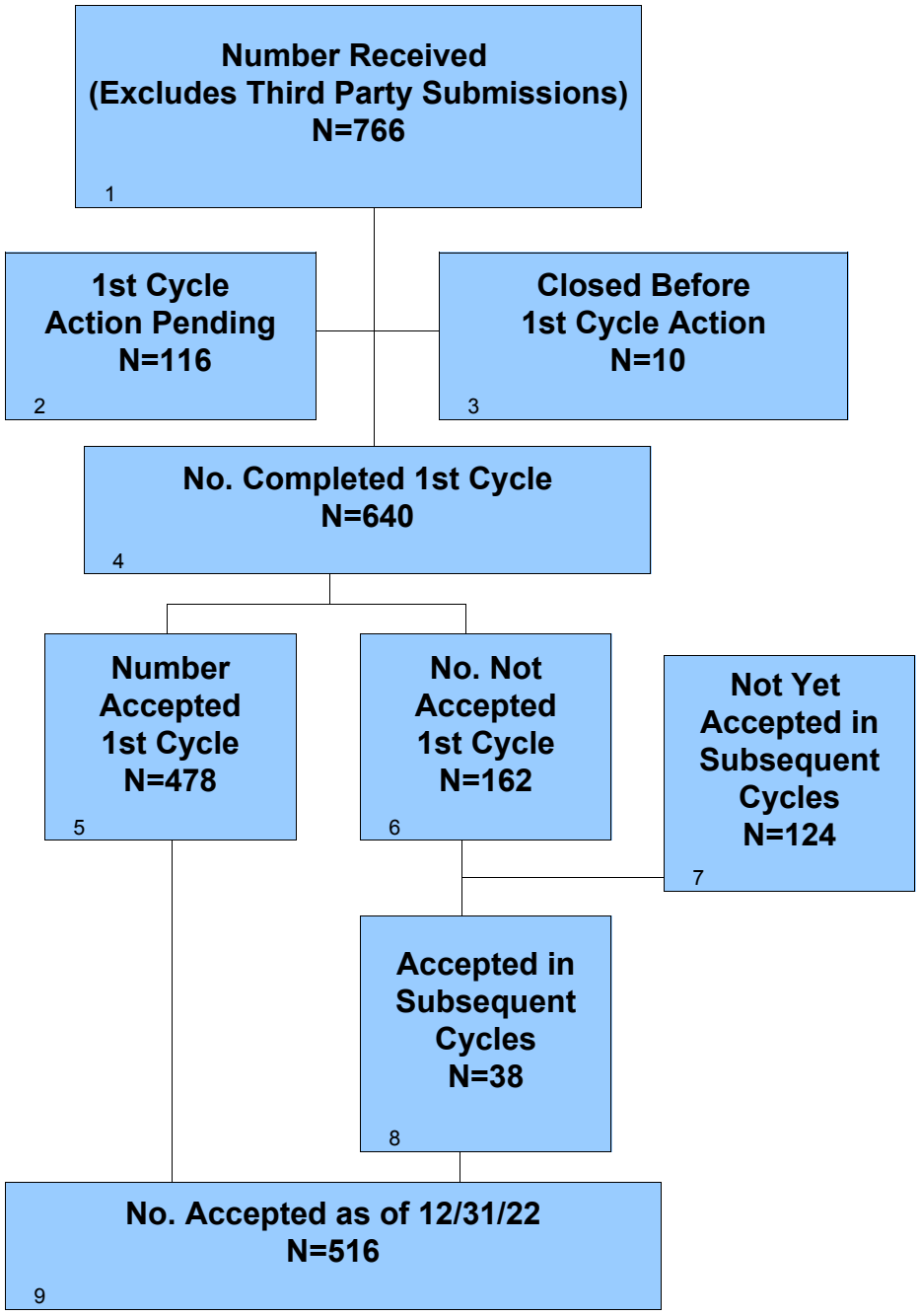
510(k)s Pending at End of Quarter/Year



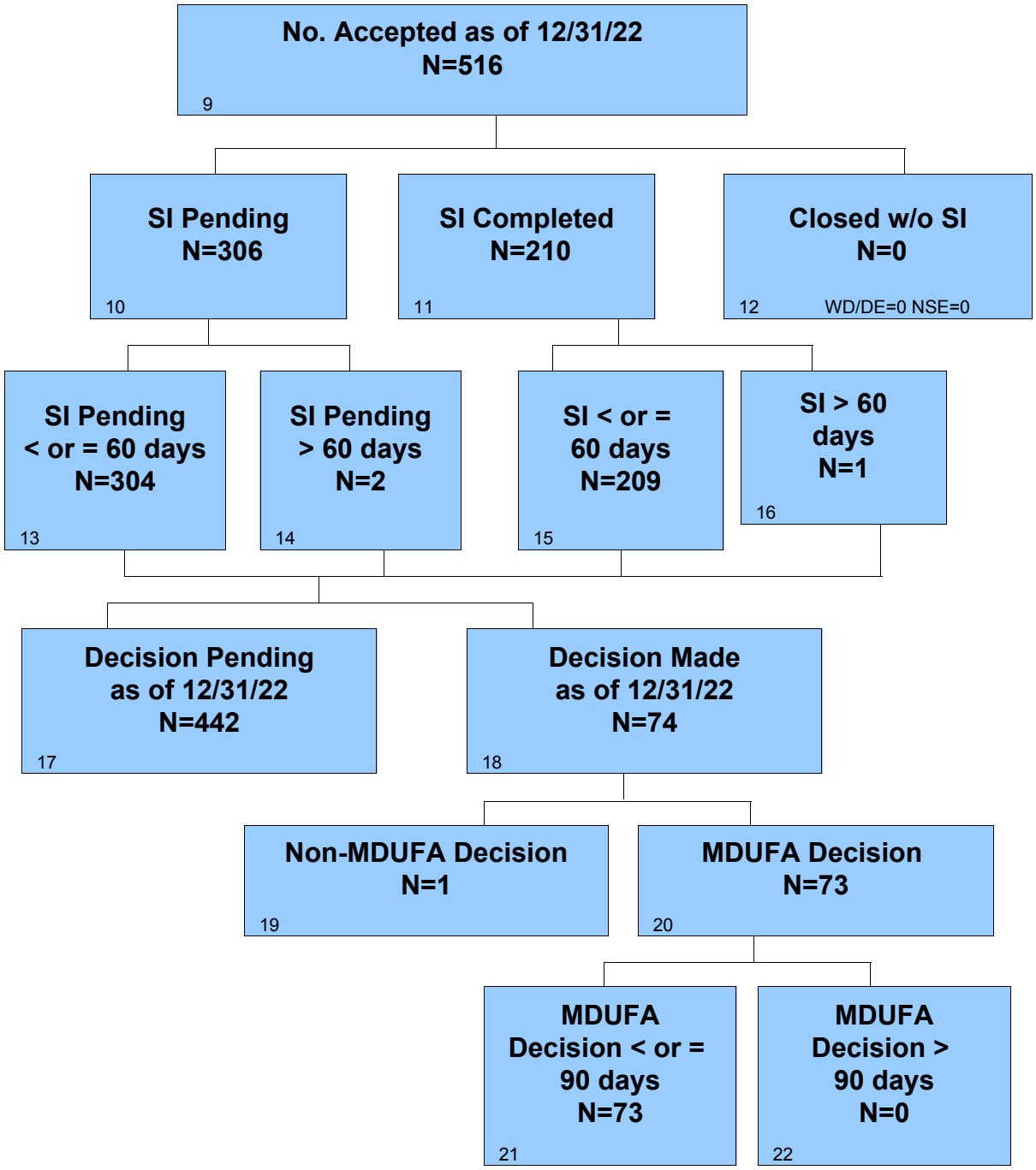
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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 84
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 13
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 12/31/22



CDRH 510(k)s - FY 2023
as of 12/31/22 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	766				
Closed Before First RTA or TS Action	10				
Number Accepted or Passed TS on First Cycle	472				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	6				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	116				
Number Not Accepted or Failed TS on First Cycle	162				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	25.31%				

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 6.2 CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	516				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	209				
SI Over 60 FDA Days	1				
SI Pending Within 60 FDA Days	304				
SI Pending Over 60 FDA Days	2				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	98.58%				

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	210				
Average Number of FDA Days to Substantive Interaction	45.06				
20th Percentile FDA Days to Substantive Interaction	29				
40th Percentile FDA Days to Substantive Interaction	46				
60th Percentile FDA Days to Substantive Interaction	54				
80th Percentile FDA Days to Substantive Interaction	58				
Maximum FDA Days to Substantive Interaction	63				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	516				
Non-MDUFA V Decision	1				
MDUFA V Decision (SE/NSE)	73				
MDUFA V Decision Within 90 FDA Days	73				
510(k)s Pending MDUFA V Decision	442				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.05				
Number With MDUFA V Decision	73				
Average Number of FDA Days to MDUFA V Decision	36.36				
20th Percentile FDA Days to MDUFA V Decision	27				
40th Percentile FDA Days to MDUFA V Decision	28				
60th Percentile FDA Days to MDUFA V Decision	30				
80th Percentile FDA Days to MDUFA V Decision	54				
Maximum FDA Days to MDUFA V Decision	66				
Average Number of Industry Days to MDUFA V Decision	0.55				
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	0				
80th Percentile Industry Days to MDUFA V Decision	0				
Maximum Industry Days to MDUFA V Decision	17				
Average Number of Total Days to MDUFA V Decision	36.90				
20th Percentile Total Days to MDUFA V Decision	27				
40th Percentile Total Days to MDUFA V Decision	28				
60th Percentile Total Days to MDUFA V Decision	32				
80th Percentile Total Days to MDUFA V Decision	55				
Maximum Total Days to MDUFA V Decision	79				

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	516				
Number With MDUFA V Decision	73				
Number of SE Decision	73				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	44				
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	38				
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	106				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	34				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	3				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	14				
Number Not Accepted or Failed TS on First Cycle	55				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	59.78%				

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 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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	45				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	13				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	31				
SI Pending Over 60 FDA Days	1				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	92.86%				

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	13				
Average Number of FDA Days to Substantive Interaction	44.62				
20th Percentile FDA Days to Substantive Interaction	29				
40th Percentile FDA Days to Substantive Interaction	48				
60th Percentile FDA Days to Substantive Interaction	51				
80th Percentile FDA Days to Substantive Interaction	55				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	45				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	4				
MDUFA V Decision Within 90 FDA Days	4				
510(k)s Pending MDUFA V Decision	41				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00				
Number With MDUFA V Decision	4				
Average Number of FDA Days to MDUFA V Decision	34.50				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	29				
60th Percentile FDA Days to MDUFA V Decision	29				
80th Percentile FDA Days to MDUFA V Decision	38				
Maximum FDA Days to MDUFA V Decision	51				
Average Number of 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 Number of Total Days to MDUFA V Decision	34.50				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	29				
60th Percentile Total Days to MDUFA V Decision	29				
80th Percentile Total Days to MDUFA V Decision	38				
Maximum Total Days to MDUFA V Decision	51				

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	45				
Number With MDUFA V Decision	4				
Number of SE Decision	4				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	76				
Closed Before First RTA or TS Action	2				
Number Accepted or Passed TS on First Cycle	48				
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	16				
Number Not Accepted or Failed TS on First Cycle	10				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	17.24%				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	52				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	25				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	27				
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 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	25				
Average Number of FDA Days to Substantive Interaction	46.60				
20th Percentile FDA Days to Substantive Interaction	29				
40th Percentile FDA Days to Substantive Interaction	48				
60th Percentile FDA Days to Substantive Interaction	53				
80th Percentile FDA Days to Substantive Interaction	57				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	52				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	7				
MDUFA V Decision Within 90 FDA Days	7				
510(k)s Pending MDUFA V Decision	45				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.14				
Number With MDUFA V Decision	7				
Average Number of FDA Days to MDUFA V Decision	41.71				
20th Percentile FDA Days to MDUFA V Decision	27				
40th Percentile FDA Days to MDUFA V Decision	29				
60th Percentile FDA Days to MDUFA V Decision	46				
80th Percentile FDA Days to MDUFA V Decision	57				
Maximum FDA Days to MDUFA V Decision	66				
Average Number of Industry Days to MDUFA V Decision	1.86				
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	0				
Maximum Industry Days to MDUFA V Decision	13				
Average Number of Total Days to MDUFA V Decision	43.57				
20th Percentile Total Days to MDUFA V Decision	27				
40th Percentile Total Days to MDUFA V Decision	29				
60th Percentile Total Days to MDUFA V Decision	46				
80th Percentile Total Days to MDUFA V Decision	57				
Maximum Total Days to MDUFA V Decision	79				

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	52				
Number With MDUFA V Decision	7				
Number of SE Decision	7				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

Table 6.7 OHT2 - Office of Cardiovascular Devices
510(k) Performance Metric - Submission Missing Performance Goal

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

Table 6.9 OHT2 - Office of Cardiovascular Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	82				
Closed Before First RTA or TS Action	3				
Number Accepted or Passed TS on First Cycle	45				
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	15				
Number Not Accepted or Failed TS on First Cycle	19				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	29.69%				

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 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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	50				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	20				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	30				
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 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	20				
Average Number of FDA Days to Substantive Interaction	48.60				
20th Percentile FDA Days to Substantive Interaction	37				
40th Percentile FDA Days to Substantive Interaction	51				
60th Percentile FDA Days to Substantive Interaction	56				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	50				
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	44				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00				
Number With MDUFA V Decision	6				
Average Number of FDA Days to MDUFA V Decision	36.00				
20th Percentile FDA Days to MDUFA V Decision	28				
40th Percentile FDA Days to MDUFA V Decision	28				
60th Percentile FDA Days to MDUFA V Decision	28				
80th Percentile FDA Days to MDUFA V Decision	45				
Maximum FDA Days to MDUFA V Decision	62				
Average Number of 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 Number of Total Days to MDUFA V Decision	36.00				
20th Percentile Total Days to MDUFA V Decision	28				
40th Percentile Total Days to MDUFA V Decision	28				
60th Percentile Total Days to MDUFA V Decision	28				
80th Percentile Total Days to MDUFA V Decision	45				
Maximum Total Days to MDUFA V Decision	62				

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	50				
Number With MDUFA V Decision	6				
Number of SE Decision	6				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	128				
Closed Before First RTA or TS Action	2				
Number Accepted or Passed TS on First Cycle	82				
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	15				
Number Not Accepted or Failed TS on First Cycle	29				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	26.13%				

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 6.2 OHT4 - Office of Surgical and Infection Control Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	88				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	42				
SI Over 60 FDA Days	1				
SI Pending Within 60 FDA Days	44				
SI Pending Over 60 FDA Days	1				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	95.45%				

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	43				
Average Number of FDA Days to Substantive Interaction	41.00				
20th Percentile FDA Days to Substantive Interaction	28				
40th Percentile FDA Days to Substantive Interaction	30				
60th Percentile FDA Days to Substantive Interaction	53				
80th Percentile FDA Days to Substantive Interaction	58				
Maximum FDA Days to Substantive Interaction	63				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	88				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	14				
MDUFA V Decision Within 90 FDA Days	14				
510(k)s Pending MDUFA V Decision	74				
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	1.07				
Number With MDUFA V Decision	14				
Average Number of FDA Days to MDUFA V Decision	32.14				
20th Percentile FDA Days to MDUFA V Decision	24				
40th Percentile FDA Days to MDUFA V Decision	28				
60th Percentile FDA Days to MDUFA V Decision	30				
80th Percentile FDA Days to MDUFA V Decision	45				
Maximum FDA Days to MDUFA V Decision	58				
Average Number of Industry Days to MDUFA V Decision	1.21				
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	17				
Average Number of Total Days to MDUFA V Decision	33.36				
20th Percentile Total Days to MDUFA V Decision	24				
40th Percentile Total Days to MDUFA V Decision	28				
60th Percentile Total Days to MDUFA V Decision	30				
80th Percentile Total Days to MDUFA V Decision	50				
Maximum Total Days to MDUFA V Decision	61				

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	88				
Number With MDUFA V Decision	14				
Number of SE Decision	14				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	62				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	45				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	5				
Number Not Accepted or Failed TS on First Cycle	11				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	19.30%				

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 6.2 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	47				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	18				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	29				
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 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	18				
Average Number of FDA Days to Substantive Interaction	48.61				
20th Percentile FDA Days to Substantive Interaction	33				
40th Percentile FDA Days to Substantive Interaction	52				
60th Percentile FDA Days to Substantive Interaction	56				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	47				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	5				
MDUFA V Decision Within 90 FDA Days	5				
510(k)s Pending MDUFA V Decision	42				
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	1.00				
Number With MDUFA V Decision	5				
Average Number of FDA Days to MDUFA V Decision	31.80				
20th Percentile FDA Days to MDUFA V Decision	28				
40th Percentile FDA Days to MDUFA V Decision	29				
60th Percentile FDA Days to MDUFA V Decision	29				
80th Percentile FDA Days to MDUFA V Decision	32				
Maximum FDA Days to MDUFA V Decision	46				
Average Number of 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 Number of Total Days to MDUFA V Decision	31.80				
20th Percentile Total Days to MDUFA V Decision	28				
40th Percentile Total Days to MDUFA V Decision	29				
60th Percentile Total Days to MDUFA V Decision	29				
80th Percentile Total Days to MDUFA V Decision	32				
Maximum Total Days to MDUFA V Decision	46				

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	47				
Number With MDUFA V Decision	5				
Number of SE Decision	5				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	142				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	91				
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	27				
Number Not Accepted or Failed TS on First Cycle	23				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	20.18%				

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 (see box 5 in flowchart).

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	101				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	37				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	64				
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	37				
Average Number of FDA Days to Substantive Interaction	44.62				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	46				
60th Percentile FDA Days to Substantive Interaction	53				
80th Percentile FDA Days to Substantive Interaction	56				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	101				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	17				
MDUFA V Decision Within 90 FDA Days	17				
510(k)s Pending MDUFA V Decision	84				
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	1.00				
Number With MDUFA V Decision	17				
Average Number of FDA Days to MDUFA V Decision	40.76				
20th Percentile FDA Days to MDUFA V Decision	24				
40th Percentile FDA Days to MDUFA V Decision	30				
60th Percentile FDA Days to MDUFA V Decision	53				
80th Percentile FDA Days to MDUFA V Decision	56				
Maximum FDA Days to MDUFA V Decision	63				
Average Number of 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 Number of Total Days to MDUFA V Decision	40.76				
20th Percentile Total Days to MDUFA V Decision	24				
40th Percentile Total Days to MDUFA V Decision	30				
60th Percentile Total Days to MDUFA V Decision	53				
80th Percentile Total Days to MDUFA V Decision	56				
Maximum Total Days to MDUFA V Decision	63				

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	101				
Number With MDUFA V Decision	17				
Number of SE Decision	17				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

Table 6.9 OHT6 - Office of Orthopedic Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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	57				
Closed Before First RTA or TS Action	2				
Number Accepted or Passed TS on First Cycle	44				
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	9				
Number Not Accepted or Failed TS on First Cycle	2				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	4.35%				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	45				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	15				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	30				
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	15				
Average Number of FDA Days to Substantive Interaction	47.20				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	51				
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 OHT7 - Office of In Vitro Diagnostics
510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	45				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	7				
MDUFA V Decision Within 90 FDA Days	7				
510(k)s Pending MDUFA V Decision	38				
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	1.00				
Number With MDUFA V Decision	7				
Average Number of FDA Days to MDUFA V Decision	36.86				
20th Percentile FDA Days to MDUFA V Decision	28				
40th Percentile FDA Days to MDUFA V Decision	29				
60th Percentile FDA Days to MDUFA V Decision	30				
80th Percentile FDA Days to MDUFA V Decision	53				
Maximum FDA Days to MDUFA V Decision	59				
Average Number of 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 Number of Total Days to MDUFA V Decision	36.86				
20th Percentile Total Days to MDUFA V Decision	28				
40th Percentile Total Days to MDUFA V Decision	29				
60th Percentile Total Days to MDUFA V Decision	30				
80th Percentile Total Days to MDUFA V Decision	53				
Maximum Total Days to MDUFA V Decision	59				

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	45				
Number With MDUFA V Decision	7				
Number of SE Decision	7				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	44				
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	38				
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	113				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	83				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	2				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	15				
Number Not Accepted or Failed TS on First Cycle	13				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	13.27%				

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 6.2 OHT8 - Office of Radiological Health
510(k) Substantive Interaction (SI) Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	88				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	39				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	49				
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	39				
Average Number of FDA Days to Substantive Interaction	44.82				
20th Percentile FDA Days to Substantive Interaction	28				
40th Percentile FDA Days to Substantive Interaction	47				
60th Percentile FDA Days to Substantive Interaction	55				
80th Percentile FDA Days to Substantive Interaction	58				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	88				
Non-MDUFA V Decision	1				
MDUFA V Decision (SE/NSE)	13				
MDUFA V Decision Within 90 FDA Days	13				
510(k)s Pending MDUFA V Decision	74				
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	1.15				
Number With MDUFA V Decision	13				
Average Number of FDA Days to MDUFA V Decision	34.46				
20th Percentile FDA Days to MDUFA V Decision	25				
40th Percentile FDA Days to MDUFA V Decision	28				
60th Percentile FDA Days to MDUFA V Decision	33				
80th Percentile FDA Days to MDUFA V Decision	48				
Maximum FDA Days to MDUFA V Decision	55				
Average Number of Industry Days to MDUFA V Decision	0.77				
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	9				
Average Number of Total Days to MDUFA V Decision	35.23				
20th Percentile Total Days to MDUFA V Decision	25				
40th Percentile Total Days to MDUFA V Decision	28				
60th Percentile Total Days to MDUFA V Decision	40				
80th Percentile Total Days to MDUFA V Decision	48				
Maximum Total Days to MDUFA V Decision	55				

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	88				
Number With MDUFA V Decision	13				
Number of SE Decision	13				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

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
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	0.00%				

Section 7 510(k) Annual General Metrics

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

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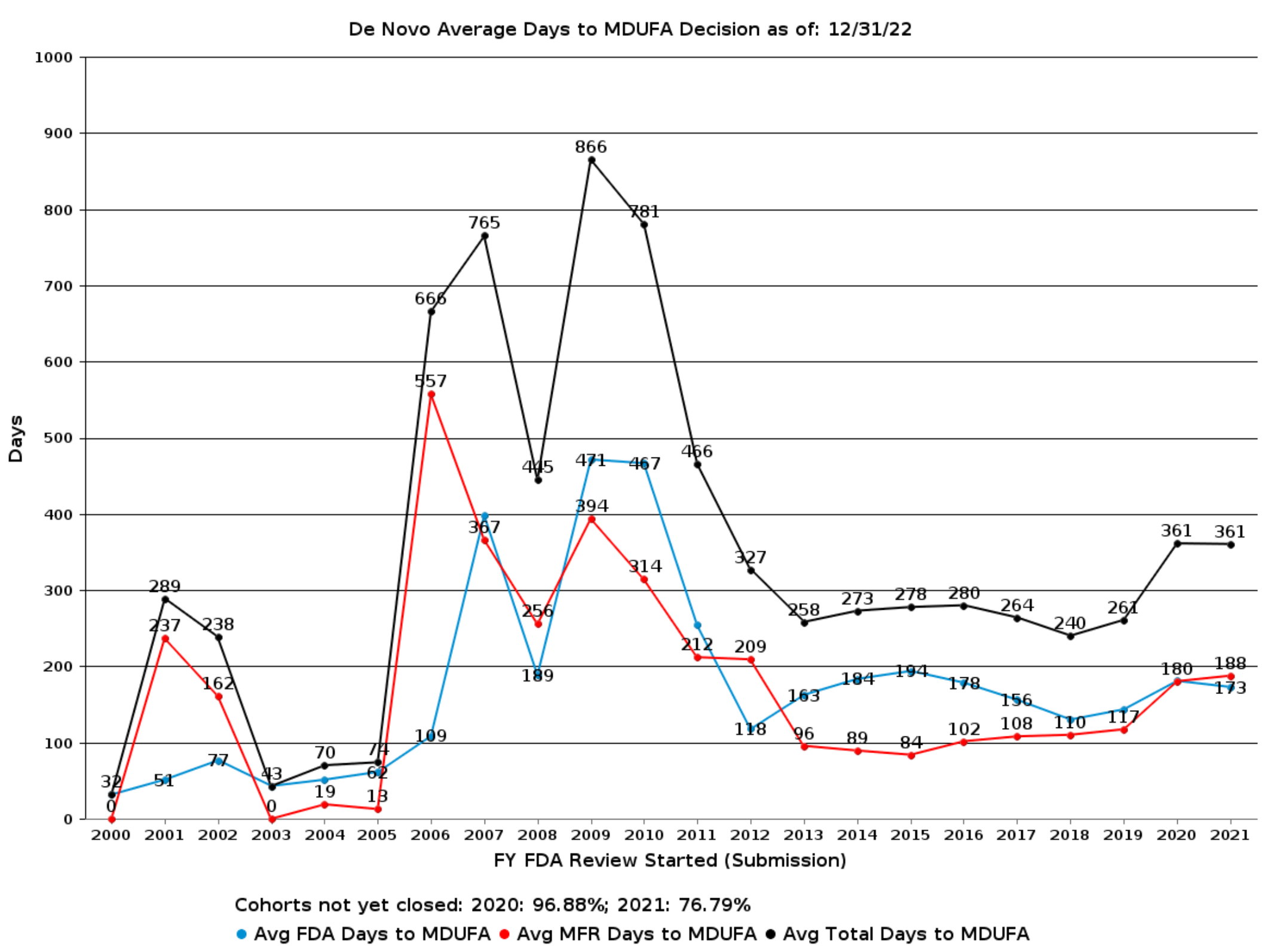
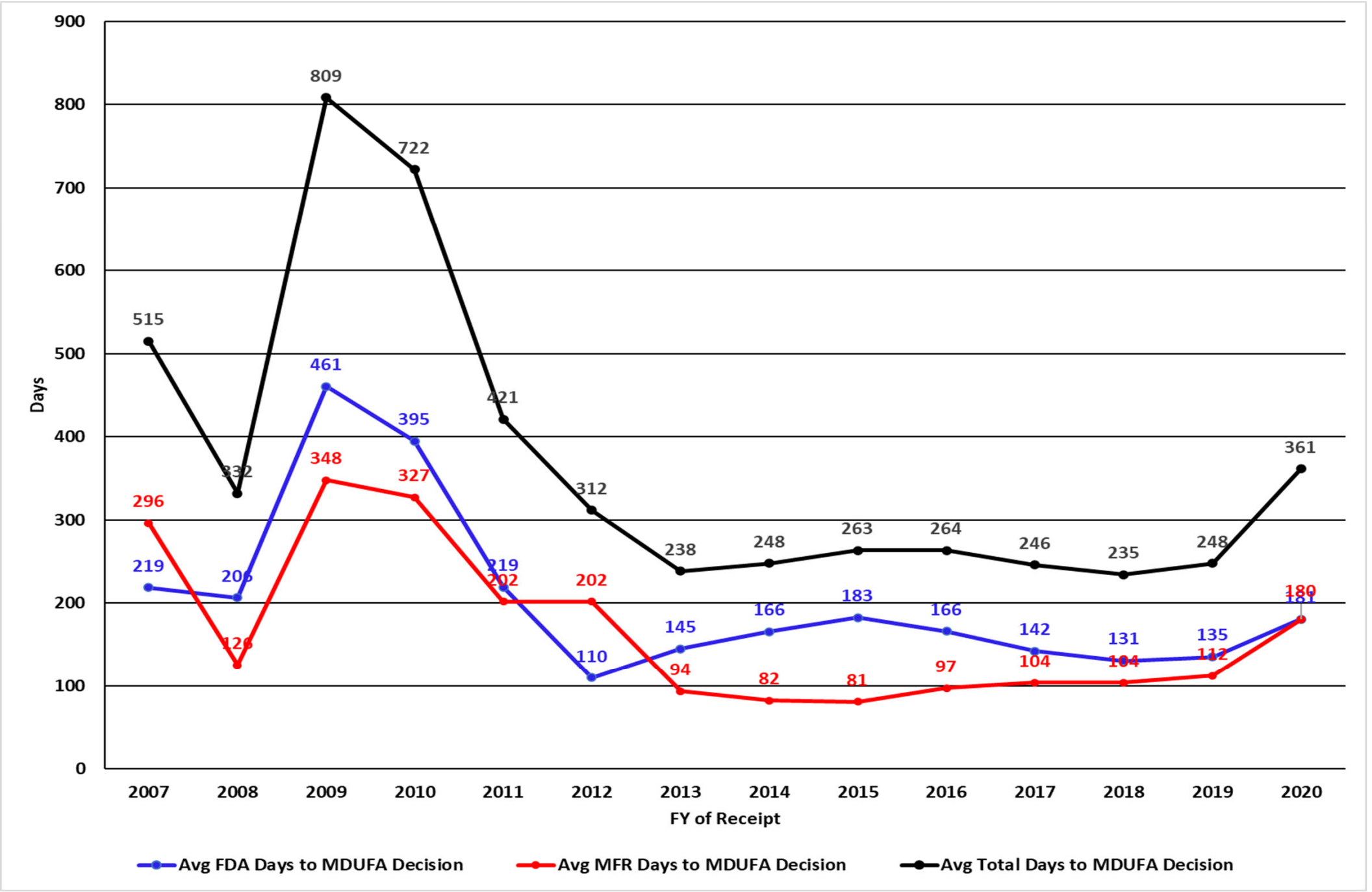
De Novos

Q1FY2023


De Novo Average Days to MDUFA Decision as of: 12/31/22
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2020: 96.88%; 2021: 76.79%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

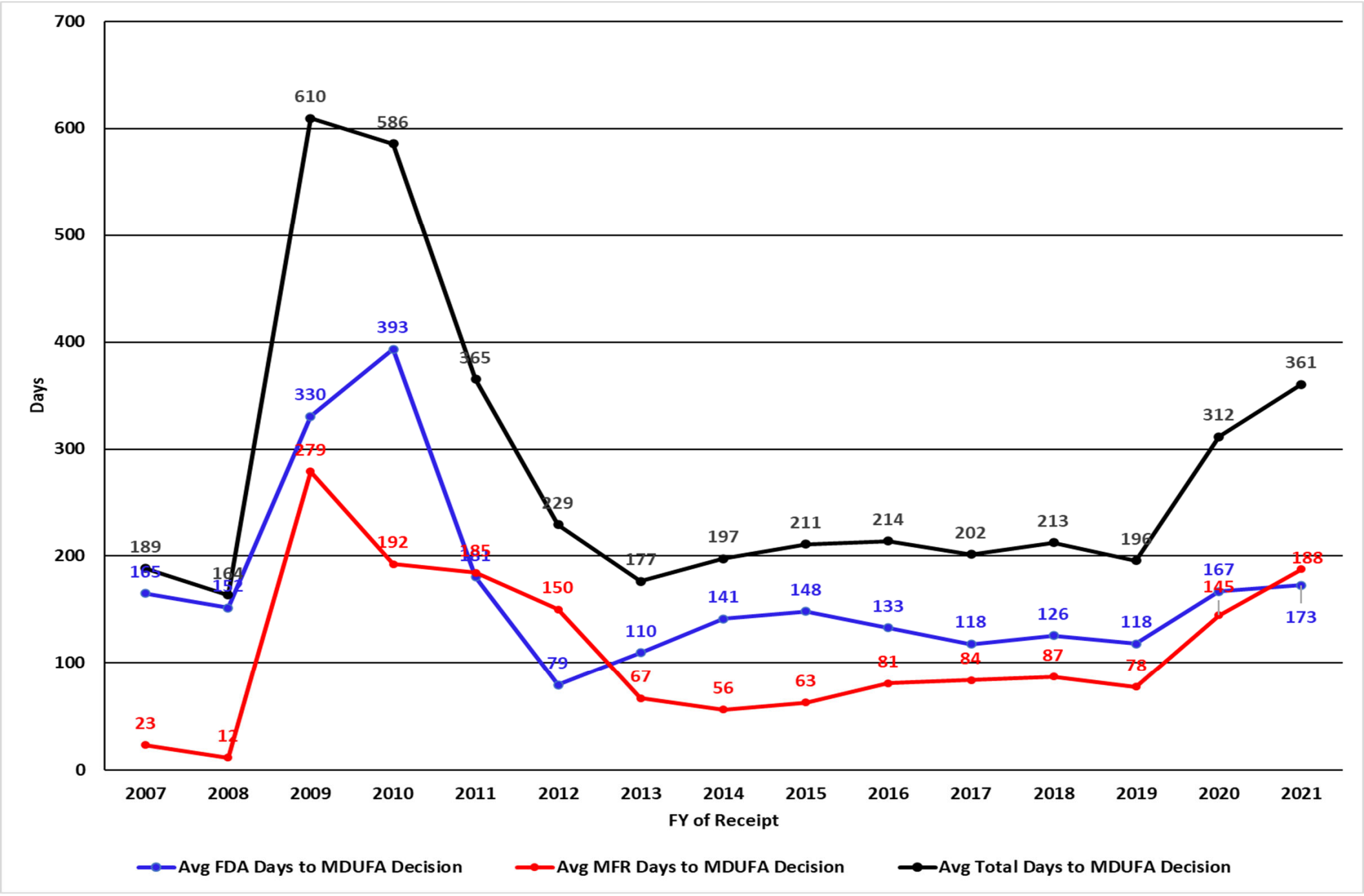
Average Time to MDUFA Decision: De Novos

(96.9% closure comparison)

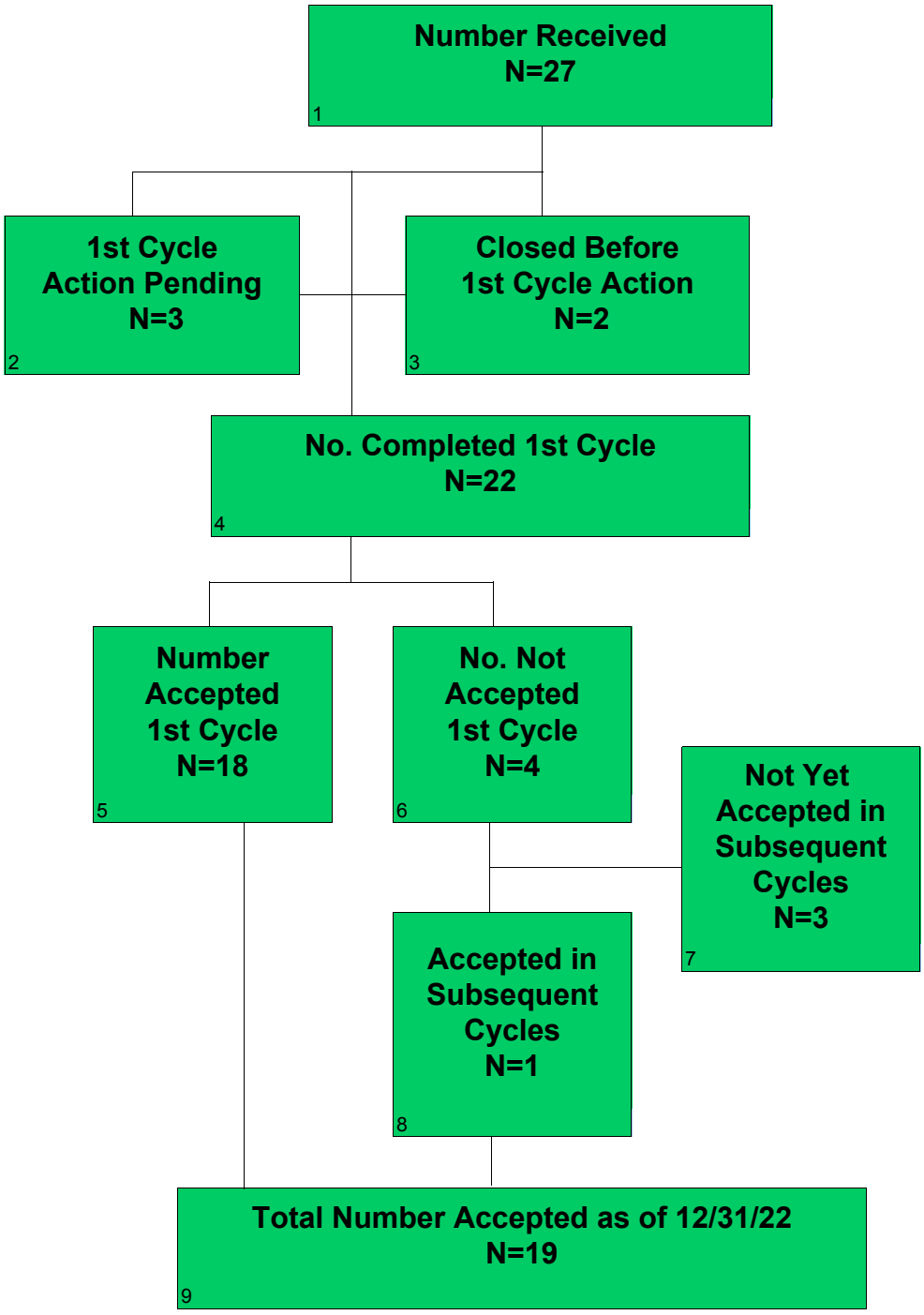


Average Time to MDUFA Decision: De Novos

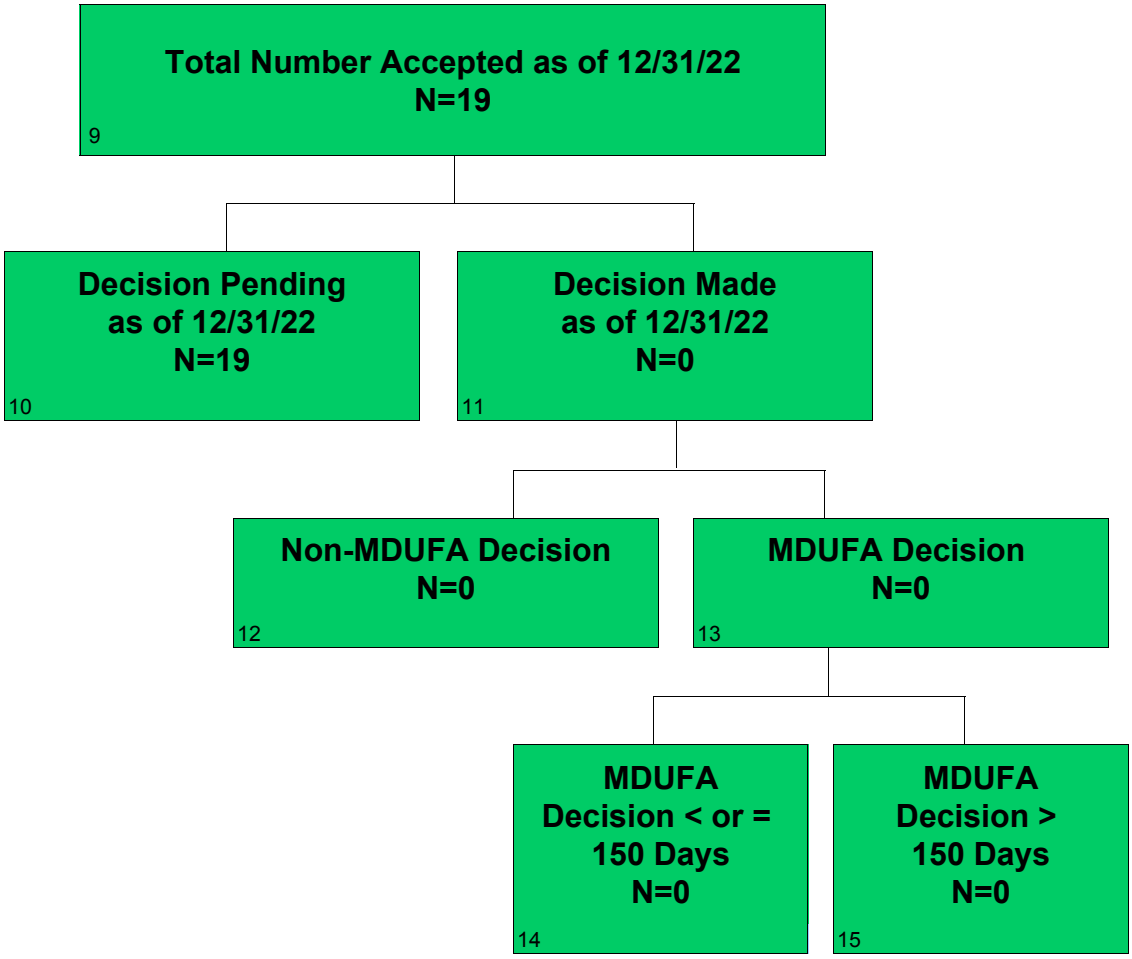
(76.8% closure comparison)



CDRH De Novo - FY 2023
as of 12/31/22



CDRH De Novo - FY 2023 as of 12/31/22 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	27				
Closed Before First RTA or TS Action	2				
Number Accepted or Passed TS on First Cycle	18				
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	3				
Number Not Accepted or Failed TS on First Cycle	4				
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 (see box 5 in flowchart).

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	19				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	19				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	0.00				
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 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	19				
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	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	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 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	0.00%				

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	4				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	4				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

Section 8 - De Novo Office Level Metrics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	2				
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	1				
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 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	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	0.00%				

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	0.00				
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 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	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	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	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 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	0.00%				

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	0.00%				

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	5				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	5				
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 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	5				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

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	0.00				
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 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	5				
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	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
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 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	0.00%				

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	0.00%				

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	2				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	2				
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 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	2				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	2				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

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	0.00				
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 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	2				
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	0.00%				
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	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0.00%				

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	0.00%				

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	6				
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	0				
Number Not Accepted or Failed TS on First Cycle	1				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	20.00%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	4				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

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	0.00				
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 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	4				
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	0.00%				
Rate of Declined Decision	0.00%				
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	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0.00%				

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	0.00%				

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	5				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	2				
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	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 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	2				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	2				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

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	0.00				
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 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	2				
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	0.00%				
Rate of Declined Decision	0.00%				
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	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0.00%				

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	0.00%				

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	0				
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	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	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	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	0.00%				

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	0.00				
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 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	0				
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	0.00%				
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	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0.00%				

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	0.00%				

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	7				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	5				
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	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 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	5				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

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	0.00				
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 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	5				
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	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
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	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0.00%				

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	4				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	4				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	0.00%				

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	0				
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	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	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	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	0.00%				

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	0.00				
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 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	0				
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	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
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	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0.00%				

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	0.00%				

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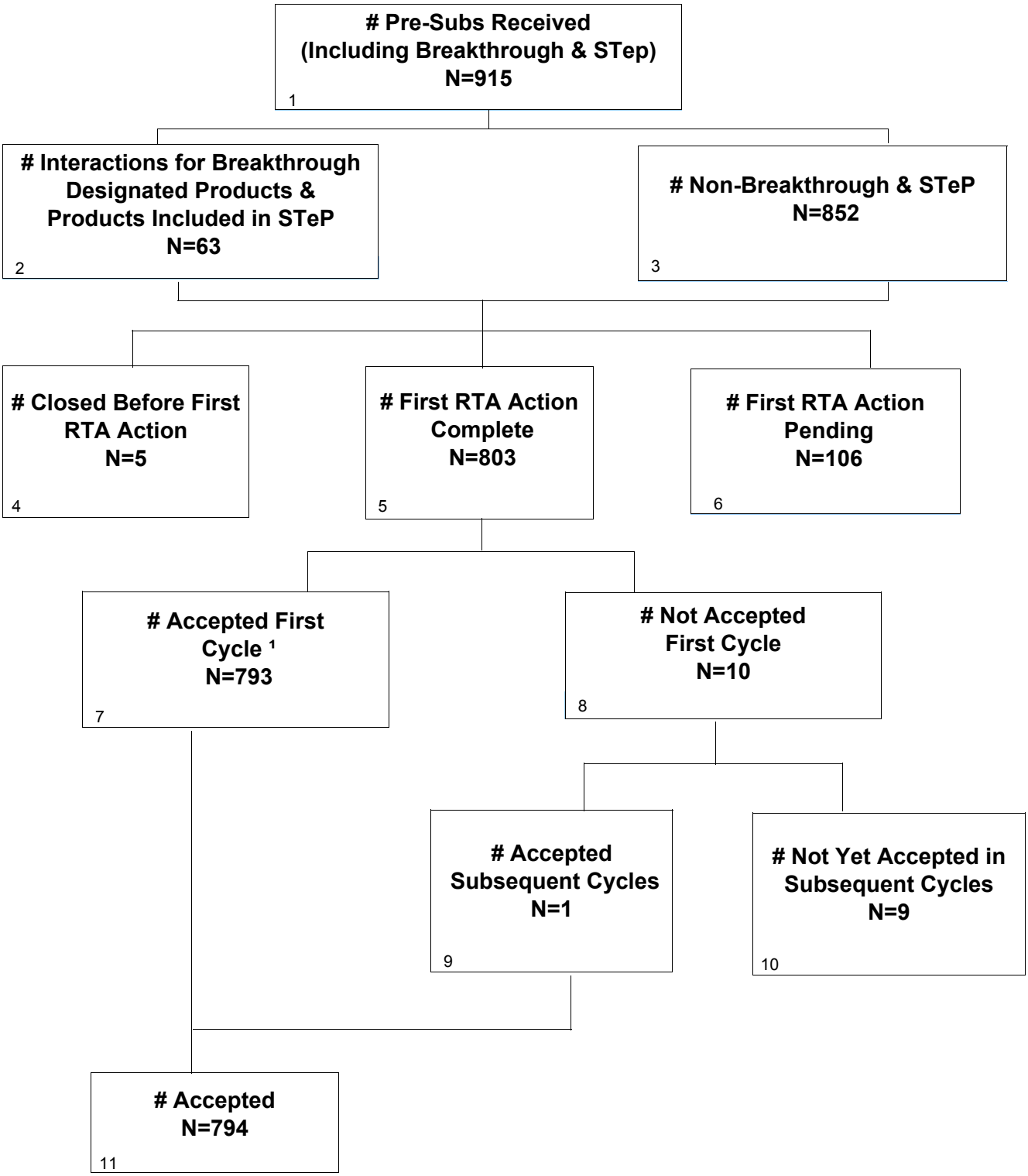
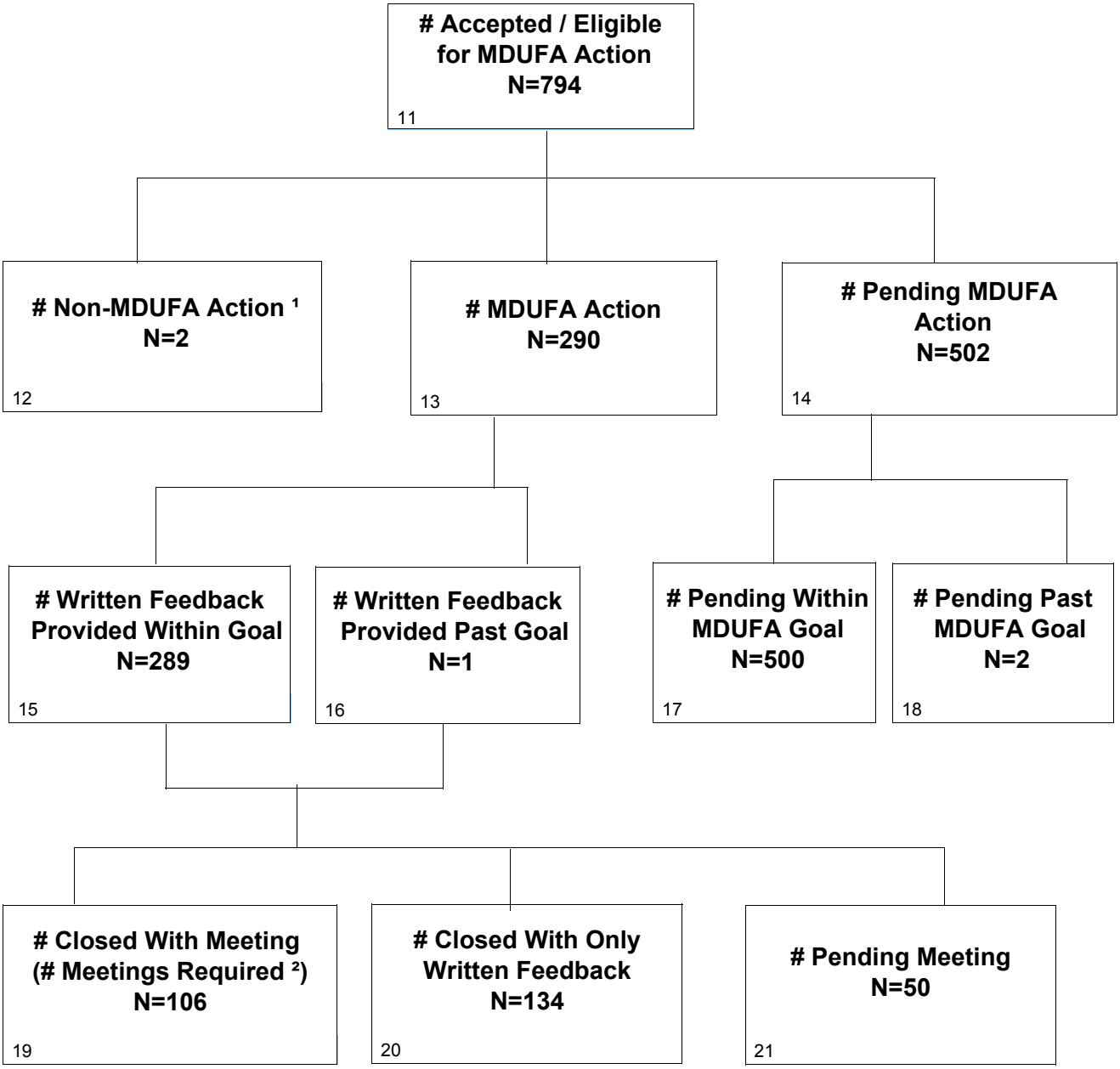
CDRH Pre-Sub - FY 2023
as of 12/31/22



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

CDRH Pre-Sub - FY 2023
as of 12/31/22 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	915				
Interactions for Breakthrough Designated Products & Products Included in STeP	63				
Number Closed Before First RTA Action	5				
Number Accepted First RTA Cycle [1]	763				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	30				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	106				
Number Not Accepted First RTA Cycle	10				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.25%				

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	794				
Number with Non-MDUFA Action [3]	2				
Number with MDUFA Action	290				
Written Feedback Provided Within Goal	289				
Number Pending MDUFA Action	502				
Pending MDUFA Action Past Goal	2				
Number in MDUFA Cohort (up to max 4300)[4]	791				
Current Performance Percent Within Goal	98.97%				

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	290				
Average FDA Days to Written Feedback	54.98				
20th Percentile FDA Days to Written Feedback	45				
40th Percentile FDA Days to Written Feedback	55				
60th Percentile FDA Days to Written Feedback	60				
80th Percentile FDA Days to Written Feedback	65				
Maximum FDA Days to Written Feedback	70				

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	17				
Average Days to Scheduling for Meetings Scheduled After Day 30	36.35				

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]	106				
Meeting Minutes Submitted Within 15 Days of Meeting	69				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	12				
Meeting Minutes Past 15 Days of Meeting	6				
Meeting Minutes Not Submitted and >15 Days Since Meeting	19				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.40%				

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	114				
Interactions for Breakthrough Designated Products & Products Included in STeP	3				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Cycle [1]	92				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	3				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	17				
Number Not Accepted First RTA Cycle	2				
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.06%				

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 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	96				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	35				
Written Feedback Provided Within Goal	35				
Number Pending MDUFA Action	61				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	96				
Current Performance Percent Within Goal	97.22%				

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

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

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

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

Table 9.3 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	35				
Average FDA Days to Written Feedback	55.66				
20th Percentile FDA Days to Written Feedback	50				
40th Percentile FDA Days to Written Feedback	58				
60th Percentile FDA Days to Written Feedback	61				
80th Percentile FDA Days to Written Feedback	65				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	6				
Average Days to Scheduling for Meetings Scheduled After Day 30	39.17				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	12				
Meeting Minutes Submitted Within 15 Days of Meeting	6				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	1				
Meeting Minutes Not Submitted and >15 Days Since Meeting	3				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	60.00%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	173				
Interactions for Breakthrough Designated Products & Products Included in STeP	24				
Number Closed Before First RTA Action	1				
Number Accepted First RTA Cycle [1]	154				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	3				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	15				
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 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	157				
Number with Non-MDUFA Action [3]	1				
Number with MDUFA Action	61				
Written Feedback Provided Within Goal	60				
Number Pending MDUFA Action	95				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	155				
Current Performance Percent Within Goal	96.77%				

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	61				
Average FDA Days to Written Feedback	52.54				
20th Percentile FDA Days to Written Feedback	43				
40th Percentile FDA Days to Written Feedback	49				
60th Percentile FDA Days to Written Feedback	58				
80th Percentile FDA Days to Written Feedback	64				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	3				
Average Days to Scheduling for Meetings Scheduled After Day 30	36.33				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	27				
Meeting Minutes Submitted Within 15 Days of Meeting	18				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	1				
Meeting Minutes Not Submitted and >15 Days Since Meeting	7				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	69.23%				

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	102				
Interactions for Breakthrough Designated Products & Products Included in STeP	7				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Cycle [1]	85				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	12				
Number Not Accepted First RTA Cycle	3				
Rate of Submissions Not Accepted for Review on First RTA Cycle	3.33%				

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	87				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	29				
Written Feedback Provided Within Goal	29				
Number Pending MDUFA Action	58				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	87				
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 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	29				
Average FDA Days to Written Feedback	54.41				
20th Percentile FDA Days to Written Feedback	45				
40th Percentile FDA Days to Written Feedback	53				
60th Percentile FDA Days to Written Feedback	57				
80th Percentile FDA Days to Written Feedback	65				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	1				
Average Days to Scheduling for Meetings Scheduled After Day 30	42.00				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	13				
Meeting Minutes Submitted Within 15 Days of Meeting	7				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	3				
Meeting Minutes Past 15 Days of Meeting	0				
Meeting Minutes Not Submitted and >15 Days Since Meeting	3				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	70.00%				

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	74				
Interactions for Breakthrough Designated Products & Products Included in STeP	2				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Cycle [1]	64				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	8				
Number Not Accepted First RTA Cycle	2				
Rate of Submissions Not Accepted for Review on First RTA Cycle	3.03%				

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

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

Table 9.2 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	64				
Number with Non-MDUFA Action [3]	1				
Number with MDUFA Action	24				
Written Feedback Provided Within Goal	24				
Number Pending MDUFA Action	39				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	63				
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	24				
Average FDA Days to Written Feedback	51.00				
20th Percentile FDA Days to Written Feedback	40				
40th Percentile FDA Days to Written Feedback	54				
60th Percentile FDA Days to Written Feedback	59				
80th Percentile FDA Days to Written Feedback	63				
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	1				
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00				

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]	9				
Meeting Minutes Submitted Within 15 Days of Meeting	5				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0				
Meeting Minutes Past 15 Days of Meeting	2				
Meeting Minutes Not Submitted and >15 Days Since Meeting	2				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	55.56%				

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	83				
Interactions for Breakthrough Designated Products & Products Included in STeP	9				
Number Closed Before First RTA Action	2				
Number Accepted First RTA Cycle [1]	66				
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)	10				
Number Not Accepted First RTA Cycle	1				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.41%				

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

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

Table 9.2 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	70				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	17				
Written Feedback Provided Within Goal	17				
Number Pending MDUFA Action	53				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	70				
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 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	17				
Average FDA Days to Written Feedback	64.47				
20th Percentile FDA Days to Written Feedback	58				
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	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5				
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00				

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]	5				
Meeting Minutes Submitted Within 15 Days of Meeting	4				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	0				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	100.00%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	74				
Interactions for Breakthrough Designated Products & Products Included in STeP	8				
Number Closed Before First RTA Action	2				
Number Accepted First RTA Cycle [1]	64				
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)	4				
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 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	68				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	21				
Written Feedback Provided Within Goal	21				
Number Pending MDUFA Action	47				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	68				
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 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	21				
Average FDA Days to Written Feedback	48.67				
20th Percentile FDA Days to Written Feedback	42				
40th Percentile FDA Days to Written Feedback	47				
60th Percentile FDA Days to Written Feedback	50				
80th Percentile FDA Days to Written Feedback	62				
Maximum FDA Days to Written Feedback	70				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	7				
Meeting Minutes Submitted Within 15 Days of Meeting	6				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0				
Meeting Minutes Past 15 Days of Meeting	0				
Meeting Minutes Not Submitted and >15 Days Since Meeting	1				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	85.71%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	225				
Interactions for Breakthrough Designated Products & Products Included in STeP	9				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Cycle [1]	179				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	14				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	31				
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 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	193				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	79				
Written Feedback Provided Within Goal	79				
Number Pending MDUFA Action	114				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	193				
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 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	79				
Average FDA Days to Written Feedback	57.01				
20th Percentile FDA Days to Written Feedback	49				
40th Percentile FDA Days to Written Feedback	59				
60th Percentile FDA Days to Written Feedback	63				
80th Percentile FDA Days to Written Feedback	66				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	1				
Average Days to Scheduling for Meetings Scheduled After Day 30	35.00				

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]	16				
Meeting Minutes Submitted Within 15 Days of Meeting	11				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	2				
Meeting Minutes Not Submitted and >15 Days Since Meeting	1				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%				

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	70				
Interactions for Breakthrough Designated Products & Products Included in STeP	1				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Cycle [1]	59				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	9				
Number Not Accepted First RTA Cycle	2				
Rate of Submissions Not Accepted for Review on First RTA Cycle	3.28%				

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

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

Table 9.2 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	59				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	24				
Written Feedback Provided Within Goal	24				
Number Pending MDUFA Action	35				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	59				
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	24				
Average FDA Days to Written Feedback	56.92				
20th Percentile FDA Days to Written Feedback	51				
40th Percentile FDA Days to Written Feedback	55				
60th Percentile FDA Days to Written Feedback	60				
80th Percentile FDA Days to Written Feedback	65				
Maximum FDA Days to Written Feedback	67				

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

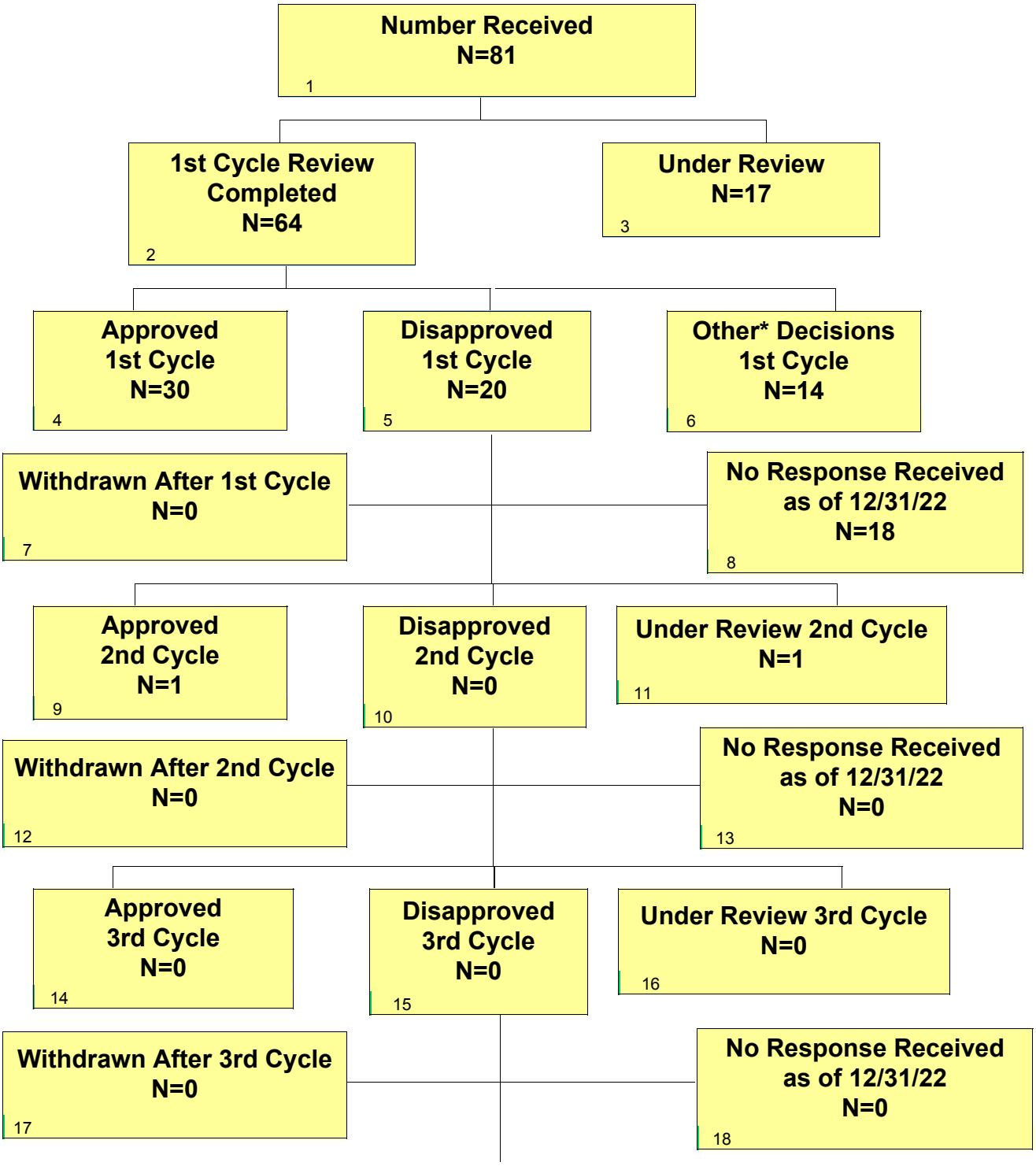
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00				

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]	17				
Meeting Minutes Submitted Within 15 Days of Meeting	12				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	3				
Meeting Minutes Past 15 Days of Meeting	0				
Meeting Minutes Not Submitted and >15 Days Since Meeting	2				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	85.71%				

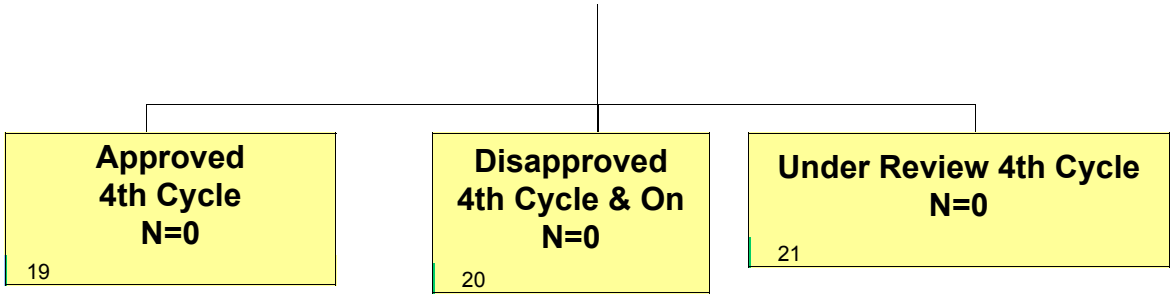
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 12/31/22



*** Other decisions include withdrawn (N=2), withdrawn and converted (N=10), RTA (N=0), nonsignificant risk device (N=2), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=0), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 12/31/22



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	81				
Average Number of Cycles to IDE Approval or Conditional Approval	1.03				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.03				

Section 10 IDE - Office Level Metric

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	9				
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 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	16				
Average Number of Cycles to IDE Approval or Conditional Approval	1.20				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.20				

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	9				
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 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	11				
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 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	16				
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 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	8				
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 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	11				
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	1				
Average Number of Cycles to IDE Approval or Conditional Approval	N/A				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	N/A				

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Section 11 CLIA Waiver Annual Metrics

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

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

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

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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 (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th 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 IV 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 IV decision and 5% of submissions with the highest number of Total Days to MDUFA IV 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 IV 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 IV 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 submissions with MDUFA decision (line 3) made within 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 IV 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 IV 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 IV 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 IV 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 /TSreview 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 IV Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA IV 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 IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA IV 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 IV 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 IV Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV 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 IV 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 PercentWithin 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 IV 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 IV 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 Feedack for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
4	40th Percentile FDA Days to Written Feedback	40th percentile FDA days to Written Feedack for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
5	60th Percentile FDA Days to Written Feedback	60th percentile FDA days to Written Feedack for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
6	80th Percentile FDA Days to Written Feedback	80th percentile FDA days to Written Feedack for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100th percentile) to Written Feedack for Pre-Subs with MDUFA IV 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 IV Decision Performance Goals – Definitions

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

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

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

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

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV 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 IV Decision - Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV 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 IV Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA IV 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 IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 180 FDA Days	Number of submissions with MDUFA IV decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	Number of submissions pending MDUFA IV Decision for more than 180 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA IV Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

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

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

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

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV 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 IV Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision, and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV 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 31 December 2022

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	2				
Closed Before RTA Action	0				
Number with Accepted RTA Review	2				
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	2				
Number Accepted	2				
Completed RTF	2				
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2				
SI Goal Met	0				
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	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	0				
Average Number of FDA Days to Substantive Interaction	0.00				
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 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

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
Number of PMAs Filed	2				
Non-MDUFA V Decision	0				
MDUFA V Decision	0				
MDUFA V Decision Goal Met	0				
PMAs Pending MDUFA V Decision	2				
PMAs Pending MDUFA V Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

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
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	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				
Maximum Industry Days to MDUFA V Decision	0				
Average Total Days to MDUFA V Decision	0.00				
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 1.8 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	2				
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 1.10 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	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
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	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
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	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2				
SI Goal Met	0				
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	N/A				

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

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

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

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

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

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

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

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

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

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

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

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	8				
Closed Before RTA Action	0				
Number Accepted	6				
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	2				
Rate of Submissions Not Accepted for Review	25.00%				

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	6				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	6				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	0				
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 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	6				
Average Number of FDA Days to Substantive Interaction	45.17				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	45				
60th Percentile FDA Days to Substantive Interaction	51				
80th Percentile FDA Days to Substantive Interaction	57				
Maximum FDA Days to Substantive Interaction	60				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	6				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	3				
MDUFA V Decision Within 90 FDA Days	3				
510(k)s Pending MDUFA V Decision	3				
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	1.00				
Number With MDUFA V Decision	3				
Average Number of FDA Days to MDUFA V Decision	49.33				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	30				
60th Percentile FDA Days to MDUFA V Decision	42				
80th Percentile FDA Days to MDUFA V Decision	66				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of 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 Number of Total Days to MDUFA V Decision	49.33				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	30				
60th Percentile Total Days to MDUFA V Decision	42				
80th Percentile Total Days to MDUFA V Decision	66				
Maximum Total Days to MDUFA V Decision	90				

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	6				
Number With MDUFA V Decision	3				
Number of SE Decision	3				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	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				

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 (see box 5 in flowchart).

Table 8.2 CBER - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	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 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	0.00				
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	0				
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	20				
Interactions for Breakthrough Designated Products & Products Included in STeP	0				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Cycle [1]	15				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	3				
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	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	17				
Number with Non-MDUFA Action [3]	0				
Number with MDUFA Action	4				
Written Feedback Provided Within Goal	4				
Number Pending MDUFA Action	12				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	16				
Current Performance Percent Within Goal	80.00%				

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

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

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

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

Table 9.3 CBER – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	4				
Average FDA Days to Written Feedback	48.25				
20th Percentile FDA Days to Written Feedback	36				
40th Percentile FDA Days to Written Feedback	52				
60th Percentile FDA Days to Written Feedback	56				
80th Percentile FDA Days to Written Feedback	63				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0				
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]	0				
Meeting Minutes Submitted Within 15 Days of Meeting	0				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0				
Meeting Minutes Past 15 Days of Meeting	0				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	N/A				

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	6				
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
****Annual Metrics and Goals will be reported in the Annual Report****

Medical Devices

Guidance Documents

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

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

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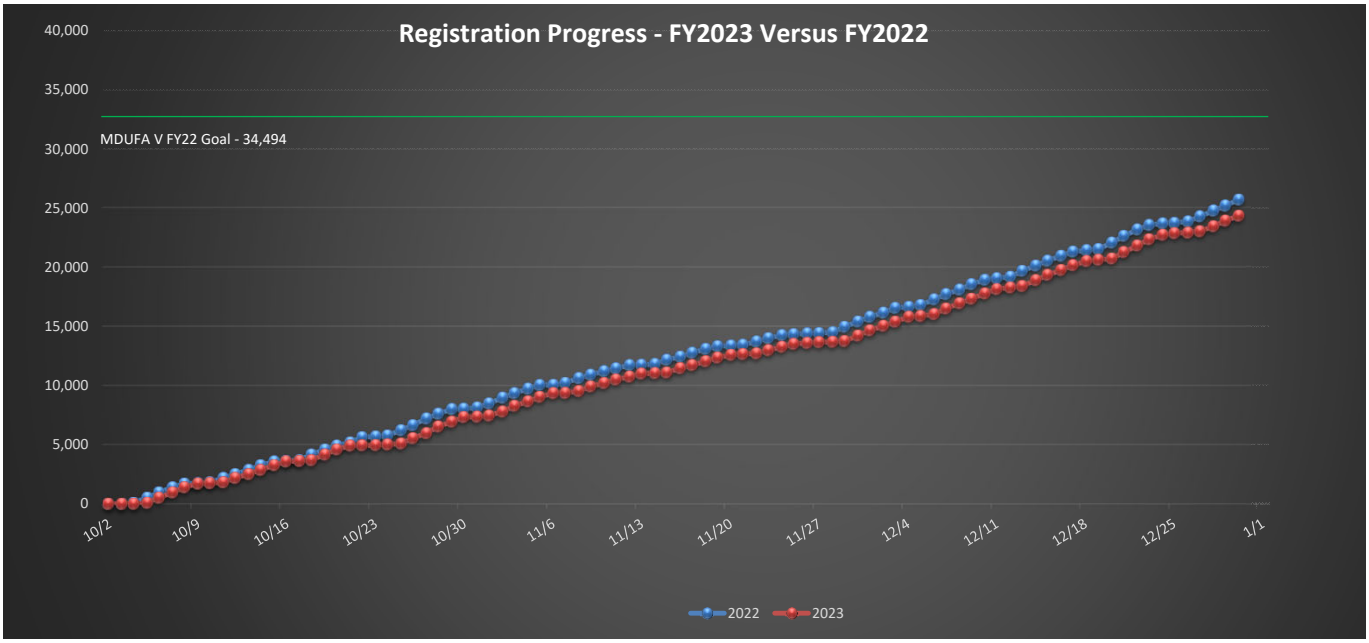
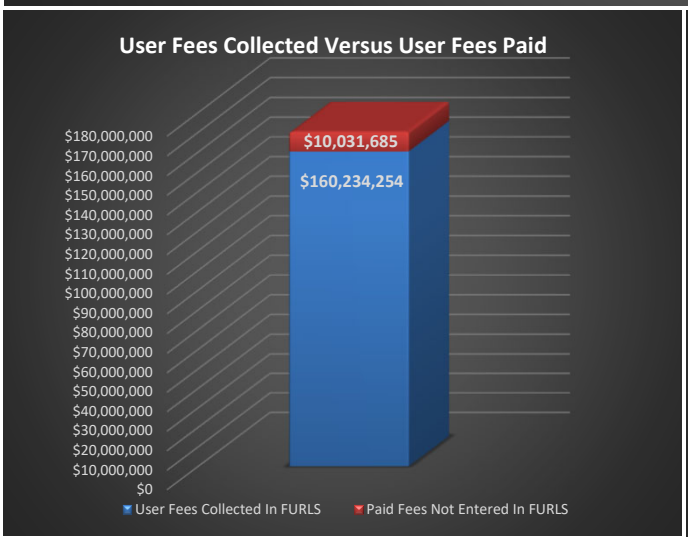
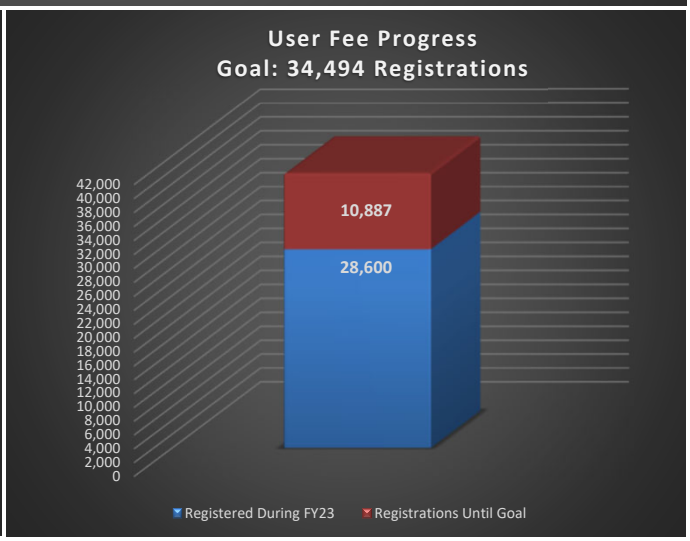
MDUFA V Registrations - 1st Quarter Summary FY2023*

Current Active Registrations by Type	FY23 Q1			FY22 Year End Active Totals			FY23 vs End FY22
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,639	10,170	15,809	6,848	12,892	19,738	80.09%
Contract Manufacturer	1,020	1,583	2,603	1,234	1,798	3,032	85.85%
Contract Sterilizer	64	154	218	68	166	234	93.16%
Specification Developer	1,312	471	1,783	1,768	573	2,341	76.16%
Reprocessor of Single Use Devices	21	4	25	25	5	30	83.33%
U.S. Manufacturer of Export Only Devices	101	0	101	138	0	138	73.19%
Repackager/Relabeler	861	169	1,030	1,178	209	1,387	74.26%
Remanufacturer	12	7	19	22	10	32	59.38%
Foreign Exporter/Private Label Distributor		910	910		1,156	1,156	78.72%
Initial Importer	2,600		2,600	3,640		3,640	71.43%
Unknown	1	4	5	6	12	18	27.78%
Total:	**11,631**	**13,472**	**25,103**	**14,927**	**16,821**	**31,748**	**79.07%**

*Note: This data is current as of 12/30/2022







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FY 2023 Medical Device User Fee Collections as of December 31th, 2022 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$163,818,852	$0	$163,818,852		
Application Fees	$20,606,695	-$47,246	$20,559,449		
Total	**$184,425,547**	**-$47,246**	**$184,378,301**	**$324,777,000**	**57%**
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	$147,161,473	$137,786,377
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,901,501	$208,750,786	$215,646,830	$275,384,378	$270,137,833
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$184,378,301				

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

CDRH Data 1st Quarter FY 2023 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	0	0
PMA	0	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	0
De Novo Classification	2	20
180-Day Supplements	1	1
Real-Time Supplements	0	4
510(k)s	13	295
30-day Notices /135 day supplements*	2	3
513(g)s	0	13
PMA Annual Report	0	12
Total	**18**	**348**

[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 4 Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually.

***135-day supplements were initially received and paid as 30-day notices; totals are combinations of both cohorts**