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

May 26, 2021, 12:30 – 1:30 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through March 31, 2021

- Report on decision goals for 2nd Quarter FY 2021

Guidance Development

Registration and Listing

Qualitative Update on Finances – 2nd Quarter FY 2021

- User fee receipts through the 2nd Quarter FY 2021

CDRH Training Update

Page intentionally left blank

Quarterly Update on
Medical Device Performance Goals
MDUFA IV CDRH Performance Data
---Action through 31 March 2021---

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

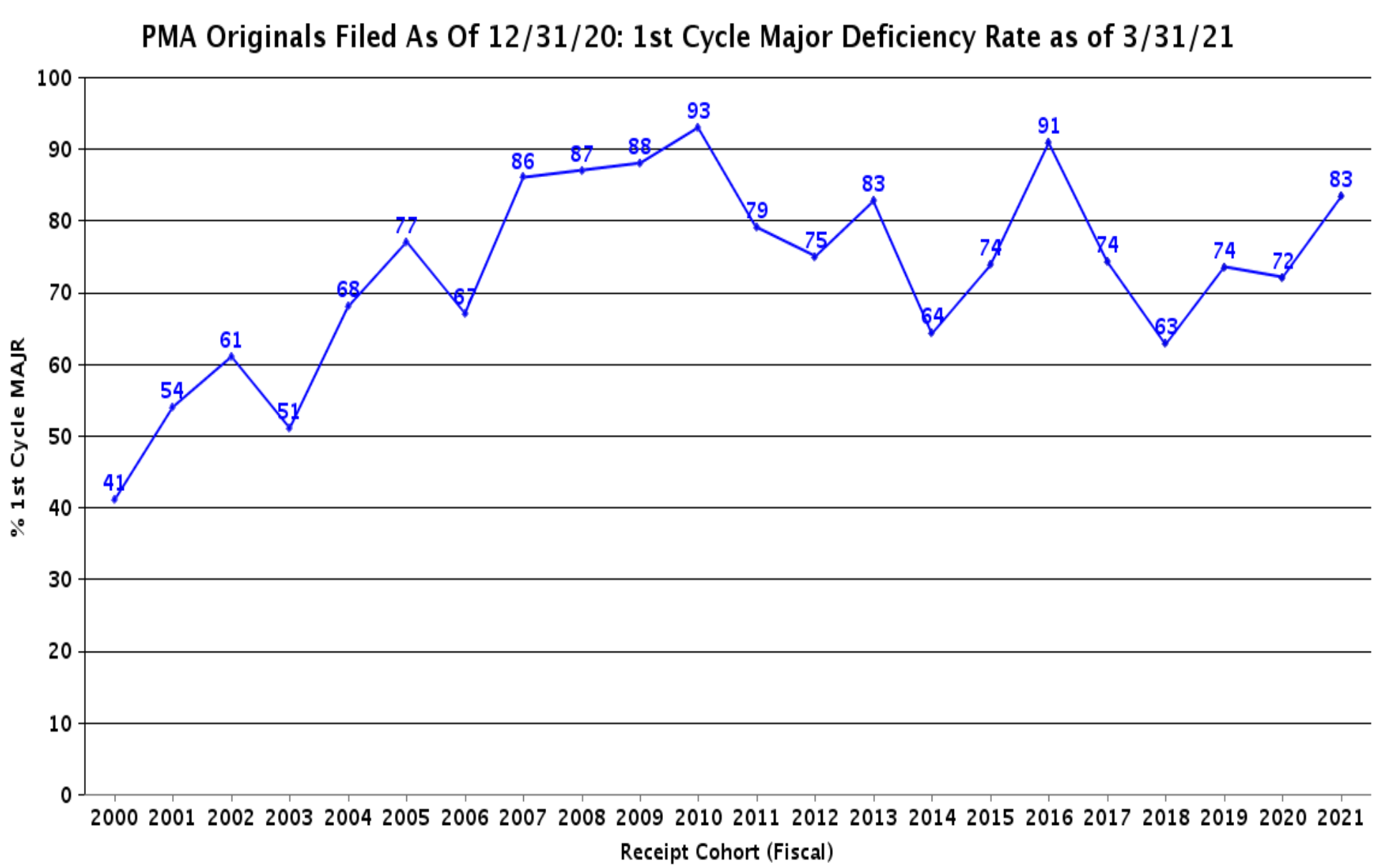
OHT7: Office of In Vitro Diagnostics and Radiological Health

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

Page intentionally left blank

PMAs

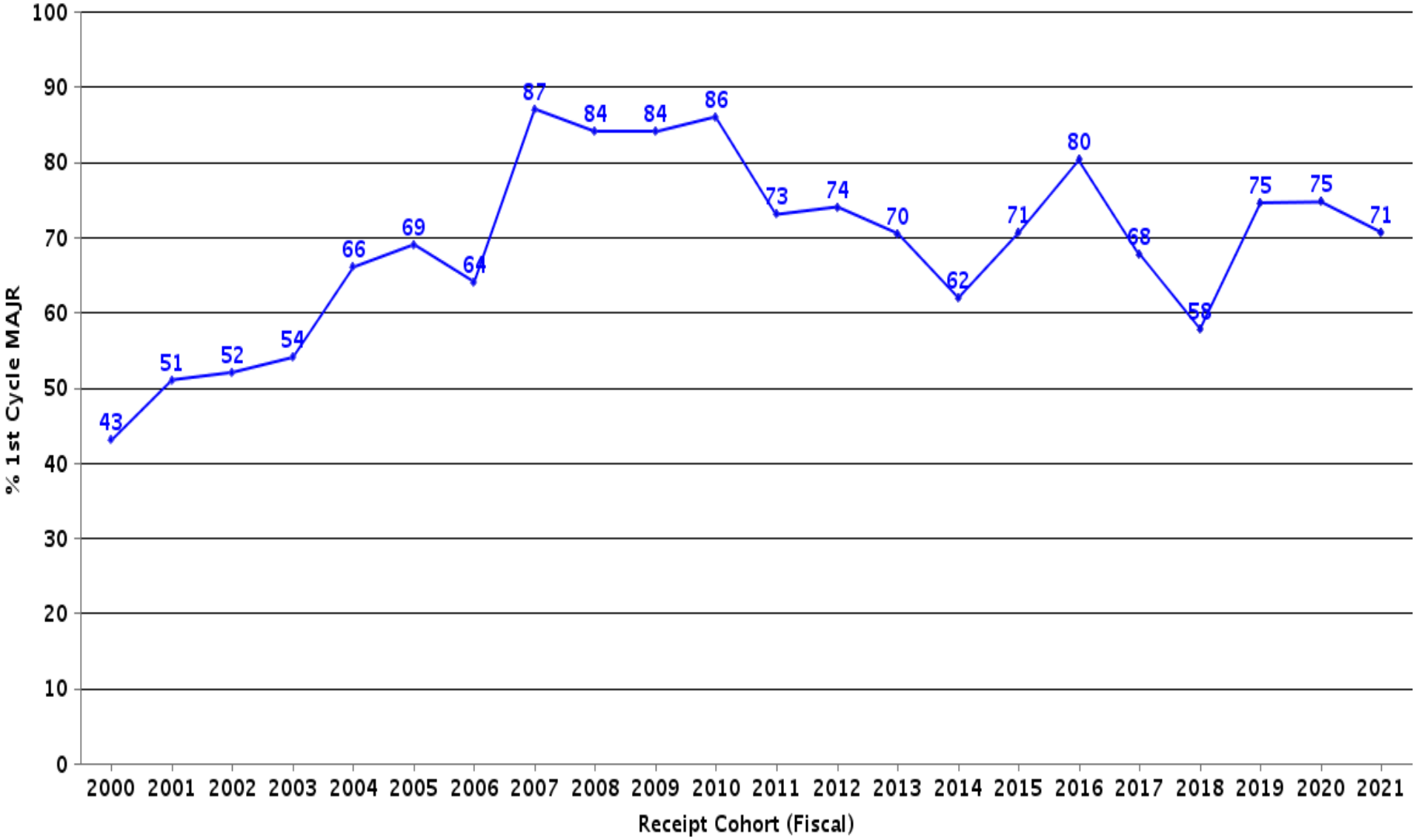
Q2FY2021



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 12/31/20. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

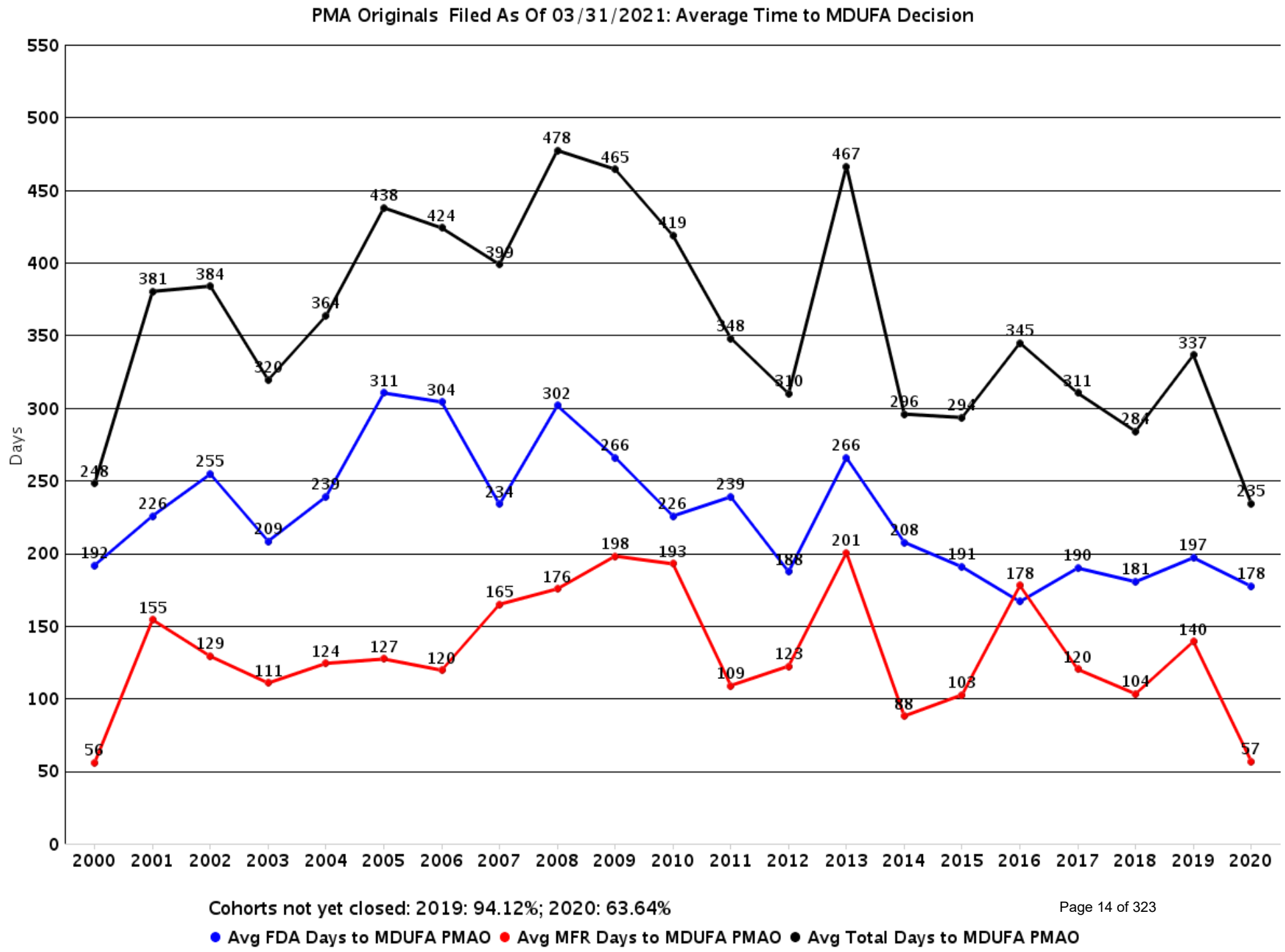
♦ % 1st Cycle MAJR PMAO

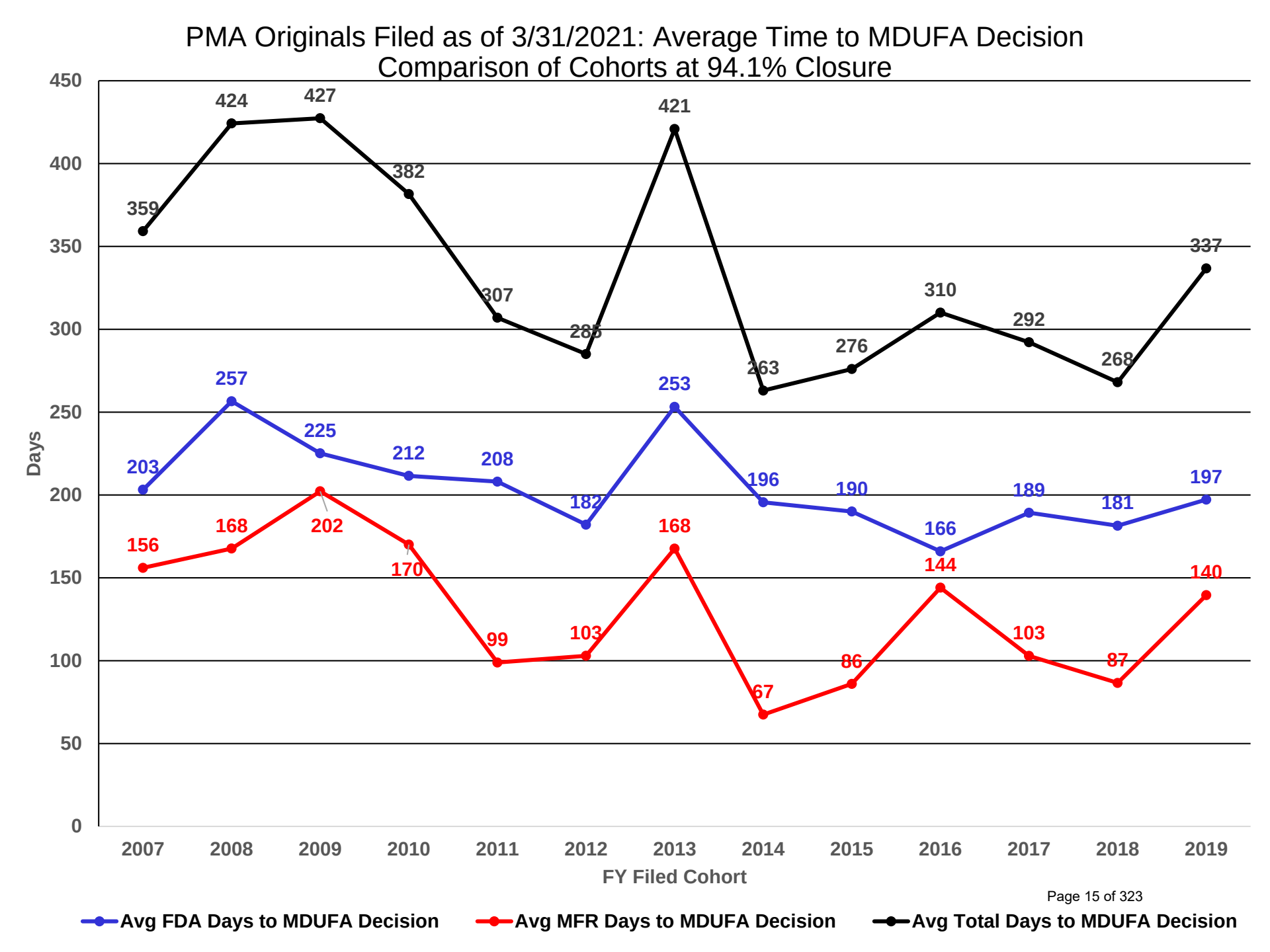
PMA Originals and Panel Track Supplements Filed As Of 12/31/20: 1st Cycle Major Deficiency Rate as of 3/31/21



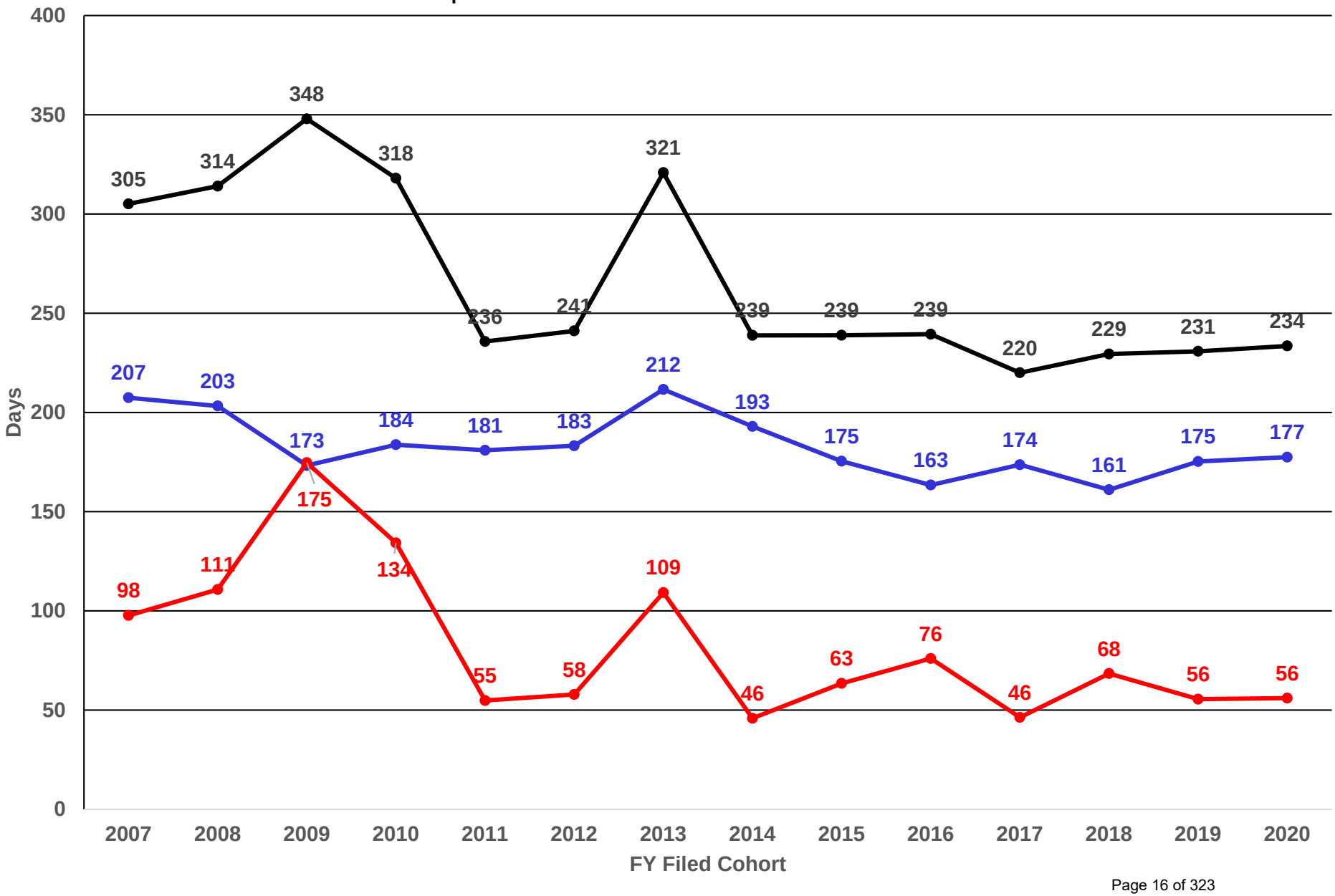
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/20. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

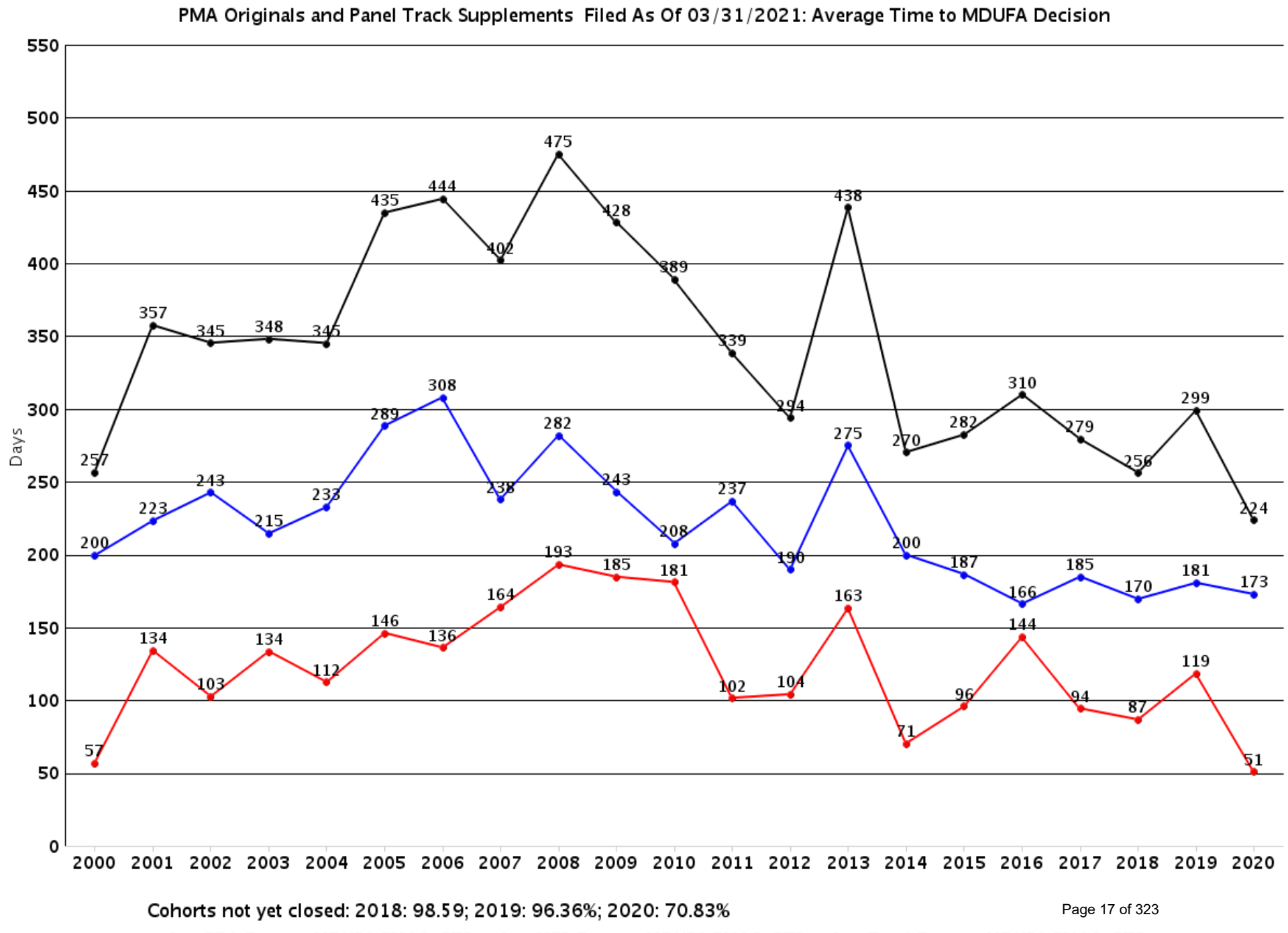
♦ % 1st Cycle MAJR PMAO/PTS


PMA Originals Filed As Of 03/31/2021: Average Time to MDUFA Decision
Days
550
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
248 381 384 320 364 438 424 399 478 465 419 348 310 467 296 294 345 311 284 337 235
192 226 255 209 239 311 304 234 302 266 226 239 188 266 208 191 178 190 181 197 178
56 155 129 111 124 127 120 165 176 198 193 109 123 201 88 103 178 120 104 140 57
Cohorts not yet closed: 2019: 94.12%; 2020: 63.64%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO

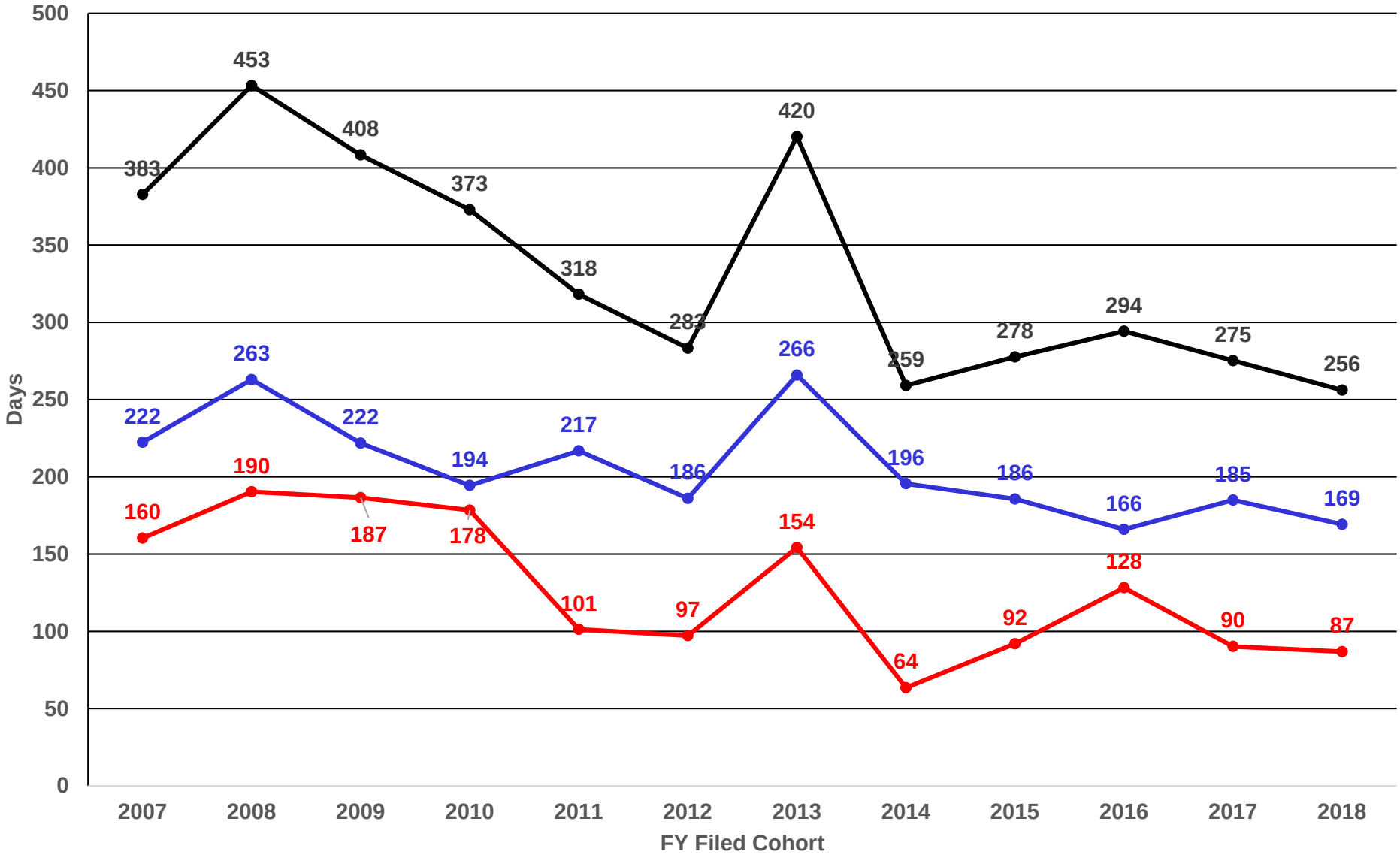

PMA Originals Filed as of 3/31/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 94.1% Closure
Days
FY Filed Cohort
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
359
424
427
382
307
285
421
263
276
310
292
268
337
203
257
225
212
208
182
253
196
190
166
189
181
197
156
168
202
170
99
103
168
67
86
144
103
87
140
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

PMA Originals Filed as of 3/31/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 63.6% Closure

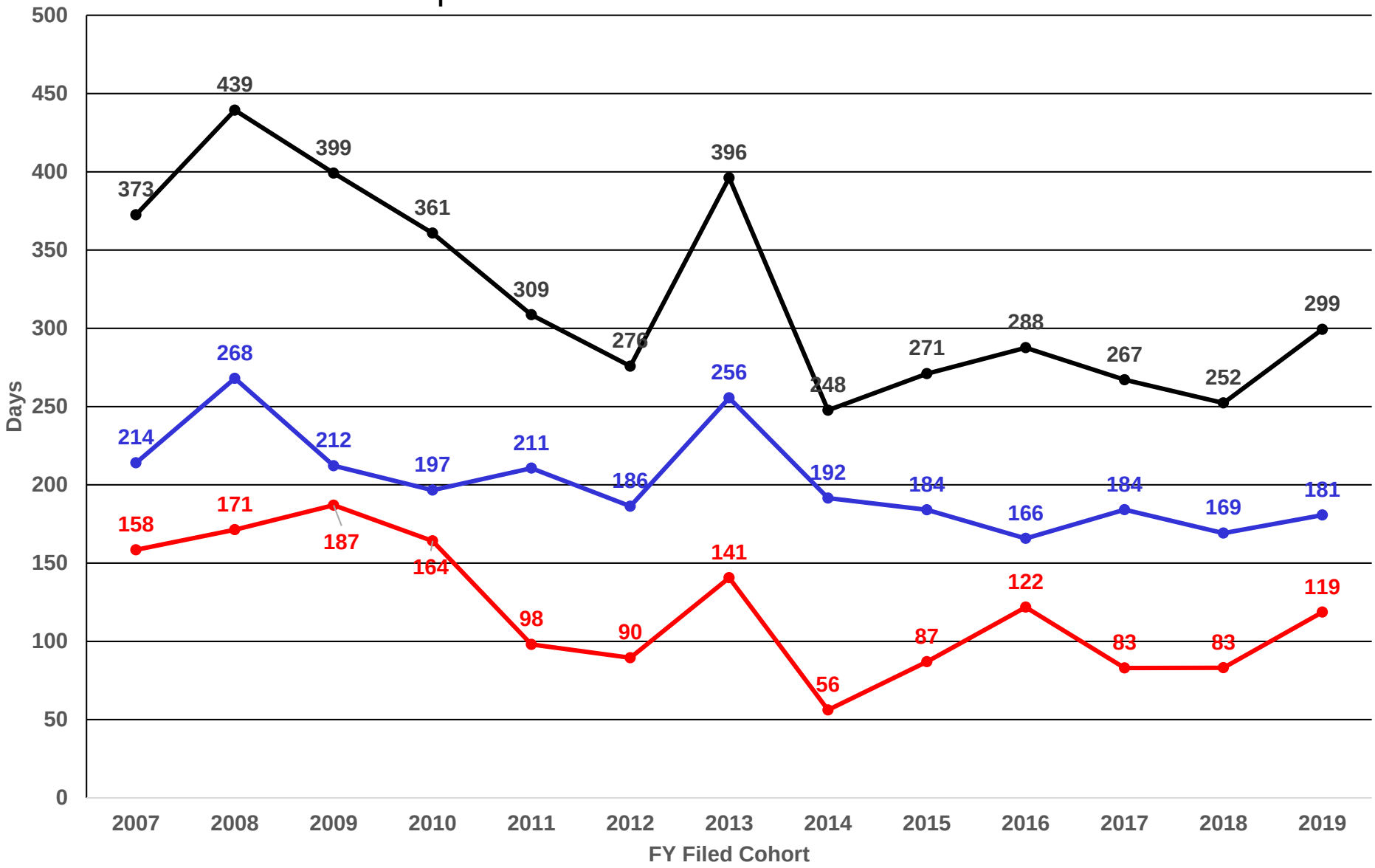



PMA Originals and Panel Track Supplements Filed As Of 03/31/2021: Average Time to MDUFA Decision
Days
550
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020
257 357 345 348 345 435 444 402 475 428 389 339 294 438 270 282 310 279 256 299 224
200 223 243 215 233 289 308 238 282 243 208 237 190 275 200 187 166 185 170 181 173
57 134 103 134 112 146 136 164 193 185 181 102 104 163 71 96 144 94 87 119 51
Cohorts not yet closed: 2018: 98.59; 2019: 96.36%; 2020: 70.83%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

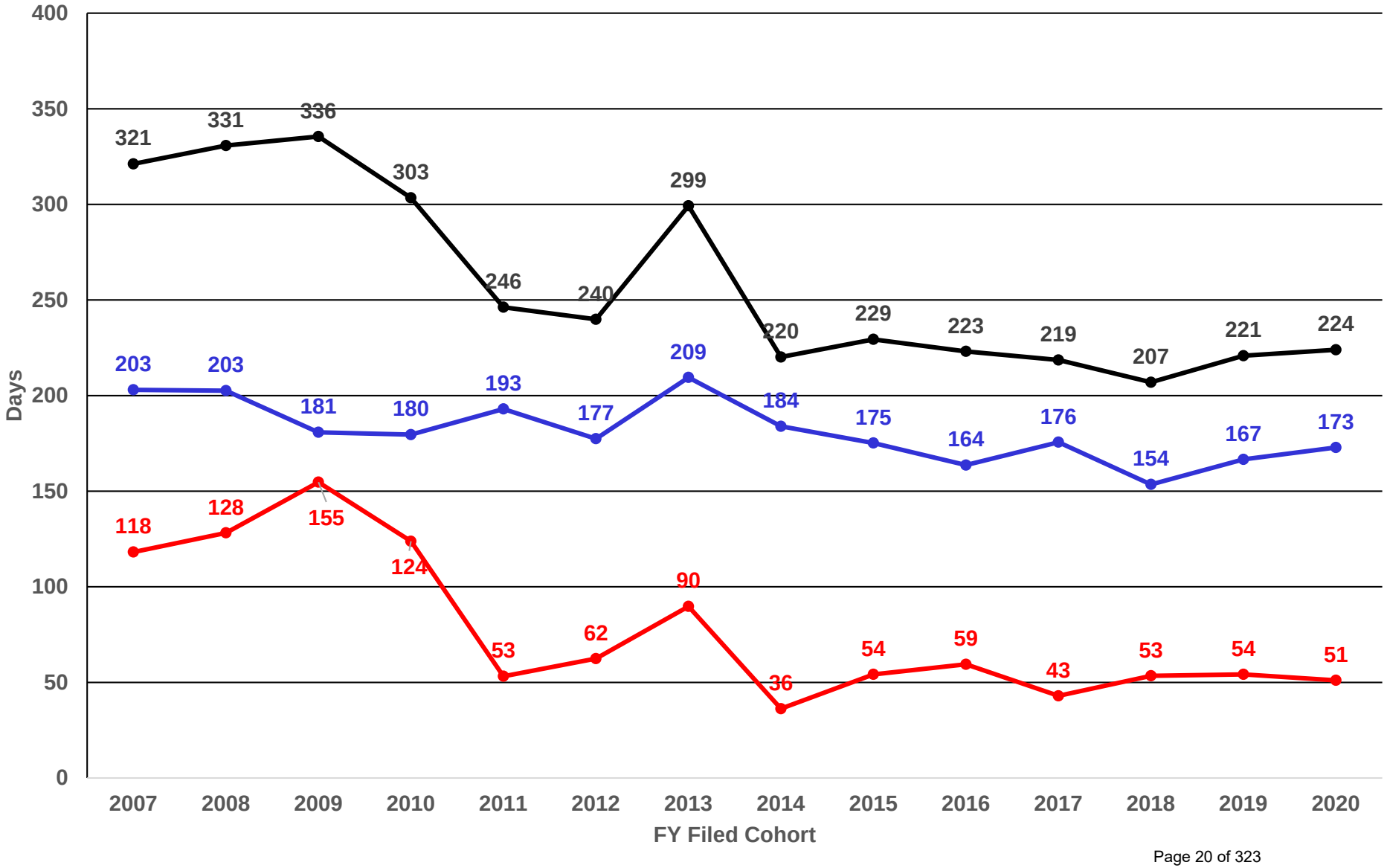
PMA Originals and Panel Track Supplements Filed as of 3/31/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 98.6% Closure

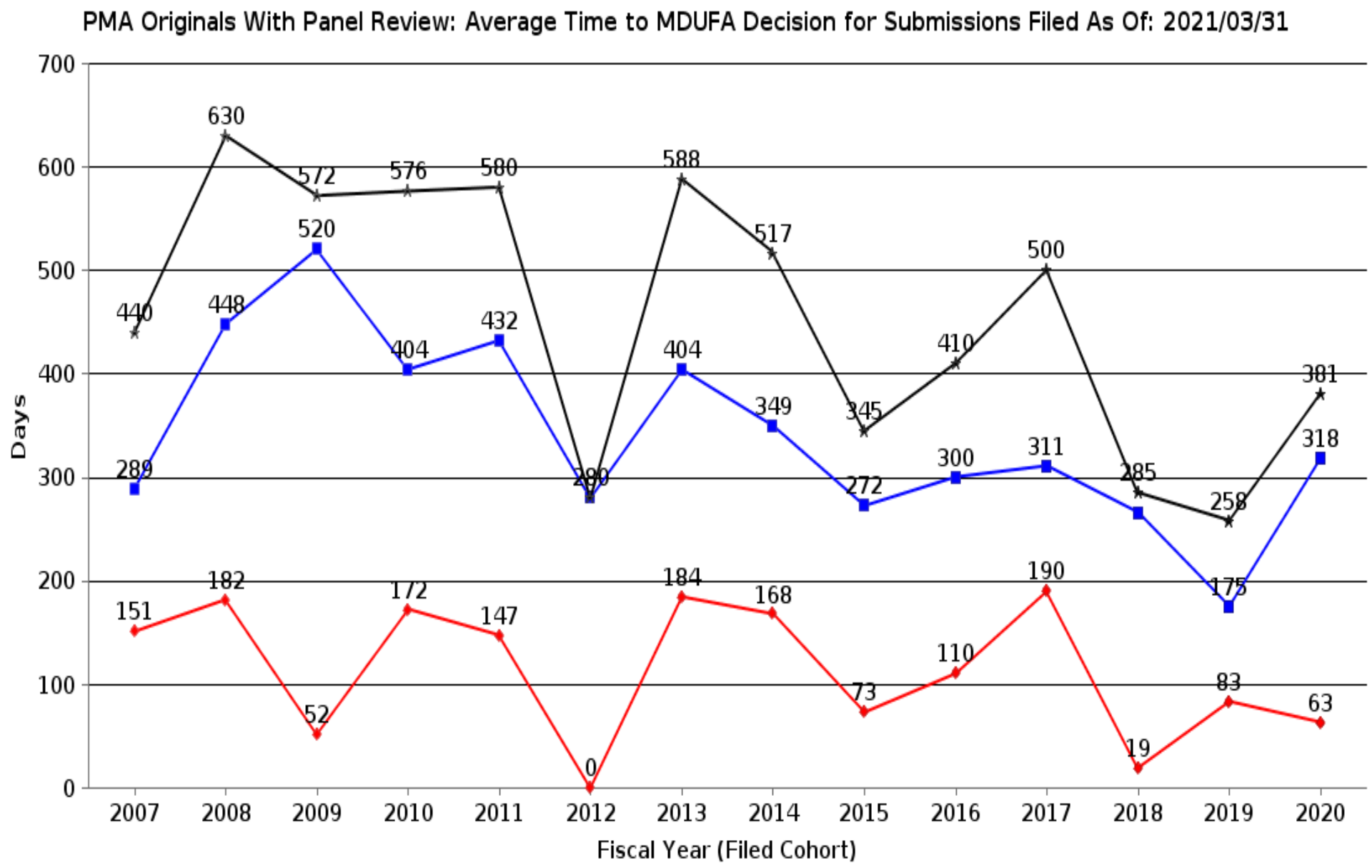


PMA Originals and Panel Track Supplements Filed as of 3/31/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 96.4% Closure



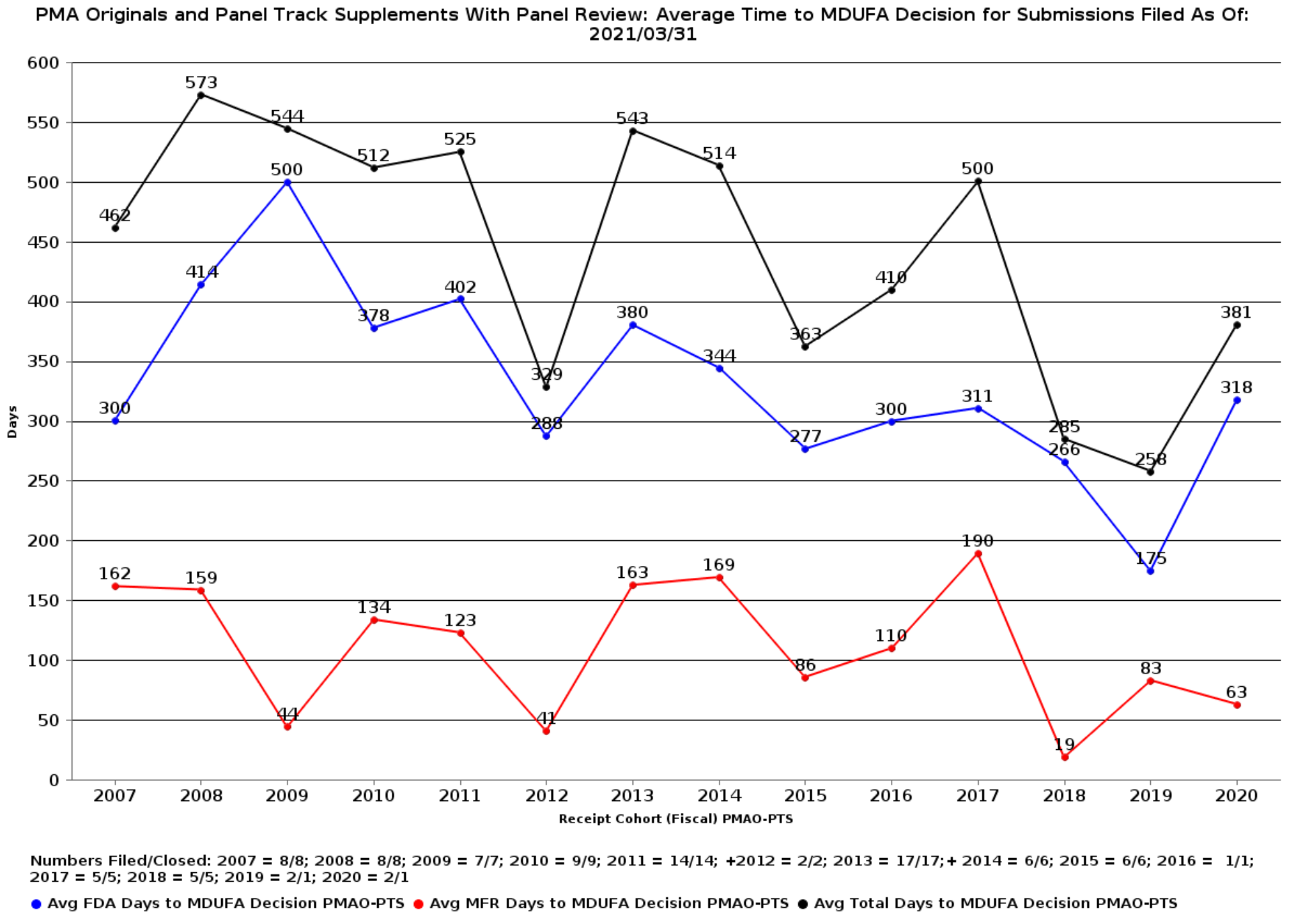
PMA Originals and Panel Track Supplements Filed as of 3/31/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 70.8% Closure



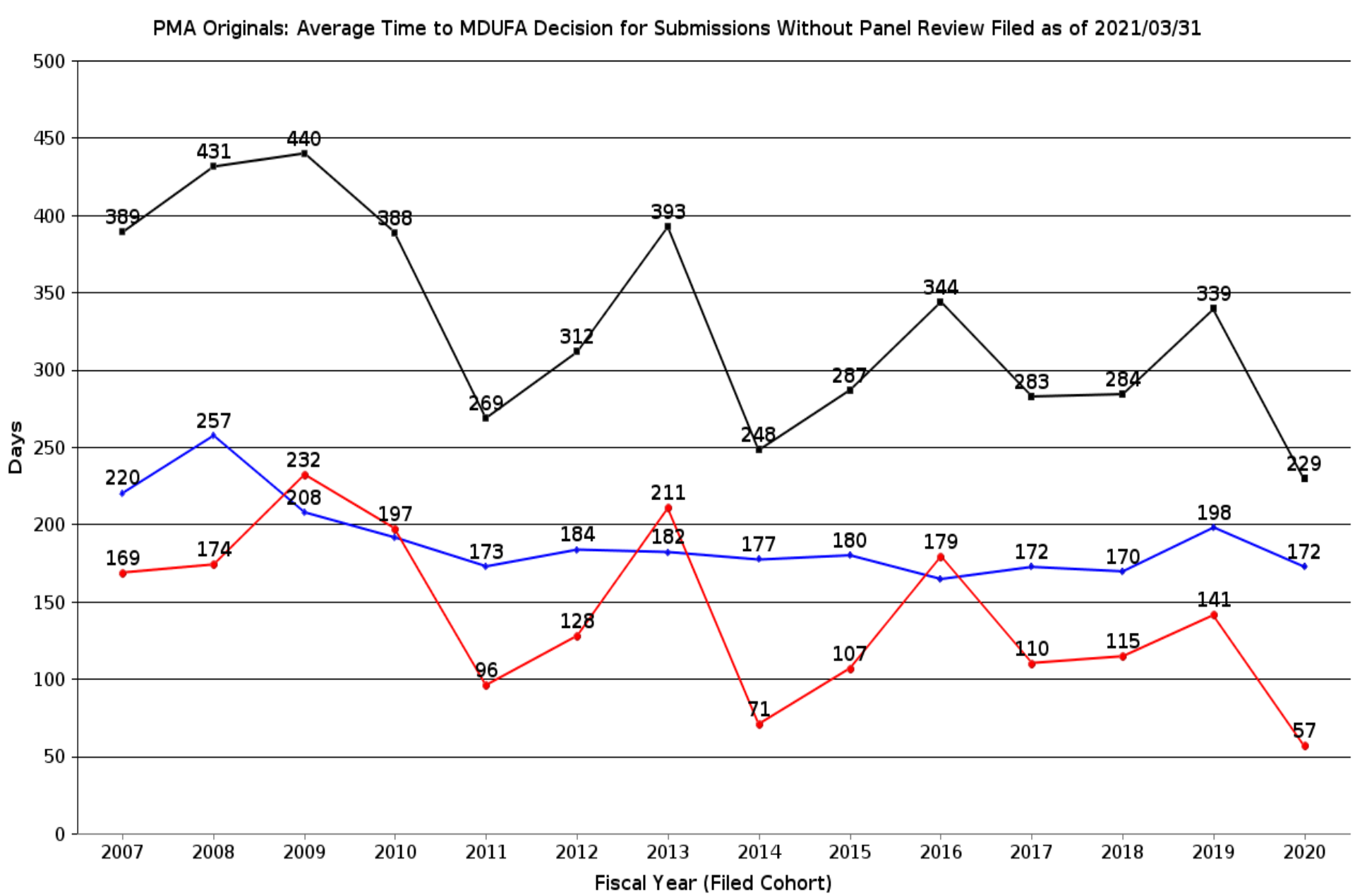


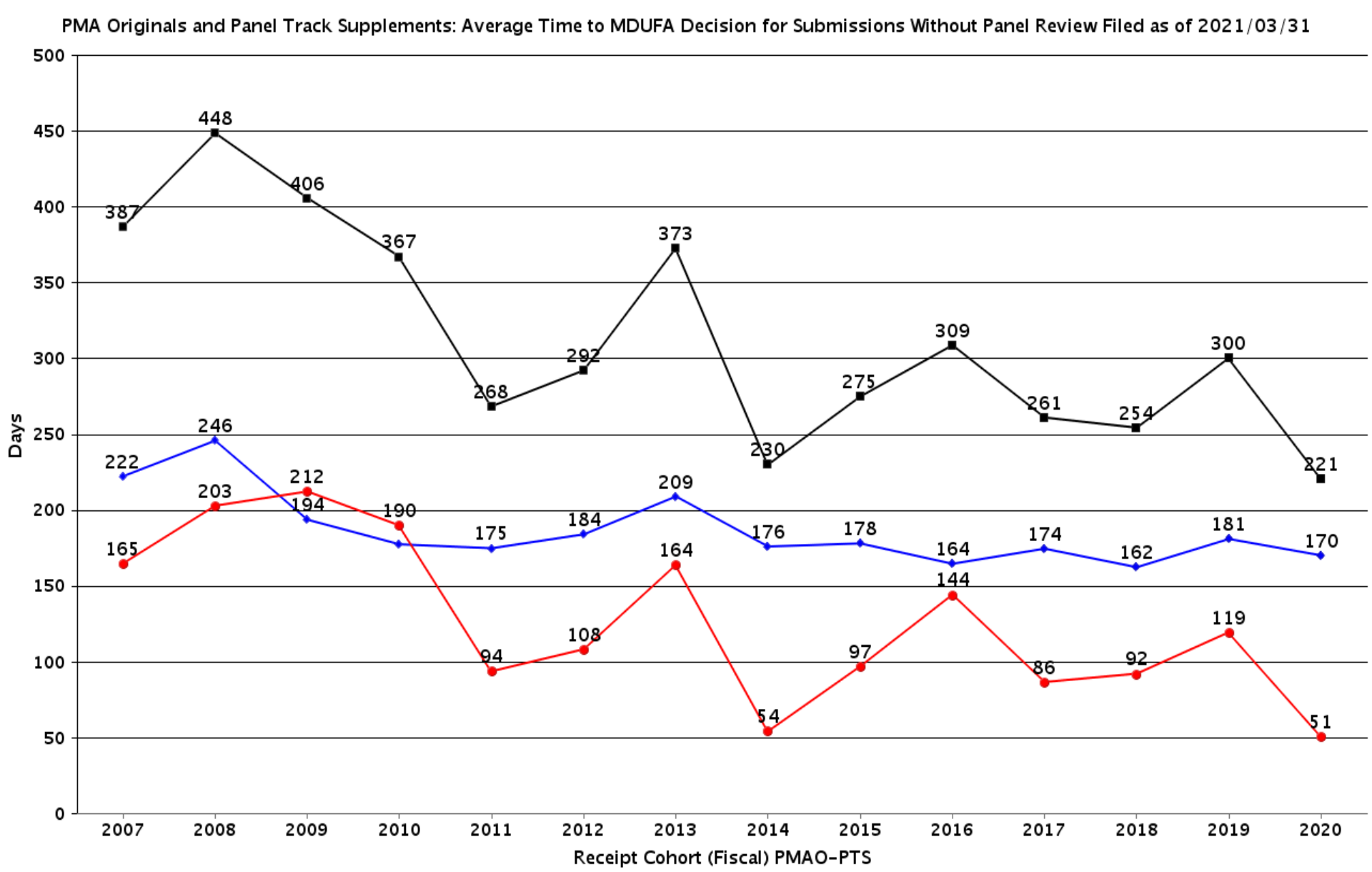
Numbers Filed/Closed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/1; 2020 = 1/1

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



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


PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2021/03/31
Days
Fiscal Year (Filed Cohort)
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020
0 50 100 150 200 250 300 350 400 450 500
389 431 440 388 269 312 393 248 287 344 283 284 339 229
220 257 208 197 173 184 182 177 180 165 172 170 198 172
169 174 232 197 96 128 211 71 107 179 110 115 141 57
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 = 32/31; 2020 = 43/27
♦ Avg FDA Days to MDUFA Decision PMAO ● Avg MFR Days to MDUFA Decision PMAO ■ Avg Total Days to MDUFA Decision PMAO

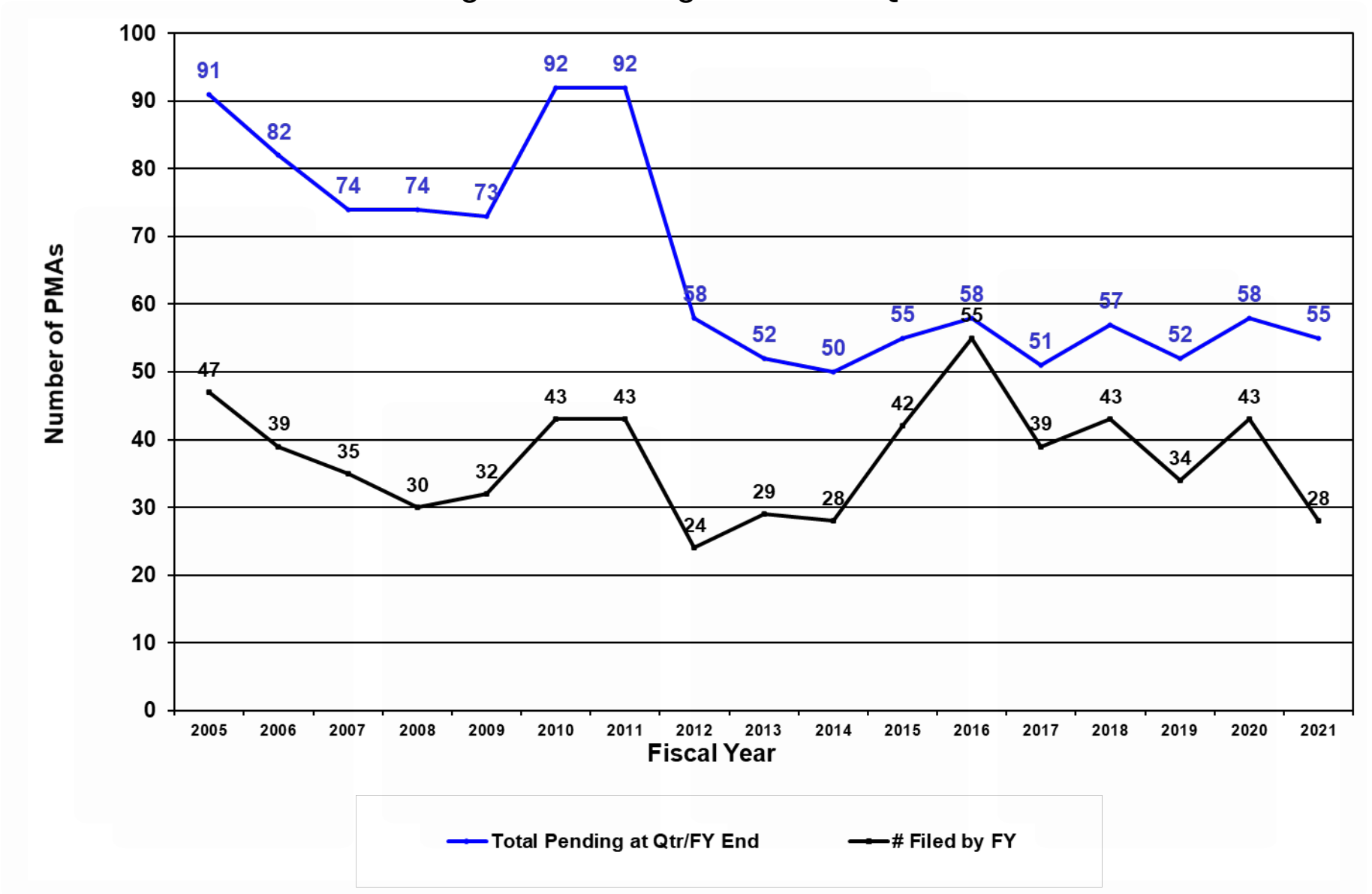


Numbers Filed: 2007 = 31; 2008 = 29; 2009 = 36; 2010 = 50; 2011 = 37; 2012 = 32; 2013 = 27; 2014 = 36; 2015 = 62; 2016 = 70; 2017 = 60; 2018 = 66; 2019 = 53; 2020 = 70

◆ Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ■ Avg Total Days to MDUFA Decision PMAO-PTS

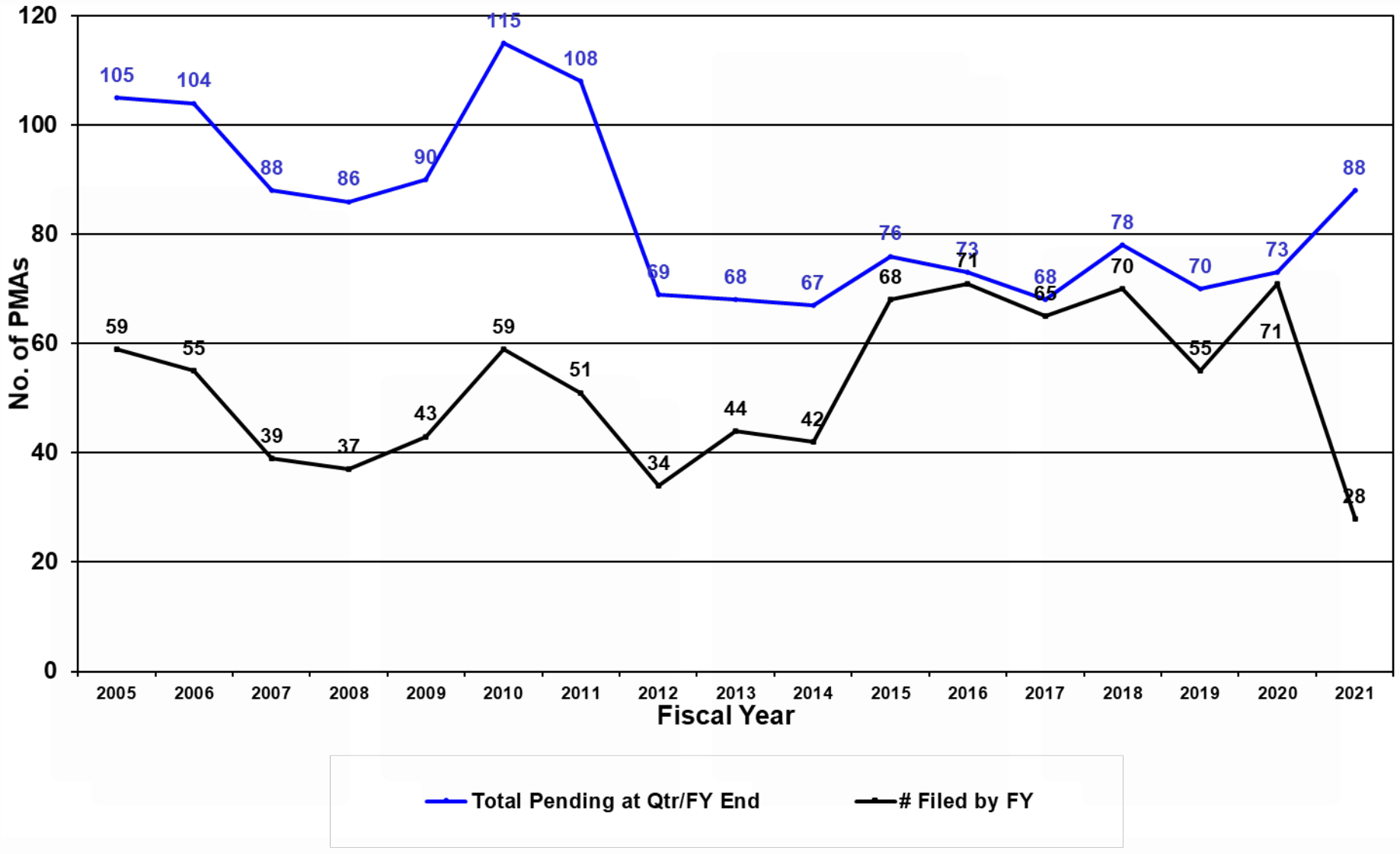
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

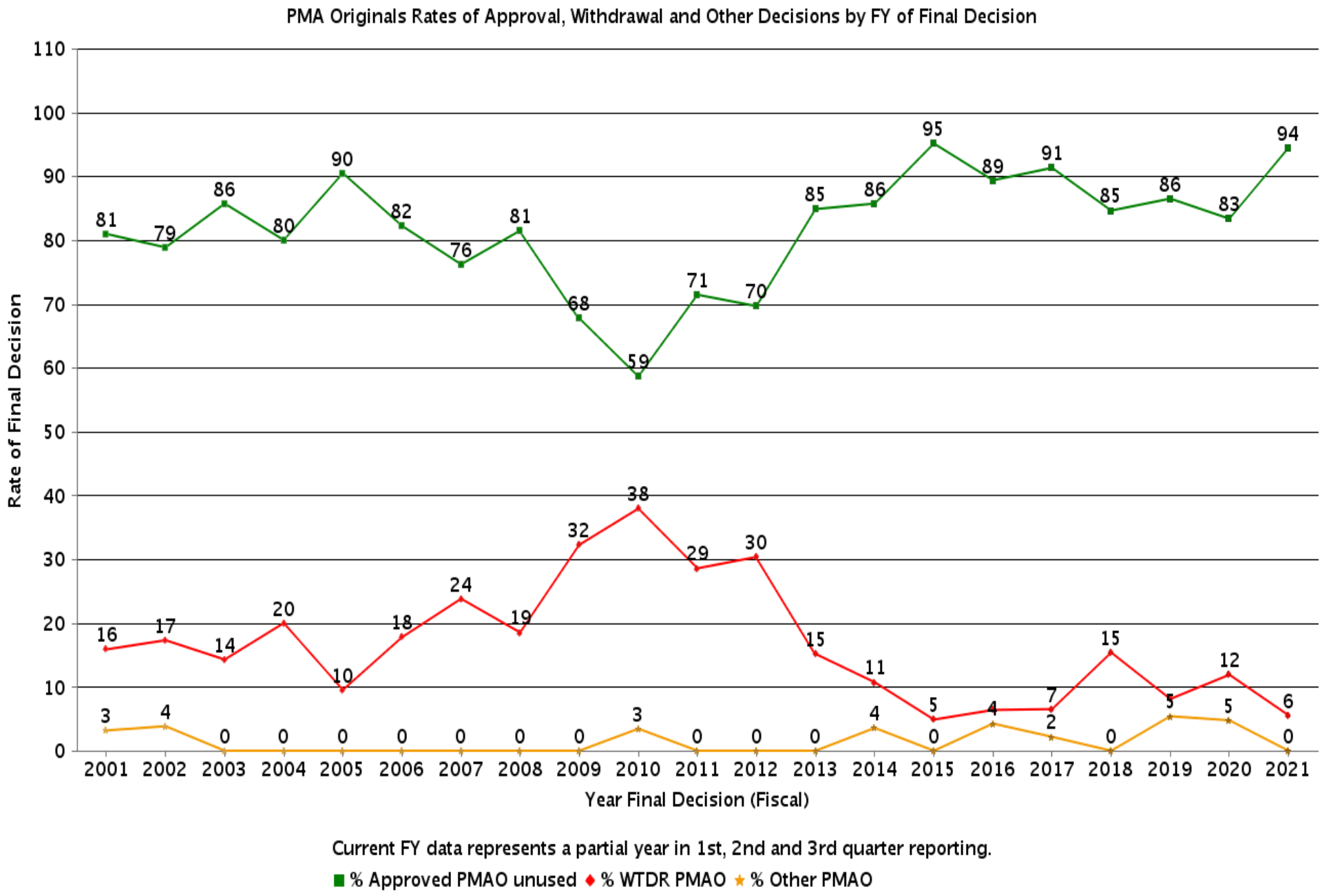


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

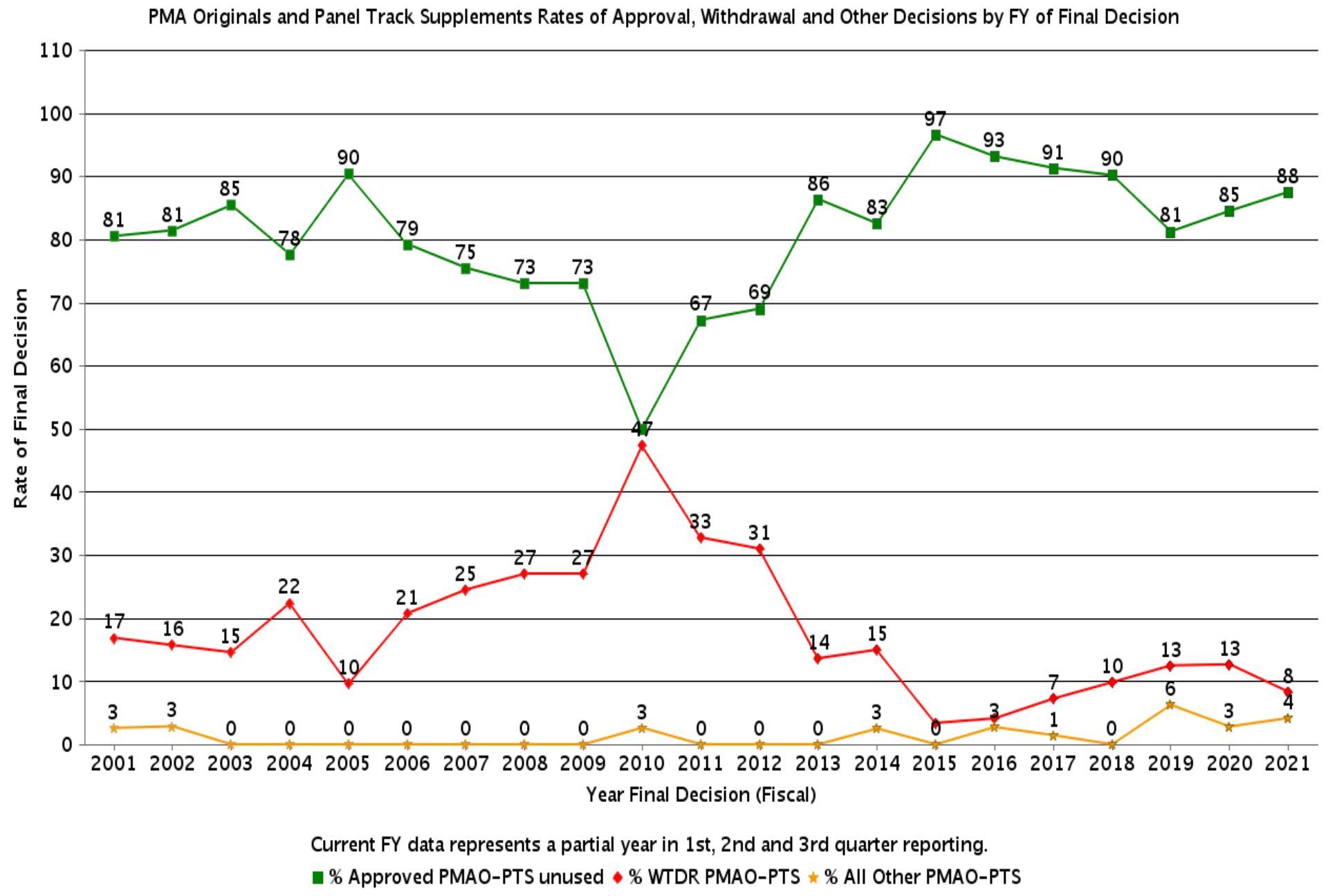
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



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

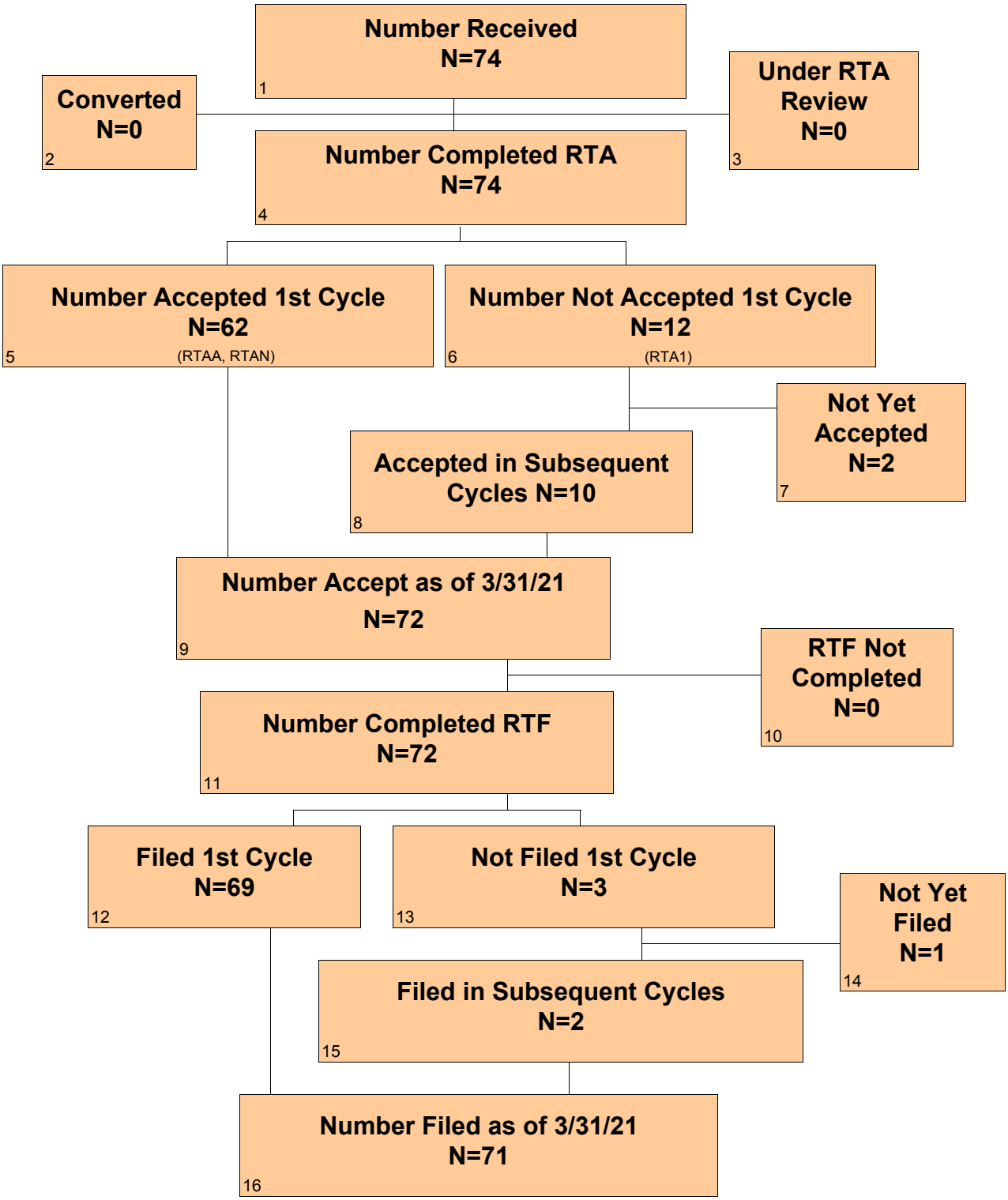


Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

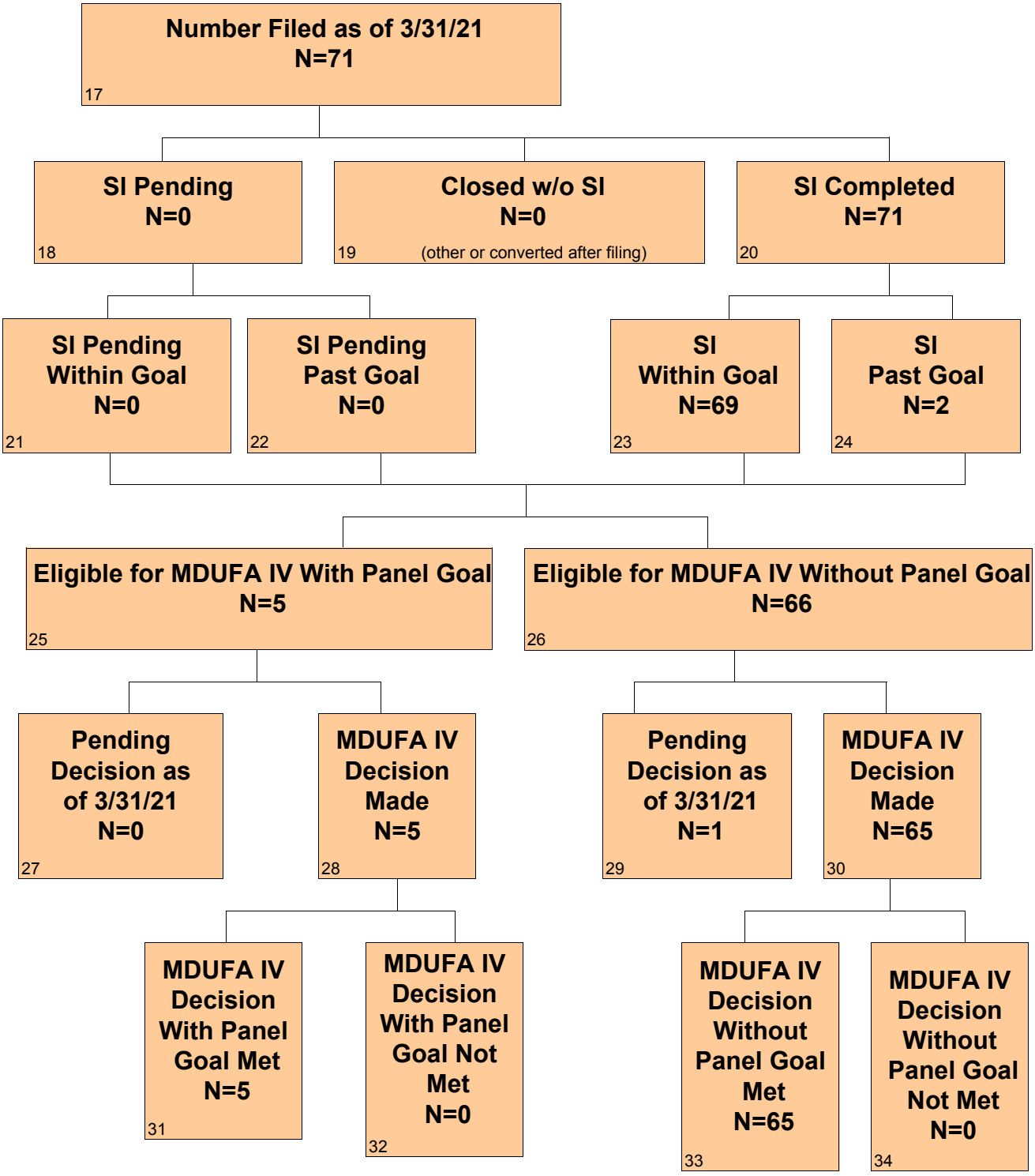


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

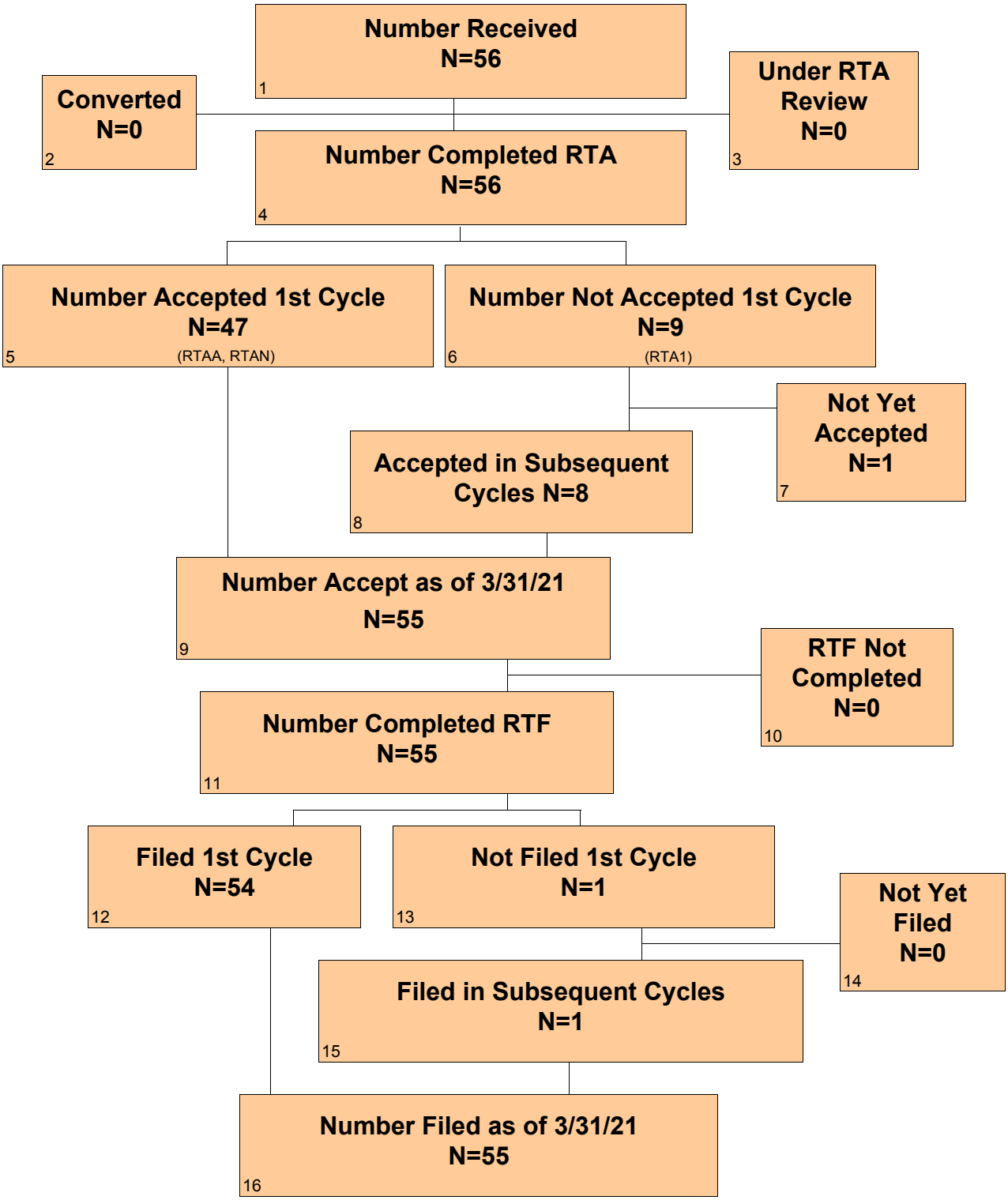
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/21



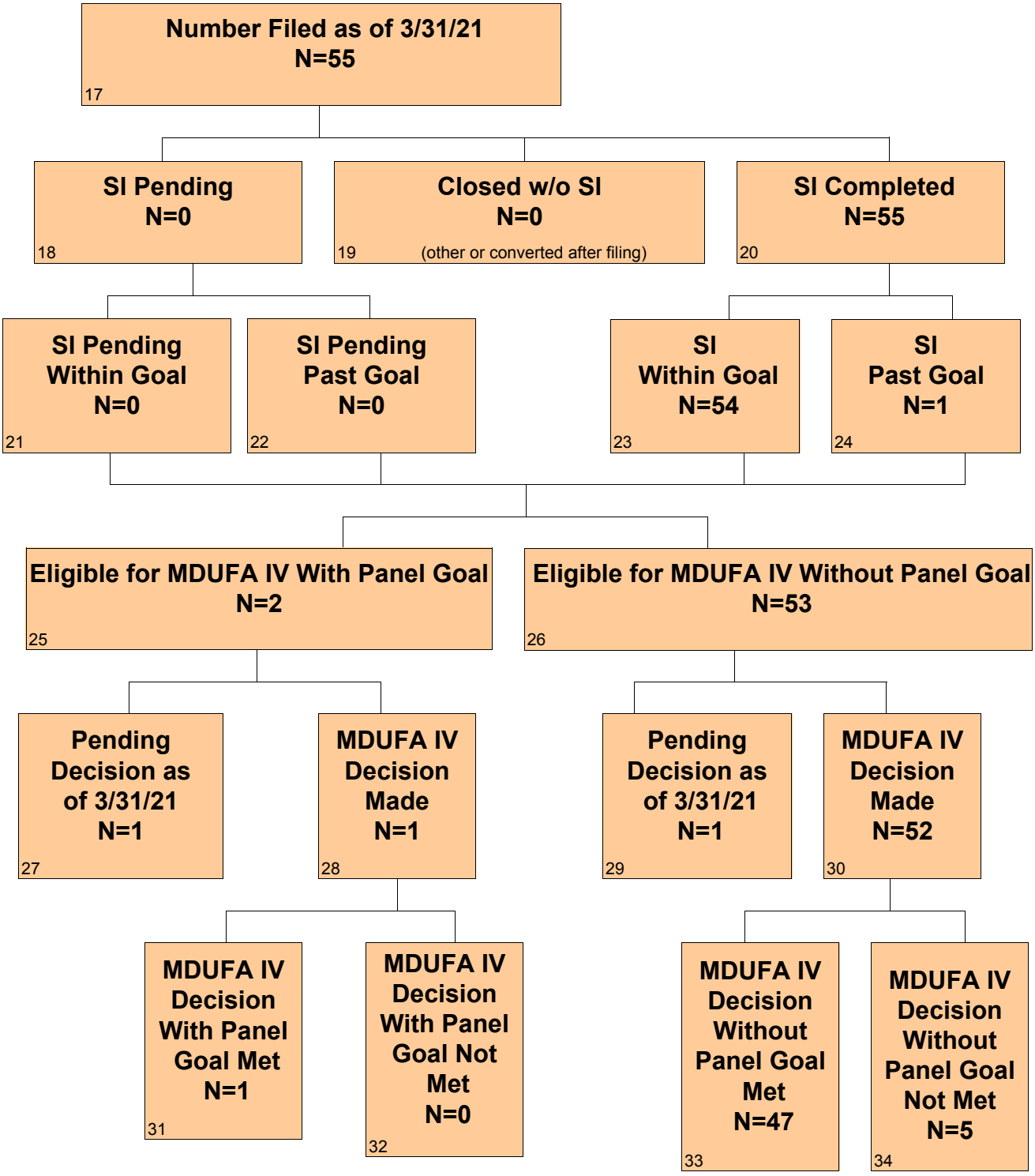
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/21 Continued



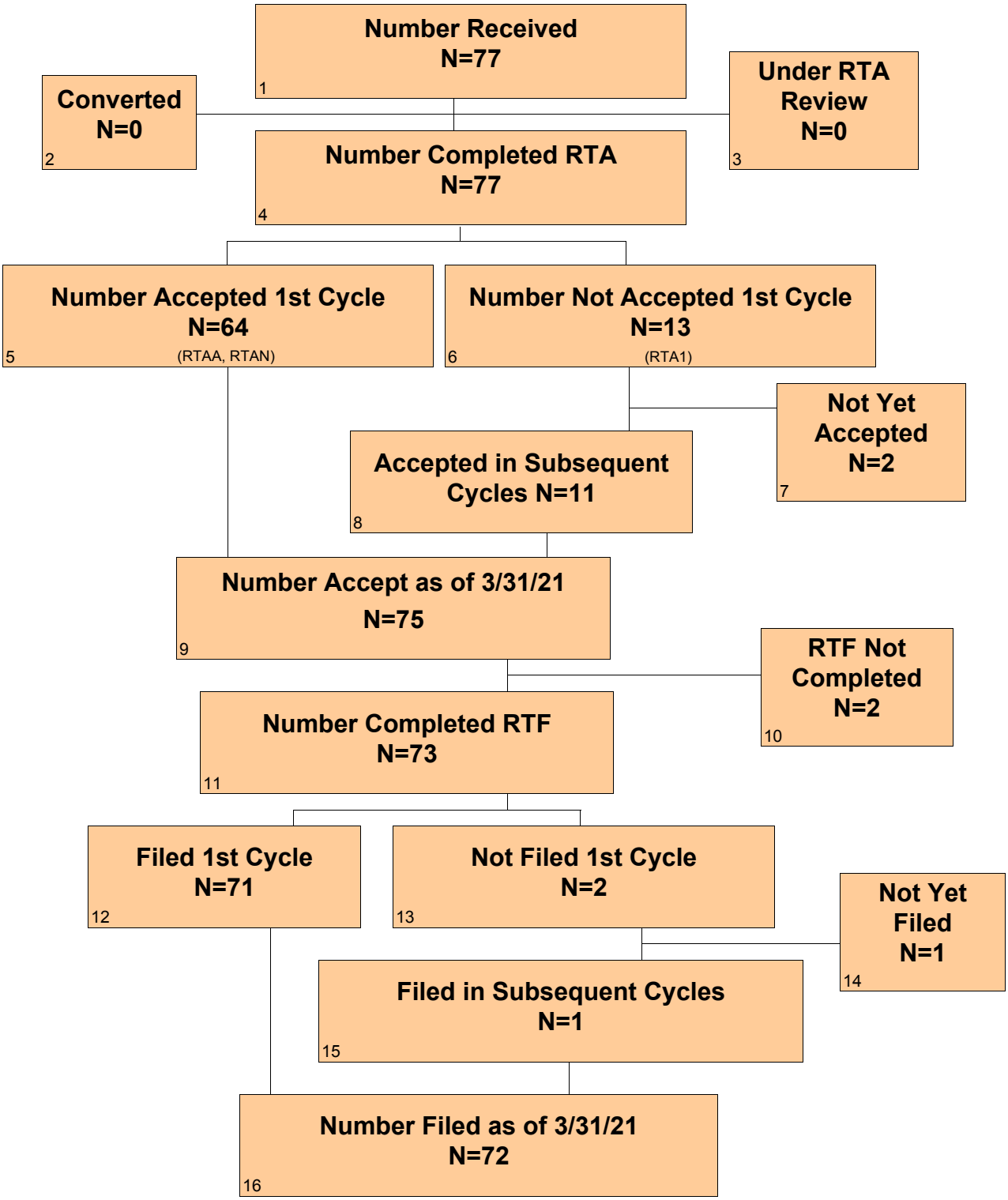
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/21



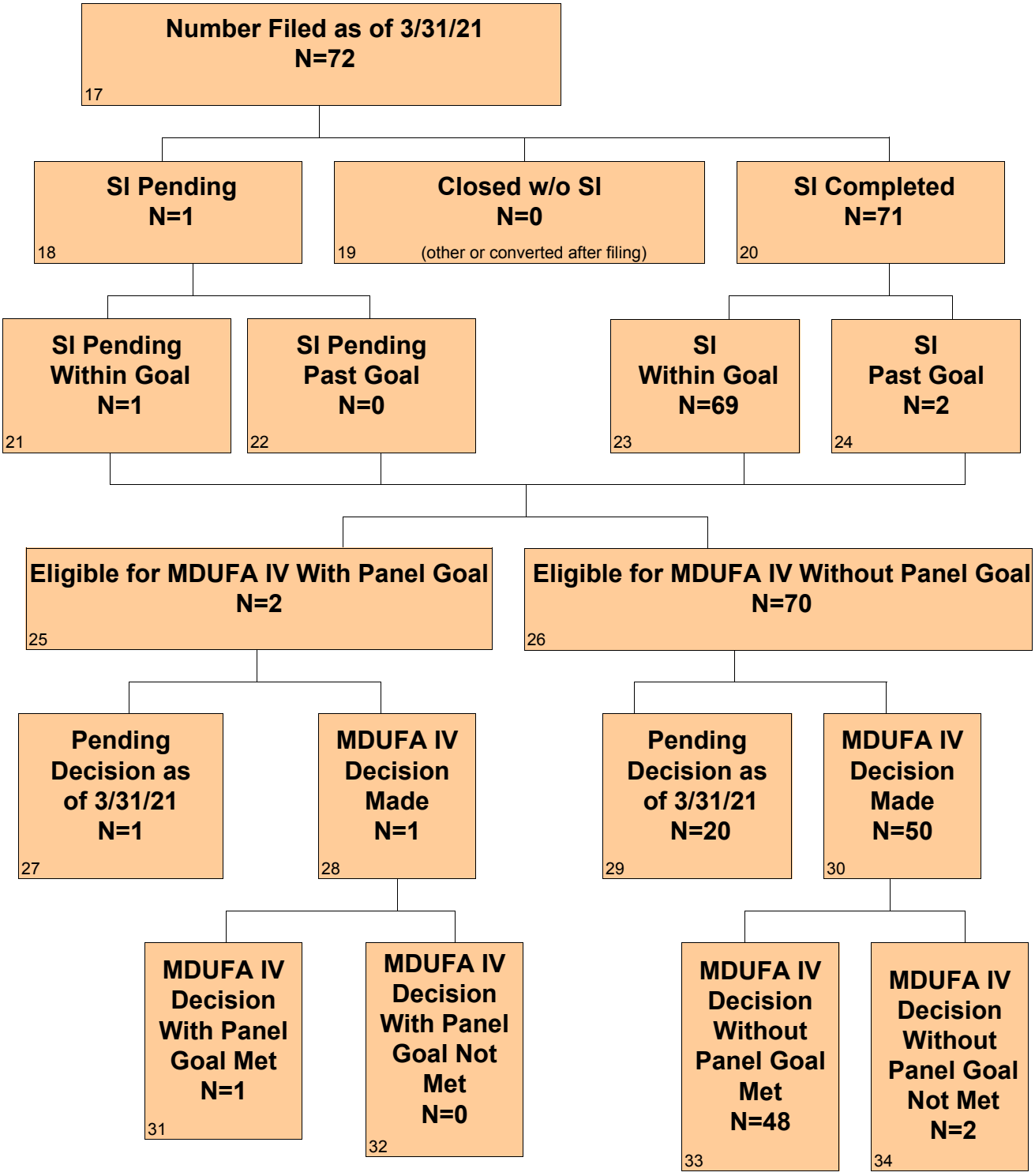
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/21 Continued



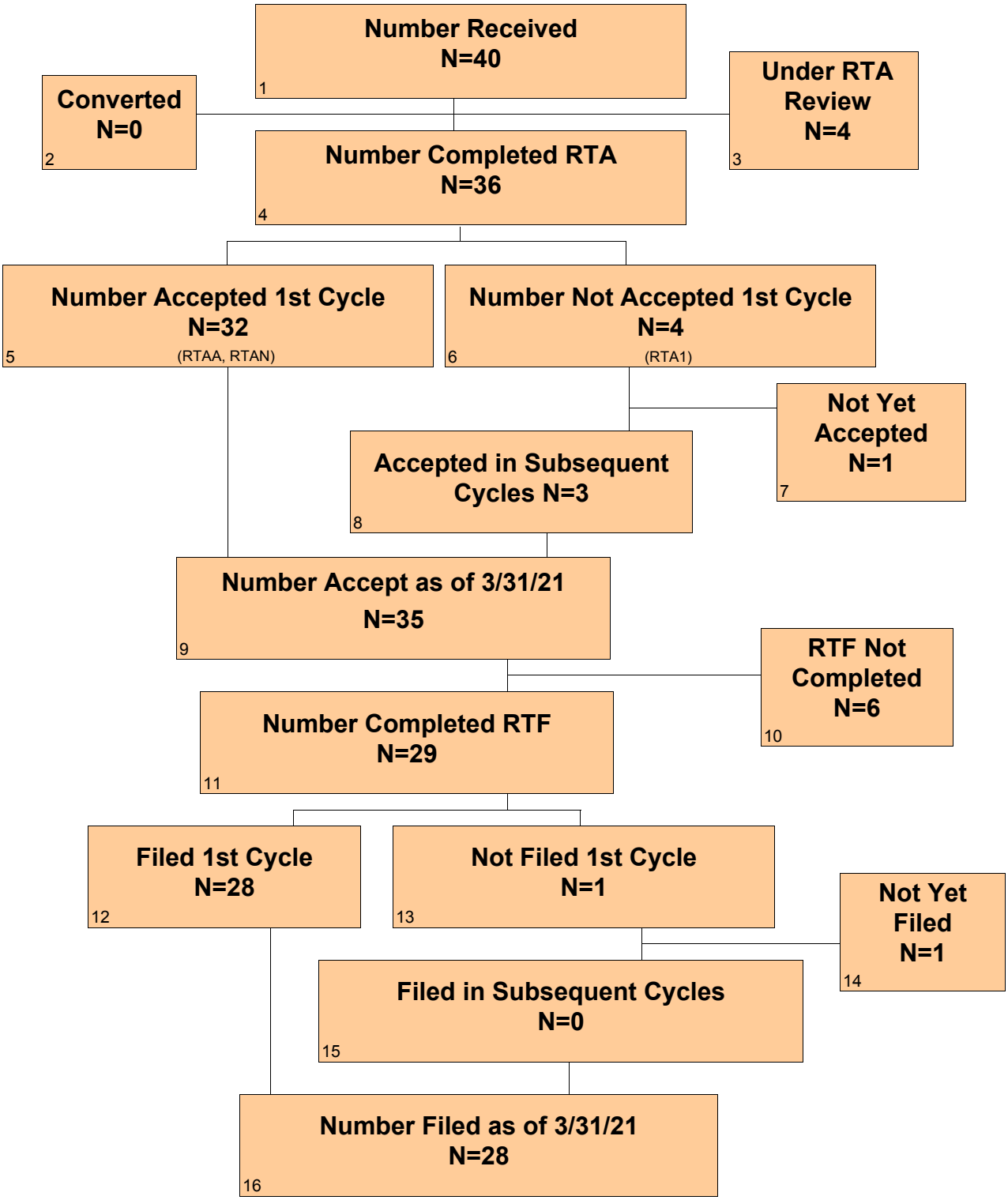
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 3/31/21



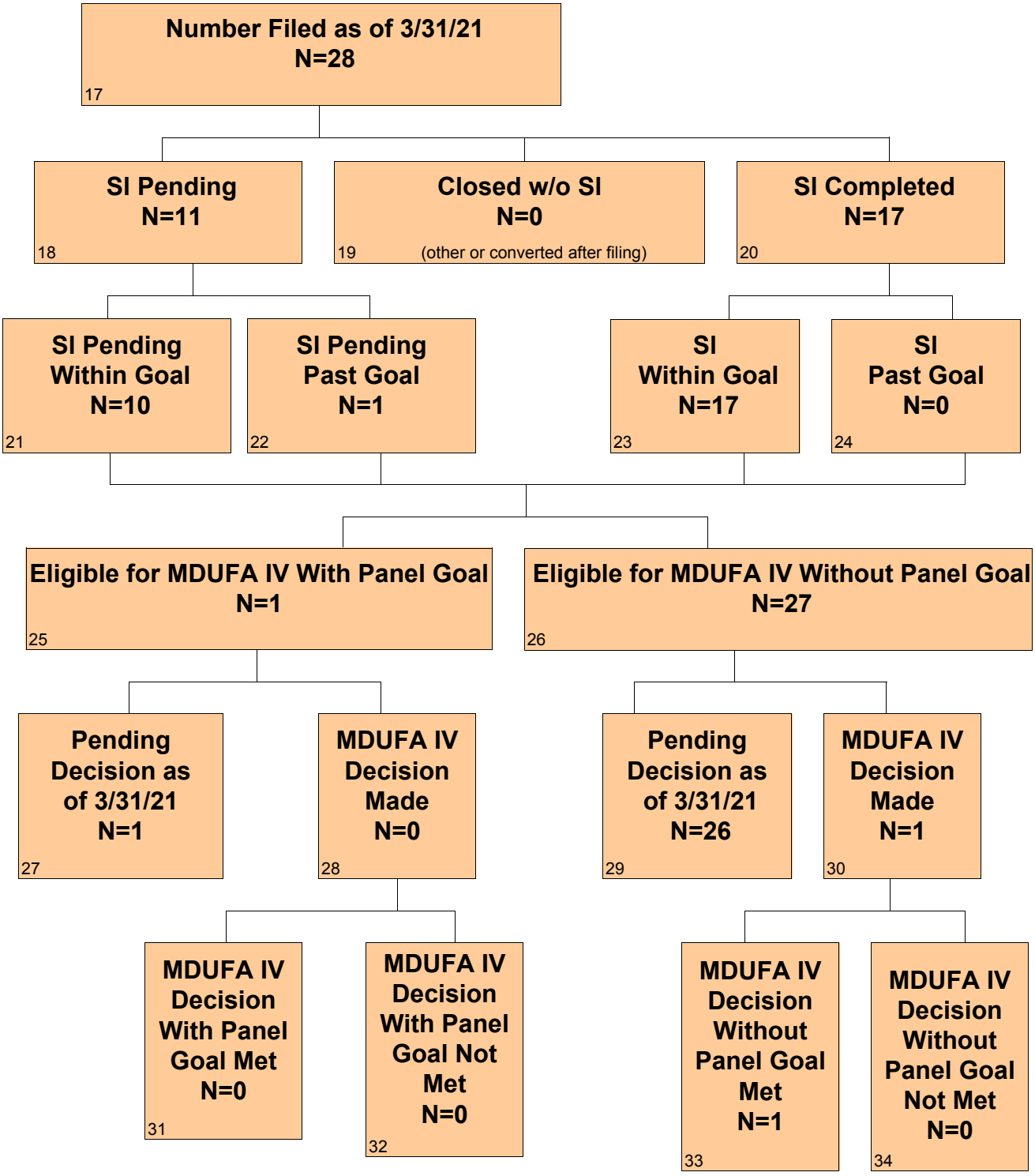
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 3/31/21 Continued



CDRH PMA Original and Panel Track Supplements - FY 2021 as of 3/31/21



CDRH PMA Original and Panel Track Supplements - FY 2021 as of 3/31/21 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	40	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	62	46	63	28	
Number Without a RTA Review and > 15 Days Since Date Received	0	1	1	4	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	4	
Number Not Accepted for Filing Review	12	9	13	4	
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	16.88%	11.11%	

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	40	
Number Accepted	62	47	64	32	
Completed RTF	72	55	73	29	
Number Not Filed	3	1	2	1	
Rate of Submissions Not Filed	4.17%	1.82%	2.74%	3.45%	

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	72	28	
SI Goal Met	69	54	69	17	
SI Goal Not Met	2	1	2	0	
SI Pending Within Goal	0	0	1	10	
SI Pending Past Goal	0	0	0	1	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	97.18%	98.18%	97.18%	94.44%	

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	71	17	
Average Number of FDA Days to Substantive Interaction	87.03	89.95	88.48	88.29	
20th Percentile FDA Days to Substantive Interaction	84	87	88	88	
40th Percentile FDA Days to Substantive Interaction	88	88	88	88	
60th Percentile FDA Days to Substantive Interaction	90	89	90	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	178	246	135	90	

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	70	27	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	65	52	50	1	
MDUFA IV Decision Goal Met	65	47	48	1	
PMAs Pending MDUFA IV Decision	1	1	20	26	
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	100.00%	90.38%	94.12%	100.00%	

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	2	1	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	5	1	1	0	
MDUFA IV Decision Goal Met	5	1	1	0	
PMAs Pending MDUFA IV Decision	0	1	1	1	
PMAs Pending MDUFA IV Decision Past Goal	0	1	0	0	
Current Performance Percent Goal Met	100.00%	50.00%	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	52	50	1	
Average FDA Days to MDUFA IV Decision	162.15	180.79	169.96	128.00	
20th Percentile FDA Days to MDUFA IV Decision	144	145	170	128	
40th Percentile FDA Days to MDUFA IV Decision	177	177	179	128	
60th Percentile FDA Days to MDUFA IV Decision	178	180	180	128	
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	128	
Maximum FDA Days to MDUFA IV Decision	279	338	406	128	
Average Industry Days to MDUFA IV Decision	93.18	119.35	50.84	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	18	26	21	0	
60th Percentile Industry Days to MDUFA IV Decision	88	122	53	0	
80th Percentile Industry Days to MDUFA IV Decision	162	186	82	0	
Maximum Industry Days to MDUFA IV Decision	360	529	257	0	
Average Total Days to MDUFA IV Decision	255.34	300.13	220.80	128.00	
20th Percentile Total Days to MDUFA IV Decision	167	175	175	128	
40th Percentile Total Days to MDUFA IV Decision	180	203	182	128	
60th Percentile Total Days to MDUFA IV Decision	257	302	230	128	
80th Percentile Total Days to MDUFA IV Decision	342	417	262	128	
Maximum Total Days to MDUFA IV Decision	540	705	458	128	

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	1	1	0	
Average FDA Days to MDUFA IV Decision	265.80	175.00	318.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	193	175	318	0	
40th Percentile FDA Days to MDUFA IV Decision	267	175	318	0	
60th Percentile FDA Days to MDUFA IV Decision	316	175	318	0	
80th Percentile FDA Days to MDUFA IV Decision	320	175	318	0	
Maximum FDA Days to MDUFA IV Decision	322	175	318	0	
Average Industry Days to MDUFA IV Decision	19.00	83.00	63.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
40th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
60th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
80th Percentile Industry Days to MDUFA IV Decision	19	83	63	0	
Maximum Industry Days to MDUFA IV Decision	95	83	63	0	
Average Total Days to MDUFA IV Decision	284.80	258.00	381.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	256	258	381	0	
40th Percentile Total Days to MDUFA IV Decision	297	258	381	0	
60th Percentile Total Days to MDUFA IV Decision	316	258	381	0	
80th Percentile Total Days to MDUFA IV Decision	320	258	381	0	
Maximum Total Days to MDUFA IV Decision	322	258	381	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	70	27	
Number with MDUFA IV Decision	65	52	50	1	
Number of Withdrawal	6	3	3	0	
Number of Not Approvable	8	7	4	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	9.23%	5.77%	6.00%	0.00%	
Rate of Not Approvable	12.31%	13.46%	8.00%	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	2	1	
Number With MDUFA IV Decision	5	1	1	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	4	1	1	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	80.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	5	3	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	266.60	206.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	235.00	22.00	0.00	

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	
Mean FDA Days for Submissions that Missed the Goal	0.00	639.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 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	3	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	3	10	0	
MDUFA IV Decision Goal Met	1	3	9	0	
PMAs Pending MDUFA IV Decision	0	1	1	3	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	90.00%	N/A	

***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	14	6	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	15	17	13	0	
MDUFA IV Decision Goal Met	15	13	12	0	
PMAs Pending MDUFA IV Decision	0	0	1	6	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	76.47%	92.31%	N/A	

***Includes submission that went to panel**

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	4	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	11	6	4	4	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	5	1	2	0	
Rate of Submissions Not Accepted for Filing Review	31.25%	14.29%	33.33%	0.00%	

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	4	
Number Accepted	11	6	4	4	
Completed RTF	16	7	6	4	
Number Not Filed	1	1	0	0	
Rate of Submissions Not Filed	6.25%	14.29%	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	4	
SI Goal Met	16	7	6	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	1	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	66.67%	

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	2	
Average Number of FDA Days to Substantive Interaction	87.13	88.86	88.00	89.50	
20th Percentile FDA Days to Substantive Interaction	86	88	87	89	
40th Percentile FDA Days to Substantive Interaction	87	89	88	89	
60th Percentile FDA Days to Substantive Interaction	90	90	88	90	
80th Percentile FDA Days to Substantive Interaction	90	90	88	90	
Maximum FDA Days to Substantive Interaction	90	90	90	90	

Table 1.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA 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	4	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	15	7	4	0	
MDUFA IV Decision Goal Met	15	7	4	0	
PMAs Pending MDUFA IV Decision	0	0	2	4	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (with Panel Review) MDUFA 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	0	0	0	
MDUFA IV Decision Goal Met	1	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	4	0	
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	176	179	180	0	
40th Percentile FDA Days to MDUFA IV Decision	178	180	180	0	
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	0	
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	0	
Maximum FDA Days to MDUFA IV Decision	180	180	180	0	
Average Industry Days to MDUFA IV Decision	130.93	65.43	71.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	4	52	0	
40th Percentile Industry Days to MDUFA IV Decision	52	20	71	0	
60th Percentile Industry Days to MDUFA IV Decision	141	50	78	0	
80th Percentile Industry Days to MDUFA IV Decision	278	148	92	0	
Maximum Industry Days to MDUFA IV Decision	360	180	108	0	
Average Total Days to MDUFA IV Decision	308.27	244.57	251.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	178	184	232	0	
40th Percentile Total Days to MDUFA IV Decision	232	200	251	0	
60th Percentile Total Days to MDUFA IV Decision	321	230	258	0	
80th Percentile Total Days to MDUFA IV Decision	450	328	272	0	
Maximum Total Days to MDUFA IV Decision	528	359	288	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	
Average FDA Days to MDUFA IV Decision	176.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	
40th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	
60th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	
80th Percentile FDA Days to MDUFA IV Decision	176	0	0	0	
Maximum FDA Days to MDUFA IV Decision	176	0	0	0	
Average Industry Days to MDUFA IV Decision	95.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	
80th Percentile Industry Days to MDUFA IV Decision	95	0	0	0	
Maximum Industry Days to MDUFA IV Decision	95	0	0	0	
Average Total Days to MDUFA IV Decision	271.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	271	0	0	0	
40th Percentile Total Days to MDUFA IV Decision	271	0	0	0	
60th Percentile Total Days to MDUFA IV Decision	271	0	0	0	
80th Percentile Total Days to MDUFA IV Decision	271	0	0	0	
Maximum Total Days to MDUFA IV Decision	271	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	4	
Number with MDUFA IV Decision	15	7	4	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	4	1	2	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	26.67%	14.29%	50.00%	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	
Number With MDUFA IV Decision	1	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	1	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	N/A	N/A	N/A	
Rate of Not Approvable	100.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.12 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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.14 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.1 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	8	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	20	11	21	8	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	3	3	2	0	
Rate of Submissions Not Accepted for Filing Review	13.04%	21.43%	8.70%	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	8	
Number Accepted	20	11	21	8	
Completed RTF	22	14	23	7	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	4.55%	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	7	
SI Goal Met	22	14	22	6	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	1	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

Table 1.4 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	22	6	
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.18	89.67	
20th Percentile FDA Days to Substantive Interaction	84	85	87	90	
40th Percentile FDA Days to Substantive Interaction	87	88	88	90	
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	90	90	90	90	

Table 1.5 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	7	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	21	12	15	1	
MDUFA IV Decision Goal Met	21	12	15	1	
PMAs Pending MDUFA IV Decision	0	0	7	6	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	1	1	0	
MDUFA IV Decision Goal Met	1	1	1	0	
PMAs Pending MDUFA IV Decision	0	1	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	1	0	0	
Current Performance Percent Goal Met	100.00%	50.00%	100.00%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	21	12	15	1	
Average FDA Days to MDUFA IV Decision	174.00	178.92	177.87	128.00	
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	128	
40th Percentile FDA Days to MDUFA IV Decision	178	178	178	128	
60th Percentile FDA Days to MDUFA IV Decision	179	180	179	128	
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	128	
Maximum FDA Days to MDUFA IV Decision	279	295	180	128	
Average Industry Days to MDUFA IV Decision	51.48	107.00	29.20	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	10	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	67	0	0	
60th Percentile Industry Days to MDUFA IV Decision	45	122	27	0	
80th Percentile Industry Days to MDUFA IV Decision	91	171	62	0	
Maximum Industry Days to MDUFA IV Decision	162	322	127	0	
Average Total Days to MDUFA IV Decision	225.48	285.92	207.07	128.00	
20th Percentile Total Days to MDUFA IV Decision	168	170	177	128	
40th Percentile Total Days to MDUFA IV Decision	180	245	179	128	
60th Percentile Total Days to MDUFA IV Decision	229	302	207	128	
80th Percentile Total Days to MDUFA IV Decision	324	363	239	128	
Maximum Total Days to MDUFA IV Decision	340	501	307	128	

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	1	1	0	
Average FDA Days to MDUFA IV Decision	197.00	175.00	318.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	197	175	318	0	
40th Percentile FDA Days to MDUFA IV Decision	197	175	318	0	
60th Percentile FDA Days to MDUFA IV Decision	197	175	318	0	
80th Percentile FDA Days to MDUFA IV Decision	197	175	318	0	
Maximum FDA Days to MDUFA IV Decision	197	175	318	0	
Average Industry Days to MDUFA IV Decision	0.00	83.00	63.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
40th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
60th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
80th Percentile Industry Days to MDUFA IV Decision	0	83	63	0	
Maximum Industry Days to MDUFA IV Decision	0	83	63	0	
Average Total Days to MDUFA IV Decision	197.00	258.00	381.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	197	258	381	0	
40th Percentile Total Days to MDUFA IV Decision	197	258	381	0	
60th Percentile Total Days to MDUFA IV Decision	197	258	381	0	
80th Percentile Total Days to MDUFA IV Decision	197	258	381	0	
Maximum Total Days to MDUFA IV Decision	197	258	381	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	7	
Number with MDUFA IV Decision	21	12	15	1	
Number of Withdrawal	0	0	1	0	
Number of Not Approvable	1	1	1	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	6.67%	0.00%	
Rate of Not Approvable	4.76%	8.33%	6.67%	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	
Number With MDUFA IV Decision	1	1	1	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	1	1	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	0.00%	100.00%	100.00%	N/A	

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

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

Table 1.12 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	
Mean FDA Days for Submissions that Missed the Goal	0.00	639.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.14 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.1 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	2	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	8	3	6	2	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	1	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	1	0	0	0	
Rate of Submissions Not Accepted for Filing Review	11.11%	0.00%	0.00%	0.00%	

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	2	
Number Accepted	8	3	7	2	
Completed RTF	9	3	7	2	
Number Not Filed	1	0	1	0	
Rate of Submissions Not Filed	11.11%	0.00%	14.29%	0.00%	

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

Substantive Interaction (SI) Goal	FY 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	2	
SI Goal Met	8	3	6	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

Table 1.4 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	2	
Average Number of FDA Days to Substantive Interaction	99.50	139.67	89.17	88.00	
20th Percentile FDA Days to Substantive Interaction	87	86	88	88	
40th Percentile FDA Days to Substantive Interaction	88	87	89	88	
60th Percentile FDA Days to Substantive Interaction	90	119	90	88	
80th Percentile FDA Days to Substantive Interaction	91	182	90	88	
Maximum FDA Days to Substantive Interaction	178	246	90	88	

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	6	2	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	5	3	0	0	
MDUFA IV Decision Goal Met	5	3	0	0	
PMAs Pending MDUFA IV Decision	0	0	6	2	
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	100.00%	100.00%	0.00%	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	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	3	0	0	0	
MDUFA IV Decision Goal Met	3	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	N/A	N/A	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	3	0	0	
Average FDA Days to MDUFA IV Decision	178.00	228.33	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	159	172	0	0	
40th Percentile FDA Days to MDUFA IV Decision	177	177	0	0	
60th Percentile FDA Days to MDUFA IV Decision	179	212	0	0	
80th Percentile FDA Days to MDUFA IV Decision	197	275	0	0	
Maximum FDA Days to MDUFA IV Decision	266	338	0	0	
Average Industry Days to MDUFA IV Decision	102.20	121.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	77	2	0	0	
40th Percentile Industry Days to MDUFA IV Decision	97	5	0	0	
60th Percentile Industry Days to MDUFA IV Decision	108	76	0	0	
80th Percentile Industry Days to MDUFA IV Decision	122	217	0	0	
Maximum Industry Days to MDUFA IV Decision	163	357	0	0	
Average Total Days to MDUFA IV Decision	280.20	349.33	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	248	247	0	0	
40th Percentile Total Days to MDUFA IV Decision	270	308	0	0	
60th Percentile Total Days to MDUFA IV Decision	285	375	0	0	
80th Percentile Total Days to MDUFA IV Decision	302	450	0	0	
Maximum Total Days to MDUFA IV Decision	350	524	0	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	0	0	
Average FDA Days to MDUFA IV Decision	318.67	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	316	0	0	0	
40th Percentile FDA Days to MDUFA IV Decision	319	0	0	0	
60th Percentile FDA Days to MDUFA IV Decision	320	0	0	0	
80th Percentile FDA Days to MDUFA IV Decision	321	0	0	0	
Maximum FDA Days to MDUFA IV Decision	322	0	0	0	
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	
Average Total Days to MDUFA IV Decision	318.67	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	316	0	0	0	
40th Percentile Total Days to MDUFA IV Decision	319	0	0	0	
60th Percentile Total Days to MDUFA IV Decision	320	0	0	0	
80th Percentile Total Days to MDUFA IV Decision	321	0	0	0	
Maximum Total Days to MDUFA IV Decision	322	0	0	0	

Table 1.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices PMA Original and Panel-Track Supplements (Without Panel Review) 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	6	2	
Number with MDUFA IV Decision	5	3	0	0	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	20.00%	0.00%	N/A	N/A	
Rate of Not Approvable	0.00%	33.33%	N/A	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	0	0	
Number With MDUFA IV Decision	3	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	3	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	N/A	N/A	N/A	
Rate of Not Approvable	100.00%	N/A	N/A	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	1	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	233.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	43.00	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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.14 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.1 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	4	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	1	1	3	0	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted for Filing Review	2	1	2	3	
Rate of Submissions Not Accepted for Filing Review	66.67%	50.00%	40.00%	100.00%	

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	4	
Number Accepted	1	1	3	0	
Completed RTF	2	2	4	2	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	

Table 1.3 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 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	2	
SI Goal Met	1	2	4	1	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	2	4	1	
Average Number of FDA Days to Substantive Interaction	93.50	90.00	89.25	86.00	
20th Percentile FDA Days to Substantive Interaction	90	90	89	86	
40th Percentile FDA Days to Substantive Interaction	92	90	89	86	
60th Percentile FDA Days to Substantive Interaction	95	90	90	86	
80th Percentile FDA Days to Substantive Interaction	97	90	90	86	
Maximum FDA Days to Substantive Interaction	99	90	90	86	

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	2	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	2	2	0	
MDUFA IV Decision Goal Met	1	1	1	0	
PMAs Pending MDUFA IV Decision	1	0	1	2	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	50.00%	50.00%	N/A	

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	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	1	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	2	2	0	
Average FDA Days to MDUFA IV Decision	159.00	181.00	191.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	159	179	184	0	
40th Percentile FDA Days to MDUFA IV Decision	159	180	189	0	
60th Percentile FDA Days to MDUFA IV Decision	159	182	193	0	
80th Percentile FDA Days to MDUFA IV Decision	159	183	198	0	
Maximum FDA Days to MDUFA IV Decision	159	184	202	0	
Average Industry Days to MDUFA IV Decision	6.00	90.00	28.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	6	49	25	0	
40th Percentile Industry Days to MDUFA IV Decision	6	76	27	0	
60th Percentile Industry Days to MDUFA IV Decision	6	104	29	0	
80th Percentile Industry Days to MDUFA IV Decision	6	131	31	0	
Maximum Industry Days to MDUFA IV Decision	6	159	33	0	
Average Total Days to MDUFA IV Decision	165.00	271.00	219.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	165	231	215	0	
40th Percentile Total Days to MDUFA IV Decision	165	258	218	0	
60th Percentile Total Days to MDUFA IV Decision	165	284	220	0	
80th Percentile Total Days to MDUFA IV Decision	165	311	223	0	
Maximum Total Days to MDUFA IV Decision	165	337	225	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	0	0	
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
Maximum Total Days to MDUFA IV Decision	0	0	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	2	
Number with MDUFA IV Decision	1	2	2	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	1	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	100.00%	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	0	
Number With MDUFA IV Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

Table 1.11 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	1	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	184.00	202.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	21.00	23.00	0.00	

Table 1.12 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

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

Table 1.13 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.14 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.1 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	5	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	3	4	1	2	
Number Without a RTA Review and > 15 Days Since Date Received	0	1	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted for Filing Review	1	0	3	1	
Rate of Submissions Not Accepted for Filing Review	25.00%	0.00%	75.00%	33.33%	

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	5	
Number Accepted	3	5	1	2	
Completed RTF	4	5	3	2	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	

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

Substantive Interaction (SI) Goal	FY 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	2	
SI Goal Met	3	5	3	1	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	75.00%	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	1	
Average Number of FDA Days to Substantive Interaction	90.50	84.80	90.00	86.00	
20th Percentile FDA Days to Substantive Interaction	90	84	90	86	
40th Percentile FDA Days to Substantive Interaction	90	90	90	86	
60th Percentile FDA Days to Substantive Interaction	90	90	90	86	
80th Percentile FDA Days to Substantive Interaction	91	90	90	86	
Maximum FDA Days to Substantive Interaction	92	90	90	86	

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	3	2	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	4	5	2	0	
MDUFA IV Decision Goal Met	4	5	2	0	
PMAs Pending MDUFA IV Decision	0	0	1	2	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

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

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

Table 1.9 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) 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	3	2	
Number with MDUFA IV Decision	4	5	2	0	
Number of Withdrawal	0	1	1	0	
Number of Not Approvable	0	2	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	20.00%	50.00%	N/A	
Rate of Not Approvable	0.00%	40.00%	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	0	0	
Number With MDUFA IV Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

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

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

Table 1.12 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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.14 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.1 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	2	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	2	2	2	2	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	2	0	0	
Rate of Submissions Not Accepted for Filing Review	0.00%	50.00%	0.00%	0.00%	

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	2	
Number Accepted	2	2	2	2	
Completed RTF	2	3	2	2	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	

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

Substantive Interaction (SI) Goal	FY 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	2	
SI Goal Met	2	3	2	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

Table 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	1	
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50	80.00	
20th Percentile FDA Days to Substantive Interaction	84	88	88	80	
40th Percentile FDA Days to Substantive Interaction	86	89	88	80	
60th Percentile FDA Days to Substantive Interaction	87	89	89	80	
80th Percentile FDA Days to Substantive Interaction	89	90	89	80	
Maximum FDA Days to Substantive Interaction	90	90	89	80	

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	2	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	2	3	2	0	
MDUFA IV Decision Goal Met	2	3	2	0	
PMAs Pending MDUFA IV Decision	0	0	0	2	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

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

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

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	
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
Maximum Total Days to MDUFA IV Decision	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	2	
Number with MDUFA IV Decision	2	3	2	0	
Number of Withdrawal	0	1	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	33.33%	0.00%	N/A	
Rate of Not Approvable	0.00%	33.33%	0.00%	N/A	

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

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

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

Table 1.12 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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

Table 1.14 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	0	0	0	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	21	30	15	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	17	19	26	10	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	4	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted for Filing Review	0	2	4	0	
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	13.33%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	21	30	15	
Number Accepted	17	19	26	14	
Completed RTF	17	21	28	10	
Number Not Filed	0	0	1	1	
Rate of Submissions Not Filed	0.00%	0.00%	3.57%	10.00%	

Table 1.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
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	17	21	28	9	
SI Goal Met	17	20	26	4	
SI Goal Not Met	0	1	2	0	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	95.24%	92.86%	100.00%	

Table 1.4 OHT7 - Office of In Vitro Diagnostics and 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	17	21	28	4	
Average Number of FDA Days to Substantive Interaction	84.29	87.76	88.39	89.00	
20th Percentile FDA Days to Substantive Interaction	84	87	87	88	
40th Percentile FDA Days to Substantive Interaction	87	88	88	88	
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	90	91	135	90	

Table 1.5 OHT7 - Office of In Vitro Diagnostics and 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	17	21	28	8	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	17	20	25	0	
MDUFA IV Decision Goal Met	17	16	24	0	
PMAs Pending MDUFA IV Decision	0	1	3	8	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	80.00%	96.00%	N/A	

Table 1.6 OHT7 - Office of In Vitro Diagnostics and 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	1	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	1	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

Table 1.7 OHT7 - Office of In Vitro Diagnostics and 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	17	20	25	0	
Average FDA Days to MDUFA IV Decision	123.35	178.70	164.24	0.00	
20th Percentile FDA Days to MDUFA IV Decision	90	133	129	0	
40th Percentile FDA Days to MDUFA IV Decision	99	166	179	0	
60th Percentile FDA Days to MDUFA IV Decision	141	176	180	0	
80th Percentile FDA Days to MDUFA IV Decision	174	197	180	0	
Maximum FDA Days to MDUFA IV Decision	180	299	406	0	
Average Industry Days to MDUFA IV Decision	86.18	122.50	59.72	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	10	22	0	
60th Percentile Industry Days to MDUFA IV Decision	75	71	58	0	
80th Percentile Industry Days to MDUFA IV Decision	149	323	94	0	
Maximum Industry Days to MDUFA IV Decision	336	529	257	0	
Average Total Days to MDUFA IV Decision	209.53	301.20	223.96	0.00	
20th Percentile Total Days to MDUFA IV Decision	90	155	156	0	
40th Percentile Total Days to MDUFA IV Decision	139	178	182	0	
60th Percentile Total Days to MDUFA IV Decision	213	223	242	0	
80th Percentile Total Days to MDUFA IV Decision	266	482	274	0	
Maximum Total Days to MDUFA IV Decision	511	705	458	0	

Table 1.8 OHT7 - Office of In Vitro Diagnostics and 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	
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
Maximum Total Days to MDUFA IV Decision	0	0	0	0	

Table 1.9 OHT7 - Office of In Vitro Diagnostics and 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	17	21	28	8	
Number with MDUFA IV Decision	17	20	25	0	
Number of Withdrawal	5	1	1	0	
Number of Not Approvable	2	1	1	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	29.41%	5.00%	4.00%	N/A	
Rate of Not Approvable	11.76%	5.00%	4.00%	N/A	

Table 1.10 OHT7 - Office of In Vitro Diagnostics and 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	1	
Number With MDUFA IV Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

Table 1.11 OHT7 - Office of In Vitro Diagnostics and 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	4	1	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	183.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	288.50	0.00	0.00	

Table 1.12 OHT7 - Office of In Vitro Diagnostics and 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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.13 OHT7 - Office of In Vitro Diagnostics and 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	1	4	11	3	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	3	10	0	
MDUFA IV Decision Goal Met	1	3	9	0	
PMAs Pending MDUFA IV Decision	0	1	1	3	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	90.00%	N/A	

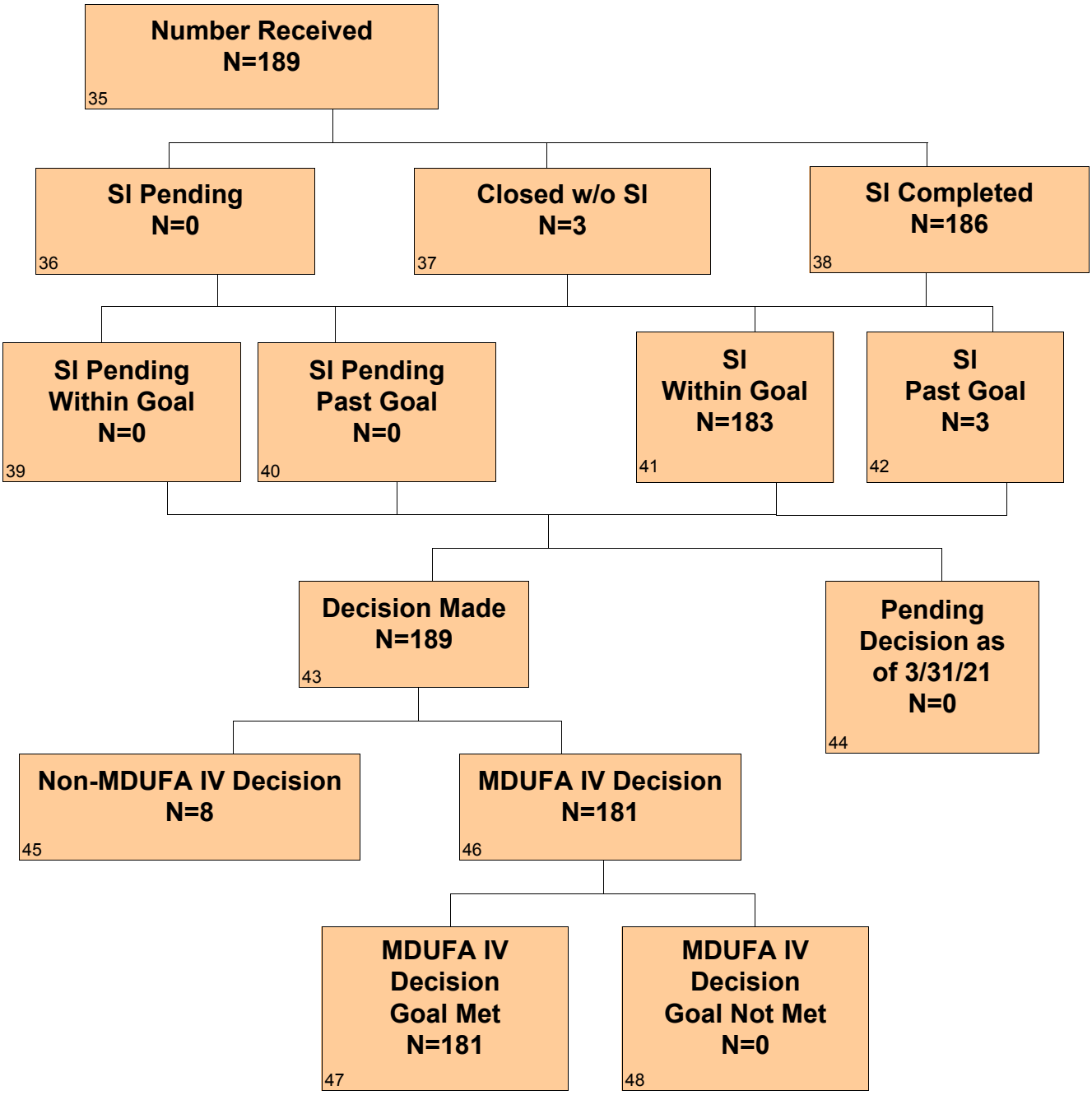
***Includes submission that went to panel**

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

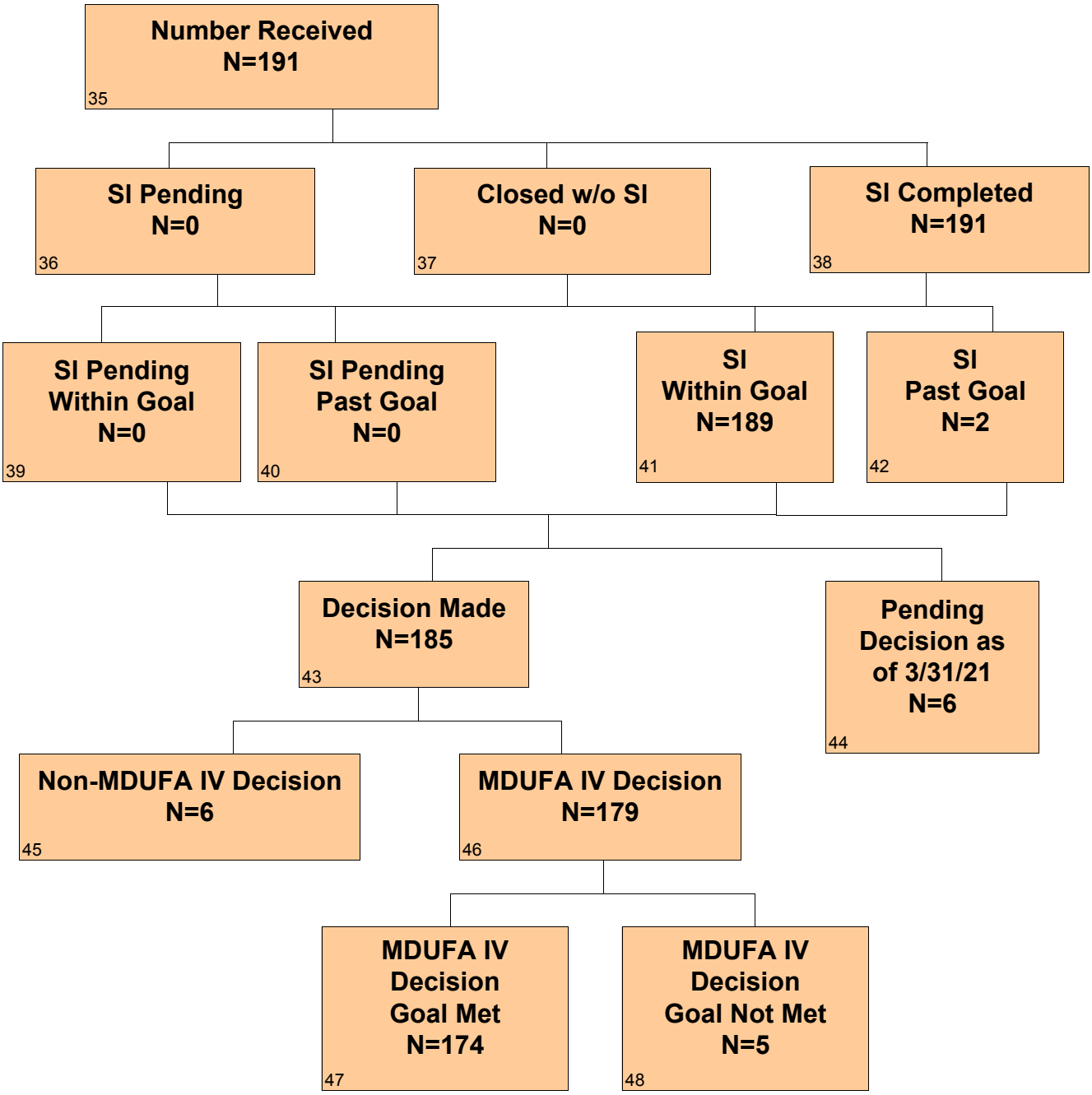
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	14	6	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	15	17	13	0	
MDUFA IV Decision Goal Met	15	13	12	0	
PMAs Pending MDUFA IV Decision	0	0	1	6	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	76.47%	92.31%	N/A	

***Includes submission that went to panel**

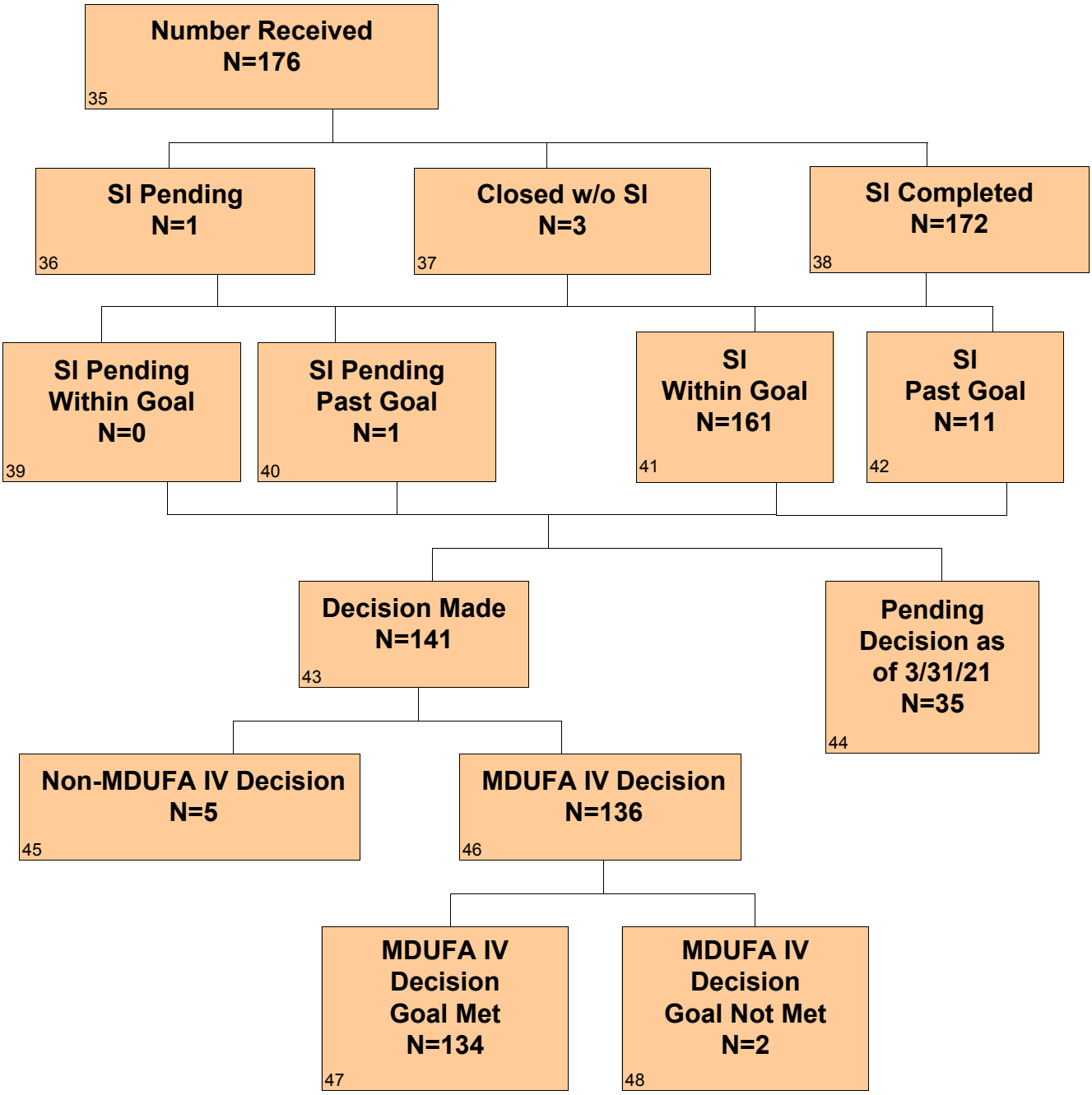
CDRH PMA 180 Day Supplements - FY 2018 as of 3/31/21



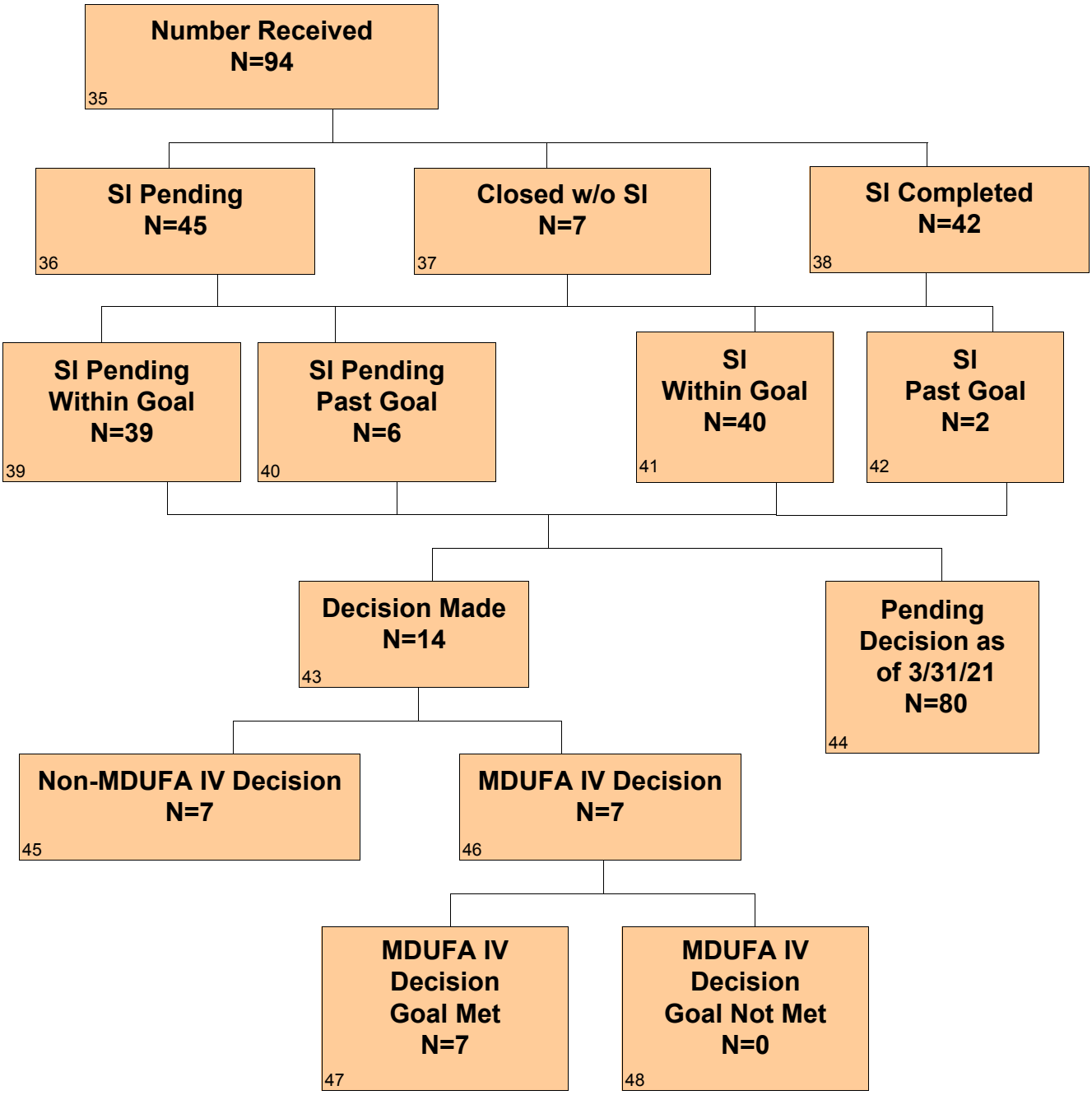
CDRH PMA 180 Day Supplements - FY 2019 as of 3/31/21



CDRH PMA 180 Day Supplements - FY 2020 as of 3/31/21



CDRH PMA 180 Day Supplements - FY 2021 as of 3/31/21



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	189	191	176	94	
SI Goal Met	183	189	161	40	
SI Goal Not Met	3	2	11	2	
SI Pending Within Goal	0	0	0	39	
SI Pending Past Goal	0	0	1	6	
Closed Without SI	3	0	3	7	
Current SI Performance Percent Goal Met	98.39%	98.95%	93.06%	83.33%	

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	189	191	176	94	
Non-MDUFA IV Decision	8	6	5	7	
MDUFA IV Decision	181	179	136	7	
MDUFA IV Decision Goal Met	181	174	134	7	
Supplements Pending MDUFA IV Decision	0	6	35	80	
Supplements Pending MDUFA IV Decision Past Goal	0	1	2	0	
Current Performance Percent Goal Met	100.00%	96.67%	97.10%	100.00%	

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	189	191	176	94	
Number with MDUFA IV Decision	181	179	136	7	
Number of Not Approvable	13	10	4	0	
Rate of Not Approvable	7.18%	5.59%	2.94%	0.00%	

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	4	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	216.40	259.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	8.20	31.25	0.00	

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 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	7	
SI Goal Met	20	36	28	4	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	3	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

Table 2.2 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	7	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	20	31	24	2	
MDUFA IV Decision Goal Met	20	30	24	2	
Supplements Pending MDUFA IV Decision	0	5	4	5	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	96.77%	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	7	
Number with MDUFA IV Decision	20	31	24	2	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	5.00%	3.23%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	302.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	41.00	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	44	
SI Goal Met	91	81	66	16	
SI Goal Not Met	1	0	4	1	
SI Pending Within Goal	0	0	0	20	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	2	0	0	7	
Current SI Performance Percent Goal Met	98.91%	100.00%	94.29%	94.12%	

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	44	
Non-MDUFA IV Decision	2	3	0	7	
MDUFA IV Decision	92	78	52	2	
MDUFA IV Decision Goal Met	92	78	52	2	
Supplements Pending MDUFA IV Decision	0	0	18	35	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	44	
Number with MDUFA IV Decision	92	78	52	2	
Number of Not Approvable	6	6	1	0	
Rate of Not Approvable	6.52%	7.69%	1.92%	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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 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	8	
SI Goal Met	14	15	16	6	
SI Goal Not Met	1	1	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	3	0	
Current SI Performance Percent Goal Met	93.33%	93.75%	100.00%	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	8	
Non-MDUFA IV Decision	0	2	5	0	
MDUFA IV Decision	15	14	11	0	
MDUFA IV Decision Goal Met	15	14	11	0	
Supplements Pending MDUFA IV Decision	0	0	3	8	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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	8	
Number with MDUFA IV Decision	15	14	11	0	
Number of Not Approvable	0	2	2	0	
Rate of Not Approvable	0.00%	14.29%	18.18%	N/A	

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

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

Table 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	7	
SI Goal Met	9	9	6	2	
SI Goal Not Met	0	1	1	0	
SI Pending Within Goal	0	0	0	4	
SI Pending Past Goal	0	0	0	1	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	90.00%	85.71%	66.67%	

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	7	
Non-MDUFA IV Decision	1	1	0	0	
MDUFA IV Decision	8	8	6	0	
MDUFA IV Decision Goal Met	8	5	6	0	
Supplements Pending MDUFA IV Decision	0	1	1	7	
Supplements Pending MDUFA IV Decision Past Goal	0	1	0	0	
Current Performance Percent Goal Met	100.00%	55.56%	100.00%	N/A	

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	7	
Number with MDUFA IV Decision	8	8	6	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	0	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	195.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	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	12	
SI Goal Met	12	16	23	6	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	6	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	1	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	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	12	
Non-MDUFA IV Decision	2	0	0	0	
MDUFA IV Decision	11	16	18	2	
MDUFA IV Decision Goal Met	11	15	18	2	
Supplements Pending MDUFA IV Decision	0	0	5	10	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	93.75%	100.00%	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	12	
Number with MDUFA IV Decision	11	16	18	2	
Number of Not Approvable	2	0	1	0	
Rate of Not Approvable	18.18%	0.00%	5.56%	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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	244.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	13.00	0.00	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	1	6	2	5	
SI Goal Met	1	6	2	3	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	2	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	60.00%	

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	1	6	2	5	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	6	1	0	
MDUFA IV Decision Goal Met	1	6	1	0	
Supplements Pending MDUFA IV Decision	0	0	1	5	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	1	6	2	5	
Number with MDUFA IV Decision	1	6	1	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

Table 2.4 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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 2.1 OHT7 - Office of In Vitro Diagnostics and 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	37	26	27	11	
SI Goal Met	36	26	20	3	
SI Goal Not Met	1	0	6	1	
SI Pending Within Goal	0	0	0	4	
SI Pending Past Goal	0	0	1	3	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	97.30%	100.00%	74.07%	42.86%	

Table 2.2 OHT7 - Office of In Vitro Diagnostics and 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	37	26	27	11	
Non-MDUFA IV Decision	3	0	0	0	
MDUFA IV Decision	34	26	24	1	
MDUFA IV Decision Goal Met	34	26	22	1	
Supplements Pending MDUFA IV Decision	0	0	3	10	
Supplements Pending MDUFA IV Decision Past Goal	0	0	2	0	
Current Performance Percent Goal Met	100.00%	100.00%	84.62%	100.00%	

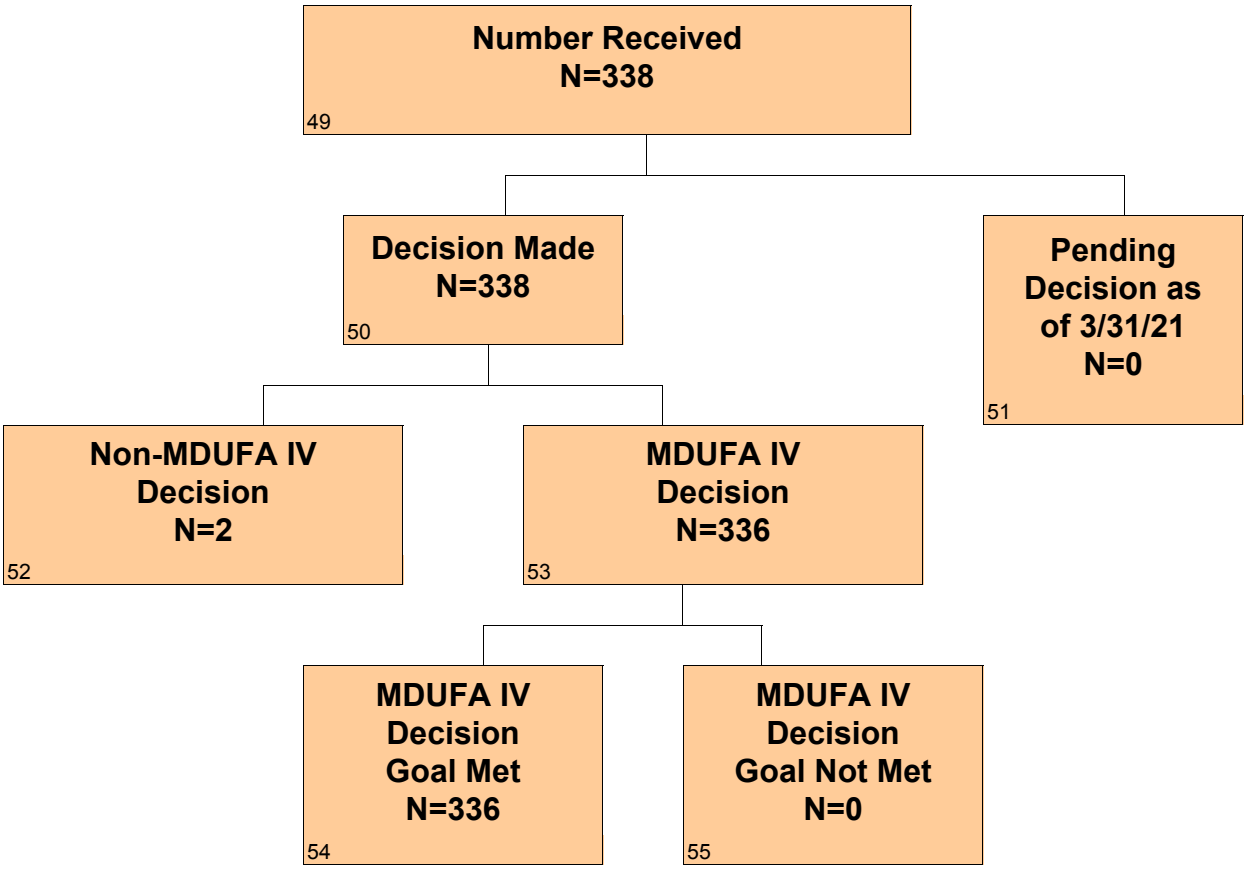
Table 2.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	26	27	11	
Number with MDUFA IV Decision	34	26	24	1	
Number of Not Approvable	4	1	0	0	
Rate of Not Approvable	11.76%	3.85%	0.00%	0.00%	

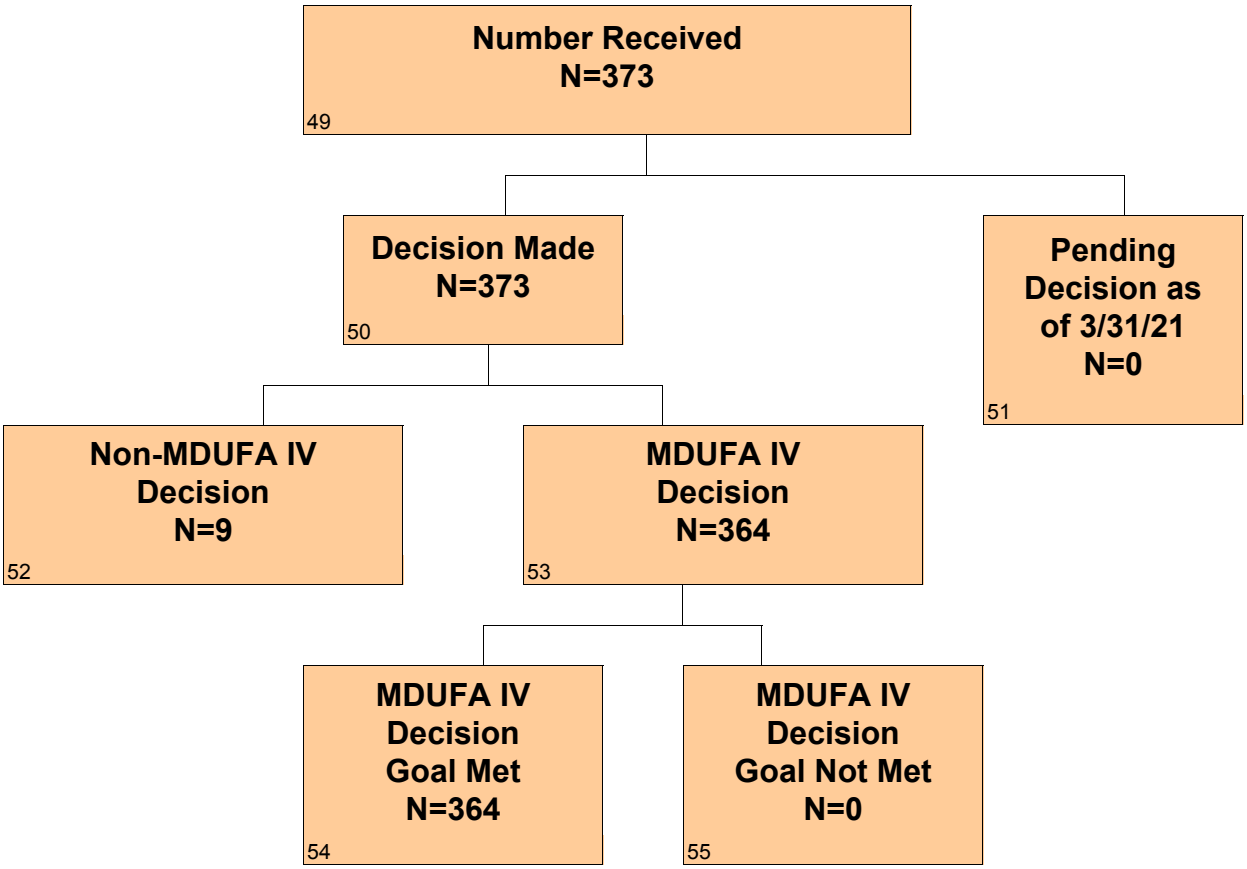
Table 2.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	259.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	31.25	0.00	

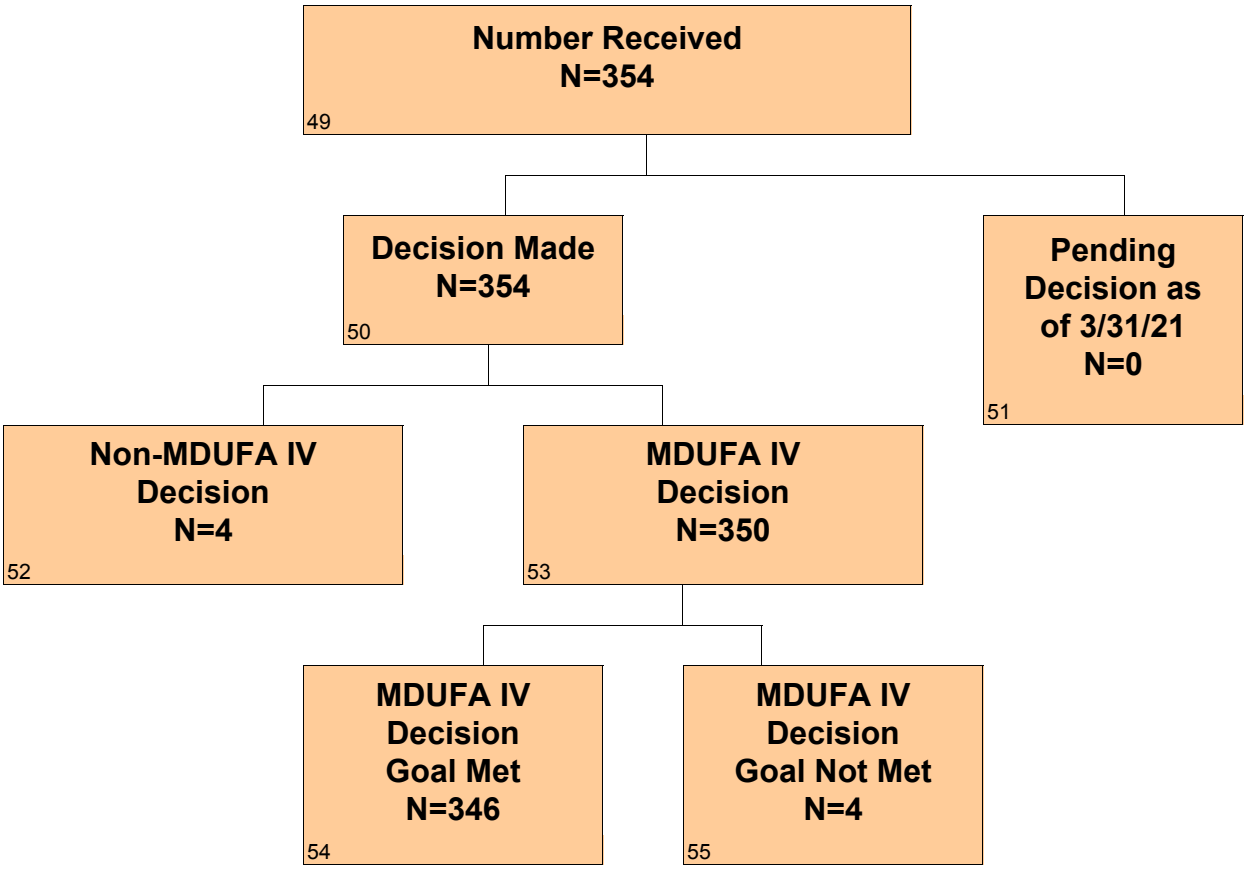
CDRH PMA Real Time Supplements - FY 2018 as of 3/31/21



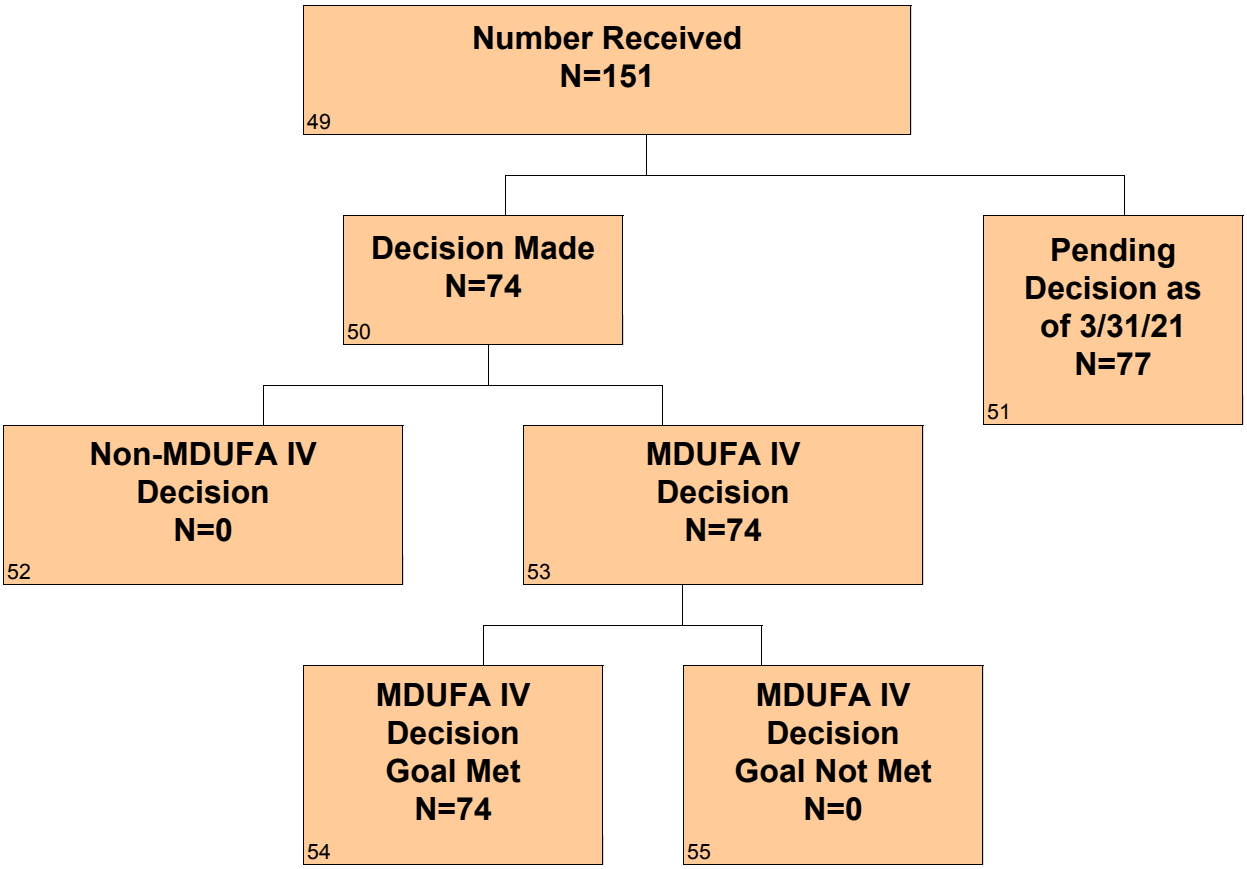
CDRH PMA Real Time Supplements - FY 2019 as of 3/31/21



CDRH PMA Real Time Supplements - FY 2020 as of 3/31/21



CDRH PMA Real Time Supplements - FY 2021 as of 3/31/21



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	354	151	
Non-MDUFA IV Decision	2	9	4	0	
MDUFA IV Decision	336	364	350	74	
MDUFA IV Decision Goal Met	336	364	346	74	
Supplements Pending MDUFA IV Decision	0	0	0	77	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	2	
Current Performance Percent Goal Met	100.00%	100.00%	98.86%	97.37%	

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	354	151	
Number With MDUFA IV Decision	336	364	350	74	
Number of Not Approvable	20	29	6	2	
Rate of Not Approvable	5.95%	7.97%	1.71%	2.70%	

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	2	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.25	138.00	
Mean Industry Days for Submissions that Missed the Goal	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	11	
Non-MDUFA IV Decision	0	2	1	0	
MDUFA IV Decision	23	38	15	7	
MDUFA IV Decision Goal Met	23	38	15	7	
Supplements Pending MDUFA IV Decision	0	0	0	4	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	40	16	11	
Number With MDUFA IV Decision	23	38	15	7	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	4.35%	2.63%	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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 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	84	
Non-MDUFA IV Decision	0	3	2	0	
MDUFA IV Decision	154	170	191	46	
MDUFA IV Decision Goal Met	154	170	190	46	
Supplements Pending MDUFA IV Decision	0	0	0	38	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	99.48%	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	84	
Number With MDUFA IV Decision	154	170	191	46	
Number of Not Approvable	12	15	1	1	
Rate of Not Approvable	7.79%	8.82%	0.52%	2.17%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	99.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	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	10	
Non-MDUFA IV Decision	0	1	0	0	
MDUFA IV Decision	20	38	36	6	
MDUFA IV Decision Goal Met	20	38	36	6	
Supplements Pending MDUFA IV Decision	0	0	0	4	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	10	
Number with MDUFA IV Decision	20	38	36	6	
Number of Not Approvable	1	8	1	0	
Rate of Not Approvable	5.00%	21.05%	2.78%	0.00%	

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

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

Table 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	4	
Non-MDUFA IV Decision	1	0	0	0	
MDUFA IV Decision	12	18	13	2	
MDUFA IV Decision Goal Met	12	18	13	2	
Supplements Pending MDUFA IV Decision	0	0	0	2	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	18	13	4	
Number with MDUFA IV Decision	12	18	13	2	
Number of Not Approvable	4	0	0	1	
Rate of Not Approvable	33.33%	0.00%	0.00%	50.00%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 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	8	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	16	32	24	4	
MDUFA IV Decision Goal Met	16	32	24	4	
Supplements Pending MDUFA IV Decision	0	0	0	4	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	8	
Number with MDUFA IV Decision	16	32	24	4	
Number of Not Approvable	0	2	3	0	
Rate of Not Approvable	0.00%	6.25%	12.50%	0.00%	

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

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

Table 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	10	2	
Non-MDUFA IV Decision	0	0	1	0	
MDUFA IV Decision	17	22	9	1	
MDUFA IV Decision Goal Met	17	22	9	1	
Supplements Pending MDUFA IV Decision	0	0	0	1	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	10	2	
Number with MDUFA IV Decision	17	22	9	1	
Number of Not Approvable	2	2	1	0	
Rate of Not Approvable	11.76%	9.09%	11.11%	0.00%	

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

Table 3.1 OHT7 - Office of In Vitro Diagnostics and 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	95	49	62	32	
Non-MDUFA IV Decision	1	3	0	0	
MDUFA IV Decision	94	46	62	8	
MDUFA IV Decision Goal Met	94	46	59	8	
Supplements Pending MDUFA IV Decision	0	0	0	24	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	2	
Current Performance Percent Goal Met	100.00%	100.00%	95.16%	80.00%	

Table 3.2 OHT7 - Office of In Vitro Diagnostics and 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	95	49	62	32	
Number with MDUFA IV Decision	94	46	62	8	
Number of Not Approvable	0	1	0	0	
Rate of Not Approvable	0.00%	2.17%	0.00%	0.00%	

Table 3.3 OHT7 - Office of In Vitro Diagnostics and 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	3	2	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.00	138.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between January 1, 2021 and March 31, 2021.

Page intentionally left blank

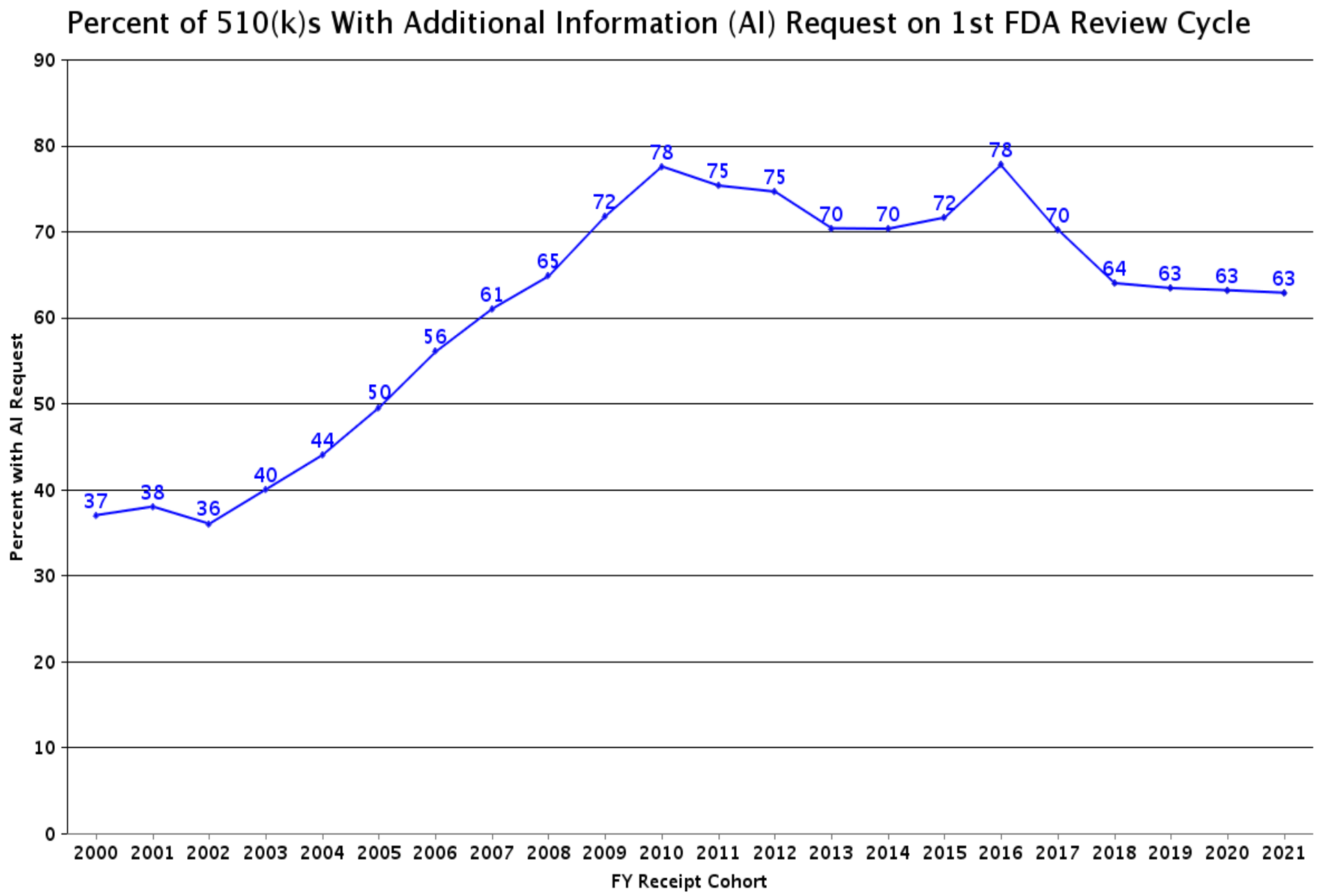
Section 5 PMA Annual Metrics and Goals

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

Page intentionally left blank

510(k)s

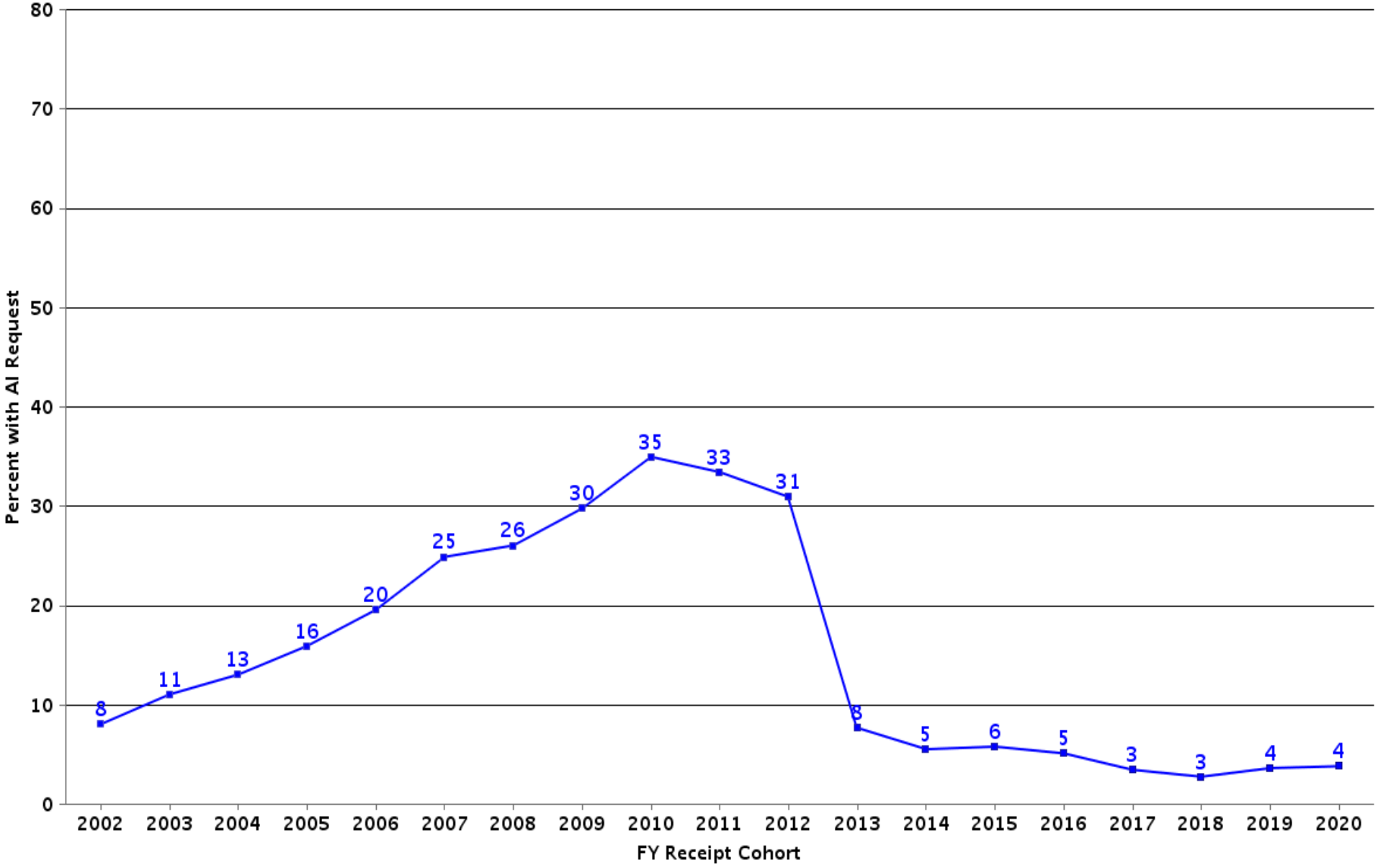
Q2FY2021



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 1/31/21

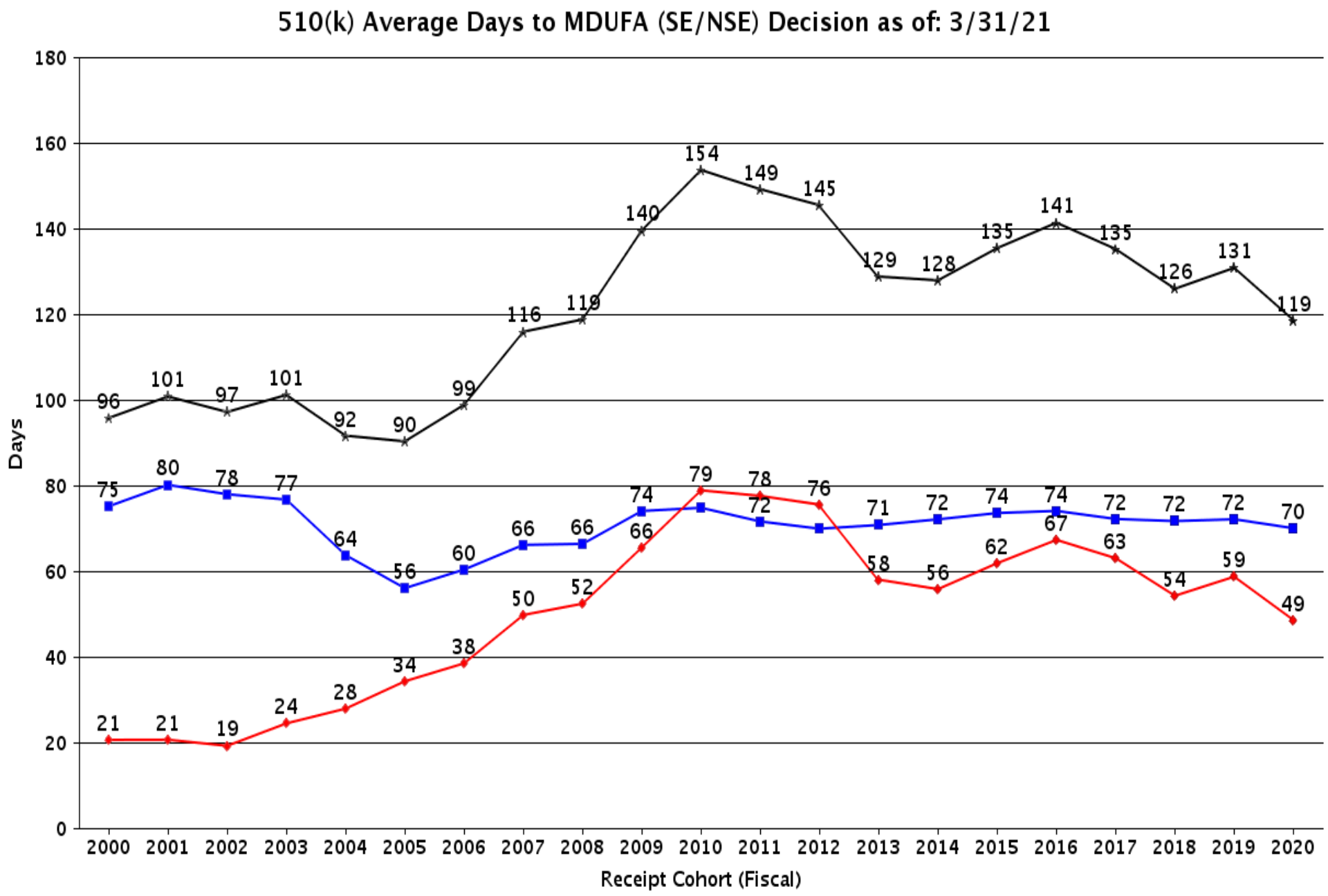
◆ % with 1st Cycle AI Request

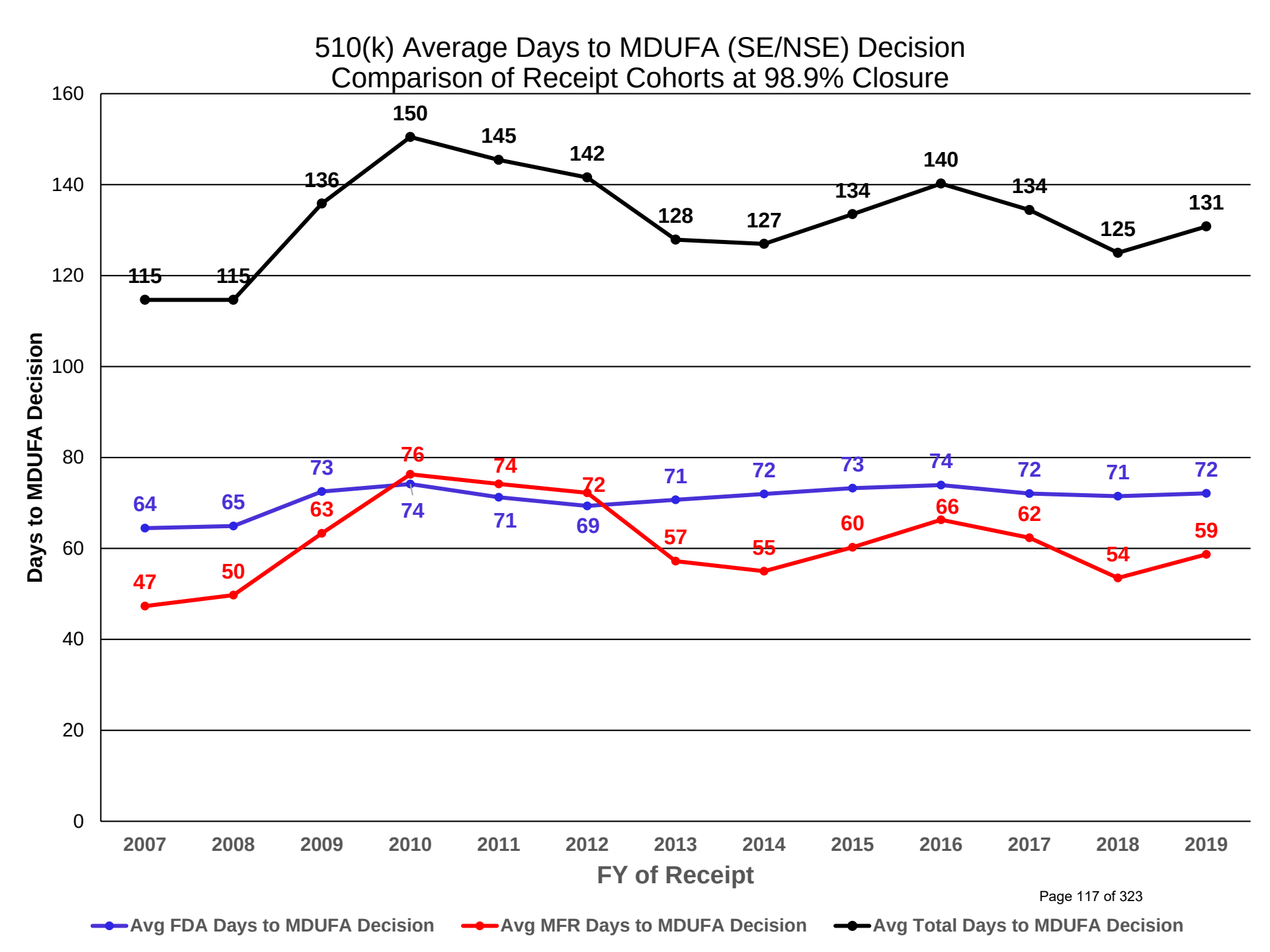
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

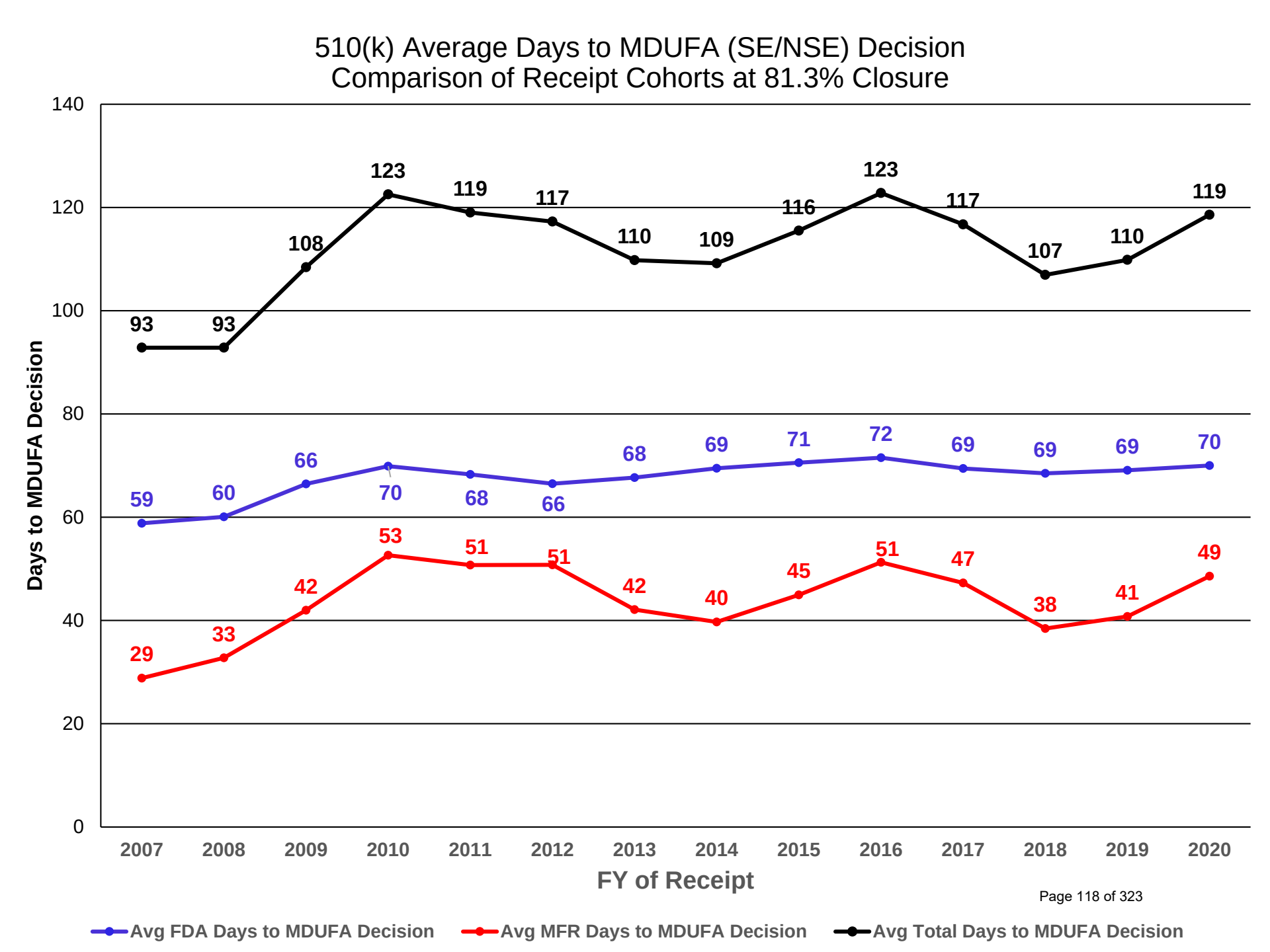


AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 8/31/20

■ % with 2nd Cycle AI Request

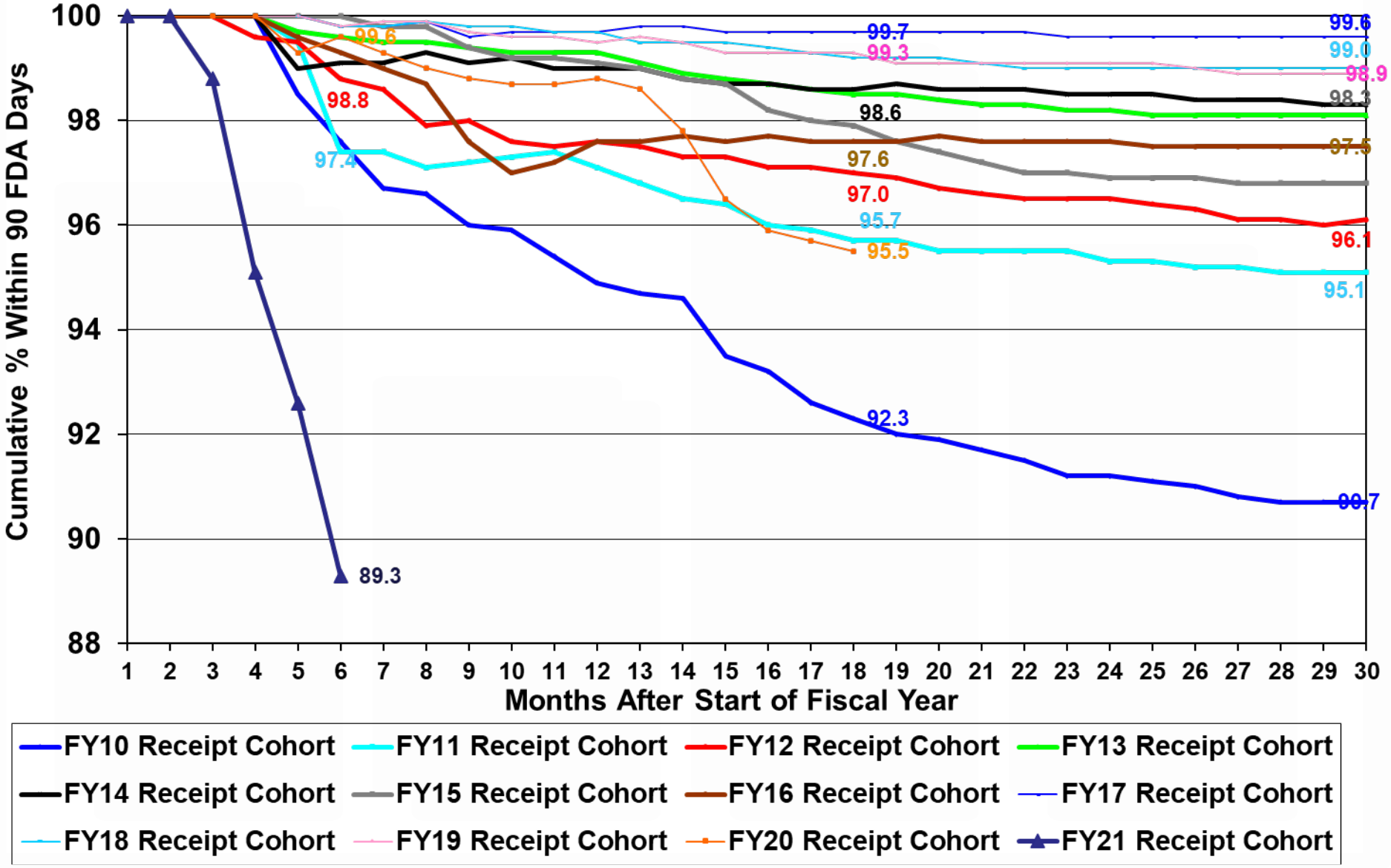

510(k) Average Days to MDUFA (SE/NSE) Decision as of: 3/31/21
Days
Receipt Cohort (Fiscal)
Cohorts not yet closed: ; 2019: 98.94%; 2020: 81.33%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision


510(k) Average Days to MDUFA (SE/NSE) Decision
Comparison of Receipt Cohorts at 98.9% Closure
Days to MDUFA Decision
160
140
120
100
80
60
40
20
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
FY of Receipt
115
115
136
150
145
142
128
127
134
140
134
125
131
64
65
73
74
71
69
71
72
73
74
72
71
72
47
50
63
76
74
72
57
55
60
66
62
54
59
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

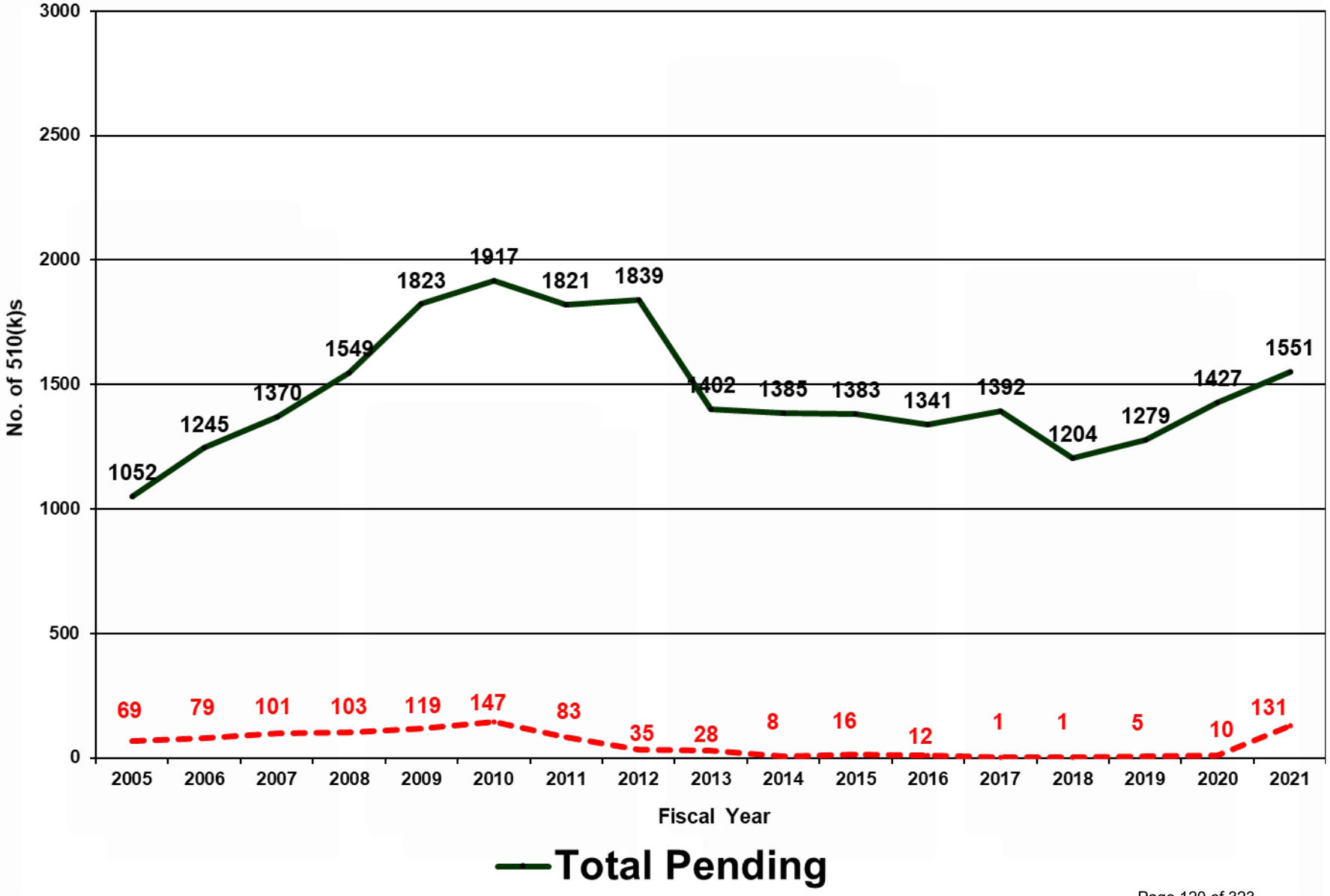

510(k) Average Days to MDUFA (SE/NSE) Decision
Comparison of Receipt Cohorts at 81.3% Closure
Days to MDUFA Decision
140
120
100
80
60
40
20
0
93 93 108 123 119 117 110 109 116 123 117 107 110 119
59 60 66 70 68 66 68 69 71 72 69 69 69 70
29 33 42 53 51 51 42 40 45 51 47 38 41 49
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020
FY of Receipt
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

Trend in 510(k) MDUFA Decision Goal Performance

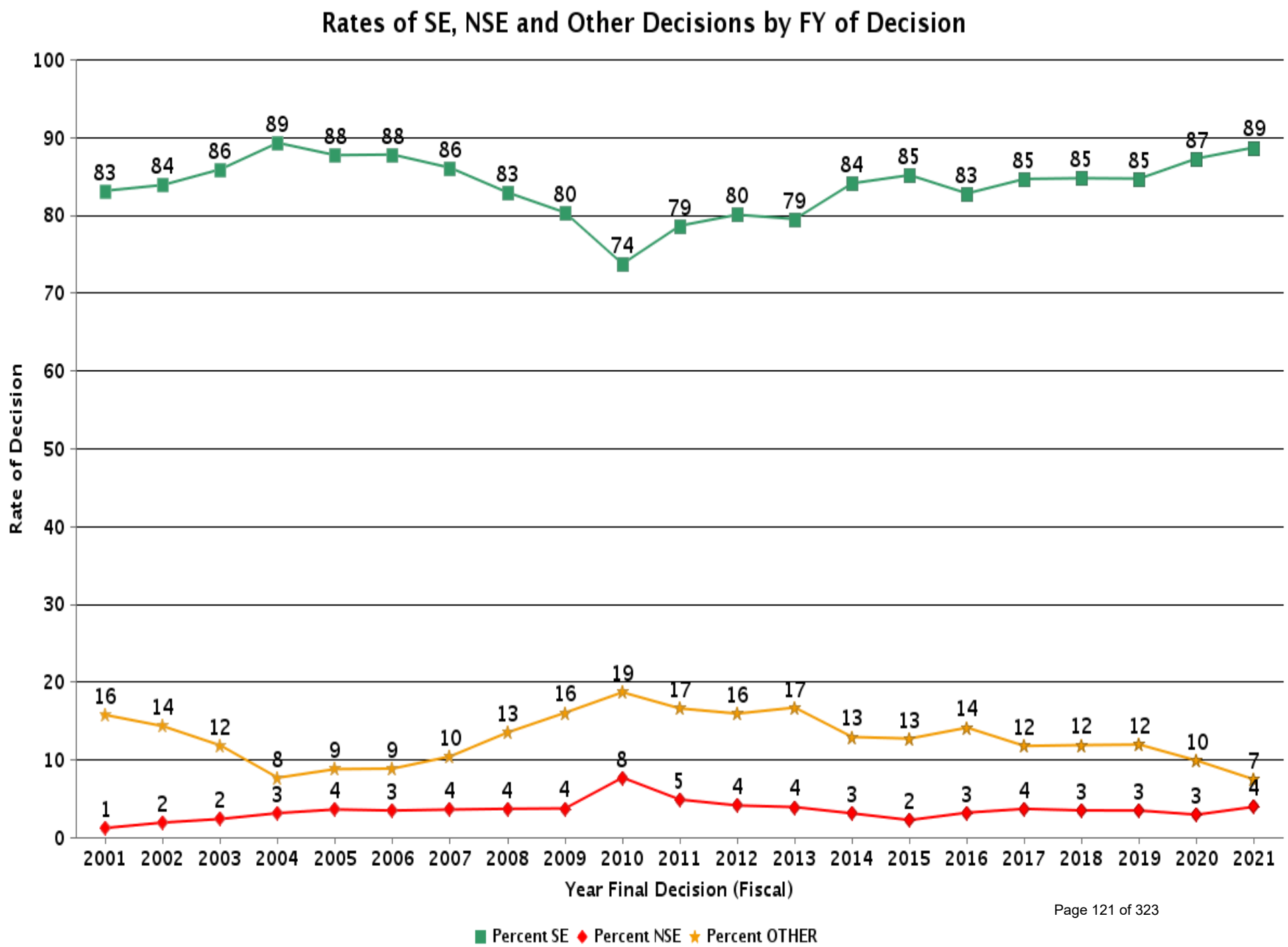
Comparison of FY10 – FY21 Receipt Cohorts



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

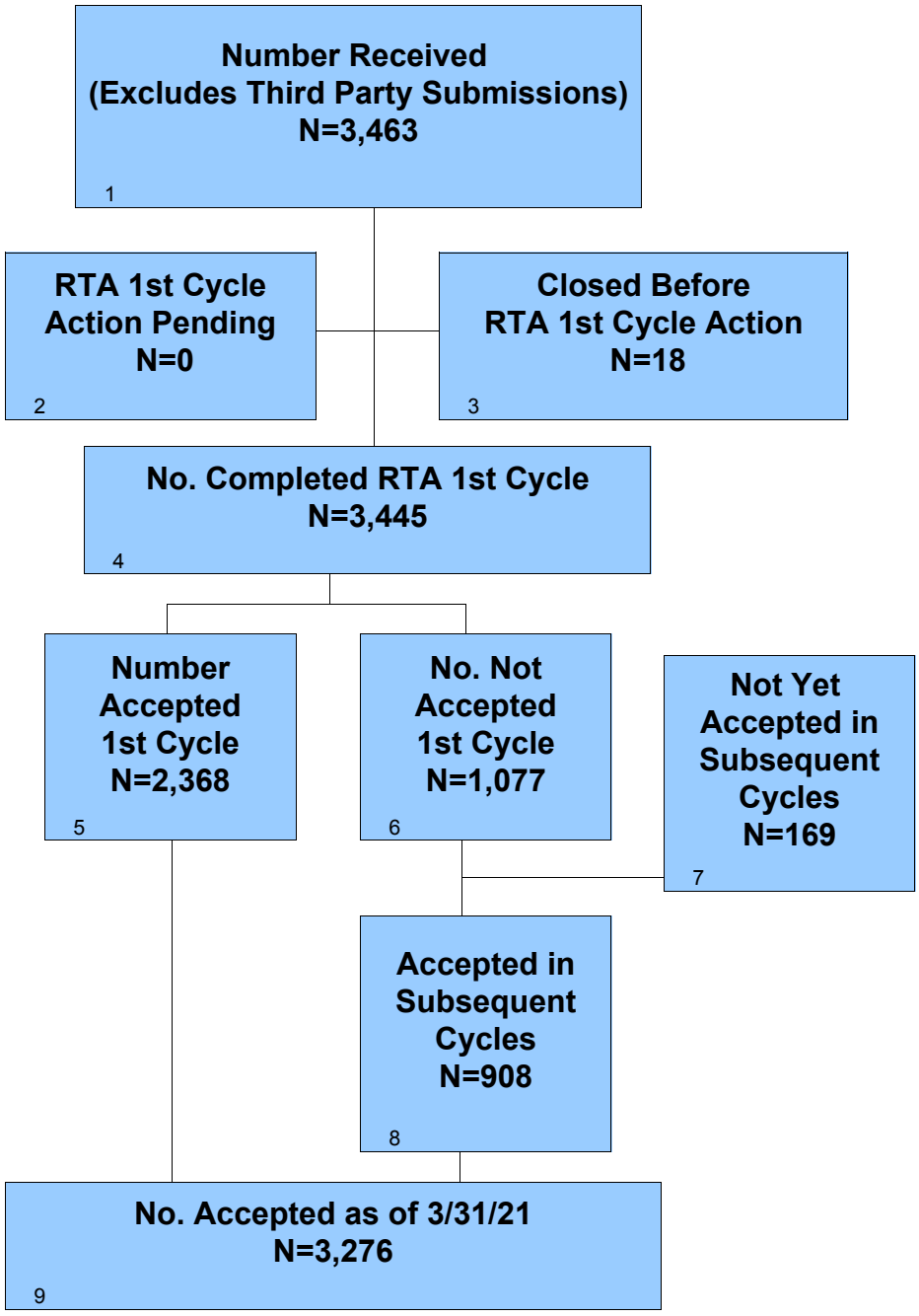


"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).

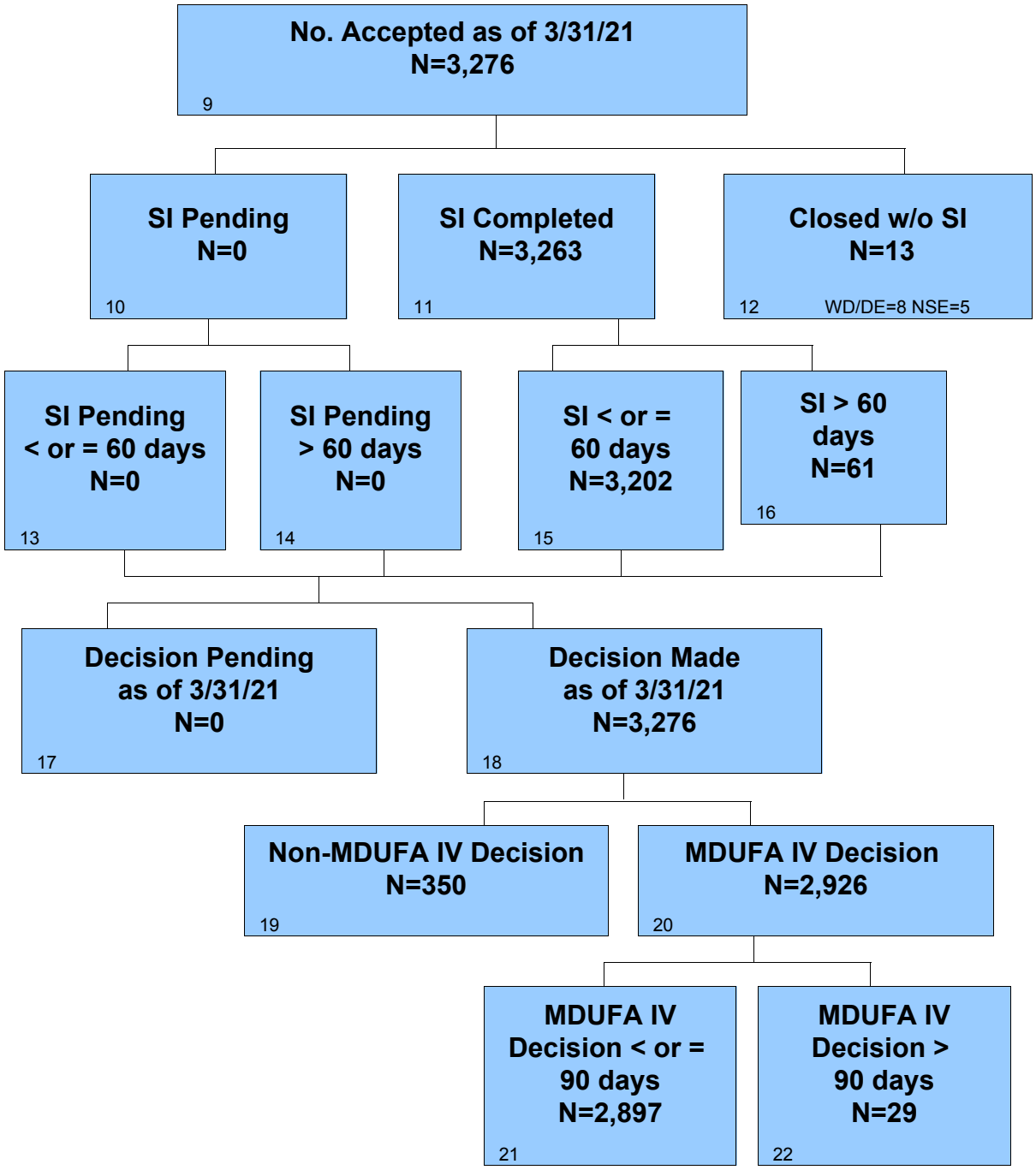

Rates of SE, NSE and Other Decisions by FY of Decision
Rate of Decision
100
90
80
70
60
50
40
30
20
10
0
83 84 86 89 88 88 86 83 80 74 79 80 79 84 85 83 85 85 85 87 89
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 7
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 4
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

Page intentionally left blank

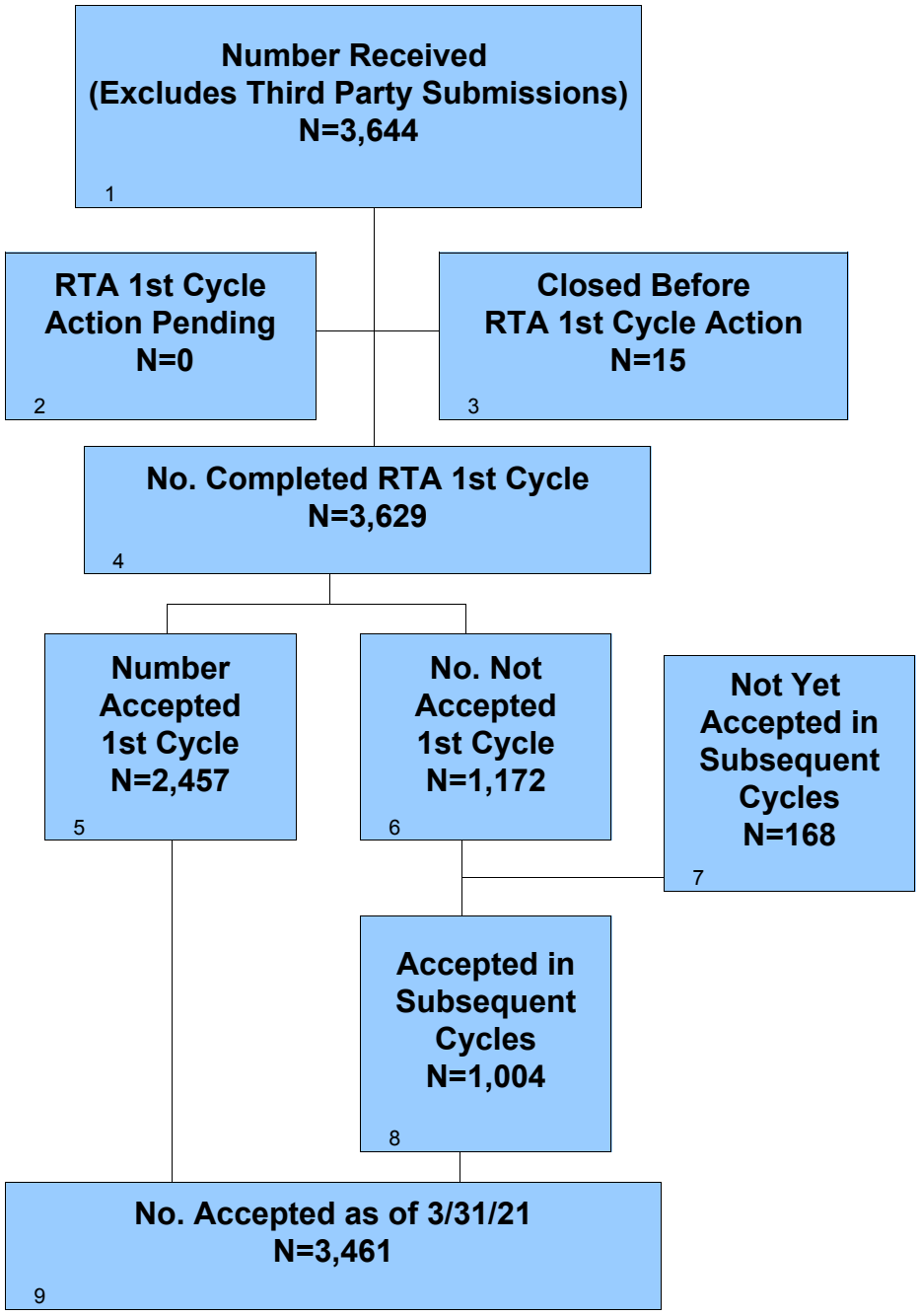
CDRH 510(k)s - FY 2018
as of 3/31/21



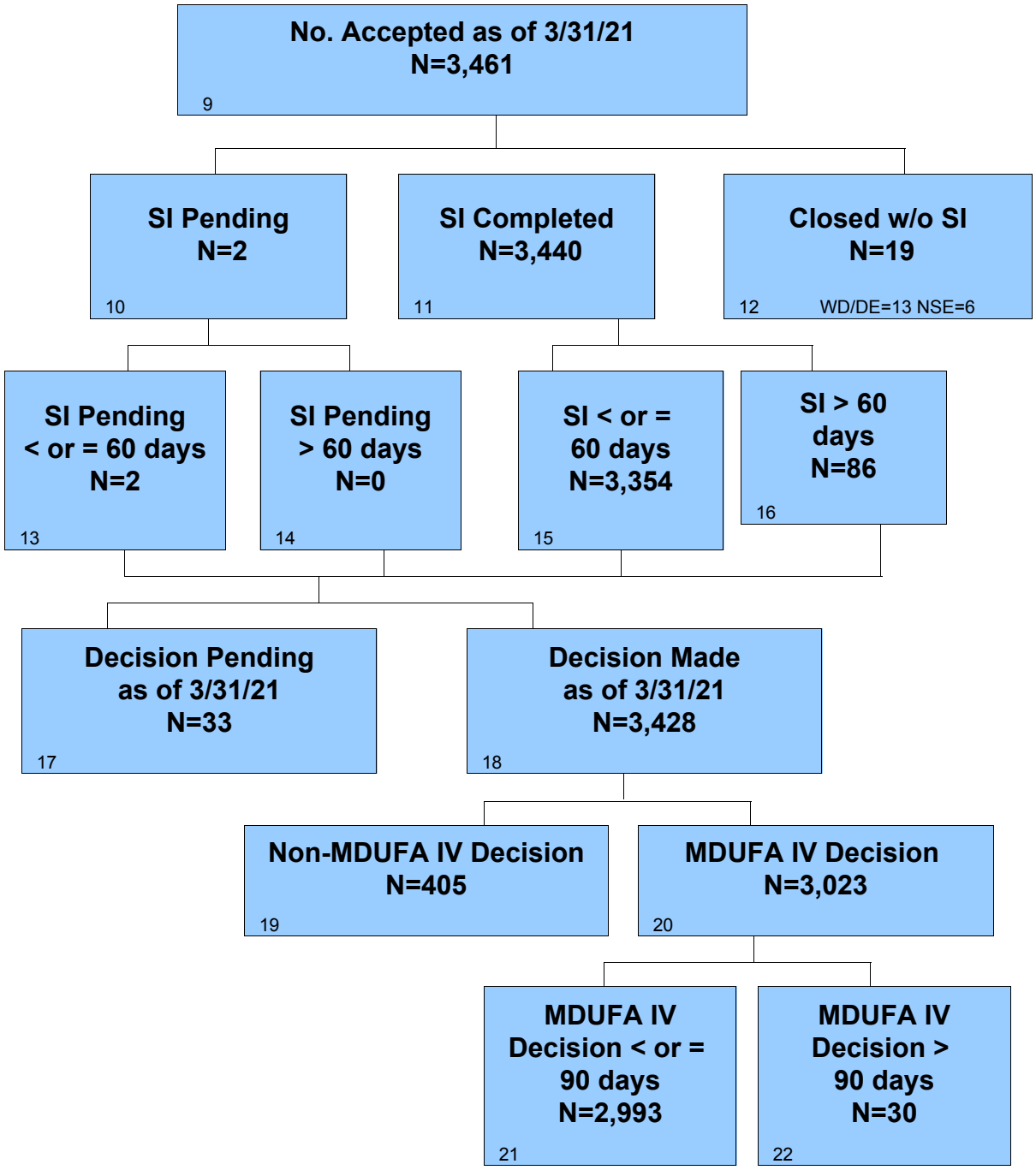
CDRH 510(k)s - FY 2018 as of 3/31/21 Continued



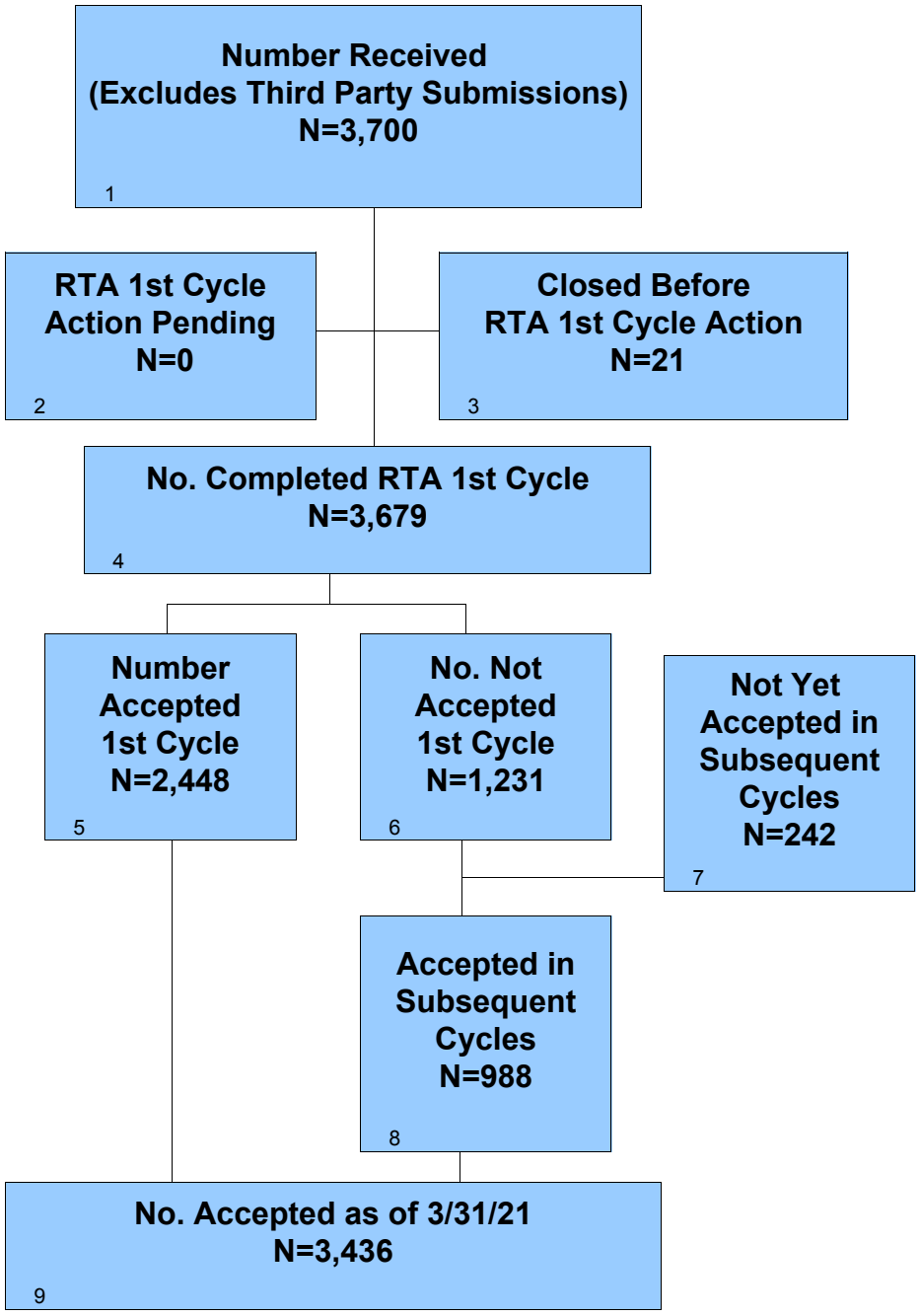
CDRH 510(k)s - FY 2019
as of 3/31/21



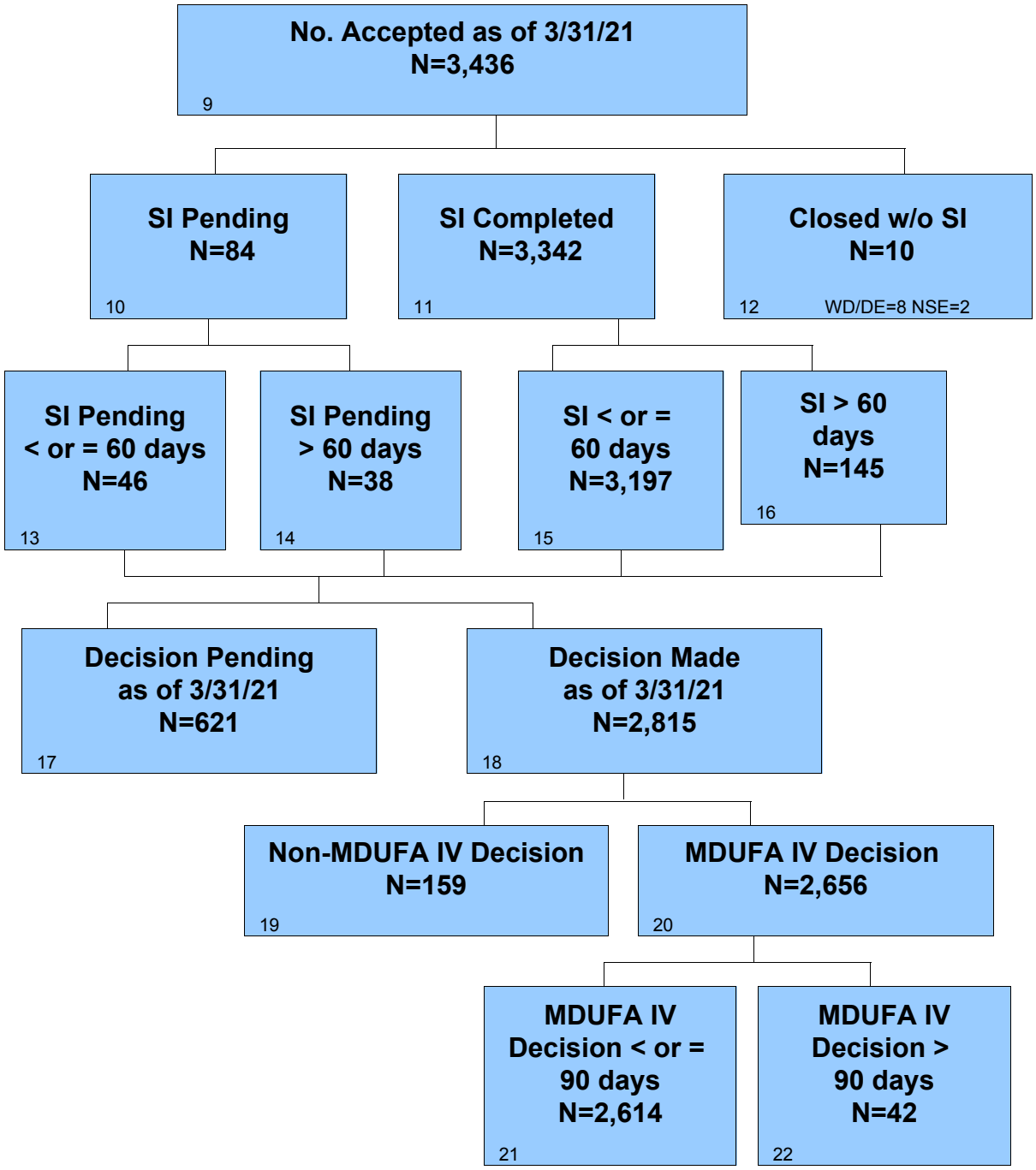
CDRH 510(k)s - FY 2019
as of 3/31/21 Continued



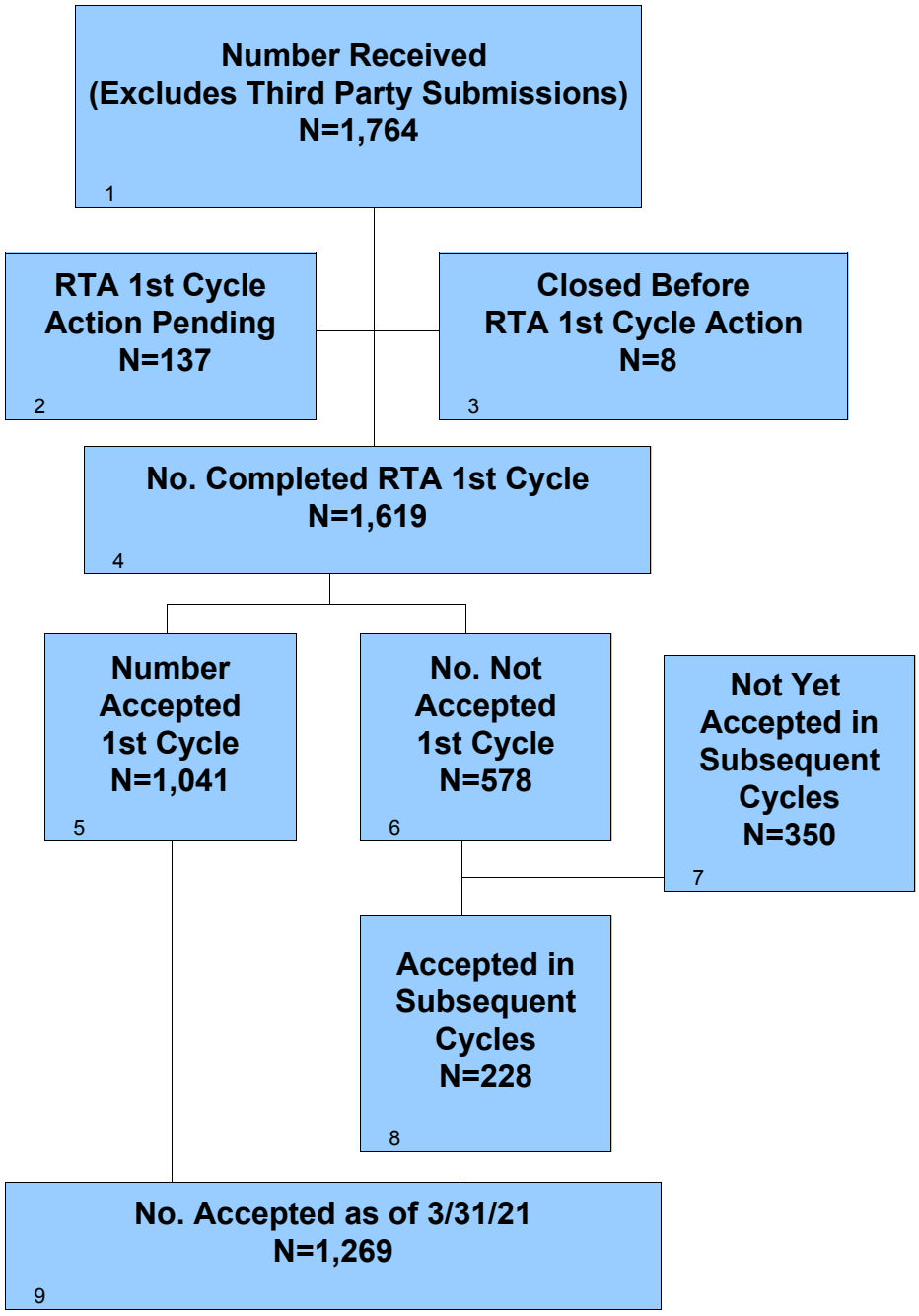
CDRH 510(k)s - FY 2020
as of 3/31/21



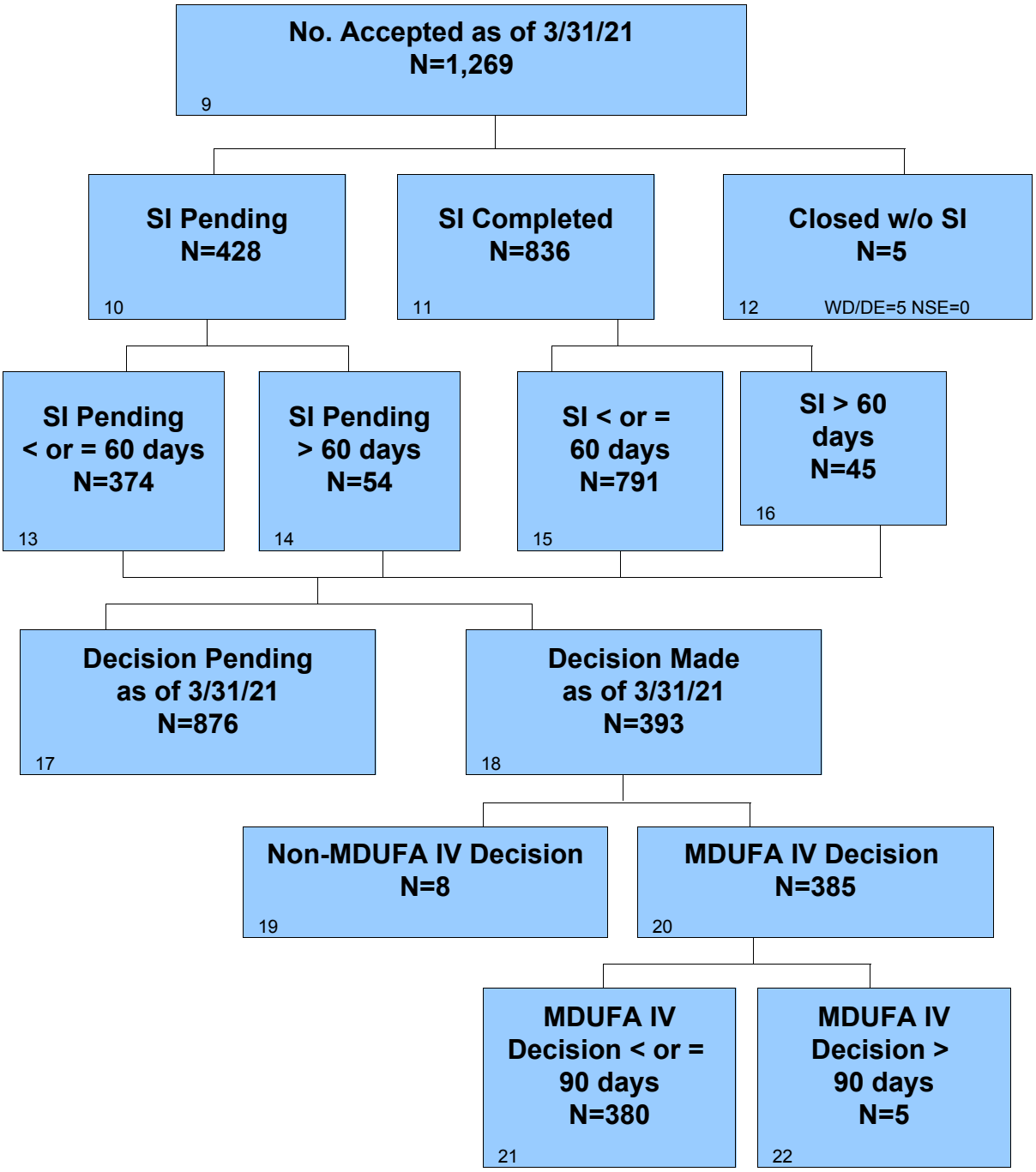
CDRH 510(k)s - FY 2020 as of 3/31/21 Continued



CDRH 510(k)s - FY 2021
as of 3/31/21



CDRH 510(k)s - FY 2021
as of 3/31/21 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	3,700	1,764	
Closed Before RTA Action	18	15	21	8	
Number Accepted	2,353	2,403	2,399	940	
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	101	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	137	
Number Not Accepted	1,077	1,172	1,231	578	
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.46%	35.70%	

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	3,461	3,436	1,269	
Deleted or Withdrawn Prior to SI	8	13	8	5	
SI Within 60 FDA Days	3,202	3,354	3,197	791	
SI Over 60 FDA Days	61	86	145	45	
SI Pending Within 60 FDA Days	0	2	46	374	
SI Pending Over 60 FDA Days	0	0	38	54	
510(k)s NSE Without SI	5	6	2	0	
Current SI Performance Percent Within 60 FDA Days	97.98%	97.33%	94.53%	88.88%	

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	3,440	3,342	836	
Average Number of FDA Days to Substantive Interaction	51.04	51.41	51.91	50.05	
20th Percentile FDA Days to Substantive Interaction	43	43	44	30	
40th Percentile FDA Days to Substantive Interaction	55	56	56	54	
60th Percentile FDA Days to Substantive Interaction	58	58	59	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	86	90	209	132	

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	3,461	3,436	1,269	
Non-MDUFA IV Decision	350	405	159	8	
MDUFA IV Decision (SE/NSE)	2,926	3,023	2,656	385	
MDUFA IV Decision Within 90 FDA Days	2,897	2,993	2,614	380	
510(k)s Pending MDUFA IV Decision	0	33	621	876	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	4	84	43	
Current Performance Percent Within 90 FDA Days	99.01%	98.88%	95.40%	88.79%	

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	2	2	2	1	
Number With MDUFA IV Decision	2,926	3,023	2,656	385	
Average Number of FDA Days to MDUFA IV Decision	72.62	73.09	71.26	54.94	
20th Percentile FDA Days to MDUFA IV Decision	54	55	49	28	
40th Percentile FDA Days to MDUFA IV Decision	79	82	79	46	
60th Percentile FDA Days to MDUFA IV Decision	87	88	87	60	
80th Percentile FDA Days to MDUFA IV Decision	89	90	89	87	
Maximum FDA Days to MDUFA IV Decision	220	207	287	132	
Average Number of Industry Days to MDUFA IV Decision	54.69	59.54	49.16	6.25	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	5	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	44	49	35	0	
80th Percentile Industry Days to MDUFA IV Decision	127	137	103	5	
Maximum Industry Days to MDUFA IV Decision	563	444	361	82	
Average Number of Total Days to MDUFA IV Decision	127.31	132.62	120.42	61.18	
20th Percentile Total Days to MDUFA IV Decision	57	57	52	28	
40th Percentile Total Days to MDUFA IV Decision	89	90	88	49	
60th Percentile Total Days to MDUFA IV Decision	128	132	120	64	
80th Percentile Total Days to MDUFA IV Decision	212	223	191	89	
Maximum Total Days to MDUFA IV Decision	783	543	464	170	

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	3,461	3,436	1,269	
Number With MDUFA IV Decision	2,926	3,023	2,656	385	
Number of SE Decision	2,810	2,911	2,588	383	
Number of NSE Decision	116	112	68	2	
Number of Withdrawal	185	210	129	8	
Number of Deleted	156	177	27	0	
Rate of SE Decision	96.04%	96.30%	97.44%	99.48%	
Rate of NSE Decision	3.96%	3.70%	2.56%	0.52%	
Rate of Withdrawal	5.65%	6.07%	3.75%	0.63%	
Rate of Deleted	4.76%	5.11%	0.79%	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	30	42	5	
Mean FDA Days for Submissions that Missed the Goal	111.38	110.93	112.52	125.80	
Mean Industry Days for Submissions that Missed the Goal	136.24	179.87	98.74	0.00	

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	0	
Non-MDUFA IV Decision	1	0	0	0	
MDUFA IV Decision (SE/NSE)	1	1	3	0	
MDUFA IV Decision Within 90 FDA Days	1	1	2	0	
510(k)s Pending MDUFA IV Decision	0	0	1	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%	N/A	

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	252	88	
Non-MDUFA IV Decision	41	35	14	2	
MDUFA IV Decision (SE/NSE)	231	238	132	9	
MDUFA IV Decision Within 90 FDA Days	230	237	121	4	
510(k)s Pending MDUFA IV Decision	0	5	106	77	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	4	78	42	
Current Performance Percent Within 90 FDA Days	99.57%	97.93%	57.62%	7.84%	

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	249	
Closed Before RTA Action	1	1	0	0	
Number Accepted	208	207	226	86	
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8	3	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	20	
Number Not Accepted	343	373	302	140	
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	61.14%	

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	550	482	144	
Deleted or Withdrawn Prior to SI	2	6	0	0	
SI Within 60 FDA Days	477	489	390	83	
SI Over 60 FDA Days	14	54	82	13	
SI Pending Within 60 FDA Days	0	0	9	48	
SI Pending Over 60 FDA Days	0	0	1	0	
510(k)s NSE Without SI	1	1	0	0	
Current SI Performance Percent Within 60 FDA Days	96.95%	89.89%	82.45%	86.46%	

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	543	472	96	
Average Number of FDA Days to Substantive Interaction	55.63	56.03	55.18	54.51	
20th Percentile FDA Days to Substantive Interaction	54	54	51	51	
40th Percentile FDA Days to Substantive Interaction	58	58	57	58	
60th Percentile FDA Days to Substantive Interaction	59	59	60	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	78	87	94	88	

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	550	482	144	
Non-MDUFA IV Decision	74	78	17	0	
MDUFA IV Decision (SE/NSE)	420	463	374	32	
MDUFA IV Decision Within 90 FDA Days	417	462	370	32	
510(k)s Pending MDUFA IV Decision	0	9	91	112	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	99.29%	99.78%	98.67%	100.00%	

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	1.66	1.31	
Number With MDUFA IV Decision	420	463	374	32	
Average Number of FDA Days to MDUFA IV Decision	81.05	82.30	79.01	70.25	
20th Percentile FDA Days to MDUFA IV Decision	77	84	68	51	
40th Percentile FDA Days to MDUFA IV Decision	87	88	87	68	
60th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	
Maximum FDA Days to MDUFA IV Decision	148	153	115	90	
Average Number of Industry Days to MDUFA IV Decision	65.45	67.59	55.31	8.72	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	18	19	8	0	
60th Percentile Industry Days to MDUFA IV Decision	63	66	47	-	
80th Percentile Industry Days to MDUFA IV Decision	152	153	115	21	
Maximum Industry Days to MDUFA IV Decision	389	284	361	48	
Average Number of Total Days to MDUFA IV Decision	146.51	149.89	134.32	78.97	
20th Percentile Total Days to MDUFA IV Decision	79	88	80	55	
40th Percentile Total Days to MDUFA IV Decision	103	106	90	71	
60th Percentile Total Days to MDUFA IV Decision	148	153	130	89	
80th Percentile Total Days to MDUFA IV Decision	241	237	201	108	
Maximum Total Days to MDUFA IV Decision	479	401	464	134	

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	550	482	144	
Number With MDUFA IV Decision	420	463	374	32	
Number of SE Decision	402	442	364	31	
Number of NSE Decision	18	21	10	1	
Number of Withdrawal	35	46	15	-	
Number of Deleted	39	29	2	-	
Rate of SE Decision	95.71%	95.46%	97.33%	96.88%	
Rate of NSE Decision	4.29%	4.54%	2.67%	3.13%	
Rate of Withdrawal	7.09%	8.36%	3.11%	0.00%	
Rate of Deleted	7.89%	5.27%	0.41%	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	1	4	0	
Mean FDA Days for Submissions that Missed the Goal	115.33	153.00	101.25	0.00	
Mean Industry Days for Submissions that Missed the Goal	107.67	248.00	167.75	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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.1 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	380	168	
Closed Before RTA Action	4	2	1	2	
Number Accepted	237	266	282	110	
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	6	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	10	
Number Not Accepted	114	100	93	40	
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.54%	25.64%	

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	367	135	
Deleted or Withdrawn Prior to SI	4	0	1	1	
SI Within 60 FDA Days	324	358	351	82	
SI Over 60 FDA Days	13	8	12	9	
SI Pending Within 60 FDA Days	0	0	2	42	
SI Pending Over 60 FDA Days	0	0	0	1	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	96.14%	97.81%	96.43%	89.13%	

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	363	91	
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.55	46.82	
20th Percentile FDA Days to Substantive Interaction	30	30	35	29	
40th Percentile FDA Days to Substantive Interaction	53	56	57	50	
60th Percentile FDA Days to Substantive Interaction	58	59	59	57	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	83	71	101	78	

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	367	135	
Non-MDUFA IV Decision	32	52	15	1	
MDUFA IV Decision (SE/NSE)	309	314	293	38	
MDUFA IV Decision Within 90 FDA Days	303	303	286	38	
510(k)s Pending MDUFA IV Decision	0	0	59	96	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	97.61%	100.00%	

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	2	2	2	1	
Number With MDUFA IV Decision	309	314	293	38	
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	72.28	42.97	
20th Percentile FDA Days to MDUFA IV Decision	50	49	44	28	
40th Percentile FDA Days to MDUFA IV Decision	80	80	85	29	
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	33	
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	60	
Maximum FDA Days to MDUFA IV Decision	159	117	101	90	
Average Number of Industry Days to MDUFA IV Decision	64.80	66.25	62.21	5.42	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	19	20	20	0	
60th Percentile Industry Days to MDUFA IV Decision	65	68	54	0	
80th Percentile Industry Days to MDUFA IV Decision	146	140	127	0	
Maximum Industry Days to MDUFA IV Decision	292	359	345	75	
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	134.48	48.39	
20th Percentile Total Days to MDUFA IV Decision	55	51	48	28	
40th Percentile Total Days to MDUFA IV Decision	102	98	106	29	
60th Percentile Total Days to MDUFA IV Decision	150	148	137	33	
80th Percentile Total Days to MDUFA IV Decision	228	227	217	65	
Maximum Total Days to MDUFA IV Decision	370	447	435	165	

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	367	135	
Number With MDUFA IV Decision	309	314	293	38	
Number of SE Decision	291	289	274	38	
Number of NSE Decision	18	25	19	0	
Number of Withdrawal	20	31	13	1	
Number of Deleted	10	20	2	0	
Rate of SE Decision	94.17%	92.04%	93.52%	100.00%	
Rate of NSE Decision	5.83%	7.96%	6.48%	0.00%	
Rate of Withdrawal	5.87%	8.47%	3.54%	0.74%	
Rate of Deleted	2.93%	5.46%	0.54%	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	7	0	
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	97.14	0.00	
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	144.86	0.00	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.1 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	454	476	443	216	
Closed Before RTA Action	3	4	4	3	
Number Accepted	333	349	289	115	
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2	5	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	17	
Number Not Accepted	116	117	148	76	
Rate of Submissions Not Accepted for Review	25.72%	24.79%	33.71%	38.78%	

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	435	453	410	148	
Deleted or Withdrawn Prior to SI	0	1	0	1	
SI Within 60 FDA Days	426	447	388	97	
SI Over 60 FDA Days	6	4	11	4	
SI Pending Within 60 FDA Days	0	0	11	46	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	3	1	0	0	
Current SI Performance Percent Within 60 FDA Days	97.93%	98.89%	97.24%	96.04%	

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	432	451	399	101	
Average Number of FDA Days to Substantive Interaction	51.16	52.58	53.16	52.46	
20th Percentile FDA Days to Substantive Interaction	44	48	50	48	
40th Percentile FDA Days to Substantive Interaction	55	57	57	57	
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	67	78	68	64	

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	435	453	410	148	
Non-MDUFA IV Decision	50	74	24	1	
MDUFA IV Decision (SE/NSE)	385	376	294	20	
MDUFA IV Decision Within 90 FDA Days	381	371	287	20	
510(k)s Pending MDUFA IV Decision	0	3	92	127	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	97.29%	100.00%	

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	1.85	1.78	1.40	
Number With MDUFA IV Decision	385	376	294	20	
Average Number of FDA Days to MDUFA IV Decision	75.81	78.15	76.69	49.45	
20th Percentile FDA Days to MDUFA IV Decision	58	60	59	27	
40th Percentile FDA Days to MDUFA IV Decision	84	87	86	38	
60th Percentile FDA Days to MDUFA IV Decision	88	88	88	58	
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	84	
Maximum FDA Days to MDUFA IV Decision	118	150	135	90	
Average Number of Industry Days to MDUFA IV Decision	75.12	95.90	81.75	11.40	
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	0	
40th Percentile Industry Days to MDUFA IV Decision	30	54	33	0	
60th Percentile Industry Days to MDUFA IV Decision	94	118	88	2	
80th Percentile Industry Days to MDUFA IV Decision	165	174	167	14	
Maximum Industry Days to MDUFA IV Decision	214	444	297	71	
Average Number of Total Days to MDUFA IV Decision	150.94	174.06	158.44	60.85	
20th Percentile Total Days to MDUFA IV Decision	65	87	71	27	
40th Percentile Total Days to MDUFA IV Decision	113	140	116	41	
60th Percentile Total Days to MDUFA IV Decision	177	205	177	59	
80th Percentile Total Days to MDUFA IV Decision	248	261	252	88	
Maximum Total Days to MDUFA IV Decision	304	540	426	160	

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	435	453	410	148	
Number With MDUFA IV Decision	385	376	294	20	
Number of SE Decision	360	353	279	20	
Number of NSE Decision	25	23	15	0	
Number of Withdrawal	20	31	18	1	
Number of Deleted	30	41	6	0	
Rate of SE Decision	93.51%	93.88%	94.90%	100.00%	
Rate of NSE Decision	6.49%	6.12%	5.10%	0.00%	
Rate of Withdrawal	4.60%	6.84%	4.39%	0.68%	
Rate of Deleted	6.90%	9.05%	1.46%	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	7	0	
Mean FDA Days for Submissions that Missed the Goal	100.00	111.20	108.57	0.00	
Mean Industry Days for Submissions that Missed the Goal	117.00	332.20	145.00	0.00	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.1 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	553	604	720	426	
Closed Before RTA Action	2	0	3	1	
Number Accepted	369	392	447	204	
Number Without a RTA Review and > 15 Days Since Date Received	6	7	5	10	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	38	
Number Not Accepted	176	205	265	173	
Rate of Submissions Not Accepted for Review	31.94%	33.94%	36.96%	44.70%	

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	517	559	637	273	
Deleted or Withdrawn Prior to SI	0	3	2	0	
SI Within 60 FDA Days	513	543	603	161	
SI Over 60 FDA Days	4	12	17	10	
SI Pending Within 60 FDA Days	0	0	13	97	
SI Pending Over 60 FDA Days	0	0	1	5	
510(k)s NSE Without SI	0	1	1	0	
Current SI Performance Percent Within 60 FDA Days	99.23%	97.66%	96.95%	91.48%	

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	517	555	620	171	
Average Number of FDA Days to Substantive Interaction	52.55	52.19	53.62	51.95	
20th Percentile FDA Days to Substantive Interaction	49	48	52	49	
40th Percentile FDA Days to Substantive Interaction	56	56	57	55	
60th Percentile FDA Days to Substantive Interaction	58	58	58	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	69	90	88	77	

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	517	559	637	273	
Non-MDUFA IV Decision	68	70	35	1	
MDUFA IV Decision (SE/NSE)	449	484	471	62	
MDUFA IV Decision Within 90 FDA Days	441	480	459	62	
510(k)s Pending MDUFA IV Decision	0	5	131	210	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	3	1	
Current Performance Percent Within 90 FDA Days	98.22%	99.17%	96.84%	98.41%	

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	1.59	1.21	
Number With MDUFA IV Decision	449	484	471	62	
Average Number of FDA Days to MDUFA IV Decision	73.76	73.11	73.98	58.31	
20th Percentile FDA Days to MDUFA IV Decision	57	55	57	28	
40th Percentile FDA Days to MDUFA IV Decision	79	81	82	54	
60th Percentile FDA Days to MDUFA IV Decision	87	87	87	65	
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	87	
Maximum FDA Days to MDUFA IV Decision	220	207	132	90	
Average Number of Industry Days to MDUFA IV Decision	48.88	54.82	49.40	4.10	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	31	41	39	0	
80th Percentile Industry Days to MDUFA IV Decision	110	128	104	4	
Maximum Industry Days to MDUFA IV Decision	563	355	269	58	
Average Number of Total Days to MDUFA IV Decision	122.64	127.93	123.38	62.40	
20th Percentile Total Days to MDUFA IV Decision	59	57	58	28	
40th Percentile Total Days to MDUFA IV Decision	88	87	88	54	
60th Percentile Total Days to MDUFA IV Decision	110	125	122	75	
80th Percentile Total Days to MDUFA IV Decision	193	210	191	88	
Maximum Total Days to MDUFA IV Decision	783	511	358	145	

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	517	559	637	273	
Number With MDUFA IV Decision	449	484	471	62	
Number of SE Decision	438	470	461	61	
Number of NSE Decision	11	14	10	1	
Number of Withdrawal	36	37	27	1	
Number of Deleted	31	31	7	0	
Rate of SE Decision	97.55%	97.11%	97.88%	98.39%	
Rate of NSE Decision	2.45%	2.89%	2.12%	1.61%	
Rate of Withdrawal	6.96%	6.62%	4.24%	0.37%	
Rate of Deleted	6.00%	5.55%	1.10%	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	4	12	0	
Mean FDA Days for Submissions that Missed the Goal	119.50	121.00	95.50	0.00	
Mean Industry Days for Submissions that Missed the Goal	168.63	132.50	82.17	0.00	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.1 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	275	261	121	
Closed Before RTA Action	3	0	3	1	
Number Accepted	147	156	110	53	
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5	3	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	9	
Number Not Accepted	107	112	143	55	
Rate of Submissions Not Accepted for Review	41.63%	40.73%	55.43%	49.55%	

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	259	229	75	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	232	254	210	49	
SI Over 60 FDA Days	4	3	9	2	
SI Pending Within 60 FDA Days	0	2	10	24	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	98.31%	98.83%	95.89%	96.08%	

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	257	219	51	
Average Number of FDA Days to Substantive Interaction	53.91	54.50	53.28	50.33	
20th Percentile FDA Days to Substantive Interaction	53	54	49	30	
40th Percentile FDA Days to Substantive Interaction	58	58	58	56	
60th Percentile FDA Days to Substantive Interaction	60	60	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	86	63	87	66	

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	259	229	75	
Non-MDUFA IV Decision	30	29	9	1	
MDUFA IV Decision (SE/NSE)	206	221	174	29	
MDUFA IV Decision Within 90 FDA Days	201	214	174	29	
510(k)s Pending MDUFA IV Decision	0	9	46	45	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	97.57%	96.83%	100.00%	100.00%	

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	1.36	1.14	
Number With MDUFA IV Decision	206	221	174	29	
Average Number of FDA Days to MDUFA IV Decision	76.47	80.07	73.07	59.59	
20th Percentile FDA Days to MDUFA IV Decision	60	67	30	29	
40th Percentile FDA Days to MDUFA IV Decision	86	88	85	35	
60th Percentile FDA Days to MDUFA IV Decision	89	90	89	83	
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	89	
Maximum FDA Days to MDUFA IV Decision	170	152	90	90	
Average Number of Industry Days to MDUFA IV Decision	42.60	51.65	29.55	2.86	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	38	37	0	0	
80th Percentile Industry Days to MDUFA IV Decision	84	118	56	0	
Maximum Industry Days to MDUFA IV Decision	187	391	277	29	
Average Number of Total Days to MDUFA IV Decision	119.07	131.72	102.62	62.45	
20th Percentile Total Days to MDUFA IV Decision	61	81	30	29	
40th Percentile Total Days to MDUFA IV Decision	89	90	88	35	
60th Percentile Total Days to MDUFA IV Decision	117	123	90	83	
80th Percentile Total Days to MDUFA IV Decision	171	208	145	90	
Maximum Total Days to MDUFA IV Decision	346	543	367	119	

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	259	229	75	
Number With MDUFA IV Decision	206	221	174	29	
Number of SE Decision	198	214	167	29	
Number of NSE Decision	8	7	7	0	
Number of Withdrawal	17	16	8	1	
Number of Deleted	10	12	1	0	
Rate of SE Decision	96.12%	96.83%	95.98%	100.00%	
Rate of NSE Decision	3.88%	3.17%	4.02%	0.00%	
Rate of Withdrawal	7.20%	6.18%	3.49%	1.33%	
Rate of Deleted	4.24%	4.63%	0.44%	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	0	
Mean FDA Days for Submissions that Missed the Goal	111.40	119.43	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	80.60	110.29	0.00	0.00	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.1 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	655	275	
Closed Before RTA Action	2	4	5	0	
Number Accepted	466	489	493	205	
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6	1	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	15	
Number Not Accepted	138	136	151	54	
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.23%	20.77%	

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	636	242	
Deleted or Withdrawn Prior to SI	0	2	3	1	
SI Within 60 FDA Days	575	617	632	188	
SI Over 60 FDA Days	19	3	1	0	
SI Pending Within 60 FDA Days	0	0	0	53	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	96.80%	99.52%	99.84%	100.00%	

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	633	188	
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.80	47.14	
20th Percentile FDA Days to Substantive Interaction	39	30	30	29	
40th Percentile FDA Days to Substantive Interaction	55	56	56	51	
60th Percentile FDA Days to Substantive Interaction	57	58	58	57	
80th Percentile FDA Days to Substantive Interaction	59	60	60	59	
Maximum FDA Days to Substantive Interaction	78	64	61	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	636	242	
Non-MDUFA IV Decision	40	45	34	1	
MDUFA IV Decision (SE/NSE)	554	575	535	118	
MDUFA IV Decision Within 90 FDA Days	552	574	535	118	
510(k)s Pending MDUFA IV Decision	0	2	67	123	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	99.64%	99.83%	100.00%	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	1.46	1.14	
Number With MDUFA IV Decision	554	575	535	118	
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	65.56	49.42	
20th Percentile FDA Days to MDUFA IV Decision	52	51	30	28	
40th Percentile FDA Days to MDUFA IV Decision	74	76	59	30	
60th Percentile FDA Days to MDUFA IV Decision	86	87	85	57	
80th Percentile FDA Days to MDUFA IV Decision	89	89	88	73	
Maximum FDA Days to MDUFA IV Decision	135	91	90	90	
Average Number of Industry Days to MDUFA IV Decision	48.84	50.98	37.51	3.52	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	10	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	34	29	12	-	
80th Percentile Industry Days to MDUFA IV Decision	103	103	71	-	
Maximum Industry Days to MDUFA IV Decision	340	444	278	82	
Average Number of Total Days to MDUFA IV Decision	120.19	121.55	103.07	52.93	
20th Percentile Total Days to MDUFA IV Decision	57	56	30	28	
40th Percentile Total Days to MDUFA IV Decision	86	87	60	39	
60th Percentile Total Days to MDUFA IV Decision	115	111	90	57	
80th Percentile Total Days to MDUFA IV Decision	189	185	155	75	
Maximum Total Days to MDUFA IV Decision	430	533	363	170	

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	636	242	
Number With MDUFA IV Decision	554	575	535	118	
Number of SE Decision	540	563	532	118	
Number of NSE Decision	14	12	3	0	
Number of Withdrawal	24	28	31	1	
Number of Deleted	16	17	3	0	
Rate of SE Decision	97.47%	97.91%	99.44%	100.00%	
Rate of NSE Decision	2.53%	2.09%	0.56%	0.00%	
Rate of Withdrawal	4.04%	4.50%	4.87%	0.41%	
Rate of Deleted	2.69%	2.73%	0.47%	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	0	
Mean FDA Days for Submissions that Missed the Goal	117.50	91.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	208.50	260.00	0.00	0.00	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision (SE/NSE)	0	0	0	0	
MDUFA IV Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA IV Decision	0	0	0	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	681	684	705	309	
Closed Before RTA Action	3	4	5	1	
Number Accepted	593	544	552	167	
Number Without a RTA Review and > 15 Days Since Date Received	2	7	19	73	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	28	
Number Not Accepted	83	129	129	40	
Rate of Submissions Not Accepted for Review	12.24%	18.97%	18.43%	14.29%	

Table 6.2 OHT7 - Office of In Vitro Diagnostics and 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	659	652	675	252	
Deleted or Withdrawn Prior to SI	2	1	2	2	
SI Within 60 FDA Days	655	646	623	131	
SI Over 60 FDA Days	1	2	13	7	
SI Pending Within 60 FDA Days	0	0	1	64	
SI Pending Over 60 FDA Days	0	0	36	48	
510(k)s NSE Without SI	1	3	0	0	
Current SI Performance Percent Within 60 FDA Days	99.70%	99.23%	92.71%	70.43%	

Table 6.3 OHT7 - Office of In Vitro Diagnostics and 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	656	648	636	138	
Average Number of FDA Days to Substantive Interaction	46.54	46.73	48.89	48.84	
20th Percentile FDA Days to Substantive Interaction	30	29	30	29	
40th Percentile FDA Days to Substantive Interaction	48	49	50	48	
60th Percentile FDA Days to Substantive Interaction	56	56	57	56	
80th Percentile FDA Days to Substantive Interaction	58	59	59	59	
Maximum FDA Days to Substantive Interaction	61	61	209	132	

Table 6.4 OHT7 - Office of In Vitro Diagnostics and 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	659	652	675	252	
Non-MDUFA IV Decision	56	57	25	3	
MDUFA IV Decision (SE/NSE)	603	590	515	86	
MDUFA IV Decision Within 90 FDA Days	602	589	503	81	
510(k)s Pending MDUFA IV Decision	0	5	135	163	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	4	79	42	
Current Performance Percent Within 90 FDA Days	99.83%	99.16%	84.68%	63.28%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.44	1.48	1.30	
Number With MDUFA IV Decision	603	590	515	86	
Average Number of FDA Days to MDUFA IV Decision	64.21	63.36	64.78	59.37	
20th Percentile FDA Days to MDUFA IV Decision	30	30	30	28	
40th Percentile FDA Days to MDUFA IV Decision	59	59	59	51	
60th Percentile FDA Days to MDUFA IV Decision	81	81	82	76	
80th Percentile FDA Days to MDUFA IV Decision	88	88	87	87	
Maximum FDA Days to MDUFA IV Decision	93	110	287	132	
Average Number of Industry Days to MDUFA IV Decision	42.78	41.63	37.17	10.94	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	25	13	23	0	
80th Percentile Industry Days to MDUFA IV Decision	91	86	66	27	
Maximum Industry Days to MDUFA IV Decision	231	353	274	67	
Average Number of Total Days to MDUFA IV Decision	106.99	105.00	101.95	70.31	
20th Percentile Total Days to MDUFA IV Decision	30	30	30	28	
40th Percentile Total Days to MDUFA IV Decision	72	60	63	55	
60th Percentile Total Days to MDUFA IV Decision	104	90	103	79	
80th Percentile Total Days to MDUFA IV Decision	177	172	153	118	
Maximum Total Days to MDUFA IV Decision	321	443	384	154	

Table 6.6 OHT7 - Office of In Vitro Diagnostics and 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	659	652	675	252	
Number With MDUFA IV Decision	603	590	515	86	
Number of SE Decision	581	580	511	86	
Number of NSE Decision	22	10	4	0	
Number of Withdrawal	33	21	17	3	
Number of Deleted	20	27	6	0	
Rate of SE Decision	96.35%	98.31%	99.22%	100.00%	
Rate of NSE Decision	3.65%	1.69%	0.78%	0.00%	
Rate of Withdrawal	5.01%	3.22%	2.52%	1.19%	
Rate of Deleted	3.03%	4.14%	0.89%	0.00%	

Table 6.7 OHT7 - Office of In Vitro Diagnostics and 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	1	1	12	5	
Mean FDA Days for Submissions that Missed the Goal	93.00	110.00	144.58	125.80	
Mean Industry Days for Submissions that Missed the Goal	202.00	175.00	38.42	0.00	

Table 6.8 OHT7 - Office of In Vitro Diagnostics and 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	2	1	4	0	
Non-MDUFA IV Decision	1	0	0	0	
MDUFA IV Decision (SE/NSE)	1	1	3	0	
MDUFA IV Decision Within 90 FDA Days	1	1	2	0	
510(k)s Pending MDUFA IV Decision	0	0	1	0	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%	N/A	

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

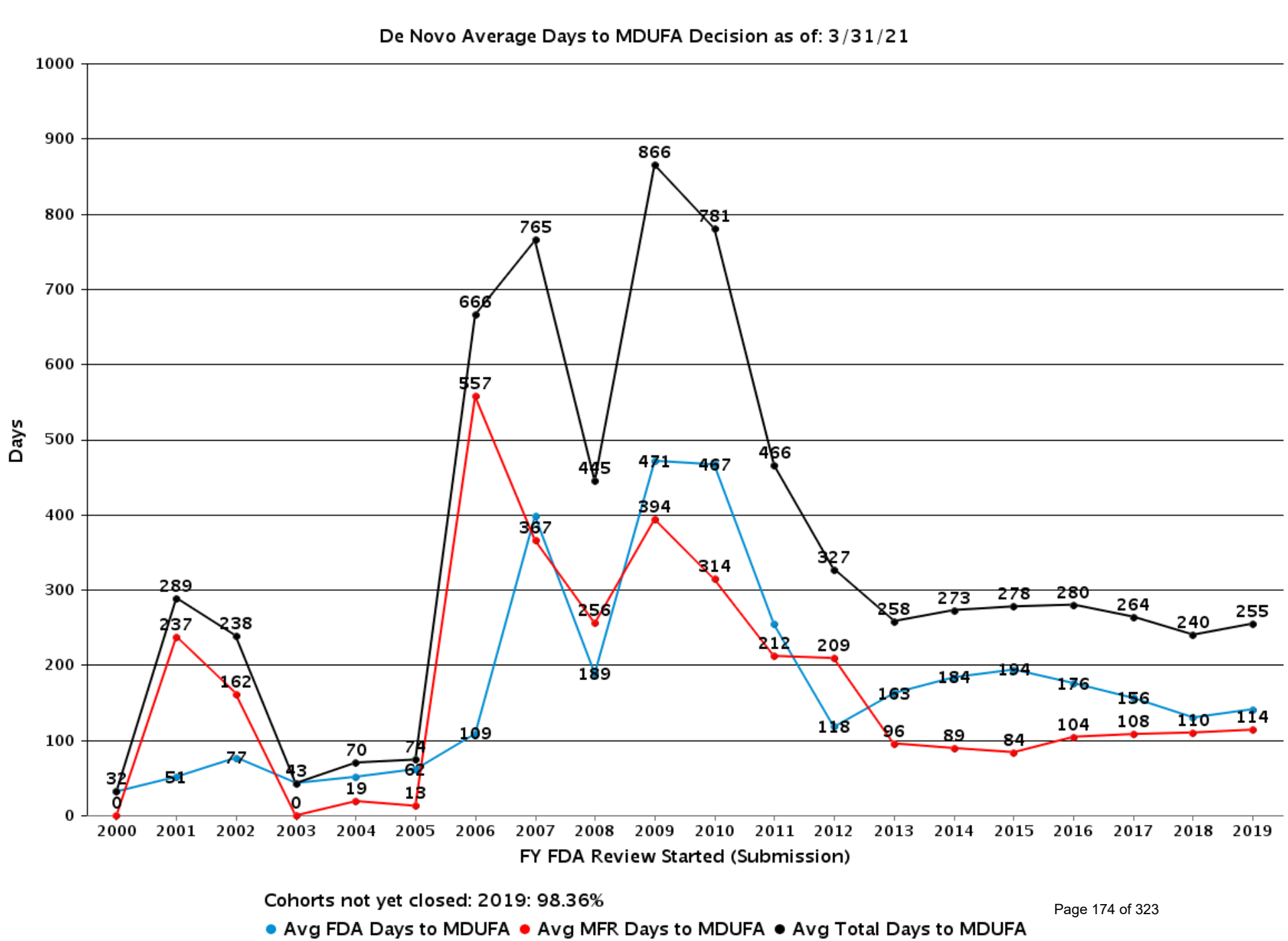
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	272	278	252	88	
Non-MDUFA IV Decision	41	35	14	2	
MDUFA IV Decision (SE/NSE)	231	238	132	9	
MDUFA IV Decision Within 90 FDA Days	230	237	121	4	
510(k)s Pending MDUFA IV Decision	0	5	106	77	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	4	78	42	
Current Performance Percent Within 90 FDA Days	99.57%	97.93%	57.62%	7.84%	

Section 7 510(k) Annual General Metrics - Annual Metrics and Goals will be reported in the Annual Report.

Page intentionally left blank

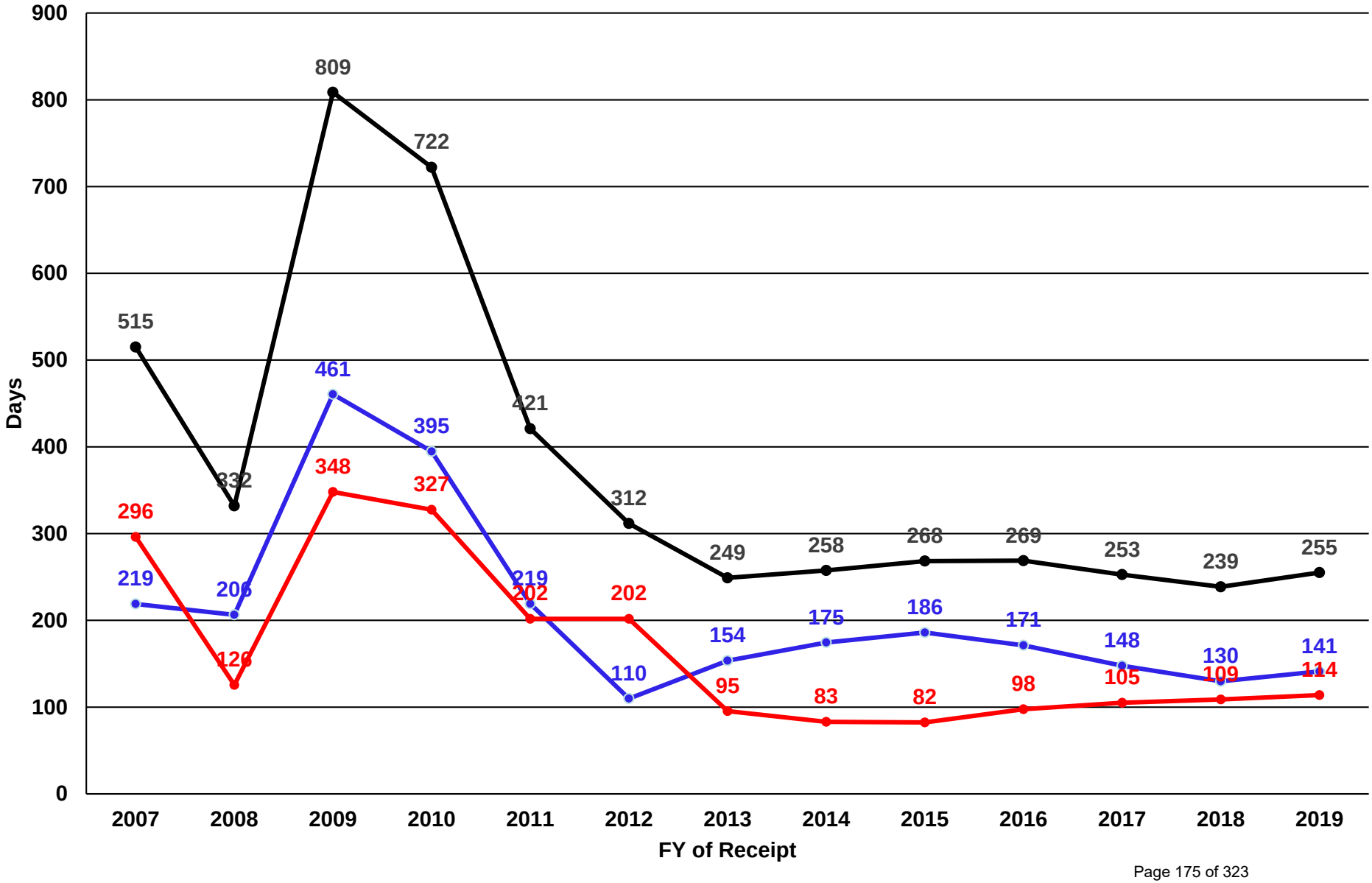
De Novos

Q2FY2021

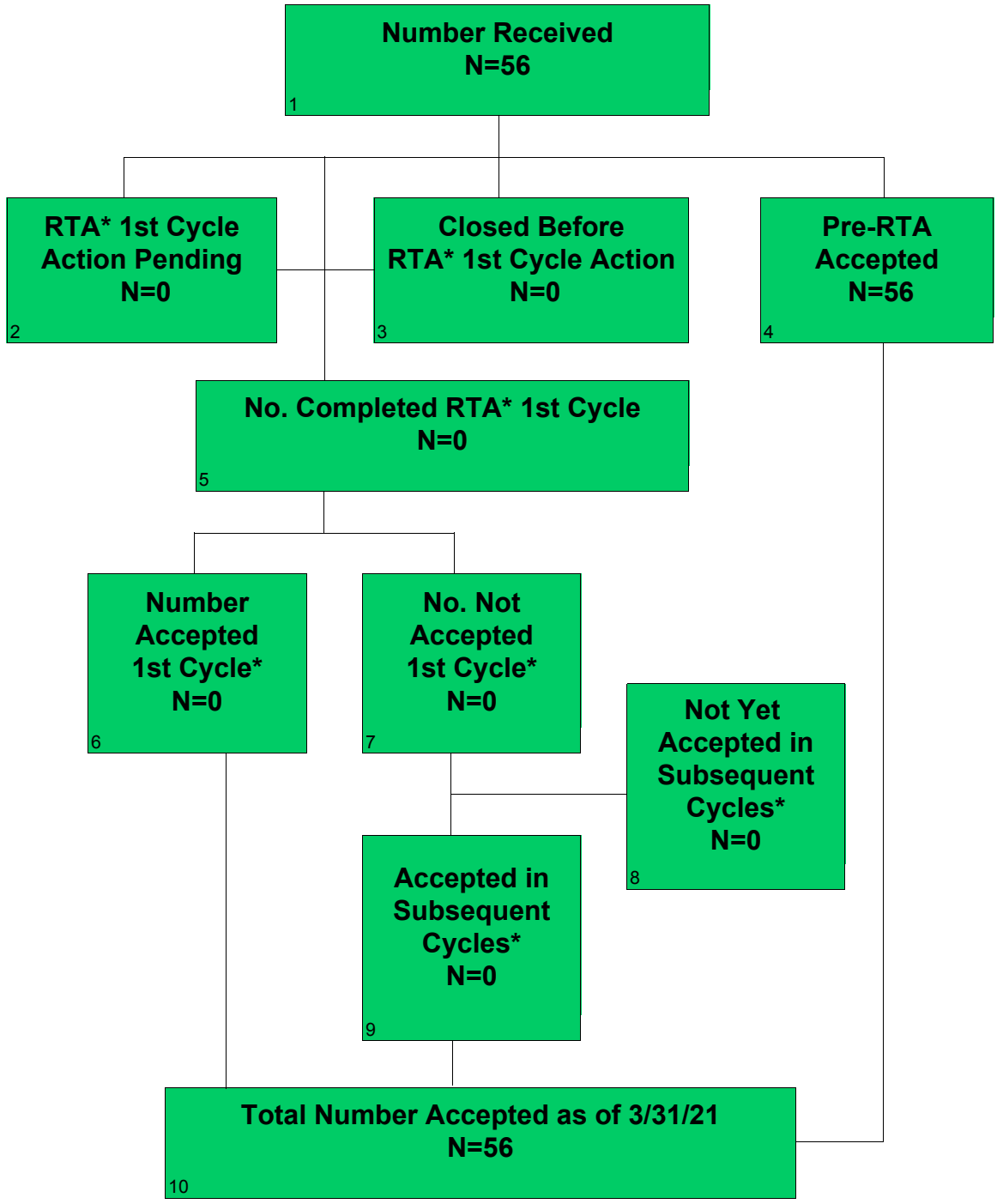

De Novo Average Days to MDUFA Decision as of: 3/31/21
Days
1000
900
800
700
600
500
400
300
200
100
0
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
FY FDA Review Started (Submission)
32
289
238
43
70
74
666
765
445
866
781
466
327
258
273
278
280
264
240
255
0
237
162
0
19
13
557
367
256
394
314
212
209
96
89
84
104
108
110
114
51
77
62
109
189
471
467
118
163
184
194
176
156
Cohorts not yet closed: 2019: 98.36%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos*

(98.4% closure comparison)

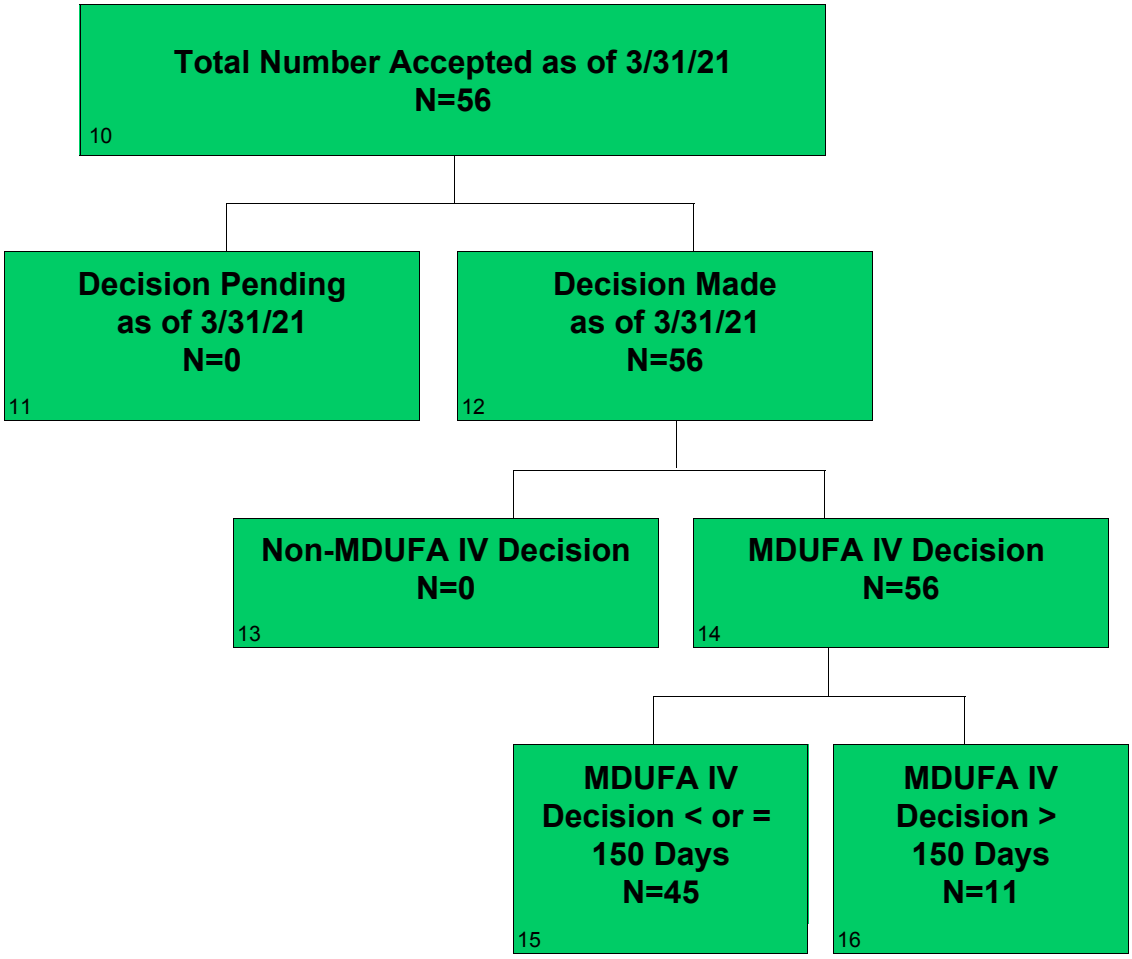


CDRH De Novo - FY 2018
as of 3/31/21

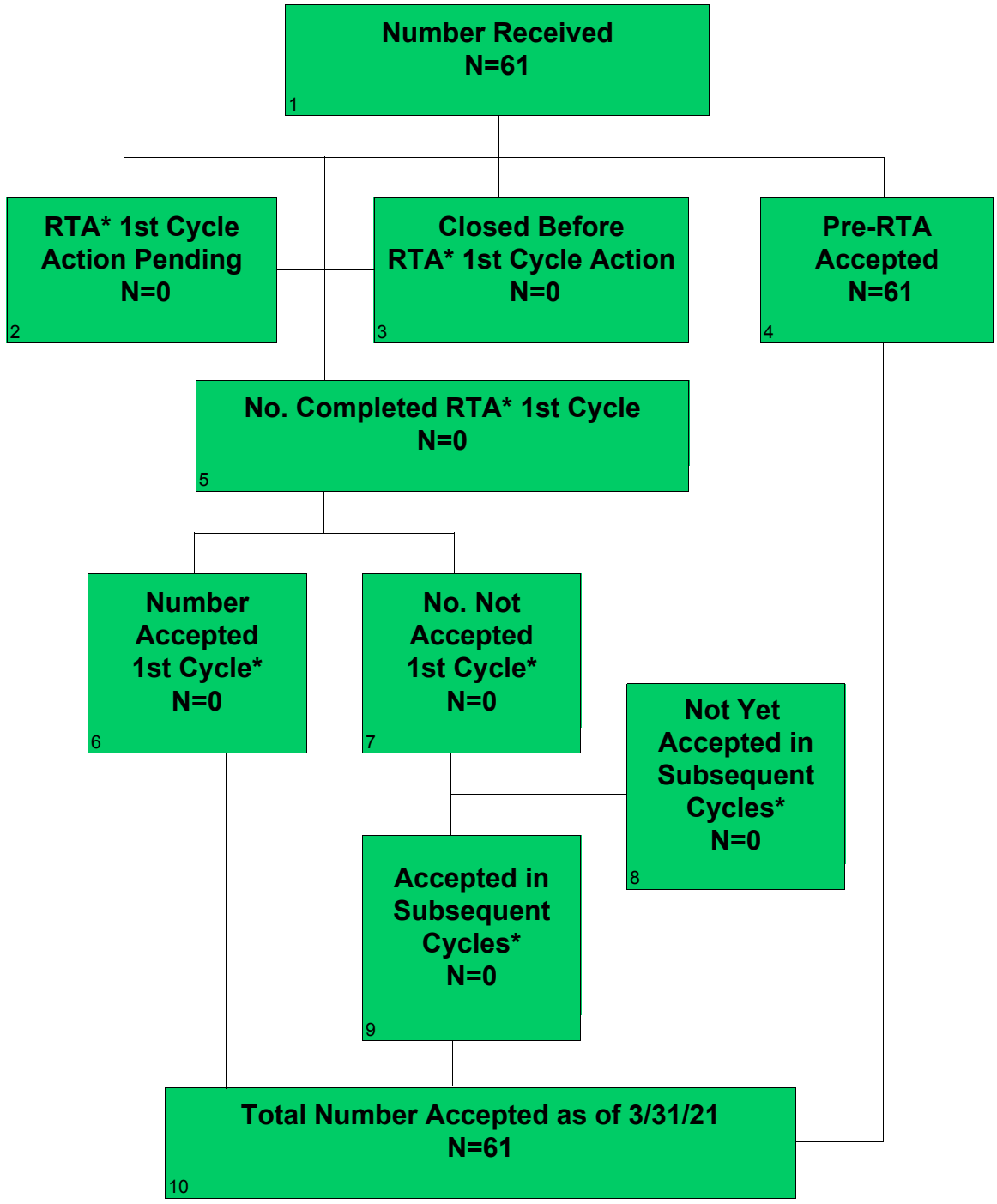


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018
as of 3/31/21 Continued

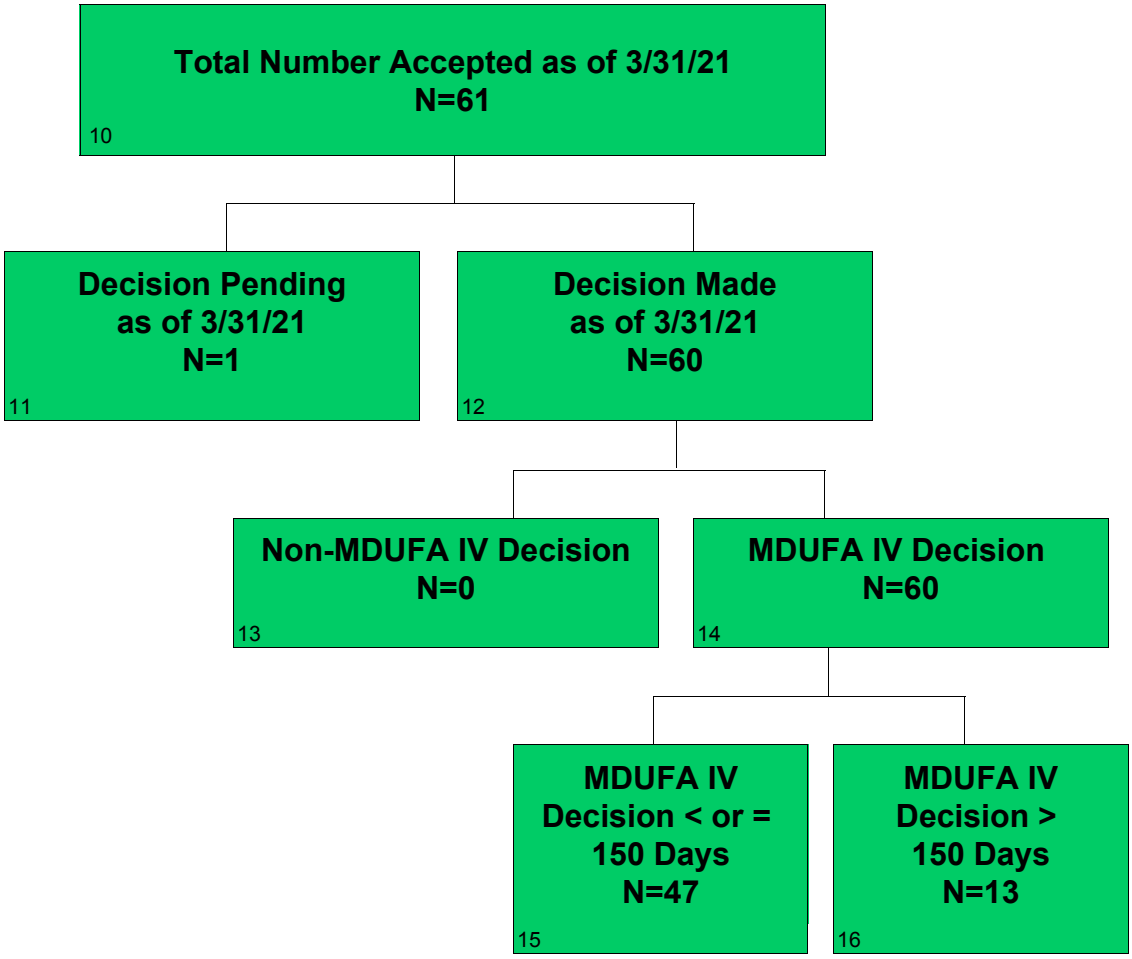


CDRH De Novo - FY 2019
as of 3/31/21

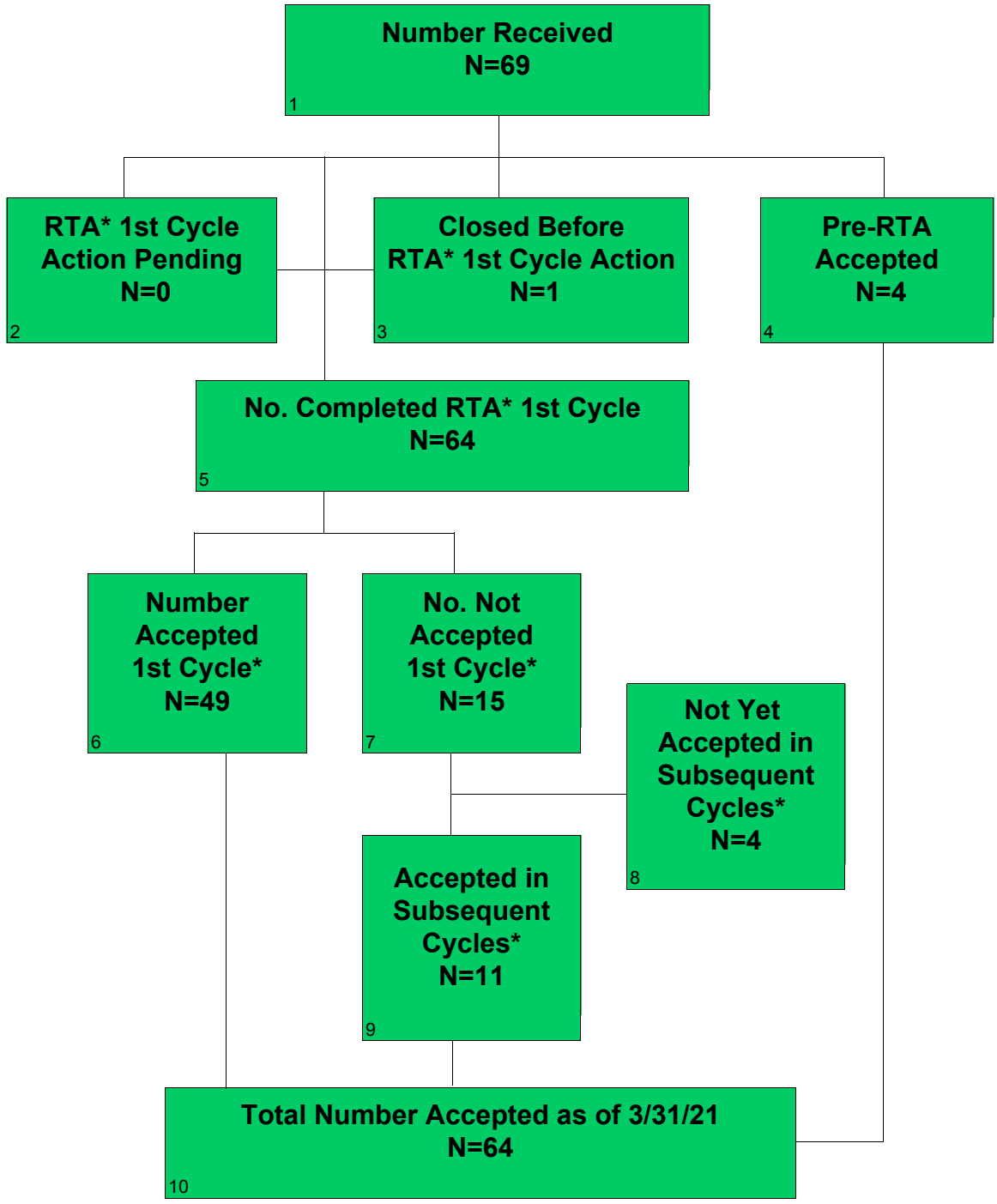


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019
as of 3/31/21 Continued

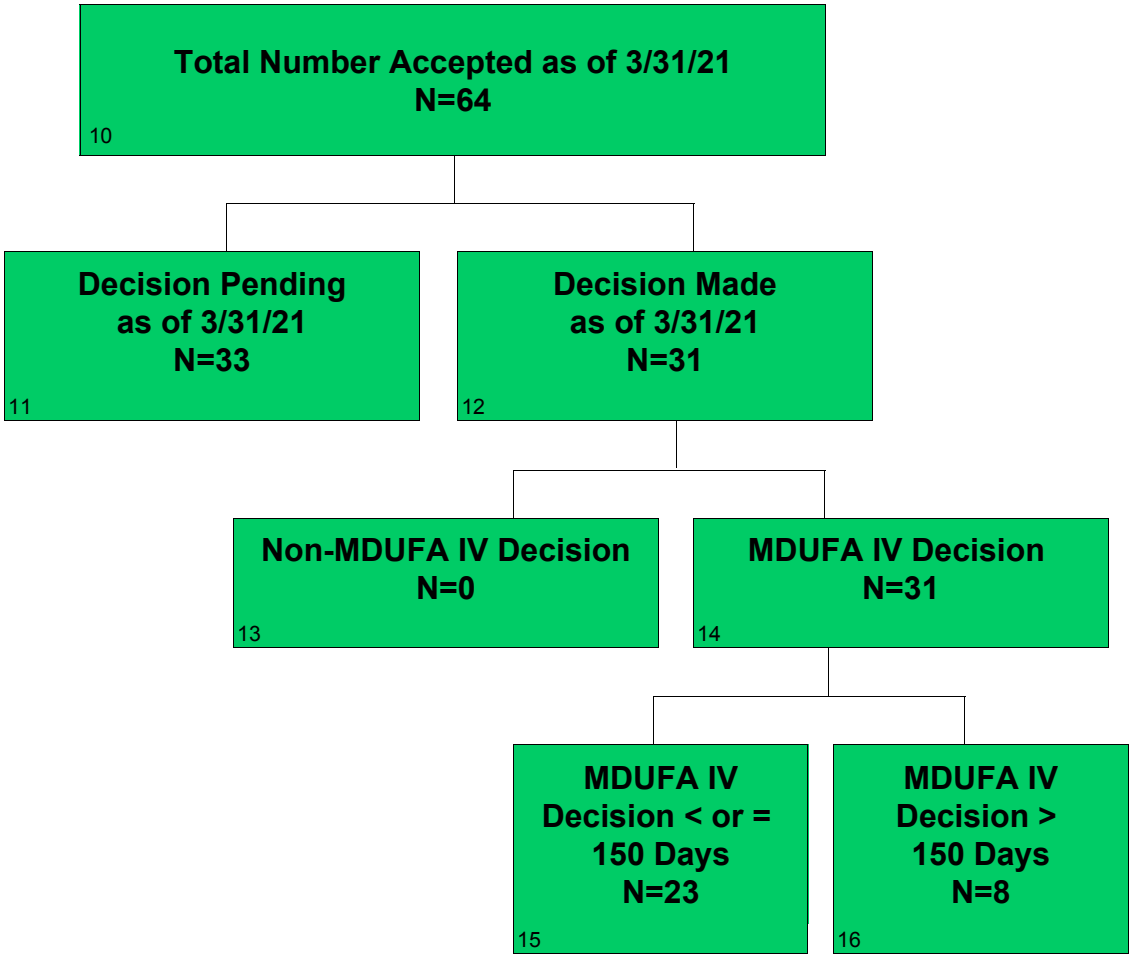


CDRH De Novo - FY 2020
as of 3/31/21

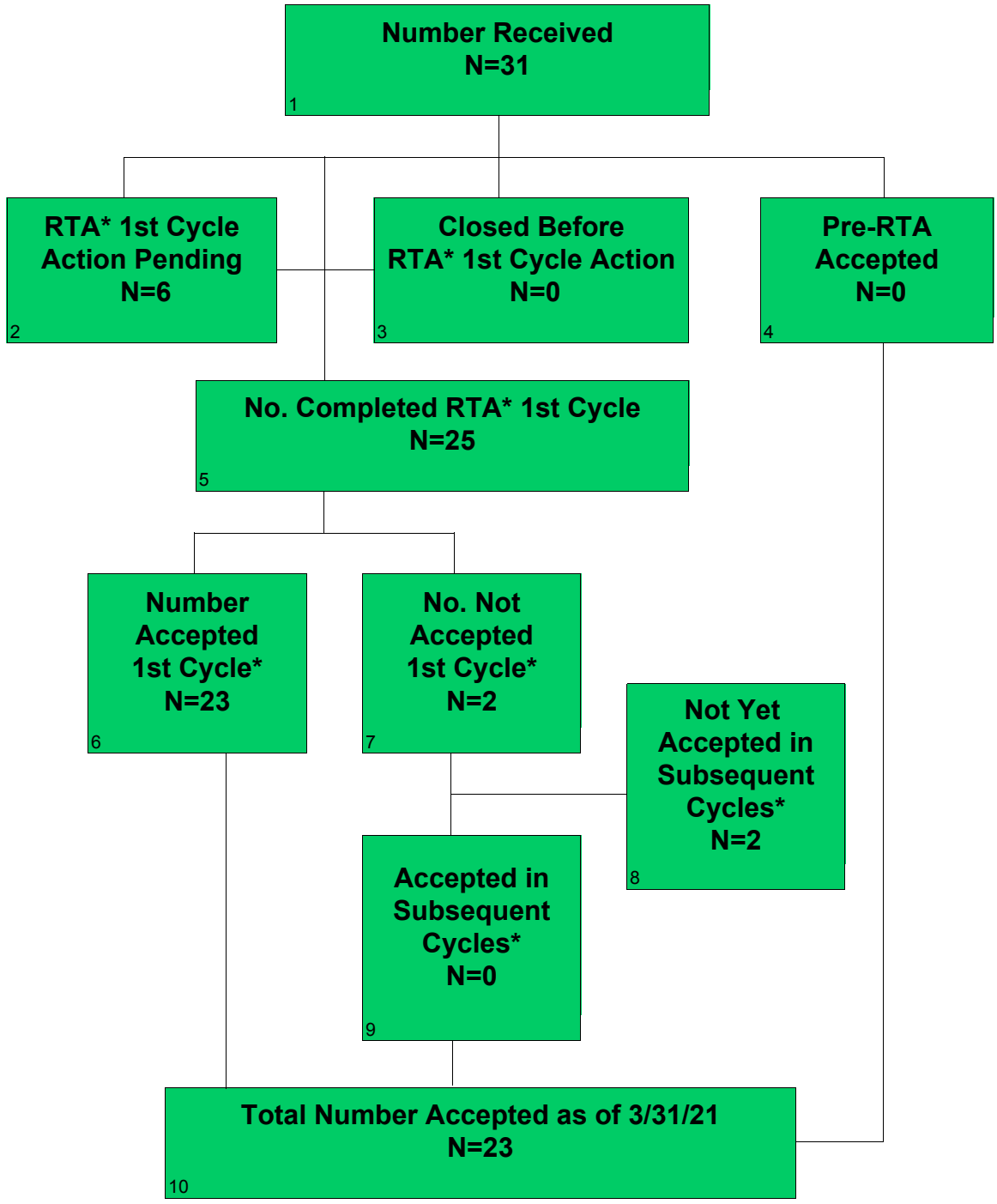


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020
as of 3/31/21 Continued

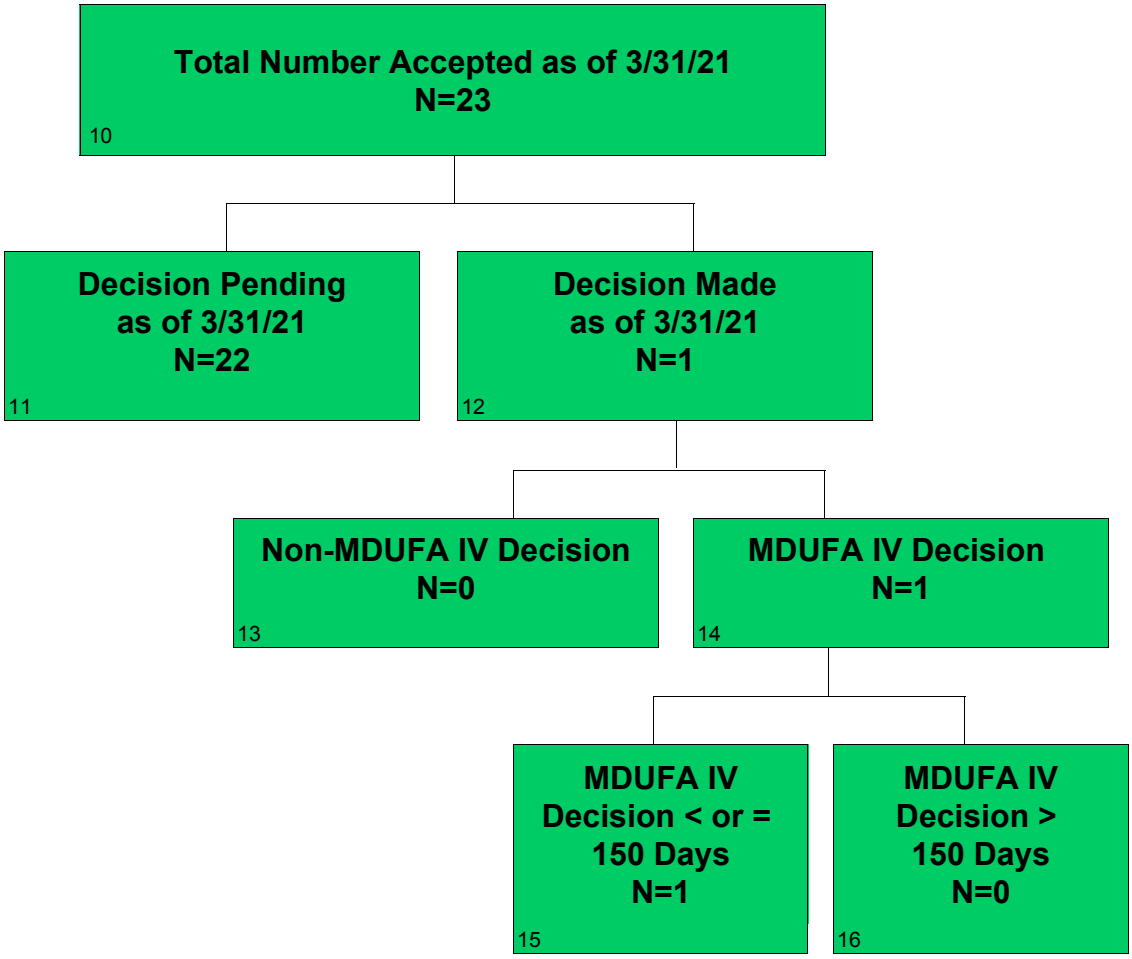


CDRH De Novo - FY 2021
as of 3/31/21



*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 3/31/21 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	31	
Closed Before RTA Action	0	0	1	0	
Number Accepted First RTA Cycle	0	0	46	17	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	3	6	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	6	
Number Not Accepted	0	0	15	2	
Rate of Submissions Not Accepted for Review	N/A	N/A	23.44%	8.00%	

***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 CDRH - 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	56	61	64	23	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	56	60	31	1	
MDUFA IV Decisions Within 150 FDA Days	45	47	23	1	
De Novos Pending MDUFA IV Decision	0	1	33	22	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	9	0	
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	57.50%	100.00%	

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	1.58	1.68	1.00	
Number With MDUFA IV Decision	56	60	31	1	
Average FDA Days to MDUFA IV Decision	130.13	141.18	149.90	71.00	
20th Percentile FDA Days to MDUFA IV Decision	75	75	75	71	
40th Percentile FDA Days to MDUFA IV Decision	145	130	148	71	
60th Percentile FDA Days to MDUFA IV Decision	150	148	150	71	
80th Percentile FDA Days to MDUFA IV Decision	150	166	175	71	
Maximum FDA Days to MDUFA IV Decision	254	485	357	71	
Average Industry Days to MDUFA IV Decision	110.13	113.90	96.84	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	89	23	57	0	
60th Percentile Industry Days to MDUFA IV Decision	166	177	105	0	
80th Percentile Industry Days to MDUFA IV Decision	180	197	171	0	
Maximum Industry Days to MDUFA IV Decision	389	373	364	0	
Average Total Days to MDUFA IV Decision	240.25	255.08	246.74	71.00	
20th Percentile Total Days to MDUFA IV Decision	145	105	147	71	
40th Percentile Total Days to MDUFA IV Decision	251	173	210	71	
60th Percentile Total Days to MDUFA IV Decision	292	303	309	71	
80th Percentile Total Days to MDUFA IV Decision	324	372	355	71	
Maximum Total Days to MDUFA IV Decision	463	680	439	71	

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	23	
Number With MDUFA IV Decisions	56	60	31	1	
Number With Granted Decisions	25	27	19	0	
Number With Declined Decisions	15	15	5	0	
Number of Withdrawals	10	13	5	1	
Number Deleted	6	5	2	0	
Rate of Granted Decisions	44.64%	45.00%	61.29%	0.00%	
Rate of Declined Decisions	26.79%	25.00%	16.13%	0.00%	
Rate of Withdrawals	17.86%	21.67%	16.13%	100.00%	
Rate of Deleted	10.71%	8.33%	6.45%	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	13	8	0	
Mean FDA Days for Submissions that Missed the Goal	192.45	245.92	231.88	0.00	
Mean Industry Days for Submissions that Missed the Goal	127.27	209.46	113.25	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	1	0	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	1	5	0	0	
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	
De Novos Pending MDUFA IV Decision	0	0	1	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	100.00%	40.00%	0.00%	N/A	

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	17	9	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	15	14	7	0	
MDUFA IV Decisions Within 150 FDA Days	15	14	6	0	
De Novos Pending MDUFA IV Decision	0	0	10	9	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	5	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	50.00%	N/A	

Section 8 De Novo Office Level Metrics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5	13	4	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	10	3	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted	0	0	2	1	
Rate of Submissions Not Accepted for Review	0.00	0.00	16.67%	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 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	3	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	8	5	7	0	
MDUFA IV Decisions Within 150 FDA Days	5	4	6	0	
De Novos Pending MDUFA IV Decision	0	0	6	3	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	62.50%	80.00%	75.00%	N/A	

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	1.57	0.00	
Number With MDUFA IV Decision	8	5	7	0	
Average FDA Days to MDUFA IV Decision	141.25	124.80	121.29	0.00	
20th Percentile FDA Days to MDUFA IV Decision	110	75	67	0	
40th Percentile FDA Days to MDUFA IV Decision	149	119	104	0	
60th Percentile FDA Days to MDUFA IV Decision	153	148	149	0	
80th Percentile FDA Days to MDUFA IV Decision	165	154	150	0	
Maximum FDA Days to MDUFA IV Decision	194	180	199	0	
Average Industry Days to MDUFA IV Decision	106.13	195.20	127.57	0.00	
20th Percentile Industry Days to MDUFA IV Decision	9	185	21	0	
40th Percentile Industry Days to MDUFA IV Decision	45	192	111	0	
60th Percentile Industry Days to MDUFA IV Decision	75	199	143	0	
80th Percentile Industry Days to MDUFA IV Decision	167	206	221	0	
Maximum Industry Days to MDUFA IV Decision	389	212	273	0	
Average Total Days to MDUFA IV Decision	247.38	320.00	248.86	0.00	
20th Percentile Total Days to MDUFA IV Decision	157	268	103	0	
40th Percentile Total Days to MDUFA IV Decision	199	304	275	0	
60th Percentile Total Days to MDUFA IV Decision	260	336	314	0	
80th Percentile Total Days to MDUFA IV Decision	332	360	341	0	
Maximum Total Days to MDUFA IV Decision	463	392	386	0	

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	3	
Number With MDUFA IV Decisions	8	5	7	0	
Number With Granted Decisions	5	2	4	0	
Number With Declined Decisions	2	1	1	0	
Number of Withdrawals	0	0	1	0	
Number Deleted	1	2	1	0	
Rate of Granted Decisions	62.50%	40.00%	57.14%	0.00%	
Rate of Declined Decisions	25.00%	20.00%	14.29%	0.00%	
Rate of Withdrawals	0.00%	0.00%	14.29%	0.00%	
Rate of Deleted	12.50%	40.00%	14.29%	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	1	0	
Mean FDA Days for Submissions that Missed the Goal	174.67	180.00	199.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	127.00	212.00	119.00	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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.1 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	1	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	6	1	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted	0	0	1	0	
Rate of Submissions Not Accepted for Review	N/A	N/A	14.29%	N/A	

***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	1	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	5	9	5	0	
MDUFA IV Decisions Within 150 FDA Days	5	8	1	0	
De Novos Pending MDUFA IV Decision	0	0	3	1	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	88.89%	20.00%	N/A	

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	1.80	0.00	
Number With MDUFA IV Decision	5	9	5	0	
Average FDA Days to MDUFA IV Decision	74.00	144.00	216.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	32	86	147	0	
40th Percentile FDA Days to MDUFA IV Decision	58	132	193	0	
60th Percentile FDA Days to MDUFA IV Decision	79	148	236	0	
80th Percentile FDA Days to MDUFA IV Decision	98	150	290	0	
Maximum FDA Days to MDUFA IV Decision	148	348	357	0	
Average Industry Days to MDUFA IV Decision	112.40	71.11	84.60	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	98	6	35	0	
60th Percentile Industry Days to MDUFA IV Decision	171	64	105	0	
80th Percentile Industry Days to MDUFA IV Decision	188	163	177	0	
Maximum Industry Days to MDUFA IV Decision	217	207	190	0	
Average Total Days to MDUFA IV Decision	186.40	215.11	300.60	0.00	
20th Percentile Total Days to MDUFA IV Decision	32	117	280	0	
40th Percentile Total Days to MDUFA IV Decision	173	153	346	0	
60th Percentile Total Days to MDUFA IV Decision	277	213	356	0	
80th Percentile Total Days to MDUFA IV Decision	296	281	363	0	
Maximum Total Days to MDUFA IV Decision	312	526	386	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	1	
Number With MDUFA IV Decisions	5	9	5	0	
Number With Granted Decisions	3	2	3	0	
Number With Declined Decisions	0	5	1	0	
Number of Withdrawals	0	1	1	0	
Number Deleted	2	1	0	0	
Rate of Granted Decisions	60.00%	22.22%	60.00%	0.00%	
Rate of Declined Decisions	0.00%	55.56%	20.00%	0.00%	
Rate of Withdrawals	0.00%	11.11%	20.00%	0.00%	
Rate of Deleted	40.00%	11.11%	0.00%	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	4	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	348.00	251.75	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	178.00	105.75	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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.1 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	1	
Closed Before RTA Action	0	0		0	
Number Accepted First RTA Cycle	0	0	4	0	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted	0	0	2	0	
Rate of Submissions Not Accepted for Review	N/A	N/A	33.33%	N/A	

***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	0	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	4	10	3	0	
MDUFA IV Decisions Within 150 FDA Days	3	5	2	0	
De Novos Pending MDUFA IV Decision	0	1	3	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	1	0	
Current Performance Percent Within 150 FDA Days	75.00%	45.45%	50.00%	N/A	

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	1.80	2.00	0.00	
Number With MDUFA IV Decision	4	10	3	0	
Average FDA Days to MDUFA IV Decision	100.00	177.30	180.33	0.00	
20th Percentile FDA Days to MDUFA IV Decision	57	148	149	0	
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	0	
60th Percentile FDA Days to MDUFA IV Decision	135	186	169	0	
80th Percentile FDA Days to MDUFA IV Decision	149	195	206	0	
Maximum FDA Days to MDUFA IV Decision	151	327	243	0	
Average Industry Days to MDUFA IV Decision	136.75	151.50	35.33	0.00	
20th Percentile Industry Days to MDUFA IV Decision	100	109	22	0	
40th Percentile Industry Days to MDUFA IV Decision	169	171	23	0	
60th Percentile Industry Days to MDUFA IV Decision	175	177	31	0	
80th Percentile Industry Days to MDUFA IV Decision	187	191	46	0	
Maximum Industry Days to MDUFA IV Decision	203	266	61	0	
Average Total Days to MDUFA IV Decision	236.75	328.80	215.67	0.00	
20th Percentile Total Days to MDUFA IV Decision	179	256	186	0	
40th Percentile Total Days to MDUFA IV Decision	293	340	201	0	
60th Percentile Total Days to MDUFA IV Decision	312	367	221	0	
80th Percentile Total Days to MDUFA IV Decision	321	394	244	0	
Maximum Total Days to MDUFA IV Decision	325	568	267	0	

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	0	
Number With MDUFA IV Decisions	4	10	3	0	
Number With Granted Decisions	0	7	2	0	
Number With Declined Decisions	3	3	1	0	
Number of Withdrawals	0	0	0	0	
Number Deleted	1	0	0	0	
Rate of Granted Decisions	0.00%	70.00%	66.67%	0.00%	
Rate of Declined Decisions	75.00%	30.00%	33.33%	0.00%	
Rate of Withdrawals	0.00%	0.00%	0.00%	0.00%	
Rate of Deleted	25.00%	0.00%	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	5	1	0	
Mean FDA Days for Submissions that Missed the Goal	151.00	220.60	243.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	167.00	186.80	24.00	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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.1 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	3	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	3	2	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	1	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted	0	0	3	0	
Rate of Submissions Not Accepted for Review	N/A	N/A	42.86%	N/A	

***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	2	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	5	6	2	0	
MDUFA IV Decisions Within 150 FDA Days	3	4	2	0	
De Novos Pending MDUFA IV Decision	0	0	5	2	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	66.67%	N/A	

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	1.00	0.00	
Number With MDUFA IV Decision	5	6	2	0	
Average FDA Days to MDUFA IV Decision	147.40	182.50	92.50	0.00	
20th Percentile FDA Days to MDUFA IV Decision	133	93	71	0	
40th Percentile FDA Days to MDUFA IV Decision	150	98	85	0	
60th Percentile FDA Days to MDUFA IV Decision	151	107	100	0	
80th Percentile FDA Days to MDUFA IV Decision	167	236	114	0	
Maximum FDA Days to MDUFA IV Decision	221	485	129	0	
Average Industry Days to MDUFA IV Decision	90.80	125.83	136.50	0.00	
20th Percentile Industry Days to MDUFA IV Decision	12	0	55	0	
40th Percentile Industry Days to MDUFA IV Decision	65	0	109	0	
60th Percentile Industry Days to MDUFA IV Decision	124	187	164	0	
80th Percentile Industry Days to MDUFA IV Decision	165	195	218	0	
Maximum Industry Days to MDUFA IV Decision	179	373	273	0	
Average Total Days to MDUFA IV Decision	238.20	308.33	229.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	145	93	125	0	
40th Percentile Total Days to MDUFA IV Decision	215	107	194	0	
60th Percentile Total Days to MDUFA IV Decision	275	285	264	0	
80th Percentile Total Days to MDUFA IV Decision	332	609	333	0	
Maximum Total Days to MDUFA IV Decision	400	680	402	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	2	
Number With MDUFA IV Decisions	5	6	2	0	
Number With Granted Decisions	3	1	0	0	
Number With Declined Decisions	1	3	0	0	
Number of Withdrawals	1	1	2	0	
Number Deleted	0	1	0	0	
Rate of Granted Decisions	60.00%	16.67%	0.00%	0.00%	
Rate of Declined Decisions	20.00%	50.00%	0.00%	0.00%	
Rate of Withdrawals	20.00%	16.67%	100.00%	0.00%	
Rate of Deleted	0.00%	16.67%	0.00%	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	0	0	
Mean FDA Days for Submissions that Missed the Goal	187.00	360.50	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	170.50	284.00	0.00	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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.1 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	6	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	5	5	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted	0	0	2	0	
Rate of Submissions Not Accepted for Review	N/A	N/A	28.57%	N/A	

***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	5	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	13	6	4	1	
MDUFA IV Decisions Within 150 FDA Days	9	6	3	1	
De Novos Pending MDUFA IV Decision	0	0	2	4	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	69.23%	100.00%	75.00%	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	1.75	1.00	
Number With MDUFA IV Decision	13	6	4	1	
Average FDA Days to MDUFA IV Decision	153.00	113.33	133.25	71.00	
20th Percentile FDA Days to MDUFA IV Decision	104	76	113	71	
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	71	
60th Percentile FDA Days to MDUFA IV Decision	150	136	150	71	
80th Percentile FDA Days to MDUFA IV Decision	219	149	160	71	
Maximum FDA Days to MDUFA IV Decision	254	150	175	71	
Average Industry Days to MDUFA IV Decision	106.08	20.17	66.75	0.00	
20th Percentile Industry Days to MDUFA IV Decision	39	0	8	0	
40th Percentile Industry Days to MDUFA IV Decision	82	0	28	0	
60th Percentile Industry Days to MDUFA IV Decision	164	0	70	0	
80th Percentile Industry Days to MDUFA IV Decision	174	45	118	0	
Maximum Industry Days to MDUFA IV Decision	183	76	169	0	
Average Total Days to MDUFA IV Decision	259.08	133.50	200.00	71.00	
20th Percentile Total Days to MDUFA IV Decision	226	76	121	71	
40th Percentile Total Days to MDUFA IV Decision	266	127	177	71	
60th Percentile Total Days to MDUFA IV Decision	316	136	220	71	
80th Percentile Total Days to MDUFA IV Decision	323	195	278	71	
Maximum Total Days to MDUFA IV Decision	371	225	344	71	

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	5	
Number With MDUFA IV Decisions	13	6	4	1	
Number With Granted Decisions	3	2	4	0	
Number With Declined Decisions	7	0	0	0	
Number of Withdrawals	3	4	0	1	
Number Deleted	0	0	0	0	
Rate of Granted Decisions	23.08%	33.33%	100.00%	0.00%	
Rate of Declined Decisions	53.85%	0.00%	0.00%	0.00%	
Rate of Withdrawals	23.08%	66.67%	0.00%	100.00%	
Rate of Deleted	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	0	
Mean FDA Days for Submissions that Missed the Goal	229.25	0.00	175.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	82.75	0.00	169.00	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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.1 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	4	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	5	2	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted	0	0	0	0	
Rate of Submissions Not Accepted for Review	N/A	N/A	N/A	N/A	

***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	2	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	4	4	3	0	
MDUFA IV Decisions Within 150 FDA Days	3	3	3	0	
De Novos Pending MDUFA IV Decision	0	0	2	2	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	75.00%	75.00%	100.00%	N/A	

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	0.00	
Number With MDUFA IV Decision	4	4	3	0	
Average FDA Days to MDUFA IV Decision	133.25	144.75	145.67	0.00	
20th Percentile FDA Days to MDUFA IV Decision	122	116	142	0	
40th Percentile FDA Days to MDUFA IV Decision	148	143	147	0	
60th Percentile FDA Days to MDUFA IV Decision	150	144	149	0	
80th Percentile FDA Days to MDUFA IV Decision	150	173	150	0	
Maximum FDA Days to MDUFA IV Decision	151	217	150	0	
Average Industry Days to MDUFA IV Decision	161.00	178.50	94.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	149	104	59	0	
40th Percentile Industry Days to MDUFA IV Decision	179	175	62	0	
60th Percentile Industry Days to MDUFA IV Decision	180	177	83	0	
80th Percentile Industry Days to MDUFA IV Decision	180	252	122	0	
Maximum Industry Days to MDUFA IV Decision	181	362	162	0	
Average Total Days to MDUFA IV Decision	294.25	323.25	239.67	0.00	
20th Percentile Total Days to MDUFA IV Decision	260	221	202	0	
40th Percentile Total Days to MDUFA IV Decision	278	333	209	0	
60th Percentile Total Days to MDUFA IV Decision	316	380	232	0	
80th Percentile Total Days to MDUFA IV Decision	330	439	272	0	
Maximum Total Days to MDUFA IV Decision	331	505	312	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	2	
Number With MDUFA IV Decisions	4	4	3	0	
Number With Granted Decisions	1	1	2	0	
Number With Declined Decisions	1	3	1	0	
Number of Withdrawals	1	0	0	0	
Number Deleted	1	0	0	0	
Rate of Granted Decisions	25.00%	25.00%	66.67%	0.00%	
Rate of Declined Decisions	25.00%	75.00%	33.33%	0.00%	
Rate of Withdrawals	25.00%	0.00%	0.00%	0.00%	
Rate of Deleted	25.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	151.00	217.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	180.00	178.00	0.00	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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 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	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	20	22	12	
Closed Before RTA Action	0	0	1	0	
Number Accepted First RTA Cycle	0	0	13	4	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	2	6	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted	0	0	5	1	
Rate of Submissions Not Accepted for Review	N/A	N/A	25.00%	9.09%	

***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 and 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	17	20	19	10	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	17	20	7	0	
MDUFA IV Decisions Within 150 FDA Days	17	17	6	0	
De Novos Pending MDUFA IV Decision	0	0	12	10	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	6	0	
Current Performance Percent Within 150 FDA Days	100.00%	85.00%	46.15%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.47	1.55	1.57	0.00	
Number With MDUFA IV Decision	17	20	7	0	
Average FDA Days to MDUFA IV Decision	125.18	121.20	146.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	108	71	132	0	
40th Percentile FDA Days to MDUFA IV Decision	127	121	142	0	
60th Percentile FDA Days to MDUFA IV Decision	146	148	149	0	
80th Percentile FDA Days to MDUFA IV Decision	150	150	150	0	
Maximum FDA Days to MDUFA IV Decision	150	243	231	0	
Average Industry Days to MDUFA IV Decision	101.88	105.65	108.29	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	84	0	28	0	
60th Percentile Industry Days to MDUFA IV Decision	169	168	120	0	
80th Percentile Industry Days to MDUFA IV Decision	179	220	167	0	
Maximum Industry Days to MDUFA IV Decision	189	276	364	0	
Average Total Days to MDUFA IV Decision	227.06	226.85	254.29	0.00	
20th Percentile Total Days to MDUFA IV Decision	137	99	148	0	
40th Percentile Total Days to MDUFA IV Decision	183	150	174	0	
60th Percentile Total Days to MDUFA IV Decision	277	278	265	0	
80th Percentile Total Days to MDUFA IV Decision	313	337	382	0	
Maximum Total Days to MDUFA IV Decision	327	509	439	0	

Table 8.4 OHT7 - Office of In Vitro Diagnostics and 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	17	20	19	10	
Number With MDUFA IV Decisions	17	20	7	0	
Number With Granted Decisions	10	12	4	0	
Number With Declined Decisions	1	0	1	0	
Number of Withdrawals	5	7	1	0	
Number Deleted	1	1	1	0	
Rate of Granted Decisions	58.82%	60.00%	57.14%	0.00%	
Rate of Declined Decisions	5.88%	0.00%	14.29%	0.00%	
Rate of Withdrawals	29.41%	35.00%	14.29%	0.00%	
Rate of Deleted	5.88%	5.00%	14.29%	0.00%	

Table 8.5 OHT7 - Office of In Vitro Diagnostics and 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	3	1	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	231.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	171.00	0.00	

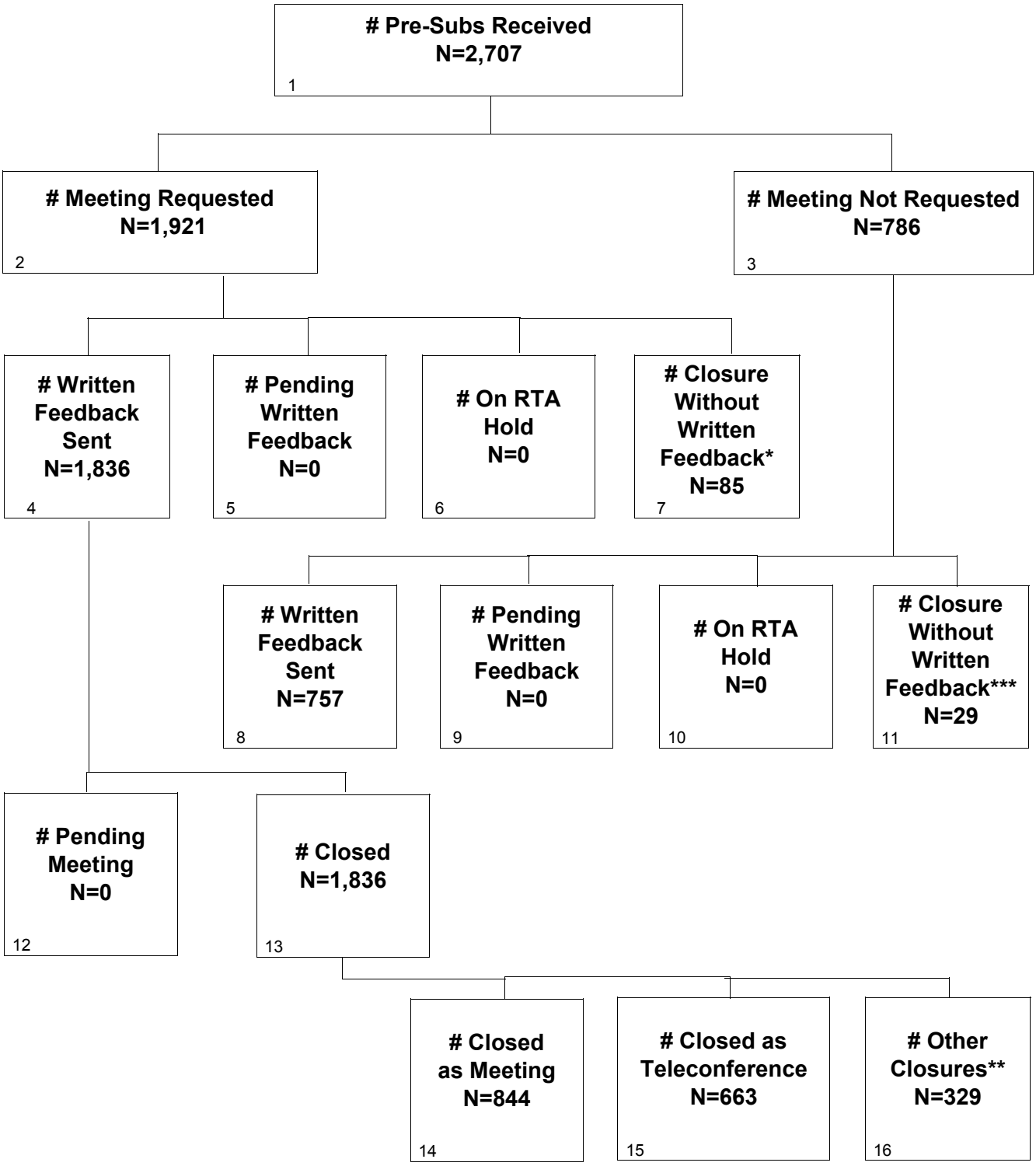
Table 8.6 OHT7 - Office of In Vitro Diagnostics and Radiological Health
LDT De Novo MDUFA IV Decision Metrics

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

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

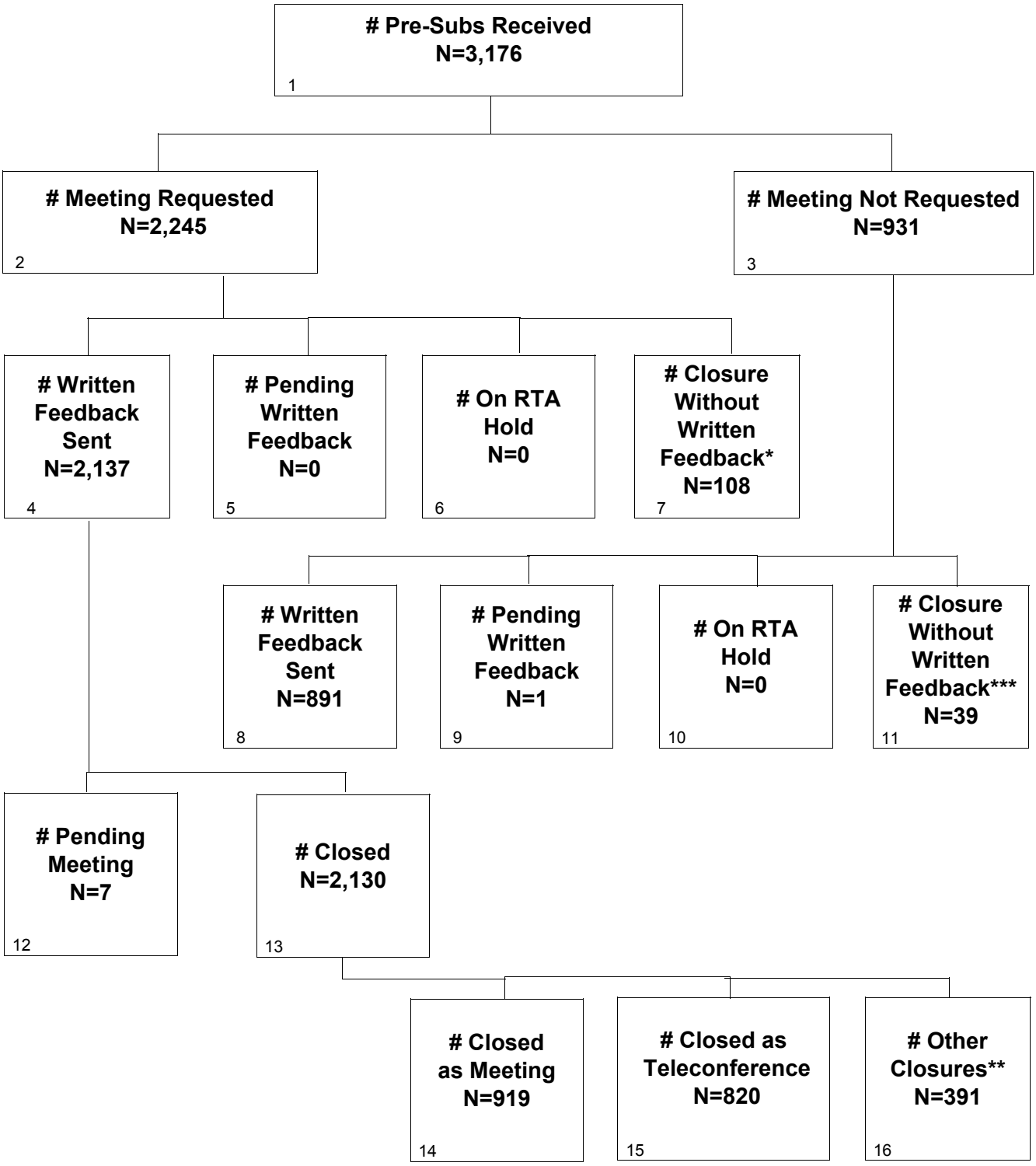
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	17	9	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	15	14	7	0	
MDUFA IV Decisions Within 150 FDA Days	15	14	6	0	
De Novos Pending MDUFA IV Decision	0	0	10	9	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	5	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	50.00%	N/A	

CDRH Pre-Sub - FY 2018
as of 3/31/21



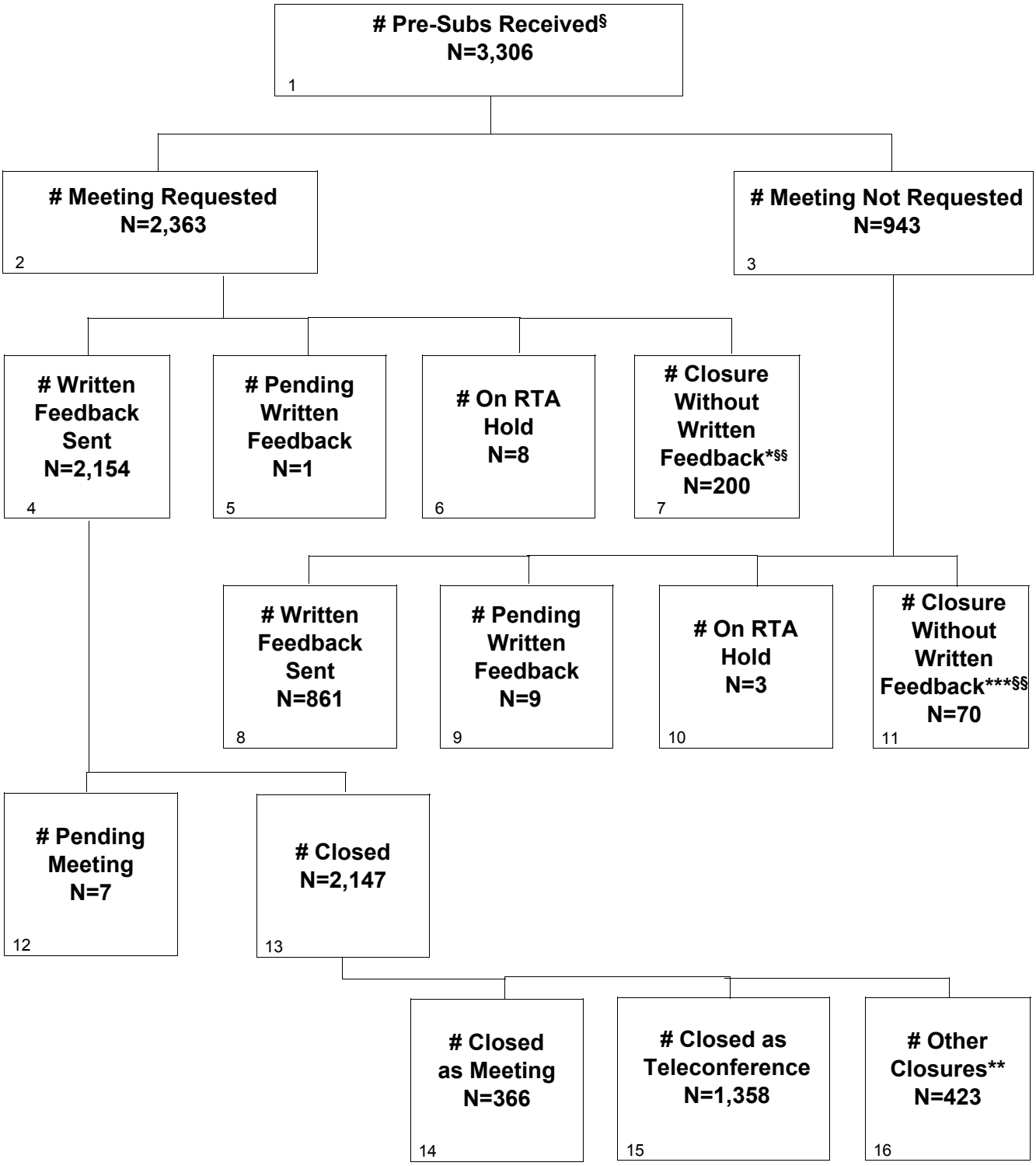
*** Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR**
**** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR**
***** Closures include JTRX, JPND, DELE & WTDR**

CDRH Pre-Sub - FY 2019
as of 3/31/21



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

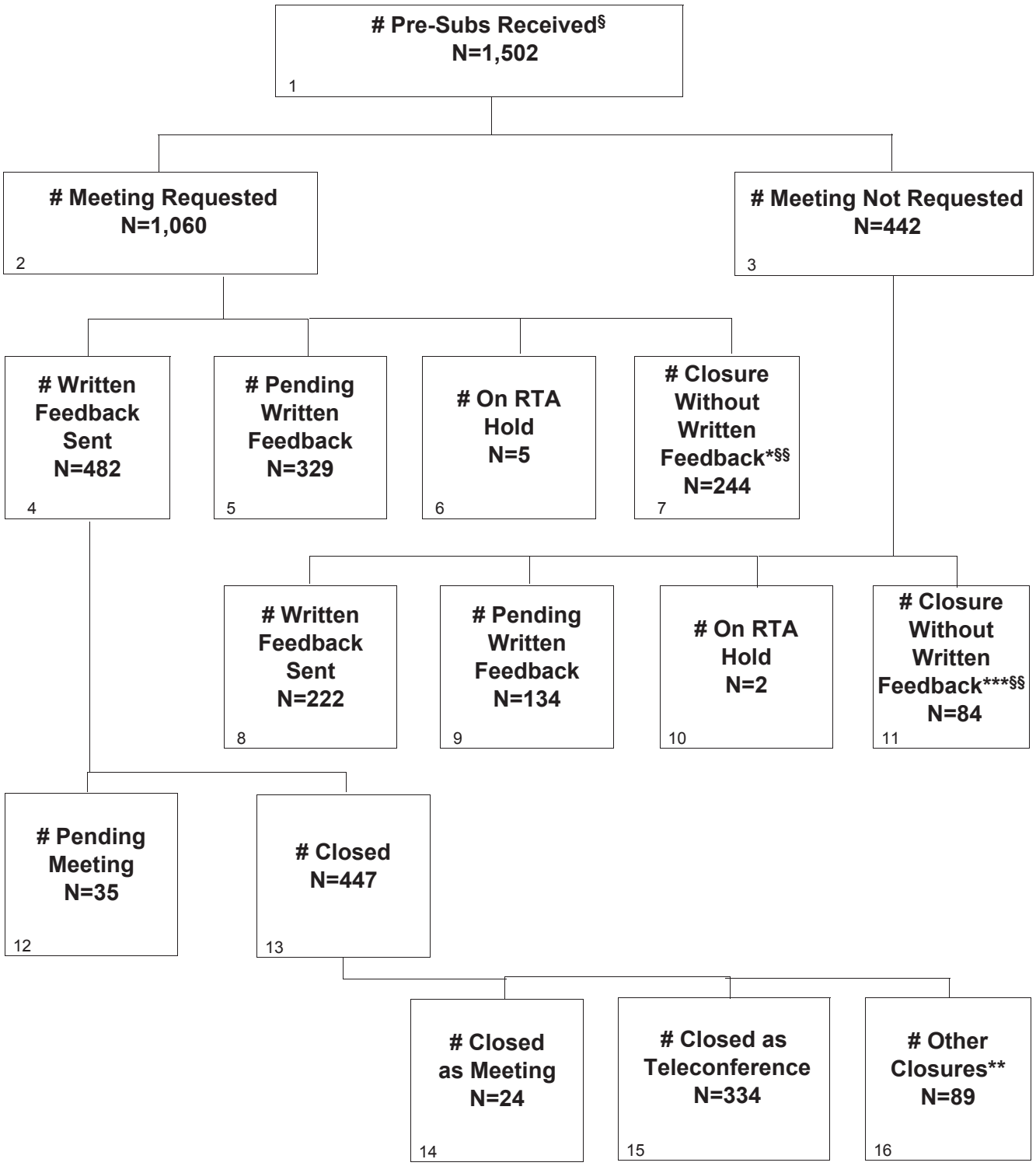
CDRH Pre-Sub - FY 2020
as of 3/31/21



* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR
** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR
*** Closures include 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 3/31/21



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

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	1,502	
Closed Before RTA Action**	27	41	109	267	
Number Accepted First RTA Cycle**	2,565	3,004	3,035	1,059	
Number Without a RTA Review and > 15 Days Since Date Received**	49	71	121	91	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	70	
Number Not Accepted	66	60	41	14	
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.28%	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 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	3,028	3,015	704	
Written Feedback Provided Within MDUFA IV Goal	2,439	2,848	2,652	581	

***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	3,028	3,015	704	
Average FDA Days to Written Feedback	58.86	59.94	62.80	62.04	
20th Percentile FDA Days to Written Feedback	49	49	52	49	
40th Percentile FDA Days to Written Feedback	59	60	62	62	
60th Percentile FDA Days to Written Feedback	65	65	66	67	
80th Percentile FDA Days to Written Feedback	69	70	70	70	
Maximum FDA Days to Written Feedback	172	397	290	139	

***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	30	
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	43.33	45.93	

***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	1,739	1,724	358	
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,111	1,109	217	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	1	34	
Meeting Minutes Past 15 Days of Meeting	483	558	536	91	
Meeting Minutes Not Submitted and >15 Days Since Meeting	53	70	78	16	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	63.89%	64.36%	66.98%	

***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	318	391	430	187	
Closed Before RTA Action	0	6	5	5	
Number Accepted First RTA Cycle	283	361	407	165	
Number Without a RTA Review and > 15 Days Since Date Received	8	9	10	5	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	9	
Number Not Accepted	27	15	8	3	
Rate of Submissions Not Accepted for Review	8.49%	3.90%	1.88%	1.73%	

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	297	361	398	108	
Written Feedback Provided Within MDUFA IV Goal	256	315	280	66	

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	297	361	398	108	
Average FDA Days to Written Feedback	64.23	64.14	70.79	70.68	
20th Percentile FDA Days to Written Feedback	56	57	62	62	
40th Percentile FDA Days to Written Feedback	64	65	66	66	
60th Percentile FDA Days to Written Feedback	69	69	70	70	
80th Percentile FDA Days to Written Feedback	70	70	74	81	
Maximum FDA Days to Written Feedback	168	119	280	139	

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	5	10	6	
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	33.40	42.40	41.83	

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	182	225	239	61	
Meeting Minutes Submitted Within 15 Days of Meeting	125	152	150	38	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	1	5	
Meeting Minutes Past 15 Days of Meeting	50	68	78	17	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	10	1	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.68%	67.56%	63.03%	67.86%	

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	675	373	
Closed Before RTA Action	6	7	4	5	
Number Accepted First RTA Cycle	506	555	648	331	
Number Without a RTA Review and > 15 Days Since Date Received	12	14	14	18	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	18	
Number Not Accepted	6	6	9	1	
Rate of Submissions Not Accepted for Review	1.15%	1.04%	1.34%	0.29%	

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	229	
Written Feedback Provided Within MDUFA IV Goal	482	535	610	205	

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	229	
Average FDA Days to Written Feedback	53.02	55.51	56.20	56.76	
20th Percentile FDA Days to Written Feedback	39	44	45	45	
40th Percentile FDA Days to Written Feedback	50	53	55	54	
60th Percentile FDA Days to Written Feedback	59	63	63	64	
80th Percentile FDA Days to Written Feedback	67	69	69	69	
Maximum FDA Days to Written Feedback	91	115	143	124	

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	10	
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	39.89	38.75	45.00	

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	323	357	99	
Meeting Minutes Submitted Within 15 Days of Meeting	183	199	212	55	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	9	
Meeting Minutes Past 15 Days of Meeting	119	104	123	29	
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	20	22	6	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	58.47%	61.61%	59.38%	61.11%	

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	379	398	191	
Closed Before RTA Action	5	7	11	26	
Number Accepted First RTA Cycle	307	356	375	145	
Number Without a RTA Review and > 15 Days Since Date Received	11	7	3	10	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	7	
Number Not Accepted	11	9	9	2	
Rate of Submissions Not Accepted for Review	3.34%	2.42%	2.33%	1.27%	

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	351	371	87	
Written Feedback Provided Within MDUFA IV Goal	300	342	351	74	

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	351	371	87	
Average FDA Days to Written Feedback	60.53	60.73	61.33	65.84	
20th Percentile FDA Days to Written Feedback	53	53	51	55	
40th Percentile FDA Days to Written Feedback	61	61	61	65	
60th Percentile FDA Days to Written Feedback	65	65	66	69	
80th Percentile FDA Days to Written Feedback	69	69	70	70	
Maximum FDA Days to Written Feedback	156	148	168	138	

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	7	1	5	
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	37.71	36.00	64.40	

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	202	220	51	
Meeting Minutes Submitted Within 15 Days of Meeting	112	124	156	35	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	7	
Meeting Minutes Past 15 Days of Meeting	64	72	61	6	
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	3	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.39%	70.91%	79.55%	

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	252	278	337	160	
Closed Before RTA Action	4	5	21	90	
Number Accepted First RTA Cycle	235	253	304	55	
Number Without a RTA Review and > 15 Days Since Date Received	6	11	7	9	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	5	
Number Not Accepted	7	9	5	1	
Rate of Submissions Not Accepted for Review	2.82%	3.30%	1.58%	1.54%	

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	235	256	300	35	
Written Feedback Provided Within MDUFA IV Goal	215	224	264	27	

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	235	256	300	35	
Average FDA Days to Written Feedback	60.65	62.62	63.10	62.97	
20th Percentile FDA Days to Written Feedback	52	55	56	51	
40th Percentile FDA Days to Written Feedback	59	63	62	63	
60th Percentile FDA Days to Written Feedback	65	66	66	66	
80th Percentile FDA Days to Written Feedback	69	70	70	70	
Maximum FDA Days to Written Feedback	121	106	268	95	

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	2	
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	42.80	40.00	

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	125	142	180	20	
Meeting Minutes Submitted Within 15 Days of Meeting	93	95	118	13	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	26	42	50	6	
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5	12	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.40%	66.90%	65.56%	68.42%	

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	308	163	
Closed Before RTA Action	3	2	2	1	
Number Accepted First RTA Cycle	232	253	285	141	
Number Without a RTA Review and > 15 Days Since Date Received	7	10	16	6	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	10	
Number Not Accepted	7	12	5	5	
Rate of Submissions Not Accepted for Review	2.85%	4.36%	1.63%	3.29%	

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	296	93	
Written Feedback Provided Within MDUFA IV Goal	202	219	184	63	

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	296	93	
Average FDA Days to Written Feedback	64.73	72.86	79.70	69.14	
20th Percentile FDA Days to Written Feedback	58	63	65	63	
40th Percentile FDA Days to Written Feedback	65	68	70	68	
60th Percentile FDA Days to Written Feedback	69	70	70	70	
80th Percentile FDA Days to Written Feedback	70	70	83	77	
Maximum FDA Days to Written Feedback	172	397	290	138	

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	6	
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00	37.50	37.50	

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	170	176	47	
Meeting Minutes Submitted Within 15 Days of Meeting	99	101	107	28	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	4	
Meeting Minutes Past 15 Days of Meeting	50	58	62	14	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	11	7	1	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.46%	59.41%	60.80%	65.12%	

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	171	179	111	
Closed Before RTA Action	1	3	1	1	
Number Accepted First RTA Cycle	127	160	168	97	
Number Without a RTA Review and > 15 Days Since Date Received	5	6	7	2	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	10	
Number Not Accepted	0	2	3	1	
Rate of Submissions Not Accepted for Review	0.00%	1.19%	1.69%	1.00%	

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	165	173	66	
Written Feedback Provided Within MDUFA IV Goal	115	152	169	65	

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	165	173	66	
Average FDA Days to Written Feedback	61.91	61.14	62.34	60.12	
20th Percentile FDA Days to Written Feedback	52	55	57	53	
40th Percentile FDA Days to Written Feedback	62	63	63	62	
60th Percentile FDA Days to Written Feedback	67	66	69	67	
80th Percentile FDA Days to Written Feedback	70	70	70	69	
Maximum FDA Days to Written Feedback	106	92	105	70	

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	0	
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	43.75	0.00	0.00	

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	28	
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	61	11	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	5	
Meeting Minutes Past 15 Days of Meeting	19	29	15	11	
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	3	1	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.22%	47.83%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	891	1,098	979	317	
Closed Before RTA Action	8	11	65	139	
Number Accepted First RTA Cycle	875	1,066	848	125	
Number Without a RTA Review and > 15 Days Since Date Received	0	14	64	41	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	11	
Number Not Accepted	8	7	2	1	
Rate of Submissions Not Accepted for Review	0.91%	0.64%	0.22%	0.60%	

Table 9.2 OHT7 - Office of In Vitro Diagnostics and Radiological Health
MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	873	1,072	817	86	
Written Feedback Provided Within MDUFA IV Goal	869	1,061	794	81	

Table 9.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	873	1,072	817	86	
Average FDA Days to Written Feedback	57.35	56.63	58.79	54.84	
20th Percentile FDA Days to Written Feedback	48	45	50	45	
40th Percentile FDA Days to Written Feedback	57	57	58	54	
60th Percentile FDA Days to Written Feedback	63	63	64	59	
80th Percentile FDA Days to Written Feedback	68	68	69	67	
Maximum FDA Days to Written Feedback	85	307	190	102	

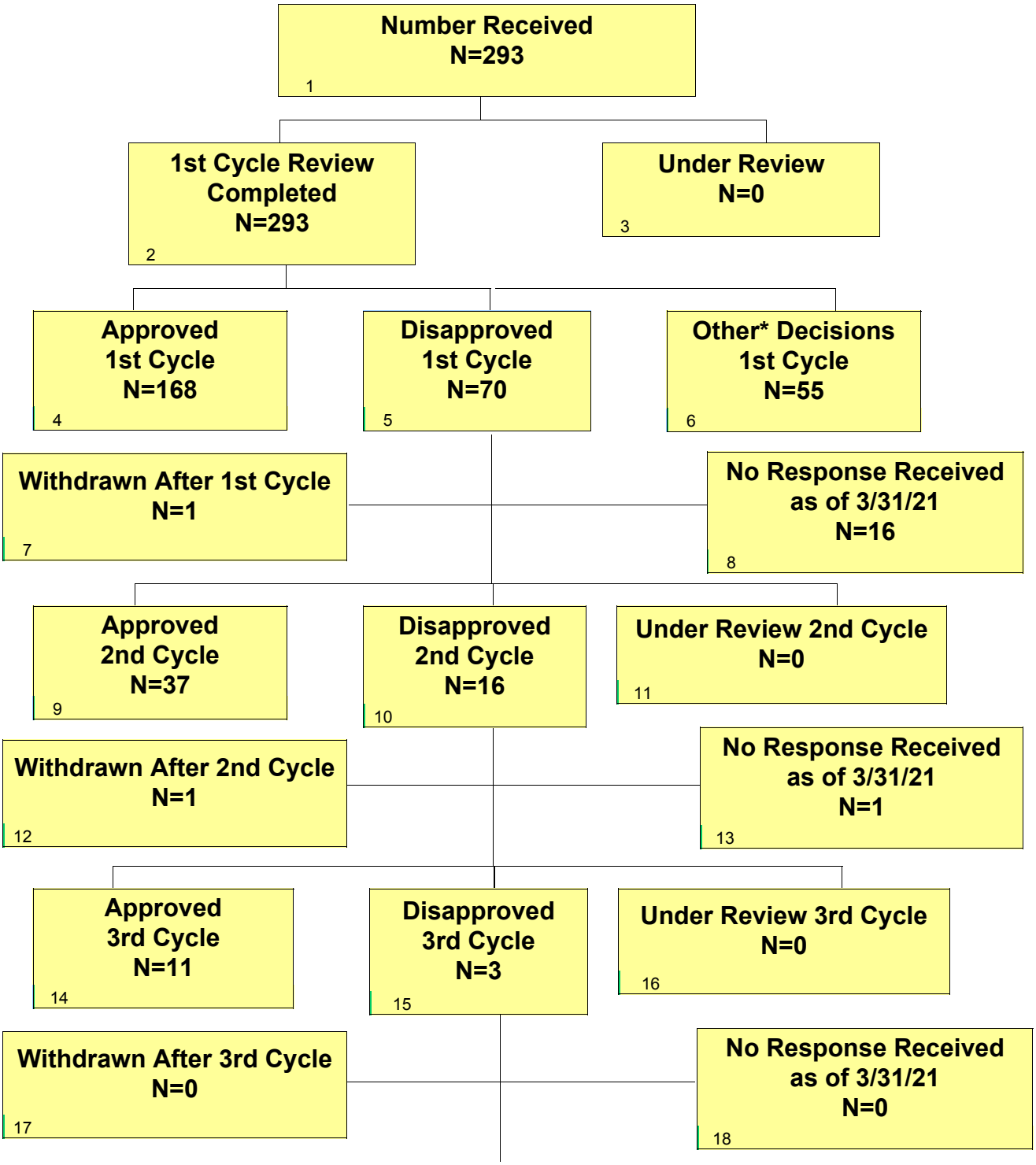
Table 9.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	6	5	6	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	35.60	53.50	50.00	

Table 9.5 OHT7 - Office of In Vitro Diagnostics and Radiological Health
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

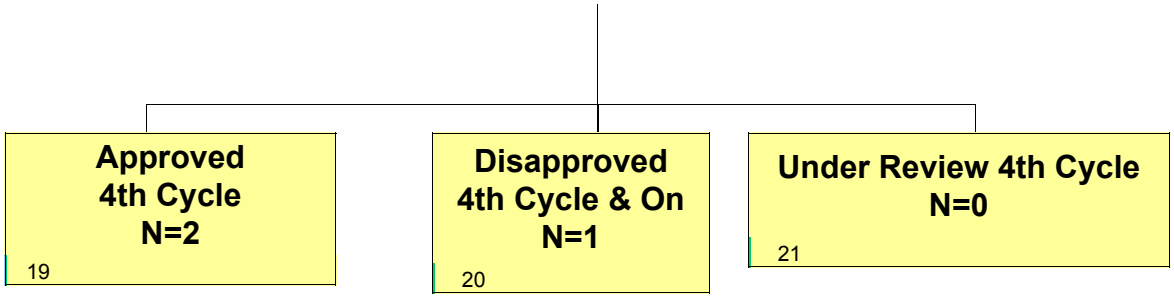
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	476	590	473	52	
Meeting Minutes Submitted Within 15 Days of Meeting	304	387	305	37	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	3	
Meeting Minutes Past 15 Days of Meeting	155	185	147	8	
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	18	21	4	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.87%	65.59%	64.48%	75.51%	

CDRH IDEs - FY 2018
as of 3/31/21

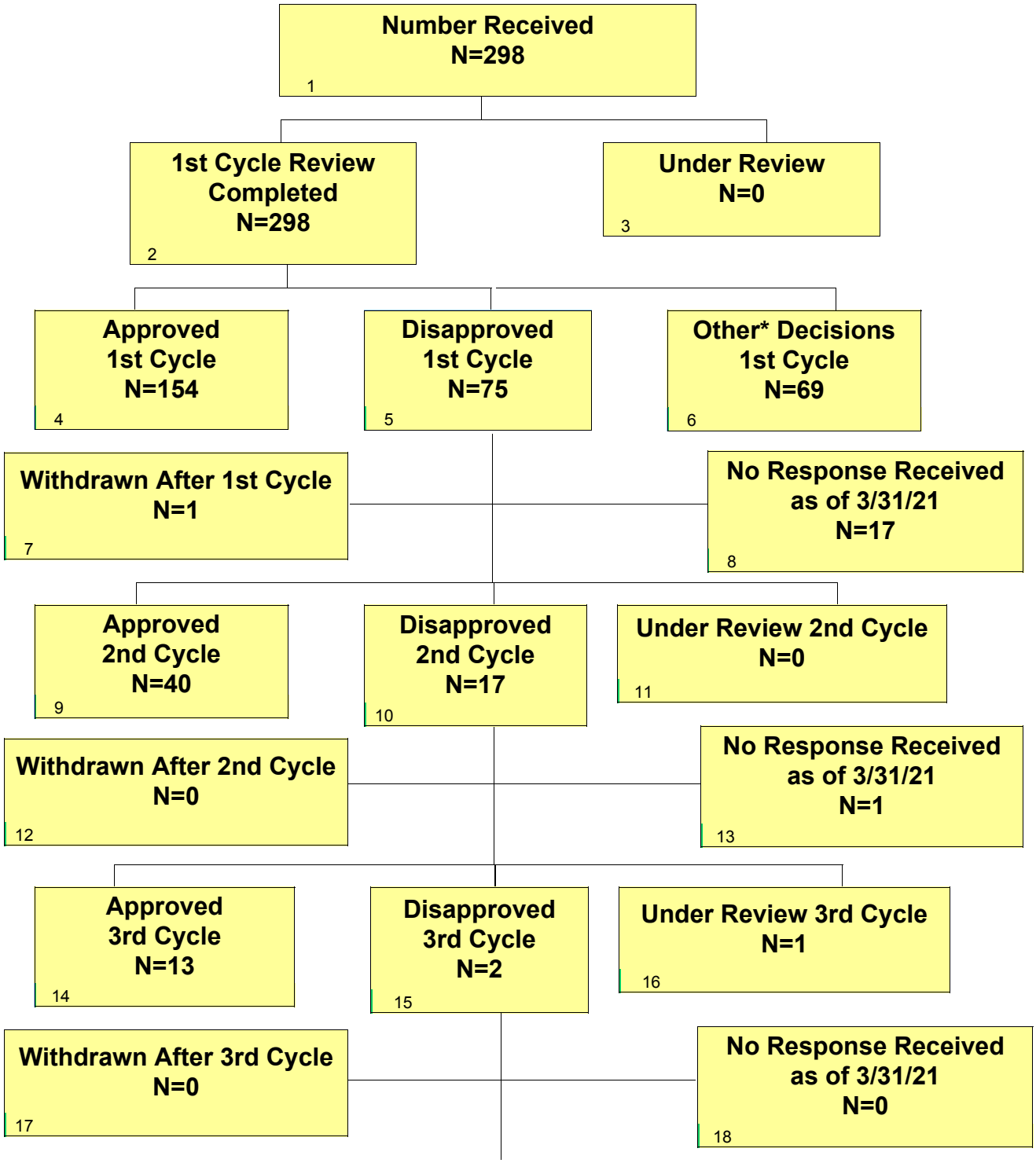


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2018
as of 3/31/21

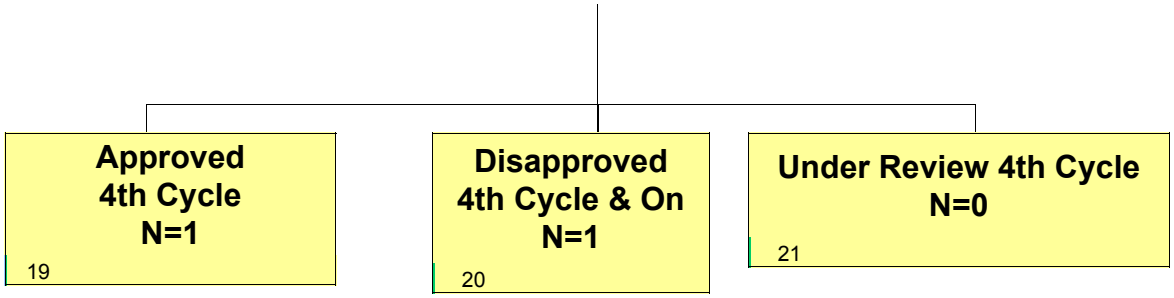


CDRH IDEs - FY 2019
as of 3/31/21

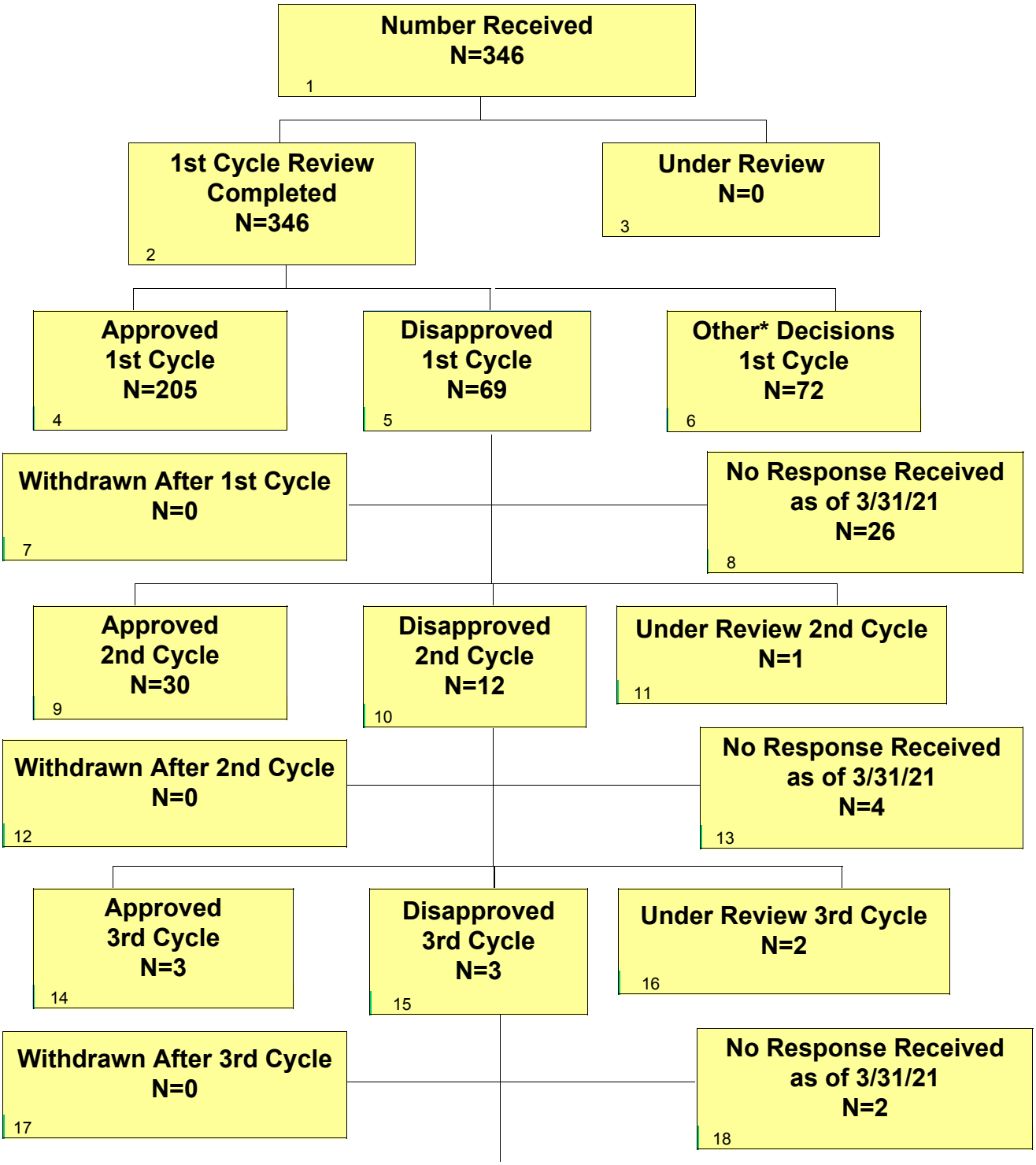


*** Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2019
as of 3/31/21

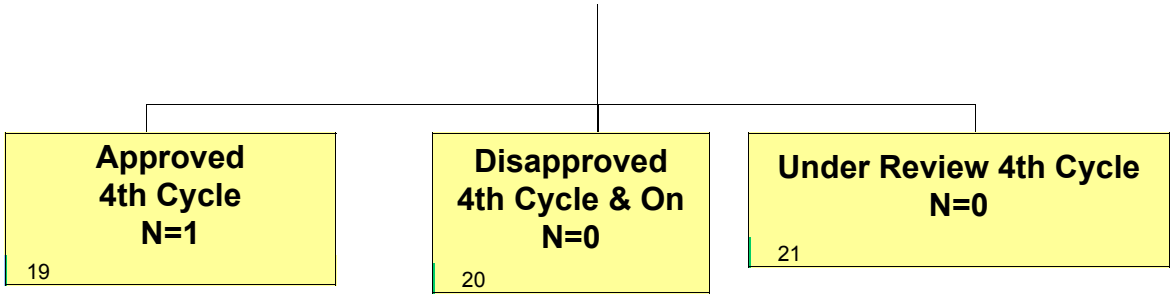


CDRH IDEs - FY 2020
as of 3/31/21

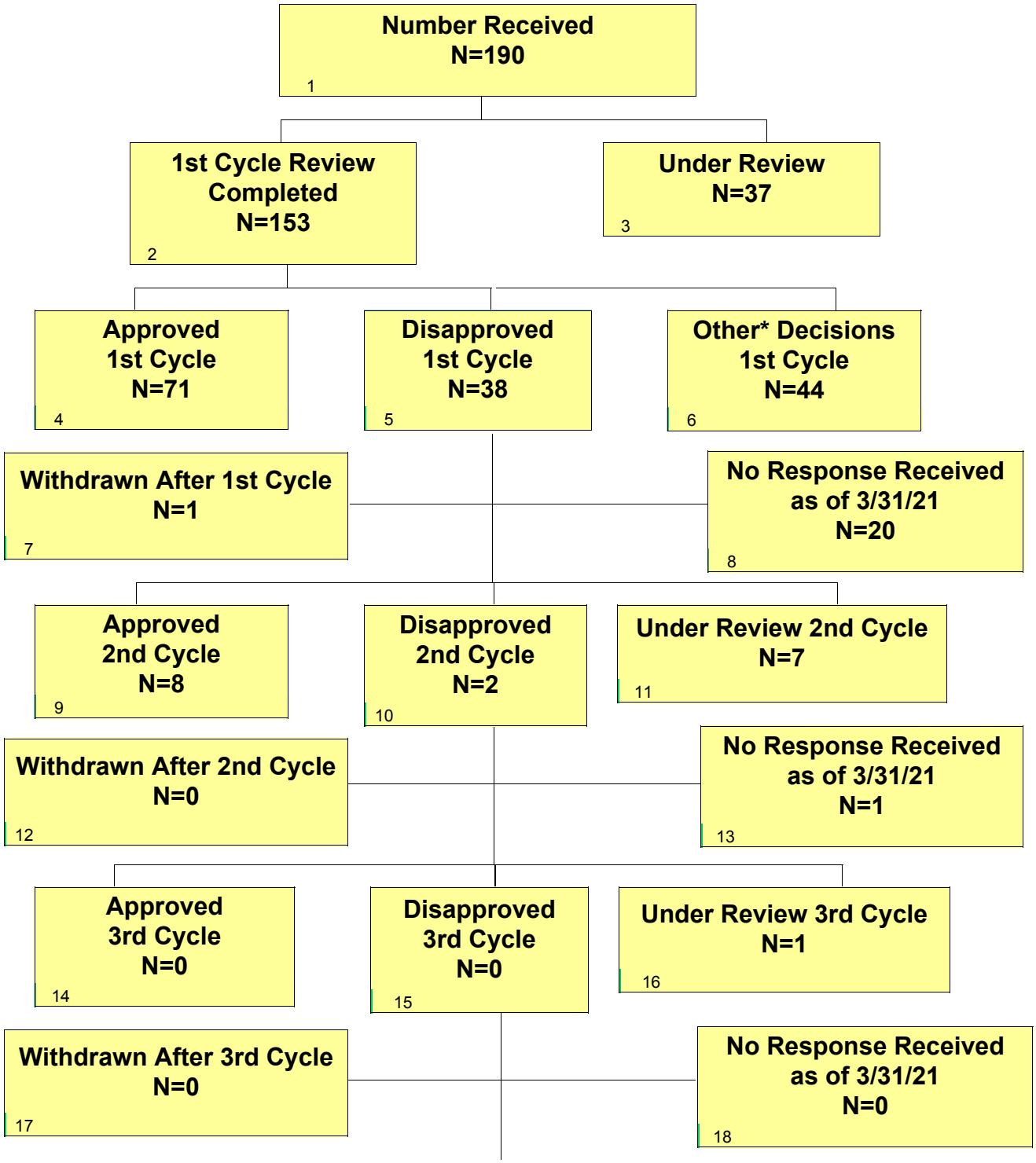


*** Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2020
as of 3/31/21

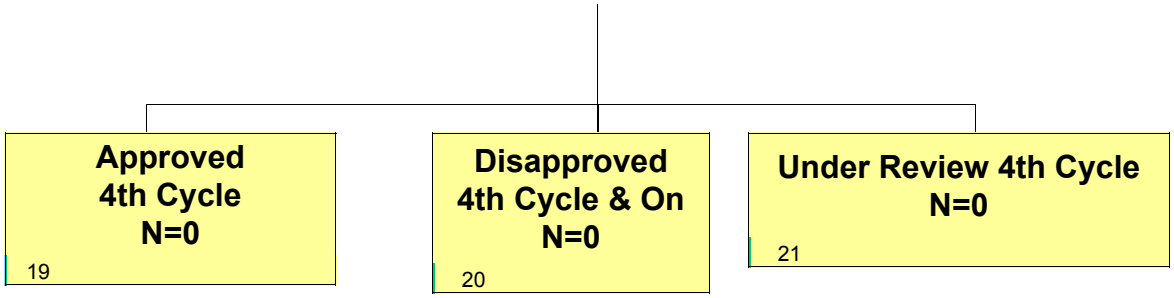


CDRH IDEs - FY 2021
as of 3/31/21



*** Other decisions include withdrawn (N=14), withdrawn and converted (N=19), RTA (N=0), nonsignificant risk device (N=9), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2021
as of 3/31/21



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	190	
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.33	1.16	1.10	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.33	0.16	0.10	

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	20	
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.26	1.09	1.25	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.26	0.09	0.25	

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	33	
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.43	1.31	1.13	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.43	0.31	0.13	

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	32	
Average Number of Cycles to IDE Approval or Conditional Approval	1.60	1.50	1.43	1.33	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.60	0.50	0.43	0.33	

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	19	
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.06	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.06	0.00	

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	35	
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.11	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.11	0.00	

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	9	
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.20	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.20	0.00	0.00	

Table 10.1 OHT7 - Office of In Vitro Diagnostics and Radiological Health
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	52	50	63	42	
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.03	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.03	0.00	0.00	

Page intentionally left blank

Section 11 CLIA Waiver Annual Metrics

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

Page intentionally left blank

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

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

Page intentionally left blank

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 (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (without Panel Review) 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.

Page intentionally left blank

Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CBER Performance Data ----
Actions through 31 Mar 2021

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	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	1	2	3	1	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	2	1	0	0	
Rate of Submissions Not Accepted for Filing Review	67%	33%	0%	0%	

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	
Number Accepted	1	2	3	1	
Completed RTF	3	3	3	1	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	33.33%	0.00%	0.00%	0.00%	

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	
SI Goal Met	2	3	2	1	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	66.67%	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	
Average Number of FDA Days to Substantive Interaction	69.00	85.33	91.33	86.00	
20th Percentile FDA Days to Substantive Interaction	50.00	82.00	81.00	86.00	
40th Percentile FDA Days to Substantive Interaction	50.00	84.00	89.00	86.00	
60th Percentile FDA Days to Substantive Interaction	88.00	84.00	89.00	86.00	
80th Percentile FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	
Maximum FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	2	3	3	0	
MDUFA IV Decision Goal Met	2	3	3	0	
PMAs Pending MDUFA IV Decision	0	0	0	1	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	2	3	3	0	
Average FDA Days to MDUFA IV Decision	164.50	162.33	164.67	0.00	
20th Percentile FDA Days to MDUFA IV Decision	156.00	140.00	150.00	0.00	
40th Percentile FDA Days to MDUFA IV Decision	156.00	171.00	169.00	0.00	
60th Percentile FDA Days to MDUFA IV Decision	173.00	171.00	169.00	0.00	
80th Percentile FDA Days to MDUFA IV Decision	173.00	176.00	175.00	0.00	
Maximum FDA Days to MDUFA IV Decision	173.00	176.00	175.00	0.00	
Average Industry Days to MDUFA IV Decision	319.50	161.00	55.33	0.00	
20th Percentile Industry Days to MDUFA IV Decision	105.00	56.00	166.00	0.00	
40th Percentile Industry Days to MDUFA IV Decision	105.00	177.00	166.00	0.00	
60th Percentile Industry Days to MDUFA IV Decision	534.00	177.00	166.00	0.00	
80th Percentile Industry Days to MDUFA IV Decision	534.00	250.00	166.00	0.00	
Maximum Industry Days to MDUFA IV Decision	534.00	250.00	166.00	0.00	
Average Total Days to MDUFA IV Decision	484.00	323.33	220.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	261.00	196.00	150.00	0.00	
40th Percentile Total Days to MDUFA IV Decision	261.00	348.00	169.00	0.00	
60th Percentile Total Days to MDUFA IV Decision	707.00	348.00	169.00	0.00	
80th Percentile Total Days to MDUFA IV Decision	707.00	426.00	341.00	0.00	
Maximum Total Days to MDUFA IV Decision	707.00	426.00	341.00	0.00	

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	
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	
Maximum FDA Days to MDUFA IV Decision	0	0	0	0	
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
Maximum Industry Days to MDUFA IV Decision	0	0	0	0	
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
60th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
80th Percentile Total Days to MDUFA IV Decision	0	0	0	0	
Maximum Total Days to MDUFA IV Decision	0	0	0	0	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	3	1	
Number with MDUFA IV Decision	2	3	3	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	1	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	50%	33%	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	
Number With MDUFA IV Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

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

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

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

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

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

Performance Metric	FY 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

***Includes submission that went to panel**

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

Performance Metric	FY 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	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	2	2	0	
MDUFA IV Decision Goal Met	1	2	2	0	
PMAs Pending MDUFA IV Decision	0	0	0	0	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

***Includes submission that went to panel**

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	1	
SI Goal Met	8	5	8	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100%	100%	100%	100%	

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	1	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	8	5	8	0	
MDUFA IV Decision Goal Met	8	5	8	0	
Supplements Pending MDUFA IV Decision	0	0	0	1	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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	1	
Number with MDUFA IV Decision	8	5	8	0	
Number of Not Approvable	0	0	1	0	
Rate of Not Approvable	0.00%	0.00%	12.50%	N/A	

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

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	6	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	3	2	5	3	
MDUFA IV Decision Goal Met	3	2	5	3	
Supplements Pending MDUFA IV Decision	0	0	0	3	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	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	6	
Number With MDUFA IV Decision	3	2	5	3	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

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	23	
Closed Before RTA Action	0	0	1	0	
Number Accepted	40	38	34	14	
Number Without a RTA Review and > 15 Days Since Date Received	2	1	1	2	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	4	
Number Not Accepted	11	15	14	3	
Rate of Submissions Not Accepted for Review	20.75%	27.78%	28.57%	15.79%	

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	16	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	49	51	42	9	
SI Over 60 FDA Days	0	0	1	0	
SI Pending Within 60 FDA Days	0	0	1	7	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	100%	100%	98%	100%	

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	43	9	
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.93	49.67	
20th Percentile FDA Days to Substantive Interaction	43	21	21	21	
40th Percentile FDA Days to Substantive Interaction	57	53	56	55	
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	60	60	64	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	16	
Non-MDUFA IV Decision	6	5	4	0	
MDUFA IV Decision (SE/NSE)	43	46	36	8	
MDUFA IV Decision Within 90 FDA Days	43	46	36	8	
510(k)s Pending MDUFA IV Decision	0	0	4	8	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100%	100%	100%	100%	

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	1.22	1.13	
Number With MDUFA IV Decision	43	46	36	8	
Average Number of FDA Days to MDUFA IV Decision	75.12	67.48	63.42	68.25	
20th Percentile FDA Days to MDUFA IV Decision	65	28	30	27	
40th Percentile FDA Days to MDUFA IV Decision	85	77	65	75	
60th Percentile FDA Days to MDUFA IV Decision	87	87	80	82	
80th Percentile FDA Days to MDUFA IV Decision	90	89	88	89	
Maximum FDA Days to MDUFA IV Decision	90	206	90	90	
Average Number of Industry Days to MDUFA IV Decision	25.23	75.76	11.89	1.63	
20th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
40th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	
60th Percentile Industry Days to MDUFA IV Decision	0.00	78.00	0.00	0.00	
80th Percentile Industry Days to MDUFA IV Decision	59.00	179.00	17.00	0.00	
Maximum Industry Days to MDUFA IV Decision	178.00	389.00	104.00	13.00	
Average Number of Total Days to MDUFA IV Decision	100.37	143.24	75.33	69.86	
20th Percentile Total Days to MDUFA IV Decision	76	59	30	27	
40th Percentile Total Days to MDUFA IV Decision	86	87	65	75	
60th Percentile Total Days to MDUFA IV Decision	90	141	80	82	
80th Percentile Total Days to MDUFA IV Decision	147	269	90	89	
Maximum Total Days to MDUFA IV Decision	268	463	193	103	

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	16	
Number With MDUFA IV Decision	43	46	36	8	
Number of SE Decision	43	43	35	8	
Number of NSE Decision	0	3	1	0	
Number of Withdrawal	2	4	3	0	
Number of Deleted	3	1	1	0	
Rate of SE Decision	100%	93%	97%	100%	
Rate of NSE Decision	0%	7%	3%	0%	
Rate of Withdrawal	4%	8%	7%	0%	
Rate of Deleted	6%	2%	2%	0%	

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

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA 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	5	
Non-MDUFA IV Decision	0	1	0	0	
MDUFA IV Decision (SE/NSE)	15	16	7	4	
MDUFA IV Decision Within 90 FDA Days	15	16	7	4	
510(k)s Pending MDUFA IV Decision	0	0	0	1	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

Section 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	
Closed Before RTA Action	N/A	N/A	0	0	
Number Accepted First RTA Cycle	N/A	N/A	0	0	
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	
Number Not Accepted	N/A	N/A	0	0	
Rate of Submissions Not Accepted for Review	N/A	N/A	0	0	

*** RTA will be implemented when the guidance, including the submission checklist, is finalized.**

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

Table 8.3 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	
Number With MDUFA IV Decision	0	1	0	0	
Average FDA Days to MDUFA IV Decision	0.00	150	0.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	
40th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	
60th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	
80th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	
Maximum FDA Days to MDUFA IV Decision	0	150	0	0	
Average Industry Days to MDUFA IV Decision	0.00	81	0.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	
60th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	
80th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	
Maximum Industry Days to MDUFA IV Decision	0	81	0	0	
Average Total Days to MDUFA IV Decision	0.00	231	0.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	0	231	0	0	
40th Percentile Total Days to MDUFA IV Decision	0	231	0	0	
60th Percentile Total Days to MDUFA IV Decision	0	231	0	0	
80th Percentile Total Days to MDUFA IV Decision	0	231	0	0	
Maximum Total Days to MDUFA IV Decision	0	231	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	
Number With MDUFA IV Decisions	0	1	0	0	
Number With Granted Decisions	0	1	0	0	
Number With Declined Decisions	0	0	0	0	
Number of Withdrawals	0	0	0	0	
Number Deleted	0	0	0	0	
Rate of Granted Decisions	N/A	1	N/A	N/A	
Rate of Declined Decisions	N/A	N/A	N/A	N/A	
Rate of Withdrawals	N/A	N/A	N/A	N/A	
Rate of Deleted	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	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 8.6 CBER - LDT De Novo MDUFA IV Decision Metrics

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1	0	0	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	1	0	0	
MDUFA IV Decisions Within 150 FDA Days	0	1	0	0	
De Novos Pending MDUFA IV Decision	0	0	0	0	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	100%	N/A	N/A	

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	34	
Closed Before RTA Action	5	3	10	0	
Number Accepted First RTA Cycle	69	70	65	27	
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	5	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted	1	1	1	0	
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.49%	0.00%	

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	18	
Written Feedback Provided Within MDUFA IV Goal	68	71	63	18	

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	18	
Average FDA Days to Written Feedback	57.86	61.00	56.70	59.17	
20th Percentile FDA Days to Written Feedback	47	55	48	53	
40th Percentile FDA Days to Written Feedback	58	60	58	64	
60th Percentile FDA Days to Written Feedback	64	63	64	65	
80th Percentile FDA Days to Written Feedback	67	68	68	66	
Maximum FDA Days to Written Feedback	72	75	77	69	

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	
Average Days to Scheduling for Meetings Scheduled After Day 30	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	5	
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	26	5	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	
Meeting Minutes Past 15 Days of Meeting	9	2	1	0	
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1	0	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	90.91%	96.30%	100.00%	

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	11	
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.63	1.07	1.29	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.63	0.07	0.29	

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 2021

#	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]Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus	10/13/2020	Yes	No	N/A	No
2	Q1	Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-biocompatibility-certain-devices-contact-intact-skin	10/15/2020	Yes	No	N/A	No
3	Q1	Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-non-clinical-assessment-medical-devices-containing-nitinol	10/15/2020	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-2020-fy-2020.
[4] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
4	Q1	Testing for Biotin Interference in In Vitro Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-biotin-interference-vitro-diagnostic-devices	10/16/2020	Yes	No	N/A	No
5	Q1	[4]Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date www.fda.gov/regulatory-information/search-fda-guidance-documents/necessary-automated-external-defibrillator-accessories-policy-regarding-compliance-date	10/28/2020	Yes	No	N/A	No
6	Q1	[5]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during	10/28/2020	Yes	No	N/A	No
7	Q1	[5]Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices	11/6/2020	No	No	N/A	No
8	Q1	Regulatory Considerations for Microneedling Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-microneedling-products	11/10/2020	Yes	No	N/A	No
9	Q1	Certificates of Confidentiality www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	11/16/2020	No	No	N/A	No
10	Q1	Electromagnetic Compatibility (EMC) of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices	11/17/2020	Yes	No	N/A	No

[5] 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
11	Q1	[4]Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-bioburden-reduction-systems-using-dry-heat-support-single-user-reuse-certain	11/25/2020	Yes	No	N/A	No
12	Q1	[4]Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	11/25/2020	No	No	N/A	No
13	Q1	[4]Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health	12/4/2020	No	No	N/A	No
14	Q1	[4]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	12/4/2020	Yes	No	N/A	No
15	Q1	Requesting FDA Feedback on Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products	12/4/2020	Yes	Yes	Section 3038 of the 21st Century Cures Act	No
16	Q1	Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/spinal-plating-systems-performance-criteria-safety-and-performance-based-pathway	12/11/2020	Yes	No	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
17	Q1	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance	12/11/2020	Yes	No	N/A	A-List
18	Q1	Magnetic Resonance (MR) Receive-only Coil - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/magnetic-resonance-mr-receive-only-coil-performance-criteria-safety-and-performance-based-pathway	12/11/2020	Yes	No	N/A	A-List
19	Q1	[5]Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices	12/22/2020	Yes	No	N/A	No
20	Q1	Product Labeling for Laparoscopic Power Morcellators www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators	12/30/2020	Yes	No	N/A	A-List
21	Q2	Mouse Embryo Assay for Assisted Reproduction Technology Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/mouse-embryo-assay-assisted-reproduction-technology-devices	1/5/2021	Yes	No	N/A	No
22	Q2	Safer Technologies Program for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices	1/6/2021	Yes	No	N/A	A-List
23	Q2	[5]Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program	1/6/2021	Yes	No	N/A	No

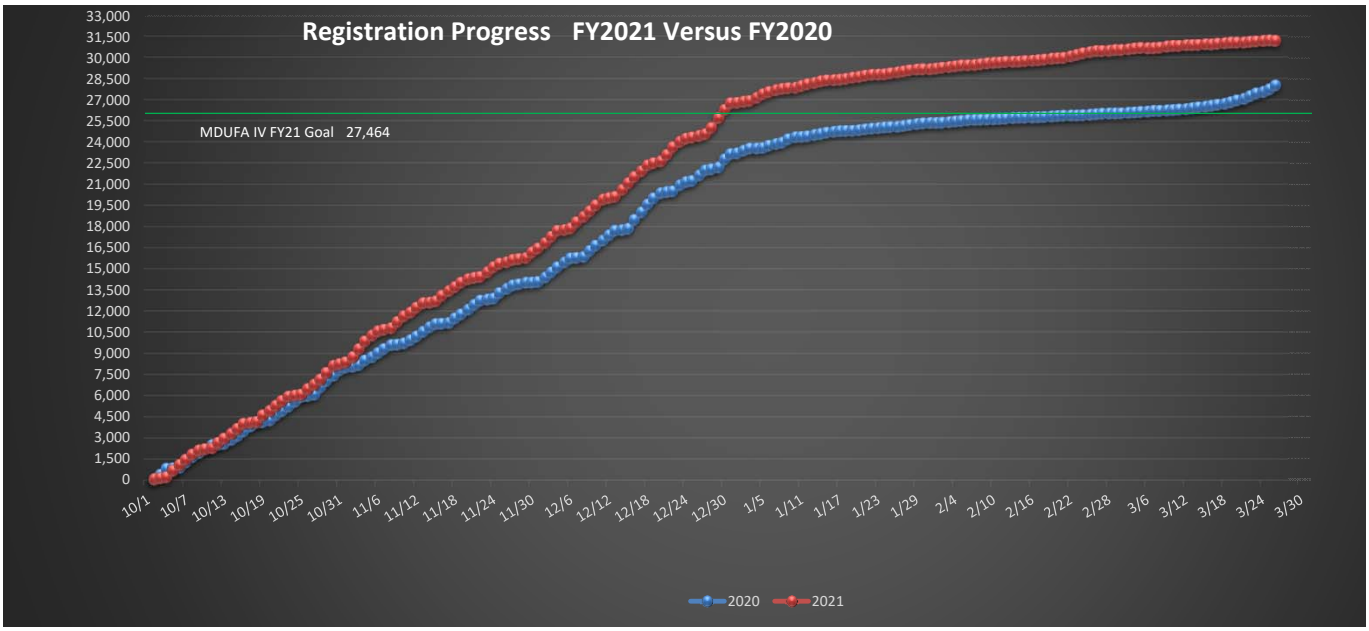
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
24	Q2	[4]Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/coagulation-systems-measurement-viscoelastic-properties-enforcement-policy-during-coronavirus	1/14/2021	Yes	No	N/A	No
25	Q2	[4]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	1/27/2021	Yes	No	N/A	No
26	Q2	[5]Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/coagulation-systems-measurement-viscoelastic-properties-enforcement-policy-during-coronavirus	1/28/2021	Yes	No	N/A	No
27	Q2	[4]Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests	2/22/2021	No	No	N/A	No

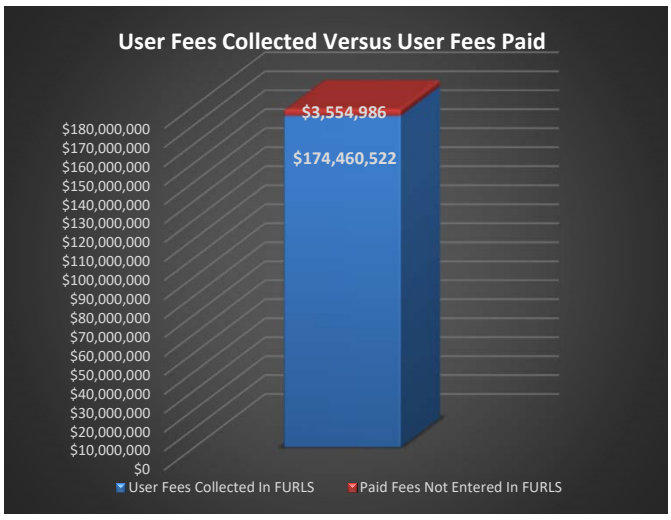
Page intentionally left blank

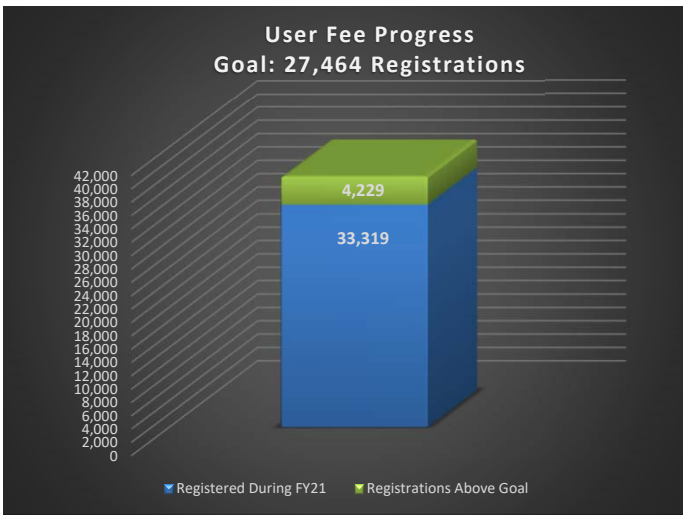
MDUFA IV Registrations - 2nd Quarter Summary FY2021*

Current Active Registrations by Type	FY21 Q2			FY20 Year End Active Totals			FY21 vs End FY20
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,588	13,024	19,612	6,750	21,519	28,269	69.38%
Contract Manufacturer	1,156	1,654	2,810	1,186	1,707	2,892	97.16%
Contract Sterilizer	69	149	218	62	143	205	106.34%
Specification Developer	1,667	552	2,219	1,784	579	2,363	93.91%
Reprocessor of Single Use Devices	27	6	33	34	6	40	82.50%
U.S. Manufacturer of Export Only Devices	116	0	116	127	0	127	91.34%
Repackager/Relabeler	1,098	210	1,308	1,232	235	1,467	89.16%
Remanufacturer	15	10	25	19	8	27	92.59%
Foreign Exporter/Private Label Distributor		1,052	1,052	1	1,203	1,204	87.38%
Initial Importer	3,764		3,764	4,768		4,768	78.94%
Unknown	7	12	19	6	40	46	41.30%
Total:	**14,507**	**16,669**	**31,176**	**15,969**	**25,440**	**41,409**	**75.29%**

*Note: This data is current as of 03/26/2021







Page intentionally left blank

FY 2021 2nd QUARTER COLLECTION TABLE

FY 2021 Medical Device User Fee Collections as of March 31st, 2021 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$175,316,381	$238,478	$175,077,903		
Application Fees	$33,935,161	$129,478	$33,805,683		
Total	**$209,251,541**	**$367,956**	**$208,883,586**	**$236,059,000**	**88%**
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	$47,513,621	$55,713,913	$63,328,995	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$100,304,233	$120,651,391	$133,990,554	$145,668,877	$136,132,745
	FY 2018	**FY 2019**	**FY 2020**	**FY2021**	
MD IV	$188,274,418	$195,070,362	$288,883,317	$208,883,586	

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 2nd Quarter FY 2021 by Submission type	# Waived	# Reduced
Full Fee applications[2/]		
PMA	6	2
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
Panel Track Supplements	3	4
De Novo Classification	2	18
180-Day Supplements	0	15
Real-Time Supplements	0	12
510(k)s	20	729
30-day Notices	7	49
513(g)s	0	18
PMA Annual Report	0	16
Total	**38**	**863**

[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 180 Day Supplements (5 reduced), 510(k)s (15 reduced), 30-day Notices (16 reduced), 513(g)s (1 reduced) and PMA Annual Reports (8 reduced).

Center for Devices and Radiological Health Internal Training Summary Report

Q2 FY21

October 2020 – March 2021

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

As of: 4/30/2021

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, 2020 and March 31, 2021. DETD offered 424 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 – FY20 CDRH Internal Training Conducted by DETD:

October 1, 2020 and March 31, 2021

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA IV	5	447	361
	ELP	6	244	3734
	Least Burdensome (Refresher)	3	324	120
	Other LAW	215	10980	8958
	LAW Subtotal:	*229*	*11995*	*13173*
Leadership Development Training (LED)	LEAD: Leadership for Managers	33	378	1021
	Leadership for Non-Managers	3	26	162
	Other LED	4	60	60
	LED Subtotal:	*40*	*464*	*1243*
Professional Development (PRO) Training	All PRO	107	6508	4045
	PRO Subtotal:	*107*	*6508*	*4045*
Center-Specific Information Technology (CIT) Training	Premarket IT	6	315	315
	Other CIT	6	95	95
	CIT Subtotal:	*12*	*410*	*410*
Science (SCI) Training	All SCI	36	1075	3759
	SCI Subtotal:	*36*	*1075*	*3759*
		424	**20452**	**22630**

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	40	1178	1516
Total:	**386**	**9395**	**24196**

Reviewer Training - RCP

Reviewer Certification Program (RCP):

The RCP curriculum is a 39.25-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:

- 13 classroom courses, including a program Orientation and Capstone, totaling 16.5 hours of training
- 18 online courses, totaling 22.75 hours
- 7 Advanced courses, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

RCP Training by Cohort: *October 1, 2020 and March 31, 2021*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 1 2020 Cohort	13	18	OPEQ	69	1944	2460
			OSEL	2	45	56
			Subtotal:	***71***	***1989***	***2516***
Fall 2 2020 Cohort	13	18	OCD	6	164	206
			OM	5	40	52
			OPEQ	17	371	458
			OSEL	7	145	178
			Subtotal:	***35***	***720***	***894***
Spring 1 2021 Cohort	13	18	OCD	5	127	163
			OPEQ	20	555	709
			OSEL	1	30	39
			Subtotal:	***26***	***712***	***911***
Total:	**39**	**54**	**-**	**132**	**3421**	**4321**

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, 2020 and March 31, 2021*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
6	244	3734	• Innovation • Digital Health

ELP Training Completed by Office: *October 1, 2020 and March 31, 2021*

Office	Total # of Attendees	Total Training Hours
OCD	1	24
OP	4	43
OPEQ	195	3356
OSEL	29	208
OST	15	103
Total:	**244**	**3734**

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, 2020 and March 31, 2021*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	33	378	1021	• Talking to Top Management: What to Say and How to Say it • Strategies in Meetings: Getting to Yes • Fostering a Respectful Workplace • Creating and Maintaining a Collaborative Department

LEAD Training Completed by OPEQ: *October 1, 2020 and March 31, 2021*

Office	Total # of Managers/Supervisors*	# of Training Participants	Training Hours Required**	% of Required Training Hours Completed
OPEQ	165	122	2640	32%

*The number of supervisors may vary by quarter based on the data provided by each Office.

**This data is based on the 16-hour minimum annual training requirement for managers with 3 or more years of experience. New supervisors within the federal government have an additional 24-hour training requirement, for a total of 40 hours.

CDRH Training Courses by Category:

The following section contains a sampling of DETD courses provided during FY'20 – FY'21.

Regulatory and Law (LAW) Training:

Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations for Premarket Approval (PMA) applications and De novo petitions.
Pre-Submission Program, Meetings with FDA, IDEs, and Clinical Trials	This course provides practical knowledge regarding the roles and responsibilities related to the Pre-submission program, meetings and clinical trials.
Introduction to Premarket Review	This course describes the essential elements in premarket review.
Premarket programs: 510k and 513g	This course provides an understanding of the device classifications.
Conducting 510k Reviews	This course provides an overview of the 510(k) flowchart.
Basics of Writing Consult Requests and Reviews	This course provides examples of the essential elements of a pre-market consulting review.
Premarket Programs: IDEs	This course provides an understanding of the regulatory submission process that permits clinical investigation of medical devices.
Premarket Programs: PMA and HDE	This training outlines the types of Premarket Application (PMA) submissions and the information necessary to determine when a PMA is required.
Premarket Review Clinic	This training prepares the participant to complete the CAPSTONE assignments distributed following completion of the Reviewer Certification Program.
Reviewer Certification CAPSTONE	This training includes interactive sessions that discuss the varying types and requirements of medical device applications.
Regulatory Basics (online)	This training identifies the sources and describes the effects of law, regulation, and guidance on the work conducted within CDRH.
MDUFA IV Overview	This training provides an overview of the Medical Device User Fee Act of 2017.

Basics of 4-Part Harmony in Lead and Consult Reviews	This training provides participants with instruction on the techniques used to write clear and concise deficiencies.
RCP: Standards Overview	This training provides an overview of Standards and how they are applied.
RCP: Standards Resources and Premarket Use	This training provides participants with instruction on locating recognized Standards and discusses how Standards are used in premarket submissions.
RCP: Basics of Standards in Premarket Review	This training provides participants with instruction on locating recognized Standards, Standard's guidance, and accessing library resources addressing Standards.
Overview of FOIA	This training provides an overview of FOIA applications and discusses the impact of OPEN Government amendments on FOIA.
SMART Template	This class provides instruction for using a programmed Microsoft Word document to create review documents.
RCP Premarket Program: De Novo Classification	This class describes the legal basis for the De Novo pathway.

Leadership Development Training for Managers and Non-Managers (LED) Training:

Handling People with Diplomacy & Tact	This course provides participants with a big-picture mentality regarding their work and a blueprint for productivity. Participants also learn techniques for empowering their team and holding them accountable.
LEAD: CDRH Manager Orientation Program	This training provides managers with resources to navigate professional development and human resource information for themselves as well as the employees they supervise.
LEAD: Diversity, Unconscious Bias	This course provides participants with an understanding of unconscious bias, the tools to confront and combat its negative effects; and the ability to recognize its impact on decision making.
LEAD: Managing Up, Communicating with Your Boss	This course focuses on the skills necessary for "managing up" including effective communication, achieving goals and providing constructive feedback.
Negotiating with Confidence	This interactive program enables participants to better communicate their needs and negotiate with confidence.
Critical Thinking and Problem Solving	This two-day workshop is designed to provide an understanding of the differences between critical thinking styles and how they are applied in the everyday world.

Professional Development (PRO) Training:

Growing Creativity and Innovation	This course explores both the nature and nurture of creativity and innovation and the capacity for putting these vital skills into everyday practice.
Strategic Planning and Analytical Thinking	This course provides participants with an understanding of the different analytical styles and how they affect and inhibit analytical thinking. Tools used in analytical thinking and ways to increase creative thinking are also addressed.
Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants learn how to accomplish TOP in a pragmatic way while maintaining precision and accuracy. Instruction also addresses the ability to think creatively and critically while ensuring that reasoning is objective.
Influencing Others for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". The course instruction includes an opportunity to translate theory into practice.

Science (SCI) Training:

Introduction to Public Health	This course provides the framework for understanding public health concepts, the fundamentals of epidemiology, medical product surveillance systems, and the public health determinants that influence medical device development.
CDRH Laboratory Waste Management – online	This course gives an overview of the requirements for waste handling in CDRH laboratories, as well as a brief description of the Laboratory Emergency Procedures.
Regenerative Medicine Series	The Regenerative Medicine Seminar Series offers a variety of seminars that examine the restoration and function of the human form within the context of translational research involving medical devices and biologics.
Reprocessing Medical Devices in Health Care Settings	This course is designed to provide staff involved in medical device regulation with the knowledge necessary to perform routine labeling evaluations based on FDA's 2015 Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

Center-Specific IT (CIT) Training

Using IT Systems in Premarket Review	This online course is designed to provide an overview of the IT systems used in medical device regulation.