Agenda for Quarterly Meeting on
MDUFA IV (FY 2018-2022) Performance

November 16, 2022, 12:00 – 1:30 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through September 30, 2022

- Report on decision goals for 4th Quarter FY 2022
- Shared outcome goals

Guidance Development

Registration and Listing

Qualitative Update on Finances – 4th Quarter FY 2022

- User fee receipts through the 4th Quarter FY 2022
- Funding to enhance scientific review capacity

Quality Management Update

- Summary of FY 2022 activities
- Planning for FY 2023 audits

CDRH Training Update

ASCA Update

Report of Implementation on Deficiency Performance Improvements

Implementation of MDUFA V

Page intentionally left blank

Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data
----Actions through 30 September 2022

Page intentionally left blank

Table of Contents

Page intentionally left blank

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

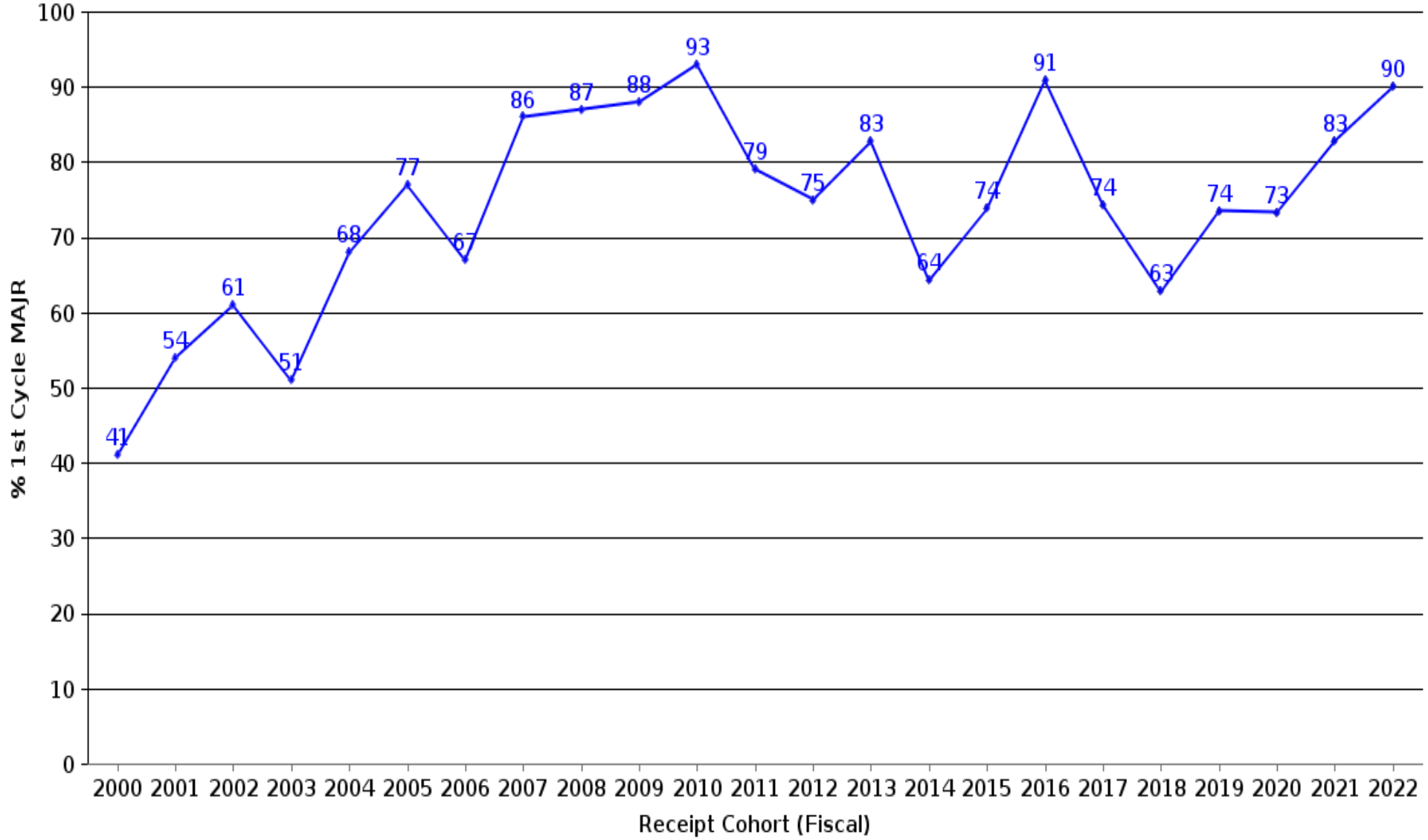
Note: Data may change in subsequent quarterly and annual reports.

Page intentionally left blank

PMAs

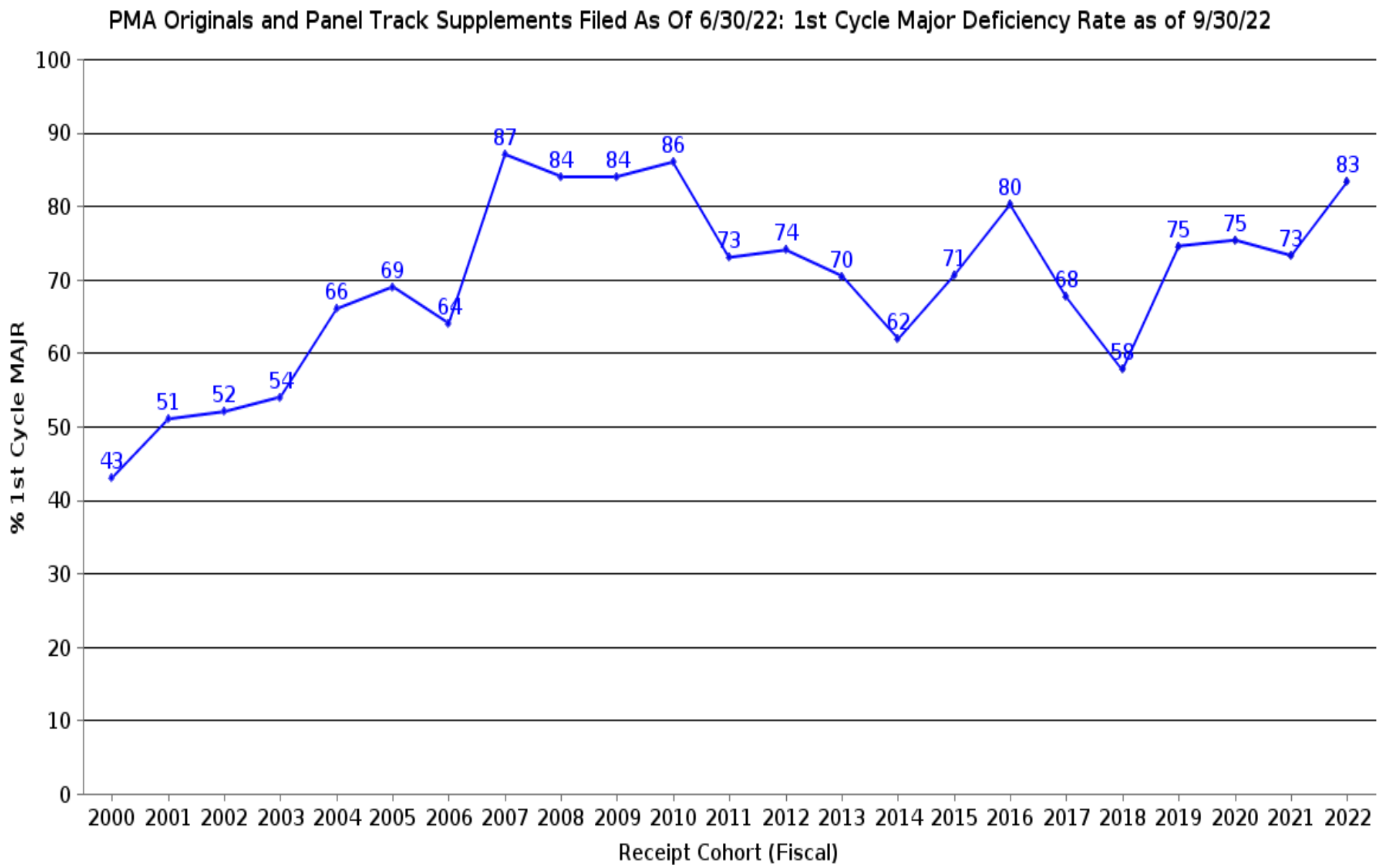
Q4FY2022

PMA Originals Filed As Of 6/30/22: 1st Cycle Major Deficiency Rate as of 9/30/22



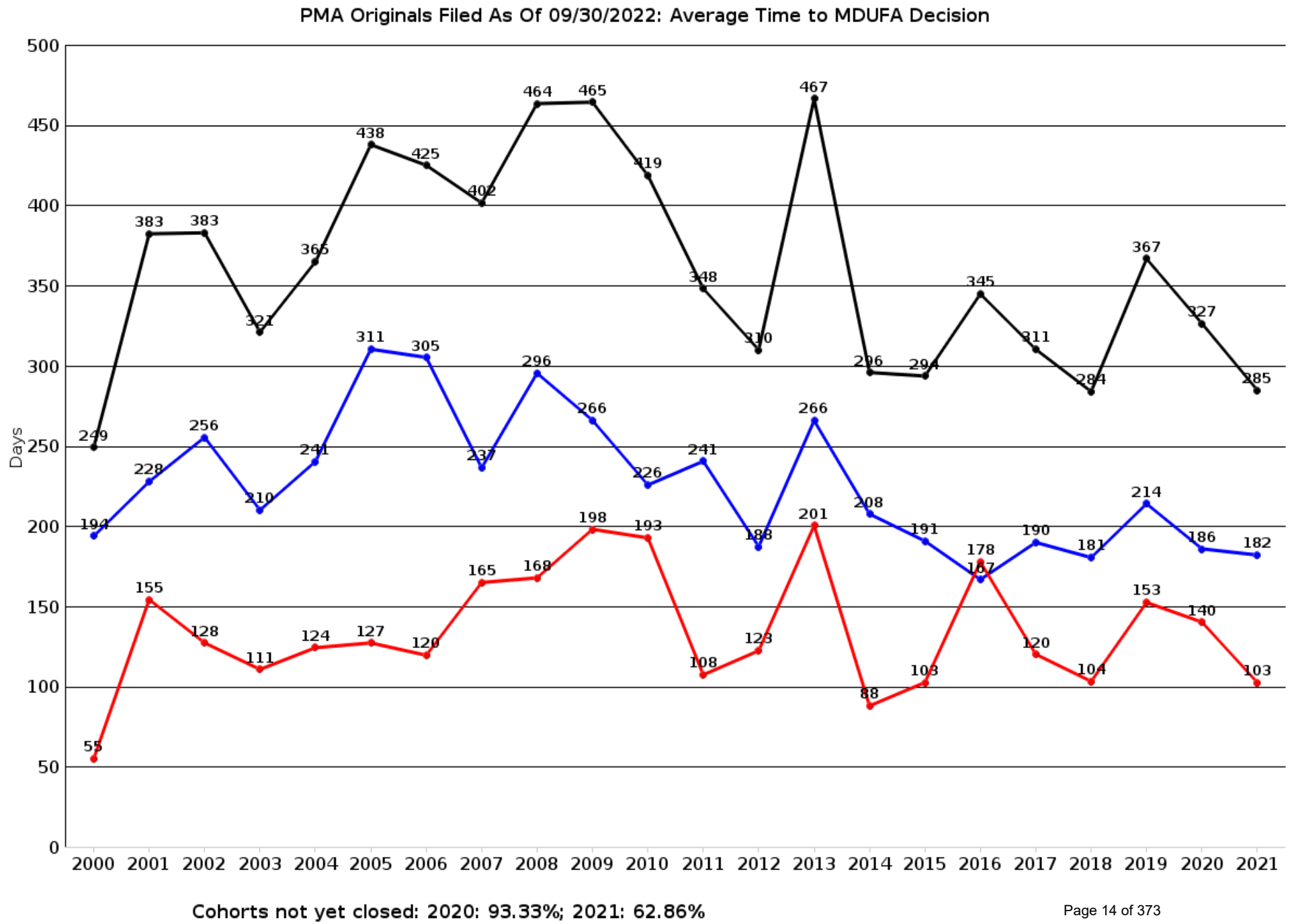
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/22.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

♦ % 1st Cycle MAJR PMAO

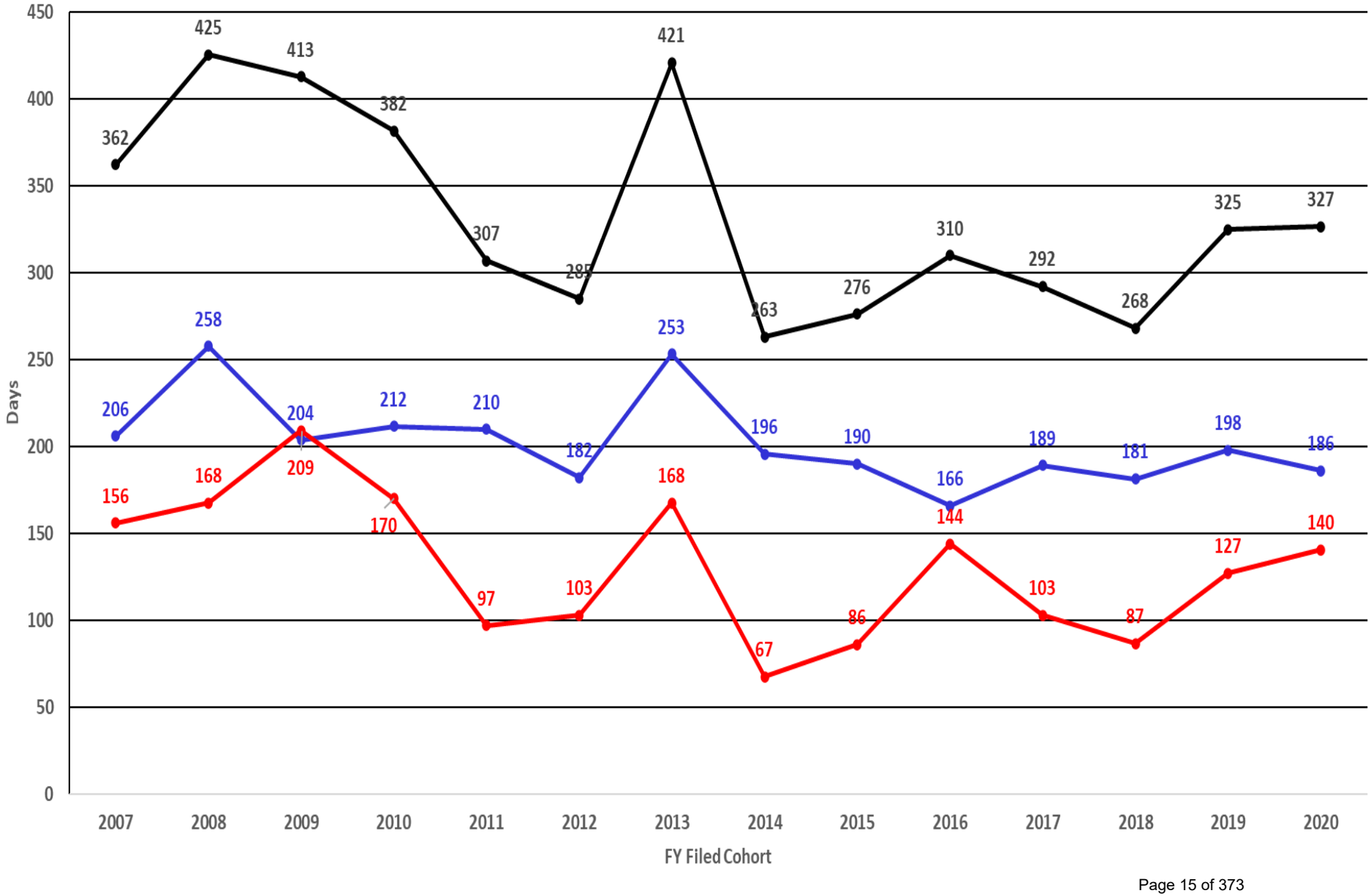


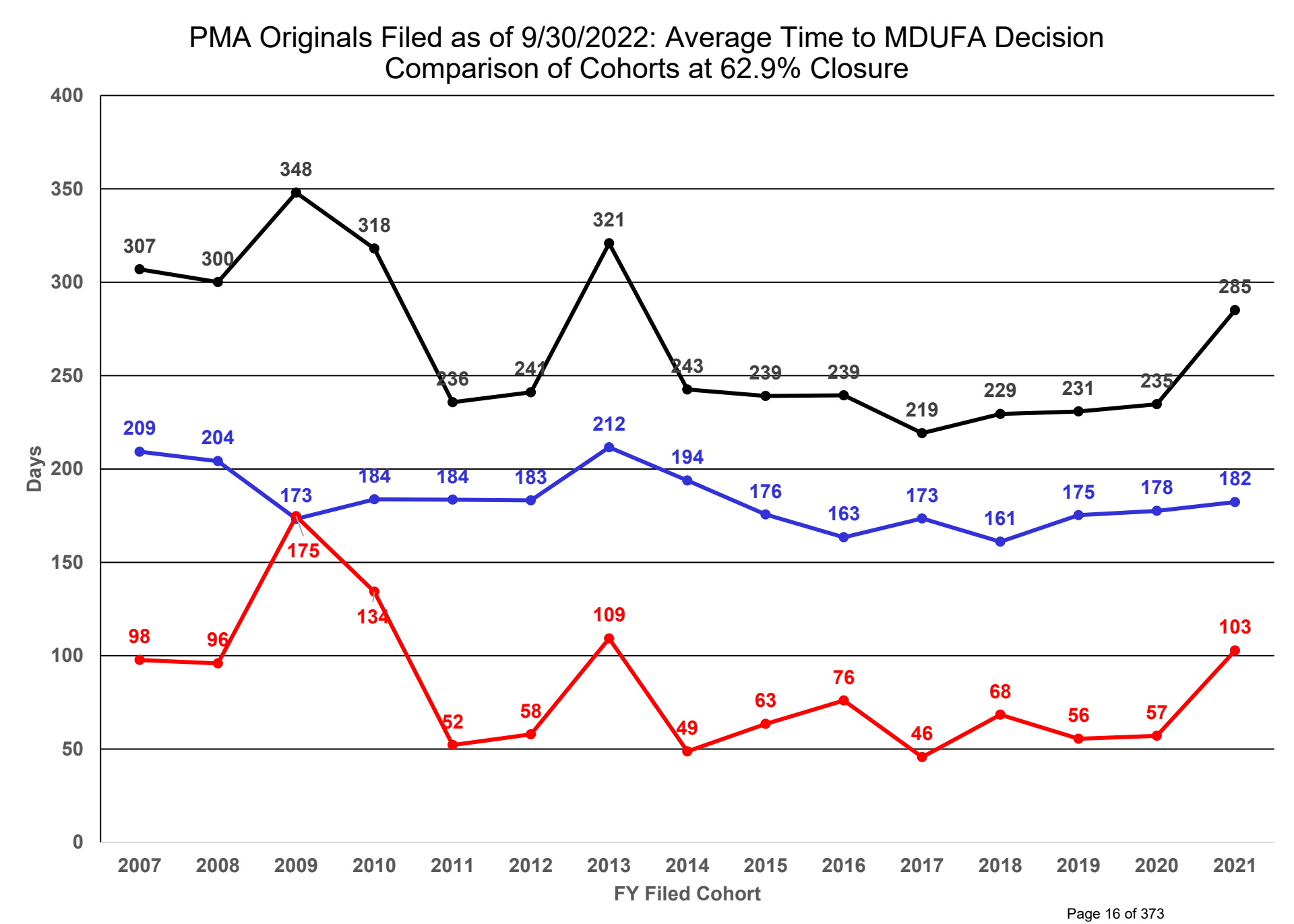
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/22. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

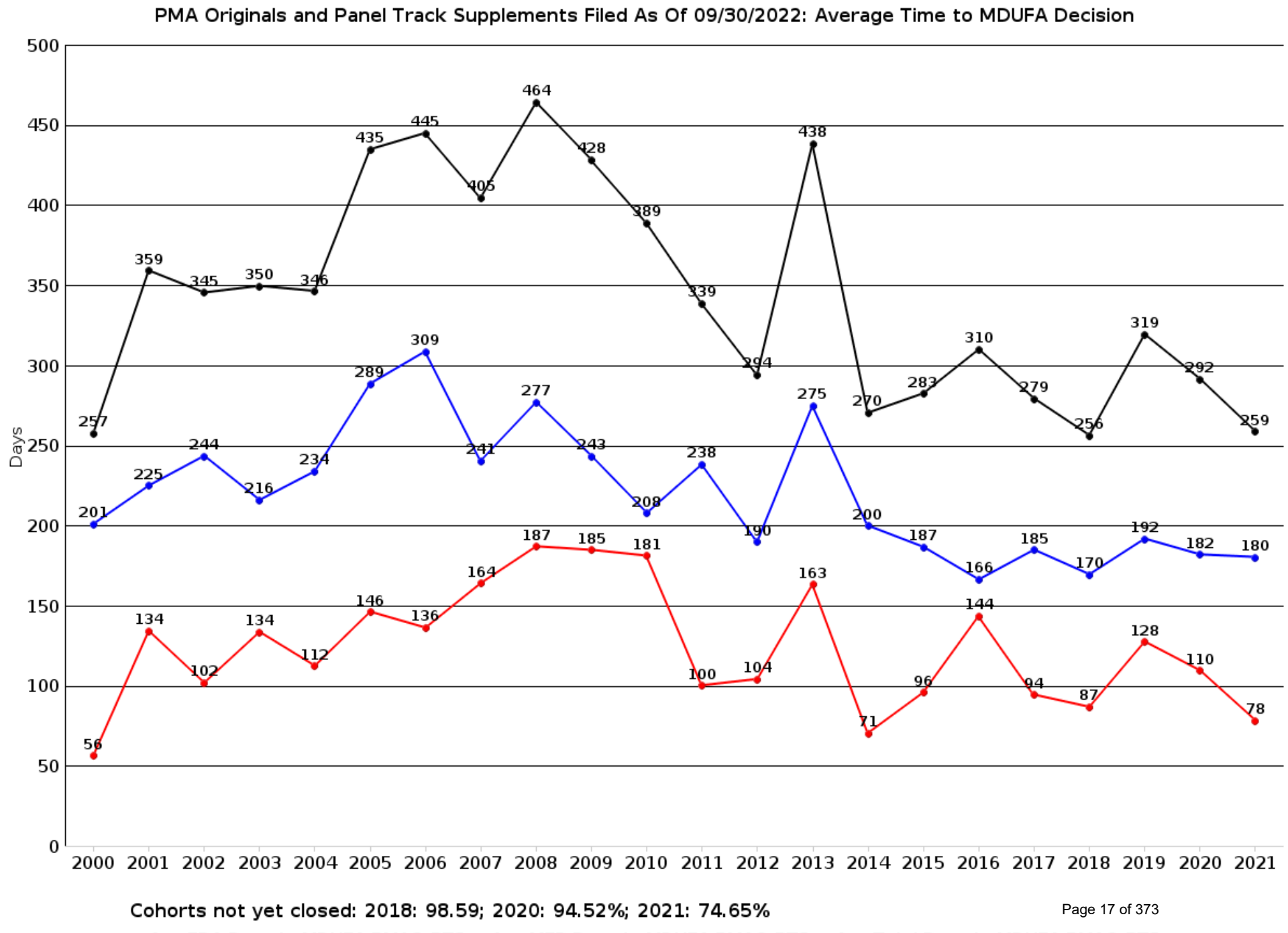
♦ % 1st Cycle MAJR PMAO/PTS


PMA Originals Filed As Of 09/30/2022: 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
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 327 285
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 88 103 167 120 104 153 140 103
Cohorts not yet closed: 2020: 93.33%; 2021: 62.86%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO

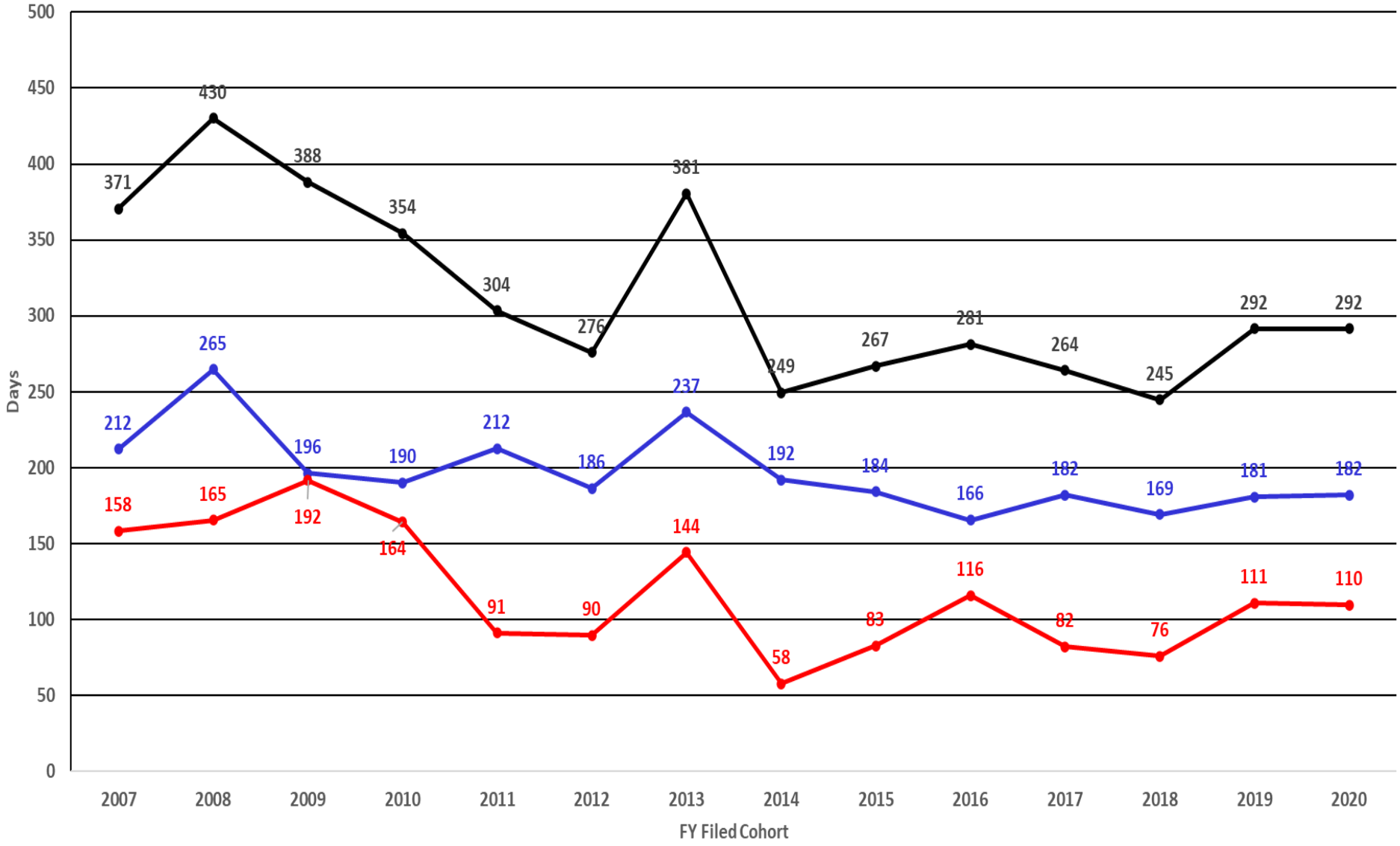
PMA Originals Filed as of 9/30/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 93.3% Closure



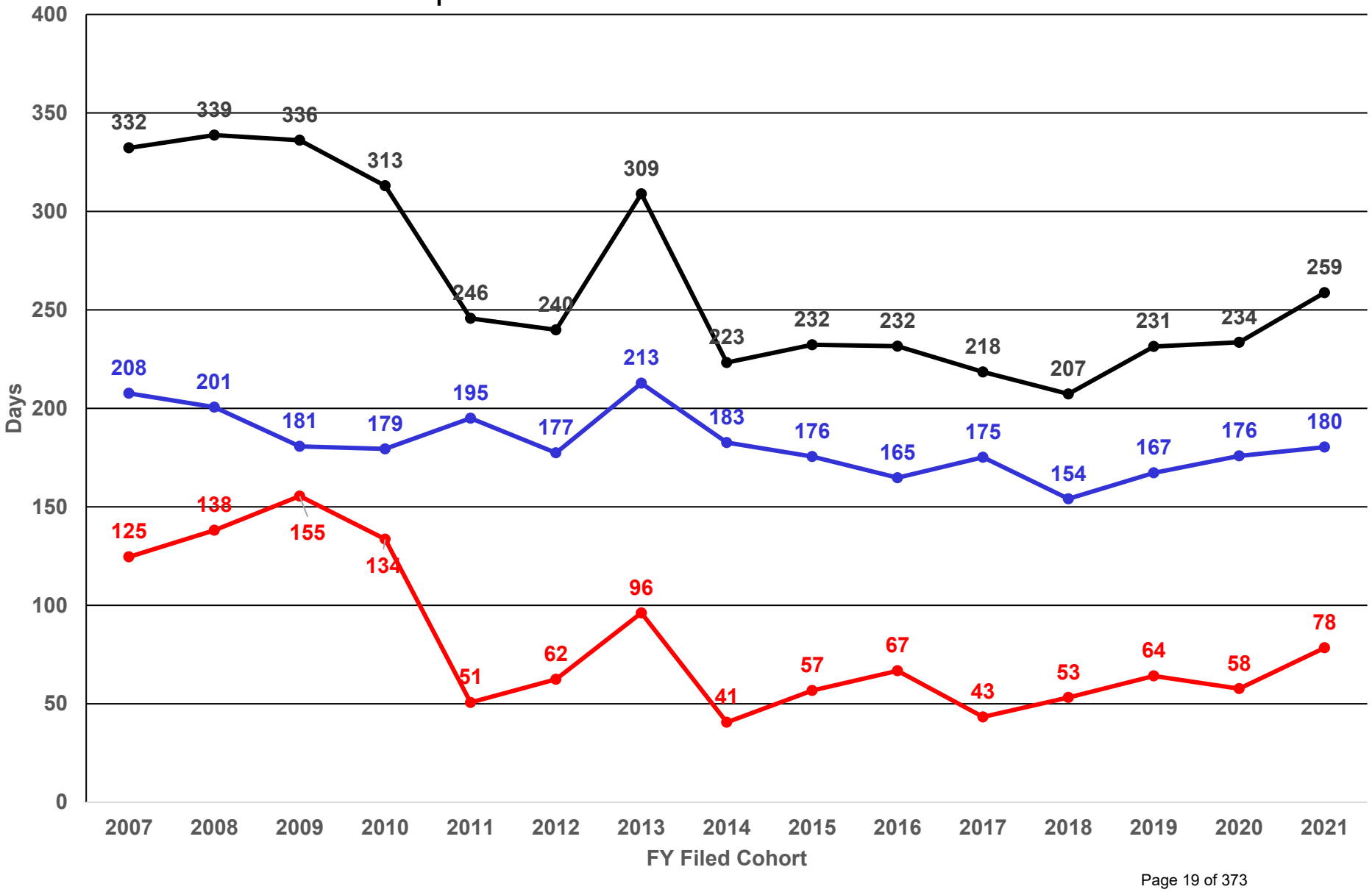

PMA Originals Filed as of 9/30/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 62.9% Closure
Days
400
350
300
250
200
150
100
50
0
307
300
348
318
236
241
321
243
239
239
219
229
231
235
285
209
204
173
184
184
183
212
194
176
163
173
161
175
178
182
98
96
175
134
52
58
109
49
63
76
46
68
56
57
103
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

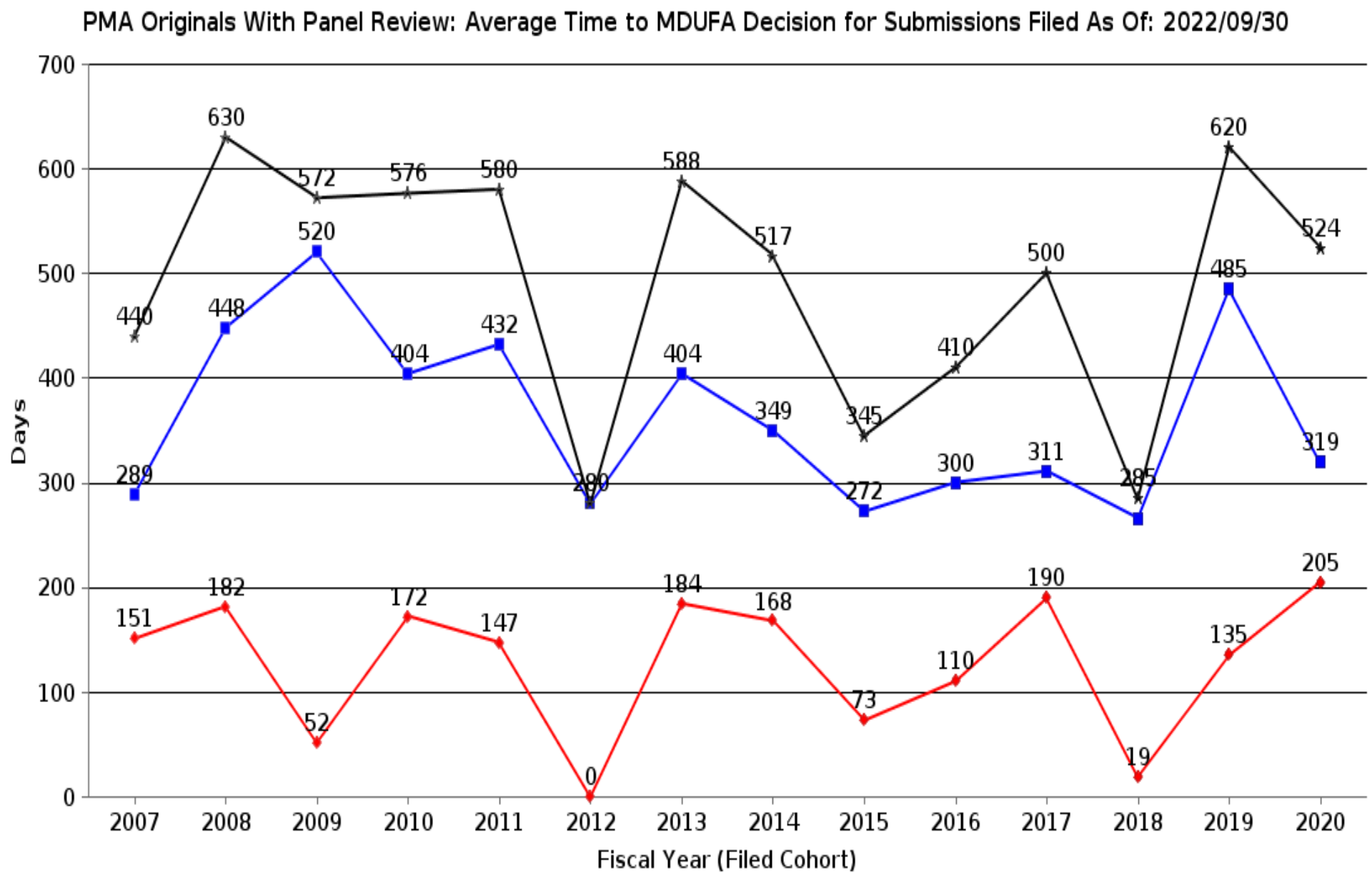

PMA Originals and Panel Track Supplements Filed As Of 09/30/2022: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 256 319 292 259
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 182 180
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 87 128 110 78
Cohorts not yet closed: 2018: 98.59; 2020: 94.52%; 2021: 74.65%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

PMA Originals and Panel Track Supplements Filed as of 9/30/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 94.5% Closure



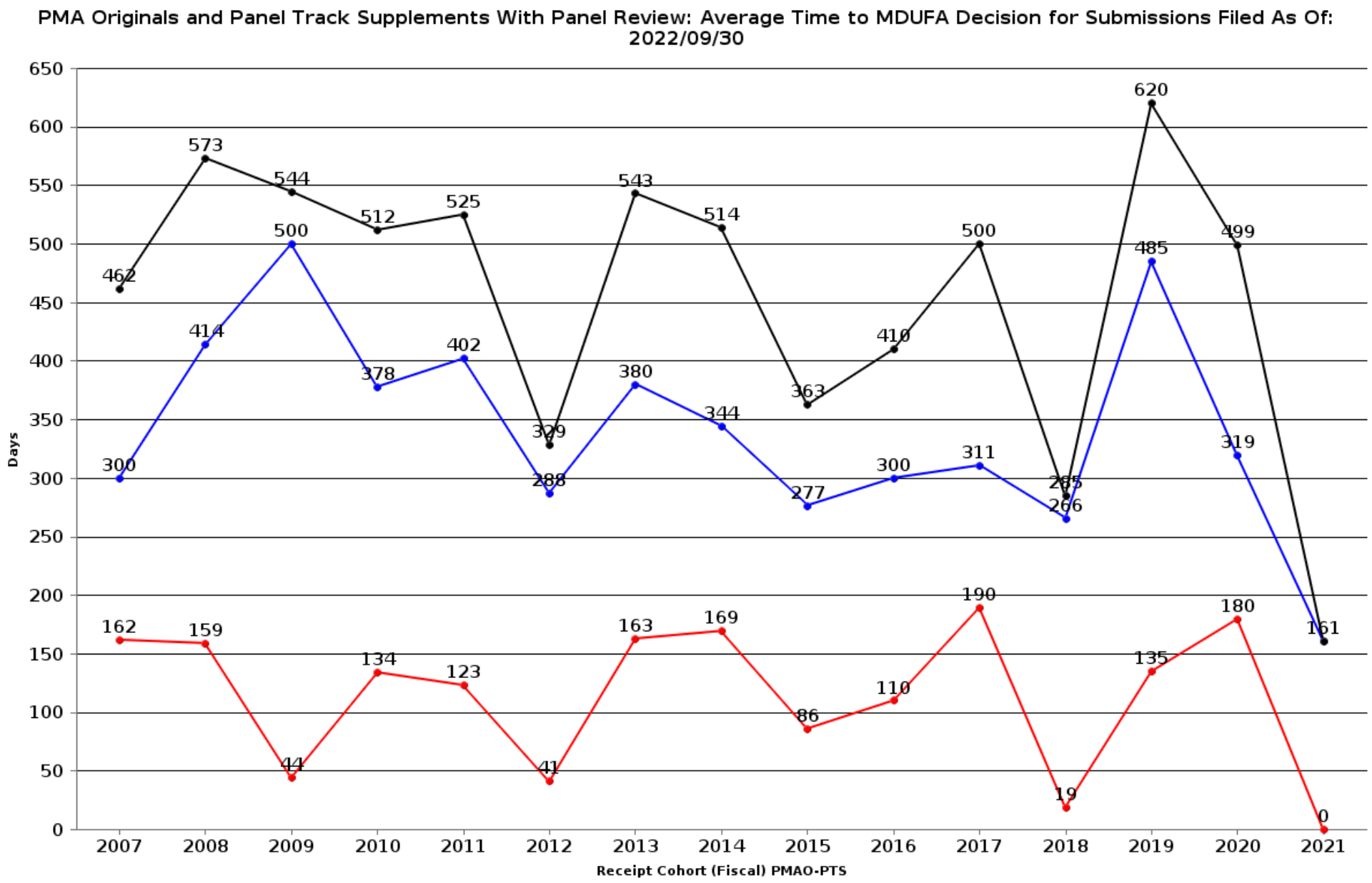
PMA Originals and Panel Track Supplements Filed as of 9/30/2022: Average Time to MDUFA Decision
Comparison of Cohorts at 74.7% Closure



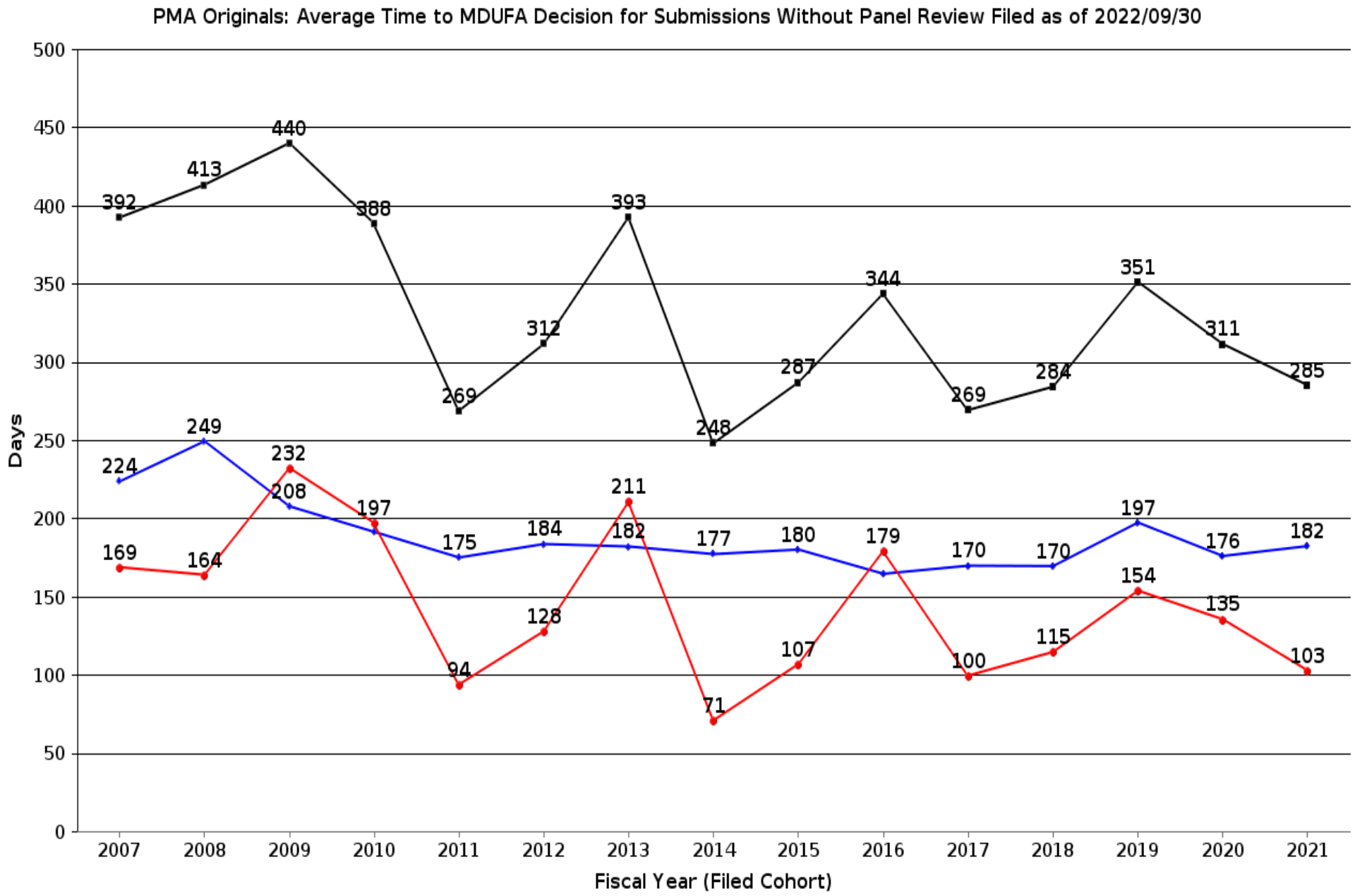


Numbers Filed/Closed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3

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

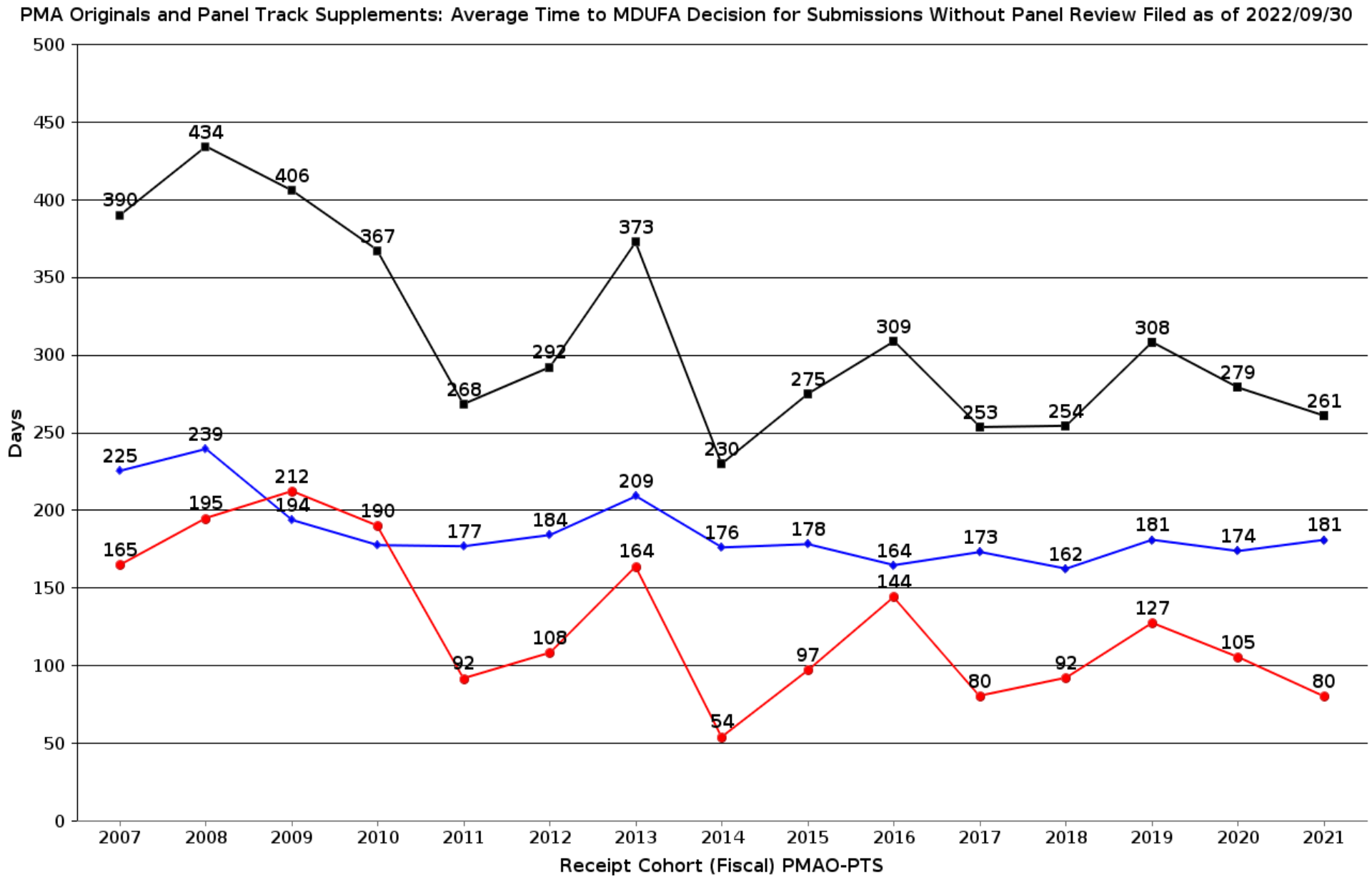


Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.



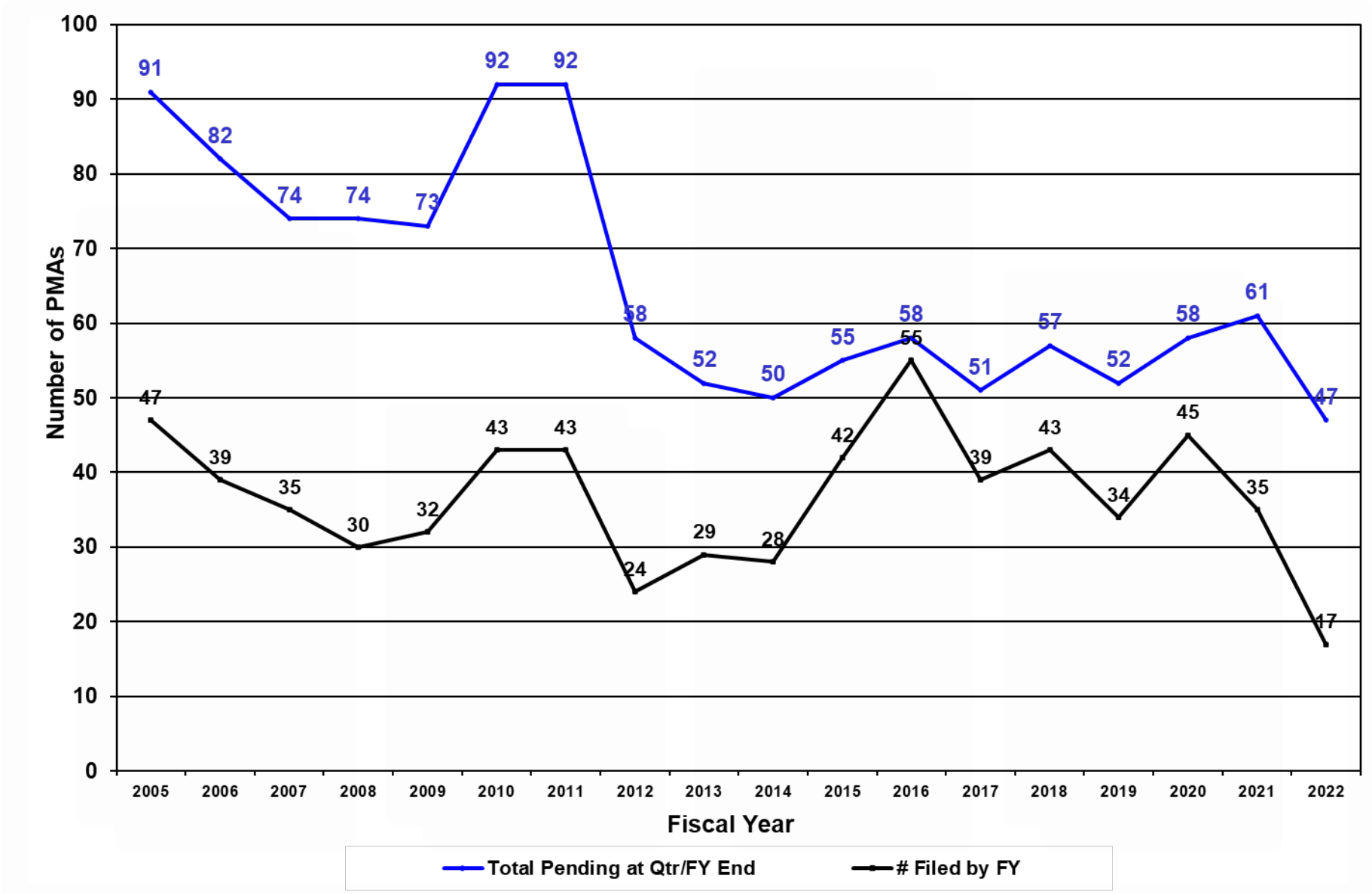
Numbers Filed/Closed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/39; 2021 = 42/22

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



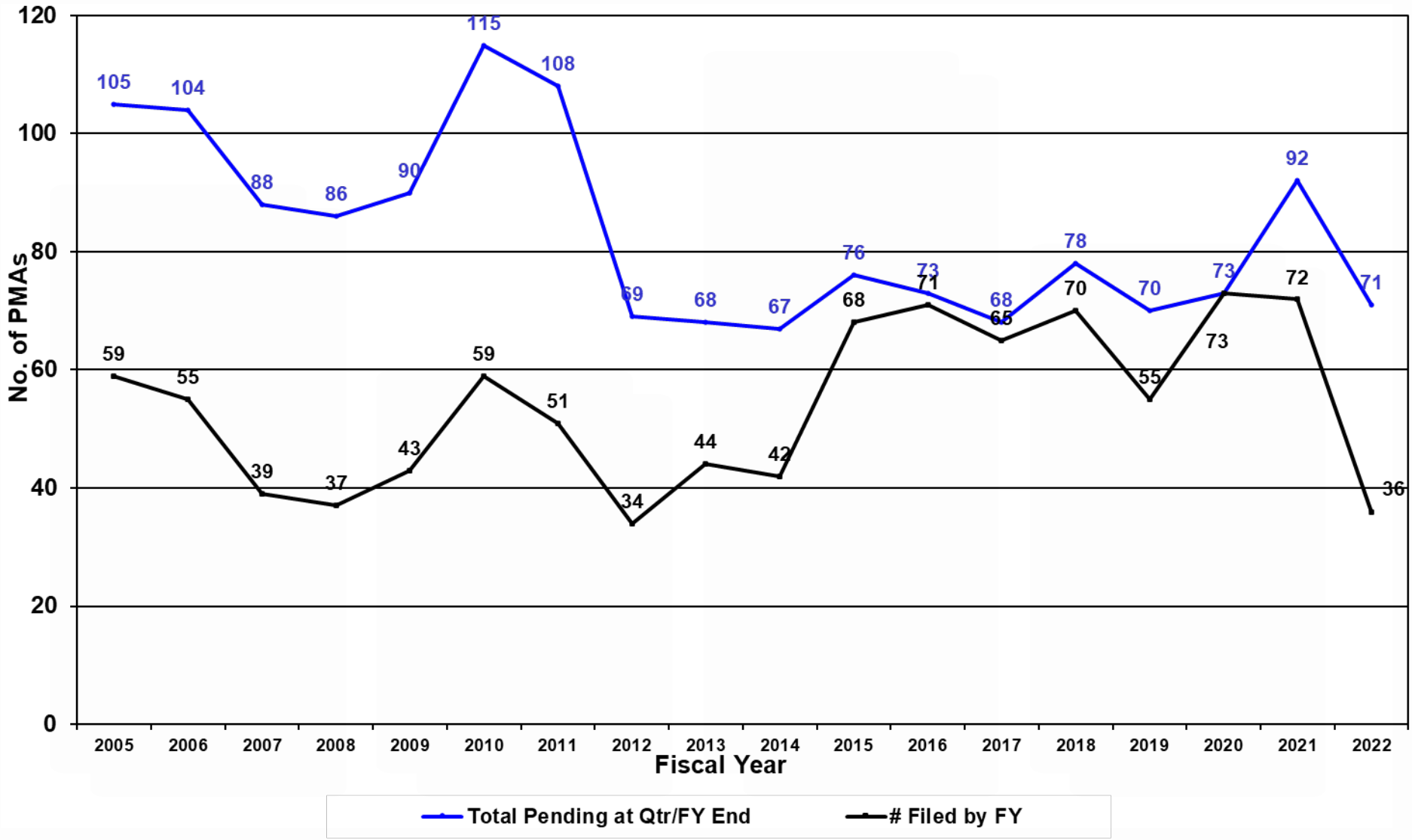
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

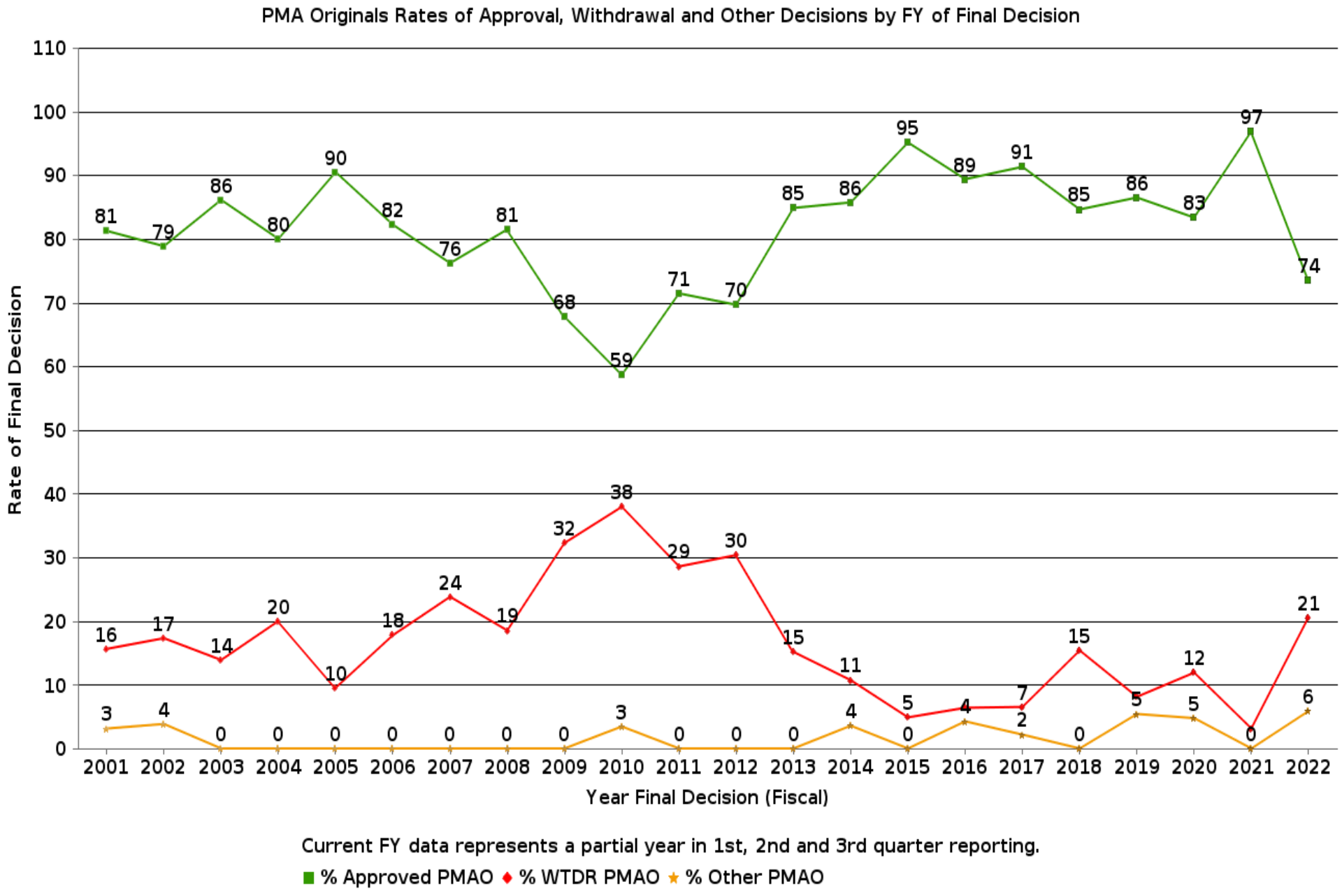


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year. For the current FY, numbers filed are updated starting in Q2.

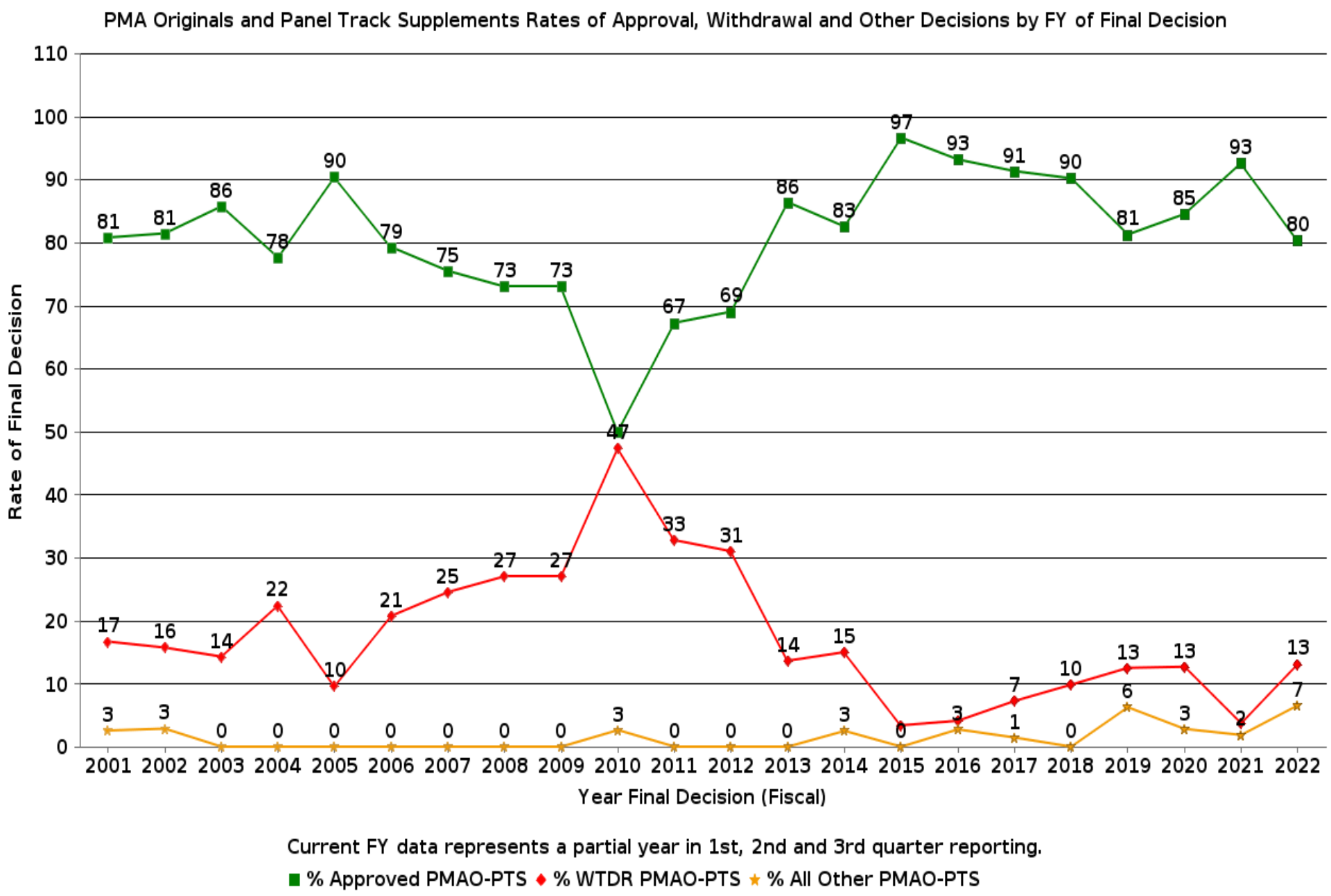
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



***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. For the current FY, numbers filed are updated starting in Q2.**

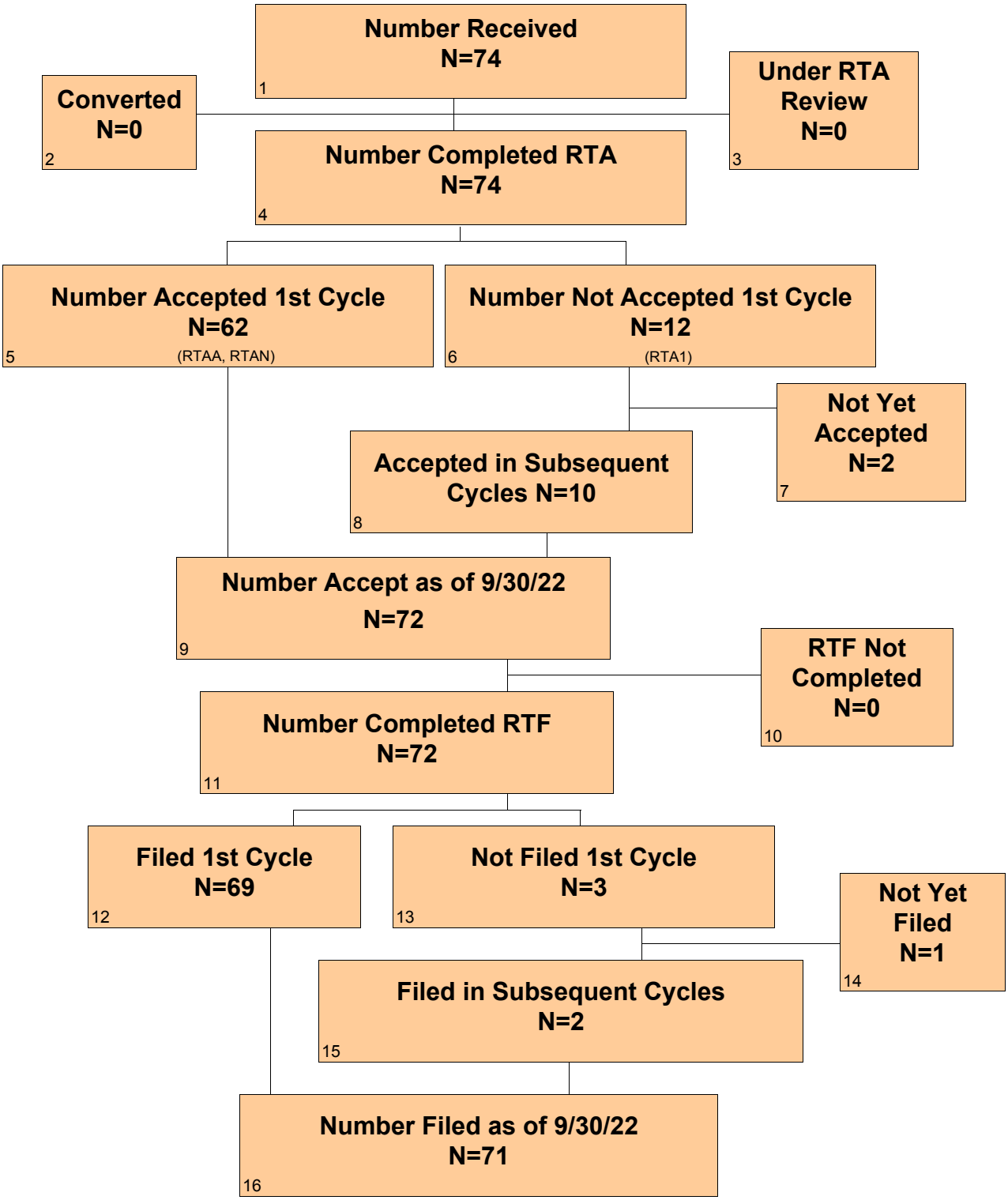


Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

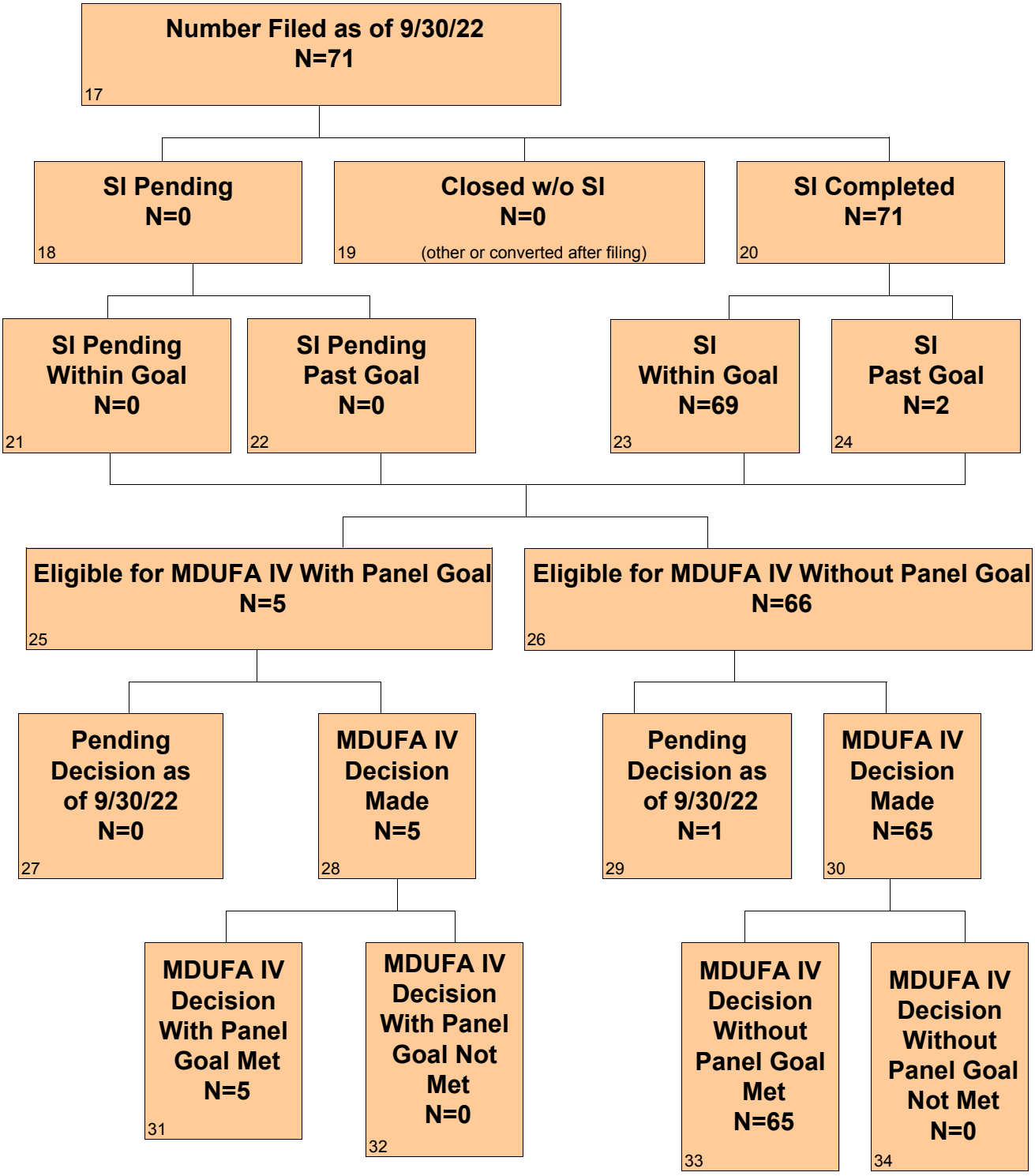


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

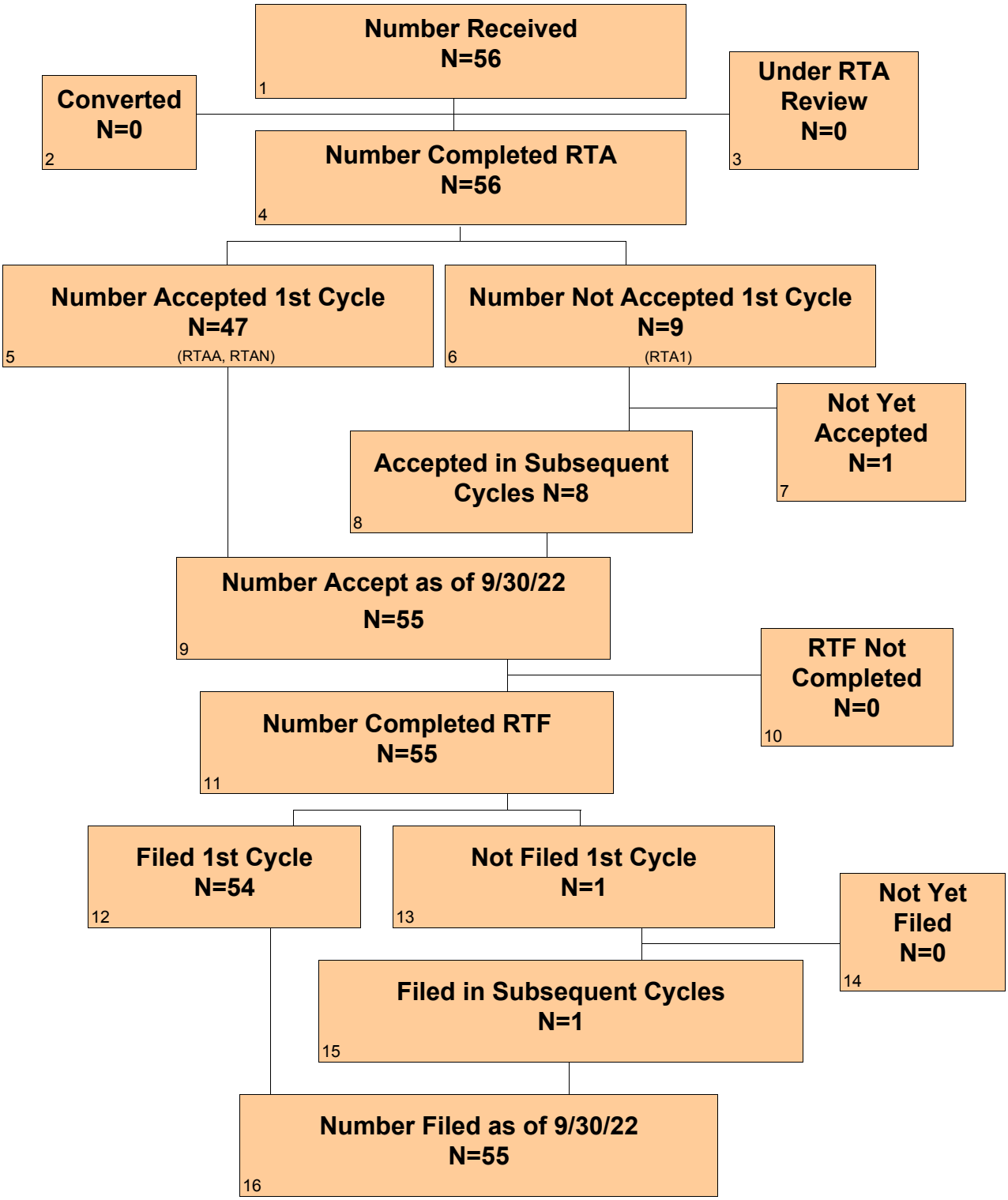
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/22



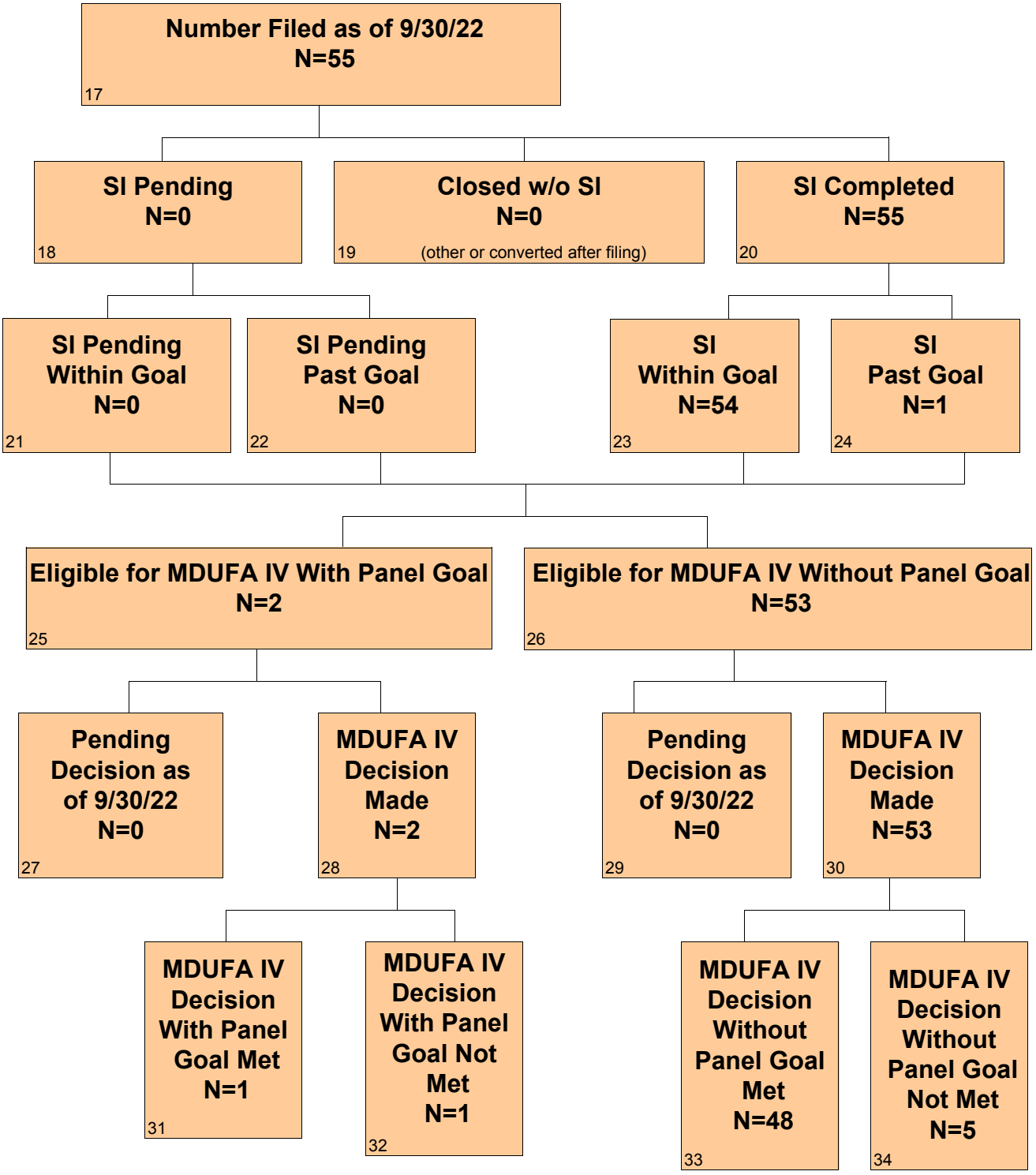
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/22 Continued



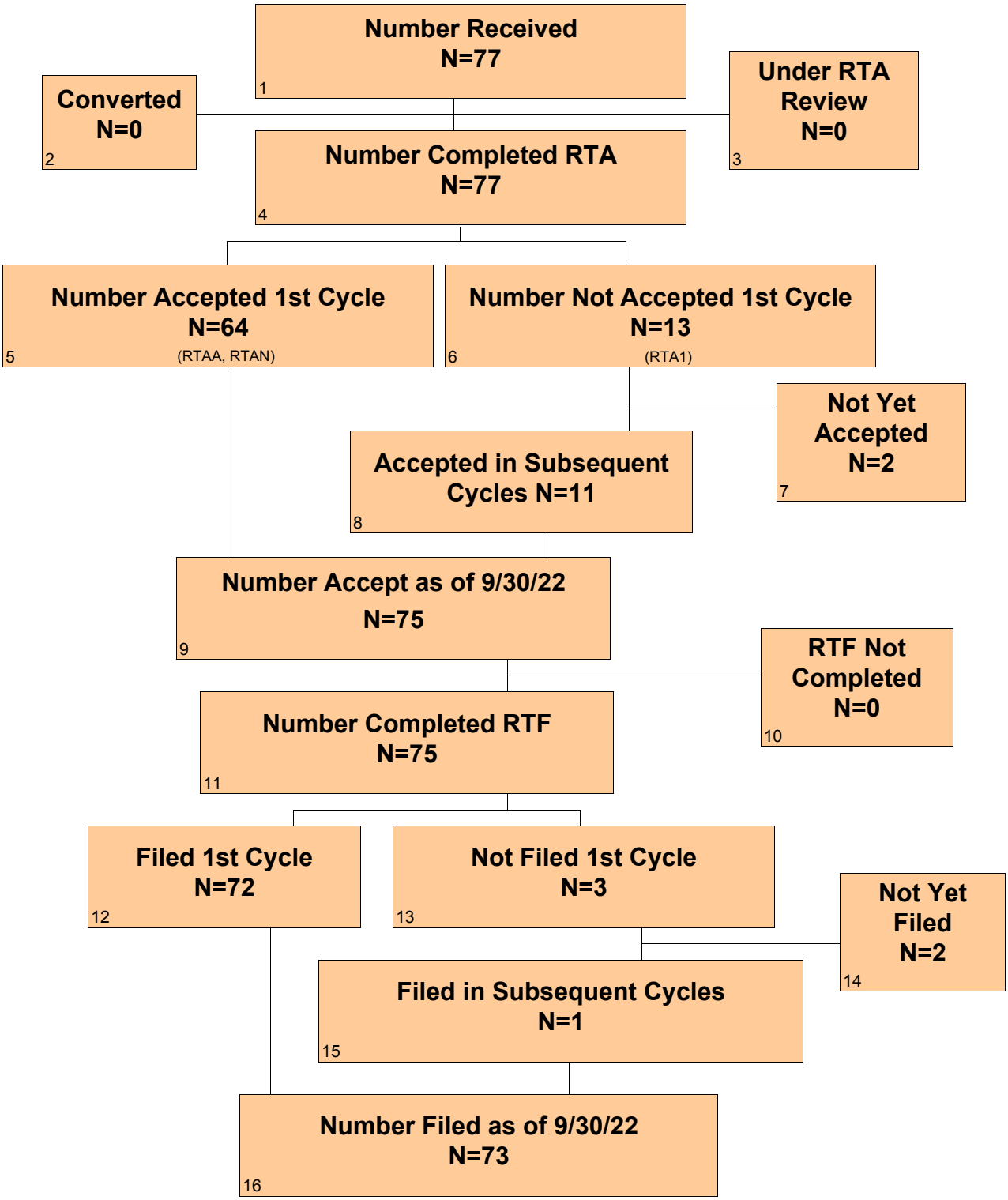
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/22



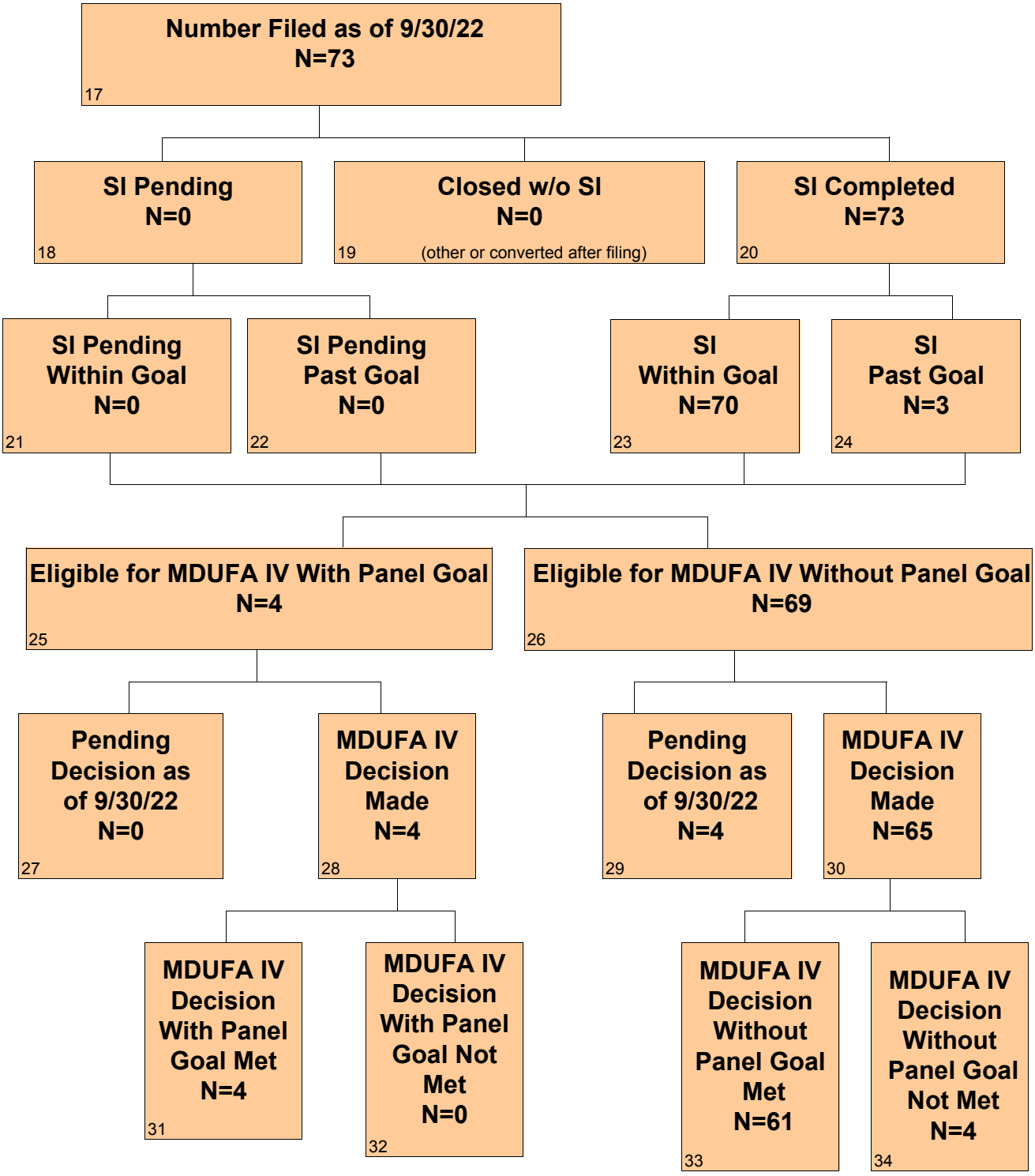
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/22 Continued



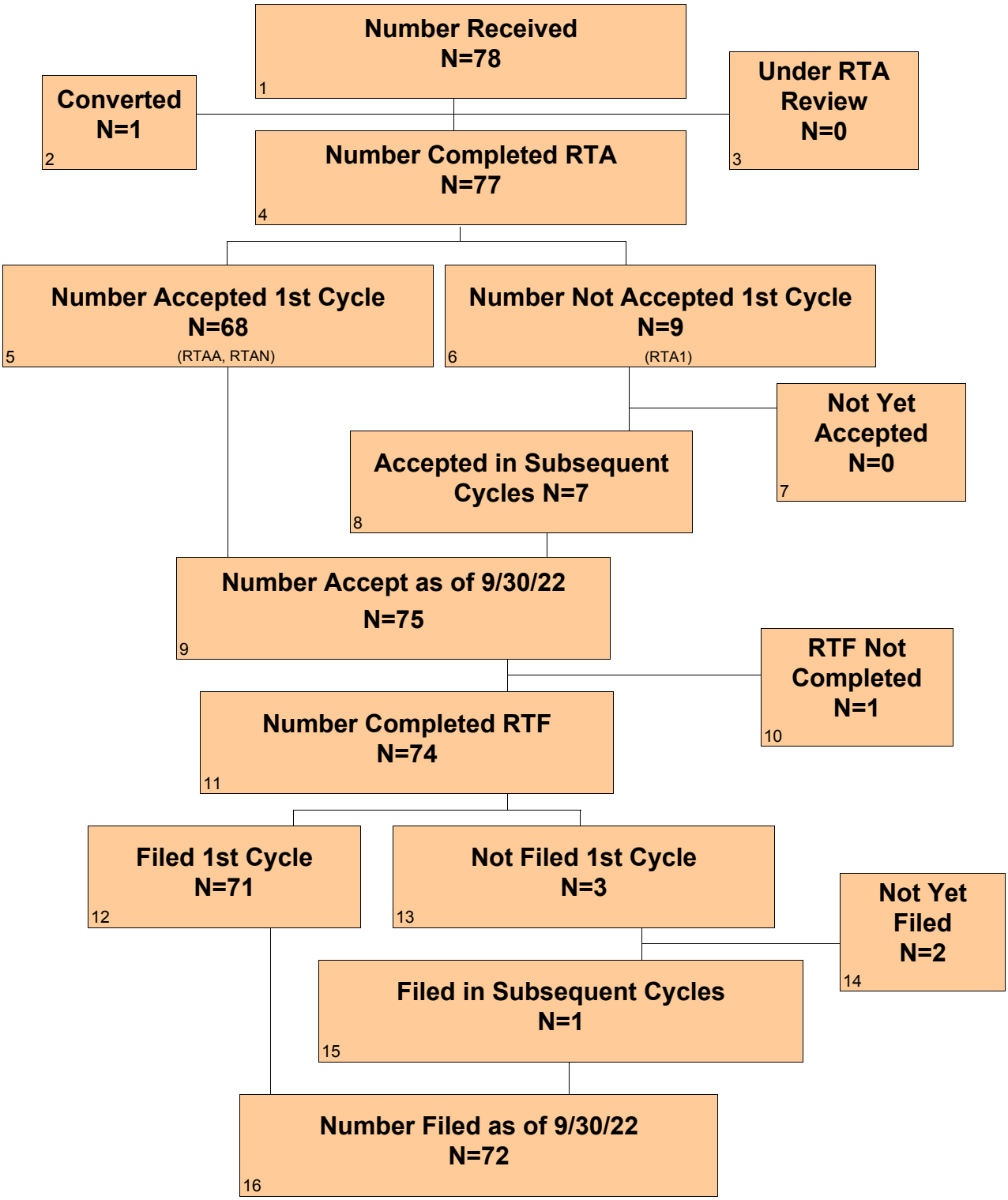
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/22



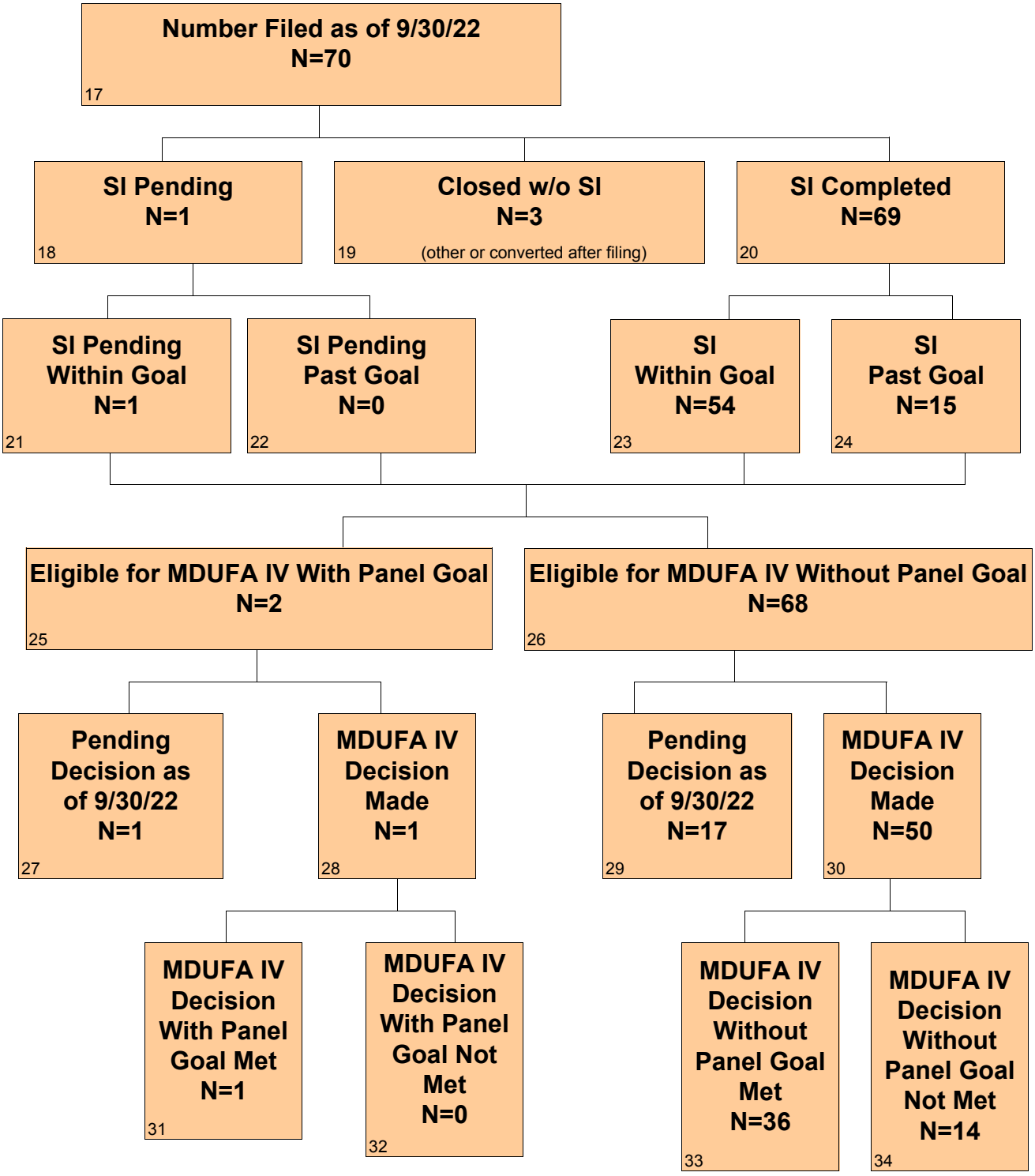
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/22 Continued



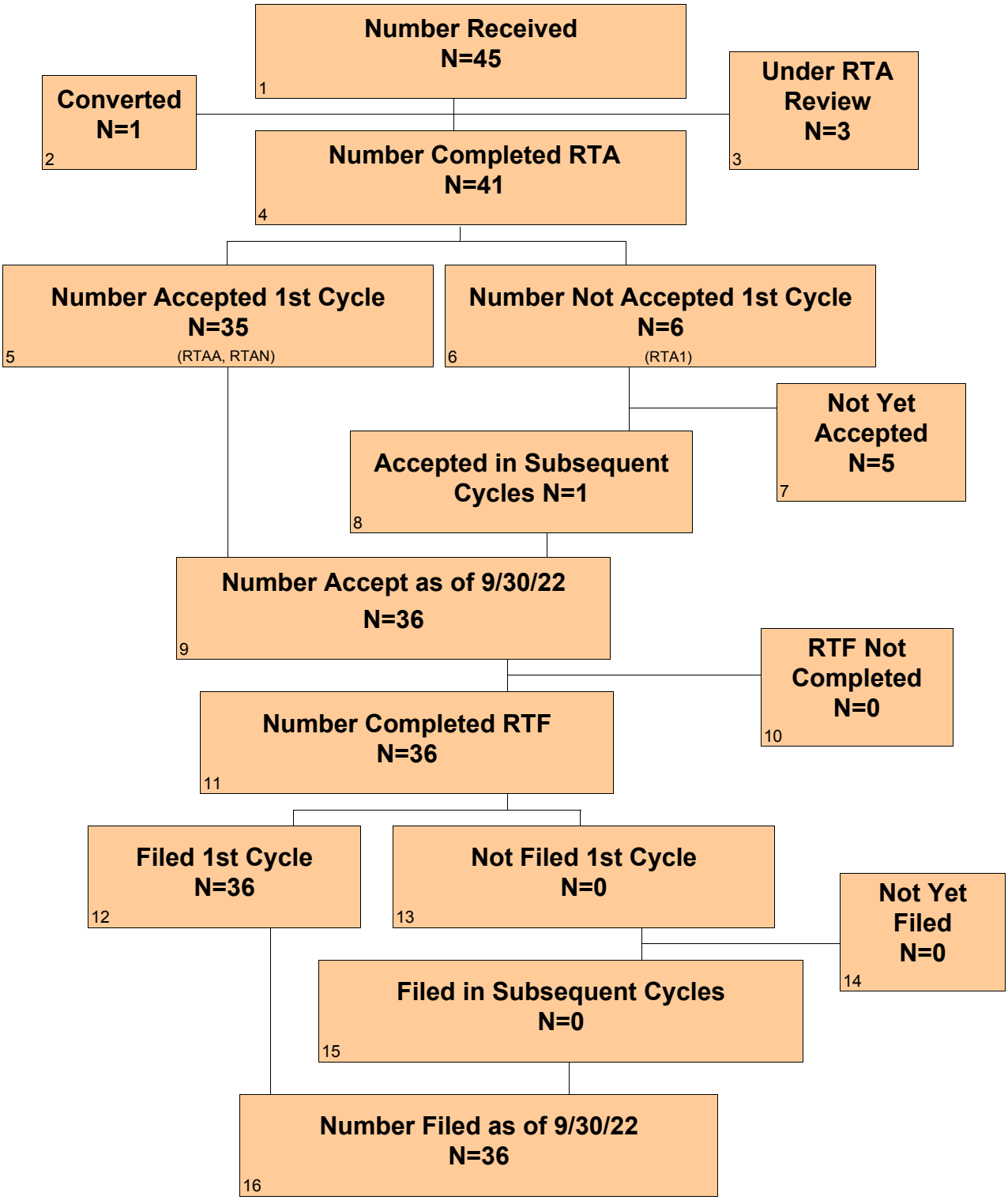
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 9/30/22



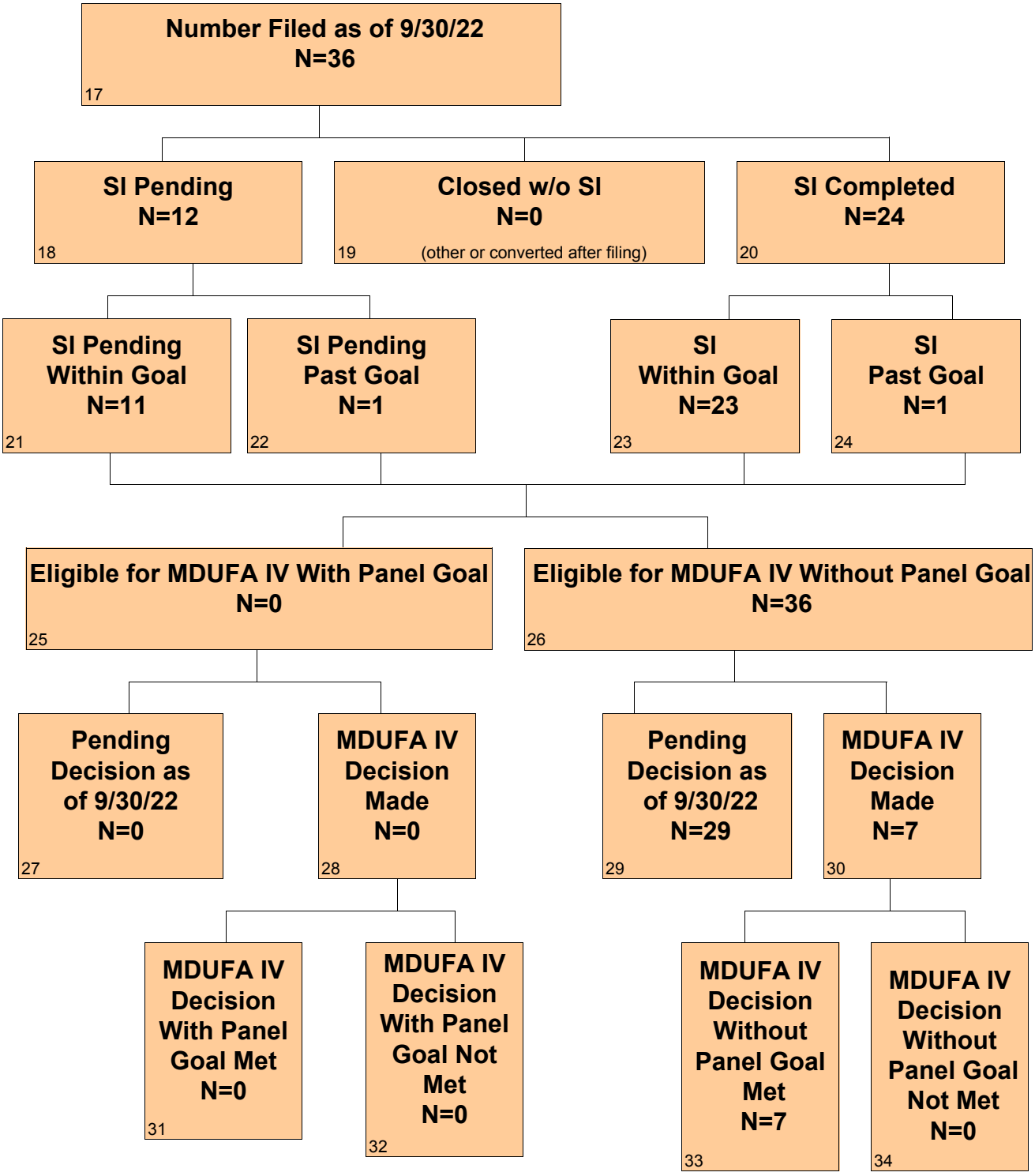
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 9/30/22 Continued



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 9/30/22



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 9/30/22 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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	74	56	77	78	45
Closed Before RTA Action	0	0	0	1	1
Number with Accepted RTA Review	62	46	63	59	35
Number Without a RTA Review and > 15 Days Since Date Received	0	1	1	9	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	3
Number Not Accepted for Filing Review	12	9	13	9	6
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	16.88%	11.69%	14.63%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	74	56	77	78	45
Number Accepted	62	47	64	68	35
Completed RTF	72	55	75	74	36
Number Not Filed	3	1	3	3	0
Rate of Submissions Not Filed	4.17%	1.82%	4.00%	4.05%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	71	55	73	72	36
SI Goal Met	69	54	70	56	23
SI Goal Not Met	2	1	3	15	1
SI Pending Within Goal	0	0	0	0	11
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	97.18%	98.18%	95.89%	78.87%	92.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	71	55	73	71	24
Average Number of FDA Days to Substantive Interaction	87.03	89.95	91.74	125.73	89.00
20th Percentile FDA Days to Substantive Interaction	84	87	88	87	87
40th Percentile FDA Days to Substantive Interaction	88	88	88	89	88
60th Percentile FDA Days to Substantive Interaction	90	89	90	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	90	91	90
Maximum FDA Days to Substantive Interaction	178	246	325	598	129

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	66	53	69	70	36
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	65	53	65	52	7
MDUFA IV Decision Goal Met	65	48	61	41	7
PMAs Pending MDUFA IV Decision	1	0	4	17	29
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	7	1
Current Performance Percent Goal Met	100.00%	90.57%	92.42%	69.49%	87.50%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	5	2	4	2	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	5	2	4	1	0
MDUFA IV Decision Goal Met	5	1	4	1	0
PMAs Pending MDUFA IV Decision	0	0	0	1	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	50.00%	100.00%	100.00%	N/A

Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision					
Performance Metric	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
Number with MDUFA IV Decision	65	53	65	52	7
Average FDA Days to MDUFA IV Decision	162.15	180.74	173.51	180.71	152.00
20th Percentile FDA Days to MDUFA IV Decision	144	147	175	158	121
40th Percentile FDA Days to MDUFA IV Decision	177	178	179	178	144
60th Percentile FDA Days to MDUFA IV Decision	178	180	180	180	176
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	181	180
Maximum FDA Days to MDUFA IV Decision	279	338	406	490	180
Average Industry Days to MDUFA IV Decision	93.18	127.28	105.23	79.92	11.43
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	31	35	27	0
60th Percentile Industry Days to MDUFA IV Decision	88	130	74	54	6
80th Percentile Industry Days to MDUFA IV Decision	162	192	183	136	20
Maximum Industry Days to MDUFA IV Decision	360	540	521	387	48
Average Total Days to MDUFA IV Decision	255.34	308.02	278.74	260.63	163.43
20th Percentile Total Days to MDUFA IV Decision	167	175	177	178	132
40th Percentile Total Days to MDUFA IV Decision	180	204	211	206	162
60th Percentile Total Days to MDUFA IV Decision	257	310	261	254	176
80th Percentile Total Days to MDUFA IV Decision	342	440	389	332	188
Maximum Total Days to MDUFA IV Decision	540	718	633	588	202

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	2	4	1	0
Average FDA Days to MDUFA IV Decision	265.80	485.00	319.25	161.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	193	299	319	161	0
40th Percentile FDA Days to MDUFA IV Decision	267	423	319	161	0
60th Percentile FDA Days to MDUFA IV Decision	316	547	320	161	0
80th Percentile FDA Days to MDUFA IV Decision	320	671	320	161	0
Maximum FDA Days to MDUFA IV Decision	322	795	320	161	0
Average Industry Days to MDUFA IV Decision	19.00	135.00	179.75	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	104	88	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	125	110	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	145	130	0	0
80th Percentile Industry Days to MDUFA IV Decision	19	166	248	0	0
Maximum Industry Days to MDUFA IV Decision	95	187	416	0	0
Average Total Days to MDUFA IV Decision	284.80	620.00	499.00	161.00	0.00
20th Percentile Total Days to MDUFA IV Decision	256	403	407	161	0
40th Percentile Total Days to MDUFA IV Decision	297	548	430	161	0
60th Percentile Total Days to MDUFA IV Decision	316	692	449	161	0
80th Percentile Total Days to MDUFA IV Decision	320	837	567	161	0
Maximum Total Days to MDUFA IV Decision	322	982	736	161	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	66	53	69	70	36
Number with MDUFA IV Decision	65	53	65	52	7
Number of Withdrawal	6	3	5	3	0
Number of Not Approvable	8	7	5	1	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	9.23%	5.66%	7.69%	5.77%	0.00%
Rate of Not Approvable	12.31%	13.21%	7.69%	1.92%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	2	4	2	0
Number With MDUFA IV Decision	5	2	4	1	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	4	1	2	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	0.00%	0.00%	N/A
Rate of Not Approvable	80.00%	50.00%	50.00%	0.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	5	5	18	1
Mean FDA Days for Submissions that Missed the Goal	0.00	266.60	283.60	289.44	207.00
Mean Industry Days for Submissions that Missed the Goal	0.00	235.00	135.00	178.72	133.00

Table 1.12 CDRH - PMA Original and Panel-Track Supplements (with Panel Review)
Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	795.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	187.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	4	11	5	6
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	11	3	1
MDUFA IV Decision Goal Met	1	4	11	3	1
PMAs Pending MDUFA IV Decision	0	0	0	2	5
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	2	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	60.00%	100.00%

***Includes submission that went to panel**

Table 1.14 CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	15	17	15	20	6
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	14	2
MDUFA IV Decision Goal Met	15	13	12	8	2
PMAs Pending MDUFA IV Decision	0	0	1	5	4
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	5	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	42.11%	100.00%

***Includes submission that went to panel**

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	8	5
Closed Before RTA Action	0	0	0	0	1
Number with Accepted RTA Review	11	6	4	6	2
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	5	1	2	2	2
Rate of Submissions Not Accepted for Filing Review	31.25%	14.29%	33.33%	25.00%	50.00%

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	8	5
Number Accepted	11	6	4	6	2
Completed RTF	16	7	6	7	3
Number Not Filed	1	1	0	0	0
Rate of Submissions Not Filed	6.25%	14.29%	0.00%	0.00%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	16	7	6	7	3
SI Goal Met	16	7	6	6	0
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	85.71%	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	16	7	6	7	0
Average Number of FDA Days to Substantive Interaction	87.13	88.86	88.00	98.71	0.00
20th Percentile FDA Days to Substantive Interaction	86	88	87	89	0
40th Percentile FDA Days to Substantive Interaction	87	89	88	90	0
60th Percentile FDA Days to Substantive Interaction	90	90	88	90	0
80th Percentile FDA Days to Substantive Interaction	90	90	88	90	0
Maximum FDA Days to Substantive Interaction	90	90	90	154	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	15	7	6	7	3
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	15	7	6	6	0
MDUFA IV Decision Goal Met	15	7	6	5	0
PMAs Pending MDUFA IV Decision	0	0	0	1	3
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	83.33%	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 IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	1	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision Goal Met	1	0	0	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	N/A	N/A	N/A	N/A

Table 1.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	15	7	6	6	0
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	168.17	0.00
20th Percentile FDA Days to MDUFA IV Decision	176	179	180	178	0
40th Percentile FDA Days to MDUFA IV Decision	178	180	180	180	0
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	180	0
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	0
Maximum FDA Days to MDUFA IV Decision	180	180	180	201	0
Average Industry Days to MDUFA IV Decision	130.93	65.43	160.17	174.17	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	4	68	47	0
40th Percentile Industry Days to MDUFA IV Decision	52	20	81	90	0
60th Percentile Industry Days to MDUFA IV Decision	141	50	108	138	0
80th Percentile Industry Days to MDUFA IV Decision	278	148	277	355	0
Maximum Industry Days to MDUFA IV Decision	360	180	400	387	0
Average Total Days to MDUFA IV Decision	308.27	244.57	340.17	342.33	0.00
20th Percentile Total Days to MDUFA IV Decision	178	184	248	227	0
40th Percentile Total Days to MDUFA IV Decision	232	200	261	268	0
60th Percentile Total Days to MDUFA IV Decision	321	230	288	318	0
80th Percentile Total Days to MDUFA IV Decision	450	328	457	445	0
Maximum Total Days to MDUFA IV Decision	528	359	580	588	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 IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	0	0	0	0
Average FDA Days to MDUFA IV Decision	176.00	0.00	0.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	0
40th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	0
60th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	0
80th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	0
Maximum FDA Days to MDUFA IV Decision	176	0	0	0	0
Average Industry Days to MDUFA IV Decision	95.00	0.00	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	0
Maximum Industry Days to MDUFA IV Decision	95	0	0	0	0
Average Total Days to MDUFA IV Decision	271.00	0.00	0.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	271	0	0	0	0
40th Percentile Total Days to MDUFA IV Decision	271	0	0	0	0
60th Percentile Total Days to MDUFA IV Decision	271	0	0	0	0
80th Percentile Total Days to MDUFA IV Decision	271	0	0	0	0
Maximum Total Days to MDUFA IV Decision	271	0	0	0	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	15	7	6	7	3
Number with MDUFA IV Decision	15	7	6	6	0
Number of Withdrawal	0	0	0	1	0
Number of Not Approvable	4	1	2	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	0.00%	16.67%	N/A
Rate of Not Approvable	26.67%	14.29%	33.33%	0.00%	N/A

Table 1.10 OHT1 -Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0	0	0	0
Number With MDUFA IV Decision	1	0	0	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	1	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	N/A	N/A	N/A	N/A
Rate of Not Approvable	100.00%	N/A	N/A	N/A	N/A

Table 1.11 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	201.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	387.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 1.13 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device LDT PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 OHT1 -Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14	23	19	13
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	20	11	21	18	12
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	1
Number Not Accepted for Filing Review	3	3	2	1	0
Rate of Submissions Not Accepted for Filing Review	13.04%	21.43%	8.70%	5.26%	0.00%

Table 1.2 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14	23	19	13
Number Accepted	20	11	21	18	12
Completed RTF	22	14	23	19	12
Number Not Filed	1	0	0	0	0
Rate of Submissions Not Filed	4.55%	0.00%	0.00%	0.00%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	22	14	23	19	12
SI Goal Met	22	14	23	19	8
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	4
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	22	14	23	19	8
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.26	88.74	88.38
20th Percentile FDA Days to Substantive Interaction	84	85	87	88	87
40th Percentile FDA Days to Substantive Interaction	87	88	88	89	88
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	90
Maximum FDA Days to Substantive Interaction	90	90	90	90	90

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	21	12	22	19	12
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	21	12	20	16	3
MDUFA IV Decision Goal Met	21	12	20	16	3
PMAs Pending MDUFA IV Decision	0	0	2	3	9
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	1	2	1	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	2	1	0	0
MDUFA IV Decision Goal Met	1	1	1	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	50.00%	100.00%	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	21	12	20	16	3
Average FDA Days to MDUFA IV Decision	174.00	178.92	178.15	175.13	176.67
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	177	174
40th Percentile FDA Days to MDUFA IV Decision	178	178	179	178	178
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	178	180
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	180
Maximum FDA Days to MDUFA IV Decision	279	295	180	180	180
Average Industry Days to MDUFA IV Decision	51.48	107.00	100.70	51.63	3.33
20th Percentile Industry Days to MDUFA IV Decision	0	10	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	67	18	37	0
60th Percentile Industry Days to MDUFA IV Decision	45	122	62	53	2
80th Percentile Industry Days to MDUFA IV Decision	91	171	160	78	6
Maximum Industry Days to MDUFA IV Decision	162	322	453	238	10
Average Total Days to MDUFA IV Decision	225.48	285.92	278.85	226.75	180.00
20th Percentile Total Days to MDUFA IV Decision	168	170	177	178	174
40th Percentile Total Days to MDUFA IV Decision	180	245	197	217	178
60th Percentile Total Days to MDUFA IV Decision	229	302	240	231	182
80th Percentile Total Days to MDUFA IV Decision	324	363	339	258	186
Maximum Total Days to MDUFA IV Decision	340	501	633	418	190

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	2	1	0	0
Average FDA Days to MDUFA IV Decision	197.00	485.00	318.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	197	299	318	0	0
40th Percentile FDA Days to MDUFA IV Decision	197	423	318	0	0
60th Percentile FDA Days to MDUFA IV Decision	197	547	318	0	0
80th Percentile FDA Days to MDUFA IV Decision	197	671	318	0	0
Maximum FDA Days to MDUFA IV Decision	197	795	318	0	0
Average Industry Days to MDUFA IV Decision	0.00	135.00	63.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	104	63	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	125	63	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	145	63	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	166	63	0	0
Maximum Industry Days to MDUFA IV Decision	0	187	63	0	0
Average Total Days to MDUFA IV Decision	197.00	620.00	381.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	197	403	381	0	0
40th Percentile Total Days to MDUFA IV Decision	197	548	381	0	0
60th Percentile Total Days to MDUFA IV Decision	197	692	381	0	0
80th Percentile Total Days to MDUFA IV Decision	197	837	381	0	0
Maximum Total Days to MDUFA IV Decision	197	982	381	0	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	21	12	22	19	12
Number with MDUFA IV Decision	21	12	20	16	3
Number of Withdrawal	0	0	1	0	0
Number of Not Approvable	1	1	1	1	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	5.00%	0.00%	0.00%
Rate of Not Approvable	4.76%	8.33%	5.00%	6.25%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	2	1	0	0
Number With MDUFA IV Decision	1	2	1	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	1	1	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	N/A
Rate of Not Approvable	0.00%	50.00%	100.00%	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	795.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	187.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 OHT2 - Office of Cardiovascular Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	3	7	4	0
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	8	3	6	4	0
Number Without a RTA Review and > 15 Days Since Date Received	0	0	1	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	1	0	0	0	0
Rate of Submissions Not Accepted for Filing Review	11.11%	0.00%	0.00%	0.00%	N/A

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	3	7	4	0
Number Accepted	8	3	7	4	0
Completed RTF	9	3	7	4	0
Number Not Filed	1	0	1	0	0
Rate of Submissions Not Filed	11.11%	0.00%	14.29%	0.00%	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	6	4	0
SI Goal Met	8	3	6	4	0
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	8	3	6	4	0
Average Number of FDA Days to Substantive Interaction	99.50	139.67	89.17	88.25	0.00
20th Percentile FDA Days to Substantive Interaction	87	86	88	88	0
40th Percentile FDA Days to Substantive Interaction	88	87	89	88	0
60th Percentile FDA Days to Substantive Interaction	90	119	90	88	0
80th Percentile FDA Days to Substantive Interaction	91	182	90	89	0
Maximum FDA Days to Substantive Interaction	178	246	90	90	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	5	3	5	4	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	5	3	4	2	0
MDUFA IV Decision Goal Met	5	3	4	2	0
PMAs Pending MDUFA IV Decision	0	0	1	2	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	0	0
Current Performance Percent Goal Met	100.00%	100.00%	80.00%	100.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	0	1	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	3	0	1	0	0
MDUFA IV Decision Goal Met	3	0	1	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	N/A	100.00%	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	3	4	2	0
Average FDA Days to MDUFA IV Decision	178.00	228.33	156.75	180.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	159	172	143	180	0
40th Percentile FDA Days to MDUFA IV Decision	177	177	179	180	0
60th Percentile FDA Days to MDUFA IV Decision	179	212	180	180	0
80th Percentile FDA Days to MDUFA IV Decision	197	275	180	180	0
Maximum FDA Days to MDUFA IV Decision	266	338	180	180	0
Average Industry Days to MDUFA IV Decision	102.20	121.00	342.00	134.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	77	2	269	69	0
40th Percentile Industry Days to MDUFA IV Decision	97	5	332	112	0
60th Percentile Industry Days to MDUFA IV Decision	108	76	338	156	0
80th Percentile Industry Days to MDUFA IV Decision	122	217	412	199	0
Maximum Industry Days to MDUFA IV Decision	163	357	521	242	0
Average Total Days to MDUFA IV Decision	280.20	349.33	498.75	314.00	0.00
20th Percentile Total Days to MDUFA IV Decision	248	247	449	249	0
40th Percentile Total Days to MDUFA IV Decision	270	308	512	292	0
60th Percentile Total Days to MDUFA IV Decision	285	375	517	336	0
80th Percentile Total Days to MDUFA IV Decision	302	450	555	379	0
Maximum Total Days to MDUFA IV Decision	350	524	609	422	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 IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	3	0	1	0	0
Average FDA Days to MDUFA IV Decision	318.67	0.00	319.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	316	0	319	0	0
40th Percentile FDA Days to MDUFA IV Decision	319	0	319	0	0
60th Percentile FDA Days to MDUFA IV Decision	320	0	319	0	0
80th Percentile FDA Days to MDUFA IV Decision	321	0	319	0	0
Maximum FDA Days to MDUFA IV Decision	322	0	319	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	136.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	136	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	136	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	136	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	136	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	136	0	0
Average Total Days to MDUFA IV Decision	318.67	0.00	455.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	316	0	455	0	0
40th Percentile Total Days to MDUFA IV Decision	319	0	455	0	0
60th Percentile Total Days to MDUFA IV Decision	320	0	455	0	0
80th Percentile Total Days to MDUFA IV Decision	321	0	455	0	0
Maximum Total Days to MDUFA IV Decision	322	0	455	0	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	3	5	4	0
Number with MDUFA IV Decision	5	3	4	2	0
Number of Withdrawal	1	0	1	0	0
Number of Not Approvable	0	1	1	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	20.00%	0.00%	25.00%	0.00%	N/A
Rate of Not Approvable	0.00%	33.33%	25.00%	0.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	3	0	1	0	0
Number With MDUFA IV Decision	3	0	1	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	3	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	N/A	0.00%	N/A	N/A
Rate of Not Approvable	100.00%	N/A	0.00%	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	1	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	494.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	335.00	0.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 1.13 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.1 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2	5	6	3
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	1	3	3	2
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	1
Number Not Accepted for Filing Review	2	1	2	3	0
Rate of Submissions Not Accepted for Filing Review	66.67%	50.00%	40.00%	50.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2	5	6	3
Number Accepted	1	1	3	3	2
Completed RTF	2	2	4	6	2
Number Not Filed	0	0	0	1	0
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	16.67%	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	2	4	5	2
SI Goal Met	1	2	4	4	1
SI Goal Not Met	1	0	0	1	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	80.00%	50.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	2	4	5	2
Average Number of FDA Days to Substantive Interaction	93.50	90.00	89.25	108.20	109.50
20th Percentile FDA Days to Substantive Interaction	90	90	89	86	98
40th Percentile FDA Days to Substantive Interaction	92	90	89	88	106
60th Percentile FDA Days to Substantive Interaction	95	90	90	90	113
80th Percentile FDA Days to Substantive Interaction	97	90	90	110	121
Maximum FDA Days to Substantive Interaction	99	90	90	189	129

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	2	3	4	2
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	2	3	4	0
MDUFA IV Decision Goal Met	1	1	1	0	0
PMAs Pending MDUFA IV Decision	1	0	0	0	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	1
Current Performance Percent Goal Met	100.00%	50.00%	33.33%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	1	1	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	1	0	0
MDUFA IV Decision Goal Met	0	0	1	0	0
PMAs Pending MDUFA IV Decision	0	0	0	1	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	100.00%	N/A	N/A

Table 1.7 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	2	3	4	0
Average FDA Days to MDUFA IV Decision	159.00	181.00	198.67	214.50	0.00
20th Percentile FDA Days to MDUFA IV Decision	159	179	189	200	0
40th Percentile FDA Days to MDUFA IV Decision	159	180	198	215	0
60th Percentile FDA Days to MDUFA IV Decision	159	182	204	223	0
80th Percentile FDA Days to MDUFA IV Decision	159	183	209	230	0
Maximum FDA Days to MDUFA IV Decision	159	184	214	237	0
Average Industry Days to MDUFA IV Decision	6.00	90.00	41.67	142.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	6	49	27	83	0
40th Percentile Industry Days to MDUFA IV Decision	6	76	31	126	0
60th Percentile Industry Days to MDUFA IV Decision	6	104	40	139	0
80th Percentile Industry Days to MDUFA IV Decision	6	131	55	197	0
Maximum Industry Days to MDUFA IV Decision	6	159	69	277	0
Average Total Days to MDUFA IV Decision	165.00	271.00	240.33	356.50	0.00
20th Percentile Total Days to MDUFA IV Decision	165	231	218	297	0
40th Percentile Total Days to MDUFA IV Decision	165	258	223	328	0
60th Percentile Total Days to MDUFA IV Decision	165	284	237	332	0
80th Percentile Total Days to MDUFA IV Decision	165	311	260	405	0
Maximum Total Days to MDUFA IV Decision	165	337	283	514	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 IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	1	0	0
Average FDA Days to MDUFA IV Decision	0.00	0.00	320.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
40th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
60th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
80th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
Maximum FDA Days to MDUFA IV Decision	0	0	320	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	104.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	104	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	104	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	104	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	104	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	104	0	0
Average Total Days to MDUFA IV Decision	0.00	0.00	424.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	0	424	0	0
40th Percentile Total Days to MDUFA IV Decision	0	0	424	0	0
60th Percentile Total Days to MDUFA IV Decision	0	0	424	0	0
80th Percentile Total Days to MDUFA IV Decision	0	0	424	0	0
Maximum Total Days to MDUFA IV Decision	0	0	424	0	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	2	3	4	2
Number with MDUFA IV Decision	1	2	3	4	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	1	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	0.00%	0.00%	N/A
Rate of Not Approvable	100.00%	0.00%	0.00%	0.00%	N/A

Table 1.10 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	1	1	0
Number With MDUFA IV Decision	0	0	1	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	0.00%	N/A	N/A
Rate of Not Approvable	N/A	N/A	0.00%	N/A	N/A

Table 1.11 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	2	4	1
Mean FDA Days for Submissions that Missed the Goal	0.00	184.00	208.00	214.50	207.00
Mean Industry Days for Submissions that Missed the Goal	0.00	21.00	46.00	142.00	133.00

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 1.13 OHT4 - Office of Surgical and Infection Control Devices
LDT PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 OHT4 - Office of Surgical and Infection Control Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5	4	9	5
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	3	4	1	8	4
Number Without a RTA Review and > 15 Days Since Date Received	0	1	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	1	0	3	1	1
Rate of Submissions Not Accepted for Filing Review	25.00%	0.00%	75.00%	11.11%	20.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5	4	9	5
Number Accepted	3	5	1	8	4
Completed RTF	4	5	3	8	4
Number Not Filed	0	0	0	0	0
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	0.00%

Table 1.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	5	3	8	4
SI Goal Met	3	5	3	8	1
SI Goal Not Met	1	0	0	0	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	75.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	5	3	8	1
Average Number of FDA Days to Substantive Interaction	90.50	84.80	90.00	87.50	90.00
20th Percentile FDA Days to Substantive Interaction	90	84	90	85	90
40th Percentile FDA Days to Substantive Interaction	90	90	90	87	90
60th Percentile FDA Days to Substantive Interaction	90	90	90	89	90
80th Percentile FDA Days to Substantive Interaction	91	90	90	90	90
Maximum FDA Days to Substantive Interaction	92	90	90	90	90

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	4	5	2	8	4
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	4	5	2	6	0
MDUFA IV Decision Goal Met	4	5	2	6	0
PMAs Pending MDUFA IV Decision	0	0	0	2	4
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	N/A

Table 1.6 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	1	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	1	0	0
MDUFA IV Decision Goal Met	0	0	1	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	100.00%	N/A	N/A

Table 1.7 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	4	5	2	6	0
Average FDA Days to MDUFA IV Decision	180.00	188.00	132.50	174.67	0.00
20th Percentile FDA Days to MDUFA IV Decision	180	162	107	167	0
40th Percentile FDA Days to MDUFA IV Decision	180	180	124	178	0
60th Percentile FDA Days to MDUFA IV Decision	180	180	141	179	0
80th Percentile FDA Days to MDUFA IV Decision	180	206	158	180	0
Maximum FDA Days to MDUFA IV Decision	180	310	175	180	0
Average Industry Days to MDUFA IV Decision	186.75	172.00	32.00	9.17	0.00
20th Percentile Industry Days to MDUFA IV Decision	56	96	13	0	0
40th Percentile Industry Days to MDUFA IV Decision	134	151	26	0	0
60th Percentile Industry Days to MDUFA IV Decision	253	184	38	0	0
80th Percentile Industry Days to MDUFA IV Decision	320	224	51	22	0
Maximum Industry Days to MDUFA IV Decision	360	343	64	33	0
Average Total Days to MDUFA IV Decision	366.75	360.00	164.50	183.83	0.00
20th Percentile Total Days to MDUFA IV Decision	236	256	158	178	0
40th Percentile Total Days to MDUFA IV Decision	314	282	162	179	0
60th Percentile Total Days to MDUFA IV Decision	433	325	167	180	0
80th Percentile Total Days to MDUFA IV Decision	500	430	171	200	0
Maximum Total Days to MDUFA IV Decision	540	653	175	202	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 IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	1	0	0
Average FDA Days to MDUFA IV Decision	0.00	0.00	320.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
40th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
60th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
80th Percentile FDA Days to MDUFA IV Decision	0	0	320	0	0
Maximum FDA Days to MDUFA IV Decision	0	0	320	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	416.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	416	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	416	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	416	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	416	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	416	0	0
Average Total Days to MDUFA IV Decision	0.00	0.00	736.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	0	736	0	0
40th Percentile Total Days to MDUFA IV Decision	0	0	736	0	0
60th Percentile Total Days to MDUFA IV Decision	0	0	736	0	0
80th Percentile Total Days to MDUFA IV Decision	0	0	736	0	0
Maximum Total Days to MDUFA IV Decision	0	0	736	0	0

Table 1.9 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	5	2	8	4
Number with MDUFA IV Decision	4	5	2	6	0
Number of Withdrawal	0	1	1	0	0
Number of Not Approvable	0	2	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	20.00%	50.00%	0.00%	N/A
Rate of Not Approvable	0.00%	40.00%	0.00%	0.00%	N/A

Table 1.10 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	1	0	0
Number With MDUFA IV Decision	0	0	1	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	0	1	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	0.00%	N/A	N/A
Rate of Not Approvable	N/A	N/A	100.00%	N/A	N/A

Table 1.11 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 1.13 OHT5 - Office of Neurological and Physical Medicine Devices
LDT PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4	2	4	3
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	2	2	2	3	2
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	2	0	1	1
Rate of Submissions Not Accepted for Filing Review	0.00%	50.00%	0.00%	25.00%	33.33%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4	2	4	3
Number Accepted	2	2	2	3	2
Completed RTF	2	3	2	4	2
Number Not Filed	0	0	0	0	0
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	2	4	2
SI Goal Met	2	3	2	4	2
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	3	2	4	2
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50	85.50	87.00
20th Percentile FDA Days to Substantive Interaction	84	88	88	81	86
40th Percentile FDA Days to Substantive Interaction	86	89	88	84	87
60th Percentile FDA Days to Substantive Interaction	87	89	89	88	87
80th Percentile FDA Days to Substantive Interaction	89	90	89	90	88
Maximum FDA Days to Substantive Interaction	90	90	89	90	89

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	2	4	2
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	3	2	2	1
MDUFA IV Decision Goal Met	2	3	2	2	1
PMAs Pending MDUFA IV Decision	0	0	0	2	1
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision Goal Met	0	0	0	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

Table 1.7 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	2	3	2	2	1
Average FDA Days to MDUFA IV Decision	180.00	146.33	178.50	168.00	180.00
20th Percentile FDA Days to MDUFA IV Decision	180	121	178	161	180
40th Percentile FDA Days to MDUFA IV Decision	180	156	178	166	180
60th Percentile FDA Days to MDUFA IV Decision	180	174	179	170	180
80th Percentile FDA Days to MDUFA IV Decision	180	177	179	175	180
Maximum FDA Days to MDUFA IV Decision	180	179	180	180	180
Average Industry Days to MDUFA IV Decision	141.50	203.67	103.50	0.00	22.00
20th Percentile Industry Days to MDUFA IV Decision	57	67	41	0	22
40th Percentile Industry Days to MDUFA IV Decision	113	122	83	0	22
60th Percentile Industry Days to MDUFA IV Decision	170	209	124	0	22
80th Percentile Industry Days to MDUFA IV Decision	226	330	166	0	22
Maximum Industry Days to MDUFA IV Decision	283	450	207	0	22
Average Total Days to MDUFA IV Decision	321.50	350.00	282.00	168.00	202.00
20th Percentile Total Days to MDUFA IV Decision	237	191	219	161	202
40th Percentile Total Days to MDUFA IV Decision	293	282	261	166	202
60th Percentile Total Days to MDUFA IV Decision	350	387	303	170	202
80th Percentile Total Days to MDUFA IV Decision	406	505	345	175	202
Maximum Total Days to MDUFA IV Decision	463	623	387	180	202

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	0	0	0
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	0
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
Maximum Total Days to MDUFA IV Decision	0	0	0	0	0

Table 1.9 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	2	4	2
Number with MDUFA IV Decision	2	3	2	2	1
Number of Withdrawal	0	1	0	0	0
Number of Not Approvable	0	1	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	33.33%	0.00%	0.00%	0.00%
Rate of Not Approvable	0.00%	33.33%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0	0	0
Number With MDUFA IV Decision	0	0	0	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	N/A	N/A	N/A
Rate of Not Approvable	N/A	N/A	N/A	N/A	N/A

Table 1.11 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 OHT6 - Office of Orthopedic Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	21	27	28	15
Closed Before RTA Action	0	0	0	1	0
Number with Accepted RTA Review	16	19	23	17	12
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	9	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	1
Number Not Accepted for Filing Review	0	2	4	1	2
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	14.81%	3.70%	14.29%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	21	27	28	15
Number Accepted	16	19	23	26	12
Completed RTF	16	21	27	26	12
Number Not Filed	0	0	2	2	0
Rate of Submissions Not Filed	0.00%	0.00%	7.41%	7.69%	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	16	21	26	25	12
SI Goal Met	16	20	23	11	10
SI Goal Not Met	0	1	3	13	0
SI Pending Within Goal	0	0	0	0	1
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	100.00%	95.24%	88.46%	45.83%	90.91%

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	16	21	26	24	10
Average Number of FDA Days to Substantive Interaction	85.63	87.76	97.35	192.25	85.60
20th Percentile FDA Days to Substantive Interaction	84	87	86	88	86
40th Percentile FDA Days to Substantive Interaction	88	88	88	90	87
60th Percentile FDA Days to Substantive Interaction	90	89	90	178	88
80th Percentile FDA Days to Substantive Interaction	90	90	90	283	89
Maximum FDA Days to Substantive Interaction	90	91	325	598	90

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	16	21	26	24	12
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	16	21	25	16	3
MDUFA IV Decision Goal Met	16	17	23	10	3
PMAs Pending MDUFA IV Decision	0	0	1	7	9
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	7	0
Current Performance Percent Goal Met	100.00%	80.95%	92.00%	43.48%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	1	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision Goal Met	0	0	0	1	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	N/A	100.00%	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 IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	16	21	25	16	3
Average FDA Days to MDUFA IV Decision	127.13	178.67	170.04	186.50	118.00
20th Percentile FDA Days to MDUFA IV Decision	90	134	129	104	113
40th Percentile FDA Days to MDUFA IV Decision	112	173	179	134	118
60th Percentile FDA Days to MDUFA IV Decision	146	177	180	180	121
80th Percentile FDA Days to MDUFA IV Decision	175	180	180	273	124
Maximum FDA Days to MDUFA IV Decision	180	299	406	490	126
Average Industry Days to MDUFA IV Decision	91.56	142.38	65.20	87.13	16.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	16	22	0	0
60th Percentile Industry Days to MDUFA IV Decision	75	81	58	85	10
80th Percentile Industry Days to MDUFA IV Decision	158	325	127	169	29
Maximum Industry Days to MDUFA IV Decision	336	540	257	334	48
Average Total Days to MDUFA IV Decision	218.69	321.05	235.24	273.63	134.00
20th Percentile Total Days to MDUFA IV Decision	90	155	156	134	122
40th Percentile Total Days to MDUFA IV Decision	146	179	182	207	125
60th Percentile Total Days to MDUFA IV Decision	225	257	242	288	132
80th Percentile Total Days to MDUFA IV Decision	270	619	307	406	144
Maximum Total Days to MDUFA IV Decision	511	718	573	548	156

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	0	1	0
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	161.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	0
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	0
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	0
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	0
Maximum FDA Days to MDUFA IV Decision	0	0	0	161	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	0
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	161.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	0	0	161	0
40th Percentile Total Days to MDUFA IV Decision	0	0	0	161	0
60th Percentile Total Days to MDUFA IV Decision	0	0	0	161	0
80th Percentile Total Days to MDUFA IV Decision	0	0	0	161	0
Maximum Total Days to MDUFA IV Decision	0	0	0	161	0

Table 1.9 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	16	21	26	24	12
Number with MDUFA IV Decision	16	21	25	16	3
Number of Withdrawal	4	1	2	2	0
Number of Not Approvable	2	1	1	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	25.00%	4.76%	8.00%	12.50%	0.00%
Rate of Not Approvable	12.50%	4.76%	4.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0	1	0
Number With MDUFA IV Decision	0	0	0	1	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	N/A	0.00%	N/A
Rate of Not Approvable	N/A	N/A	N/A	0.00%	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	2	13	0
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	254.00	319.31	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	288.50	124.00	174.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	4	11	5	6
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	11	3	1
MDUFA IV Decision Goal Met	1	4	11	3	1
PMAs Pending MDUFA IV Decision	0	0	0	2	5
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	2	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	60.00%	100.00%

***Includes submission that went to panel**

Table 1.14 OHT7 - Office of In Vitro Diagnostics
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	15	17	15	20	6
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	14	2
MDUFA IV Decision Goal Met	15	13	12	8	2
PMAs Pending MDUFA IV Decision	0	0	1	5	4
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	5	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	42.11%	100.00%

***Includes submission that went to panel**

Table 1.1 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0	3	0	1
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	0	3	0	1
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	0	0	0	0
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	0.00%	N/A	0.00%

Table 1.2 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0	3	0	1
Number Accepted	1	0	3	0	1
Completed RTF	1	0	3	0	1
Number Not Filed	0	0	0	0	0
Rate of Submissions Not Filed	0.00%	N/A	0.00%	N/A	0.00%

Table 1.3 OHT8 - Office of Radiological Health

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	3	0	1
SI Goal Met	1	0	3	0	1
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	N/A	100.00%	N/A	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	1	0	3	0	1
Average Number of FDA Days to Substantive Interaction	63.00	0.00	89.67	0.00	90.00
20th Percentile FDA Days to Substantive Interaction	63	0	89	0	90
40th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
60th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
80th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
Maximum FDA Days to Substantive Interaction	63	0	90	0	90

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	3	0	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	0	3	0	0
MDUFA IV Decision Goal Met	1	0	3	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	1
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	N/A	100.00%	N/A	N/A

Table 1.6 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision Goal Met	0	0	0	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

Table 1.7 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	0	3	0	0
Average FDA Days to MDUFA IV Decision	63.00	0.00	179.67	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	63	0	179	0	0
40th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
60th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
80th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
Maximum FDA Days to MDUFA IV Decision	63	0	180	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	157.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	118	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	150	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	177	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	198	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	219	0	0
Average Total Days to MDUFA IV Decision	63.00	0.00	336.67	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	63	0	298	0	0
40th Percentile Total Days to MDUFA IV Decision	63	0	330	0	0
60th Percentile Total Days to MDUFA IV Decision	63	0	356	0	0
80th Percentile Total Days to MDUFA IV Decision	63	0	377	0	0
Maximum Total Days to MDUFA IV Decision	63	0	398	0	0

Table 1.8 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	0	0	0
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	0
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
Maximum Total Days to MDUFA IV Decision	0	0	0	0	0

Table 1.9 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0	3	0	1
Number with MDUFA IV Decision	1	0	3	0	0
Number of Withdrawal	1	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	100.00%	N/A	0.00%	N/A	N/A
Rate of Not Approvable	0.00%	N/A	0.00%	N/A	N/A

Table 1.10 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0	0	0
Number With MDUFA IV Decision	0	0	0	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	N/A	N/A	N/A
Rate of Not Approvable	N/A	N/A	N/A	N/A	N/A

Table 1.11 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

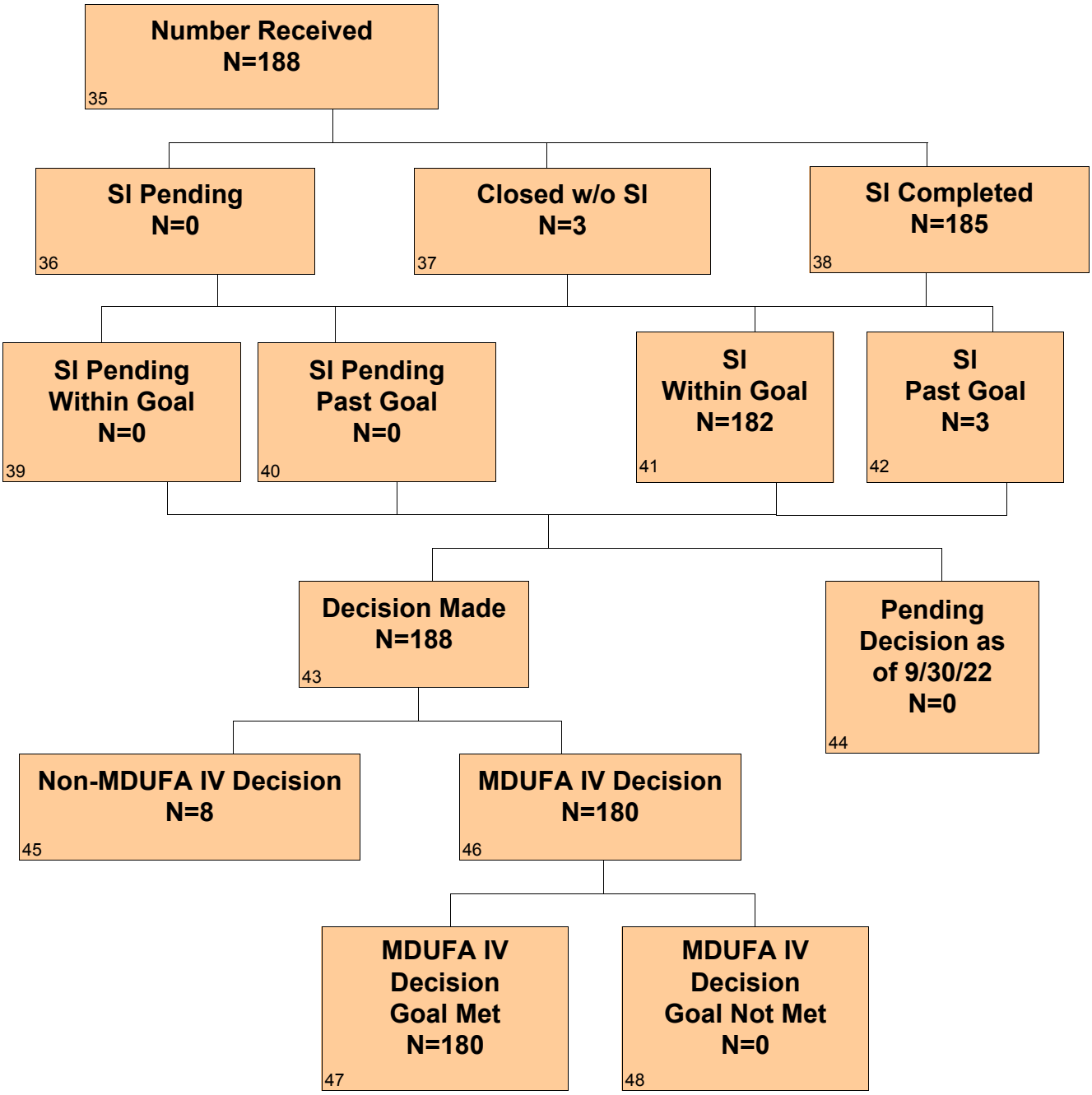
***Includes submission that went to panel**

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

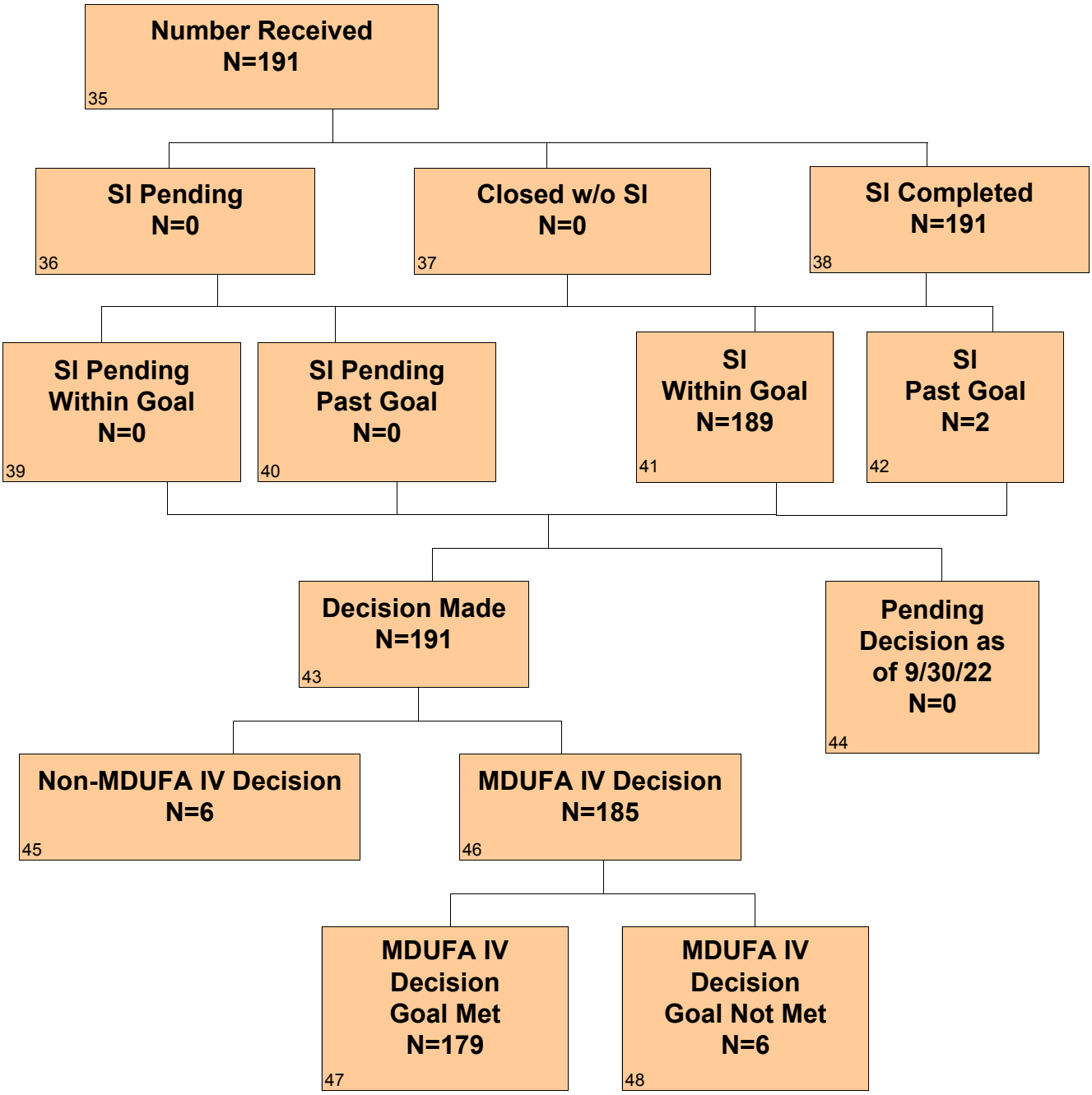
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

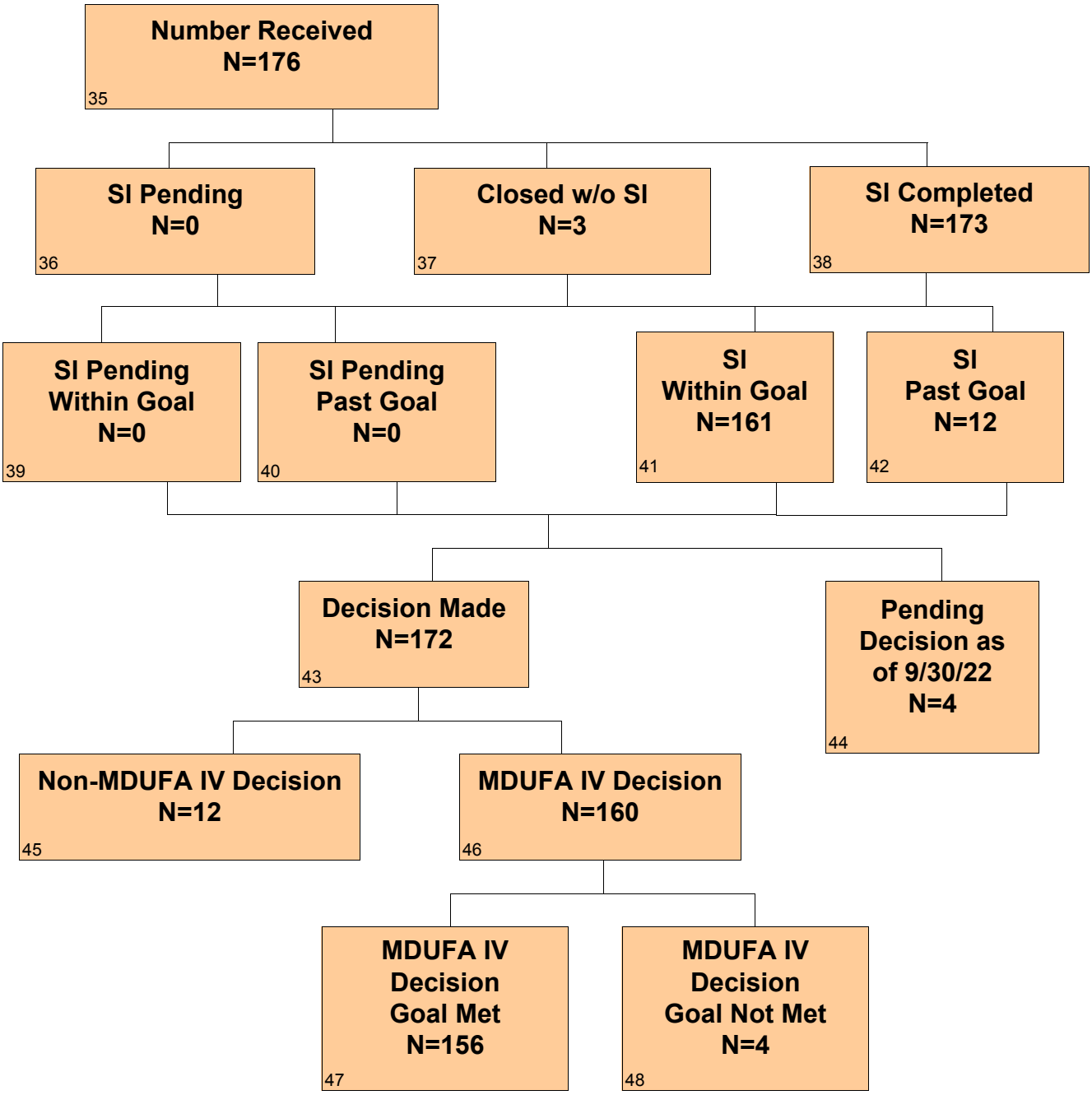
CDRH PMA 180 Day Supplements - FY 2018 as of 9/30/22



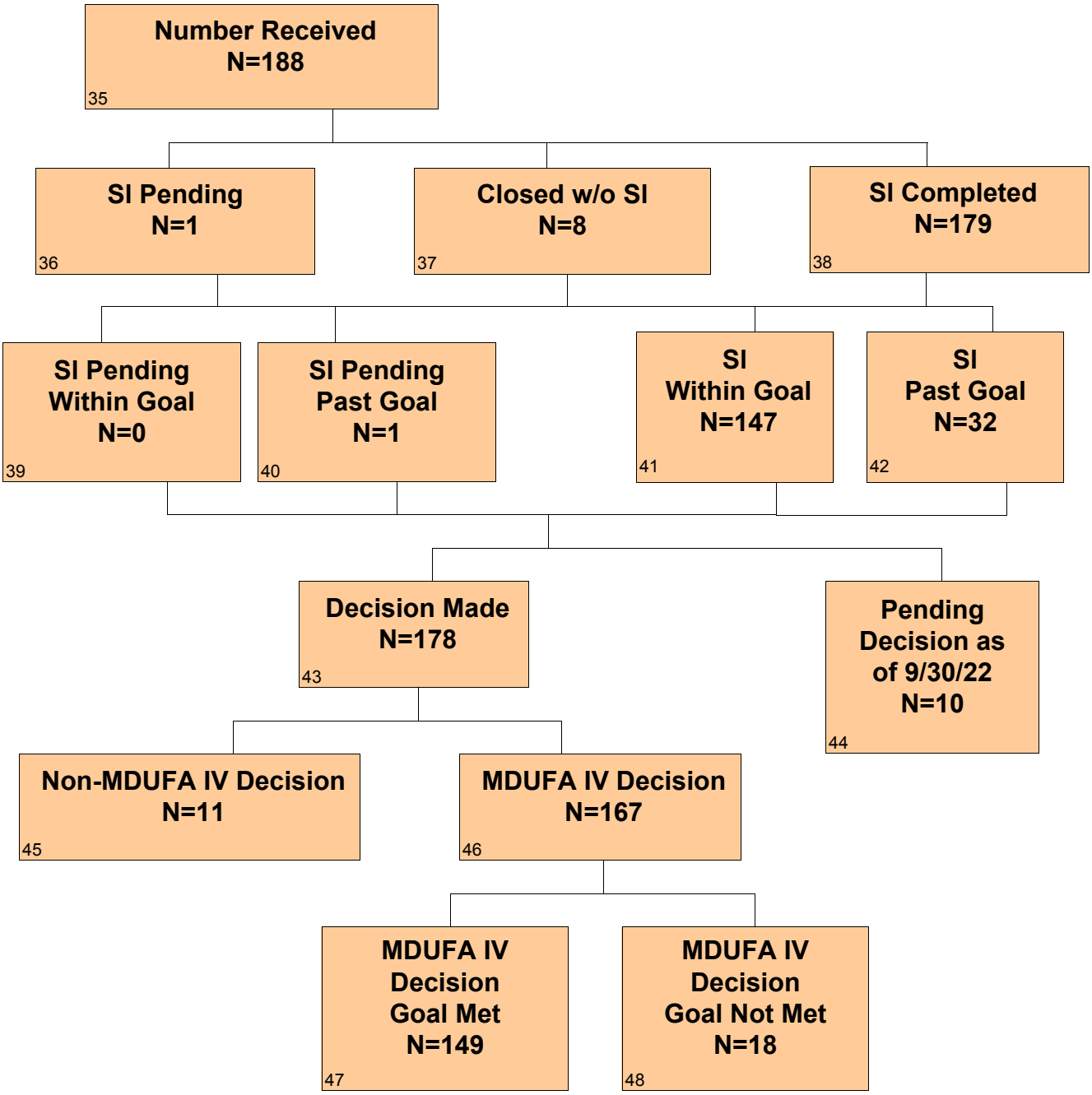
CDRH PMA 180 Day Supplements - FY 2019 as of 9/30/22



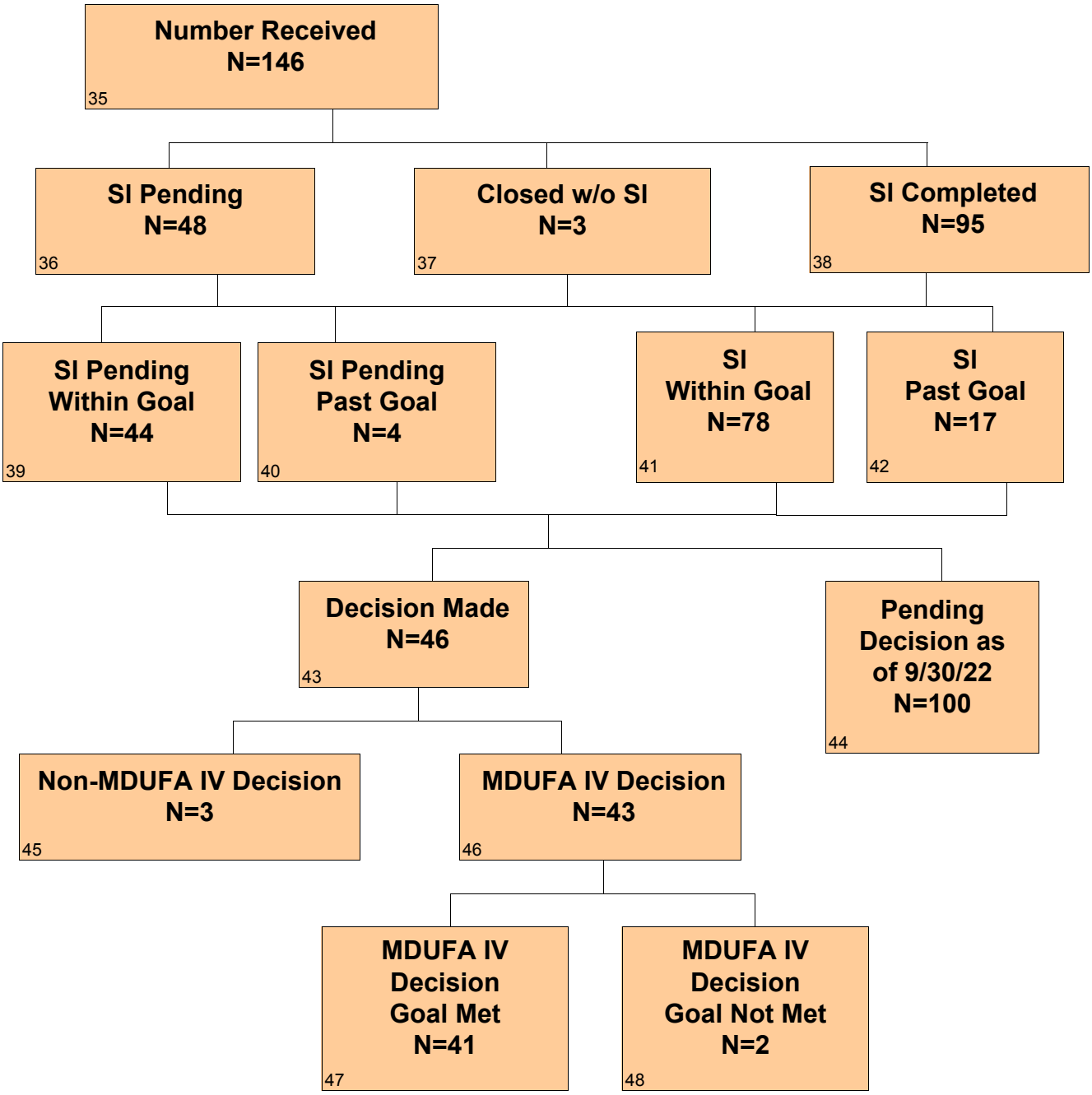
CDRH PMA 180 Day Supplements - FY 2020 as of 9/30/22



CDRH PMA 180 Day Supplements - FY 2021 as of 9/30/22



CDRH PMA 180 Day Supplements - FY 2022 as of 9/30/22



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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	188	191	176	188	146
SI Goal Met	182	189	161	147	78
SI Goal Not Met	3	2	12	32	17
SI Pending Within Goal	0	0	0	0	44
SI Pending Past Goal	0	0	0	1	4
Closed Without SI	3	0	3	8	3
Current SI Performance Percent Goal Met	98.38%	98.95%	93.06%	81.67%	78.79%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	188	191	176	188	146
Non-MDUFA IV Decision	8	6	12	11	3
MDUFA IV Decision	180	185	160	167	43
MDUFA IV Decision Goal Met	180	179	156	149	41
Supplements Pending MDUFA IV Decision	0	0	4	10	100
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	2	2
Current Performance Percent Goal Met	100.00%	96.76%	96.89%	88.17%	91.11%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	188	191	176	188	146
Number with MDUFA IV Decision	180	185	160	167	43
Number of Not Approvable	13	10	9	10	1
Rate of Not Approvable	7.22%	5.41%	5.63%	5.99%	2.33%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	6	5	20	4
Mean FDA Days for Submissions that Missed the Goal	0.00	263.33	407.20	238.20	208.25
Mean Industry Days for Submissions that Missed the Goal	0.00	69.67	85.20	43.90	56.50

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	20	36	28	15	19
SI Goal Met	20	36	28	14	16
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	93.33%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	20	36	28	15	19
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	20	36	28	13	9
MDUFA IV Decision Goal Met	20	35	28	13	9
Supplements Pending MDUFA IV Decision	0	0	0	1	10
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	97.22%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	20	36	28	15	19
Number with MDUFA IV Decision	20	36	28	13	9
Number of Not Approvable	1	1	1	2	1
Rate of Not Approvable	5.00%	2.78%	3.57%	15.38%	11.11%

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	302.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	41.00	0.00	0.00	0.00

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	94	81	70	94	51
SI Goal Met	91	81	66	79	29
SI Goal Not Met	1	0	4	7	8
SI Pending Within Goal	0	0	0	0	13
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	2	0	0	8	0
Current SI Performance Percent Goal Met	98.91%	100.00%	94.29%	91.86%	76.32%

Table 2.2 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	94	81	70	94	51
Non-MDUFA IV Decision	2	3	2	8	0
MDUFA IV Decision	92	78	65	83	20
MDUFA IV Decision Goal Met	92	78	65	83	20
Supplements Pending MDUFA IV Decision	0	0	3	3	31
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

Table 2.3 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	94	81	70	94	51
Number with MDUFA IV Decision	92	78	65	83	20
Number of Not Approvable	6	6	4	8	0
Rate of Not Approvable	6.52%	7.69%	6.15%	9.64%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	15	16	19	19	16
SI Goal Met	14	15	16	18	10
SI Goal Not Met	1	1	0	1	0
SI Pending Within Goal	0	0	0	0	4
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	3	0	2
Current SI Performance Percent Goal Met	93.33%	93.75%	100.00%	94.74%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	15	16	19	19	16
Non-MDUFA IV Decision	0	2	7	2	2
MDUFA IV Decision	15	14	12	17	2
MDUFA IV Decision Goal Met	15	14	12	16	2
Supplements Pending MDUFA IV Decision	0	0	0	0	12
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	94.12%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	16	19	19	16
Number with MDUFA IV Decision	15	14	12	17	2
Number of Not Approvable	0	2	3	0	0
Rate of Not Approvable	0.00%	14.29%	25.00%	0.00%	0.00%

Table 2.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	233.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	49.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	9	10	7	15	11
SI Goal Met	9	9	6	5	3
SI Goal Not Met	0	1	1	9	0
SI Pending Within Goal	0	0	0	0	4
SI Pending Past Goal	0	0	0	1	3
Closed Without SI	0	0	0	0	1
Current SI Performance Percent Goal Met	100.00%	90.00%	85.71%	33.33%	50.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	9	10	7	15	11
Non-MDUFA IV Decision	1	1	0	0	1
MDUFA IV Decision	8	9	7	13	1
MDUFA IV Decision Goal Met	8	5	6	8	1
Supplements Pending MDUFA IV Decision	0	0	0	2	9
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	1
Current Performance Percent Goal Met	100.00%	55.56%	85.71%	57.14%	50.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	10	7	15	11
Number with MDUFA IV Decision	8	9	7	13	1
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	1	6	1
Mean FDA Days for Submissions that Missed the Goal	0.00	258.50	383.00	255.00	261.00
Mean Industry Days for Submissions that Missed the Goal	0.00	91.00	223.00	12.00	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	13	16	23	20	18
SI Goal Met	12	16	23	19	11
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	7
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	1	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	95.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	13	16	23	20	18
Non-MDUFA IV Decision	2	0	2	0	0
MDUFA IV Decision	11	16	21	17	3
MDUFA IV Decision Goal Met	11	15	21	16	3
Supplements Pending MDUFA IV Decision	0	0	0	3	15
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	93.75%	100.00%	94.12%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	16	23	20	18
Number with MDUFA IV Decision	11	16	21	17	3
Number of Not Approvable	2	0	1	0	0
Rate of Not Approvable	18.18%	0.00%	4.76%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	244.00	0.00	181.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	13.00	0.00	75.00	0.00

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	6	2	4	3
SI Goal Met	0	6	2	4	1
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	2
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	N/A	100.00%	100.00%	100.00%	100.00%

Table 2.2 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	6	2	4	3
Non-MDUFA IV Decision	0	0	1	0	0
MDUFA IV Decision	0	6	1	4	0
MDUFA IV Decision Goal Met	0	6	1	4	0
Supplements Pending MDUFA IV Decision	0	0	0	0	3
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	100.00%	100.00%	100.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	0	6	2	4	3
Number with MDUFA IV Decision	0	6	1	4	0
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	N/A	0.00%	0.00%	0.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	35	23	25	21	27
SI Goal Met	34	23	18	8	7
SI Goal Not Met	1	0	7	13	9
SI Pending Within Goal	0	0	0	0	11
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	97.14%	100.00%	72.00%	38.10%	43.75%

Table 2.2 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	35	23	25	21	27
Non-MDUFA IV Decision	2	0	0	0	0
MDUFA IV Decision	33	23	24	20	7
MDUFA IV Decision Goal Met	33	23	21	9	5
Supplements Pending MDUFA IV Decision	0	0	1	1	20
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	1	1
Current Performance Percent Goal Met	100.00%	100.00%	84.00%	42.86%	62.50%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	35	23	25	21	27
Number with MDUFA IV Decision	33	23	24	20	7
Number of Not Approvable	4	1	0	0	0
Rate of Not Approvable	12.12%	4.35%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	12	3
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	413.25	235.00	190.67
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	50.75	56.83	75.33

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	2	0	1
SI Goal Met	2	3	2	0	1
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	100.00%

Table 2.2 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	2	0	1
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	1	3	2	0	1
MDUFA IV Decision Goal Met	1	3	2	0	1
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	100.00%

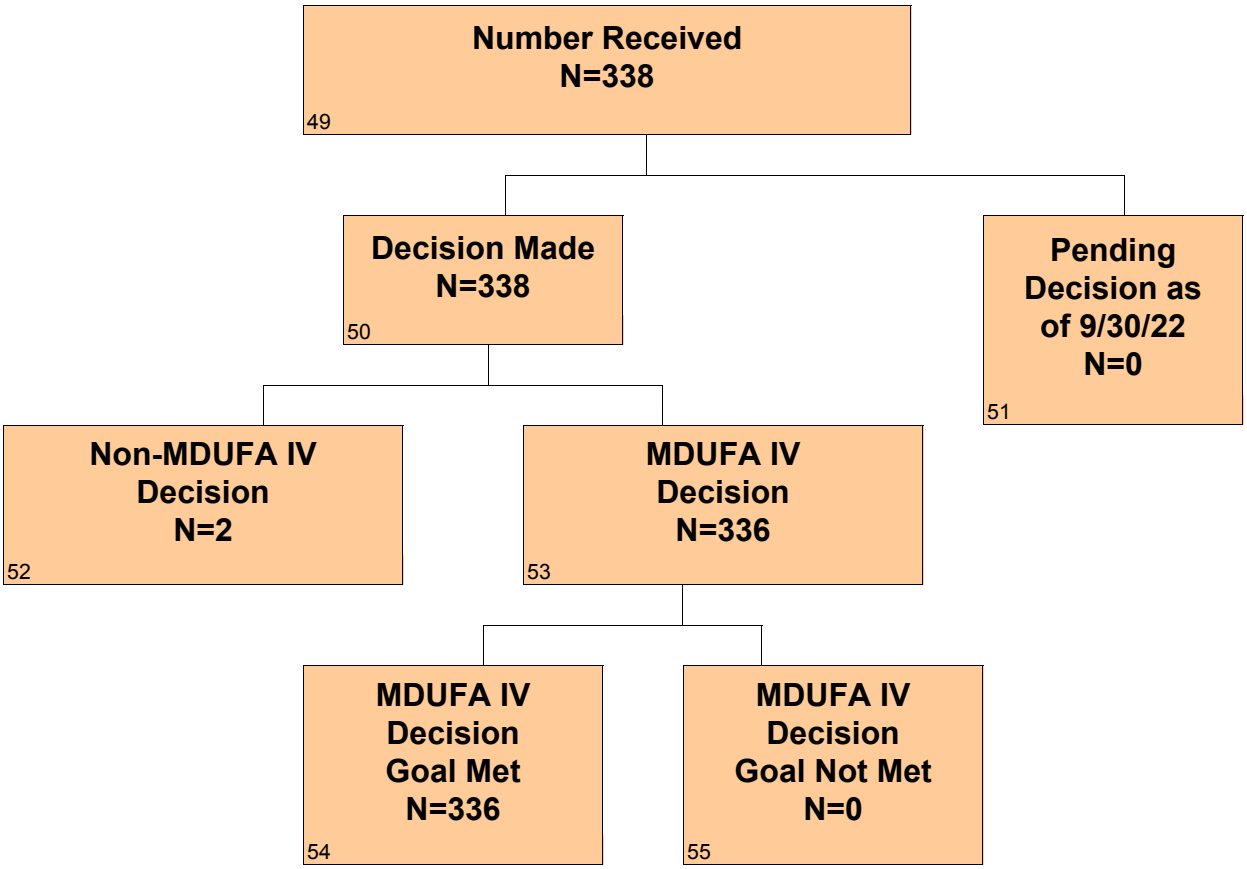
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	3	2	0	1
Number with MDUFA IV Decision	1	3	2	0	1
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	0.00%

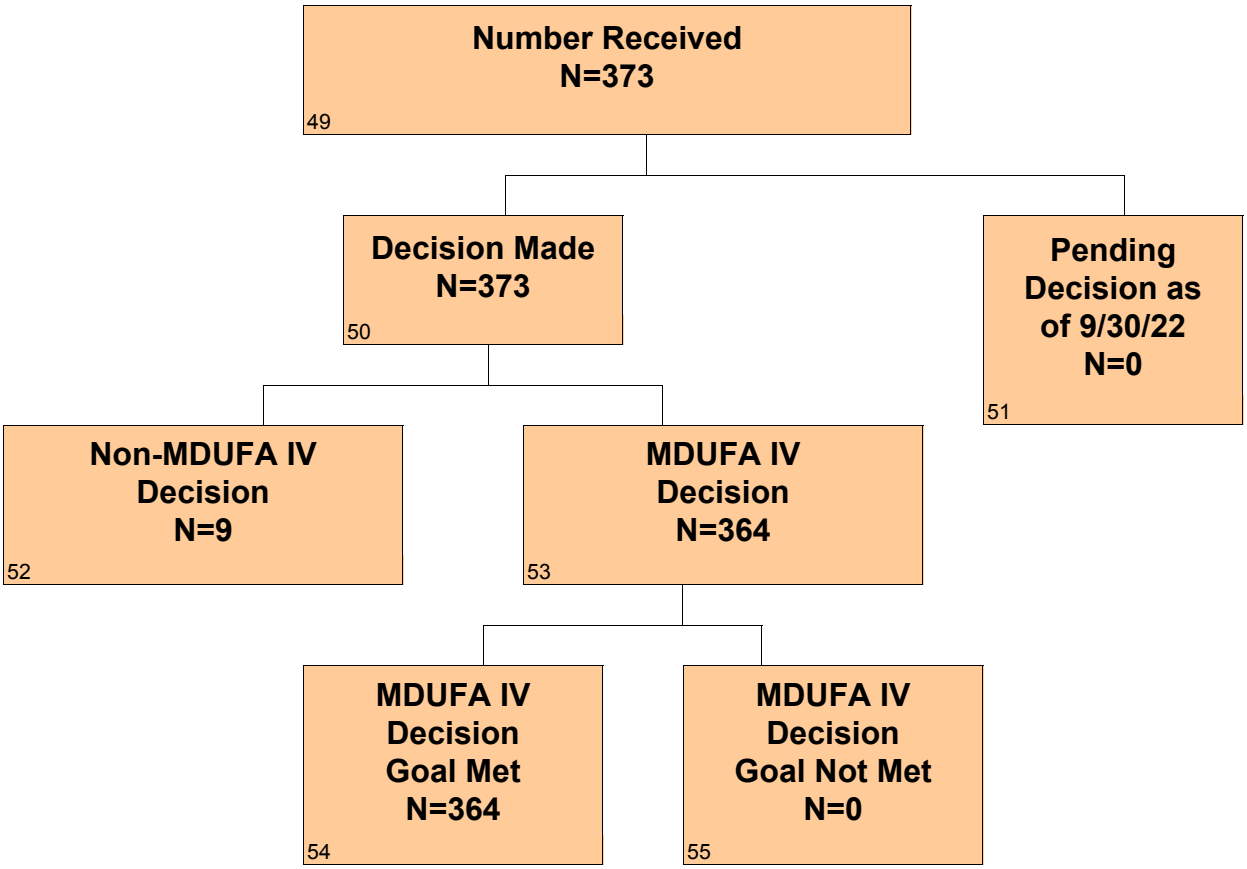
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

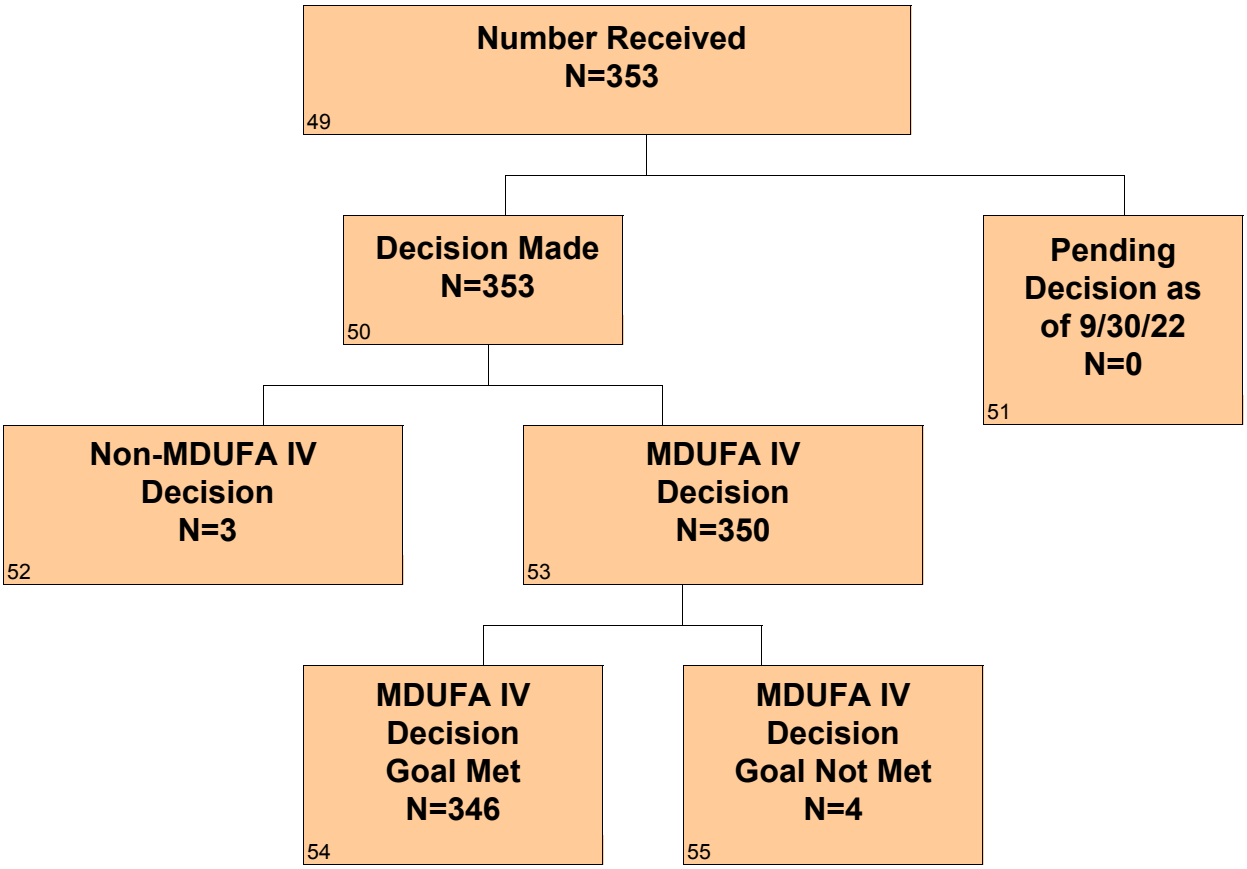
CDRH PMA Real Time Supplements - FY 2018 as of 9/30/22



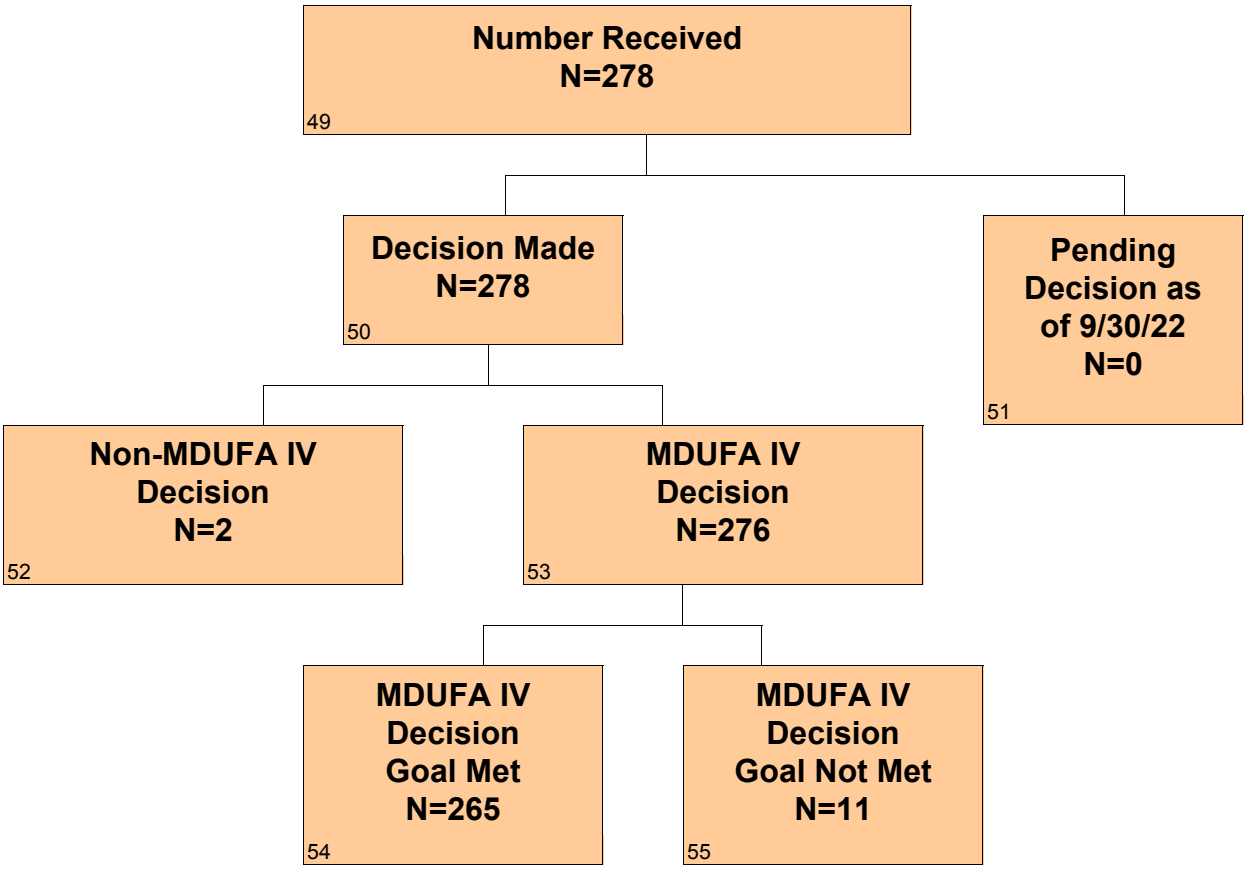
CDRH PMA Real Time Supplements - FY 2019 as of 9/30/22



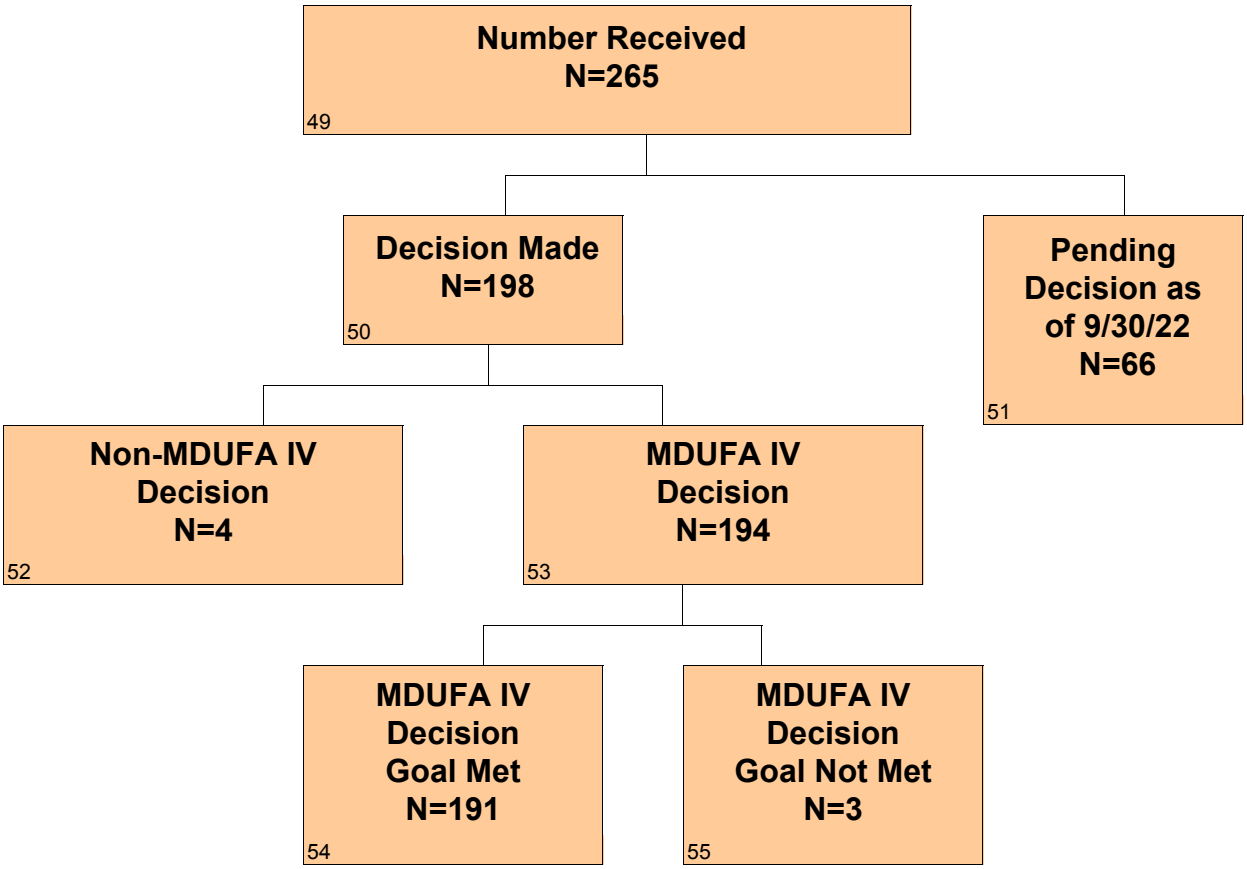
CDRH PMA Real Time Supplements - FY 2020 as of 9/30/22



CDRH PMA Real Time Supplements - FY 2021 as of 9/30/22



CDRH PMA Real Time Supplements - FY 2022 as of 9/30/22



Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	338	373	353	278	265
Non-MDUFA IV Decision	2	9	3	2	4
MDUFA IV Decision	336	364	350	276	195
MDUFA IV Decision Goal Met	336	364	346	265	192
Supplements Pending MDUFA IV Decision	0	0	0	0	66
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	4
Current Performance Percent Goal Met	100.00%	100.00%	98.86%	96.01%	96.48%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	338	373	353	278	265
Number With MDUFA IV Decision	336	364	350	276	195
Number of Not Approvable	20	29	6	10	8
Rate of Not Approvable	5.95%	7.97%	1.71%	3.62%	4.10%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	11	7
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.25	194.55	151.29
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	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 IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	23	40	16	21	24
Non-MDUFA IV Decision	0	2	1	0	0
MDUFA IV Decision	23	38	15	21	14
MDUFA IV Decision Goal Met	23	38	15	21	14
Supplements Pending MDUFA IV Decision	0	0	0	0	10
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	40	16	21	24
Number With MDUFA IV Decision	23	38	15	21	14
Number of Not Approvable	1	1	0	0	0
Rate of Not Approvable	4.35%	2.63%	0.00%	0.00%	0.00%

Table 3.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	154	173	193	147	122
Non-MDUFA IV Decision	0	3	2	0	1
MDUFA IV Decision	154	170	191	147	89
MDUFA IV Decision Goal Met	154	170	190	146	89
Supplements Pending MDUFA IV Decision	0	0	0	0	32
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	99.48%	99.32%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	173	193	147	122
Number With MDUFA IV Decision	154	170	191	147	89
Number of Not Approvable	12	15	1	2	2
Rate of Not Approvable	7.79%	8.82%	0.52%	1.36%	2.25%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	1	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	99.00	134.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	20	39	36	16	27
Non-MDUFA IV Decision	0	1	0	2	0
MDUFA IV Decision	20	38	36	14	24
MDUFA IV Decision Goal Met	20	38	36	14	24
Supplements Pending MDUFA IV Decision	0	0	0	0	3
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	20	39	36	16	27
Number with MDUFA IV Decision	20	38	36	14	24
Number of Not Approvable	1	8	1	0	3
Rate of Not Approvable	5.00%	21.05%	2.78%	0.00%	12.50%

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	13	18	13	13	6
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	12	18	13	13	3
MDUFA IV Decision Goal Met	12	18	13	10	2
Supplements Pending MDUFA IV Decision	0	0	0	0	3
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	3
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	76.92%	33.33%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	18	13	13	6
Number with MDUFA IV Decision	12	18	13	13	3
Number of Not Approvable	4	0	0	1	0
Rate of Not Approvable	33.33%	0.00%	0.00%	7.69%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	3	4
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	205.33	177.50
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	16	32	24	22	31
Non-MDUFA IV Decision	0	0	0	0	1
MDUFA IV Decision	16	32	24	22	25
MDUFA IV Decision Goal Met	16	32	24	22	25
Supplements Pending MDUFA IV Decision	0	0	0	0	5
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	32	24	22	31
Number with MDUFA IV Decision	16	32	24	22	25
Number of Not Approvable	0	2	3	1	1
Rate of Not Approvable	0.00%	6.25%	12.50%	4.55%	4.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 3.1 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	17	22	9	3	9
Non-MDUFA IV Decision	0	0	0	0	1
MDUFA IV Decision	17	22	9	3	7
MDUFA IV Decision Goal Met	17	22	9	3	7
Supplements Pending MDUFA IV Decision	0	0	0	0	1
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	22	9	3	9
Number with MDUFA IV Decision	17	22	9	3	7
Number of Not Approvable	2	2	1	1	1
Rate of Not Approvable	11.76%	9.09%	11.11%	33.33%	14.29%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	93	48	61	55	46
Non-MDUFA IV Decision	1	3	0	0	1
MDUFA IV Decision	92	45	61	55	33
MDUFA IV Decision Goal Met	92	45	58	48	31
Supplements Pending MDUFA IV Decision	0	0	0	0	12
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	1
Current Performance Percent Goal Met	100.00%	100.00%	95.08%	87.27%	91.18%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	93	48	61	55	46
Number with MDUFA IV Decision	92	45	61	55	33
Number of Not Approvable	0	1	0	5	1
Rate of Not Approvable	0.00%	2.22%	0.00%	9.09%	3.03%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	3	7	3
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.00	198.57	116.33
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	2	1	1	1	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	1	1	1	0
MDUFA IV Decision Goal Met	2	1	1	1	0
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	1	1	1	0
Number with MDUFA IV Decision	2	1	1	1	0
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.00%	0.00%	0.00%	0.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Page intentionally left blank

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2021 and September 30, 2022.

Page intentionally left blank

Section 5 PMA Annual General Metrics

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

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0	0	0	0
Original PMAs (Panel) - Breakthrough Device	1	0	1	0	0
Original PMAs (No Panel) - Breakthrough Device	3	2	5	7	1
Original PMAs (Panel) - Non-Breakthrough Device	4	2	2	1	0
Original PMAs (No Panel) - Non-Breakthrough Device	38	31	40	32	21
Panel-Tracked Supplements (Panel) - Breakthrough Device	0	0	0	0	0
Panel-Tracked Supplements (No Panel) - Breakthrough Device	1	0	1	0	1
Panel-Tracked Supplements (Panel) - Non-Breakthrough Device	0	0	1	1	0
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	27	21	27	37	22
PMA Modules	64	73	70	73	88
180-Day Supplements	188	191	176	188	146
Real-Time Supplements	338	373	353	278	265

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	71	55	73	72	36
Number With a Decision (MDUFA or Non-MDUFA)	70	55	69	53	7
% of FY Closed	98.59%	100.00%	94.52%	73.61%	19.44%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	3 Year Cohort 320 FDA Days	3 Year Cohort 315 FDA Days	3 Year Cohort 310 FDA Days	3 Year Cohort 300 FDA Days	3 Year Cohort 290 FDA Days
Number With a MDUFA Decision	198	183	190	175	129
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	180	165	172	159	117
Three-year Rolling Average Total Time to MDUFA Decision	264.04	264.42	N/A	N/A	N/A

PM Originals and Panel Track Supplements (FY22 Q4)					
Amendment Type	**FY2018**	**FY2019**	**FY2020**	**FY2021**	**FY2022**
MAJR - Response to MAJR Deficiency Letter	37	40	32	43	13
ADEF - Response to Approvable Pending Deficiency Letter	0	0	0	0	0
NOAP - Response to Mot Approvable Deficiency Letter	5	7	0	1	1
UMAJ - Unsolicited Major Amendment	5	5	1	1	0
UMIN - Unsolicited Minor Amendment	64	54	62	54	22

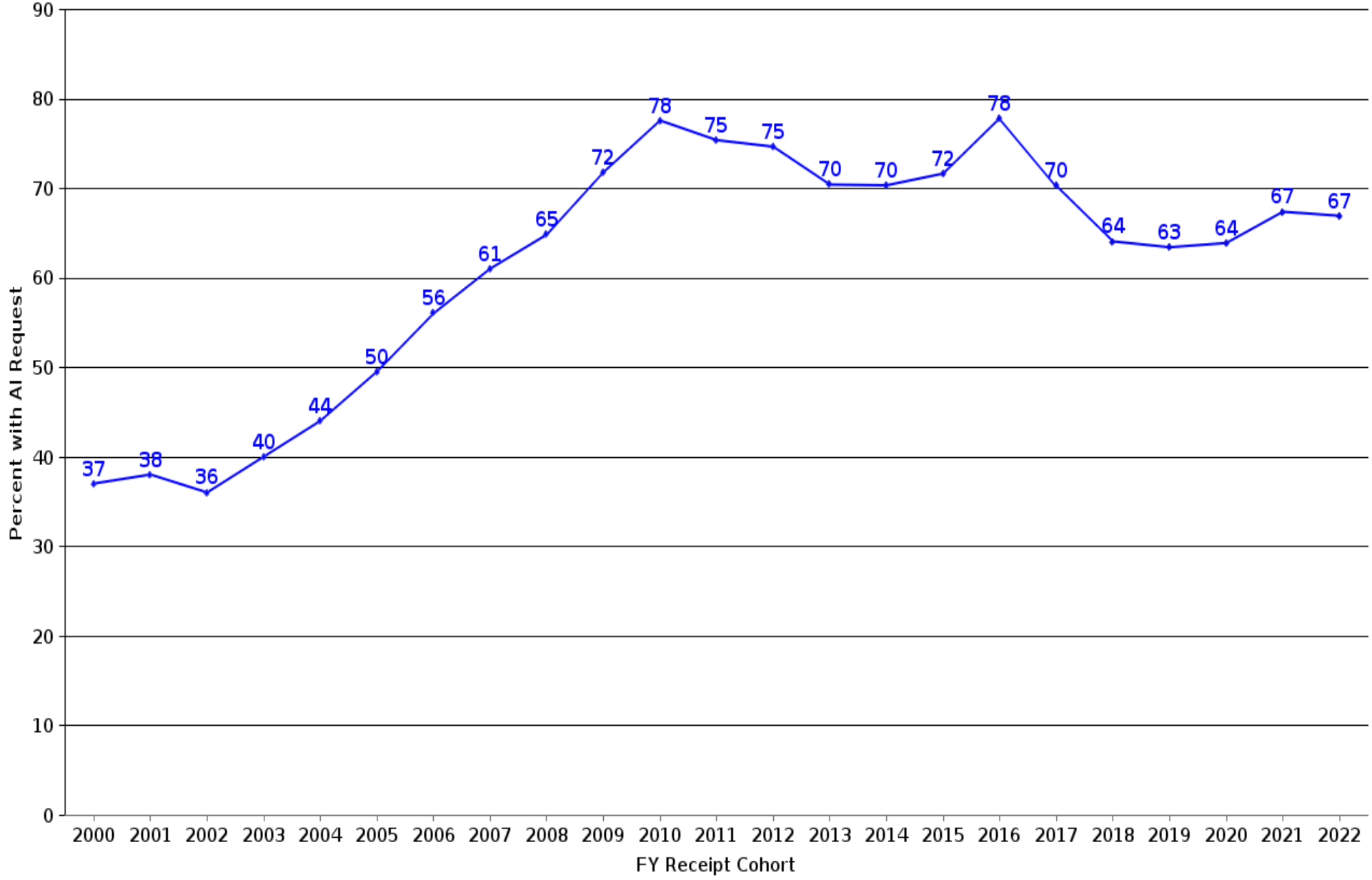
PM 180-Day Supplements (FY22 Q4)					
Amendment Type	**FY2018**	**FY2019**	**FY2020**	**FY2021**	**FY2022**
MAJR - Response to MAJR Deficiency Letter	92	92	93	103	29
ADEF - Response to Approvable Pending Deficiency Letter	2	2	1	0	0
NOAP - Response to Mot Approvable Deficiency Letter	14	8	7	3	1
UMAJ - Unsolicited Major Amendment	0	0	0	0	0
UMIN - Unsolicited Minor Amendment	34	63	48	17	10

PM Real-Time Supplements (FY22 Q4)					
Amendment Type	**FY2018**	**FY2019**	**FY2020**	**FY2021**	**FY2022**
MAJR - Response to MAJR Deficiency Letter	0	0	0	0	0
ADEF - Response to Approvable Pending Deficiency Letter	3	8	0	2	0
NOAP - Response to Mot Approvable Deficiency Letter	8	26	5	9	2
UMAJ - Unsolicited Major Amendment	0	0	0	0	0
UMIN - Unsolicited Minor Amendment	11	39	26	21	13

510(k)s

Q4FY2022

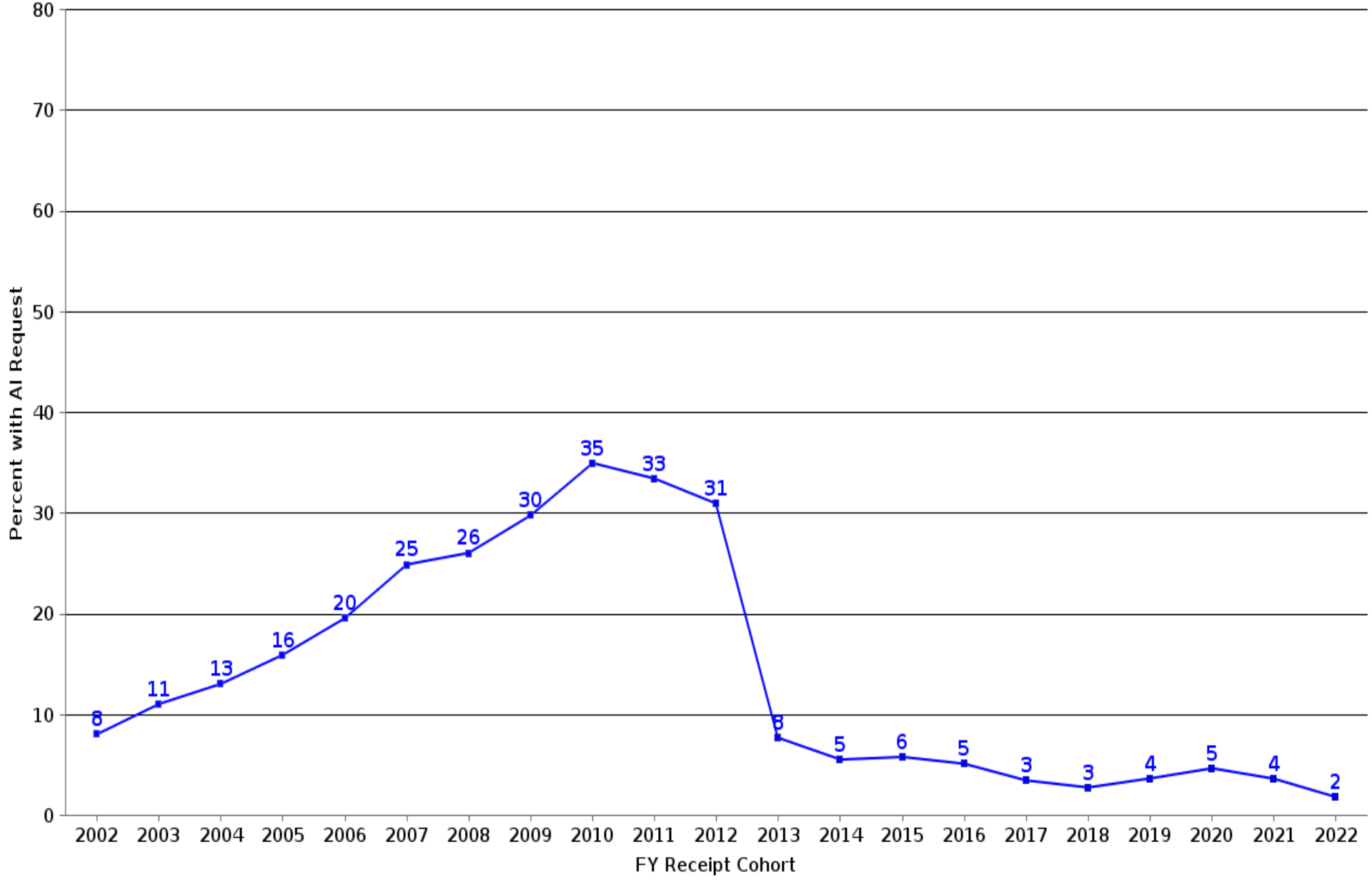
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/22

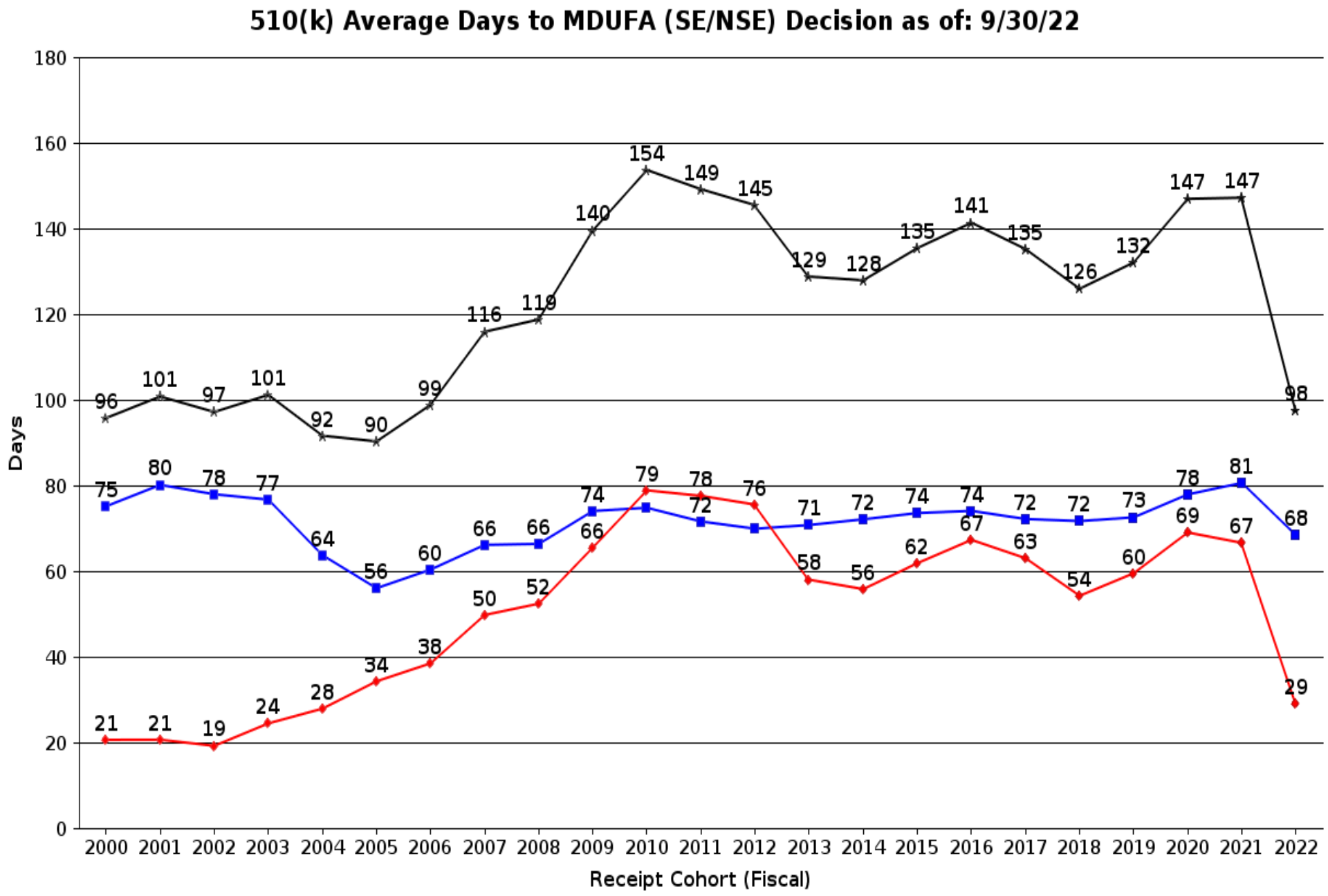
♦ % with 1st Cycle AI Request

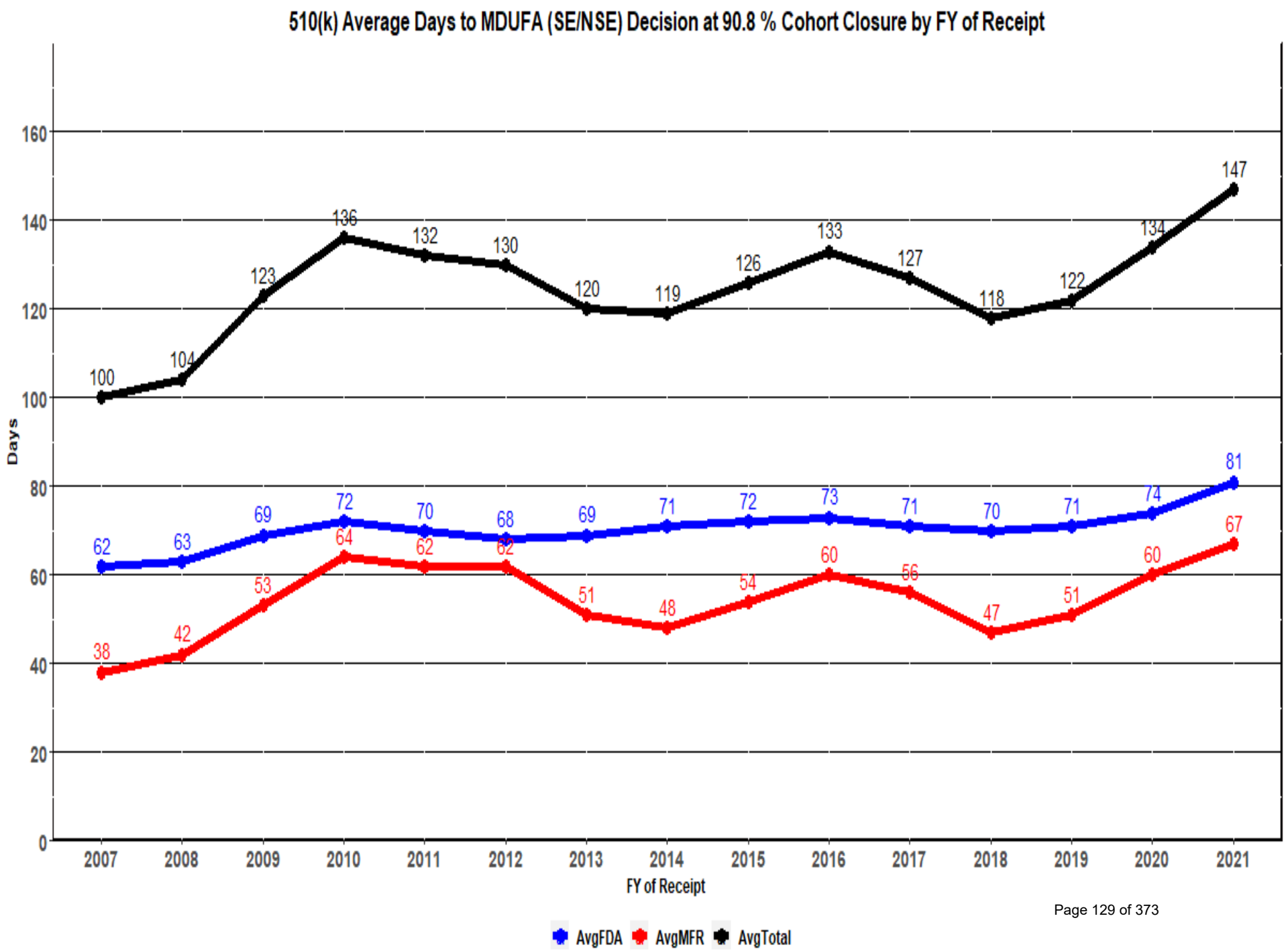
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

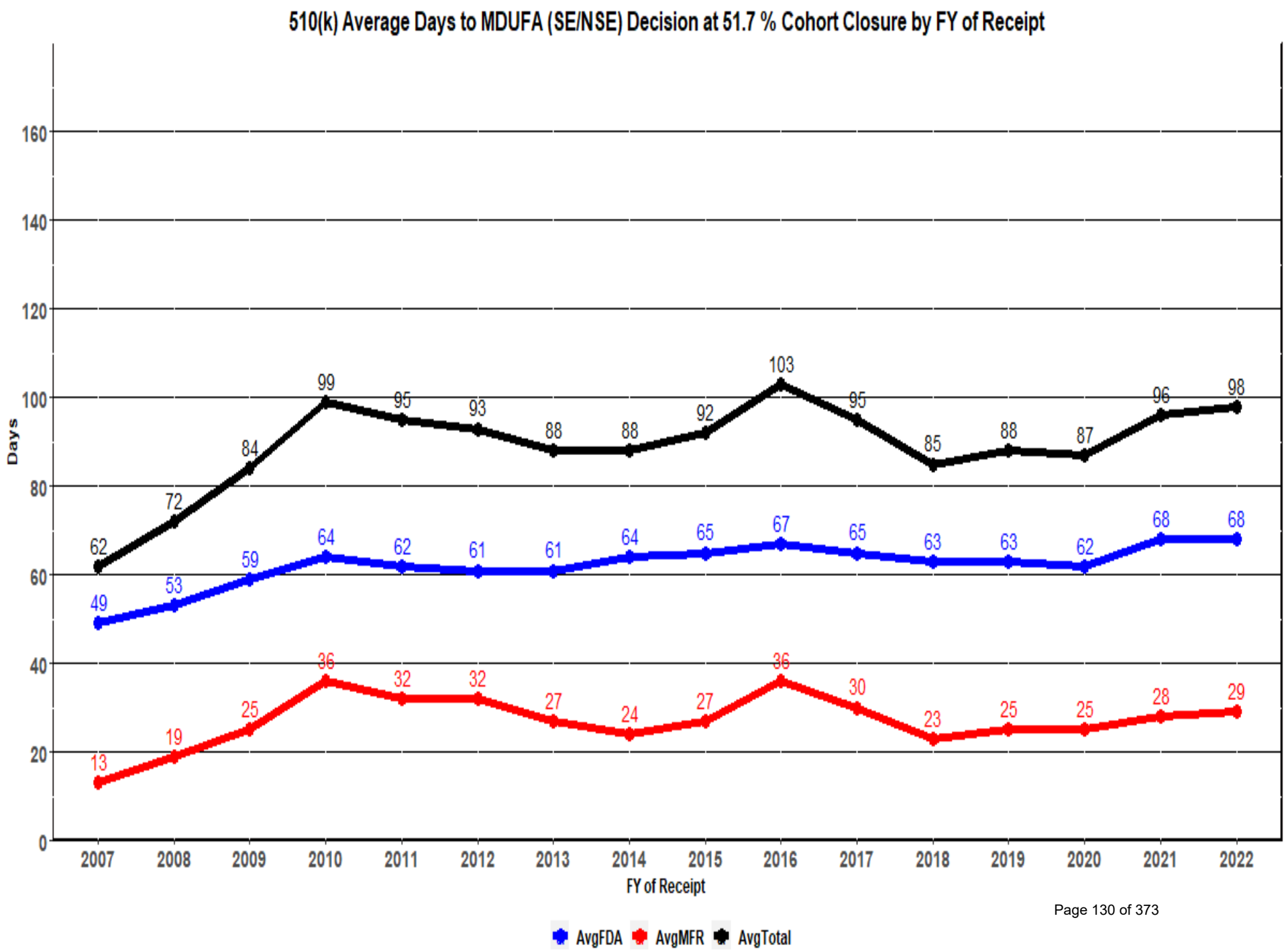


AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 2/28/22

■ % with 2nd Cycle AI Request

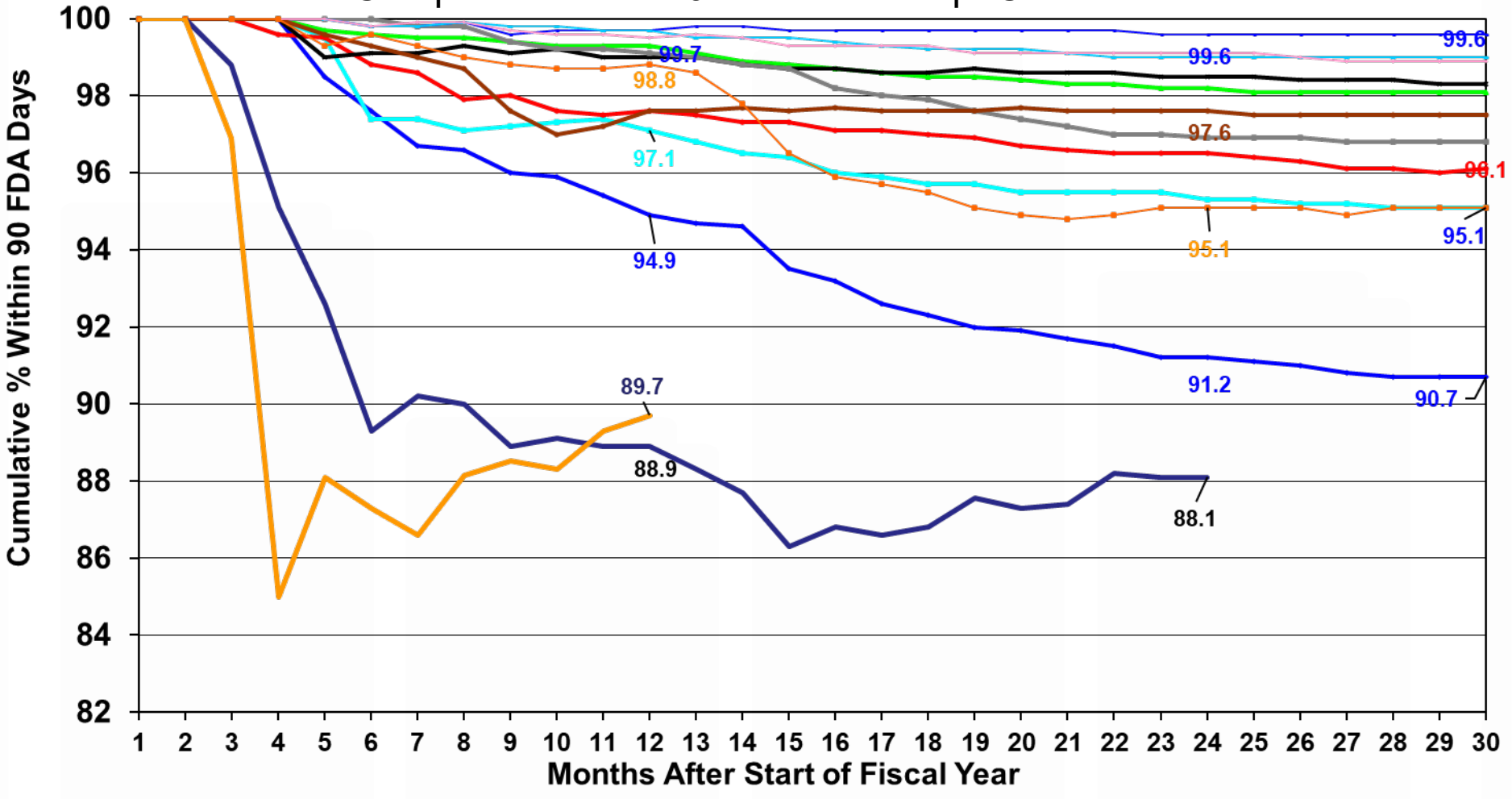

510(k) Average Days to MDUFA (SE/NSE) Decision as of: 9/30/22
Days
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2019: 99.97%; 2020: 99.25%; 2021: 90.78%; 2022: 51.66%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision


510(k) Average Days to MDUFA (SE/NSE) Decision at 90.8 % 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
100
104
123
136
132
130
120
119
126
133
127
118
122
134
147
62
63
69
72
70
68
69
71
72
73
71
70
71
74
81
38
42
53
64
62
62
51
48
54
60
56
47
51
60
67

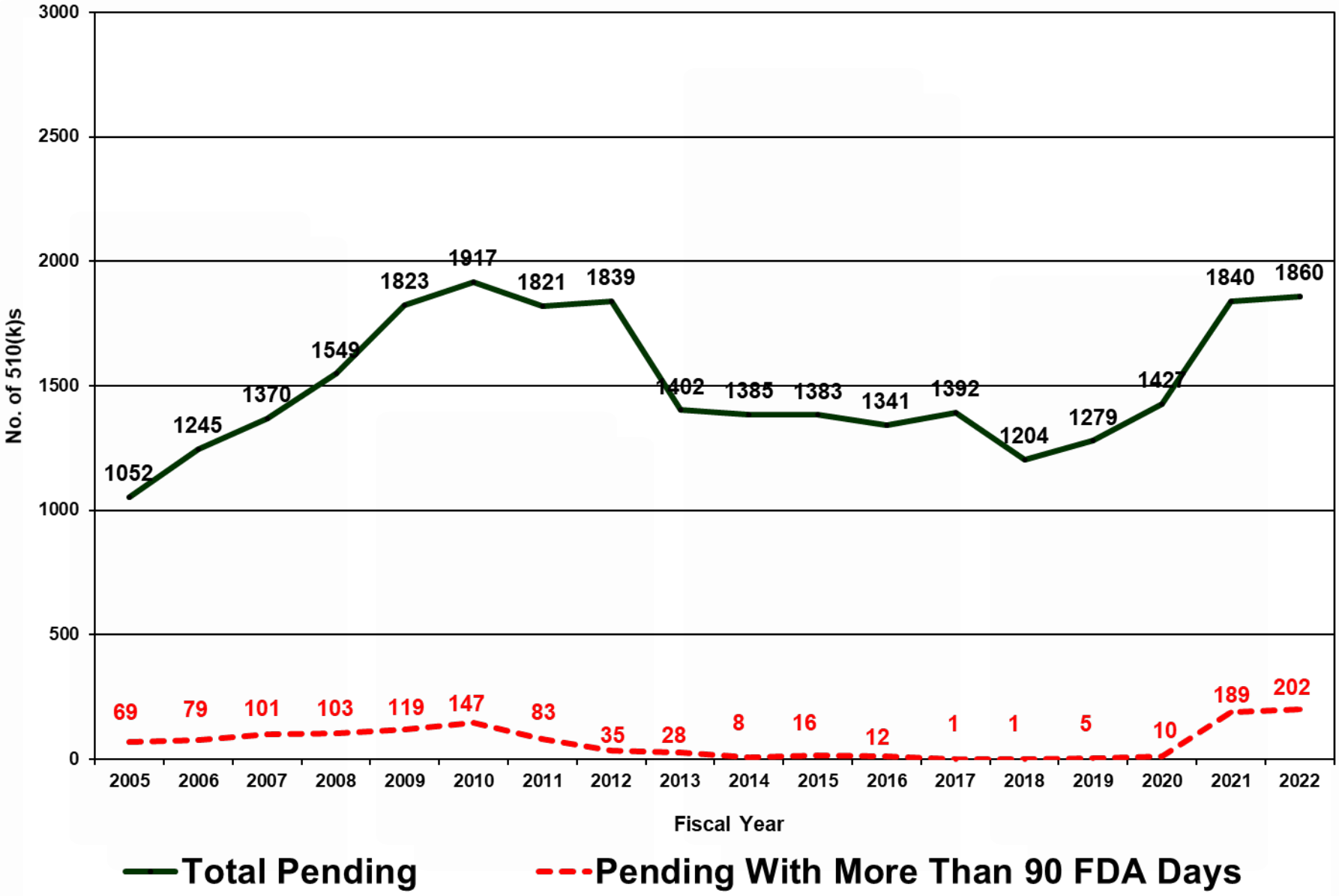

510(k) Average Days to MDUFA (SE/NSE) Decision at 51.7 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY of Receipt
62
72
84
99
95
93
88
88
92
103
95
85
88
87
96
98
49
53
59
64
62
61
61
64
65
67
65
63
63
62
68
68
13
19
25
36
32
32
27
24
27
36
30
23
25
25
28
29
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

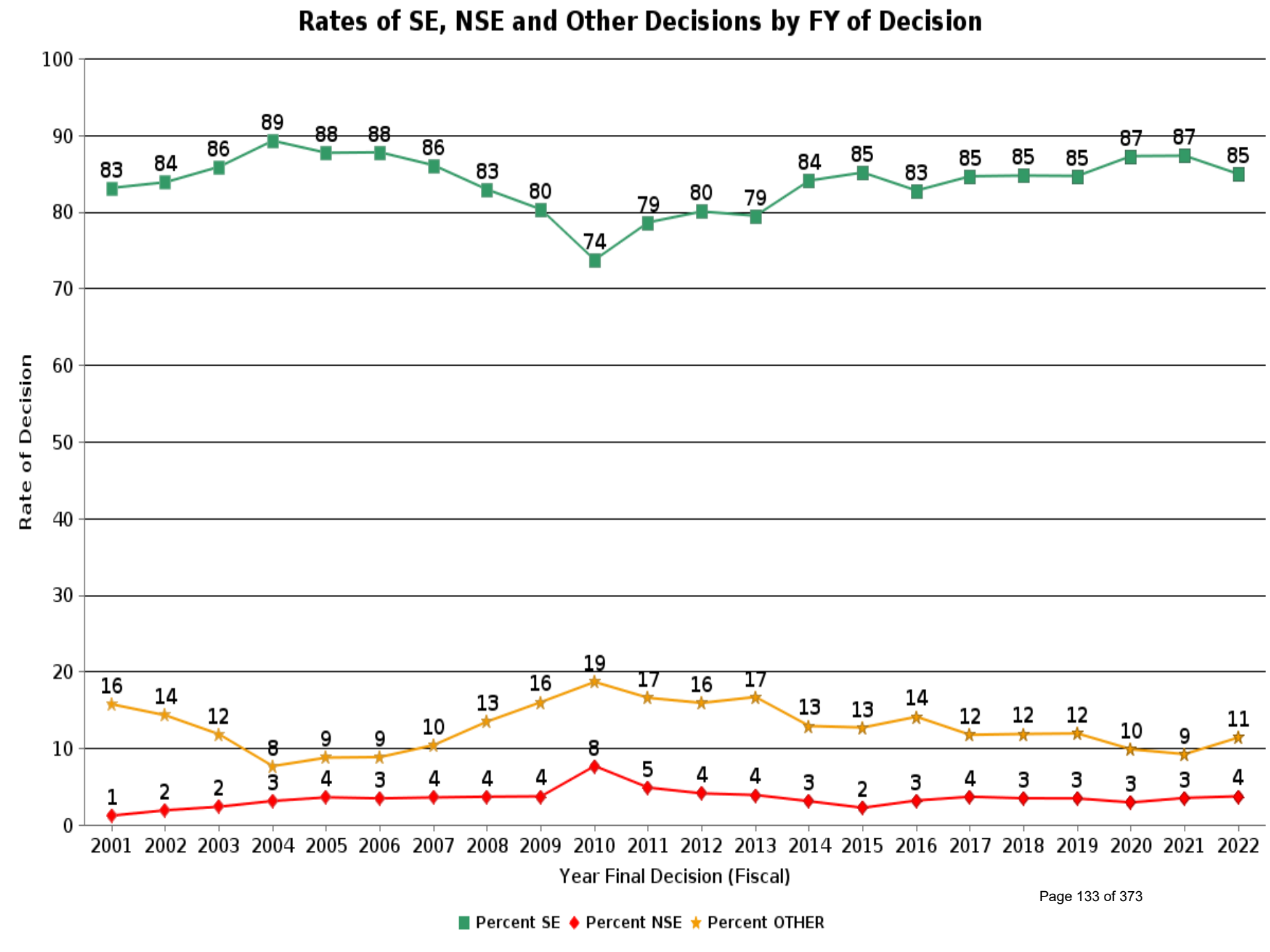
Comparison of FY10 – FY22 Receipt Cohorts



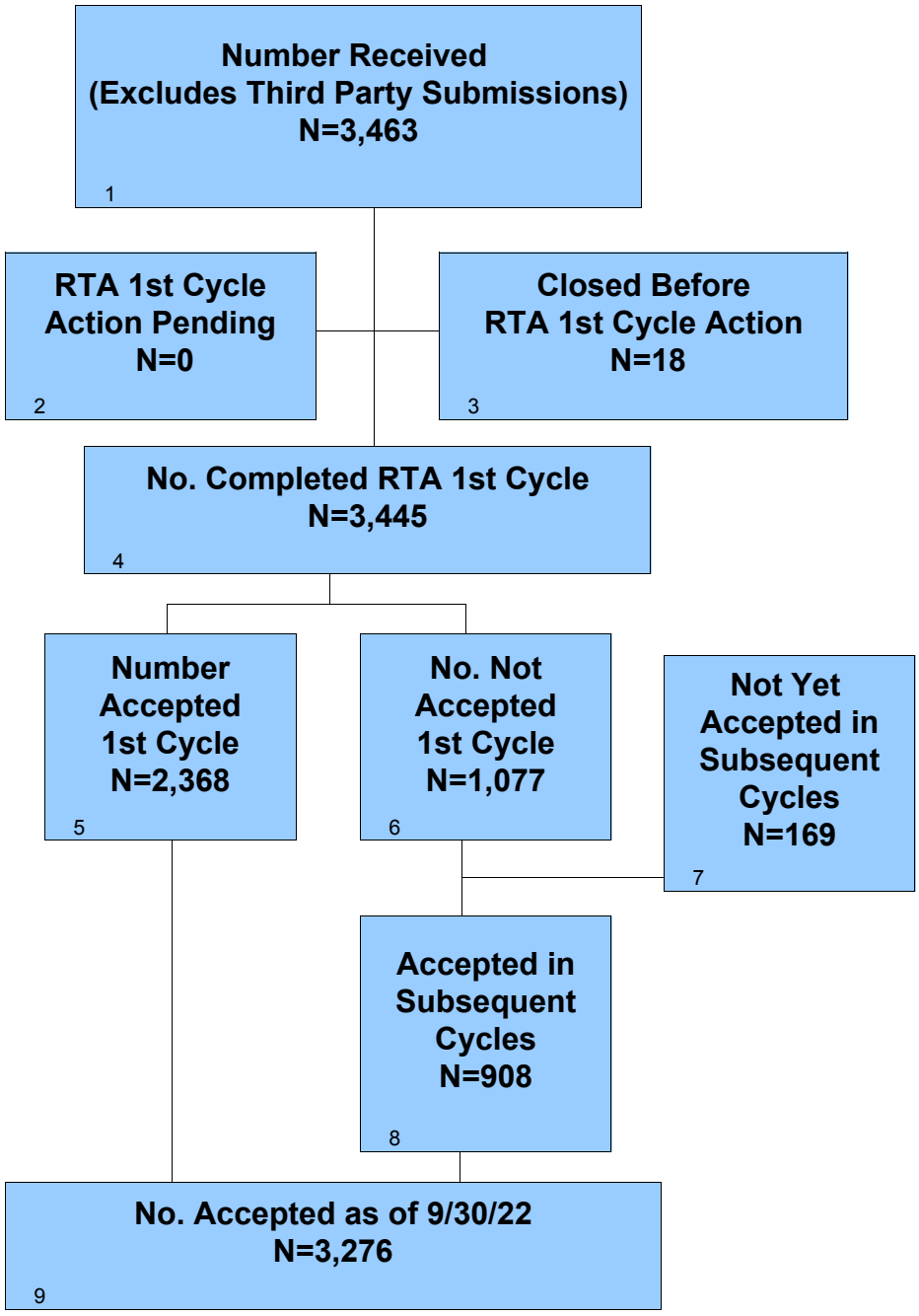
510(k)s Pending at End of Quarter/Year



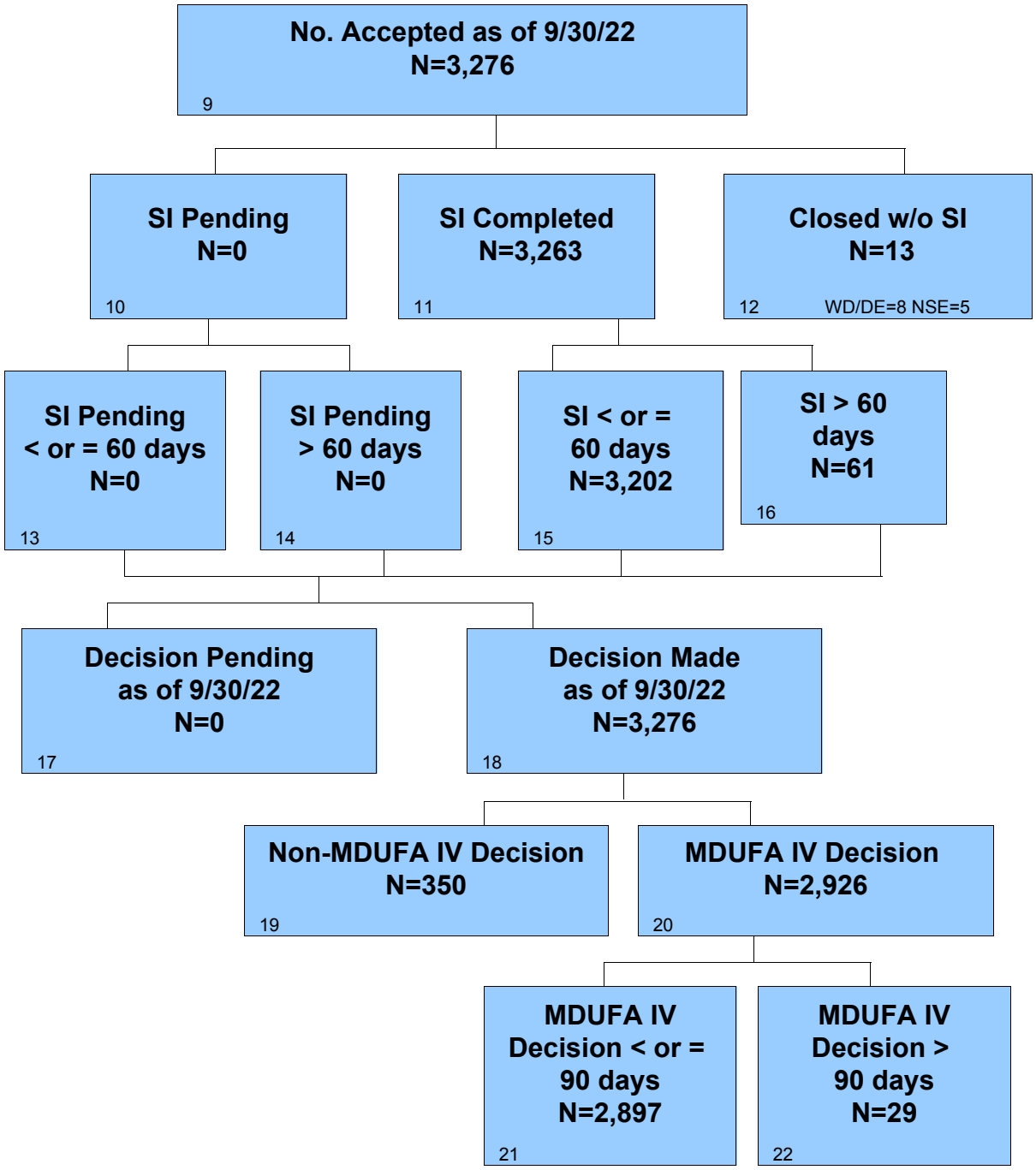
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

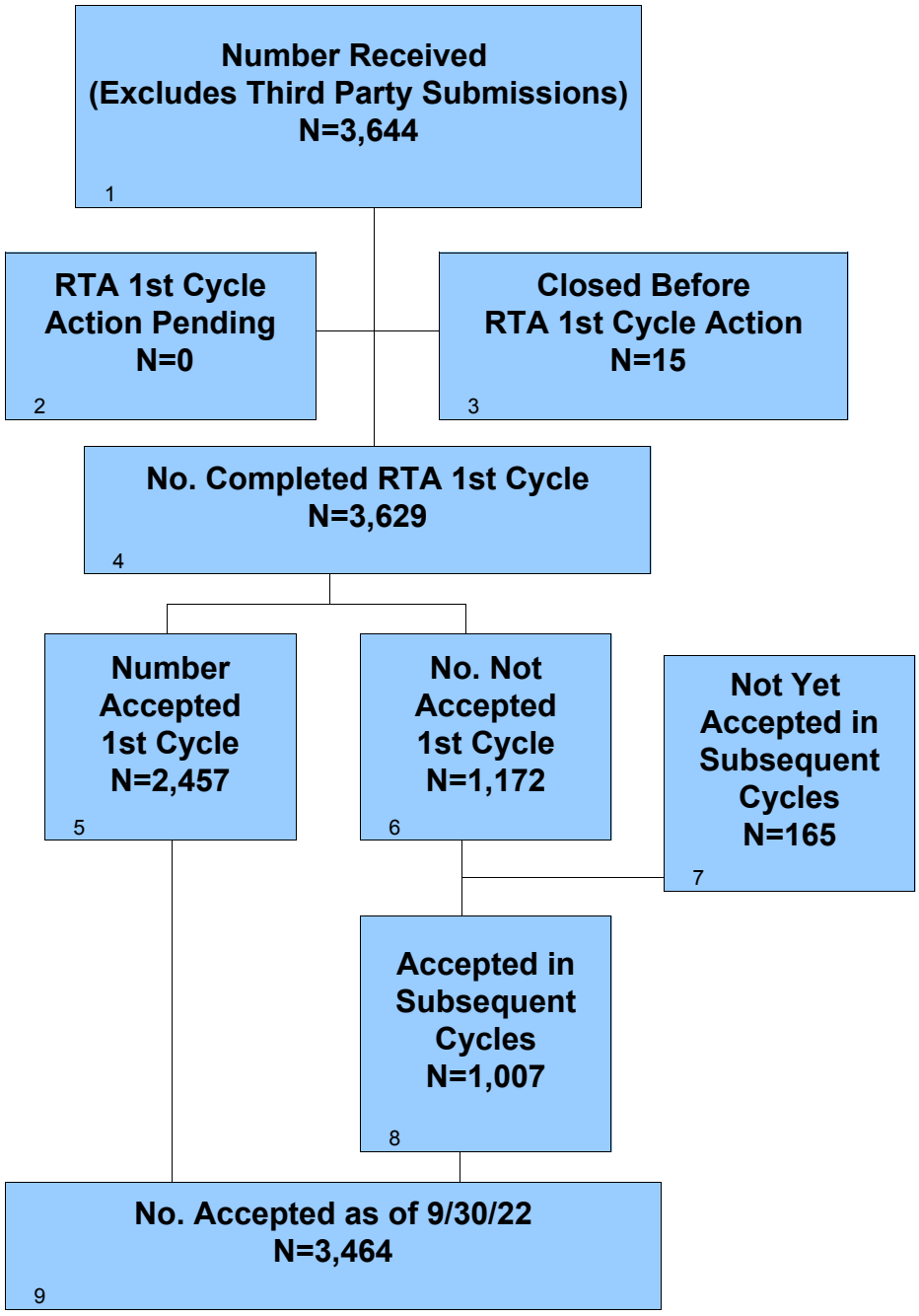
CDRH 510(k)s - FY 2018
as of 9/30/22



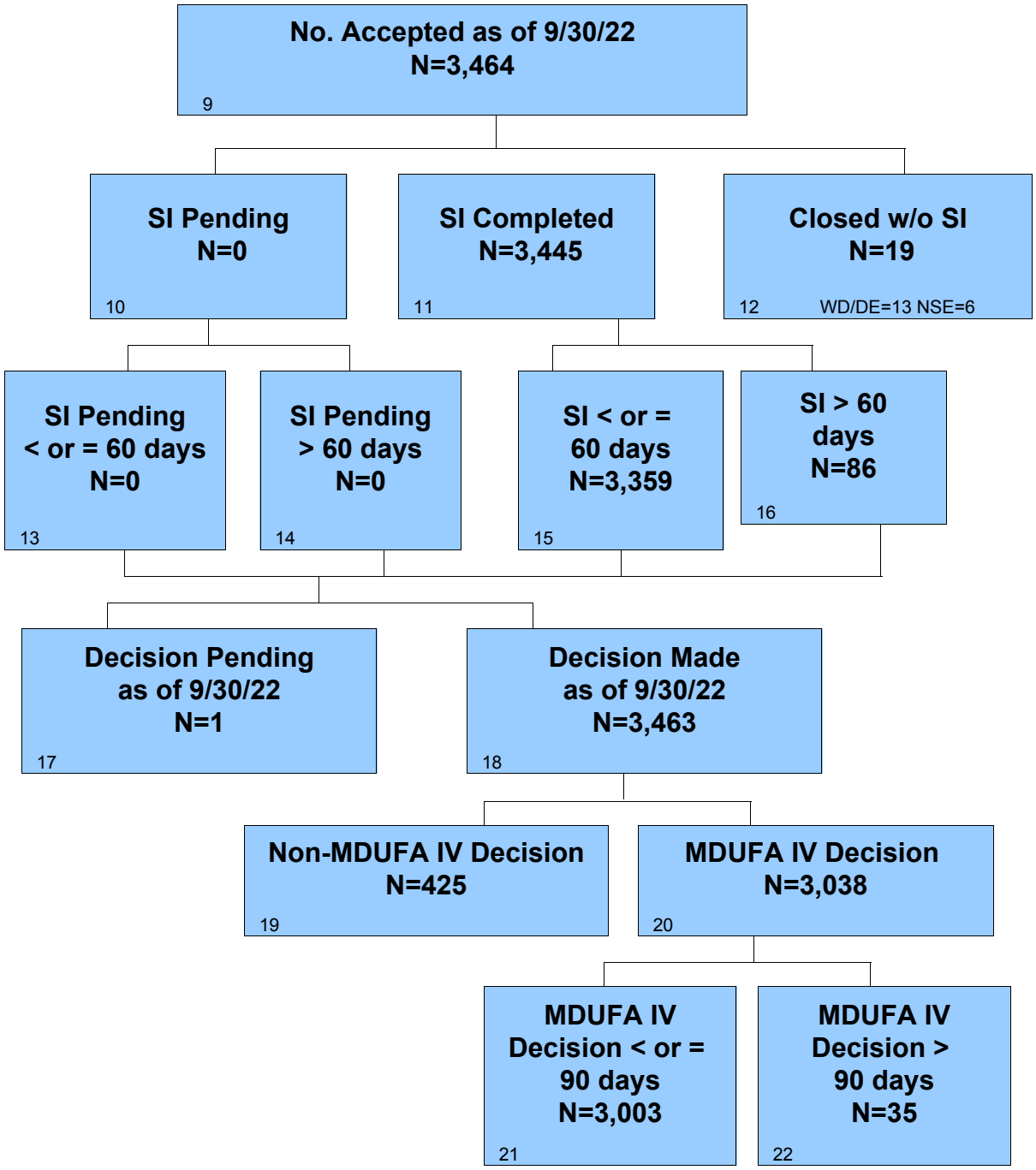
CDRH 510(k)s - FY 2018 as of 9/30/22 Continued



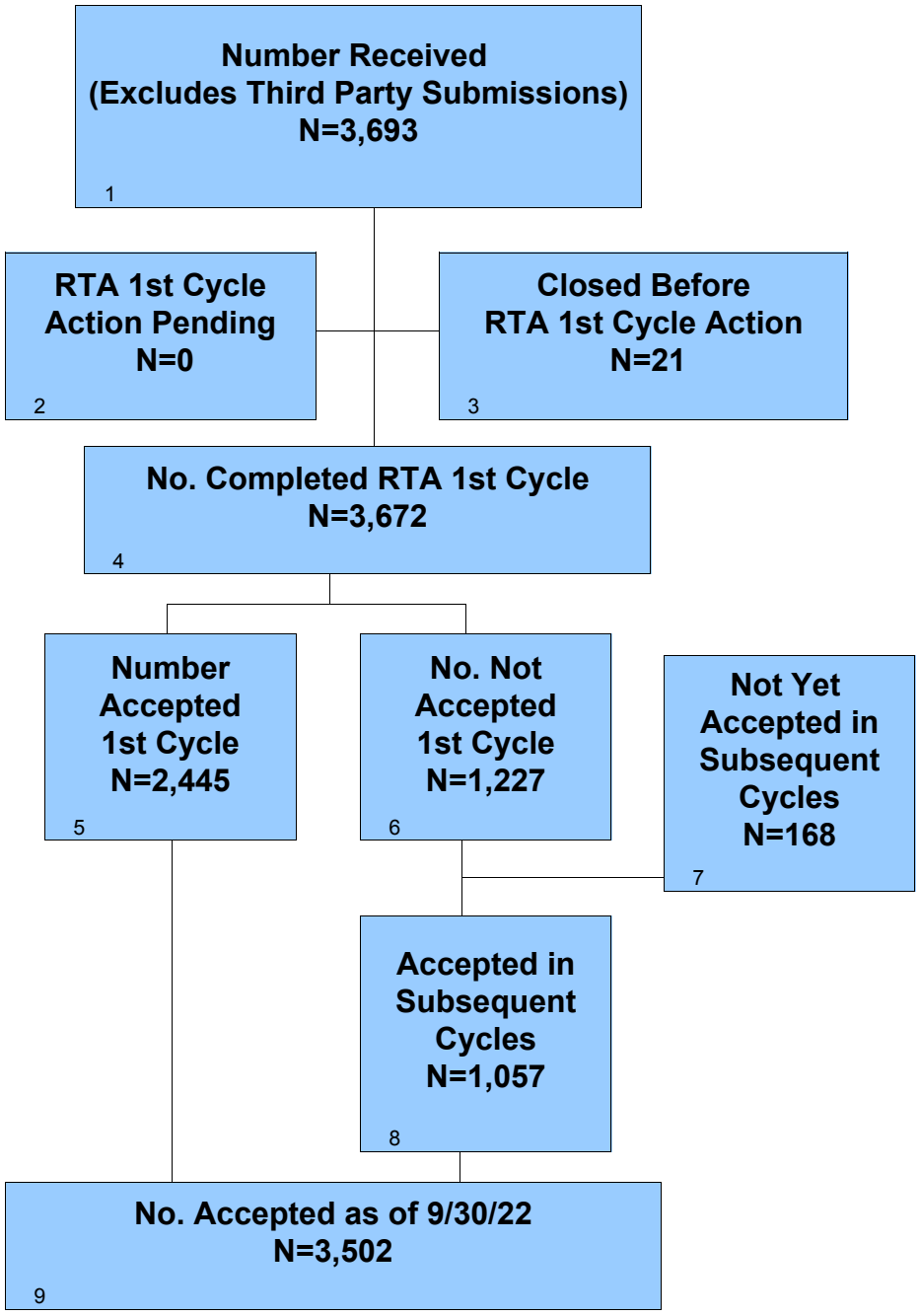
CDRH 510(k)s - FY 2019
as of 9/30/22



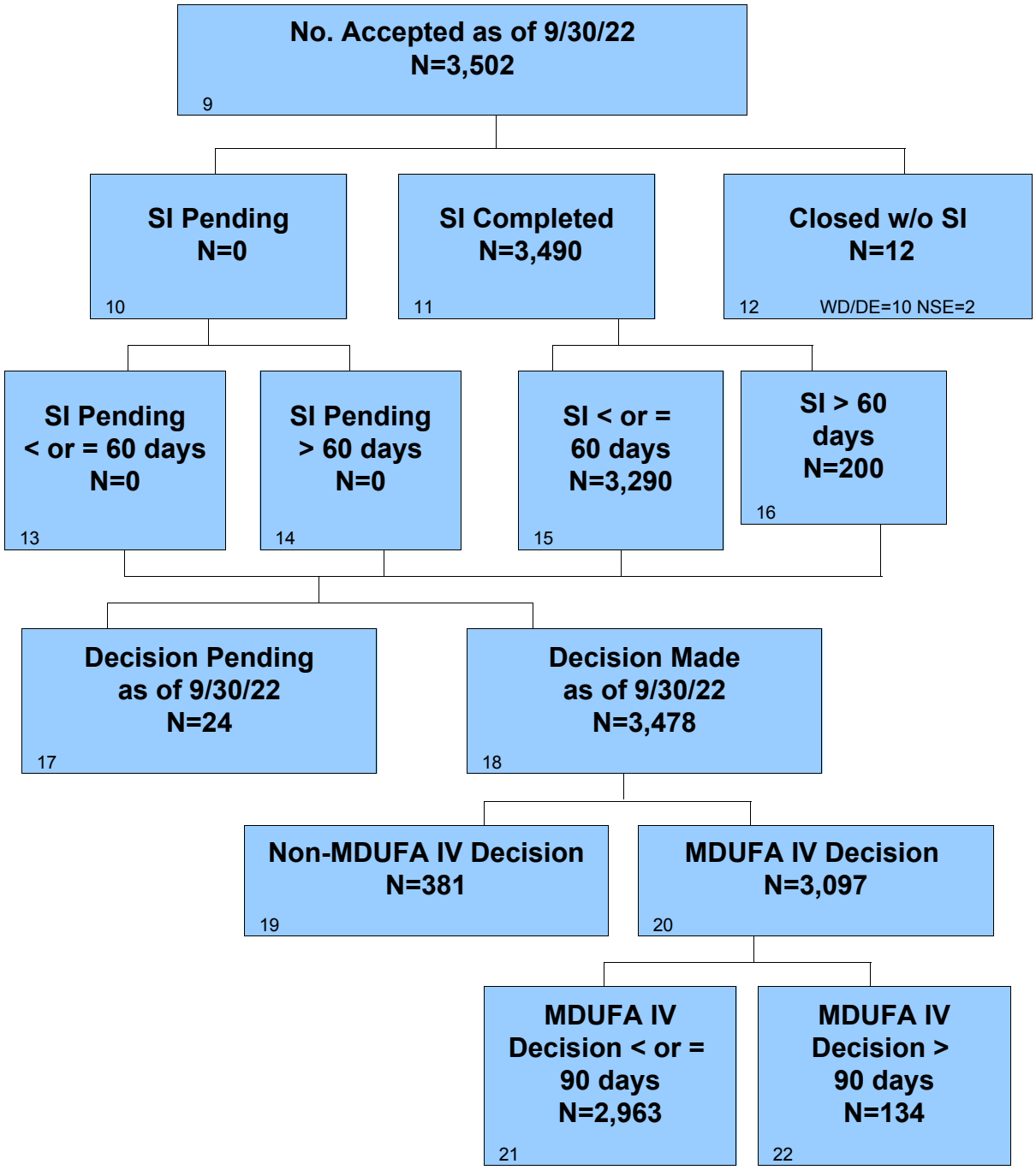
CDRH 510(k)s - FY 2019 as of 9/30/22 Continued



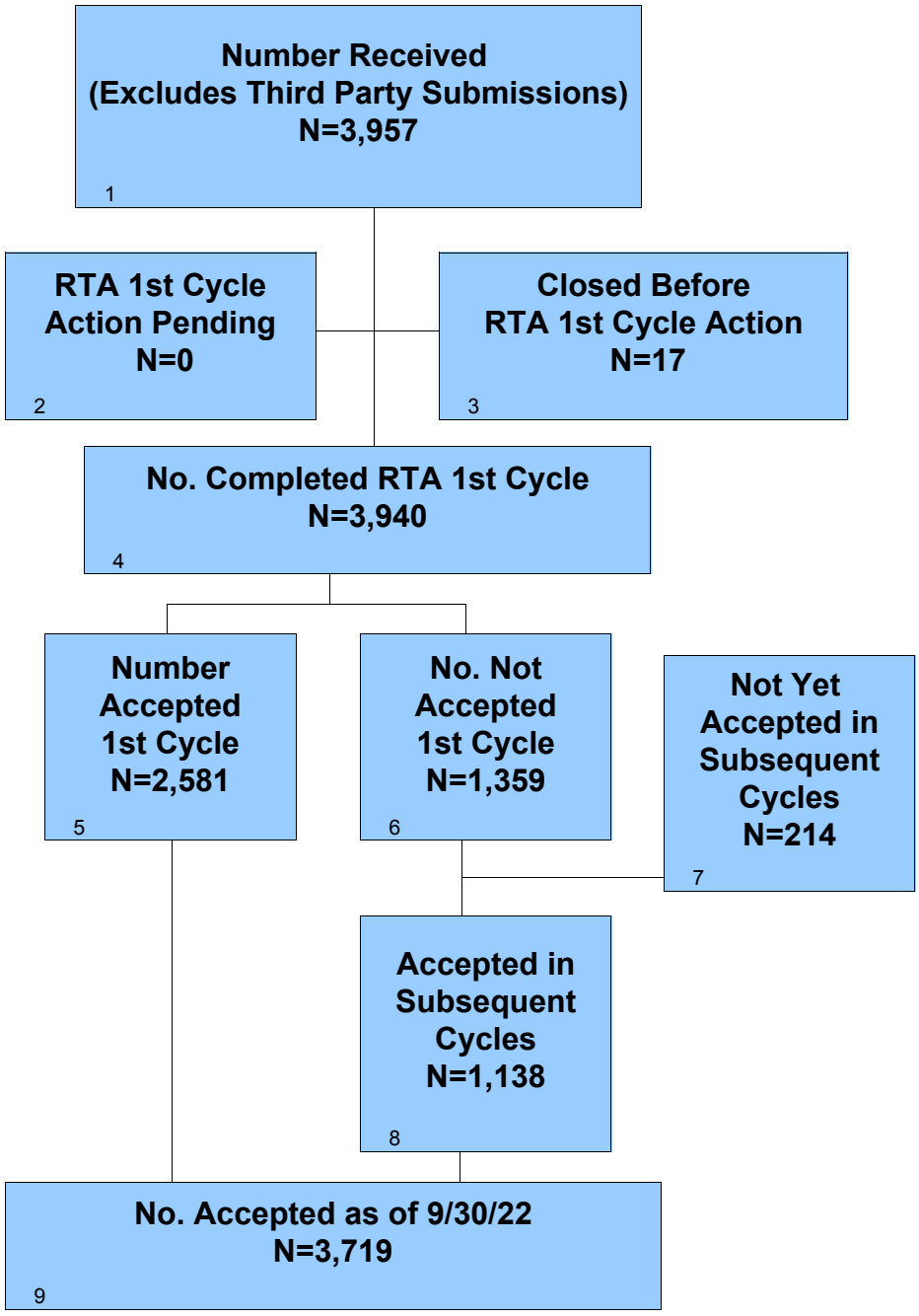
CDRH 510(k)s - FY 2020
as of 9/30/22



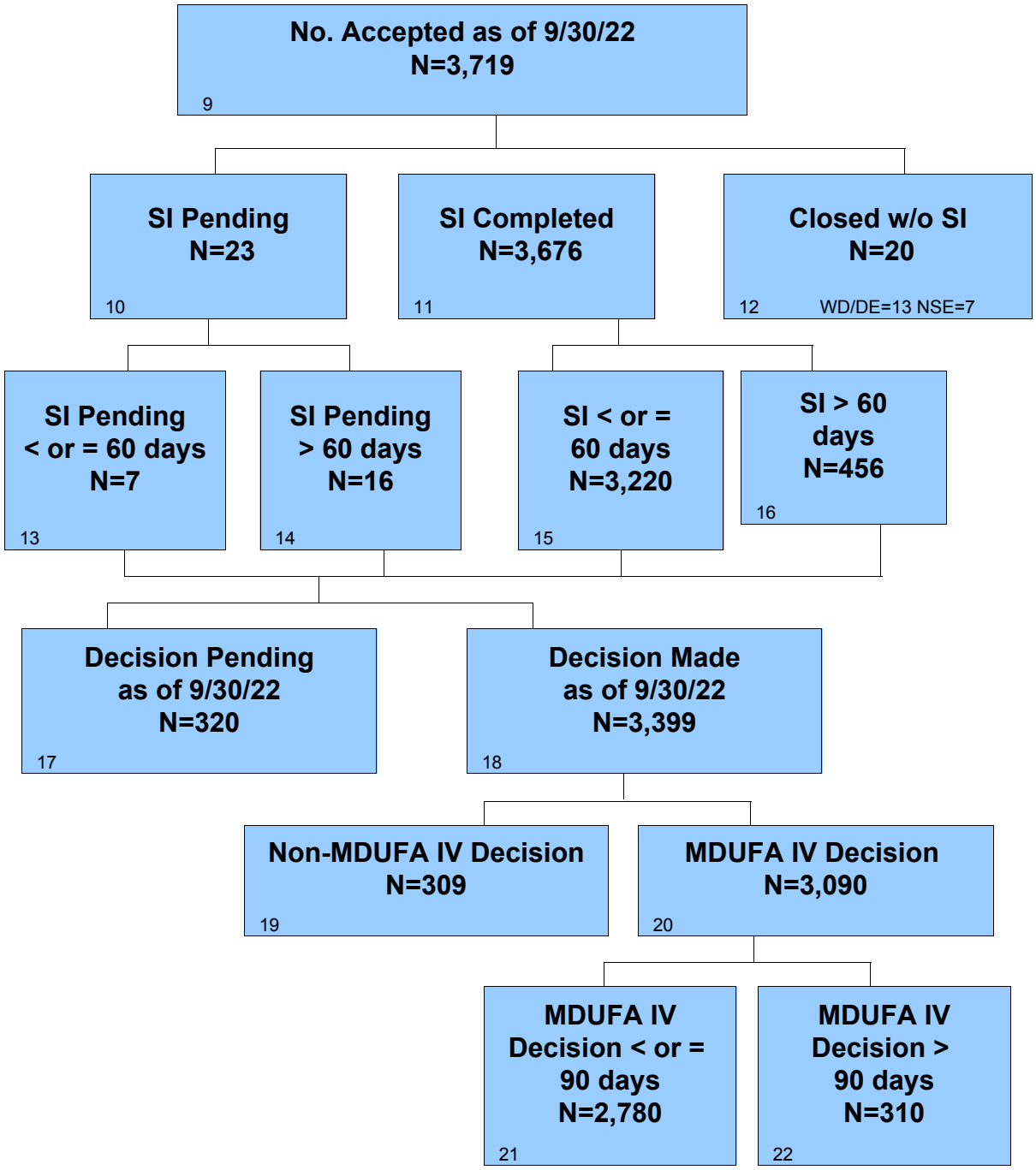
CDRH 510(k)s - FY 2020
as of 9/30/22 Continued



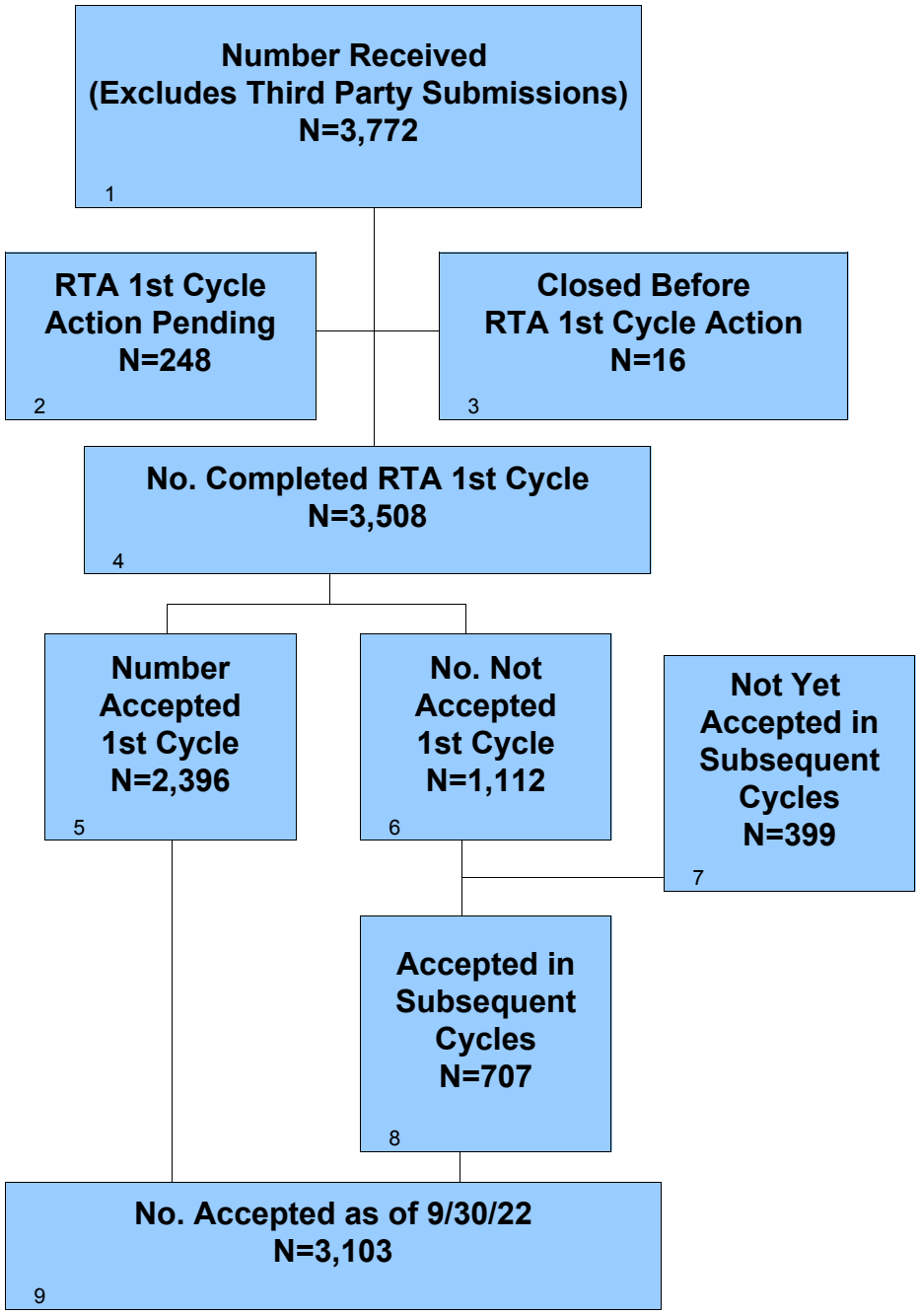
CDRH 510(k)s - FY 2021
as of 9/30/22



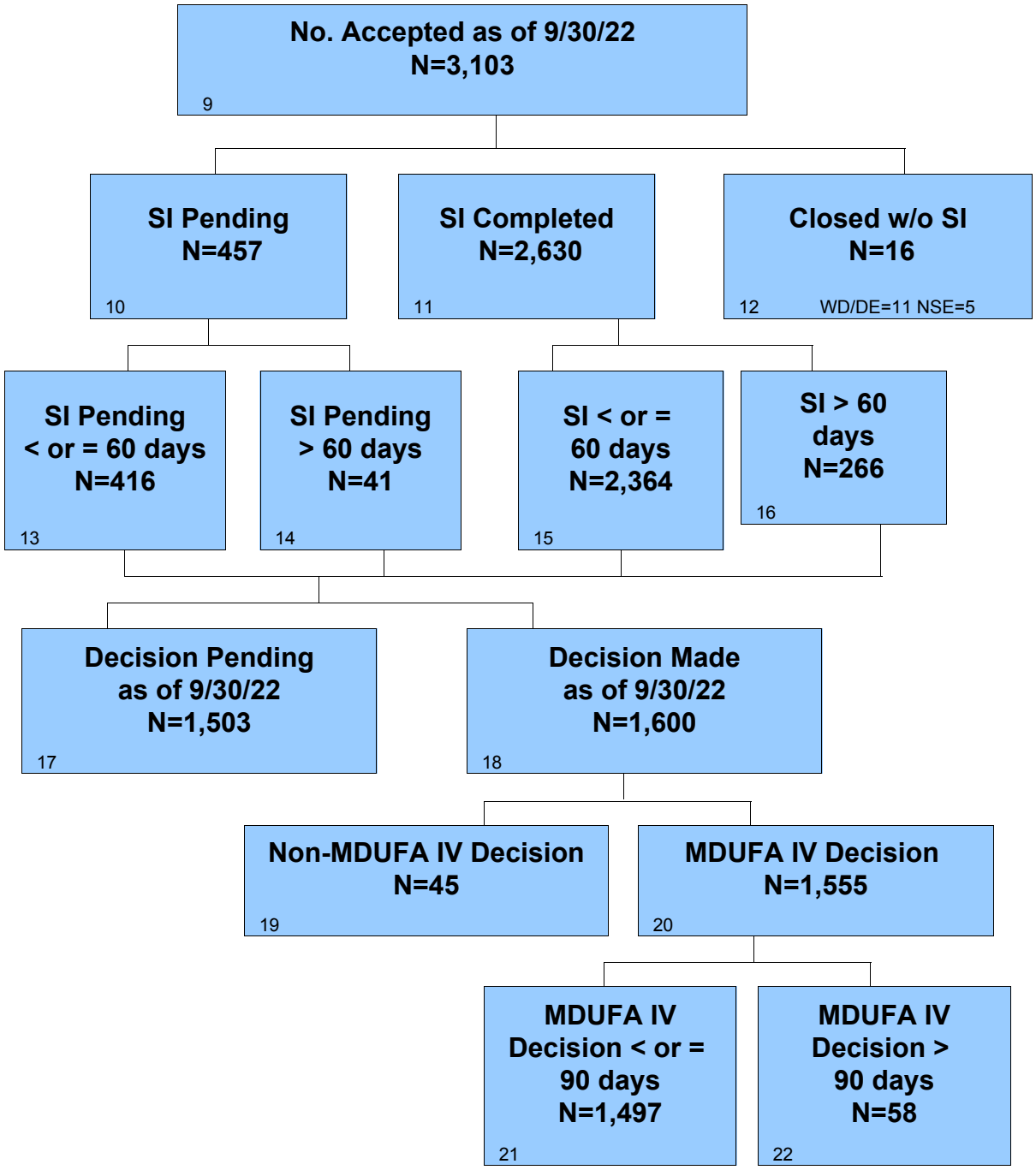
CDRH 510(k)s - FY 2021
as of 9/30/22 Continued



CDRH 510(k)s - FY 2022
as of 9/30/22



CDRH 510(k)s - FY 2022
as of 9/30/22 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3,463	3,644	3,693	3,957	3,772
Closed Before RTA Action or TS	18	15	21	17	16
Number Accepted	2,353	2,403	2,396	2,361	2,053
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	220	343
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	248
Number Not Accepted	1,077	1,172	1,227	1,359	1,112
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.42%	34.49%	31.70%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3,276	3,464	3,502	3,719	3,103
Deleted or Withdrawn Prior to SI	8	13	10	13	11
SI Within 60 FDA Days	3,202	3,359	3,290	3,220	2,364
SI Over 60 FDA Days	61	86	200	456	266
SI Pending Within 60 FDA Days	0	0	0	7	416
SI Pending Over 60 FDA Days	0	0	0	16	41
510(k)s NSE Without SI	5	6	2	7	5
Current SI Performance Percent Within 60 FDA Days	97.98%	97.33%	94.22%	87.05%	88.34%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	3,263	3,445	3,490	3,676	2,630
Average Number of FDA Days to Substantive Interaction	51.04	51.42	55.02	59.42	56.02
20th Percentile FDA Days to Substantive Interaction	43	43	46	50	49
40th Percentile FDA Days to Substantive Interaction	55	56	56	57	57
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	86	90	496	381	210

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3,276	3,464	3,502	3,719	3,103
Non-MDUFA IV Decision	350	425	381	309	45
MDUFA IV Decision (SE/NSE)	2,926	3,038	3,097	3,090	1,555
MDUFA IV Decision Within 90 FDA Days	2,897	3,003	2,963	2,780	1,497
510(k)s Pending MDUFA IV Decision	0	1	24	320	1,503
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	10	73	120
Current Performance Percent Within 90 FDA Days	99.01%	98.85%	95.37%	87.89%	89.37%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.62	1.62	1.64	1.64	1.47
Number With MDUFA IV Decision	2,926	3,038	3,097	3,090	1,555
Average Number of FDA Days to MDUFA IV Decision	72.62	73.54	79.11	81.68	70.16
20th Percentile FDA Days to MDUFA IV Decision	54	55	55	57	48
40th Percentile FDA Days to MDUFA IV Decision	79	82	84	85	62
60th Percentile FDA Days to MDUFA IV Decision	87	88	88	88	86
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	89
Maximum FDA Days to MDUFA IV Decision	220	655	673	389	237
Average Number of Industry Days to MDUFA IV Decision	54.69	60.36	69.92	67.49	30.03
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	5	0	5	8	0
60th Percentile Industry Days to MDUFA IV Decision	44	49	54	57	15
80th Percentile Industry Days to MDUFA IV Decision	127	139	146	139	56
Maximum Industry Days to MDUFA IV Decision	563	507	834	535	257
Average Number of Total Days to MDUFA IV Decision	127.31	133.90	149.03	149.17	100.19
20th Percentile Total Days to MDUFA IV Decision	57	57	56	59	50
40th Percentile Total Days to MDUFA IV Decision	89	90	90	95	73
60th Percentile Total Days to MDUFA IV Decision	128	133	140	149	100
80th Percentile Total Days to MDUFA IV Decision	212	224	239	234	146
Maximum Total Days to MDUFA IV Decision	783	871	990	647	347

Table 6.6 CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	3,276	3,464	3,502	3,719	3,103
Number With MDUFA IV Decision	2,926	3,038	3,097	3,090	1,555
Number of SE Decision	2,810	2,923	2,993	2,968	1,524
Number of NSE Decision	116	115	104	122	31
Number of Withdrawal	185	213	211	197	45
Number of Deleted	156	194	166	109	0
Rate of SE Decision	96.04%	96.21%	96.64%	96.05%	98.01%
Rate of NSE Decision	3.96%	3.79%	3.36%	3.95%	1.99%
Rate of Withdrawal	5.65%	6.15%	6.03%	5.30%	1.45%
Rate of Deleted	4.76%	5.60%	4.74%	2.93%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	29	35	134	310	58
Mean FDA Days for Submissions that Missed the Goal	111.38	140.80	227.16	154.98	138.69
Mean Industry Days for Submissions that Missed the Goal	136.24	201.94	169.18	78.60	30.36

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	2	1	4	1	4
Non-MDUFA IV Decision	1	0	0	1	0
MDUFA IV Decision (SE/NSE)	1	1	4	0	0
MDUFA IV Decision Within 90 FDA Days	1	1	2	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	4
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%	0.00%	0.00%

Table 6.9 CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	272	278	253	195	201
Non-MDUFA IV Decision	41	37	49	26	4
MDUFA IV Decision (SE/NSE)	231	241	196	122	40
MDUFA IV Decision Within 90 FDA Days	230	237	122	13	11
510(k)s Pending MDUFA IV Decision	0	0	8	47	157
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	8	44	104
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	59.80%	7.83%	7.64%

Section 6 510(k) Office Level Metrics (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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	552	593	536	533	595
Closed Before RTA Action	1	1	0	0	2
Number Accepted	208	207	226	207	207
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8	11	30
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	47
Number Not Accepted	343	373	302	315	309
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	59.10%	56.59%

Table 6.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	494	551	505	487	422
Deleted or Withdrawn Prior to SI	2	6	0	0	0
SI Within 60 FDA Days	477	490	415	416	309
SI Over 60 FDA Days	14	54	90	70	43
SI Pending Within 60 FDA Days	0	0	0	1	70
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	1	1	0	0	0
Current SI Performance Percent Within 60 FDA Days	96.95%	89.91%	82.18%	85.60%	87.78%

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	491	544	505	486	352
Average Number of FDA Days to Substantive Interaction	55.63	56.04	55.38	55.97	55.55
20th Percentile FDA Days to Substantive Interaction	54	54	51	54	53
40th Percentile FDA Days to Substantive Interaction	58	58	57	58	58
60th Percentile FDA Days to Substantive Interaction	59	59	60	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	78	87	94	88	82

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	494	551	505	487	422
Non-MDUFA IV Decision	74	85	63	56	4
MDUFA IV Decision (SE/NSE)	420	465	438	373	175
MDUFA IV Decision Within 90 FDA Days	417	463	434	372	175
510(k)s Pending MDUFA IV Decision	0	1	4	58	243
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	4	1
Current Performance Percent Within 90 FDA Days	99.29%	99.57%	99.09%	98.67%	99.43%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.67	1.69	1.70	1.68	1.53
Number With MDUFA IV Decision	420	465	438	373	175
Average Number of FDA Days to MDUFA IV Decision	81.05	82.39	79.90	79.53	74.18
20th Percentile FDA Days to MDUFA IV Decision	77	84	76	60	58
40th Percentile FDA Days to MDUFA IV Decision	87	88	87	87	85
60th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	88
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	148	153	115	127	90
Average Number of Industry Days to MDUFA IV Decision	65.45	68.64	72.45	77.46	35.31
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	20	17	21	0
60th Percentile Industry Days to MDUFA IV Decision	63	67	64	80	25
80th Percentile Industry Days to MDUFA IV Decision	152	153	153	155	85
Maximum Industry Days to MDUFA IV Decision	389	356	497	500	178
Average Number of Total Days to MDUFA IV Decision	146.51	151.03	152.35	156.99	109.49
20th Percentile Total Days to MDUFA IV Decision	79	88	84	78	59
40th Percentile Total Days to MDUFA IV Decision	103	106	99	106	88
60th Percentile Total Days to MDUFA IV Decision	148	153	150	167	112
80th Percentile Total Days to MDUFA IV Decision	241	242	241	244	172
Maximum Total Days to MDUFA IV Decision	479	446	585	590	266

Table 6.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	494	551	505	487	422
Number With MDUFA IV Decision	420	465	438	373	175
Number of SE Decision	402	442	422	360	172
Number of NSE Decision	18	23	16	13	3
Number of Withdrawal	35	48	35	45	4
Number of Deleted	39	34	28	9	0
Rate of SE Decision	95.71%	95.05%	96.35%	96.51%	98.29%
Rate of NSE Decision	4.29%	4.95%	3.65%	3.49%	1.71%
Rate of Withdrawal	7.09%	8.71%	6.93%	9.24%	0.95%
Rate of Deleted	7.89%	6.17%	5.54%	1.85%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	3	2	4	1	0
Mean FDA Days for Submissions that Missed the Goal	115.33	133.50	101.25	127.00	0.00
Mean Industry Days for Submissions that Missed the Goal	107.67	258.00	167.75	359.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0%	0%	0%	0%	0%

Table 6.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0%	0%	0%	0%	0%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	357	378	376	385	364
Closed Before RTA Action	4	2	1	2	0
Number Accepted	237	266	281	274	236
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	17	32
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	21
Number Not Accepted	114	100	90	92	75
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.00%	24.02%	21.87%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	341	366	368	376	322
Deleted or Withdrawn Prior to SI	4	0	1	1	6
SI Within 60 FDA Days	324	358	354	354	275
SI Over 60 FDA Days	13	8	12	18	8
SI Pending Within 60 FDA Days	0	0	0	0	32
SI Pending Over 60 FDA Days	0	0	0	1	0
510(k)s NSE Without SI	0	0	1	2	1
Current SI Performance Percent Within 60 FDA Days	96.14%	97.81%	96.46%	94.40%	96.83%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	337	366	366	372	283
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.63	51.34	51.07
20th Percentile FDA Days to Substantive Interaction	30	30	36	30	43
40th Percentile FDA Days to Substantive Interaction	53	56	57	57	55
60th Percentile FDA Days to Substantive Interaction	58	59	59	59	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	83	71	101	89	66

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	341	366	368	376	322
Non-MDUFA IV Decision	32	52	31	30	11
MDUFA IV Decision (SE/NSE)	309	314	335	314	144
MDUFA IV Decision Within 90 FDA Days	303	303	320	307	142
510(k)s Pending MDUFA IV Decision	0	0	2	32	167
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	1	0
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	95.52%	97.46%	98.61%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.71	1.70	1.82	1.78	1.65
Number With MDUFA IV Decision	309	314	335	314	144
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	75.07	73.33	66.83
20th Percentile FDA Days to MDUFA IV Decision	50	49	55	54	42
40th Percentile FDA Days to MDUFA IV Decision	80	80	86	86	59
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	88	87
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	89
Maximum FDA Days to MDUFA IV Decision	159	117	245	293	99
Average Number of Industry Days to MDUFA IV Decision	64.80	66.25	89.59	88.75	42.92
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	19	20	29	35	7
60th Percentile Industry Days to MDUFA IV Decision	65	68	81	90	32
80th Percentile Industry Days to MDUFA IV Decision	146	140	159	168	88
Maximum Industry Days to MDUFA IV Decision	292	359	607	386	188
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	164.65	162.08	109.74
20th Percentile Total Days to MDUFA IV Decision	55	51	56	58	44
40th Percentile Total Days to MDUFA IV Decision	102	98	118	119	84
60th Percentile Total Days to MDUFA IV Decision	150	148	166	179	115
80th Percentile Total Days to MDUFA IV Decision	228	227	250	257	175
Maximum Total Days to MDUFA IV Decision	370	447	707	485	278

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	341	366	368	376	322
Number With MDUFA IV Decision	309	314	335	314	144
Number of SE Decision	291	289	308	274	134
Number of NSE Decision	18	25	27	40	10
Number of Withdrawal	20	31	21	21	11
Number of Deleted	10	20	10	9	0
Rate of SE Decision	94.17%	92.04%	91.94%	87.26%	93.06%
Rate of NSE Decision	5.83%	7.96%	8.06%	12.74%	6.94%
Rate of Withdrawal	5.87%	8.47%	5.71%	5.59%	3.42%
Rate of Deleted	2.93%	5.46%	2.72%	2.39%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	6	11	15	7	2
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	110.13	127.14	95.00
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	261.60	204.43	81.50

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	455	477	440	511	447
Closed Before RTA Action	3	4	4	6	1
Number Accepted	334	350	287	292	245
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2	14	37
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	33
Number Not Accepted	116	117	147	199	131
Rate of Submissions Not Accepted for Review	25.66%	24.74%	33.72%	39.41%	31.72%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	436	454	418	470	372
Deleted or Withdrawn Prior to SI	0	1	1	2	0
SI Within 60 FDA Days	427	448	404	433	307
SI Over 60 FDA Days	6	4	13	25	17
SI Pending Within 60 FDA Days	0	0	0	1	48
SI Pending Over 60 FDA Days	0	0	0	7	0
510(k)s NSE Without SI	3	1	0	2	0
Current SI Performance Percent Within 60 FDA Days	97.94%	98.90%	96.88%	92.72%	94.75%

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	433	452	417	458	324
Average Number of FDA Days to Substantive Interaction	51.10	52.60	53.39	54.10	54.98
20th Percentile FDA Days to Substantive Interaction	44	48	51	53	56
40th Percentile FDA Days to Substantive Interaction	55	57	57	57	58
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	67	78	68	77	80

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	436	454	418	470	372
Non-MDUFA IV Decision	50	77	56	40	3
MDUFA IV Decision (SE/NSE)	386	377	357	386	159
MDUFA IV Decision Within 90 FDA Days	382	372	348	378	157
510(k)s Pending MDUFA IV Decision	0	0	5	44	210
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	7	1
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	97.21%	96.18%	98.13%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.74	1.84	1.83	1.81	1.62
Number With MDUFA IV Decision	386	377	357	386	159
Average Number of FDA Days to MDUFA IV Decision	75.68	78.18	78.88	80.75	74.01
20th Percentile FDA Days to MDUFA IV Decision	58	60	66	81	57
40th Percentile FDA Days to MDUFA IV Decision	84	87	87	88	86
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	89	89
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	118	150	156	199	95
Average Number of Industry Days to MDUFA IV Decision	74.93	95.65	106.57	96.72	42.65
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	29	53	55	56	5
60th Percentile Industry Days to MDUFA IV Decision	94	118	126	109	34
80th Percentile Industry Days to MDUFA IV Decision	165	174	179	167	83
Maximum Industry Days to MDUFA IV Decision	214	444	834	397	210
Average Number of Total Days to MDUFA IV Decision	150.61	173.83	185.45	177.46	116.67
20th Percentile Total Days to MDUFA IV Decision	64	87	87	89	58
40th Percentile Total Days to MDUFA IV Decision	113	140	138	144	90
60th Percentile Total Days to MDUFA IV Decision	177	205	214	195	123
80th Percentile Total Days to MDUFA IV Decision	248	261	266	257	172
Maximum Total Days to MDUFA IV Decision	304	540	990	502	300

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	436	454	418	470	372
Number With MDUFA IV Decision	386	377	357	386	159
Number of SE Decision	361	354	335	354	153
Number of NSE Decision	25	23	22	32	6
Number of Withdrawal	20	31	26	20	3
Number of Deleted	30	44	29	20	0
Rate of SE Decision	93.52%	93.90%	93.84%	91.71%	96.23%
Rate of NSE Decision	6.48%	6.10%	6.16%	8.29%	3.77%
Rate of Withdrawal	4.59%	6.83%	6.22%	4.26%	0.81%
Rate of Deleted	6.88%	9.69%	6.94%	4.26%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	4	5	9	8	2
Mean FDA Days for Submissions that Missed the Goal	100.00	111.20	113.78	144.38	93.50
Mean Industry Days for Submissions that Missed the Goal	117.00	332.20	264.33	201.50	37.50

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

Table 6.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

Table 6.1 OHT4 - Office of Surgical and Infection Control Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	552	604	719	1,018	753
Closed Before RTA Action	2	0	3	4	1
Number Accepted	368	392	447	601	407
Number Without a RTA Review and > 15 Days Since Date Received	6	7	5	36	71
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	42
Number Not Accepted	176	205	264	377	232
Rate of Submissions Not Accepted for Review	32.00%	33.94%	36.87%	37.18%	32.68%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	559	654	933	615
Deleted or Withdrawn Prior to SI	0	3	2	3	1
SI Within 60 FDA Days	512	543	626	750	453
SI Over 60 FDA Days	4	12	25	170	72
SI Pending Within 60 FDA Days	0	0	0	3	81
SI Pending Over 60 FDA Days	0	0	0	7	7
510(k)s NSE Without SI	0	1	1	0	1
Current SI Performance Percent Within 60 FDA Days	99.22%	97.66%	96.01%	80.91%	84.99%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	516	555	651	920	525
Average Number of FDA Days to Substantive Interaction	52.60	52.19	53.97	58.14	55.04
20th Percentile FDA Days to Substantive Interaction	50	48	52	54	49
40th Percentile FDA Days to Substantive Interaction	57	56	57	57	56
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	69	90	91	332	176

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	559	654	933	615
Non-MDUFA IV Decision	68	74	84	76	11
MDUFA IV Decision (SE/NSE)	448	485	567	779	359
MDUFA IV Decision Within 90 FDA Days	440	480	537	596	335
510(k)s Pending MDUFA IV Decision	0	0	3	78	245
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	17	13
Current Performance Percent Within 90 FDA Days	98.21%	98.97%	94.54%	74.87%	90.05%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.56	1.58	1.68	1.66	1.47
Number With MDUFA IV Decision	448	485	567	779	359
Average Number of FDA Days to MDUFA IV Decision	73.88	73.19	77.55	84.64	71.25
20th Percentile FDA Days to MDUFA IV Decision	57	55	59	74	52
40th Percentile FDA Days to MDUFA IV Decision	79	81	84	87	70
60th Percentile FDA Days to MDUFA IV Decision	87	87	87	89	86
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	92	89
Maximum FDA Days to MDUFA IV Decision	220	207	358	283	193
Average Number of Industry Days to MDUFA IV Decision	48.98	55.75	67.11	59.76	25.91
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	11	8	0
60th Percentile Industry Days to MDUFA IV Decision	31	41	63	42	14
80th Percentile Industry Days to MDUFA IV Decision	110	129	140	119	47
Maximum Industry Days to MDUFA IV Decision	563	507	419	404	221
Average Number of Total Days to MDUFA IV Decision	122.86	128.95	144.66	144.40	97.16
20th Percentile Total Days to MDUFA IV Decision	59	57	60	82	54
40th Percentile Total Days to MDUFA IV Decision	88	88	91	96	83
60th Percentile Total Days to MDUFA IV Decision	110	125	146	137	98
80th Percentile Total Days to MDUFA IV Decision	193	211	228	213	133
Maximum Total Days to MDUFA IV Decision	783	623	717	588	307

Table 6.6 OHT4 - Office of Surgical and Infection Control Devices
510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	516	559	654	933	615
Number With MDUFA IV Decision	448	485	567	779	359
Number of SE Decision	437	471	554	769	356
Number of NSE Decision	11	14	13	10	3
Number of Withdrawal	36	37	37	32	11
Number of Deleted	31	35	46	43	0
Rate of SE Decision	97.54%	97.11%	97.71%	98.72%	99.16%
Rate of NSE Decision	2.46%	2.89%	2.29%	1.28%	0.84%
Rate of Withdrawal	6.98%	6.62%	5.66%	3.43%	1.79%
Rate of Deleted	6.01%	6.26%	7.03%	4.61%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	8	5	30	183	24
Mean FDA Days for Submissions that Missed the Goal	119.50	120.00	120.33	110.73	110.33
Mean Industry Days for Submissions that Missed the Goal	168.63	207.40	154.73	70.90	35.17

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

Table 6.9 OHT4 - Office of Surgical and Infection Control Devices
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	260	274	261	276	293
Closed Before RTA Action	3	0	3	1	2
Number Accepted	147	155	110	135	132
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5	8	22
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	24
Number Not Accepted	107	112	143	132	113
Rate of Submissions Not Accepted for Review	41.63%	40.88%	55.43%	48.00%	42.32%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	236	260	240	258	217
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	232	257	231	255	180
SI Over 60 FDA Days	4	3	9	2	3
SI Pending Within 60 FDA Days	0	0	0	1	34
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	0
Current SI Performance Percent Within 60 FDA Days	98.31%	98.85%	96.25%	99.22%	98.36%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	236	260	240	257	183
Average Number of FDA Days to Substantive Interaction	53.91	54.53	53.39	53.67	54.26
20th Percentile FDA Days to Substantive Interaction	53	54	49	54	56
40th Percentile FDA Days to Substantive Interaction	58	58	58	58	58
60th Percentile FDA Days to Substantive Interaction	60	60	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	86	63	87	66	62

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	236	260	240	258	217
Non-MDUFA IV Decision	30	31	17	22	1
MDUFA IV Decision (SE/NSE)	206	229	221	212	113
MDUFA IV Decision Within 90 FDA Days	201	222	221	211	112
510(k)s Pending MDUFA IV Decision	0	0	2	24	103
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	97.57%	96.94%	100.00%	99.53%	99.12%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.52	1.60	1.46	1.58	1.51
Number With MDUFA IV Decision	206	229	221	212	113
Average Number of FDA Days to MDUFA IV Decision	76.47	80.32	75.70	75.72	74.04
20th Percentile FDA Days to MDUFA IV Decision	60	69	60	57	58
40th Percentile FDA Days to MDUFA IV Decision	86	88	87	86	84
60th Percentile FDA Days to MDUFA IV Decision	89	90	89	89	89
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	170	152	90	131	91
Average Number of Industry Days to MDUFA IV Decision	42.60	55.79	61.13	67.49	36.09
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	38	39	26	54	21
80th Percentile Industry Days to MDUFA IV Decision	84	129	125	153	68
Maximum Industry Days to MDUFA IV Decision	187	391	360	360	220
Average Number of Total Days to MDUFA IV Decision	119.07	136.10	136.83	143.21	110.12
20th Percentile Total Days to MDUFA IV Decision	61	83	60	60	58
40th Percentile Total Days to MDUFA IV Decision	89	90	89	89	87
60th Percentile Total Days to MDUFA IV Decision	117	125	113	140	106
80th Percentile Total Days to MDUFA IV Decision	171	219	212	244	157
Maximum Total Days to MDUFA IV Decision	346	543	449	450	307

Table 6.6 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	236	260	240	258	217
Number With MDUFA IV Decision	206	229	221	212	113
Number of SE Decision	198	222	210	201	108
Number of NSE Decision	8	7	11	11	5
Number of Withdrawal	17	16	13	15	1
Number of Deleted	10	14	4	7	0
Rate of SE Decision	96.12%	96.94%	95.02%	94.81%	95.58%
Rate of NSE Decision	3.88%	3.06%	4.98%	5.19%	4.42%
Rate of Withdrawal	7.20%	6.15%	5.42%	5.81%	0.46%
Rate of Deleted	4.24%	5.38%	1.67%	2.71%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	5	7	0	1	1
Mean FDA Days for Submissions that Missed the Goal	111.40	119.43	0.00	131.00	91.00
Mean Industry Days for Submissions that Missed the Goal	80.60	110.29	0.00	153.00	87.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

Table 6.9 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	634	656	578	603
Closed Before RTA Action	2	4	5	2	2
Number Accepted	466	489	493	435	366
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6	6	45
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	32
Number Not Accepted	138	136	152	135	158
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.35%	23.44%	27.77%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	594	622	638	560	528
Deleted or Withdrawn Prior to SI	0	2	3	1	2
SI Within 60 FDA Days	575	617	634	558	445
SI Over 60 FDA Days	19	3	1	1	0
SI Pending Within 60 FDA Days	0	0	0	0	79
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	2
Current SI Performance Percent Within 60 FDA Days	96.80%	99.52%	99.84%	99.82%	99.55%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	594	620	635	559	445
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.83	50.31	51.76
20th Percentile FDA Days to Substantive Interaction	39	30	30	35	46
40th Percentile FDA Days to Substantive Interaction	55	56	56	55	56
60th Percentile FDA Days to Substantive Interaction	57	58	58	58	58
80th Percentile FDA Days to Substantive Interaction	59	60	60	59	60
Maximum FDA Days to Substantive Interaction	78	64	61	90	60

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	594	622	638	560	528
Non-MDUFA IV Decision	40	47	61	37	8
MDUFA IV Decision (SE/NSE)	554	575	577	500	298
MDUFA IV Decision Within 90 FDA Days	552	574	577	499	298
510(k)s Pending MDUFA IV Decision	0	0	0	23	222
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	99.64%	99.83%	100.00%	99.80%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.67	1.62	1.51	1.52	1.36
Number With MDUFA IV Decision	554	575	577	500	298
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	66.97	65.96	62.98
20th Percentile FDA Days to MDUFA IV Decision	52	51	37	41	30
40th Percentile FDA Days to MDUFA IV Decision	74	76	60	59	58
60th Percentile FDA Days to MDUFA IV Decision	86	87	86	84	80
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	88
Maximum FDA Days to MDUFA IV Decision	135	91	90	151	90
Average Number of Industry Days to MDUFA IV Decision	48.84	50.98	54.44	51.40	22.74
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	10	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	34	29	20	27	0
80th Percentile Industry Days to MDUFA IV Decision	103	103	98	98	42
Maximum Industry Days to MDUFA IV Decision	340	444	667	535	199
Average Number of Total Days to MDUFA IV Decision	120.19	121.55	121.41	117.36	85.72
20th Percentile Total Days to MDUFA IV Decision	57	56	38	46	32
40th Percentile Total Days to MDUFA IV Decision	86	87	67	62	59
60th Percentile Total Days to MDUFA IV Decision	115	111	103	102	87
80th Percentile Total Days to MDUFA IV Decision	189	185	184	181	123
Maximum Total Days to MDUFA IV Decision	430	533	756	623	285

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	594	622	638	560	528
Number With MDUFA IV Decision	554	575	577	500	298
Number of SE Decision	540	563	573	496	296
Number of NSE Decision	14	12	4	4	2
Number of Withdrawal	24	28	38	29	8
Number of Deleted	16	19	23	8	0
Rate of SE Decision	97.47%	97.91%	99.31%	99.20%	99.33%
Rate of NSE Decision	2.53%	2.09%	0.69%	0.80%	0.67%
Rate of Withdrawal	4.04%	4.50%	5.96%	5.18%	1.52%
Rate of Deleted	2.69%	3.05%	3.61%	1.43%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	1	0	1	0
Mean FDA Days for Submissions that Missed the Goal	118	91	0	151	0
Mean Industry Days for Submissions that Missed the Goal	209	260	0	109	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	290	300	271	205	242
Closed Before RTA Action	3	3	3	1	6
Number Accepted	245	237	191	56	117
Number Without a RTA Review and > 15 Days Since Date Received	1	4	18	116	77
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	14
Number Not Accepted	41	56	59	32	28
Rate of Submissions Not Accepted for Review	14.29%	18.86%	22.01%	15.69%	12.61%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	274	279	257	196	205
Deleted or Withdrawn Prior to SI	1	1	3	6	2
SI Within 60 FDA Days	271	273	204	19	11
SI Over 60 FDA Days	1	2	50	170	123
SI Pending Within 60 FDA Days	0	0	0	0	35
SI Pending Over 60 FDA Days	0	0	0	1	34
510(k)s NSE Without SI	1	3	0	0	0
Current SI Performance Percent Within 60 FDA Days	99.27%	98.20%	80.31%	10.00%	6.55%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	272	275	254	189	134
Average Number of FDA Days to Substantive Interaction	50.56	49.13	93.22	162.53	111.88
20th Percentile FDA Days to Substantive Interaction	44	30	45	116	97
40th Percentile FDA Days to Substantive Interaction	54	53	58	128	116
60th Percentile FDA Days to Substantive Interaction	58	58	60	173	119
80th Percentile FDA Days to Substantive Interaction	59	60	60	238	121
Maximum FDA Days to Substantive Interaction	61	61	496	381	210

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	274	279	257	196	205
Non-MDUFA IV Decision	42	37	49	27	4
MDUFA IV Decision (SE/NSE)	232	242	200	122	40
MDUFA IV Decision Within 90 FDA Days	231	238	124	13	11
510(k)s Pending MDUFA IV Decision	0	0	8	47	161
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	8	44	105
Current Performance Percent Within 90 FDA Days	99.57%	98.35%	59.62%	7.83%	7.59%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.36	1.57	1.49	1.23
Number With MDUFA IV Decision	232	242	200	122	40
Average Number of FDA Days to MDUFA IV Decision	72.98	71.48	159.08	213.57	134.33
20th Percentile FDA Days to MDUFA IV Decision	53	31	56	132	63
40th Percentile FDA Days to MDUFA IV Decision	84	60	87	206	120
60th Percentile FDA Days to MDUFA IV Decision	88	87	90	235	165
80th Percentile FDA Days to MDUFA IV Decision	90	90	297	291	210
Maximum FDA Days to MDUFA IV Decision	93	655	673	389	237
Average Number of Industry Days to MDUFA IV Decision	58.27	46.80	78.77	64.11	14.80
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	52	0	66	47	0
80th Percentile Industry Days to MDUFA IV Decision	145	129	161	159	13
Maximum Industry Days to MDUFA IV Decision	231	448	617	375	189
Average Number of Total Days to MDUFA IV Decision	131.25	118.28	237.85	277.67	149.13
20th Percentile Total Days to MDUFA IV Decision	55	31	58	136	63
40th Percentile Total Days to MDUFA IV Decision	88	67	90	213	120
60th Percentile Total Days to MDUFA IV Decision	134	90	224	322	205
80th Percentile Total Days to MDUFA IV Decision	235	194	463	400	210
Maximum Total Days to MDUFA IV Decision	321	871	876	647	343

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	274	279	257	196	205
Number With MDUFA IV Decision	232	242	200	122	40
Number of SE Decision	221	234	194	120	40
Number of NSE Decision	11	8	6	2	0
Number of Withdrawal	26	14	28	22	4
Number of Deleted	15	23	20	5	0
Rate of SE Decision	95.26%	96.69%	97.00%	98.36%	100.00%
Rate of NSE Decision	4.74%	3.31%	3.00%	1.64%	0.00%
Rate of Withdrawal	9.49%	5.02%	10.89%	11.22%	1.95%
Rate of Deleted	5.47%	8.24%	7.78%	2.55%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	4	76	109	29
Mean FDA Days for Submissions that Missed the Goal	93.00	370.00	312.47	232.35	169.93
Mean Industry Days for Submissions that Missed the Goal	202.00	268.00	145.45	70.90	20.41

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	2	1	4	1	4
Non-MDUFA IV Decision	1	0	0	1	0
MDUFA IV Decision (SE/NSE)	1	1	4	0	0
MDUFA IV Decision Within 90 FDA Days	1	1	2	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	4
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%	0.00%	0.00%

Table 6.9 OHT7 - Office of In Vitro Diagnostics
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	272	278	253	195	201
Non-MDUFA IV Decision	41	37	49	26	4
MDUFA IV Decision (SE/NSE)	231	241	196	122	40
MDUFA IV Decision Within 90 FDA Days	230	237	122	13	11
510(k)s Pending MDUFA IV Decision	0	0	8	47	157
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	8	44	104
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	59.80%	7.83%	7.64%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	391	384	434	451	475
Closed Before RTA Action	0	1	2	1	2
Number Accepted	348	307	361	361	343
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	12	29
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	35
Number Not Accepted	42	73	70	77	66
Rate of Submissions Not Accepted for Review	10.74%	19.06%	16.20%	17.11%	15.07%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	385	373	422	439	422
Deleted or Withdrawn Prior to SI	1	0	0	0	0
SI Within 60 FDA Days	384	373	422	435	384
SI Over 60 FDA Days	0	0	0	0	0
SI Pending Within 60 FDA Days	0	0	0	1	37
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	3	1
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	100.00%	99.32%	99.74%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	384	373	422	435	384
Average Number of FDA Days to Substantive Interaction	43.70	44.96	46.49	48.77	48.60
20th Percentile FDA Days to Substantive Interaction	29	28	29	36	32
40th Percentile FDA Days to Substantive Interaction	42	47	49	51	51
60th Percentile FDA Days to Substantive Interaction	52	54	55	56	57
80th Percentile FDA Days to Substantive Interaction	57	58	58	59	59
Maximum FDA Days to Substantive Interaction	60	60	60	60	60

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	385	373	422	439	422
Non-MDUFA IV Decision	14	22	20	21	3
MDUFA IV Decision (SE/NSE)	371	351	402	404	267
MDUFA IV Decision Within 90 FDA Days	371	351	402	404	267
510(k)s Pending MDUFA IV Decision	0	0	0	14	152
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.50	1.54	1.55	1.40
Number With MDUFA IV Decision	371	351	402	404	267
Average Number of FDA Days to MDUFA IV Decision	58.72	61.13	63.56	68.08	62.30
20th Percentile FDA Days to MDUFA IV Decision	30	28	29	47	29
40th Percentile FDA Days to MDUFA IV Decision	55	58	60	70	57
60th Percentile FDA Days to MDUFA IV Decision	73	77	82	86	80
80th Percentile FDA Days to MDUFA IV Decision	84	86	87	88	88
Maximum FDA Days to MDUFA IV Decision	90	90	90	90	90
Average Number of Industry Days to MDUFA IV Decision	33.09	40.27	44.85	49.69	25.51
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	19	23	32	33	4
80th Percentile Industry Days to MDUFA IV Decision	56	81	87	99	48
Maximum Industry Days to MDUFA IV Decision	181	329	357	361	257
Average Number of Total Days to MDUFA IV Decision	91.81	101.40	108.41	117.78	87.82
20th Percentile Total Days to MDUFA IV Decision	30	28	29	48	29
40th Percentile Total Days to MDUFA IV Decision	58	59	63	78	57
60th Percentile Total Days to MDUFA IV Decision	93	103	114	116	90
80th Percentile Total Days to MDUFA IV Decision	138	165	167	187	133
Maximum Total Days to MDUFA IV Decision	270	416	447	449	347

Table 6.6 OHT8 - Office of Radiological Health
510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	385	373	422	439	422
Number With MDUFA IV Decision	371	351	402	404	267
Number of SE Decision	360	348	397	394	265
Number of NSE Decision	11	3	5	10	2
Number of Withdrawal	7	8	13	13	3
Number of Deleted	5	5	6	8	0
Rate of SE Decision	97.04%	99.15%	98.76%	97.52%	99.25%
Rate of NSE Decision	2.96%	0.85%	1.24%	2.48%	0.75%
Rate of Withdrawal	1.82%	2.14%	3.08%	2.96%	0.71%
Rate of Deleted	1.30%	1.34%	1.42%	1.82%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

Section 7 510(k) Annual General Metrics

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	3,351	3,542	3,587	3,809	3,180
Number of Traditional Submissions	2,789	2,907	2,910	3,189	2,689
Number of Special Submissions	419	493	517	449	371
Number of Abbreviated Submissions	68	64	75	81	43
Average Number of Days to Accept/Refuse to Accept	10.58	11.20	11.43	11.79	11.58
Number of Third Party Submissions	75	78	85	90	77

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	124 Days	120 Days	116 Days	112 Days	108 Days
Number Accepted	3,351	3,542	3,587	3,809	3,180
Currently Under Review	0	1	24	321	1,513
Number With Non-MDUFA IV Decision	355	432	388	326	49
Number With MDUFA IV Decision	2,996	3,109	3,175	3,162	1,618
Percent of Cohort Closed	100.00%	99.97%	99.25%	90.78%	51.68%
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	2,851	2,977	3,044	NA	NA
Average Total Time to MDUFA IV Decision	123.40	127.98	140.00	NA	NA

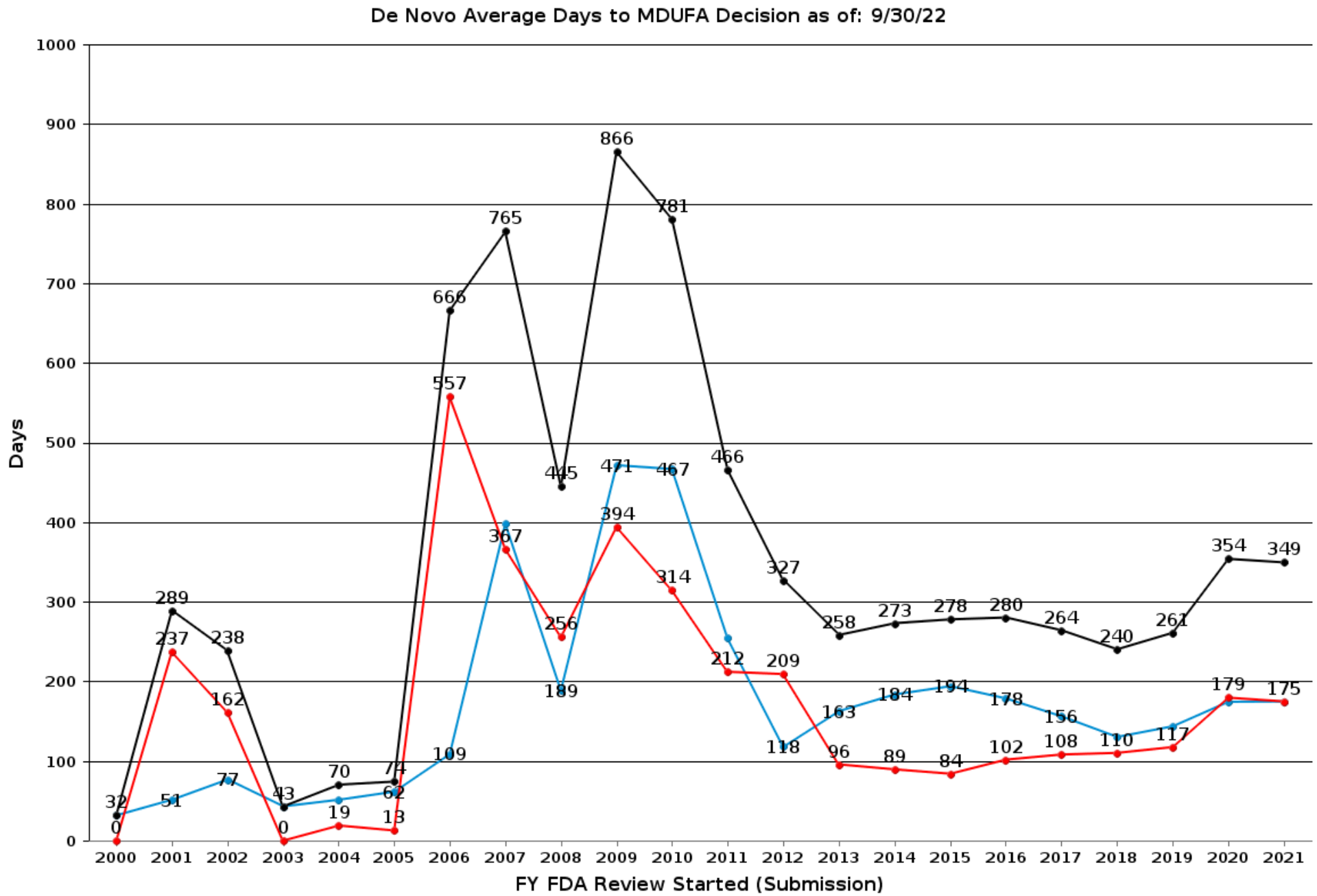
Table 7.3 CDRH - 510(k) Third Party Performance

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	75	78	85	90	77
90th Percentile FDA Days to MDUFA IV Decision	55.40	52.00	33.10	46.70	31.80

Page intentionally left blank

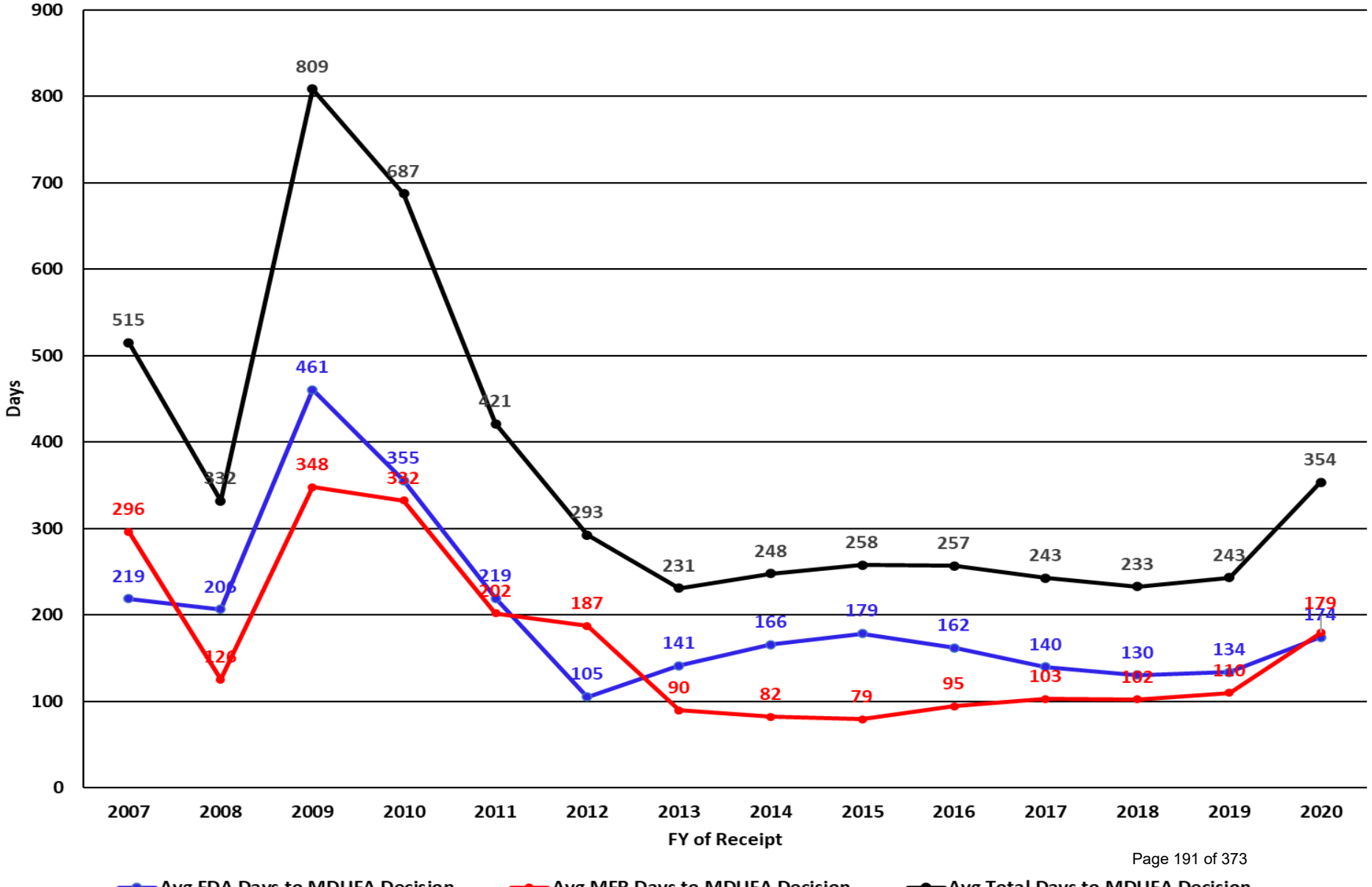
De Novos

Q4FY2022


De Novo Average Days to MDUFA Decision as of: 9/30/22
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2020: 95.31%; 2021: 71.43%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

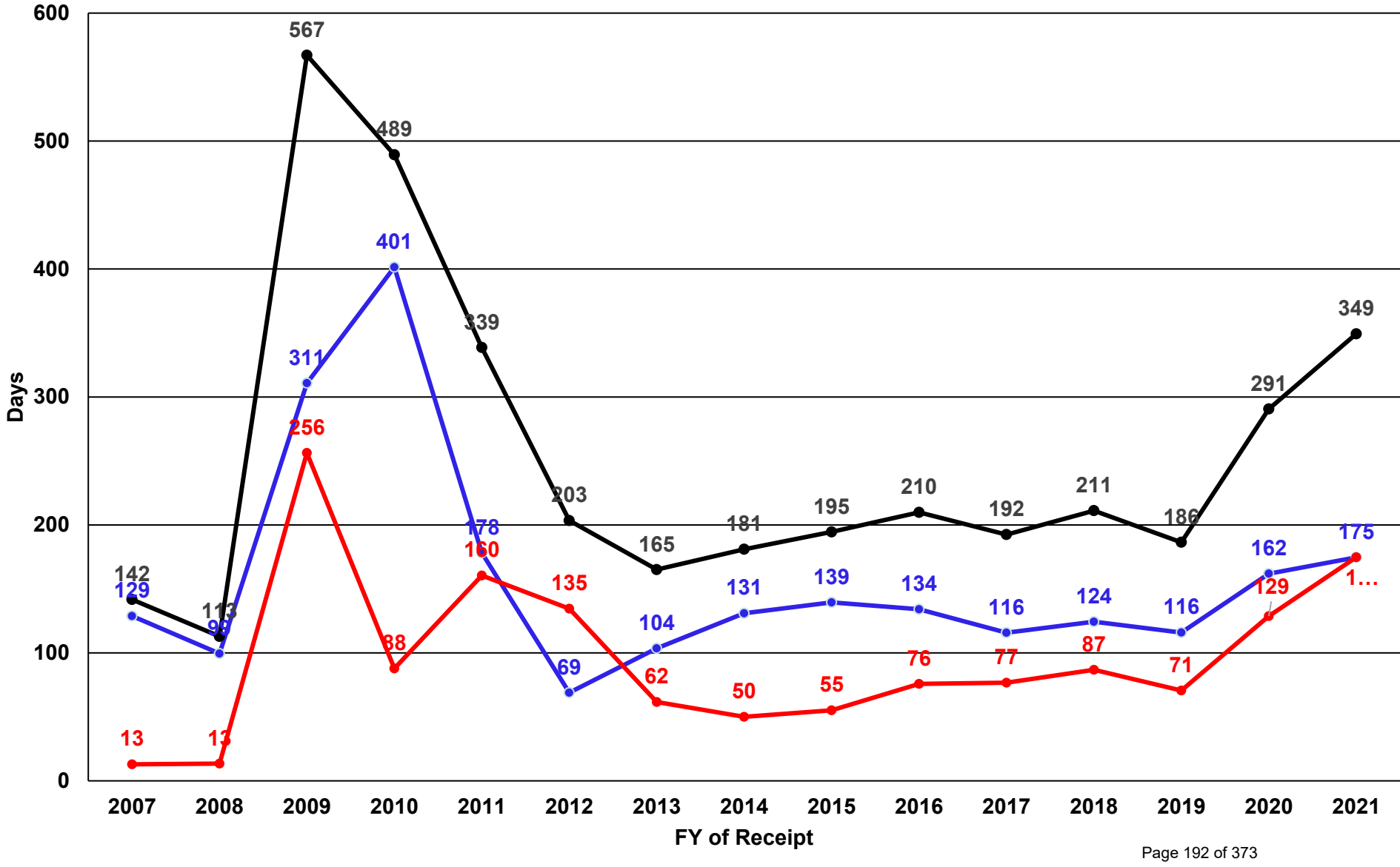
Average Time to MDUFA Decision: De Novos

(95.3% closure comparison)

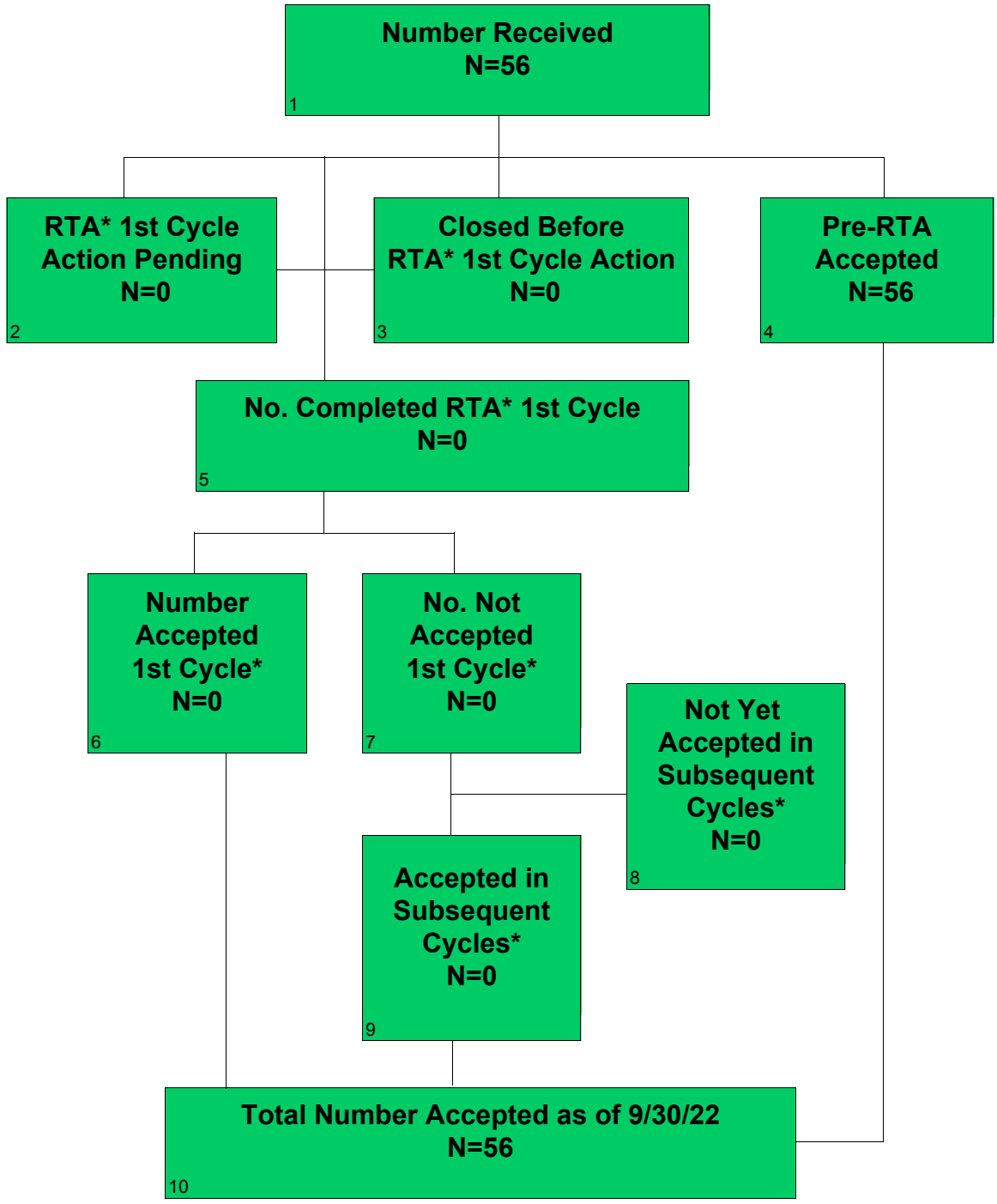


Average Time to MDUFA Decision: De Novos

(71.4% closure comparison)

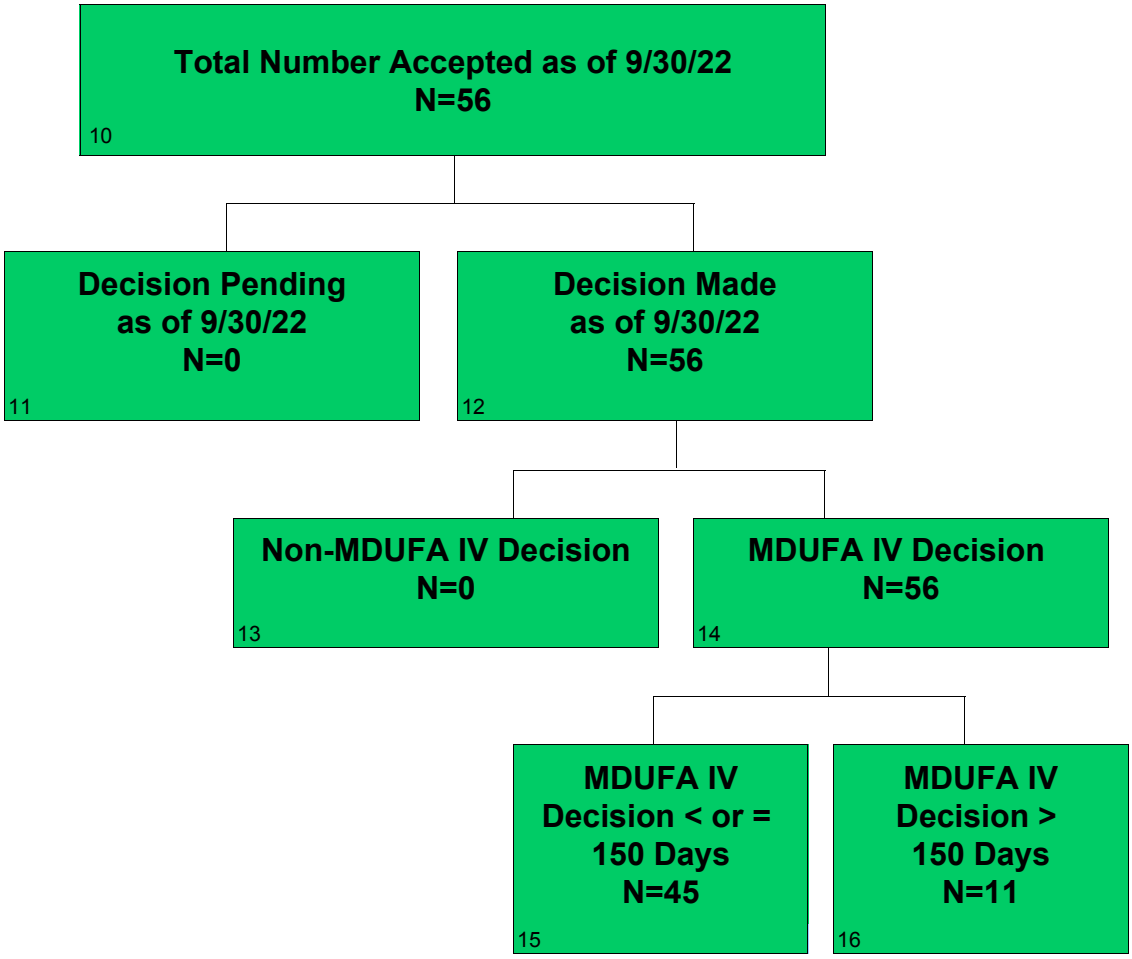


CDRH De Novo - FY 2018
as of 9/30/22

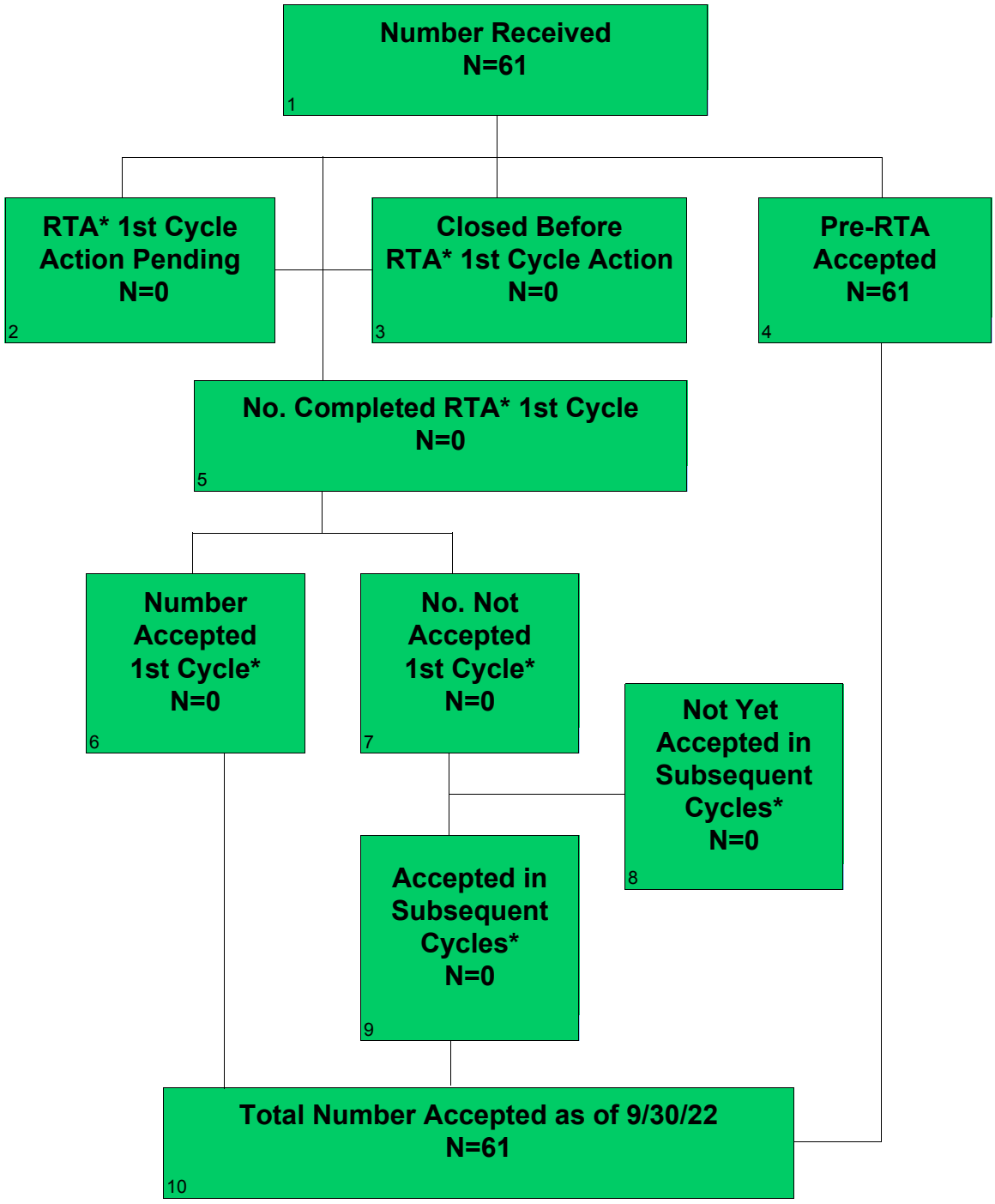


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018
as of 9/30/22 Continued

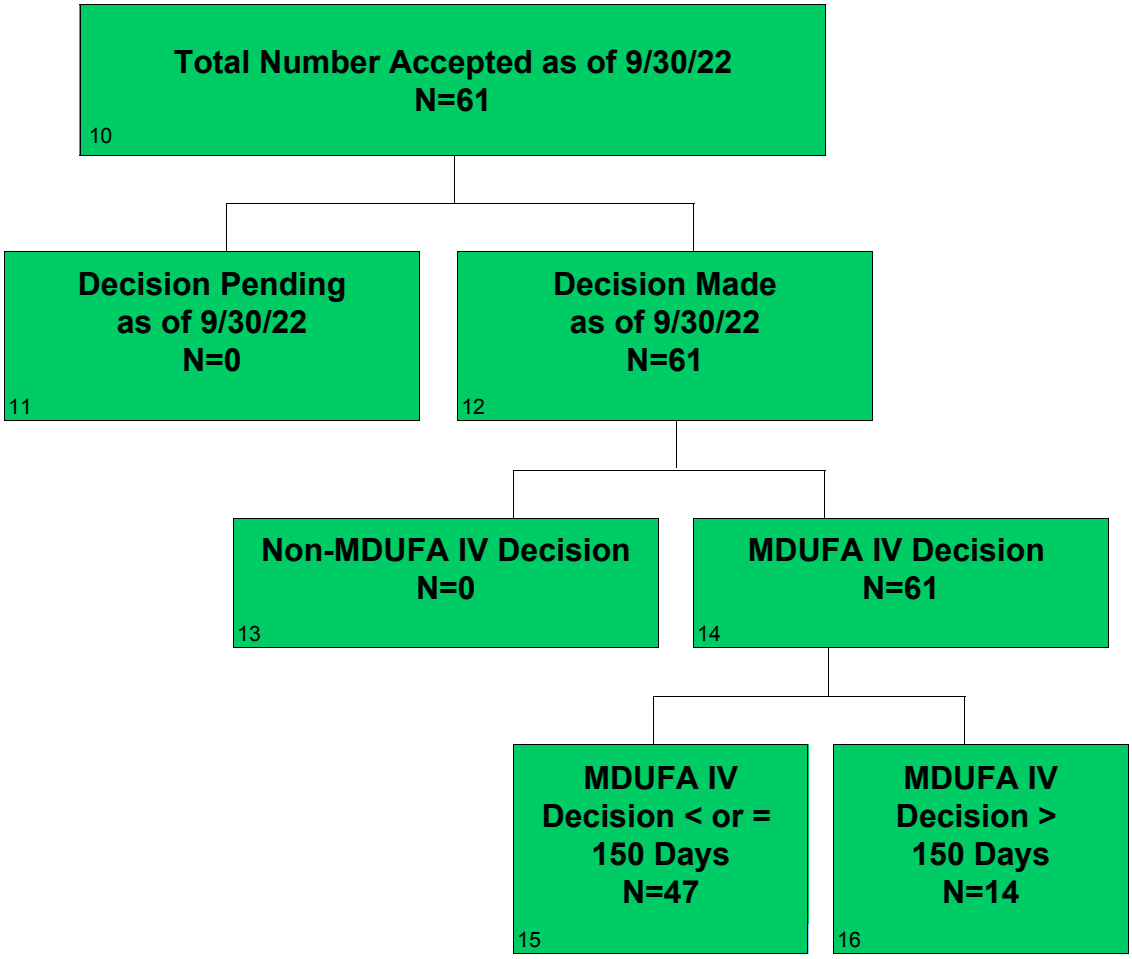


CDRH De Novo - FY 2019
as of 9/30/22

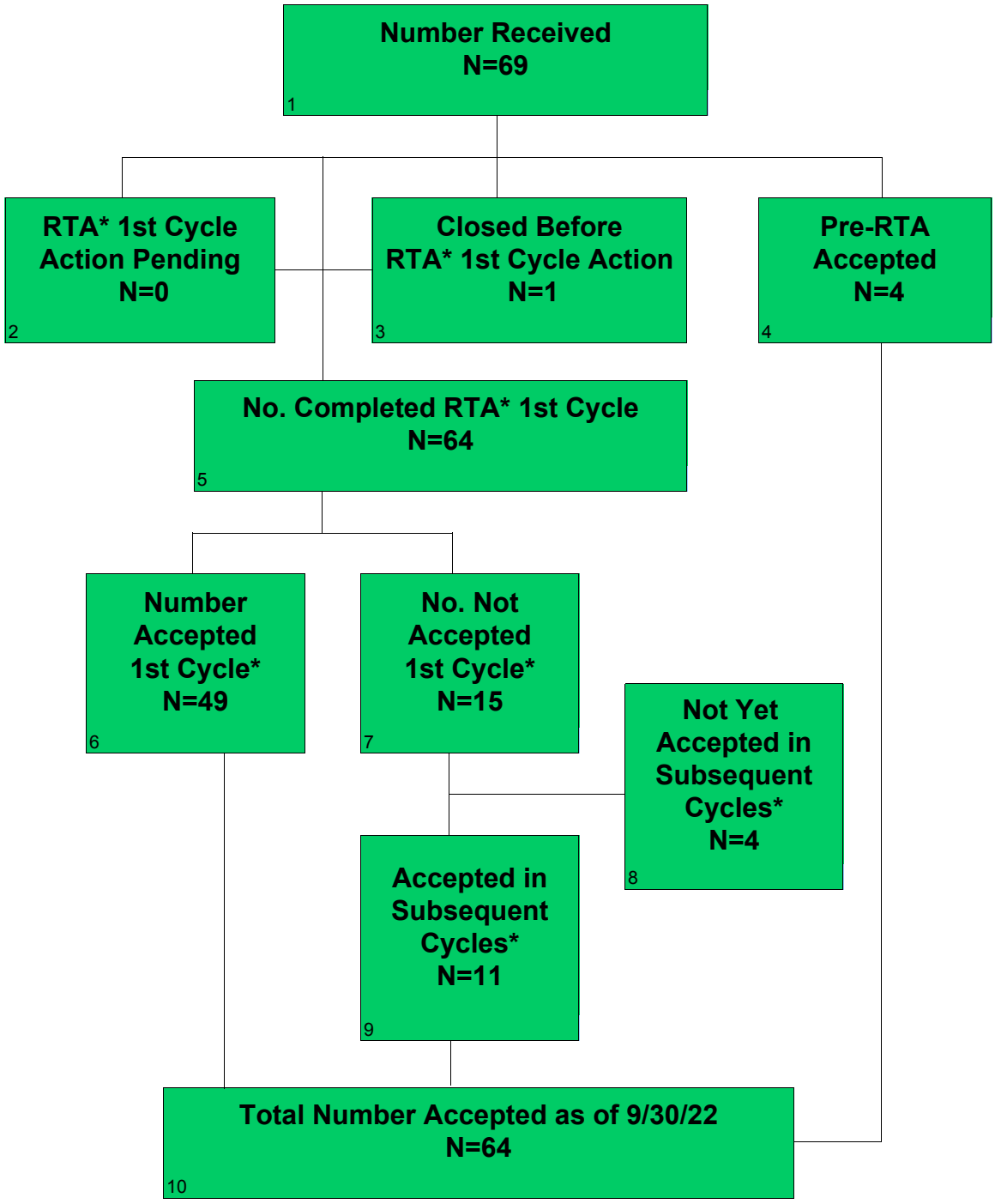


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019
as of 9/30/22 Continued

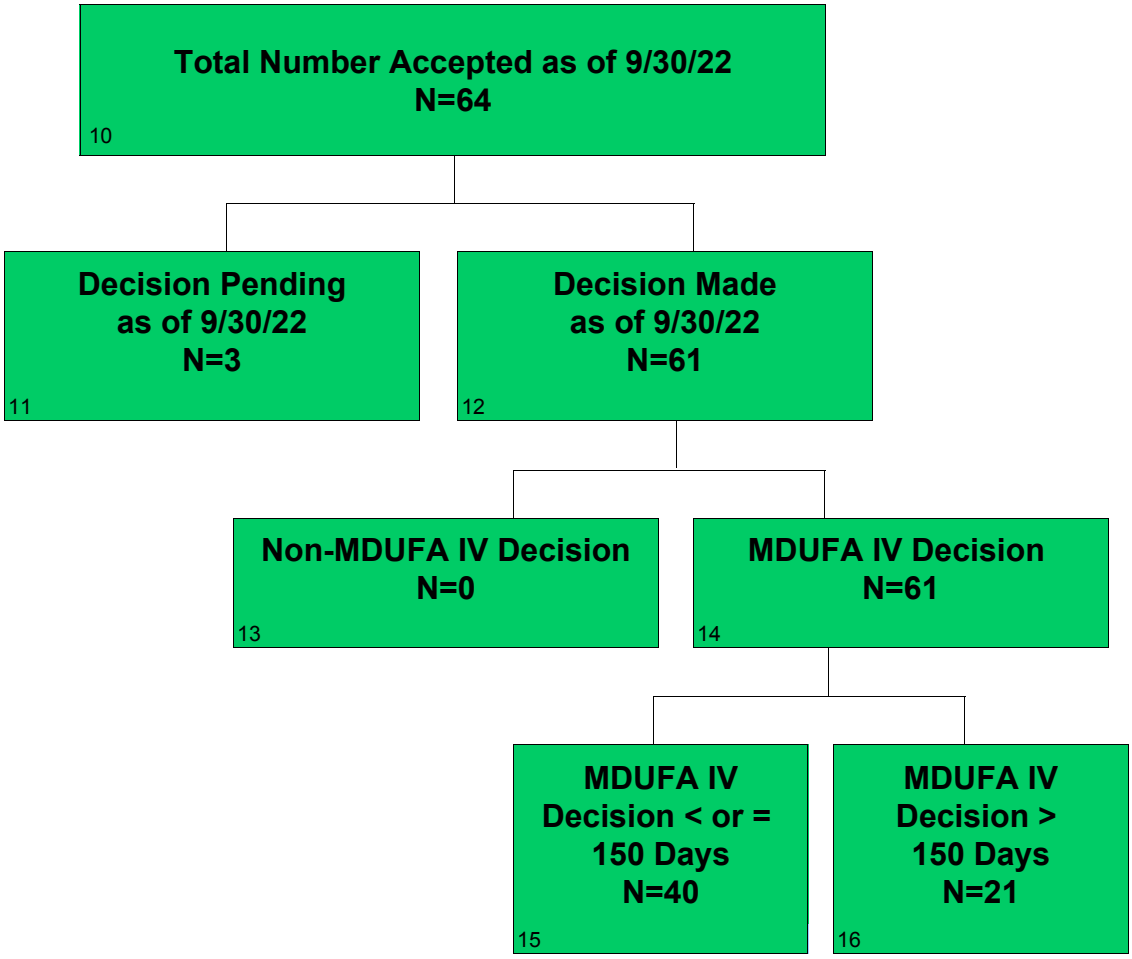


CDRH De Novo - FY 2020
as of 9/30/22

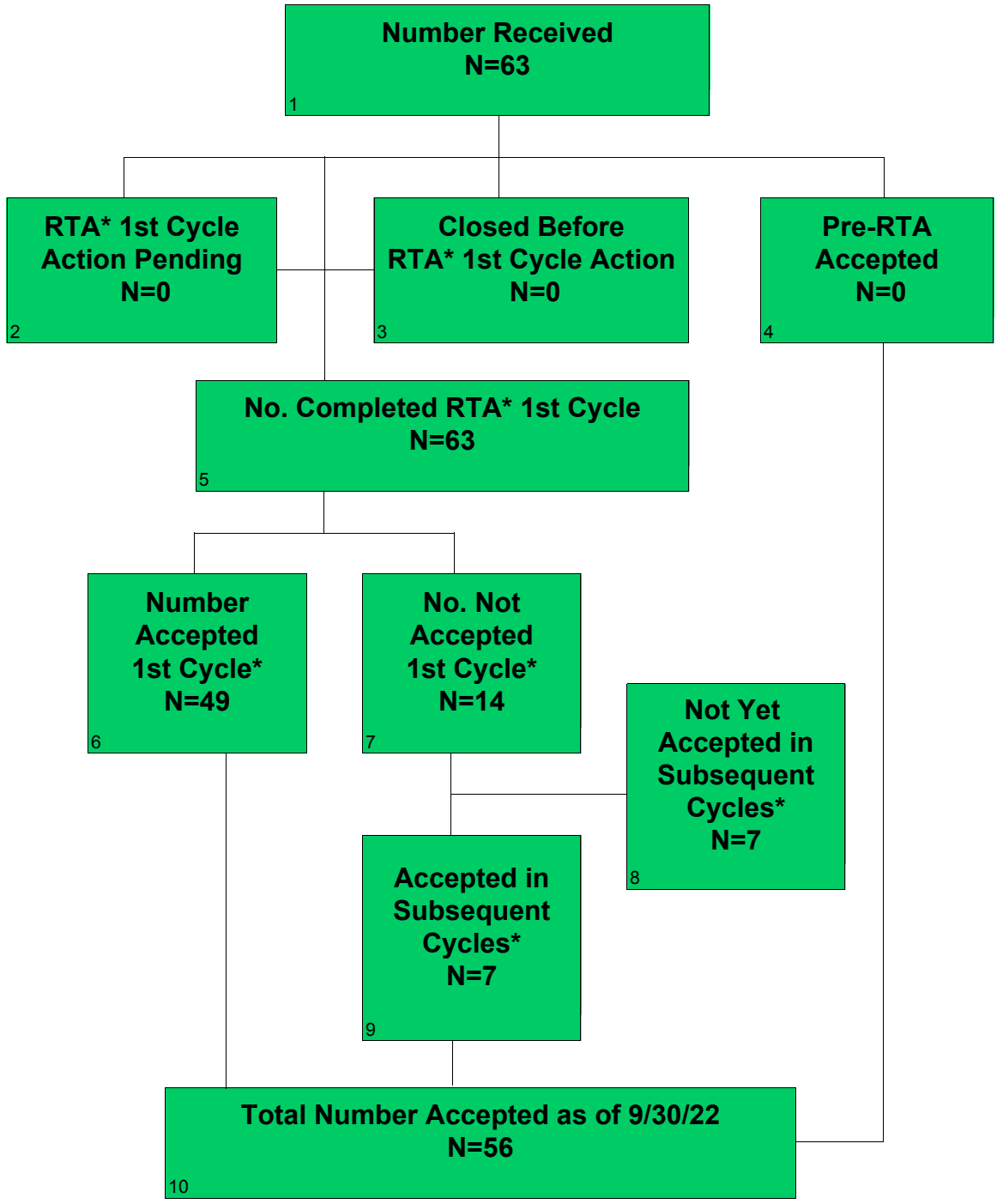


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020
as of 9/30/22 Continued

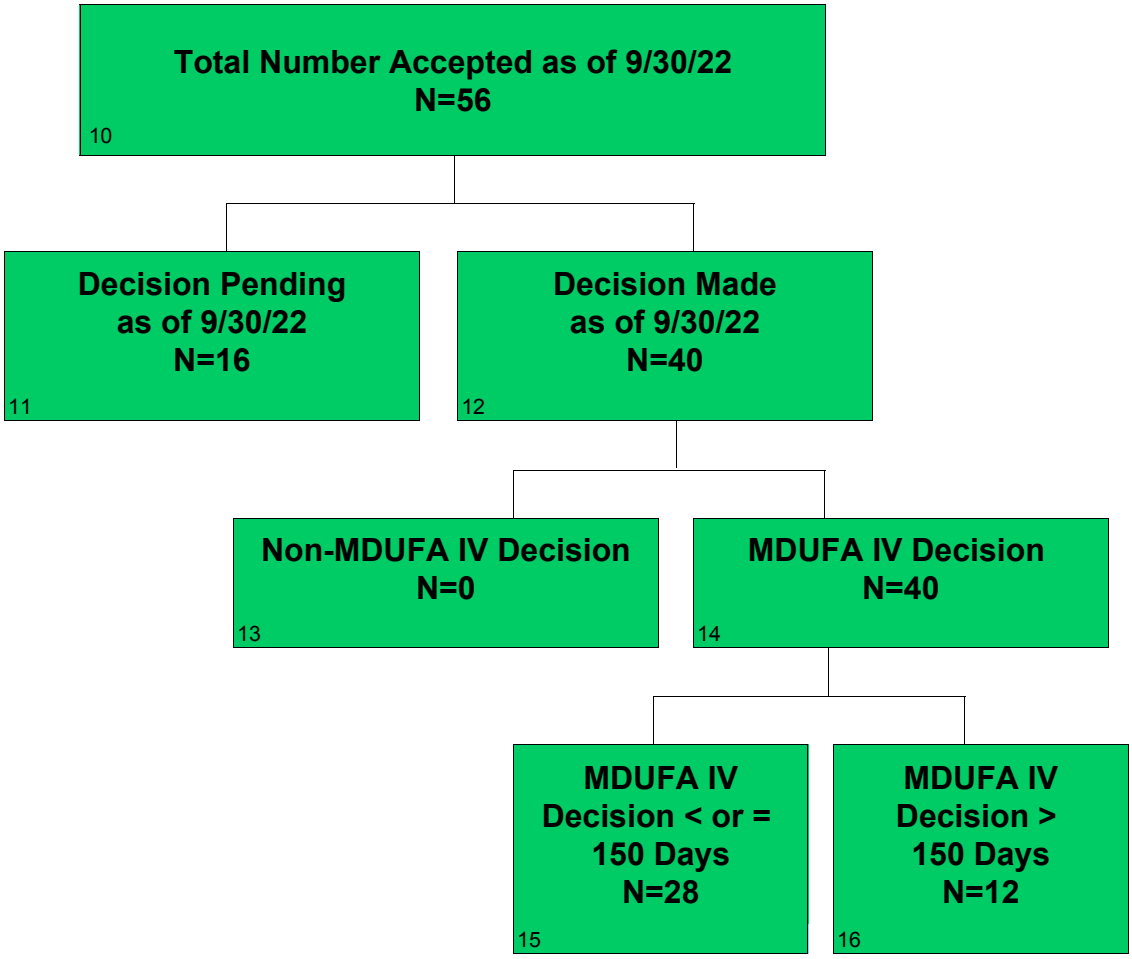


CDRH De Novo - FY 2021
as of 9/30/22

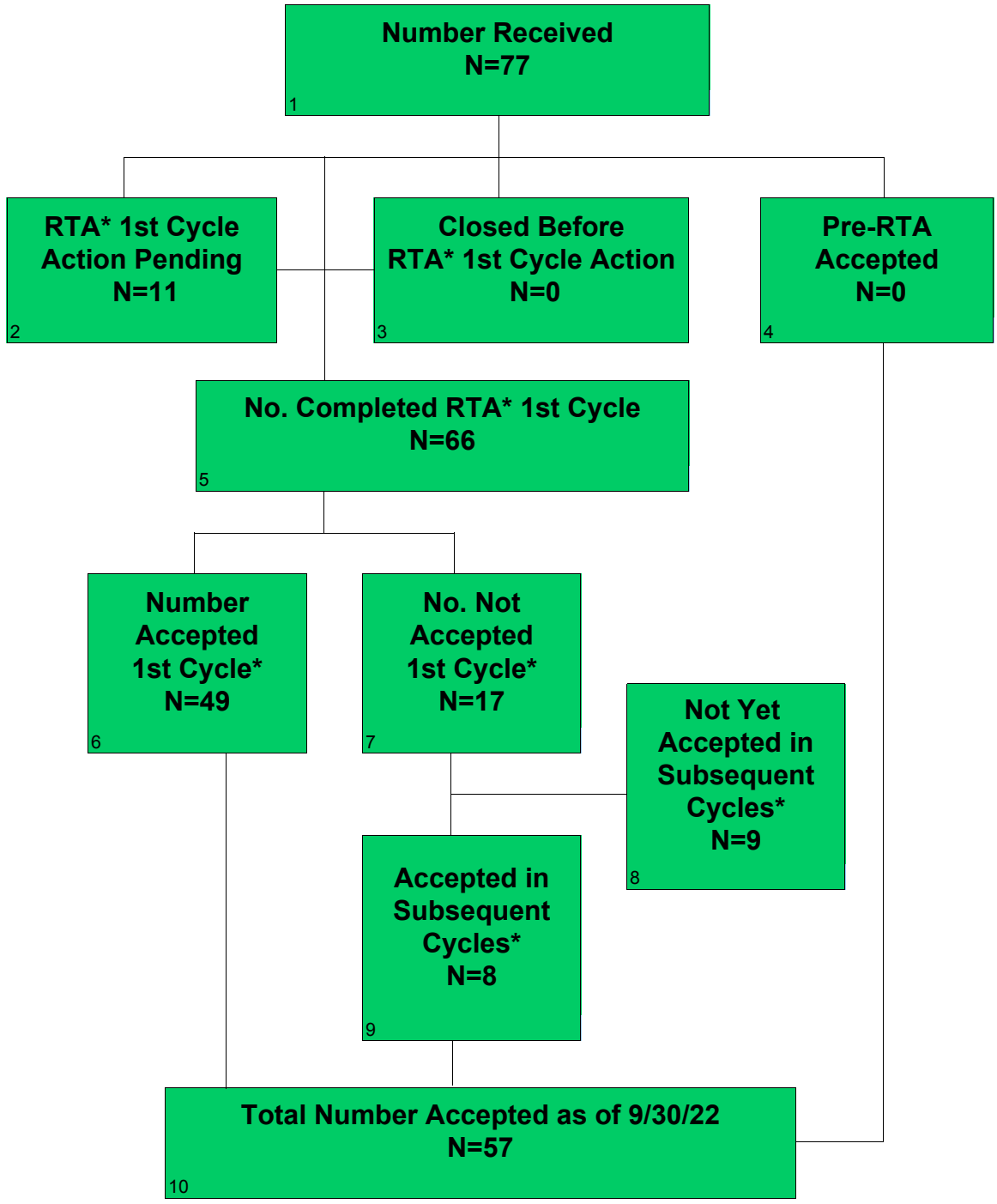


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2021
as of 9/30/22 Continued

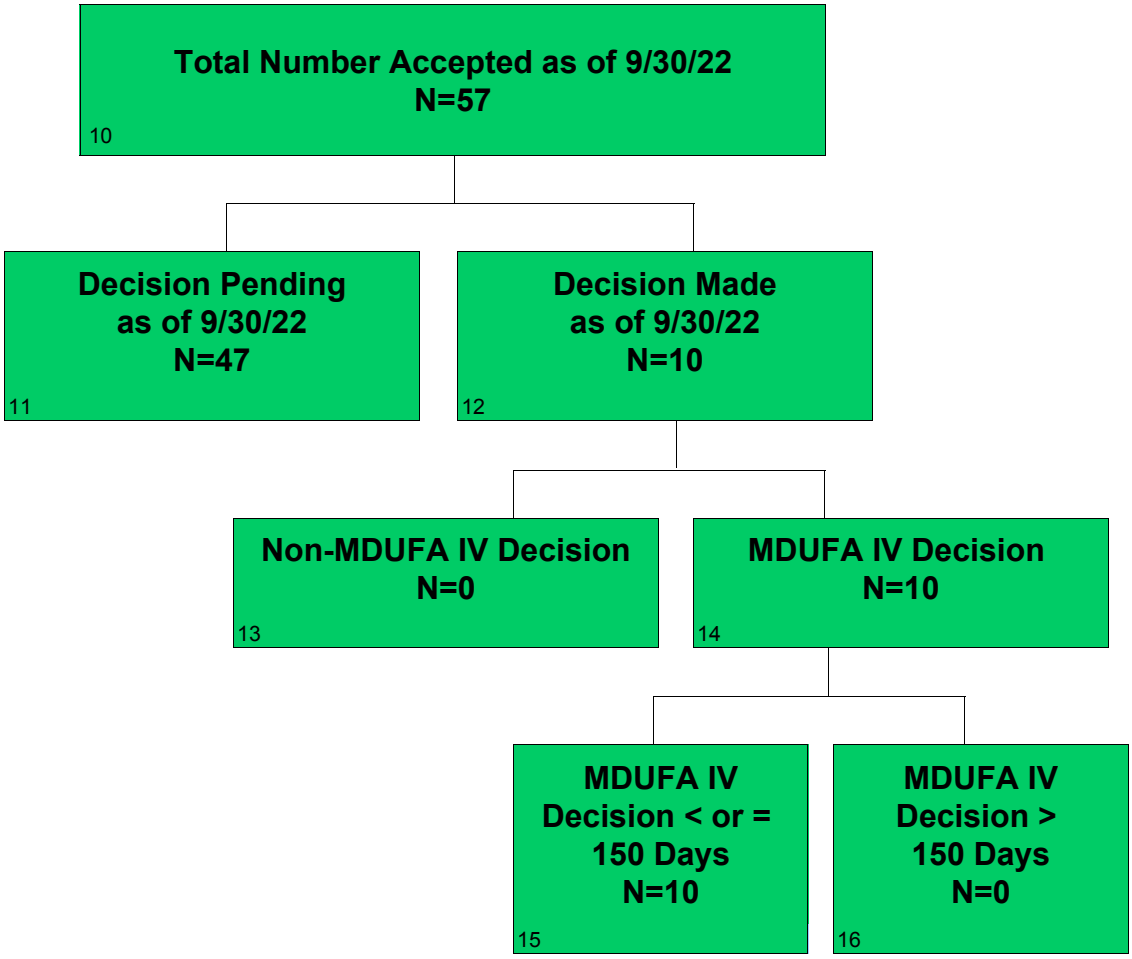


CDRH De Novo - FY 2022
as of 9/30/22



***RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.**

CDRH De Novo - FY 2022
as of 9/30/22 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	56	61	69	63	77
Closed Before RTA Action	N/A	N/A	1	0	0
Number Accepted First RTA Cycle	N/A	N/A	46	41	40
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	3	8	9
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	11
Number Not Accepted	N/A	N/A	15	14	17
Rate of Submissions Not Accepted for Review	N/A	N/A	23.44%	22.22%	25.76%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	56	61	64	56	57
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	56	61	61	40	10
MDUFA IV Decisions Within 150 FDA Days	45	47	40	28	10
De Novos Pending MDUFA IV Decision	0	0	3	16	47
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	3	3	4
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	62.50%	65.12%	71.43%

Table 8.3 CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.57	1.61	1.77	1.73	1.40
Number With MDUFA IV Decision	56	61	61	40	10
Average FDA Days to MDUFA IV Decision	130.13	143.57	174.31	174.63	111.00
20th Percentile FDA Days to MDUFA IV Decision	75	76	115	138	68
40th Percentile FDA Days to MDUFA IV Decision	145	130	149	149	117
60th Percentile FDA Days to MDUFA IV Decision	150	148	150	150	149
80th Percentile FDA Days to MDUFA IV Decision	150	180	212	211	150
Maximum FDA Days to MDUFA IV Decision	254	485	497	459	150
Average Industry Days to MDUFA IV Decision	110.13	117.44	179.49	174.73	64.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	60	0
40th Percentile Industry Days to MDUFA IV Decision	89	29	136	104	34
60th Percentile Industry Days to MDUFA IV Decision	166	177	222	177	89
80th Percentile Industry Days to MDUFA IV Decision	180	204	326	357	123
Maximum Industry Days to MDUFA IV Decision	389	373	431	388	140
Average Total Days to MDUFA IV Decision	240.25	261.02	353.80	349.35	175.00
20th Percentile Total Days to MDUFA IV Decision	145	107	210	222	128
40th Percentile Total Days to MDUFA IV Decision	251	179	312	260	166
60th Percentile Total Days to MDUFA IV Decision	292	304	395	383	219
80th Percentile Total Days to MDUFA IV Decision	324	388	474	509	233
Maximum Total Days to MDUFA IV Decision	463	680	928	680	290

Table 8.4 CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	56	61	64	56	57
Number With MDUFA IV Decisions	56	61	61	40	10
Number With Granted Decisions	25	28	31	21	4
Number With Declined Decisions	15	15	16	7	1
Number of Withdrawals	10	13	9	8	5
Number Deleted	6	5	5	4	0
Rate of Granted Decisions	44.64%	45.90%	50.82%	52.50%	40.00%
Rate of Declined Decisions	26.79%	24.59%	26.23%	17.50%	10.00%
Rate of Withdrawals	17.86%	21.31%	14.75%	20.00%	50.00%
Rate of Deleted	10.71%	8.20%	8.20%	10.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	11	14	21	12	0
Mean FDA Days for Submissions that Missed the Goal	192.45	248.29	270.29	277.67	0.00
Mean Industry Days for Submissions that Missed the Goal	127.27	218.64	196.76	208.50	0.00

Table 8.6 CDRH - LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5	2	0	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	2	0	1
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	1
De Novos Pending MDUFA IV Decision	0	0	0	0	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	40.00%	0.00%	0.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	16	13	11
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	14	8	0
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	2	5	11
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	3	2
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	9.09%	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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5	13	11	12
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	10	8	6
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	2	3	6
Rate of Submissions Not Accepted for Review	N/A	N/A	16.67%	27.27%	50.00%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	8	5	13	10	10
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	8	5	12	5	2
MDUFA IV Decisions Within 150 FDA Days	5	4	10	5	2
De Novos Pending MDUFA IV Decision	0	0	1	5	8
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	0	1
Current Performance Percent Within 150 FDA Days	62.50%	80.00%	76.92%	100.00%	66.67%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.63	1.80	1.75	2.00	1.50
Number With MDUFA IV Decision	8	5	12	5	2
Average FDA Days to MDUFA IV Decision	141.25	124.80	138.17	148.60	150.00
20th Percentile FDA Days to MDUFA IV Decision	110	75	74	148	150
40th Percentile FDA Days to MDUFA IV Decision	149	119	148	149	150
60th Percentile FDA Days to MDUFA IV Decision	153	148	149	149	150
80th Percentile FDA Days to MDUFA IV Decision	165	154	150	150	150
Maximum FDA Days to MDUFA IV Decision	194	180	287	150	150
Average Industry Days to MDUFA IV Decision	106.13	195.20	197.50	171.40	70.00
20th Percentile Industry Days to MDUFA IV Decision	9	185	108	81	28
40th Percentile Industry Days to MDUFA IV Decision	45	192	152	112	56
60th Percentile Industry Days to MDUFA IV Decision	75	199	259	151	84
80th Percentile Industry Days to MDUFA IV Decision	167	206	312	222	112
Maximum Industry Days to MDUFA IV Decision	389	212	366	388	140
Average Total Days to MDUFA IV Decision	247.38	320.00	335.67	320.00	220.00
20th Percentile Total Days to MDUFA IV Decision	157	268	262	231	178
40th Percentile Total Days to MDUFA IV Decision	199	304	313	261	206
60th Percentile Total Days to MDUFA IV Decision	260	336	370	298	234
80th Percentile Total Days to MDUFA IV Decision	332	360	435	368	262
Maximum Total Days to MDUFA IV Decision	463	392	653	538	290

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	8	5	13	10	10
Number With MDUFA IV Decisions	8	5	12	5	2
Number With Granted Decisions	5	2	5	3	1
Number With Declined Decisions	2	1	4	1	1
Number of Withdrawals	0	0	2	1	0
Number Deleted	1	2	1	0	0
Rate of Granted Decisions	62.50%	40.00%	41.67%	60.00%	50.00%
Rate of Declined Decisions	25.00%	20.00%	33.33%	20.00%	50.00%
Rate of Withdrawals	0.00%	0.00%	16.67%	20.00%	0.00%
Rate of Deleted	12.50%	40.00%	8.33%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	3	1	2	0	0
Mean FDA Days for Submissions that Missed the Goal	174.67	180.00	243.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	127.00	212.00	242.50	0.00	0.00

Table 8.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	9	8	6	9
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	6	4	5
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	3
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	1
Number Not Accepted	N/A	N/A	1	2	0
Rate of Submissions Not Accepted for Review	N/A	N/A	14.29%	33.33%	0.00%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

Table 8.2 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	9	8	5	8
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	9	8	5	0
MDUFA IV Decisions Within 150 FDA Days	5	8	3	5	0
De Novos Pending MDUFA IV Decision	0	0	0	0	8
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	88.89%	37.50%	100.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.20	1.44	2.00	1.40	0.00
Number With MDUFA IV Decision	5	9	8	5	0
Average FDA Days to MDUFA IV Decision	74.00	144.00	200.50	102.80	0.00
20th Percentile FDA Days to MDUFA IV Decision	32	86	150	74	0
40th Percentile FDA Days to MDUFA IV Decision	58	132	162	75	0
60th Percentile FDA Days to MDUFA IV Decision	79	148	214	102	0
80th Percentile FDA Days to MDUFA IV Decision	98	150	253	144	0
Maximum FDA Days to MDUFA IV Decision	148	348	357	150	0
Average Industry Days to MDUFA IV Decision	112.40	71.11	161.75	209.20	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	91	0
40th Percentile Industry Days to MDUFA IV Decision	98	6	96	148	0
60th Percentile Industry Days to MDUFA IV Decision	171	64	177	251	0
80th Percentile Industry Days to MDUFA IV Decision	188	163	279	363	0
Maximum Industry Days to MDUFA IV Decision	217	207	427	365	0
Average Total Days to MDUFA IV Decision	186.40	215.11	362.25	312.00	0.00
20th Percentile Total Days to MDUFA IV Decision	32	117	286	237	0
40th Percentile Total Days to MDUFA IV Decision	173	153	350	253	0
60th Percentile Total Days to MDUFA IV Decision	277	213	363	326	0
80th Percentile Total Days to MDUFA IV Decision	296	281	448	436	0
Maximum Total Days to MDUFA IV Decision	312	526	651	440	0

Table 8.4 OHT2 - Office of Cardiovascular Devices
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	9	8	5	8
Number With MDUFA IV Decisions	5	9	8	5	0
Number With Granted Decisions	3	2	5	2	0
Number With Declined Decisions	0	5	2	0	0
Number of Withdrawals	0	1	1	1	0
Number Deleted	2	1	0	2	0
Rate of Granted Decisions	60.00%	22.22%	62.50%	40.00%	0.00%
Rate of Declined Decisions	0.00%	55.56%	25.00%	0.00%	0.00%
Rate of Withdrawals	0.00%	11.11%	12.50%	20.00%	0.00%
Rate of Deleted	40.00%	11.11%	0.00%	40.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	5	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	348.00	246.20	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	178.00	170.00	0.00	0.00

Table 8.6 OHT2 - Office of Cardiovascular Devices
LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	11	6	6	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	4	5	4
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	1
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	1
Number Not Accepted	N/A	N/A	2	1	1
Rate of Submissions Not Accepted for Review	N/A	N/A	33.33%	16.67%	16.67%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	11	6	6	6
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	11	6	5	4
MDUFA IV Decisions Within 150 FDA Days	3	5	4	5	4
De Novos Pending MDUFA IV Decision	0	0	0	1	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	75.00%	45.45%	66.67%	100.00%	100.00%

Table 8.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.82	1.83	2.00	1.50
Number With MDUFA IV Decision	4	11	6	5	4
Average FDA Days to MDUFA IV Decision	100.00	186.55	161.50	149.00	112.50
20th Percentile FDA Days to MDUFA IV Decision	57	148	148	148	83
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	149	120
60th Percentile FDA Days to MDUFA IV Decision	135	191	150	150	142
80th Percentile FDA Days to MDUFA IV Decision	149	211	203	150	149
Maximum FDA Days to MDUFA IV Decision	151	327	243	150	150
Average Industry Days to MDUFA IV Decision	136.75	168.45	116.83	112.40	57.50
20th Percentile Industry Days to MDUFA IV Decision	100	136	21	79	0
40th Percentile Industry Days to MDUFA IV Decision	169	175	24	99	22
60th Percentile Industry Days to MDUFA IV Decision	175	177	61	116	89
80th Percentile Industry Days to MDUFA IV Decision	187	241	222	148	114
Maximum Industry Days to MDUFA IV Decision	203	338	363	201	119
Average Total Days to MDUFA IV Decision	236.75	355.00	278.33	261.40	170.00
20th Percentile Total Days to MDUFA IV Decision	179	283	209	227	105
40th Percentile Total Days to MDUFA IV Decision	293	347	213	246	165
60th Percentile Total Days to MDUFA IV Decision	312	368	267	265	209
80th Percentile Total Days to MDUFA IV Decision	321	416	372	298	242
Maximum Total Days to MDUFA IV Decision	325	617	438	351	268

Table 8.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	11	6	6	6
Number With MDUFA IV Decisions	4	11	6	5	4
Number With Granted Decisions	0	8	3	4	2
Number With Declined Decisions	3	3	2	1	0
Number of Withdrawals	0	0	0	0	2
Number Deleted	1	0	1	0	0
Rate of Granted Decisions	0.00%	72.73%	50.00%	80.00%	50.00%
Rate of Declined Decisions	75.00%	27.27%	33.33%	20.00%	0.00%
Rate of Withdrawals	0.00%	0.00%	0.00%	0.00%	50.00%
Rate of Deleted	25.00%	0.00%	16.67%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	6	2	0	0
Mean FDA Days for Submissions that Missed the Goal	151.00	230.33	223.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	167.00	212.00	17.00	0.00	0.00

Table 8.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	6	8	8	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	3	4	3
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	1	1	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	2
Number Not Accepted	N/A	N/A	3	3	2
Rate of Submissions Not Accepted for Review	N/A	N/A	42.86%	37.50%	40.00%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	6	7	7	5
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	6	7	3	0
MDUFA IV Decisions Within 150 FDA Days	3	4	3	1	0
De Novos Pending MDUFA IV Decision	0	0	0	4	5
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	1
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	42.86%	33.33%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.80	1.50	1.57	1.33	0.00
Number With MDUFA IV Decision	5	6	7	3	0
Average FDA Days to MDUFA IV Decision	147.40	182.50	165.14	165.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	133	93	113	128	0
40th Percentile FDA Days to MDUFA IV Decision	150	98	146	175	0
60th Percentile FDA Days to MDUFA IV Decision	151	107	174	201	0
80th Percentile FDA Days to MDUFA IV Decision	167	236	189	208	0
Maximum FDA Days to MDUFA IV Decision	221	485	323	215	0
Average Industry Days to MDUFA IV Decision	90.80	125.83	231.86	332.67	0.00
20th Percentile Industry Days to MDUFA IV Decision	12	0	161	308	0
40th Percentile Industry Days to MDUFA IV Decision	65	0	248	345	0
60th Percentile Industry Days to MDUFA IV Decision	124	187	267	363	0
80th Percentile Industry Days to MDUFA IV Decision	165	195	331	364	0
Maximum Industry Days to MDUFA IV Decision	179	373	365	364	0
Average Total Days to MDUFA IV Decision	238.20	308.33	397.00	497.67	0.00
20th Percentile Total Days to MDUFA IV Decision	145	93	331	462	0
40th Percentile Total Days to MDUFA IV Decision	215	107	408	478	0
60th Percentile Total Days to MDUFA IV Decision	275	285	436	501	0
80th Percentile Total Days to MDUFA IV Decision	332	609	469	531	0
Maximum Total Days to MDUFA IV Decision	400	680	668	561	0

Table 8.4 OHT4 - Office of Surgical and Infection Control Devices
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	6	7	7	5
Number With MDUFA IV Decisions	5	6	7	3	0
Number With Granted Decisions	3	1	1	1	0
Number With Declined Decisions	1	3	3	0	0
Number of Withdrawals	1	1	2	0	0
Number Deleted	0	1	1	2	0
Rate of Granted Decisions	60.00%	16.67%	14.29%	33.33%	0.00%
Rate of Declined Decisions	20.00%	50.00%	42.86%	0.00%	0.00%
Rate of Withdrawals	20.00%	16.67%	28.57%	0.00%	0.00%
Rate of Deleted	0.00%	16.67%	14.29%	66.67%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	2	4	2	0
Mean FDA Days for Submissions that Missed the Goal	187.00	360.50	215.50	206.50	0.00
Mean Industry Days for Submissions that Missed the Goal	170.50	284.00	246.25	317.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	6	7	9	10
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	7	4
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	3
Number Not Accepted	N/A	N/A	2	2	3
Rate of Submissions Not Accepted for Review	N/A	N/A	28.57%	22.22%	42.86%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	6	6	7	4
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	13	6	6	6	2
MDUFA IV Decisions Within 150 FDA Days	9	6	5	5	2
De Novos Pending MDUFA IV Decision	0	0	0	1	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	69.23%	100.00%	83.33%	83.33%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.77	1.33	1.83	1.83	1.50
Number With MDUFA IV Decision	13	6	6	6	2
Average FDA Days to MDUFA IV Decision	153.00	113.33	138.67	156.33	112.50
20th Percentile FDA Days to MDUFA IV Decision	104	76	149	148	90
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	149	105
60th Percentile FDA Days to MDUFA IV Decision	150	136	150	150	120
80th Percentile FDA Days to MDUFA IV Decision	219	149	150	150	135
Maximum FDA Days to MDUFA IV Decision	254	150	175	270	150
Average Industry Days to MDUFA IV Decision	106.08	20.17	134.67	83.33	107.00
20th Percentile Industry Days to MDUFA IV Decision	39	0	14	51	87
40th Percentile Industry Days to MDUFA IV Decision	82	0	84	62	100
60th Percentile Industry Days to MDUFA IV Decision	164	0	125	80	114
80th Percentile Industry Days to MDUFA IV Decision	174	45	169	141	127
Maximum Industry Days to MDUFA IV Decision	183	76	416	166	140
Average Total Days to MDUFA IV Decision	259.08	133.50	273.33	239.67	219.50
20th Percentile Total Days to MDUFA IV Decision	226	76	163	201	217
40th Percentile Total Days to MDUFA IV Decision	266	127	234	211	219
60th Percentile Total Days to MDUFA IV Decision	316	136	274	230	220
80th Percentile Total Days to MDUFA IV Decision	323	195	344	289	222
Maximum Total Days to MDUFA IV Decision	371	225	566	436	224

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	13	6	6	7	4
Number With MDUFA IV Decisions	13	6	6	6	2
Number With Granted Decisions	3	2	6	3	1
Number With Declined Decisions	7	0	0	2	0
Number of Withdrawals	3	4	0	1	1
Number Deleted	0	0	0	0	0
Rate of Granted Decisions	23.08%	33.33%	100.00%	50.00%	50.00%
Rate of Declined Decisions	53.85%	0.00%	0.00%	33.33%	0.00%
Rate of Withdrawals	23.08%	66.67%	0.00%	16.67%	50.00%
Rate of Deleted	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	4	0	1	1	0
Mean FDA Days for Submissions that Missed the Goal	229.25	0.00	175.00	270.00	0.00
Mean Industry Days for Submissions that Missed the Goal	82.75	0.00	169.00	166.00	0.00

Table 8.6 OHT5 - Office of Neurological and Physical Medicine Devices
LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	4	5	6	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	5	6
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	1
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	0	1	0
Rate of Submissions Not Accepted for Review	N/A	N/A	0.00%	16.67%	0.00%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

Table 8.2 OHT6 - Office of Orthopedic Devices
De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	4	5	6	7
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	4	5	6	0
MDUFA IV Decisions Within 150 FDA Days	3	3	5	4	0
De Novos Pending MDUFA IV Decision	0	0	0	0	7
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	75.00%	75.00%	100.00%	66.67%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.75	2.00	1.67	0.00
Number With MDUFA IV Decision	4	4	5	6	0
Average FDA Days to MDUFA IV Decision	133.25	144.75	147.40	165.83	0.00
20th Percentile FDA Days to MDUFA IV Decision	122	116	147	139	0
40th Percentile FDA Days to MDUFA IV Decision	148	143	150	141	0
60th Percentile FDA Days to MDUFA IV Decision	150	144	150	147	0
80th Percentile FDA Days to MDUFA IV Decision	150	173	150	204	0
Maximum FDA Days to MDUFA IV Decision	151	217	150	231	0
Average Industry Days to MDUFA IV Decision	161.00	178.50	132.60	147.83	0.00
20th Percentile Industry Days to MDUFA IV Decision	149	104	62	0	0
40th Percentile Industry Days to MDUFA IV Decision	179	175	107	74	0
60th Percentile Industry Days to MDUFA IV Decision	180	177	146	98	0
80th Percentile Industry Days to MDUFA IV Decision	180	252	179	357	0
Maximum Industry Days to MDUFA IV Decision	181	362	245	358	0
Average Total Days to MDUFA IV Decision	294.25	323.25	280.00	313.67	0.00
20th Percentile Total Days to MDUFA IV Decision	260	221	209	213	0
40th Percentile Total Days to MDUFA IV Decision	278	333	256	231	0
60th Percentile Total Days to MDUFA IV Decision	316	380	296	302	0
80th Percentile Total Days to MDUFA IV Decision	330	439	329	491	0
Maximum Total Days to MDUFA IV Decision	331	505	395	504	0

Table 8.4 OHT6 - Office of Orthopedic Devices
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	4	5	6	7
Number With MDUFA IV Decisions	4	4	5	6	0
Number With Granted Decisions	1	1	3	3	0
Number With Declined Decisions	1	3	2	1	0
Number of Withdrawals	1	0	0	2	0
Number Deleted	1	0	0	0	0
Rate of Granted Decisions	25.00%	25.00%	60.00%	50.00%	0.00%
Rate of Declined Decisions	25.00%	75.00%	40.00%	16.67%	0.00%
Rate of Withdrawals	25.00%	0.00%	0.00%	33.33%	0.00%
Rate of Deleted	25.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	1	0	2	0
Mean FDA Days for Submissions that Missed the Goal	151.00	217.00	0.00	217.50	0.00
Mean Industry Days for Submissions that Missed the Goal	180.00	178.00	0.00	49.00	0.00

Table 8.6 OHT6 - Office of Orthopedic Devices
LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	19	21	15	19
Closed Before RTA Action	N/A	N/A	1	0	0
Number Accepted First RTA Cycle	N/A	N/A	12	6	10
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	2	7	2
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	3
Number Not Accepted	N/A	N/A	5	2	4
Rate of Submissions Not Accepted for Review	N/A	N/A	26.32%	13.33%	25.00%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

Table 8.2 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	16	19	18	13	13
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	16	19	16	8	1
MDUFA IV Decisions Within 150 FDA Days	16	16	9	1	1
De Novos Pending MDUFA IV Decision	0	0	2	5	12
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	3	2
Current Performance Percent Within 150 FDA Days	100.00%	84.21%	50.00%	9.09%	33.33%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.58	1.63	1.75	1.00
Number With MDUFA IV Decision	16	19	16	8	1
Average FDA Days to MDUFA IV Decision	126.25	120.16	220.56	291.75	120.00
20th Percentile FDA Days to MDUFA IV Decision	109	71	115	209	120
40th Percentile FDA Days to MDUFA IV Decision	132	118	147	220	120
60th Percentile FDA Days to MDUFA IV Decision	147	148	211	306	120
80th Percentile FDA Days to MDUFA IV Decision	150	150	364	419	120
Maximum FDA Days to MDUFA IV Decision	150	243	497	459	120
Average Industry Days to MDUFA IV Decision	108.25	110.00	195.63	200.50	56.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	71	92	56
40th Percentile Industry Days to MDUFA IV Decision	121	0	171	173	56
60th Percentile Industry Days to MDUFA IV Decision	175	176	232	240	56
80th Percentile Industry Days to MDUFA IV Decision	180	222	326	322	56
Maximum Industry Days to MDUFA IV Decision	189	276	431	358	56
Average Total Days to MDUFA IV Decision	234.50	230.16	416.19	492.25	176.00
20th Percentile Total Days to MDUFA IV Decision	145	90	210	369	176
40th Percentile Total Days to MDUFA IV Decision	236	150	402	532	176
60th Percentile Total Days to MDUFA IV Decision	281	295	441	581	176
80th Percentile Total Days to MDUFA IV Decision	313	340	502	622	176
Maximum Total Days to MDUFA IV Decision	327	509	928	680	176

Table 8.4 OHT7 - Office of In Vitro Diagnostics
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	16	19	18	13	13
Number With MDUFA IV Decisions	16	19	16	8	1
Number With Granted Decisions	9	11	7	5	0
Number With Declined Decisions	1	0	3	1	0
Number of Withdrawals	5	7	4	2	1
Number Deleted	1	1	2	0	0
Rate of Granted Decisions	56.25%	57.89%	43.75%	62.50%	0.00%
Rate of Declined Decisions	6.25%	0.00%	18.75%	12.50%	0.00%
Rate of Withdrawals	31.25%	36.84%	25.00%	25.00%	100.00%
Rate of Deleted	6.25%	5.26%	12.50%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	3	7	7	0
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	353.71	316.29	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	229.86	229.14	0.00

Table 8.6 OHT7 - Office of In Vitro Diagnostics
LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5	2	0	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	2	0	1
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	1
De Novos Pending MDUFA IV Decision	0	0	0	0	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	40.00%	0.00%	0.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	16	13	11
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	14	8	0
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	2	5	11
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	3	2
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	9.09%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	1	1	2	6
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	1	2	2
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	2
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	1
Number Not Accepted	N/A	N/A	0	0	1
Rate of Submissions Not Accepted for Review	N/A	N/A	0.00%	0.00%	20.00%

***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

Table 8.2 OHT8 - Office of Radiological Health
De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	1	1	1	2	4
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	1	1	2	1
MDUFA IV Decisions Within 150 FDA Days	1	1	1	2	1
De Novos Pending MDUFA IV Decision	0	0	0	0	3
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00	2.00	2.00	1.50	1.00
Number With MDUFA IV Decision	1	1	1	2	1
Average FDA Days to MDUFA IV Decision	108.00	149.00	148.00	110.50	15.00
20th Percentile FDA Days to MDUFA IV Decision	108	149	148	87	15
40th Percentile FDA Days to MDUFA IV Decision	108	149	148	103	15
60th Percentile FDA Days to MDUFA IV Decision	108	149	148	118	15
80th Percentile FDA Days to MDUFA IV Decision	108	149	148	134	15
Maximum FDA Days to MDUFA IV Decision	108	149	148	149	15
Average Industry Days to MDUFA IV Decision	0.00	15.00	360.00	267.50	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	15	360	213	0
40th Percentile Industry Days to MDUFA IV Decision	0	15	360	249	0
60th Percentile Industry Days to MDUFA IV Decision	0	15	360	286	0
80th Percentile Industry Days to MDUFA IV Decision	0	15	360	322	0
Maximum Industry Days to MDUFA IV Decision	0	15	360	358	0
Average Total Days to MDUFA IV Decision	108.00	164.00	508.00	378.00	15.00
20th Percentile Total Days to MDUFA IV Decision	108	164	508	347	15
40th Percentile Total Days to MDUFA IV Decision	108	164	508	368	15
60th Percentile Total Days to MDUFA IV Decision	108	164	508	388	15
80th Percentile Total Days to MDUFA IV Decision	108	164	508	409	15
Maximum Total Days to MDUFA IV Decision	108	164	508	430	15

Table 8.4 OHT8 - Office of Radiological Health
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	1	1	2	4
Number With MDUFA IV Decisions	1	1	1	2	1
Number With Granted Decisions	1	1	1	0	0
Number With Declined Decisions	0	0	0	1	0
Number of Withdrawals	0	0	0	1	1
Number Deleted	0	0	0	0	0
Rate of Granted Decisions	100.00%	100.00%	100.00%	0.00%	0.00%
Rate of Declined Decisions	0.00%	0.00%	0.00%	50.00%	0.00%
Rate of Withdrawals	0.00%	0.00%	0.00%	50.00%	100.00%
Rate of Deleted	0.00%	0.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

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

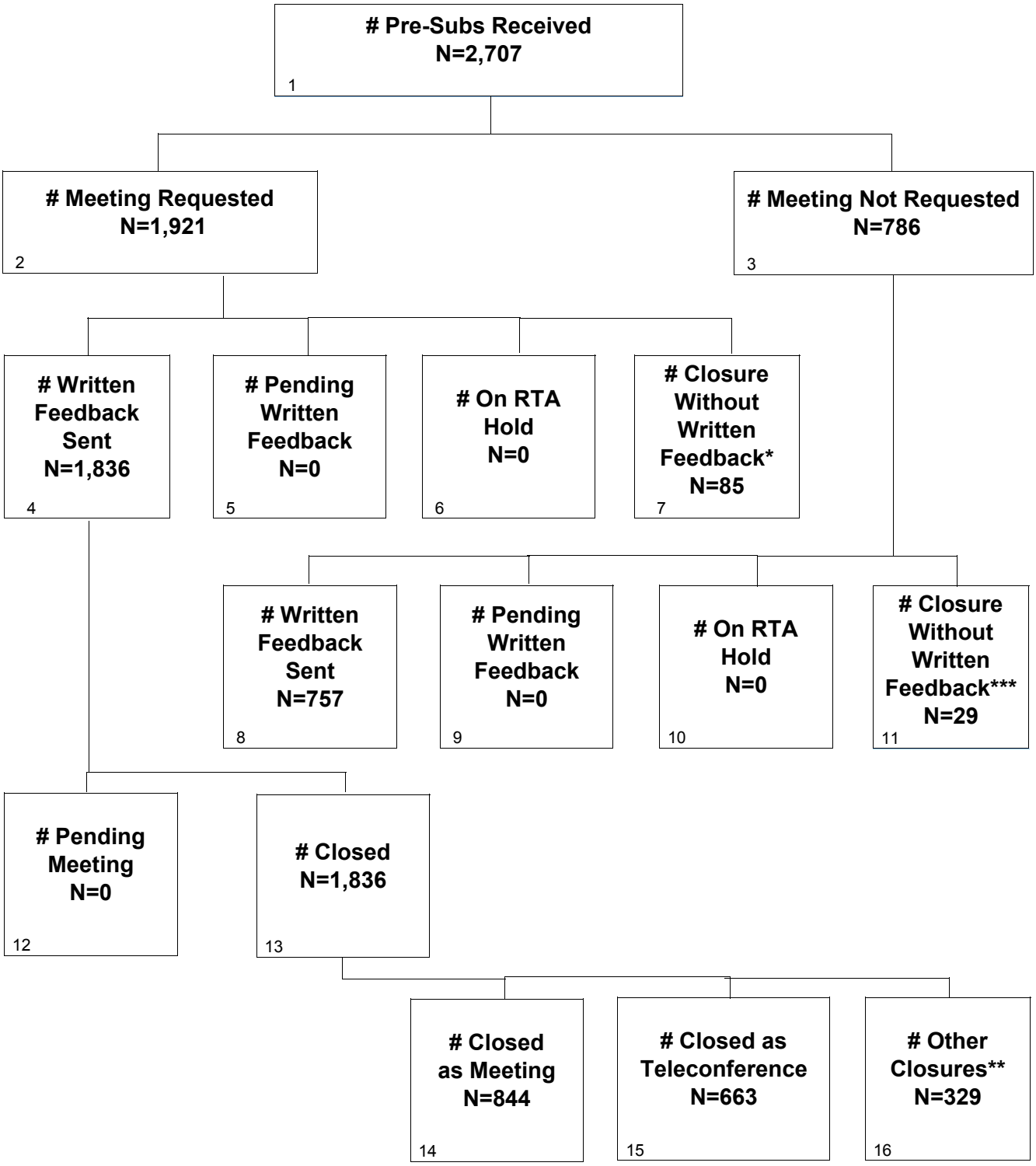
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	0.00%	0.00%	0.00%	0.00%	0.00%

Table 8.8 CDRH - De Novo Annual General Metrics*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted First RTA Cycle	56	61	64	56	57
Average Number of Days to Accept / Refuse to Accept*	N/A	N/A	11.61	12.68	12.18

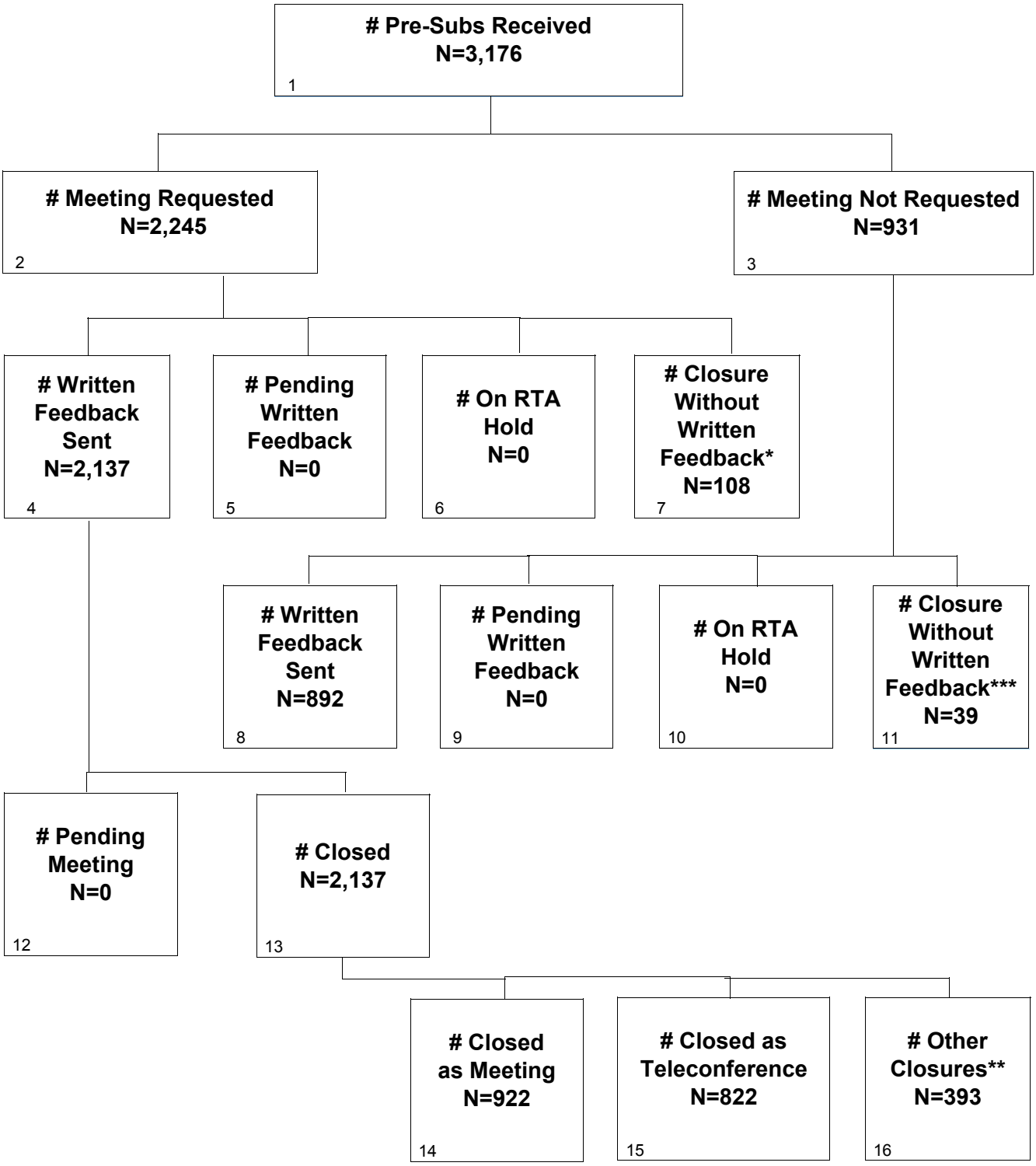
***RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.**

CDRH Pre-Sub - FY 2018
as of 9/30/22



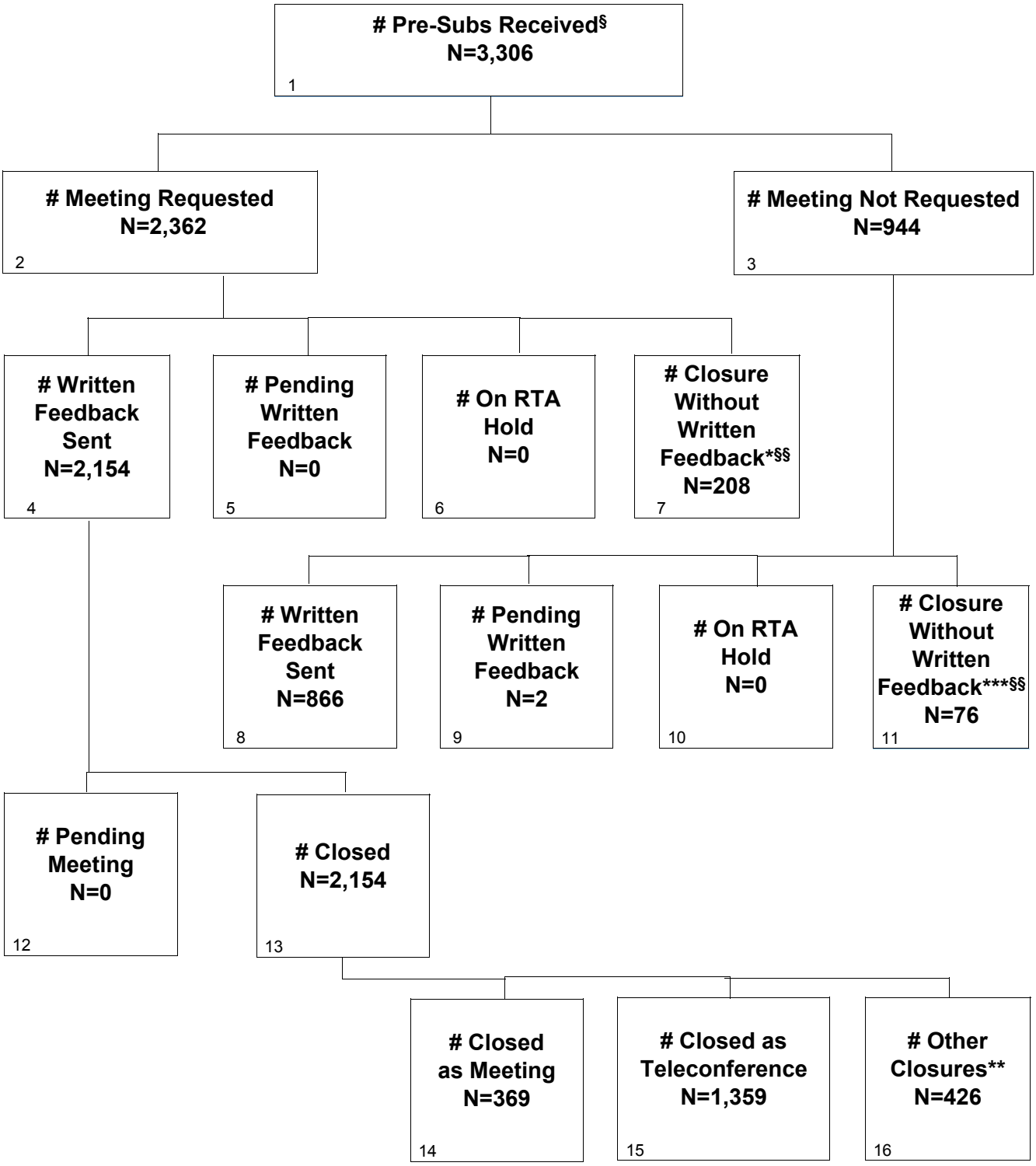
*** Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR**
**** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR**
***** Closures include JTRX, JPND, DELE & WTDR**

CDRH Pre-Sub - FY 2019
as of 9/30/22



*** Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR**
**** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR**
***** Closures include JTRX, JPND, DELE & WTDR**

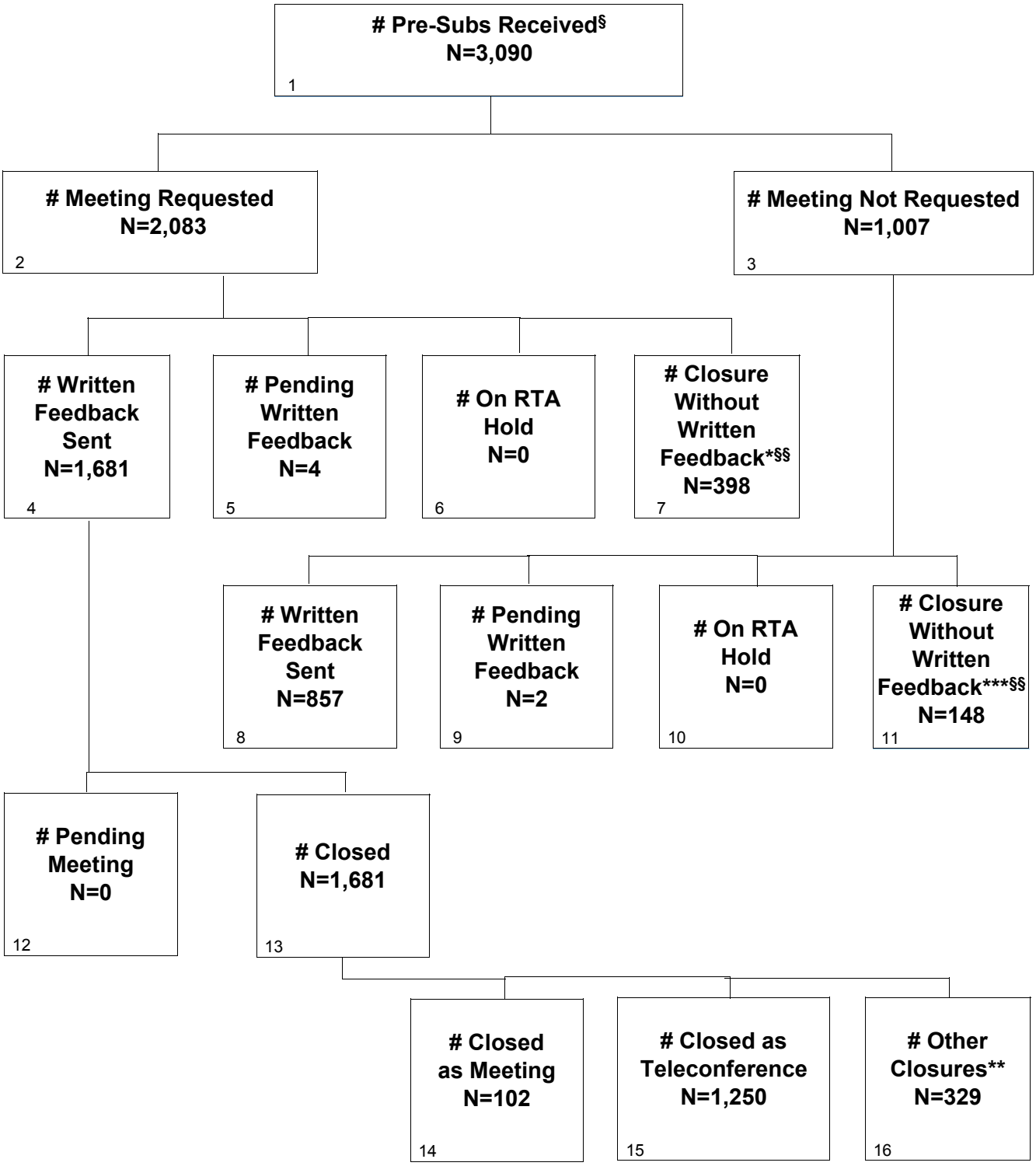
CDRH Pre-Sub - FY 2020
as of 9/30/22



* Closures include TCON, MTNG, CNLR, CNLF, CCOV, JTRX, JPND, DELE & WTDR
** Closures include CNLR, CNLF, CCOV, JTRX, JPND, DELE & WTDR
*** Closures include CCOV, JTRX, JPND, DELE & WTDR

§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.
§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

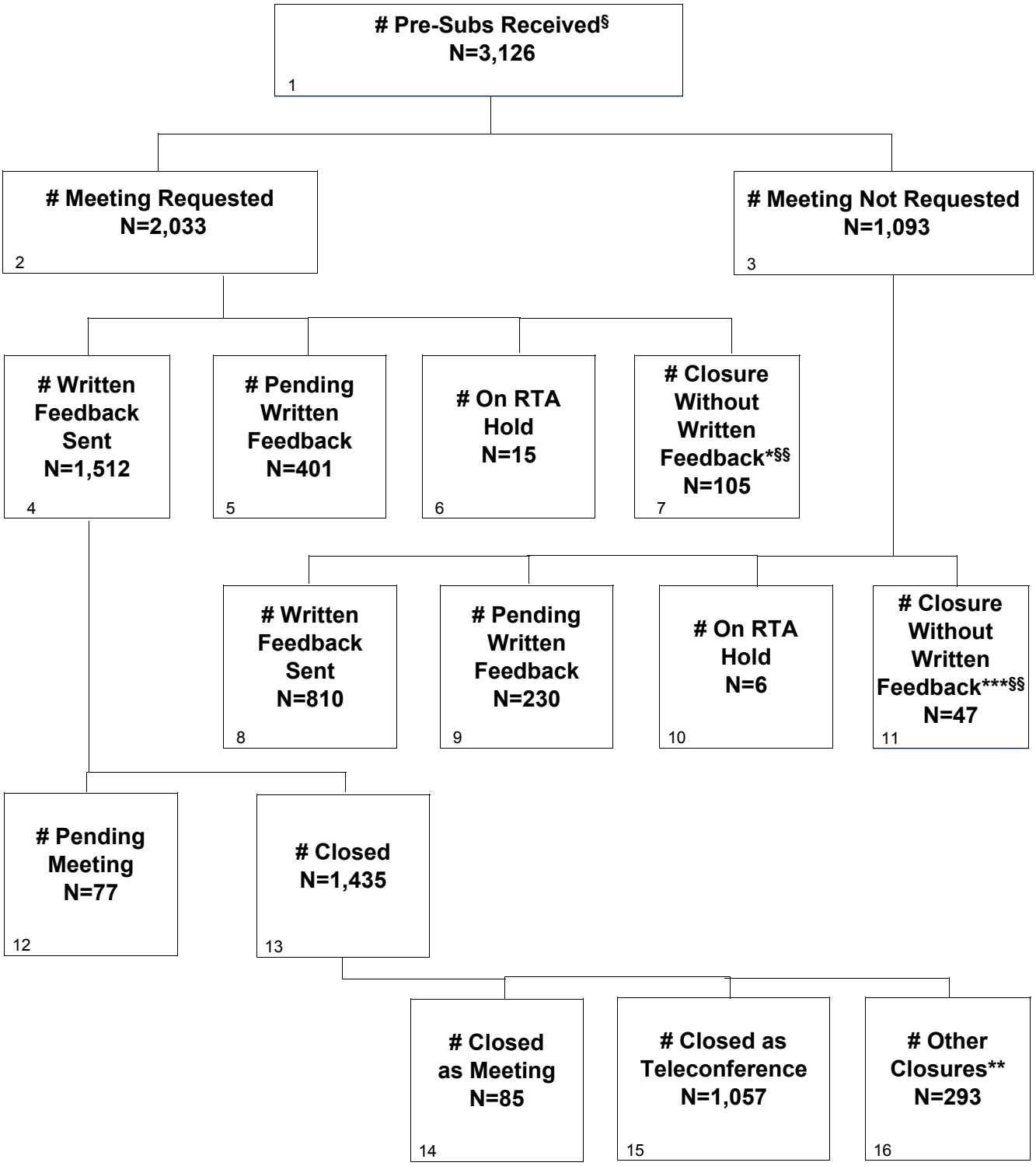
CDRH Pre-Sub - FY 2021
as of 9/30/22



*** Closures include CCOV, TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR**
**** Closures include CCOV, CNLR, CNLF, JTRX, JPND, DELE & WTDR**
***** Closures include CCOV, JTRX, JPND, DELE & WTDR**

§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.
§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

CDRH Pre-Sub - FY 2022
as of 9/30/22



*** Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, CCOV, DELE & WTDR**
**** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR**
***** Closures include JTRX, JPND, CCOV, DELE & WTDR**

§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.
§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	3,176	3,306	3,090	3,126
Closed Before RTA Action**	27	41	109	388	63
Number Accepted First RTA Cycle**	2,565	3,004	3,035	2,449	2,639
Number Without a RTA Review and > 15 Days Since Date Received**	49	71	121	224	279
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	105
Number Not Accepted	66	60	41	29	40
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.28%	1.07%	1.35%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**
****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

Table 9.2 CDRH - MDUFA IV Pre-Sub Performance Goals*

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	2,594	3,029	3,020	2,538	2,322
Written Feedback Provided Within MDUFA IV Goal	2,439	2,848	2,652	2,022	1,822

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 CDRH - Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	2,594	3,029	3,020	2,538	2,322
Average FDA Days to Written Feedback	58.86	60.22	63.26	68.47	66.29
20th Percentile FDA Days to Written Feedback	49	49	52	52	54
40th Percentile FDA Days to Written Feedback	59	60	62	63	64
60th Percentile FDA Days to Written Feedback	65	65	66	67	68
80th Percentile FDA Days to Written Feedback	69	70	70	70	70
Maximum FDA Days to Written Feedback	172	950	389	591	309

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	37	45	30	89	115
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	43.33	48.15	50.15

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	1,507	1,744	1,727	1,352	1,142
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,113	1,110	890	728
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	40
Meeting Minutes Past 15 Days of Meeting	483	560	539	419	321
Meeting Minutes Not Submitted and >15 Days Since Meeting	53	71	78	43	53
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	63.82%	64.27%	65.83%	66.06%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	319	389	430	401	387
Closed Before RTA Action**	0	6	5	8	1
Number Accepted First RTA Cycle**	284	359	407	376	345
Number Without a RTA Review and > 15 Days Since Date Received**	8	9	10	13	21
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	13
Number Not Accepted	27	15	8	4	7
Rate of Submissions Not Accepted for Review	8.46%	3.92%	1.88%	1.02%	1.88%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	298	359	402	378	303
Written Feedback Provided Within MDUFA IV Goal	256	314	280	225	182

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	298	359	402	378	303
Average FDA Days to Written Feedback	64.18	64.05	73.30	73.35	73.82
20th Percentile FDA Days to Written Feedback	56	57	62	63	63
40th Percentile FDA Days to Written Feedback	64	65	66	67	68
60th Percentile FDA Days to Written Feedback	69	69	70	70	70
80th Percentile FDA Days to Written Feedback	70	70	74	81	81
Maximum FDA Days to Written Feedback	168	119	389	219	280

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	4	10	18	23
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	34.00	42.40	60.50	49.43

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	183	224	243	222	161
Meeting Minutes Submitted Within 15 Days of Meeting	126	151	152	143	94
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	4
Meeting Minutes Past 15 Days of Meeting	50	68	80	75	52
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	11	4	11
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.85%	67.41%	62.55%	64.41%	59.87%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	530	582	674	773	668
Closed Before RTA Action**	6	7	4	7	1
Number Accepted First RTA Cycle**	506	555	648	738	623
Number Without a RTA Review and > 15 Days Since Date Received**	12	14	13	24	21
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	19
Number Not Accepted	6	6	9	4	4
Rate of Submissions Not Accepted for Review	1.15%	1.04%	1.34%	0.52%	0.62%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	512	563	660	746	562
Written Feedback Provided Within MDUFA IV Goal	482	535	610	676	516

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT2 - Office of Cardiovascular Devices
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	512	563	660	746	562
Average FDA Days to Written Feedback	53.02	55.51	56.18	58.80	59.02
20th Percentile FDA Days to Written Feedback	39	44	45	45	46
40th Percentile FDA Days to Written Feedback	50	53	55	57	58
60th Percentile FDA Days to Written Feedback	59	63	63	64	65
80th Percentile FDA Days to Written Feedback	67	69	69	69	69
Maximum FDA Days to Written Feedback	91	115	143	222	294

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT2 - Office of Cardiovascular Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	9	4	20	9
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	39.89	38.75	41.00	49.00

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT2 - Office of Cardiovascular Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	313	324	357	385	274
Meeting Minutes Submitted Within 15 Days of Meeting	183	199	212	248	177
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	7
Meeting Minutes Past 15 Days of Meeting	119	105	123	126	78
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	20	22	11	12
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	58.47%	61.42%	59.38%	64.42%	66.29%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Pre-Sub Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	334	382	400	378	377
Closed Before RTA Action**	5	7	11	31	1
Number Accepted First RTA Cycle**	307	359	376	326	334
Number Without a RTA Review and > 15 Days Since Date Received**	11	7	4	16	24
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	9
Number Not Accepted	11	9	9	5	9
Rate of Submissions Not Accepted for Review	3.34%	2.40%	2.31%	1.44%	2.45%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

Table 9.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA IV Pre-Sub Performance Goals*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	313	355	372	336	304
Written Feedback Provided Within MDUFA IV Goal	300	344	352	294	278

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	313	355	372	336	304
Average FDA Days to Written Feedback	60.53	63.35	61.36	65.67	63.42
20th Percentile FDA Days to Written Feedback	53	53	51	58	59
40th Percentile FDA Days to Written Feedback	61	61	61	64	64
60th Percentile FDA Days to Written Feedback	65	66	66	67	67
80th Percentile FDA Days to Written Feedback	69	69	70	70	70
Maximum FDA Days to Written Feedback	156	950	168	204	114

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	8	1	9	11
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	36.88	36.00	52.11	42.91

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	178	204	220	197	157
Meeting Minutes Submitted Within 15 Days of Meeting	112	125	156	141	110
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	3
Meeting Minutes Past 15 Days of Meeting	64	73	61	52	40
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	4	4
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.27%	70.91%	71.57%	71.43%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.1 OHT4 - Office of Surgical and Infection Control Devices
Pre-Sub Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	251	275	335	313	304
Closed Before RTA Action**	4	5	21	117	1
Number Accepted First RTA Cycle**	234	250	302	164	273
Number Without a RTA Review and > 15 Days Since Date Received**	6	11	7	29	16
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	8
Number Not Accepted	7	9	5	3	6
Rate of Submissions Not Accepted for Review	2.83%	3.33%	1.59%	1.53%	2.03%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	234	253	298	179	232
Written Feedback Provided Within MDUFA IV Goal	215	221	262	118	160

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT4 - Office of Surgical and Infection Control Devices
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	234	253	298	179	232
Average FDA Days to Written Feedback	60.70	62.60	63.10	72.40	66.93
20th Percentile FDA Days to Written Feedback	52	55	56	55	54
40th Percentile FDA Days to Written Feedback	59	63	62	64	64
60th Percentile FDA Days to Written Feedback	65	66	66	69	68
80th Percentile FDA Days to Written Feedback	69	70	70	80	75
Maximum FDA Days to Written Feedback	121	106	268	413	180

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT4 - Office of Surgical and Infection Control Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	4	8	5	19	20
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	42.80	42.84	53.75

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT4 - Office of Surgical and Infection Control Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	124	141	178	96	125
Meeting Minutes Submitted Within 15 Days of Meeting	92	95	117	69	72
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	6
Meeting Minutes Past 15 Days of Meeting	26	41	49	23	38
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5	12	4	9
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.19%	67.38%	65.73%	71.88%	60.50%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	249	277	309	342	357
Closed Before RTA Action**	3	2	2	2	3
Number Accepted First RTA Cycle**	232	253	286	317	315
Number Without a RTA Review and > 15 Days Since Date Received**	7	10	16	15	15
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	16
Number Not Accepted	7	12	5	8	8
Rate of Submissions Not Accepted for Review	2.85%	4.36%	1.63%	2.35%	2.37%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	260	298	328	243
Written Feedback Provided Within MDUFA IV Goal	202	219	185	216	159

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	260	298	328	243
Average FDA Days to Written Feedback	64.73	72.86	80.68	85.59	73.95
20th Percentile FDA Days to Written Feedback	58	63	65	64	64
40th Percentile FDA Days to Written Feedback	65	68	70	69	67
60th Percentile FDA Days to Written Feedback	69	70	70	70	70
80th Percentile FDA Days to Written Feedback	70	70	84	87	78
Maximum FDA Days to Written Feedback	172	397	385	591	255

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	5	7	4	16	22
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00	37.50	38.50	40.95

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	156	174	177	174	141
Meeting Minutes Submitted Within 15 Days of Meeting	99	103	107	107	83
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	7
Meeting Minutes Past 15 Days of Meeting	50	59	63	57	46
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	12	7	10	5
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.46%	59.20%	60.45%	61.49%	61.94%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	133	173	179	241	263
Closed Before RTA Action**	1	3	1	2	1
Number Accepted First RTA Cycle**	127	162	168	230	242
Number Without a RTA Review and > 15 Days Since Date Received**	5	6	7	6	6
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	11
Number Not Accepted	0	2	3	3	3
Rate of Submissions Not Accepted for Review	0.00%	1.18%	1.69%	1.26%	1.20%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	167	173	227	206
Written Feedback Provided Within MDUFA IV Goal	115	154	169	224	203

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT6 - Office of Orthopedic Devices
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	167	173	227	206
Average FDA Days to Written Feedback	61.91	61.18	62.34	58.92	56.60
20th Percentile FDA Days to Written Feedback	52	55	57	45	44
40th Percentile FDA Days to Written Feedback	62	62	63	60	56
60th Percentile FDA Days to Written Feedback	67	66	69	65	63
80th Percentile FDA Days to Written Feedback	70	70	70	70	68
Maximum FDA Days to Written Feedback	106	92	105	78	71

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT6 - Office of Orthopedic Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	4	0	2	4
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	43.75	0.00	31.00	34.75

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT6 - Office of Orthopedic Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	77	87	79	100	92
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	61	63	65
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	4
Meeting Minutes Past 15 Days of Meeting	19	29	15	35	18
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	3	2	5
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.22%	63.00%	73.86%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	759	906	766	434	529
Closed Before RTA Action**	7	7	61	221	51
Number Accepted First RTA Cycle**	749	885	645	99	281
Number Without a RTA Review and > 15 Days Since Date Received**	0	12	60	113	173
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	23
Number Not Accepted	3	2	0	1	1
Rate of Submissions Not Accepted for Review	0.40%	0.22%	0.00%	0.47%	0.22%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	746	891	610	139	277
Written Feedback Provided Within MDUFA IV Goal	743	881	590	64	130

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT7 - Office of In Vitro Diagnostics
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	746	891	610	139	277
Average FDA Days to Written Feedback	58.34	57.48	59.87	101.55	81.24
20th Percentile FDA Days to Written Feedback	49	46	51	52	60
40th Percentile FDA Days to Written Feedback	59	58	60	69	70
60th Percentile FDA Days to Written Feedback	64	64	65	92	77
80th Percentile FDA Days to Written Feedback	69	69	69	130	100
Maximum FDA Days to Written Feedback	85	307	142	525	309

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT7 - Office of In Vitro Diagnostics
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	5	4	6	4	23
Average Days to Scheduling for Meetings Scheduled After Day 30	34.40	35.50	53.50	95.25	63.39

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT7 - Office of In Vitro Diagnostics
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	390	475	334	27	62
Meeting Minutes Submitted Within 15 Days of Meeting	239	310	213	18	39
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	4
Meeting Minutes Past 15 Days of Meeting	134	150	108	6	16
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	15	13	3	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	61.28%	65.26%	63.77%	66.67%	67.24%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	132	192	213	208	241
Closed Before RTA Action**	1	4	4	0	4
Number Accepted First RTA Cycle**	126	181	203	199	226
Number Without a RTA Review and > 15 Days Since Date Received**	0	2	4	8	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	6
Number Not Accepted	5	5	2	1	2
Rate of Submissions Not Accepted for Review	3.82%	2.66%	0.96%	0.48%	0.87%

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

****Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	181	207	205	195
Written Feedback Provided Within MDUFA IV Goal	126	180	204	205	194

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.3 OHT8 - Office of Radiological Health
Pre-Sub Time to MDUFA IV Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	181	207	205	195
Average FDA Days to Written Feedback	51.53	52.29	55.62	56.54	58.75
20th Percentile FDA Days to Written Feedback	43	39	48	49	51
40th Percentile FDA Days to Written Feedback	49	52	55	56	58
60th Percentile FDA Days to Written Feedback	56	57	59	61	63
80th Percentile FDA Days to Written Feedback	61	65	65	65	66
Maximum FDA Days to Written Feedback	70	70	190	70	72

***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.4 OHT8 - Office of Radiological Health
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	1	0	1	3
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00	36.00	0.00	34.00	48.00

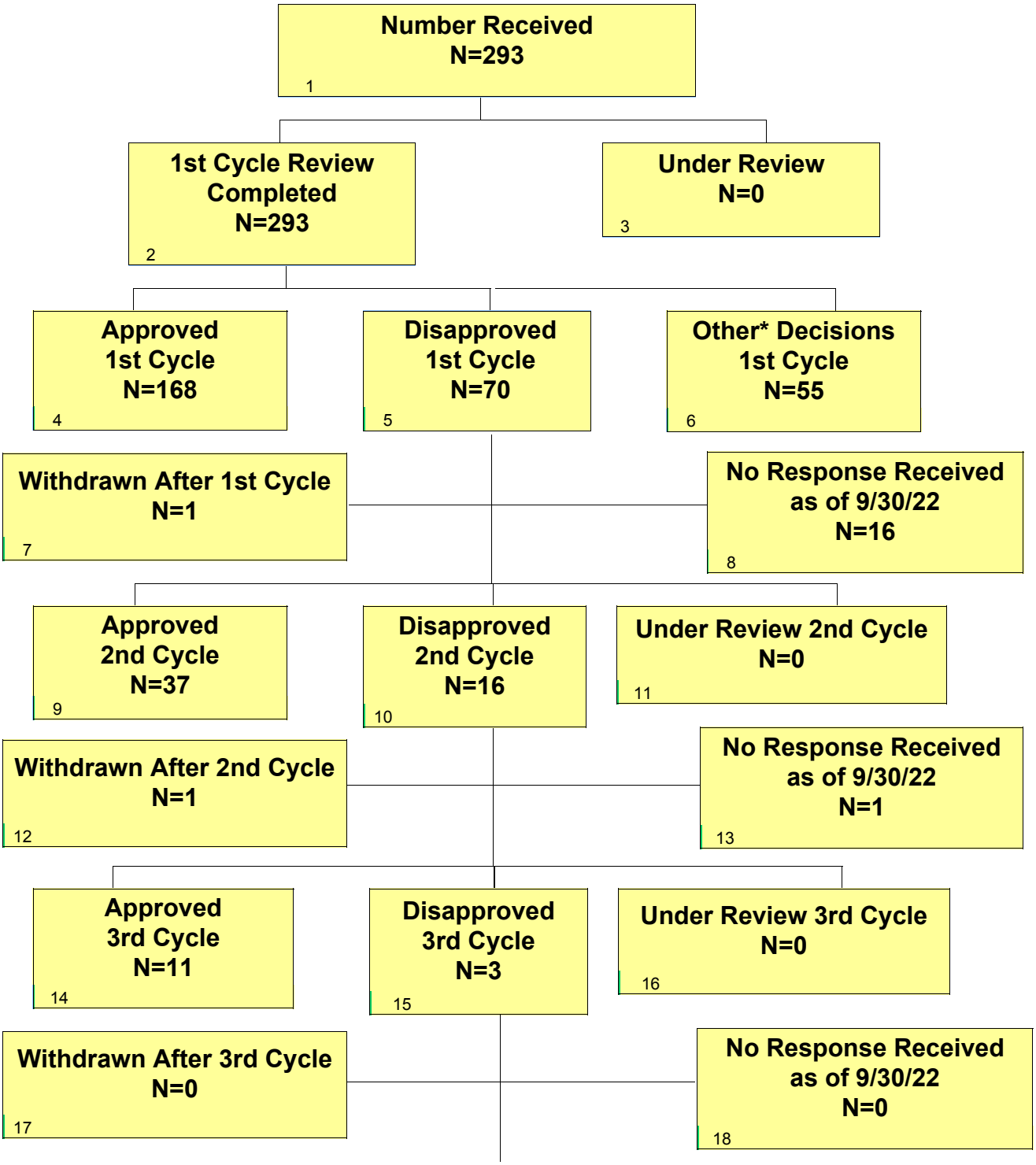
***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

Table 9.5 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	86	115	139	151	130
Meeting Minutes Submitted Within 15 Days of Meeting	65	77	92	101	88
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	5
Meeting Minutes Past 15 Days of Meeting	21	35	40	45	33
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	3	7	5	4
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.58%	66.96%	66.19%	66.89%	70.40%

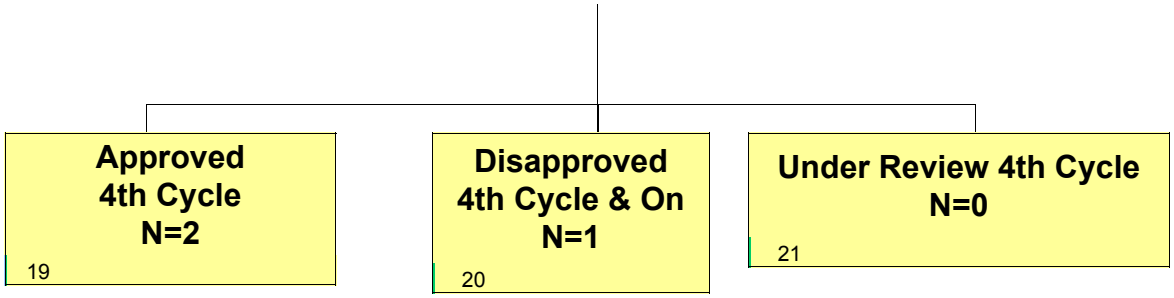
***Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.**

CDRH IDEs - FY 2018
as of 9/30/22

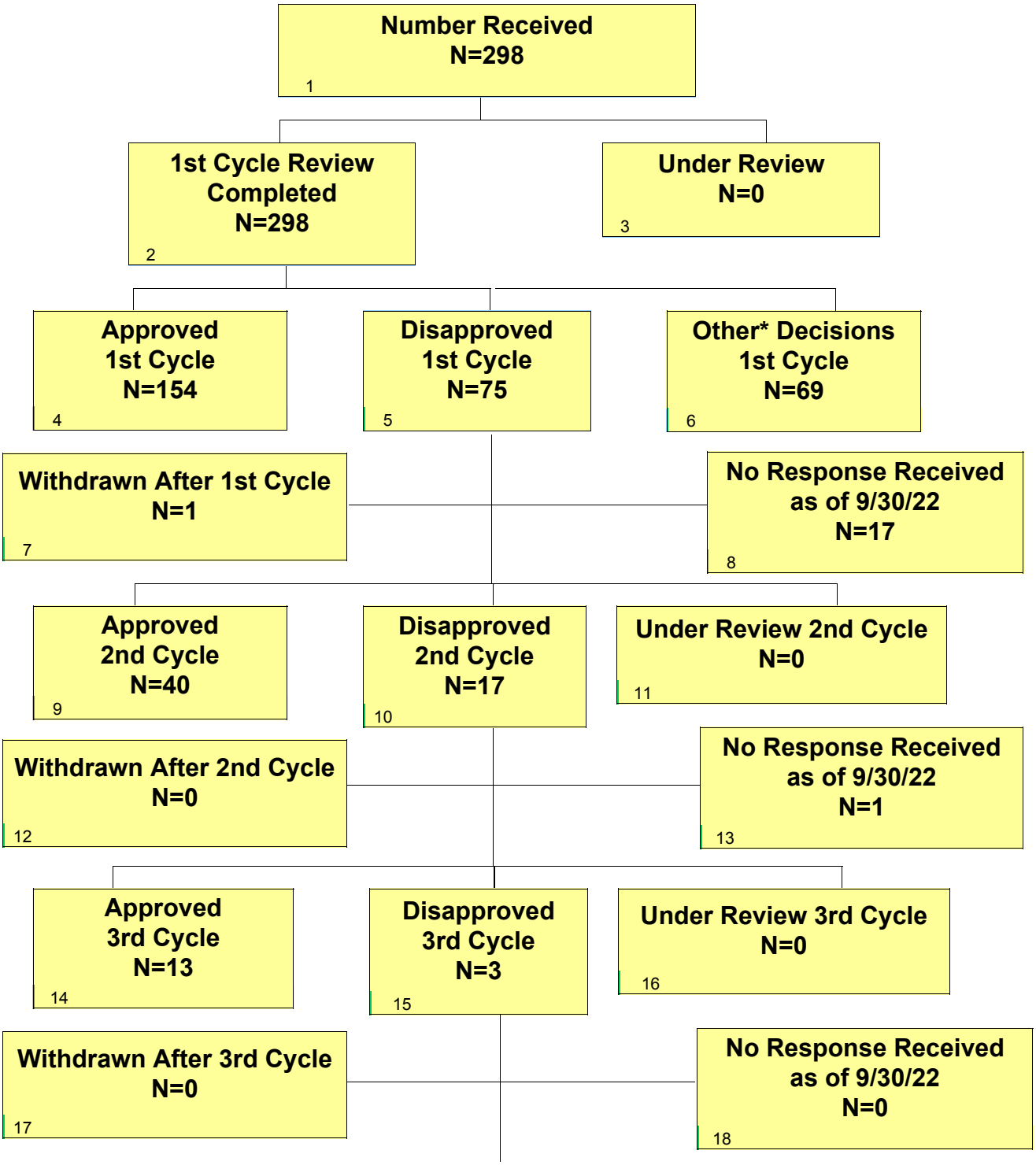


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2018
as of 9/30/22

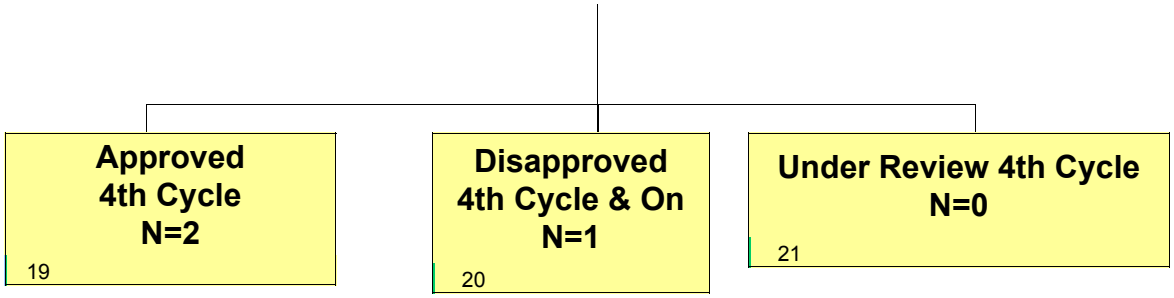


CDRH IDEs - FY 2019
as of 9/30/22

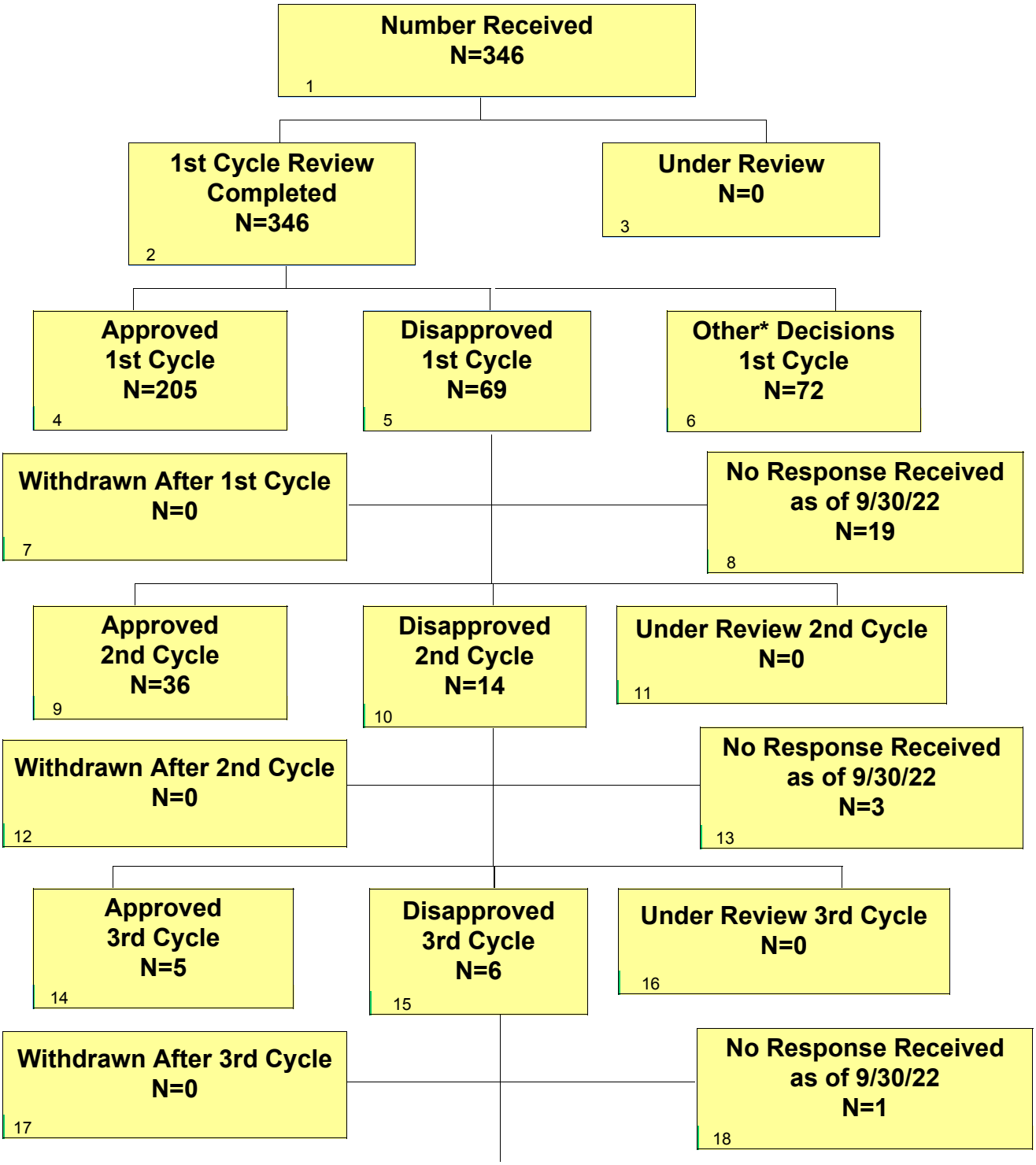


*** Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2019
as of 9/30/22

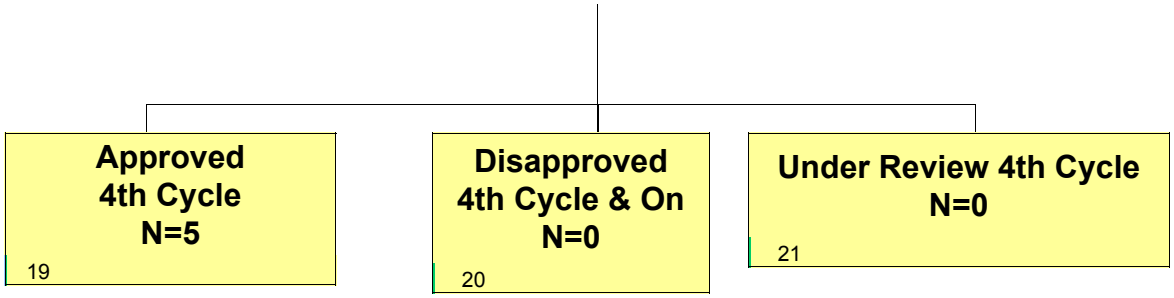


CDRH IDEs - FY 2020
as of 9/30/22

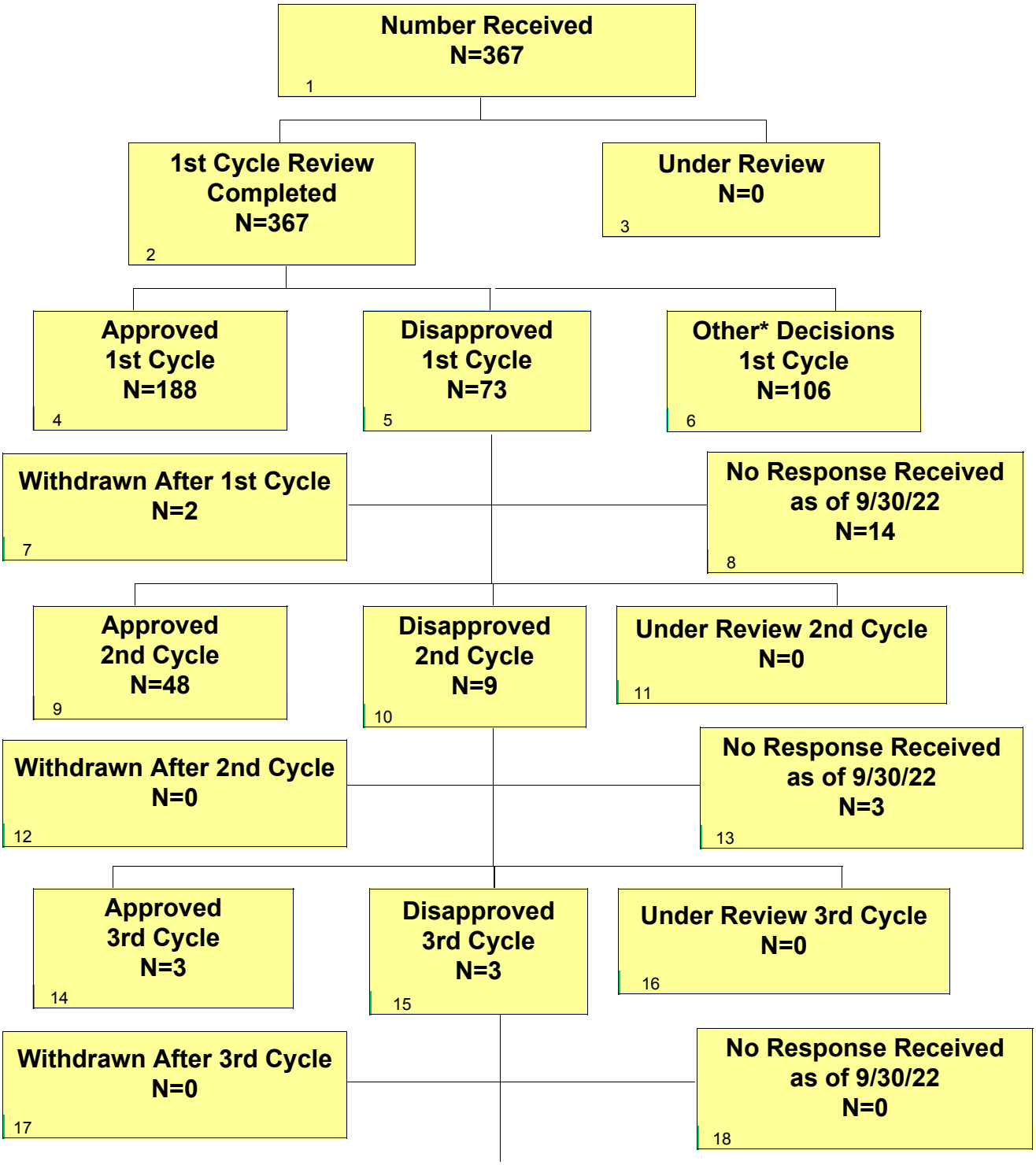


*** Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2020
as of 9/30/22

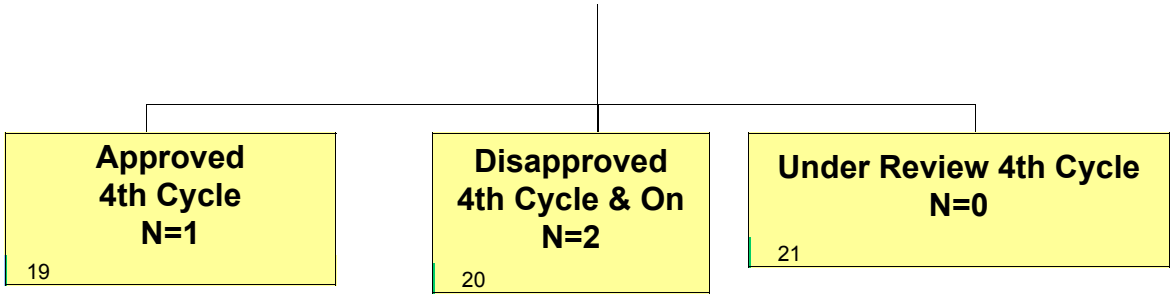


CDRH IDEs - FY 2021
as of 9/30/22

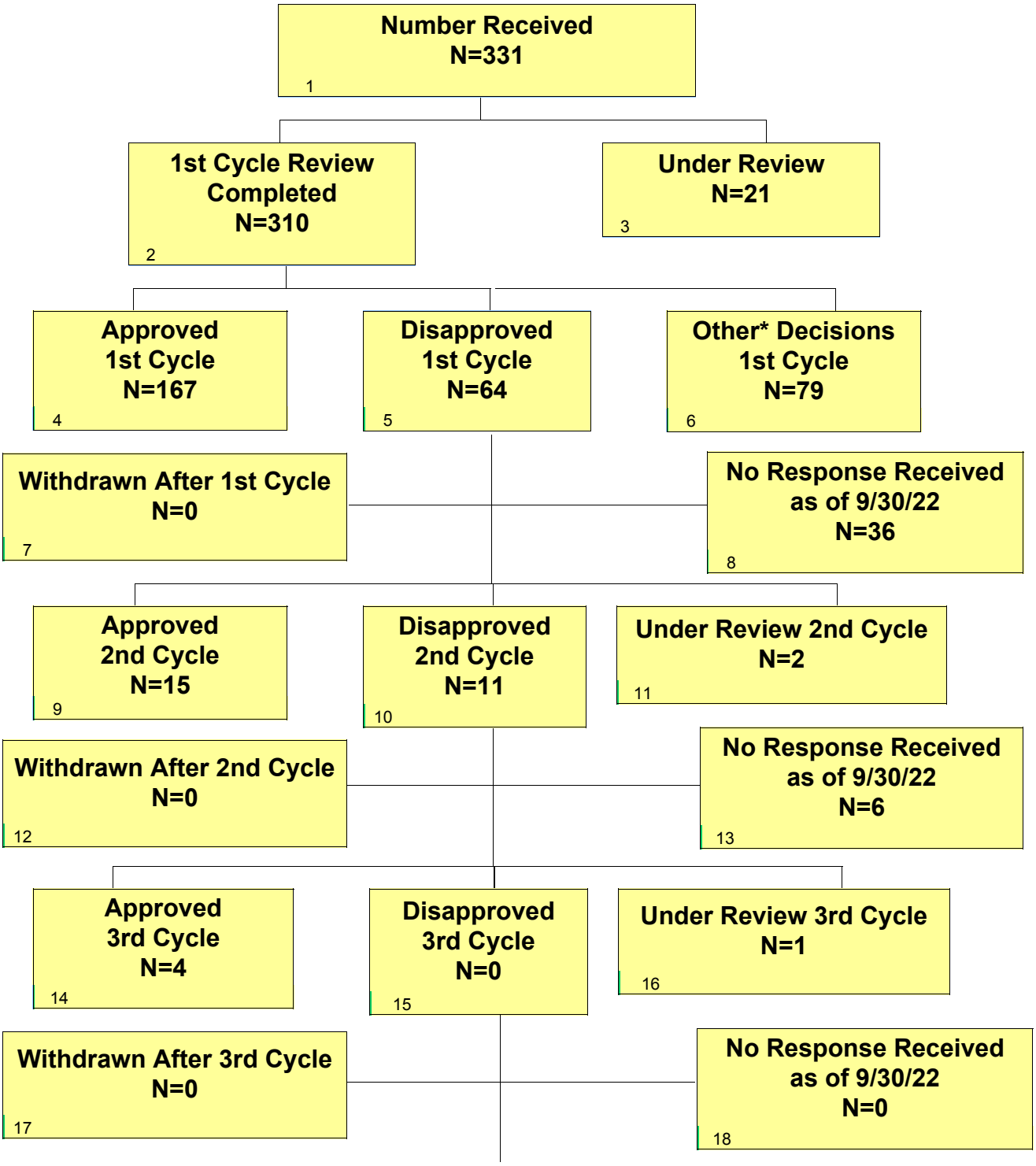


*** Other decisions include withdrawn (N=26), withdrawn and converted (N=56), RTA (N=0), nonsignificant risk device (N=17), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2021
as of 9/30/22

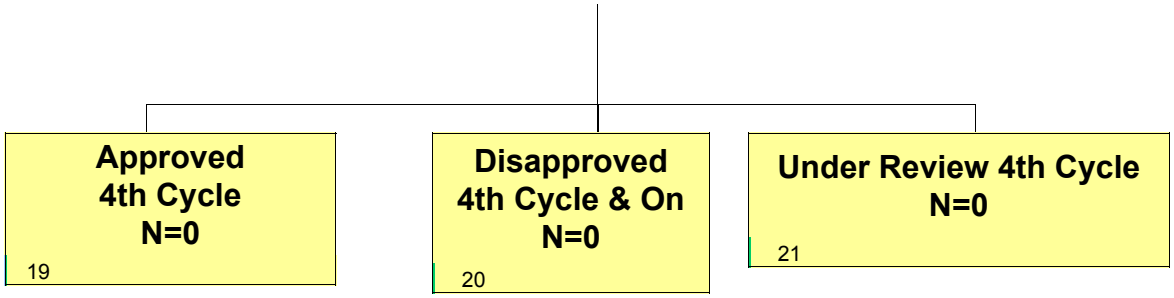


CDRH IDEs - FY 2022
as of 9/30/22



*** Other decisions include withdrawn (N=16), withdrawn and converted (N=43), RTA (N=0), nonsignificant risk device (N=10), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=7), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2022
as of 9/30/22



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	293	298	346	367	331
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.34	1.24	1.25	1.12
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.34	0.24	0.25	0.12

Section 10 IDE - Office Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	44	35	41	37	31
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.36	1.32	1.45	1.16
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.36	0.32	0.45	0.16

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	57	57	70	77	79
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.43	1.45	1.48	1.39
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.43	0.45	0.48	0.39

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	33	43	47	47	40
Average Number of Cycles to IDE Approval or Conditional Approval	1.6	1.5	1.45	1.41	1.04
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.6	0.5	0.45	0.41	0.04

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	29	32	42	42	38
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.11	1.15	1.09
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.11	0.15	0.09

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	62	70	66	59	59
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.17	1.14	1.09
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.17	0.14	0.09

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	16	11	17	19	11
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.20	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.20	0.00	0.00	0.00

Table 10.1 OHT7 - Office of In Vitro Diagnostics
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	44	43	53	76	64
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.03	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.03	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	8	7	10	10	9
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00	0.00	0.00	0.00

Section 11 CLIA Waiver Annual Metrics

Table 11.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	4	8 (12)	1	3 (4)	1 (5)
Withdrawn prior to SI	0	1 (1)	0	0 (0)	0 (0)
SI within 90 FDA days	4	7 (11)	0	0 (0)	0 (0)
SI over 90 FDA days	0	0 (0)	0	3 (3)	0 (3)
SI pending within 90 FDA days	0	0 (0)	0	0 (0)	1 (1)
SI pending over 90 FDA days	0	0 (0)	0	0 (0)	0 (0)
Denial without SI	0	0 (0)	1	0 (1)	0 (1)
Current SI Performance Percent within 90 FDA days	N/A*	100.00%	N/A*	N/A*	N/A*

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	7	0	3	0
Average number of FDA days to Substantive Interaction	59.50	59.86	0.00	177.67	0.00
20th Percentile FDA days to Substantive Interaction	39	49	0	145	0
40th Percentile FDA days to Substantive Interaction	48	55	0	180	0
60th Percentile FDA days to Substantive Interaction	67	65	0	203	0
80th Percentile FDA days to Substantive Interaction	79	84	0	214	0
Maximum FDA days to Substantive Interaction	88	90	0	225	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	4	8 (12)	1	3 (4)	1 (5)
Non-MDUFA IV Decisions	0	1 (1)	0	0 (0)	0 (0)
MDUFA IV Decisions	4	8 (12)	1	1 (2)	0 (2)
MDUFA IV Decisions within 150 FDA Days	4	7 (11)	0	1 (1)	0 (1)
CLIA Waiver Applications pending MDUFA IV Decision	0	0 (0)	0	2 (2)	1 (3)
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0	0 (0)	0	2 (2)	0 (2)
Current Performance Percent within 150 FDA Days	N/A*	91.67%	N/A*	N/A*	N/A*

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decisions	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions within 320 FDA Days	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0	0	0
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*	N/A*	N/A*

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA decision	4	8	1	1	0
Average FDA days to MDUFA IV decision	119.50	82.25	462.00	111.00	0.00
20th Percentile FDA days to MDUFA IV decision	102	47	462	111	0
40th Percentile FDA days to MDUFA IV decision	143	50	462	111	0
60th Percentile FDA days to MDUFA IV decision	145	64	462	111	0
80th Percentile FDA days to MDUFA IV decision	147	80	462	111	0
Maximum FDA days to MDUFA IV decision	148	281	462	111	0
Average Industry days to MDUFA IV decision	150.50	145.38	0.00	0.00	0.00
20th Percentile Industry days to MDUFA IV decision	86	0	0	0	0
40th Percentile Industry days to MDUFA IV decision	151	138	0	0	0
60th Percentile Industry days to MDUFA IV decision	173	180	0	0	0
80th Percentile Industry days to MDUFA IV decision	219	180	0	0	0
Maximum Industry days to MDUFA IV decision	278	450	0	0	0
Average Total days to MDUFA IV decision	270.00	227.63	462.00	111.00	0.00
20th Percentile Total days to MDUFA IV decision	192	55	462	111	0
40th Percentile Total days to MDUFA IV decision	236	167	462	111	0
60th Percentile Total days to MDUFA IV decision	276	228	462	111	0
80th Percentile Total days to MDUFA IV decision	342	260	462	111	0
Maximum Total days to MDUFA IV decision	420	731	462	111	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA decision	0	0	0	0	0
Average FDA days to MDUFA IV decision	0.00	0.00	0.00	0.00	0.00
20th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
40th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
60th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
80th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
Maximum FDA days to MDUFA IV decision	0	0	0	0	0
Average Industry days to MDUFA IV decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
40th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
60th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
80th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
Maximum Industry days to MDUFA IV decision	0	0	0	0	0
Average Total days to MDUFA IV decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Total days to MDUFA IV decision	0	0	0	0	0
40th Percentile Total days to MDUFA IV decision	0	0	0	0	0
60th Percentile Total days to MDUFA IV decision	0	0	0	0	0
80th Percentile Total days to MDUFA IV decision	0	0	0	0	0
Maximum Total days to MDUFA IV decision	0	0	0	0	0

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

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

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	11	5	6 (11)	4	9 (13)
Withdrawn prior to SI	0	0	0	0	0 (0)
SI within 90 FDA days	11	5	6 (11)	0	0 (0)
SI over 90 FDA days	0	0	0	4	2 (6)
SI pending within 90 FDA days	0	0	0	0	3 (3)
SI pending over 90 FDA days	0	0	0	0	4 (4)
Denial without SI	0	0	0	0	0 (0)
Current SI Performance Percent within 90 FDA days*	100.00%	N/A*	100.00%	N/A*	0.00%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	11	5	6	4	2
Average number of FDA days to Substantive Interaction	85.18	86.60	85.00	270	172
20th Percentile FDA days to Substantive Interaction	84	87	82	213	148
40th Percentile FDA days to Substantive Interaction	87	88	86	299	164
60th Percentile FDA days to Substantive Interaction	87	88	88	313	179
80th Percentile FDA days to Substantive Interaction	88	88	90	341	195
Maximum FDA days to Substantive Interaction	90	88	90	375	210

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Eligible for MDUFA IV Decision	11	5	6 (11)	4	9 (13)
Non-MDUFA IV Decisions	0	1	0 (1)	0	0 (0)
MDUFA IV Decisions	11	5	6 (11)	2	0 (2)
MDUFA IV Decisions within 180 FDA Days	11	4	4 (8)	1	0 (1)
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0 (0)	2	9 (11)
CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	0	0	0 (0)	2	2 (4)
Current Performance Percent within 180 FDA Days*	100.00%	N/A*	72.73%	N/A*	16.67%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decision	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions with in 320 FDA Days	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0	0	0
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*	N/A*	N/A*

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV decision	11	5	6	2	0
Average FDA days to MDUFA IV decision	139.64	142.60	200.17	262.50	0.00
20th Percentile FDA days to MDUFA IV decision	87	88	82	160	0
40th Percentile FDA days to MDUFA IV decision	140	137	148	228	0
60th Percentile FDA days to MDUFA IV decision	176	173	180	297	0
80th Percentile FDA days to MDUFA IV decision	180	180	285	365	0
Maximum FDA days to MDUFA IV decision	180	190	432	433	0
Average Industry days to MDUFA IV decision	42.18	142.20	252.33	174.50	0.00
20th Percentile Industry days to MDUFA IV decision	0	69	144	172	0
40th Percentile Industry days to MDUFA IV decision	0	139	266	174	0
60th Percentile Industry days to MDUFA IV decision	0	177	355	175	0
80th Percentile Industry days to MDUFA IV decision	110	198	373	177	0
Maximum Industry days to MDUFA IV decision	180	270	376	178	0
Average Total days to MDUFA IV decision	181.82	284.80	452.50	437.00	0.00
20th Percentile Total days to MDUFA IV decision	87	243	226	337	0
40th Percentile Total days to MDUFA IV decision	155	263	450	404	0
60th Percentile Total days to MDUFA IV decision	177	302	521	470	0
80th Percentile Total days to MDUFA IV decision	270	353	551	537	0
Maximum Total days to MDUFA IV decision	354	358	787	604	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV decision	0	0	0	0	0
Average FDA days to MDUFA IV decision	0.00	0.00	0.00	0.00	0.00
20th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
40th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
60th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
80th Percentile FDA days to MDUFA IV decision	0	0	0	0	0
Maximum FDA days to MDUFA IV decision	0	0	0	0	0
Average Industry days to MDUFA IV decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
40th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
60th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
80th Percentile Industry days to MDUFA IV decision	0	0	0	0	0
Maximum Industry days to MDUFA IV decision	0	0	0	0	0
Average Total days to MDUFA IV decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Total days to MDUFA IV decision	0	0	0	0	0
40th Percentile Total days to MDUFA IV decision	0	0	0	0	0
60th Percentile Total days to MDUFA IV decision	0	0	0	0	0
80th Percentile Total days to MDUFA IV decision	0	0	0	0	0
Maximum Total days to MDUFA IV decision	0	0	0	0	0

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

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

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without 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 RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	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	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 Original 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	Number with 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 & Panel Track Supplements Substantive Interaction Performance Goals - 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 Metrics – 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 & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals - 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 IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.6 and Tables 1.6.x PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals - 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 IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.7 and Tables 1.7.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions

#	Measure	Description
1	Number with MDUFA IV 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 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 1.8 and Tables 1.8.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions

#	Measure	Description
1	Number with MDUFA IV 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 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 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - 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 IV decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	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 Withdrawals	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 Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - 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 Withdrawals	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 Withdrawals	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 (line2).

Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - 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 FDA days to MDUFA IV decision exceeding number of goal 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 goal	Mean industry days for submissions that missed the goal (line 1).

Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - 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 IV decision exceeding number of goal 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 goal	Mean industry days for submissions that missed the goal (line 1).

Tables 1.13 and Tables 1.13.x LDT PMA Originals & Panel-Track Supplements Metric* MDUFA Decision Performance Goals - 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 IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV 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 Metric* MDUFA Decision Performance Goals - 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 IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV 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 Goals – 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 Decision Performance Goals – Definitions

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

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

Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – 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 Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals – 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 MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with 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 IV 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 RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision in the first RTA review cycle.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that received a "Did not perform RTA" (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15th day of that cycle..
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage of the sum of the Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (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 deemed accepted via the RTA process as of quarter end date (RTAA, RTAN, RTAW or RTAS).
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 under review over 60 FDA days and that do not have an SI.
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 ofthe number of submissions that either had an SI (line 3 and line 4), the number of submissions that received an SI after 60 days had elapsed (line 6), and the number of submissions that were found NSE without first 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 accepted 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 Decision Performance Goal – Definitions

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

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA IV 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 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 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) Performance Metrics – Rate 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 IV Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

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

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

Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA IV 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 IV Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA IV Decision over 90 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA IV 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 IV Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed 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 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 IV decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA IV Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA IV decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum ofNumber Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA IV decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA IV 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 IV decision.
7	Average Total Time to MDUFA IV 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 IV Decision	The 90th percentile of FDA days to MDUFA IV decision on 3rd Party 510(k) submissions received in this fiscal year

Section 8 De Novo MDUFA IV 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 RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a 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 RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage the sum of the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

Tables 8.2 and Tables 8.2.x De Novo MDUFA IV Decision Performance Goals – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not GrantedDeclined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (GrantedDeclined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV 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 IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA IV 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 IV decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision.
	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 to MDUFA IV decision.

Table 8.4 and Tables 8.4.x De Novo Performance Metrics – Rate of Grant, Decline, Withdrawal and Delete Decisions – 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 IV decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA IV decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA IV decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA IV decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA IV decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA IV decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA IV decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA IV decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA IV 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 De Novo submissions accepted in this fiscal year that had a MDUFA IV decision with more than 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 IV 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 IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn orDeleted).
4	MDUFA IV Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA IV 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 IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA IV 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 IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance PercentWithin 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV 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 IV Decisions (line 3) and pending non-LDT IVD submissions that already failed 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 First RTA Cycle	Number of De Novo submissions accepted in the first RTA cycle in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept*	Average number of days in the first RTA review cycle De Novo submissions..

*RTA will be implemented when the guidance, including the submission checklist, is finalized.

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 submissions received in this fiscal year.
2	Closed before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days Since Date Received	Number Received (line 1) that had "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.
5	Number Without a RTA Review and <= 15 days Since Date Received	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that had "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions

#	Measure	Description
1	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) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Written Feedback Provided Within MDUFA IV Goal	Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request).

Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions

#	Measure	Description
1	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 Pre-Submissions Performance Metrics Meeting Scheduling-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 Pre-Submissions Performance Metrics Meeting Minutes- Definitions

#	Measure	Description
1	Meetings Held	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date.
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 IV CBER Performance Data ----
Actions through 30 Sep 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 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3	3	1	2
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	2	3	1	1
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	2	1	0	0	1
Rate of Submissions Not Accepted for Filing Review	67%	33%	0%	0%	50%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3	3	1	2
Number Accepted	1	2	3	1	1
Completed RTF	3	3	3	1	2
Number Not Filed	1	0	0	0	1
Rate of Submissions Not Filed	33.33%	0.00%	0.00%	0.00%	50.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	3	1	1
SI Goal Met	2	3	2	1	1
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	66.67%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	3	3	1	1
Average Number of FDA Days to Substantive Interaction	69.00	85.33	91.33	86.00	85.00
20th Percentile FDA Days to Substantive Interaction	50.00	82.00	81.00	86.00	85.00
40th Percentile FDA Days to Substantive Interaction	50.00	84.00	89.00	86.00	85.00
60th Percentile FDA Days to Substantive Interaction	88.00	84.00	89.00	86.00	85.00
80th Percentile FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	85.00
Maximum FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	85.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	3	3	1	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	3	3	1	1
MDUFA IV Decision Goal Met	2	3	3	1	1
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision Goal Met	0	0	0	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	2	3	3	1	1
Average FDA Days to MDUFA IV Decision	164.50	162.33	164.67	177.00	123.00
20th Percentile FDA Days to MDUFA IV Decision	156	140	150	177	123
40th Percentile FDA Days to MDUFA IV Decision	156	171	169	177	123
60th Percentile FDA Days to MDUFA IV Decision	173	171	169	177	123
80th Percentile FDA Days to MDUFA IV Decision	173	176	175	177	123
Maximum FDA Days to MDUFA IV Decision	173	176	175	177	123
Average Industry Days to MDUFA IV Decision	319.50	161.00	55.33	0.00	70.00
20th Percentile Industry Days to MDUFA IV Decision	105	56	166	0	70
40th Percentile Industry Days to MDUFA IV Decision	105	177	166	0	70
60th Percentile Industry Days to MDUFA IV Decision	534	177	166	0	70
80th Percentile Industry Days to MDUFA IV Decision	534	250	166	0	70
Maximum Industry Days to MDUFA IV Decision	534	250	166	0	70
Average Total Days to MDUFA IV Decision	484.00	323.33	220.00	177.00	193.00
20th Percentile Total Days to MDUFA IV Decision	261	196	150	177	193
40th Percentile Total Days to MDUFA IV Decision	261	348	169	177	193
60th Percentile Total Days to MDUFA IV Decision	707	348	169	177	193
80th Percentile Total Days to MDUFA IV Decision	707	426	341	177	193
Maximum Total Days to MDUFA IV Decision	707	426	341	177	193

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	0	0	0
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	0
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	0
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	0
Maximum Total Days to MDUFA IV Decision	0	0	0	0	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	3	1	1
Number with MDUFA IV Decision	2	3	3	1	1
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	1	1	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	N/A	N/A	N/A
Rate of Not Approvable	50.00%	33.33%	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0	0	0
Number With MDUFA IV Decision	0	0	0	0	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	N/A	N/A	N/A	N/A	N/A
Rate of Not Approvable	N/A	N/A	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 1.12 CBER - PMA Original and Panel-Track Supplements (with Panel Review)
Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 1.13 CBER - LDT PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision Goal Met	0	0	0	0	0
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

***Includes submission that went to panel**

Table 1.14 CBER - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	1	2	2	0	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	2	2	0	1
MDUFA IV Decision Goal Met	1	2	2	0	1
PMAs Pending MDUFA IV Decision	0	0	0	0	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	100.00%

***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 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	5	8	7	7
SI Goal Met	8	5	8	4	6
SI Goal Not Met	0	0	0	0	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	3	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	85.71%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	8	5	8	7	7
Non-MDUFA IV Decision	0	0	0	4	0
MDUFA IV Decision	8	5	8	3	3
MDUFA IV Decision Goal Met	8	5	8	3	3
Supplements Pending MDUFA IV Decision	0	0	0	0	4
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5	8	7	7
Number with MDUFA IV Decision	8	5	8	3	3
Number of Not Approvable	0	0	1	0	0
Rate of Not Approvable	0.00%	0.00%	12.50%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CBER - PMA Real-Time Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	2	5	9	9
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	3	2	5	9	7
MDUFA IV Decision Goal Met	3	2	5	9	7
Supplements Pending MDUFA IV Decision	0	0	0	0	2
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2	5	9	9
Number With MDUFA IV Decision	3	2	5	9	7
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	0%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Section 5 PMA Annual Metrics and Goals

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

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0	0	0	0
Original PMAs (Panel) – Priority	0	0	0	0	0
Original PMAs (No Panel) – Priority	0	0	0	0	0
Original PMAs (Panel) – Non-Priority	0	0	0	0	0
Original PMAs (No Panel) – Non-Priority	3	3	2	0	1
Panel-Tracked Supplements (Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (Panel) – Non-Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Non-Priority	0	0	1	1	1
PMA Modules	7	1	0	0	0
180-Day Supplements	8	5	8	7	7
Real-Time Supplements	3	2	5	9	9

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	3	1	1
Number with a decision (MDUFA or Non-MDUFA)	2	3	3	1	1
% of FY closed	100.00%	100.00%	100.00%	100.00%	100.00%

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	54	50	45	37
Closed Before RTA Action	0	0	1	1	0
Number Accepted	40	38	34	36	31
Number Without a RTA Review and > 15 Days Since Date Received	2	1	1	3	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	11	15	14	5	6
Rate of Submissions Not Accepted for Review	20.75%	27.78%	28.57%	11.36%	16.22%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	49	51	44	40	35
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	49	51	43	40	32
SI Over 60 FDA Days	0	0	1	0	0
SI Pending Within 60 FDA Days	0	0	0	0	3
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	0
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	97.73%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	49	51	44	40	32
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.98	53.63	50.00
20th Percentile FDA Days to Substantive Interaction	43	21	21	56	34
40th Percentile FDA Days to Substantive Interaction	57	53	55	58	57
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	60	60	64	60	60

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	49	51	44	40	35
Non-MDUFA IV Decision	6	5	7	0	1
MDUFA IV Decision (SE/NSE)	43	46	37	33	20
MDUFA IV Decision Within 90 FDA Days	43	46	37	33	20
510(k)s Pending MDUFA IV Decision	0	0	0	7	14
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

Table 6.5 CBER - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.30	1.48	1.24	1.34	1.40
Number With MDUFA IV Decision	43	46	37	33	20
Average Number of FDA Days to MDUFA IV Decision	75.58	67.48	64.08	75.12	68.40
20th Percentile FDA Days to MDUFA IV Decision	65	28	30	66	30
40th Percentile FDA Days to MDUFA IV Decision	85	77	65	81	76
60th Percentile FDA Days to MDUFA IV Decision	88	87	82	87	84
80th Percentile FDA Days to MDUFA IV Decision	90	89	88	90	88
Maximum FDA Days to MDUFA IV Decision	90	206	90	96	90
Average Number of Industry Days to MDUFA IV Decision	25.26	75.76	16.95	42.24	39.95
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	78	0	0	1
80th Percentile Industry Days to MDUFA IV Decision	59	179	29	89	101
Maximum Industry Days to MDUFA IV Decision	178	389	199	360	179
Average Number of Total Days to MDUFA IV Decision	100.84	143.24	81.05	117.36	108.35
20th Percentile Total Days to MDUFA IV Decision	76	59	30	66	30
40th Percentile Total Days to MDUFA IV Decision	86	87	65	81	83
60th Percentile Total Days to MDUFA IV Decision	90	141	82	89	90
80th Percentile Total Days to MDUFA IV Decision	147	269	105	178	173
Maximum Total Days to MDUFA IV Decision	268	463	287	450	269

Table 6.6 CBER - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	49	51	44	40	35
Number With MDUFA IV Decision	43	46	37	33	20
Number of SE Decision	43	43	35	33	18
Number of NSE Decision	0	3	2	0	2
Number of Withdrawal	2	4	4	0	1
Number of Deleted	3	1	3	0	0
Rate of SE Decision	100.00%	93.48%	94.59%	100.00%	90.00%
Rate of NSE Decision	0.00%	6.52%	5.41%	0.00%	10.00%
Rate of Withdrawal	4.08%	7.84%	9.09%	0.00%	2.86%
Rate of Deleted	6.12%	1.96%	6.82%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0	0	0	0	0
Mean Industry Days for Submissions that Missed the Goal	0	0	0	0	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	0	0	0	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision (SE/NSE)	0	0	0	0	0
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	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	15	17	7	19	10
Non-MDUFA IV Decision	0	1	0	0	0
MDUFA IV Decision (SE/NSE)	15	16	7	14	9
MDUFA IV Decision Within 90 FDA Days	15	16	7	14	9
510(k)s Pending MDUFA IV Decision	0	0	0	5	1
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

Section 7 510(k) Annual General Metrics

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	49	51	44	40	35
Number of Traditional Submissions	41	35	34	35	28
Number of Special Submissions	8	16	10	5	7
Number of Abbreviated Submissions	0	0	0	0	0
Average Number of Days to Accept/Refuse to Accept	12.69	12.57	12.57	12.08	12.00
Number of Third Party Submissions	0	0	0	0	0

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	124 Days	120 Days	116 Days	112 Days	108 Days
Number Accepted	49.00	51.00	44.00	40.00	35.00
Currently Under Review	0.00	0.00	0.00	7.00	14.00
Number With Non-MDUFA IV Decision	6.00	5.00	7.00	0.00	1.00
Number With MDUFA IV Decision	43.00	46.00	37.00	33.00	20.00
Percent of Cohort Closed	100.00%	100.00%	100.00%	82.50%	58.82%
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	41	44	35	31	18
Average Total Time to MDUFA IV Decision	100.84	143.24	81.05	117.36	108.35

Table 7.3 CBER - 510(k) Third Party Performance

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	0.00	0.00	0.00	0.00	0.00
90th Percentile FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	0	1	0	0	3
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	0	0	2
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	0	0	1
Rate of Submissions Not Accepted for Review	N/A	N/A	0	0	33.33%

Table 8.2 CBER - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	0	1	0	0	3
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	1	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	1	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	3
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	N/A	100%	N/A	N/A	N/A

Table 8.3 CBER - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00	2	0.00	0.00	0.00
Number With MDUFA IV Decision	0	1	0	0	0
Average FDA Days to MDUFA IV Decision	0.00	150	0.00	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	0
40th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	0
60th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	0
80th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	0
Maximum FDA Days to MDUFA IV Decision	0	150	0	0	0
Average Industry Days to MDUFA IV Decision	0.00	81	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
Maximum Industry Days to MDUFA IV Decision	0	81	0	0	0
Average Total Days to MDUFA IV Decision	0.00	231	0.00	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	0	231	0	0	0
40th Percentile Total Days to MDUFA IV Decision	0	231	0	0	0
60th Percentile Total Days to MDUFA IV Decision	0	231	0	0	0
80th Percentile Total Days to MDUFA IV Decision	0	231	0	0	0
Maximum Total Days to MDUFA IV Decision	0	231	0	0	0

Table 8.4 CBER - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1	0	0	3
Number With MDUFA IV Decisions	0	1	0	0	0
Number With Granted Decisions	0	1	0	0	0
Number With Declined Decisions	0	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number Deleted	0	0	0	0	0
Rate of Granted Decisions	N/A	1	N/A	N/A	N/A
Rate of Declined Decisions	N/A	N/A	N/A	N/A	N/A
Rate of Withdrawals	N/A	N/A	N/A	N/A	N/A
Rate of Deleted	N/A	N/A	N/A	N/A	N/A

Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 8.6 CBER - LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	1	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	1	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	N/A	100%	N/A	N/A	N/A

Table 8.8 CBER - De Novo Annual General Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted First RTA Cycle	N/A	N/A	0	0	2
Average Number of Days to Accept / Refuse to Accept	N/A	N/A	0	0	11

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	76	77	77	80	49
Closed Before RTA Action	5	3	10	7	1
Number Accepted First RTA Cycle	69	70	65	67	42
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	6	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	2
Number Not Accepted	1	1	1	0	1
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.49%	0.00%	2.17%

Table 9.2 CBER - MDUFA IV Pre-Sub Performance Goals

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	70	74	68	71	40
Written Feedback Provided Within MDUFA IV Goal	68	71	63	67	37

Table 9.3 CBER - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	70	74	68	71	40
Average FDA Days to Written Feedback	57.86	61.00	56.70	62.28	58.68
20th Percentile FDA Days to Written Feedback	47	55	48	54	50.8
40th Percentile FDA Days to Written Feedback	58	60	58	62	60
60th Percentile FDA Days to Written Feedback	64	63	64	64	63.4
80th Percentile FDA Days to Written Feedback	67	68	68	66	69
Maximum FDA Days to Written Feedback	72	75	77	156	80

Table 9.4 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0	0	0	0
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00	0.00	0.00	0.00

Table 9.5 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	42	33	27	39	16
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	26	33	12
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	9	2	1	6	4
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1	0	0	0
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	90.91%	96.30%	84.62%	75.00%

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	15	21	20	19
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.63	1.07	1.25	1.17
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.63	0.07	0.25	0.17

BLA
CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard BLAs Filed	14	4	0	2	1
Number of Standard BLA First Actions less than or equal to 10 months	14	4	0	2	0
Number of Standard BLA Frist Actions greater than 10 months	0	0	0	0	0
Number of Standard BLAs Pending	0	0	0	0	1
Number of Priority BLA Filed	0	0	0	0	0
Number of Priority BLA First Actions less than or equal to 6 months	0	0	0	0	0
Number of Priority BLA Frist Actions greater than 6 months	0	0	0	0	0
Number of Priority BLAs Pending	0	0	0	0	0

BLA Efficacy Supplements
CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard Efficacy Supplements Filed	8	2	0	0	0
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	8	2	0	0	0
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0	0	0	0	0
Number of Standard Efficacy Supplements Pending	0	0	0	0	0
Number of Priority Efficacy Supplements Filed	0	0	0	0	0
Number of Priority Efficacy Supplements First Actions less than or equal to 6 months	0	0	0	0	0
Number of Priority Efficacy Supplements Frist Actions greater than 6 months	0	0	0	0	0
Number of Priority Efficacy Supplements Pending	0	0	0	0	0

BLA Prior Approval Manufacturing Supplements
CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard PAS Supplements Filed	94	54	92	52	48
Number of Standard PAS Supplements First Actions less than or equal to 4months	94	53	92	52	39
Number of Standard PAS Supplements First Actions greater than 4 months	0	1	0	0	0
Number of Standard PAS Supplements Pending	0	0	0	0	9

BLA/BLA Resubmissions
CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Class 1 Resubmissions Received	1	17	0	0	0
Number of Class 1 Resubmission Actions less than or equal to 2 months	1	17	0	0	0
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0	0	0
Number of Class 1 Resbumssions Pending	0	0	0	0	0
Number of Class 2 Resubmissions Received	7	0	1	0	2
Number of Class 2 Resubmission Actions less than or equal to 6 months	7	0	1	0	2
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0	0	0
Number of Class 2 Resubmissions Pending	0	0	0	0	0

Shared Outcome Goals (FY 2018 through FY 2022)

FDA has two shared outcome goals each fiscal year, one for Original PMAs and Panel-Track Supplements and one for 510(k)s. FDA committed to report the average TTD within a closed cohort and based on the methodology prescribed in the MDUFA IV commitment letter. A PMA cohort is considered closed when 95 percent of applications have reached a decision. A 510(k) cohort is considered closed when 99 percent of accepted submissions have reached a decision. Both the 510(k) and PMA cohorts include submissions reviewed in CDRH and CBER. Performance for submission types that are meeting or exceeding the goal as of September 30, 2022 is shown in **bold** text.

As of September 30, 2022, the 510(k) cohorts for FY 2018, FY 2019, FY2020 and the PMA cohorts for FY 2018 and FY2019 met the decision threshold to calculate the average TTD.

As of September 30, 2022, the PMA cohorts for FY 2020, FY 2021, and FY 2022 have not met the decision threshold to calculate the average TTD. The 510(k) cohort for FY 2020 met the decision threshold to calculate the average TTD and is reported in the table below. FDA will report the average TTD for PMA cohorts for FY 2020, FY 2021 and FY 2022 and for 510(k) cohorts for FY 2021 and FY 2022 in future reports once the cohorts have met the decision threshold.

MDUFA IV Shared Outcome Goals

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs and Panel-Track PMA Supplements					
TTD Goal (Days)	320	315	310	300	290
Current Performance (Days)	**272**	**267**	*	*	*
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
Current Performance (Days)	**123**	128	139	*	*

* As of September 30, 2022, fiscal year cohort has not met the decision threshold to calculate performance.

Page intentionally left blank

Medical Devices

Guidance Documents

Pursuant to the MDUFA IV 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 IV 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 2022

#	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]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	10/5/2021	Yes	No	N/A	No
2	Q1	[4]De Novo Classification Process (Evaluation of Automatic Class III Designation) www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation15	10/5/2021	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	10/5/2021	Yes	No	N/A	No
4	Q1	[4]Acceptance Review for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests	10/5/2021	Yes	No	N/A	No

[1] www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.
[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-2022-fy2022.
[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	Surgical Staplers and Staples for Internal Use - Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations	10/8/2021	Yes	No	N/A	A-List
6	Q1	Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification	10/14/21	No	No	N/A	A-List
7	Q1	Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products	10/20/21	No	Yes	Section 709(c) of the FDA Reauthorization Act	No
8	Q1	Content of Premarket Submissions for Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions	11/4/21	Yes	Yes	MDUFA IV Commitment Letter Section IV.I.3.c.	A-List
9	Q1	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	11/15/21	No	No	N/A	No
10	Q1	[5]Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health	11/15/21	Yes	No	N/A	No

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

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
11	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	12/16/21	No	No	N/A	No
12	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations	12/23/21	Yes	No	N/A	No
13	Q1	Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease	12/23/21	Yes	No	N/A	A-List
14	Q1	Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease	12/23/21	Yes	No	N/A	A-List
15	Q1	Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-medical-devices-physiologic-closed-loop-control-technology	12/23/21	Yes	No	N/A	No
16	Q1	Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions	12/23/21	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
17	Q1	Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/arthroscopy-pump-tubing-sets-intended-multiple-patient-use-premarket-notification-510k-submissions	12/23/21	Yes	No	N/A	No
18	Q1	Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/pathology-peer-review-nonclinical-toxicology-studies-questions-and-answers	12/27/21	Yes	No	N/A	No
19	Q1	Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia-bph	12/27/21	Yes	No	N/A	No
20	Q2	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	1/11/22	No	No	N/A	A-List
21	Q2	Patient Engagement in the Design and Conduct of Medical Device Clinical Studies www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies	1/26/22	Yes	No	N/A	B-List
22	Q2	Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use	1/26/22	Yes	Yes	MDUFA Commitment Letter IV.F.3.a	No
23	Q2	Principles of Premarket Pathways for Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-premarket-pathways-combination-products	1/31/22	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
24	Q2	Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions	3/2/22	No	No	N/A	No
25	Q2	[4]Center for Devices and Radiological Health (CDRH) Appeals Processes www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes	3/2/22	No	No	N/A	No
26	Q2	Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c	3/4/22	No	No	N/A	No
27	Q2	Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR Part 4 Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/certain-ophthalmic-products-policy-regarding-compliance-21-cfr-part-4-guidance-industry	3/23/22	No	No	N/A	No
28	Q3	Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/use-whole-slide-imaging-nonclinical-toxicology-studies-questions-and-answers	4/8/22	Yes	No	N/A	No
29	Q3	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions	4/8/22	Yes	No	N/A	A-List
30	Q3	[5]Surgical Sutures - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-sutures-performance-criteria-safety-and-performance-based-pathway	4/11/22	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
31	Q3	[5]Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-fracture-fixation-plates-performance-criteria-safety-and-performance-based-pathway	4/11/22	Yes	No	N/A	No
32	Q3	Facet Screw Systems - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/facet-screw-systems-performance-criteria-safety-and-performance-based-pathway	4/13/22	Yes	No	N/A	No
33	Q3	Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/denture-base-resins-performance-criteria-safety-and-performance-based-pathway	4/13/22	Yes	No	N/A	No
34	Q3	Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations	4/14/22	Yes	No	N/A	No
35	Q3	[4]Refuse to Accept Policy for 510(k)s www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks	4/21/22	Yes	No	N/A	No
36	Q3	[5]Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/supplements-approved-premarket-approval-pma-or-humanitarian-device-exemption-hde-submissions-during	5/4/22	Yes	No	N/A	No
37	Q3	Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program www.fda.gov/regulatory-information/search-fda-guidance-documents/fostering-medical-device-improvement-fda-activities-and-engagement-voluntary-improvement-program	5/6/22	No	No	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
38	Q3	Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus www.fda.gov/regulatory-information/search-fda-guidance-documents/feasibility-and-early-feasibility-clinical-studies-certain-medical-devices-intended-therapeutically	5/6/22	Yes	No	N/A	No
39	Q3	Electromagnetic Compatibility (EMC) of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices	6/6/22	Yes	No	N/A	No
40	Q3	Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-quantitative-imaging-radiological-device-premarket-submissions	6/16/22	Yes	No	N/A	No
41	Q3	Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-performance-assessment-tissue-containment-systems-used-during-power-morcellation	6/21/22	Yes	No	N/A	No
42	Q4	Conducting Remote Regulatory Assessments Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers	7/25/22	No	No	N/A	No
43	Q4	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices	7/25/22	No	No	N/A	No
44	Q4	Laser-Assisted In Situ Keratomileusis (LASIK) Lasers - Patient Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-assisted-situ-keratomileusis-lasik-lasers-patient-labeling-recommendations	7/28/22	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
45	Q4	Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/hydrogen-peroxide-based-contact-lens-care-products-consumer-labeling-recommendations-premarket	8/17/22	Yes	No	N/A	B-List
46	Q4	Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/replacement-reagent-and-instrument-family-policy-in-vitro-diagnostic-devices	8/17/22	Yes	No	N/A	B-List
47	Q4	Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products	8/17/22	No	Yes	Section 709(c) of the FDA Reauthorization Act	No
48	Q4	[5]Policy for Monkeypox Tests to Address the Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-monkeypox-tests-address-public-health-emergency	9/7/22	No	No	N/A	No
49	Q4	Computer Software Assurance for Production and Quality System Software www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software	9/13/22	No	No	N/A	A-List
50	Q4	Electronic Submission Template for Medical Device 510(k) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions	9/22/22	Yes	Yes	745A(b)	A-List
51	Q4	Ethical Considerations for Clinical Investigations of Medical Products Involving Children www.fda.gov/regulatory-information/search-fda-guidance-documents/ethical-considerations-clinical-investigations-medical-products-involving-children	9/26/22	No	No	N/A	No

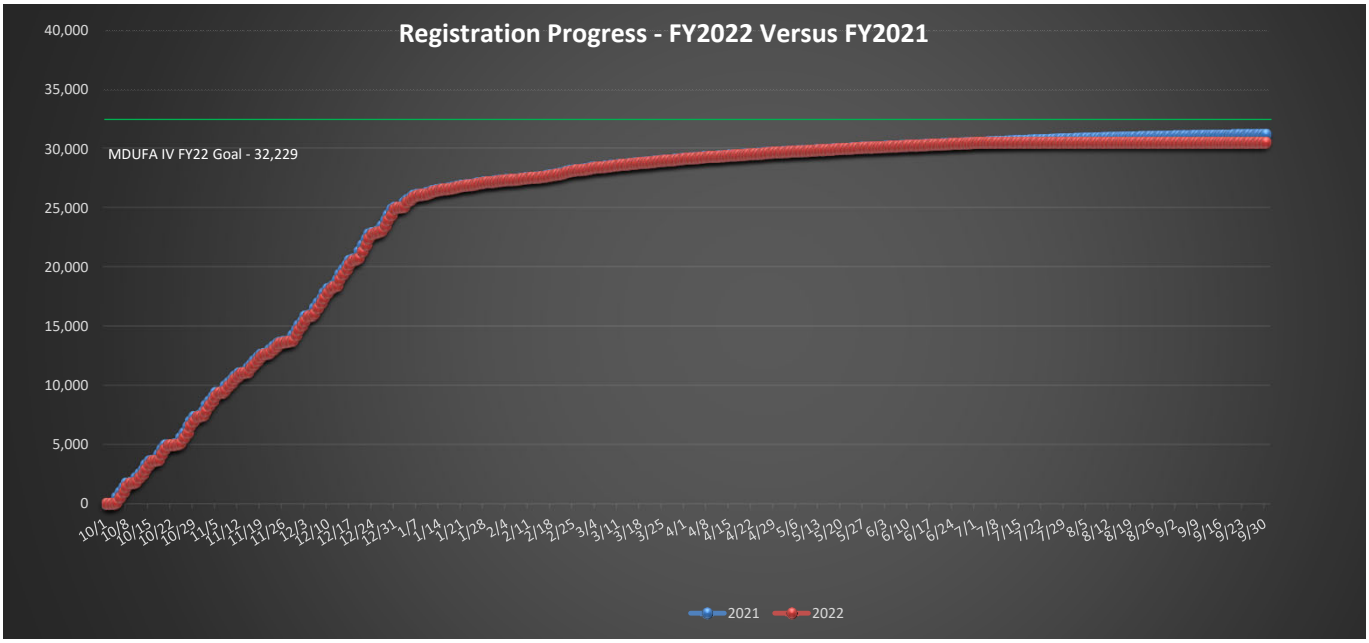
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
52	Q4	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	9/27/22	No	No	N/A	No
53	Q4	[4]Policy for Device Software Functions and Mobile Medical Applications www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications	9/28/22	Yes	No	N/A	No
54	Q4	[4]Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices	9/28/22	Yes	No	N/A	No
55	Q4	[4]Display Devices for Diagnostic Radiology www.fda.gov/regulatory-information/search-fda-guidance-documents/display-devices-diagnostic-radiology	9/28/22	Yes	No	N/A	No
56	Q4	[4]Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-assisted-detection-devices-applied-radiology-images-and-radiology-device-data-premarket	9/28/22	Yes	No	N/A	No
57	Q4	Clinical Decision Support Software www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software	9/28/22	Yes	No	N/A	A-List
58	Q4	[4]Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-performance-assessment-considerations-computer-assisted-detection-devices-applied-radiology	9/28/22	Yes	No	N/A	No

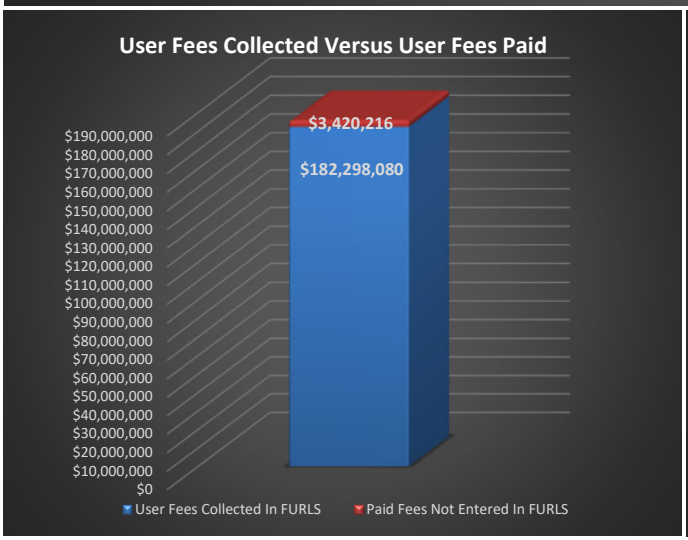
Page intentionally left blank

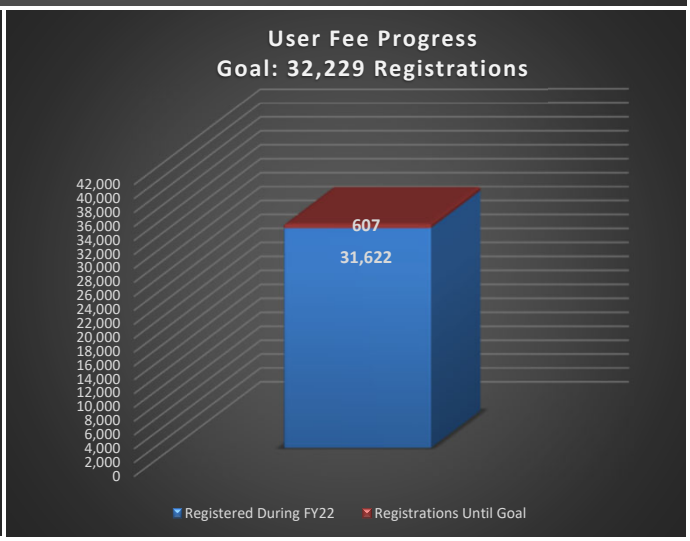
MDUFA IV Registrations - 4th Quarter Summary FY2022*

Current Active Registrations by Type	FY22 Q4			FY21 Year End Active Totals			FY22 vs End FY21
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,848	12,892	19,738	6,899	14,017	20,916	94.37%
Contract Manufacturer	1,234	1,798	3,032	1,213	1,745	2,958	102.50%
Contract Sterilizer	68	166	234	70	156	226	103.54%
Specification Developer	1,768	573	2,341	1,785	594	2,379	98.40%
Reprocessor of Single Use Devices	25	5	30	30	8	38	78.95%
U.S. Manufacturer of Export Only Devices	138	0	138	133	0	133	103.76%
Repackager/Relabeler	1,178	209	1,387	1,186	230	1,416	97.95%
Remanufacturer	22	10	32	17	11	28	114.29%
Foreign Exporter/Private Label Distributor		1,156	1,156		1,179	1,179	98.05%
Initial Importer	3,640		3,640	4,125		4,125	88.24%
Unknown	6	12	18	4	5	9	200.00%
Total:	**14,927**	**16,821**	**31,748**	**15,462**	**17,945**	**33,407**	**95.03%**

*Note: This data is current as of 9/30/2022







FY 2022 Medical Device User Fee Collections as of September 30, 2022 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$182,610,590	-$629,595	$181,980,995		
Application Fees	$71,338,501	-$1,491,343	$69,847,158		
Total	**$253,949,091**	**-$2,120,938**	**$251,828,153**	**$243,473,000**	**103%**

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	$136,096,316	$147,149,475	$137,778,305
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,461,056	$202,327,570	$290,543,931	$275,792,900	$251,828,153

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

CDRH and CBER Combined Data 4th Quarter FY 2022 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	6	0
PMA	6	0
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
Panel Track Supplements	1	1
De Novo Classification	4	54
180-Day Supplements	0	31
Real-Time Supplements	1	37
510(k)s	51	1,757
30-day Notices	14	81
513(g)s	0	57
PMA Annual Report	0	58
Total	**77**	**2,076**

[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. CBER counts are included in PMA's (1 waived), DeNovo Classifiation (2 reduced), 180 Day Supplements (1 reduced), Real-Time Supplements (1 reduced), 510(k)s (8 reduced), 30-day Notices (7 reduced), and PMA Annual Reports (3 reduced).

A. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2022 Summary meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[1]

> *"VI. Performance Reports…3. In addition, the Agency will provide the following information on an annual basis… 3.14. Report on quality management program 3.15. Summary of quality system audits…"*

B. CDRH Quality Management Program

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[2]

> *"...The Agency will establish a dedicated Quality Management (QM) Unit that reports directly to the CDRH Director or Deputy Director..."*

C. Quality Management Unit Expertise

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

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

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

---

[1] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 23; 12/02/2016
[2] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; pages 10-11; 12/02/2016

C.4. Quality Management Training

To support the adoption of quality management across CDRH, the following training was provided in FY 2022:

- ISO 9001:2015 Requirements from A-Z
- ASQ Certified Quality Auditor Training
- ASQ Lean Six Sigma Yellow Belt
- ASQ Lean Six Sigma Green Belt

D. CDRH Quality Management System (QMS)

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[3]

> *"…and establish a quality management framework for the premarket submission process in CDRH. The Framework will include infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation…"*

D.1. ISO 9001:2015 Certification

- In FY 2022, a recertification audit was conducted on October 21, 2021, and a surveillance audit on August 24, 2022.
- During the Recertification Audit (October 21, 2021), the external auditor found one minor nonconformance related to quality management review documentation. The nonconformance was investigated and corrected under NCR-2021-00128.
- On the follow-up Surveillance Audit (August 24, 2022), the external auditor reviewed the prior nonconformance and assessed conformance to the standard. The QMOE program was found to have corrected the previous minor nonconformance and maintained certification with no reported nonconformances.

D.2. **Voice of the Customer (VOC).** The CDRH customer satisfaction survey is available through FDA.gov and is included in all CDRH staff email correspondence. Overall, industry continued to be highly satisfied with CDRH. Industry's customer service satisfaction rate with CDRH was 95 percent in FY 2022. Industry respondents continued to comment positively about their satisfaction with the premarket review process.

D.3. **Feedback✓CDRH.** Feedback✓CDRH is the internal system used to collect internal staff input. The input is assigned to offices who determine whether actions need to be taken. After feedback is addressed, a summary of actions taken is made available to all CDRH staff. In FY 2022, 68 percent of the feedback received was about OPEQ processes and procedures, with 50 percent of that feedback related to premarket review. All feedback was examined and addressed within the established CDRH timelines.

[3] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; pages 10-11; 12/02/2016

E. Document Control

E.1. **Document Control System (DCS) – FY 2022 Improvements.** The DCS was migrated from SharePoint 2010 to SharePoint Online in anticipation of SharePoint 2010 decommissioning at the end of FY 2022. The system continues to be CDRH's repository for all controlled documents.

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

E.3. **Conforming Offices Documentation.** All documents related to the management and execution of the premarket review program processes are controlled using the CDRH DCS. The system houses over 1193 operating procedures, work instructions, forms, and templates. Sixty-two (62) percent (735/1193) of CDRH controlled documentation pertains to OPEQ core processes, including those associated with premarket review.

F. Internal Audits

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[4]

> *"…At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's Corrective and Preventive Action (CAPA) process. FDA will expand the scope of its annual audits as it implements and builds up its auditing capability. As part of these ongoing audits, high-performing premarket review processes utilized in one division will be identified and shared accordingly with other divisions to improve efficiencies and effectiveness. At a minimum, FDA audits in the following areas will be completed by the end of FY 2020: Deficiency Letters and Pre-Submissions. Additional audits in the following areas will be completed by the end of FY 2022: Submission Issue Meetings, Interactive Review, Withdrawals and Special 510(k) conversions…"*

F.1. **Audit Schedule FY 2023.** The audit program completed a process improvement to shift audit calendar development from calendar to fiscal year schedule. The FY 2023 data call for audit topics was submitted in Q3 FY 2022 and the audit schedule was finalized in Q1 FY 2023.

Industry Recommendations	
Evaluate Biocompatibility requests in AI Letters	To be conducted during the MDUFA V required audit of deficiency letters
Evaluate Special 510(k) Conversions to Traditional	Conducted in FY 2022. See AF-2021-00028, below.

FY 2023 Audit Schedule*
ISO Required Audits of at least six QMS Functions
MDUFA V Required audit of Deficiency Letters, with accompanying baseline assessment
***Additional programmatic audits under consideration**

[4] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 11; 12/02/2016

F.2. Audit Schedule FY 2022. The following internal audits were completed in FY 2022:

Title	Purpose	Findings
AF-2020-00010	Withdrawals Audit	MDUFA Required Audit, 1 Finding
AF-2021-00025	QMOE Tools and Services (TSR)	Internal audit, No Findings
AF-2021-00026	Submission Issue Request	MDUFA Required Audit, No Findings
AF-2021-00027	Interactive Review	MDUFA Required Audit, 2 Findings
AF-2021-00028	Special 510(k) Conversion	MDUFA Required Audit, 1 Finding
AF-2021-00029	ASCA	Requested Audit, 1 Finding
AF-2022-00030	Document Control System (DCS)	Internal audit, No Findings
AF-2022-00031	Risk, Nonconformance and Corrective Action	Internal audit, No Findings
AF-2022-00067	Audit Management System (AMS)	Internal audit, 1 Finding
AF-2022-00068	Design, Development, Verification, Validation	Internal audit, No Findings
AF-2022-00069	Quality Management Review (QMR)	Internal audit, No Findings
AF-2022-00070	Training and Competence	Internal audit, No Findings
AF-2022-00071	FeedbackCDRH	Internal audit, No Findings

F.3. CDRH QMS Audits (AF-2021-00025; AF-2022-00030; AF-2022-00031; AF-2022-00067; AF-2022-00068; AF-2022-00069; AF-2022-00070, AF-2022-00071). One nonconformity (NCR-2022-00131) was found and eight opportunities for improvement and one best practice were identified. The nonconformity related to two findings: (i) audit opening meetings and (ii) audit party definitions. The nonconformity has been resolved.

F.4. AF-2020-00010: Withdrawals Audit

Purpose: Determine whether guidance, procedures, and established practices associated with withdrawals are being followed and, where possible, working as intended.

Findings: All except one of the withdrawn files analyzed were initially requested by the submitter. The single case where the submitter did not initially request withdrawal was for a 510(k)-exempt device. All lead reviewer memos analyzed contained certification by the lead reviewer that the lead reviewer did not request the withdrawal. One nonconformity related to the storage of reviewer documentation (NCR-2022-00133) was found.

F.5. AF-2021-00017: Pre-Submissions Audit (Report; audit completed in FY 2021)

Purpose: Assess the use of FDA feedback; specifically, compare feedback given during Pre-Submission meetings to requests for additional information, where available.

Findings: No contradictions between Pre-Submission feedback and requests for additional information were found. No nonconformities were found.

F.6. AF-2021-00026: Submission Issue Request (SIR) Audit

Purpose: Determine whether guidance, procedures, and established practices associated with SIRs are being followed, and, where possible, working as intended. The audit included how SIRs are being used by industry.

Findings: All SIR questions reviewed corresponded to a deficiency. Slightly over 50 percent of those SIRs asked for pre-review. Of those asking for pre-review, one quarter were in response to a suggestion by FDA to submit data for pre-review. Less than five percent of the SIR questions reviewed asked for information already provided in the AI request. No nonconformities were found.

F.7. AF-2021-00027: Interactive Review (IR) Audit

Purpose: Determine whether guidance, procedures, and established practices associated with Interactive Review are being followed and, where possible, working as intended.

Findings: Interactive Review was used in over 80 percent of submissions sampled. Over 50 percent of interactions provided deadlines to sponsors (NCR-2022-0134). Over 90 percent of all deadlines provided by FDA were within the recommended 7 calendar days. Over 90 percent of the time, sponsor responses met the FDA-provided deadlines. Two nonconformities were found: one related to documentation of interactions (NCR-2022-0133) and one related to FDA providing deadlines to sponsors (NCR-2022-0134).

F.8. AF-2021-00028: Special 510(k) Conversion Audit

Purpose: Determine whether guidance, procedures, and established practices associated with Special 510(k)s are being followed and, where possible, working as intended.

Findings: Slightly over 50 percent of the conversions reviewed contained a reason for conversion. Of those, over 70 percent contained a reason for conversion consistent with the conversion guidance document. Where reasons for conversion were found, slightly over 90 percent of those had explanations for the reason for conversion that were consistent with the conversion guidance document. One nonconformity related to the storage of reviewer documentation (NCR-2022-00133) was found.

F.9. AF-2021-00029: ASCA

Purpose: Assess whether the ASCA program met its established policies, procedures, and MDUFA IV commitments.

Findings: The ASCA Pilot has met all applicable MDUFA IV commitments. All Accreditation Body work items met internal self-imposed timelines. Approximately 30 percent of Testing Laboratory work items met internal self-imposed timelines. A nonconformity related to the Testing Laboratory timelines was opened by the program before the audit start date.

F.10. Audit Findings Next Steps. Where nonconformities were found, the auditee is working to address them. Additional information will be provided as the nonconformities are addressed.

G. Continual Improvement.

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

CDRH's Simplicity Strategic Priority and Digital Transformation initiatives continued through FY 2022. CDRH continues to lean CDRH core businesses processes. BPI objectives include:

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

G.2. Innovative Technological Improvements: eSTAR Submission Tool

In 2022, CDRH continued to advance innovative technologies and meet the MDUFA IV commitment to develop electronic submission templates to improve the sponsor submission process through the electronic Submission Template and Resource (eSTAR) pilot. eSTAR is a voluntary alternate method for industry to submit submissions in an effort to develop resources to aid sponsors in providing structured electronic submissions. With the publication of the guidance "Electronic Submission Template for Medical Device 510(k) Submissions" on September 22, 2022, 510(k) submissions prepared as eSTARs will be required starting on October 1, 2023.

- As of 9/30/2022, CDRH received 474 eSTAR 510k submissions, with 213 SE, 6 NSE, and 28 withdrawn, deleted or other decisions; 227 are pending.
- As of 9/30/2022, CDRH received 13 eSTAR De Novo submissions, with 1 withdrawn and 12 pending.
- On November 29, 2021, De Novo content of both nIVD and IVD eSTAR templates was deployed for use.
- eSTAR templates for 513(g)s, IDEs, and Q-Subs are in development.

Positive sentiments were received from 30 unique firms, with no negative sentiments received.

G.3. Innovative Technological Improvements: Submission Memo and Review Template (SMART) Development

Another innovative technological solution is the continued development of the submission memo and review templates (SMART) program to increase consistency and efficiency for FDA review staff.

The SMART program was expanded to include an Expert Review SMART Template for consults. This review document is designed to pair with the lead reviewer versions of all the SMART templates in such a way that consultant review data can easily be exported directly to the lead reviewer's template.

The IDE SMART Template was expanded to include a partner SMART template for all IDE Supplement types. This tool was internally approved by OPEQ's Tool and Templates Committee in Spring 2022. Sequential deployment to the OHTs began shortly after, and the IDE SMART Template for Supplements continues to be piloted by the OHTs with approximately half of them using the document. Full deployment to all OHTs is expected by the end of December 2022.

The PMA SMART Template was updated with significant changes. Additionally, the template was refined based on user feedback and Guidance updates to include additional review help surrounding post-approval studies. Corresponding changes were made to the Correspondence Generator to include these letter revisions.

The IVD-specific PMA SMART Template finished construction in Summer 2022, was reviewed by OPEQ's Tools and Templates Committee, and was deployed to OHT7.

The Mandated SMART Template also finished construction, was reviewed by OPEQ's Tools and Templates Committee, and was deployed to all OHTs. The tool was significantly updated to reflect a major Guidance Document revision and deployed alongside that Guidance Document release in October 2022.

IVD-specific SMART Templates now are available for use for 510(k)s, De Novos, and PMAs. Of the main premarket submission types, only an HDE SMART template remains to be developed.

G.4. Innovative Technological Improvements: CDRH Portal

CDRH continues to innovate as it adds capabilities to the CDRH Portal. Originally, the portal allowed the Official Correspondent of a Traditional, Special, or Abbreviated 510(k) to track the progress of that submission. With the recent release of self-registration and online upload functionality for the portal, any industry member can use the portal to upload any CDRH-led premarket submission type in any stage of review directly to CDRH instead of mailing it to our document control center. This saves both time and resources for our industry members and helps CDRH get the information needed to complete a review in a more expedient manner.

G.5. BPI: ASCA BPI for Digital Transformation (complete)

This project was initiated with the goal of improving and streamlining the Accreditation Scheme for Conformity Assessment (ASCA) process for efficiency and effectiveness and identifying the business requirements for providing the required capabilities in the Digital Transformation (DT) platform.

The team applied a Lean Six Sigma approach to document a new end-to-end business process that harmonized all 16 unique work items into a single workflow that reduces burden on applicants and ASCA staff, prepares ASCA for programmatic growth, simplifies training and onboarding, and streamlines communications with key stakeholders. As part of this effort, the team also captured 70 unique business requirements to address the following capabilities:

- Automate business processes to decrease processing time and manual data entry,
- Use automated workflows to reduce manual workload, streamline the process, and capture metrics,
- Configure common platform and eliminate need to store information and documentation in multiple systems, and
- Reduce rework by ensuring documentation intake was accurate and complete.

The BPI team delivered the to-be process and business requirements to the DT Discovery Team in May 2022. DT is prioritizing their efforts and working on the development and release schedule.

G.6. BPI: Cybersecurity BPI for Digital Transformation (complete)

The goal of this project was to document and standardize the CDRH process for the management and analysis of reported medical device cybersecurity incidents and vulnerabilities. The team applied a Lean Six Sigma approach to document the post-market cybersecurity vulnerability process and define key organizational roles and responsibilities for improved coordination and transparency. Additionally, the team identified process performance metrics to inform management decisions and documented 105 unique business requirements to accelerate the discovery phase of the Digital Transformation initiative for the Medical Device Cybersecurity Program. Collectively, these efforts should enable CDRH to deliver increased patient protection by increasing the security and safety of devices and the underlying infrastructure when cybersecurity vulnerabilities are identified.

The BPI team completed its work in September 2022 and delivered the to-be process and business requirements to the DT Discovery Team in several waves. Formal discovery efforts will commence in FY23.

G.7. BPI: TPLC Advisory Program (TAP) (complete)

A BPI project launched in June 2022 to design the pilot processes, define the FDA organizational roles and responsibilities, and document a detailed implementation plan for the TPLC Advisory Program (TAP). The team followed an Agile approach to design the ideal state process and iterate on the to-be process to a sufficient level of detail so that Standard Operating Procedures and other work aids could be developed to enable the execution of the program. Additionally, the team identified changes to supporting technology in order to capture and report on program metrics and measure value to sponsors, customers, and FDA. CDRH expects to further refine the to-be process after launching the pilot.

H. Independent Assessment of Review Process

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[5]

"*…For Phase 2 of the independent assessment, FDA will award the contract no later than 3/31/2020. However, the contractor would not begin the audit of deficiency letters and Pre-Submissions before 10/1/2020. The contractor will publish comprehensive findings and recommendations within 1 year.*

For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable. FDA will incorporate findings and recommendations, as appropriate, into its management of the premarket review program. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness.

During the second phase, the contractor will:

1. *Evaluate FDA's premarket review program to identify efficiencies that should be realized*

[5] DELIVERABLE 12: MDUFA IV INDEPENDENT ASSESSMENT – FINAL REPORT, Section 4.5.2.2, Audit Results. https://www.fda.gov/media/152594/download; 09/30/2021.

as a result of the process improvements and investments under MDUFA III and IV;

2. *Evaluate premarket review program infrastructure and allocation of FTEs;*
3. *Assess the alignment of resource needs with the training and expertise of hires;*
4. *Identify and share best practices across branches in ODE and OIR;*
5. *Assess the effectiveness of programs targeted for improvement under this agreement, including the:*
    a. *Quality Management program,*
    b. *Proportion of deficiencies in which FDA references the basis for the deficiency determination,*
    c. *Pre-Submission program (assess whether (a) CDRH is providing guidance specific to the questions being asked; (b) CDRH is using Pre-Submissions appropriately; and (c) CDRH and Industry are adhering to the procedural aspects as set forth in this agreement),*
    d. *Third Party Review program (assess efficiency of program and suggest process improvements),*
    e. *Digital Health program,*
    f. *Patient Engagement program, and*
    g. *Real World Evidence program;*

6. *Analyze conversions of Special 510(k)s to Traditional 510(k)s; and*
7. *Assess other key areas identified by FDA and industry as resources permit."*

H.1. **Final Report.** CDRH finalized phase two of the MDUFA IV Independent Assessment in FY 2021. The independent assessment final report, Deliverable 12: MDUFA IV Independent Assessment – Final Report[6], was published on September 30, 2021 (due October 1, 2021; FY 2022).

[6] DELIVERABLE 12: MDUFA IV INDEPENDENT ASSESSMENT – FINAL REPORT, Section 4.5.2.2, Audit Results. https://www.fda.gov/media/152594/download; 09/30/2021.

Center for Devices and Radiological Health Internal Training Summary Report

Q4 FY 22

October 2021 – September 2022

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

As of: 10/14/2022

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

Table X provides a summary of internal training conducted in CDRH between October 1, 2021 and September 30, 2022. DETD offered 728 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. The training was designed to support the Medical Device User Fee Amendment (MDUFA) goals and program activities.

Table of Contents

Table X – FY'22 CDRH Internal Training Conducted by DETD:

October 1, 2021 and September 30, 2022

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA IV	5	814	654
	ELP	4	170	1360
	Least Burdensome (Refresher)	3	607	224
	Other LAW	332	15873	16586
	LAW Subtotal:	*344*	*17464*	*18824*
Leadership Development Training (LED)	LEAD: Leadership for Managers	55	1177	2596
	Leadership for Non-Managers	4	64	593
	Other LED	21	395	1906
	LED Subtotal:	*80*	*1636*	*5095*
Professional Development (PRO) Training	All PRO	155	2777	5932
	New Employee Orientation	*13*	*143*	*429*
	PRO Subtotal:	*168*	*2920*	*6361*
Center-Specific Information Technology (CIT) Training	Premarket IT	3	460	460
	CIT Subtotal:	*3*	*460*	*460*
Science (SCI) Training	All SCI	133	6443	7645
	SCI Subtotal:	*133*	*6443*	*7645*
		728	**28923**	**38385**

CDRH Informal Training

CDRH Informal Training:

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

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

CDRH Informal Training:

Year	# of Learning Events	Total # of Participants	Total Contact Hours
FY'15	34	1249	3350
FY'16	42	978	2122
FY'17	113	2845	8956
FY'18	61	1692	5650
FY'19	39	575	1170
FY'20	57	878	1432
FY'21	112	3476	3953
FY'22	67	2611	3203
Total:	**525**	**14304**	**29836**

Reviewer Training - RCP

Reviewer Certification Program (RCP):

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

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

RCP Training by Cohort: *October 1, 2021 and September 30, 2022*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 1 2021 Cohort	14	16	OCD	1	31	40
			OPEQ	44	1061	1314
			OP	7	66	75
			OSEL	7	193	242
			Subtotal:	***59***	***1351***	***1671***
Fall 2 2021 Cohort	14	16	OPEQ	18	412	513
			OP	3	7	4
			Subtotal:	***21***	***419***	***517***
Spring 1 2022 Cohort	14	16	OCD	1	26	33
			OPEQ	23	546	690
			OP	1	7	11
			OSEL	2	50	63
			OST	3	77	98
			Subtotal:	***30***	***706***	***895***
Spring 2 2022 Cohort	14	16	OCE	1	6	6
			OPEQ	21	514	615
			OSEL	5	120	146
			OST	2	18	20
			Subtotal:	***29***	***658***	***787***
Summer 1 2022 Cohort	14	16	OPEQ	9	242	310
			OSEL	5	111	141
			OST	2	55	70
			Subtotal:	***16***	***408***	***521***
Summer 2 2022 Cohort	14	16	OPEQ	40	870	1110
			OSEL	3	70	89
			OST	1	23	29
			Subtotal:	***44***	***963***	***1228***
Total:	**84**	**96**	**-**	**199**	**4505**	**5619**

Reviewer Training - ELP

Experiential Learning Program (ELP):

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

ELP Training Completed: *October 1, 2021 and September 30, 2022*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
4	170	1360	• Innovation • Digital Health • Biocompatibility • Reprocessing • Sterlization

ELP Training Completed by Office: *October 1, 2021 and September 30, 2022*

Office	Total # of Completions	Total Training Hours
OM	4	32
OPEQ	154	1232
OSEL	9	72
OST	3	24
Total:	**170**	**1360**

Leadership Training - LEAD

Leadership Enhancement and Development (LEAD) Program:

The LEAD Program is a mandatory Supervisory Training Program targeting CDRH Supervisors, Managers, and Non-Bargaining Unit Team Leaders. The LEAD curriculum supports the CDRH Management Competencies and addresses the supervisory training requirements as mandated in 5 CFR 412.

LEAD Training Completed: *October 1, 2021 and September 30, 2022*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	55	1177	2596	• Leading Hybrid Teams • Leading Virtual and Remote Teams • Leading with Emotional Intelligence/Stress Management • Leadership and Influence • Delivering Critical Feedback