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

November 16, 2021, 12:00 – 1:30 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through September 30, 2021

- Report on decision goals for 4th Quarter FY 2021
- Shared outcome goals

Guidance Development

Registration and Listing

Qualitative Update on Finances – 4th Quarter FY 2021

- User fee receipts through the 4th Quarter FY 2021

Quality Management Update

- Summary of FY 2021 activities
- Planning for FY 2022 audits
- Independent Assessment Update

CDRH Training Update

Annual Reporting Updates

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Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data ----
Actions through 30 September 2021

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Acronyms and Abbreviations

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

Office Organizations

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

OHT2: Office of Cardiovascular Devices

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

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics and Radiological Health

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

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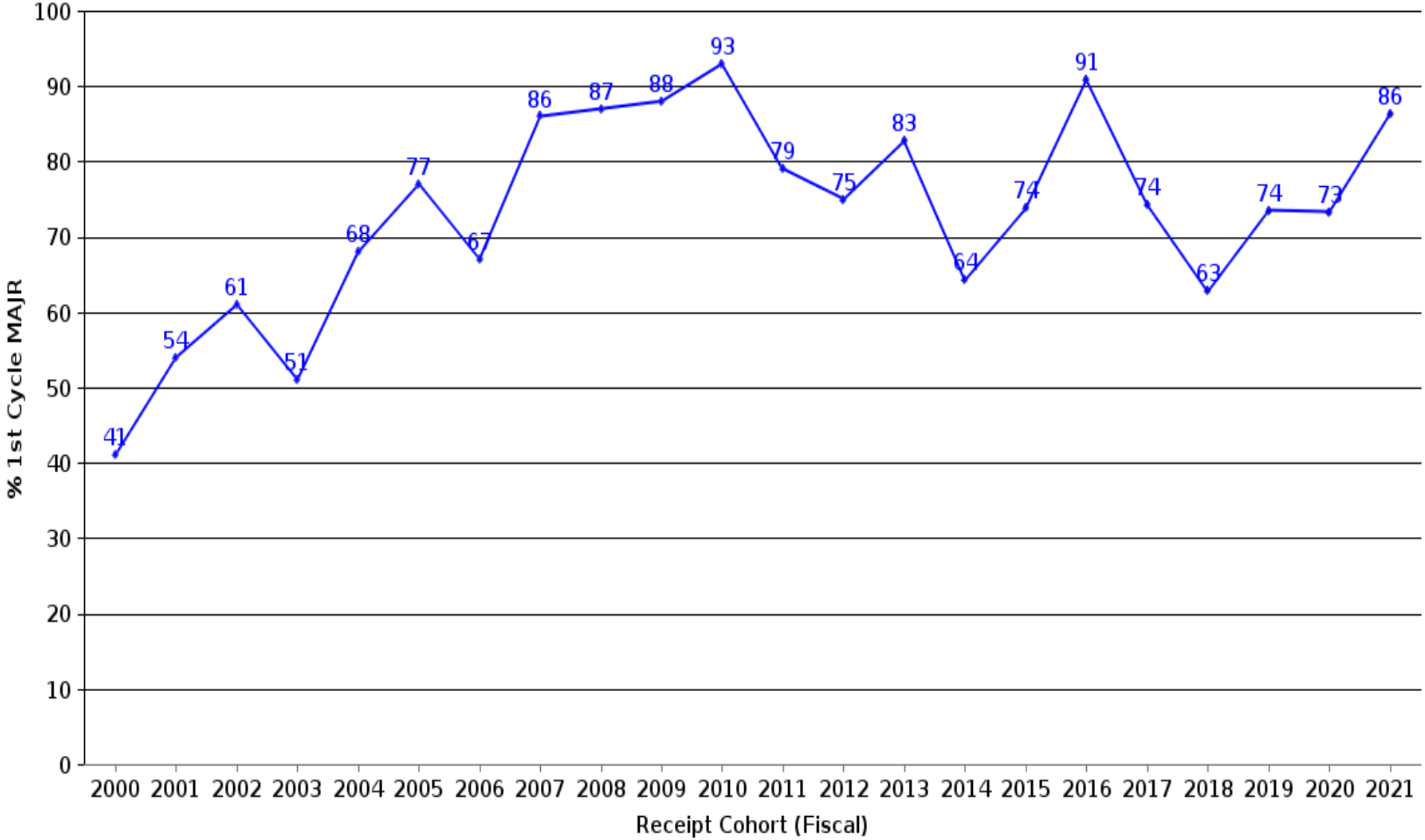
PMAs

Q4FY2021

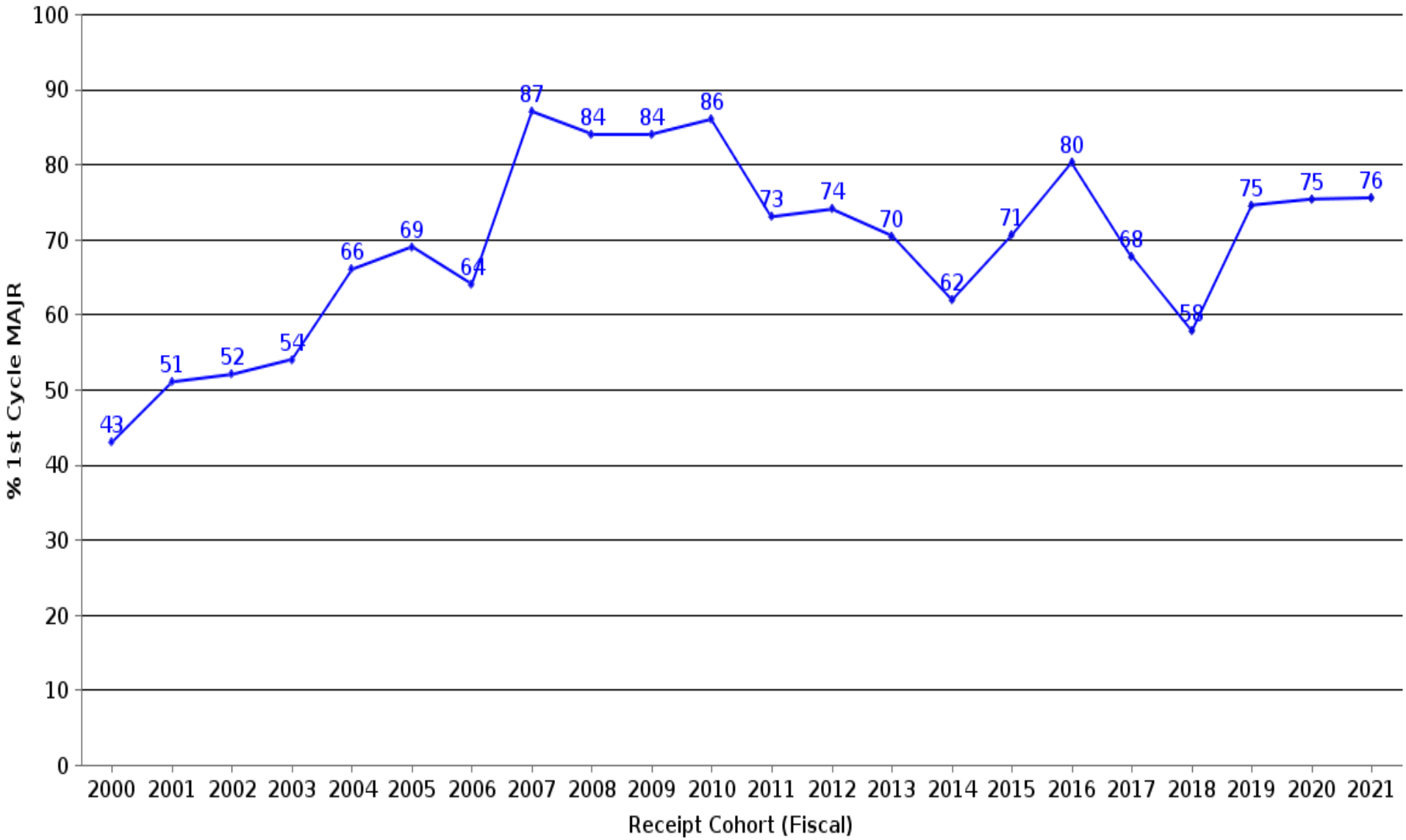
PMA Originals Filed As Of 6/30/21: 1st Cycle Major Deficiency Rate as of 9/30/21



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 6/30/21.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

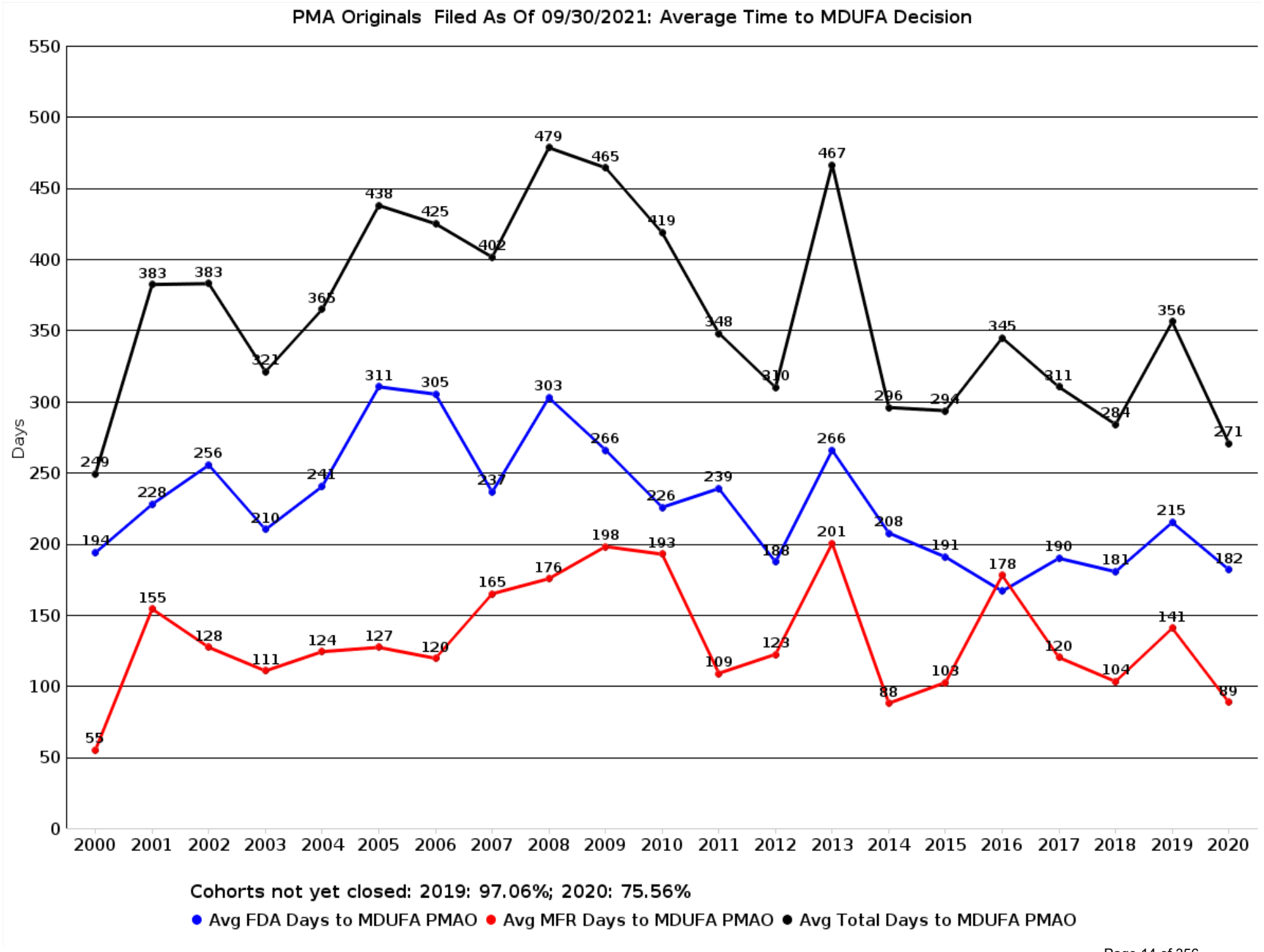
♦ % 1st Cycle MAJR PMAO

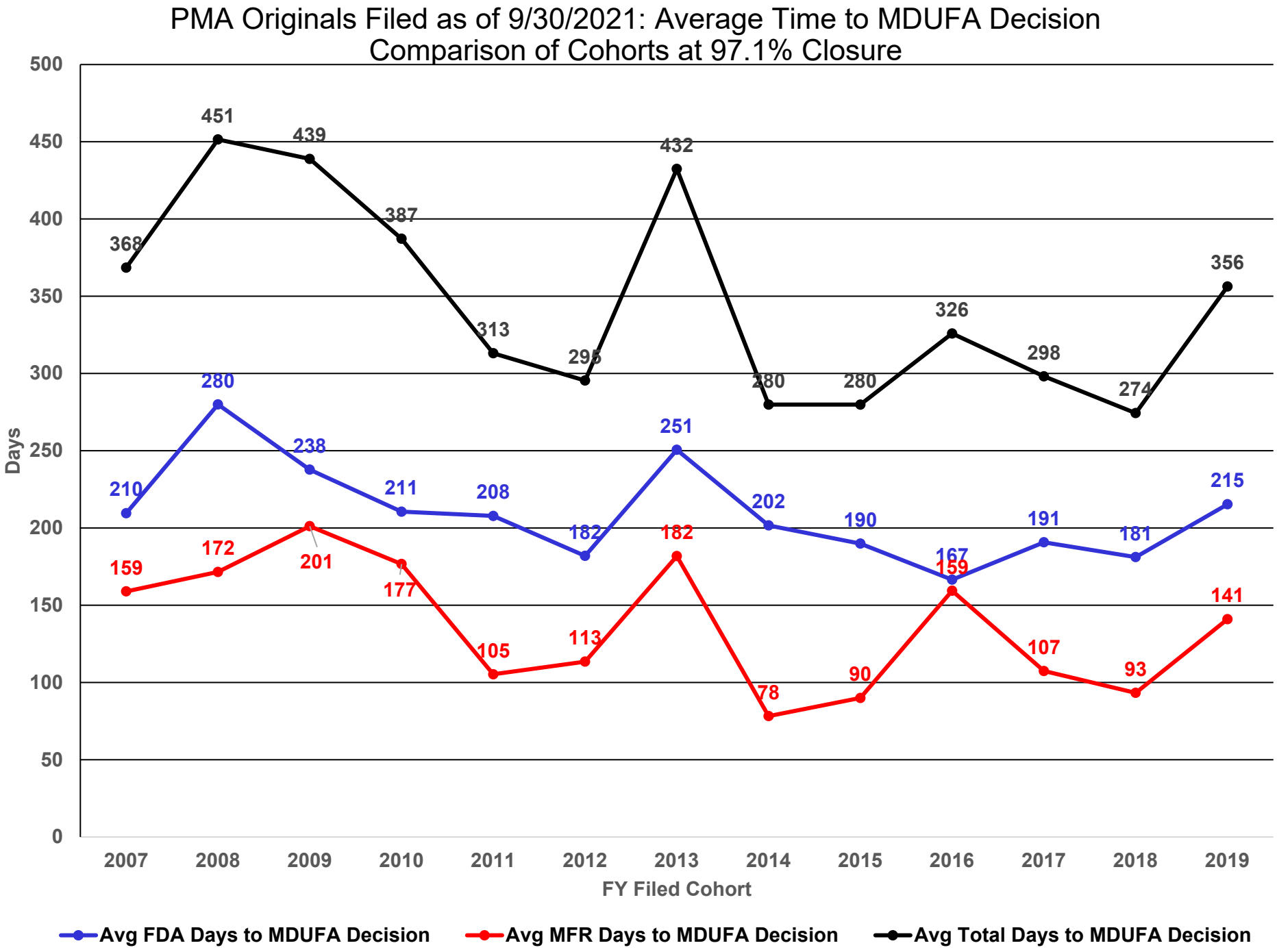
PMA Originals and Panel Track Supplements Filed As Of 6/30/21: 1st Cycle Major Deficiency Rate as of 9/30/21

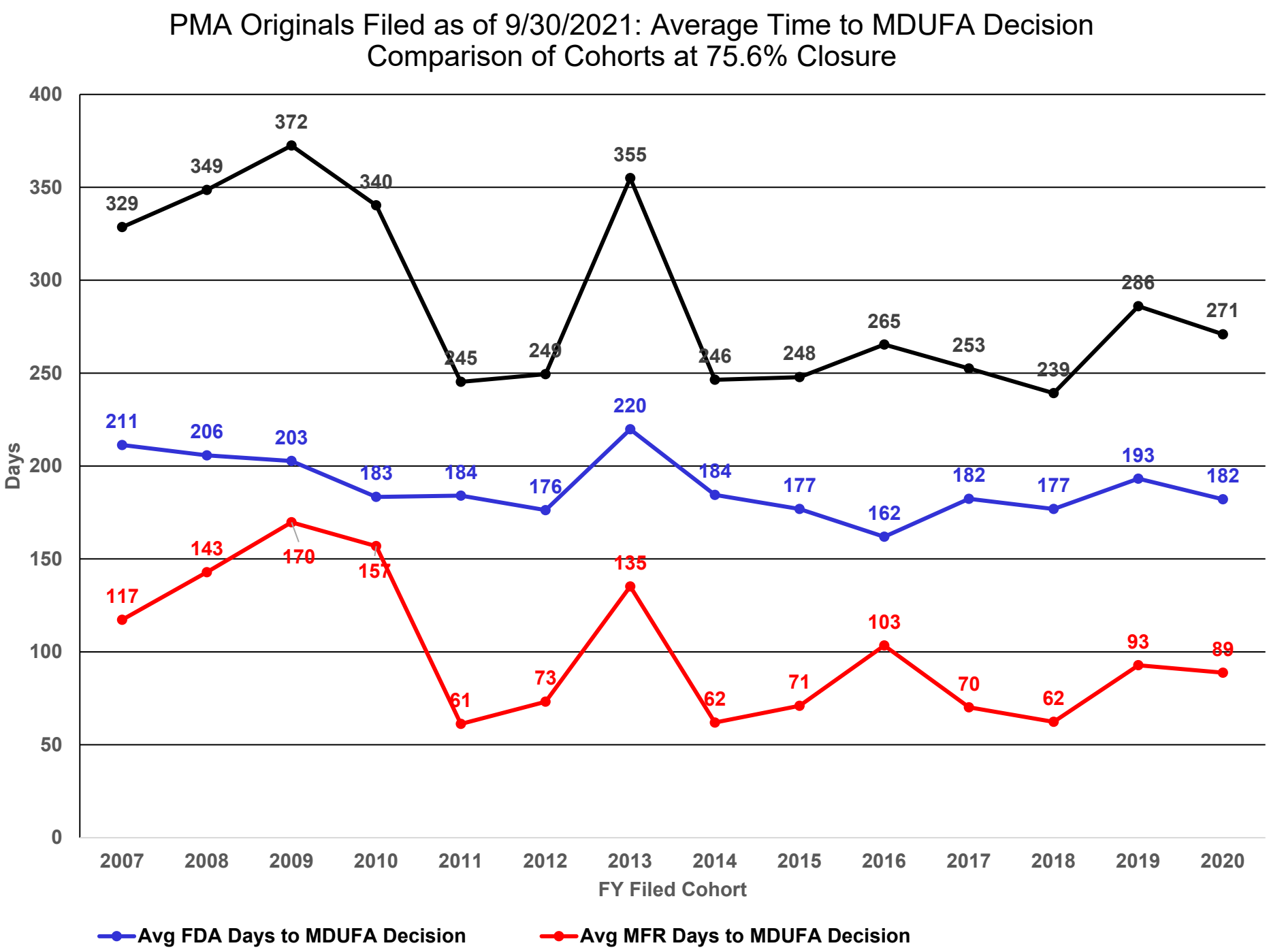


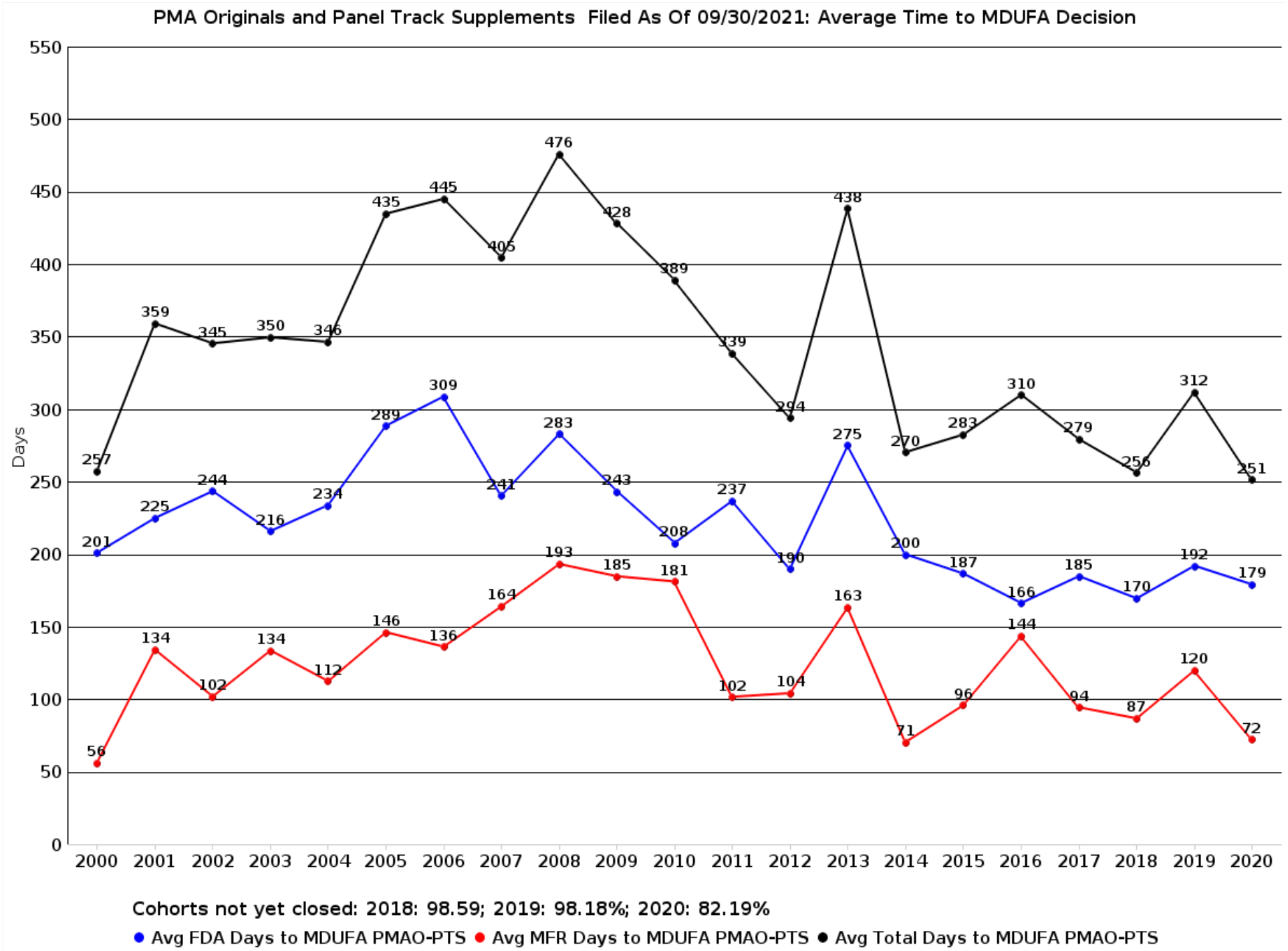
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/21. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

♦ % 1st Cycle MAJR PMAO/PTS

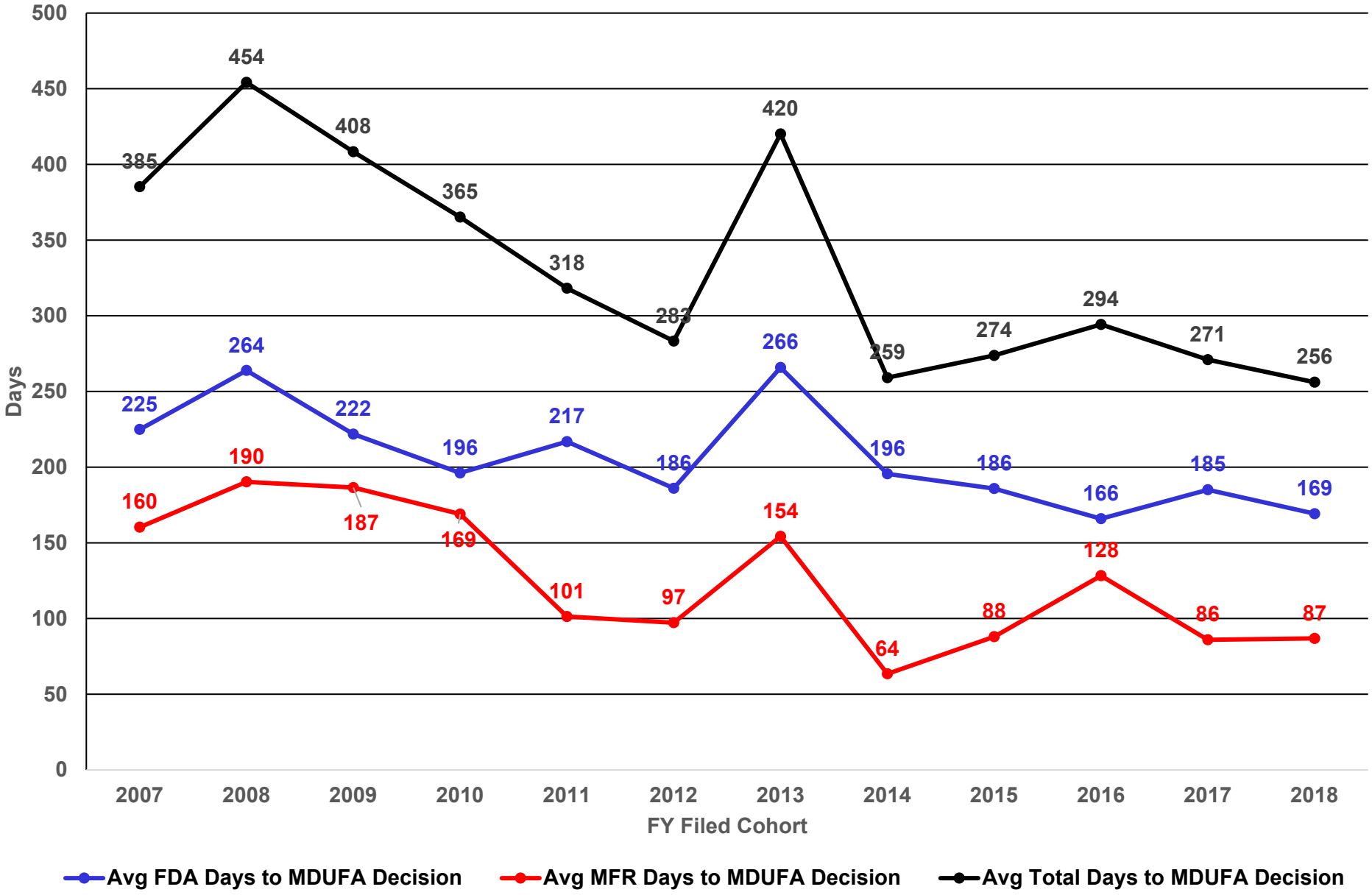

PMA Originals Filed As Of 09/30/2021: Average Time to MDUFA Decision
Days
550
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020
249 383 383 321 365 438 425 402 479 465 419 348 310 467 296 294 345 311 284 356 271
194 228 256 210 241 311 305 237 303 266 226 239 188 266 208 191 178 190 181 215 182
55 155 128 111 124 127 120 165 176 198 193 109 123 201 88 103 178 120 104 141 89
Cohorts not yet closed: 2019: 97.06%; 2020: 75.56%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO


PMA Originals Filed as of 9/30/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 97.1% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
FY Filed Cohort
368
451
439
387
313
295
432
280
280
326
298
274
356
210
280
238
211
208
182
251
202
190
167
191
181
215
159
172
201
177
105
113
182
78
90
159
107
93
141
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

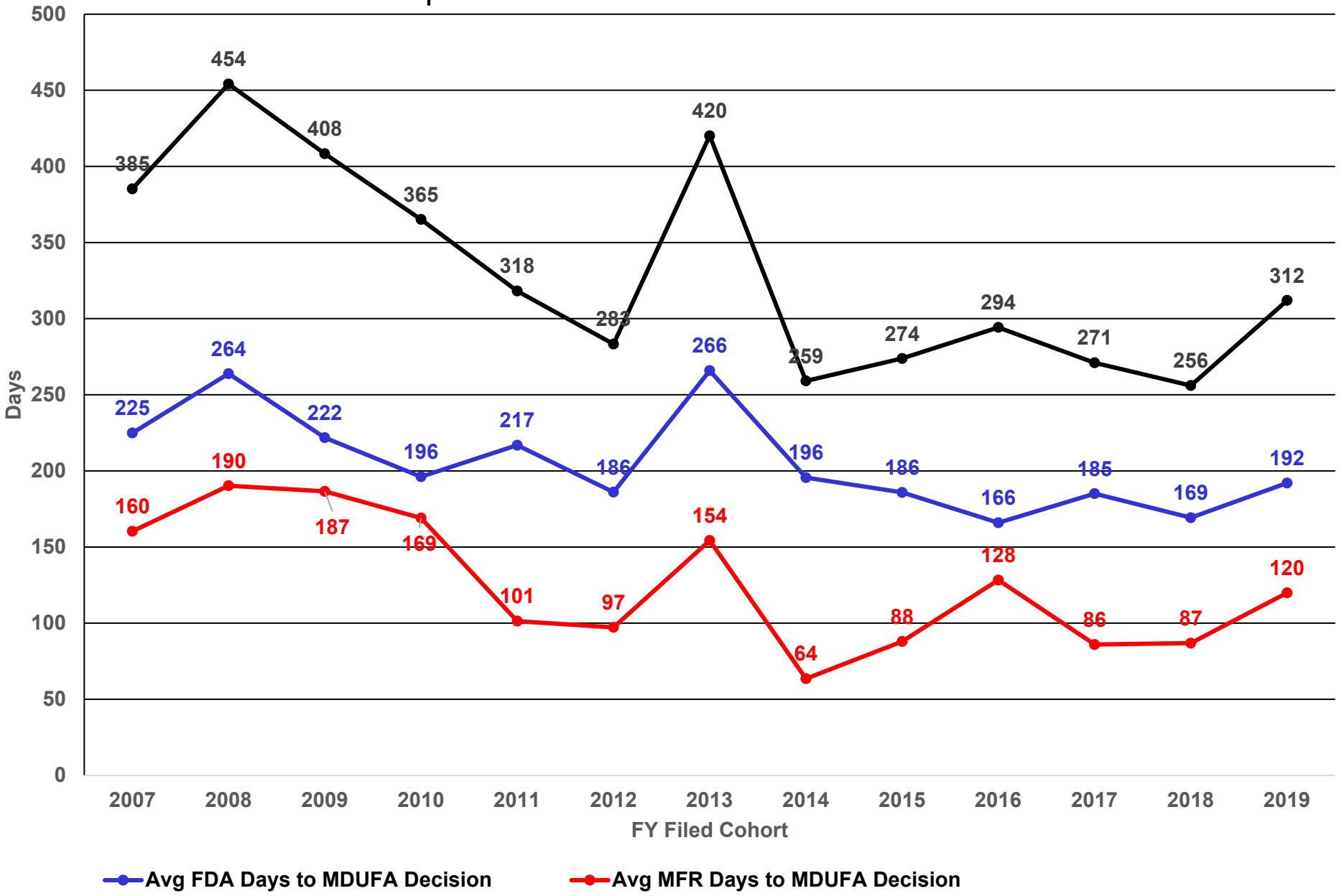

PMA Originals Filed as of 9/30/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 75.6% Closure
Days
400
350
300
250
200
150
100
50
0
329
349
372
340
245
249
355
246
248
265
253
239
286
271
211
206
203
183
184
176
220
184
177
162
182
177
193
182
117
143
170
157
61
73
135
62
71
103
70
62
93
89
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
FY Filed Cohort
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed As Of 09/30/2021: 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
257 359 345 350 346 435 445 405 476 428 389 339 294 438 270 283 310 279 256 312 251
201 225 244 216 234 289 309 241 283 243 208 237 190 275 200 187 166 185 170 192 179
56 134 102 134 112 146 136 164 193 185 181 102 104 163 71 96 144 94 87 120 72
Cohorts not yet closed: 2018: 98.59; 2019: 98.18%; 2020: 82.19%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

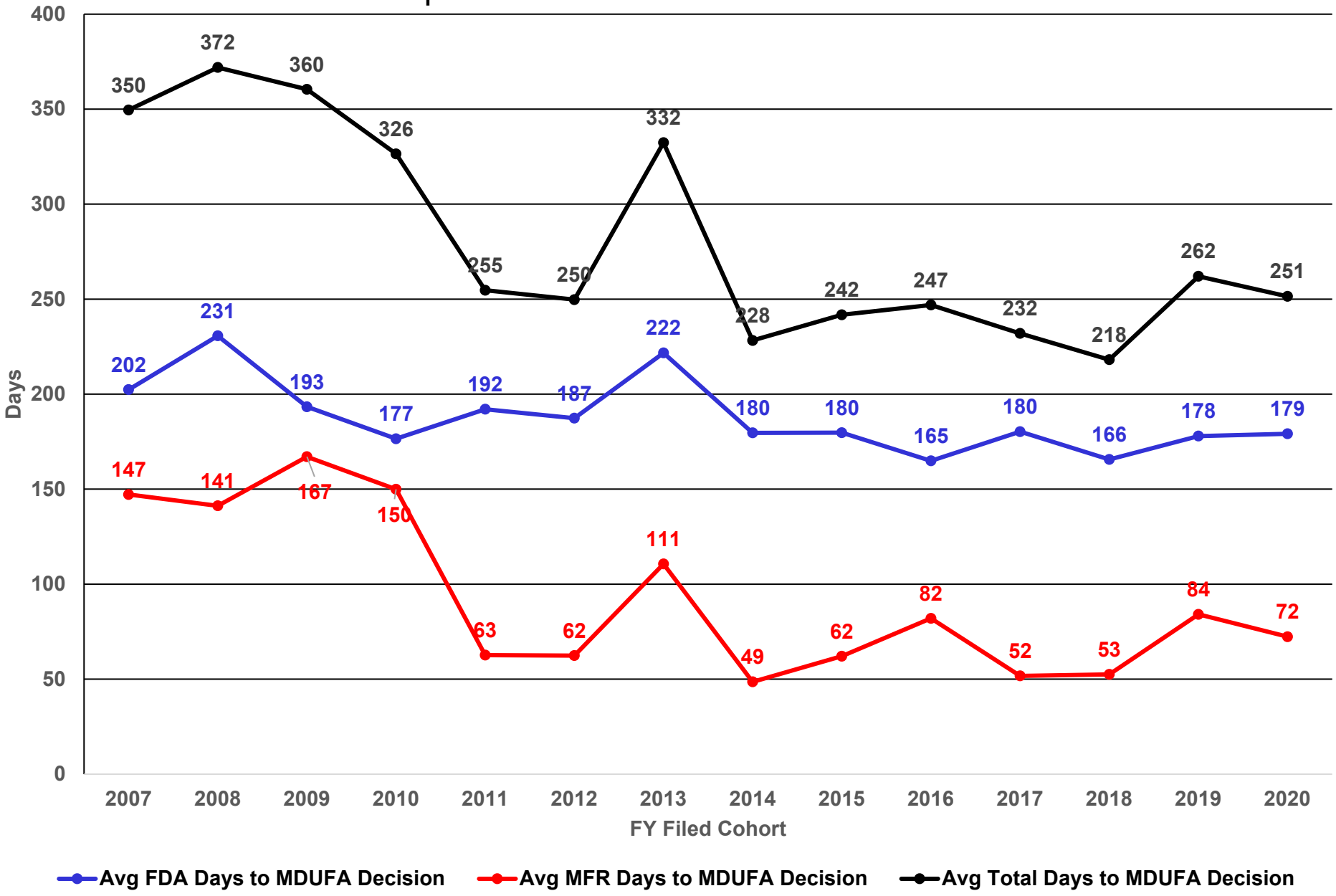
PMA Originals and Panel Track Supplements Filed as of 9/30/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 98.6% Closure

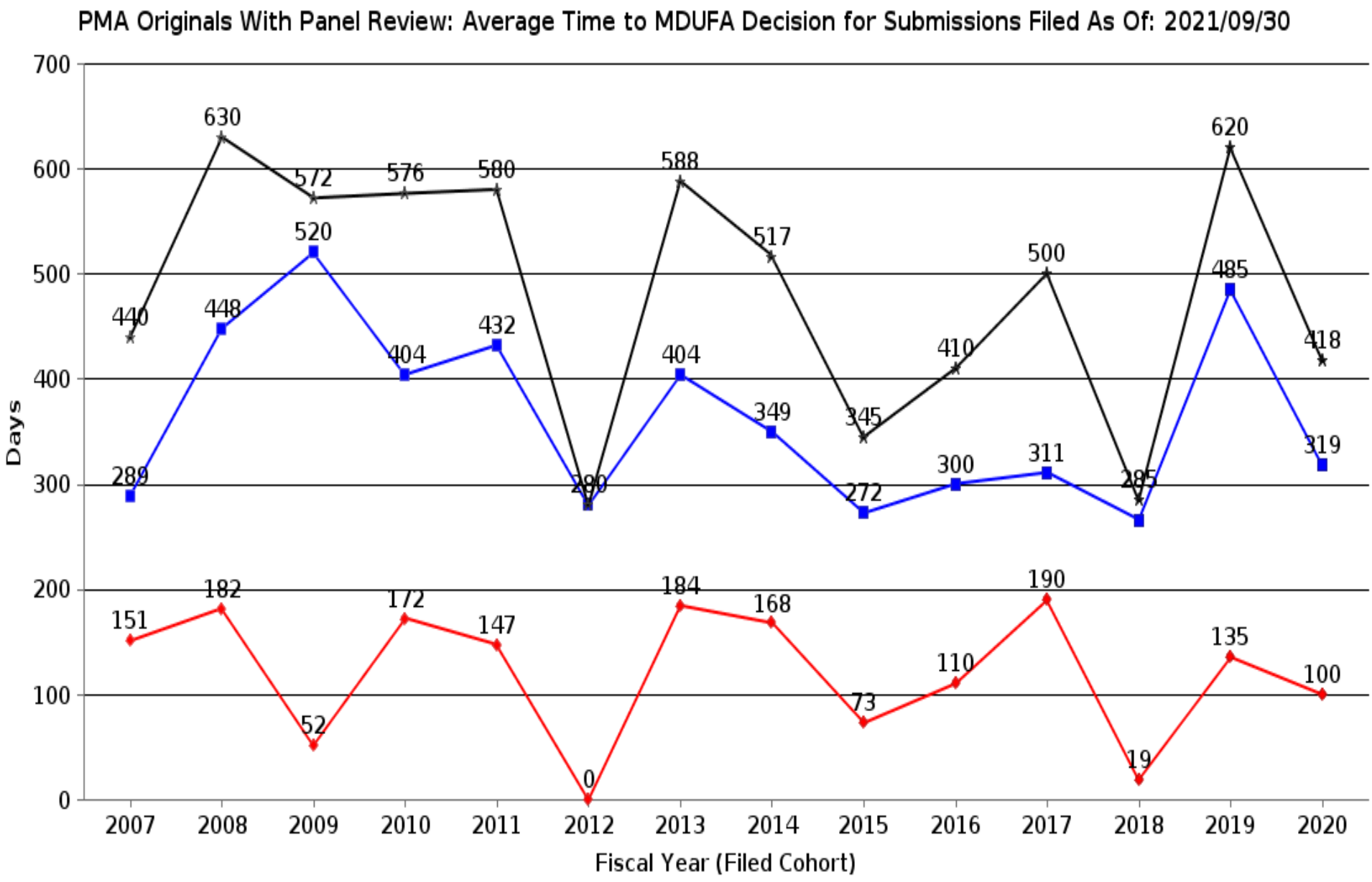


PMA Originals and Panel Track Supplements Filed as of 9/30/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 98.2% Closure



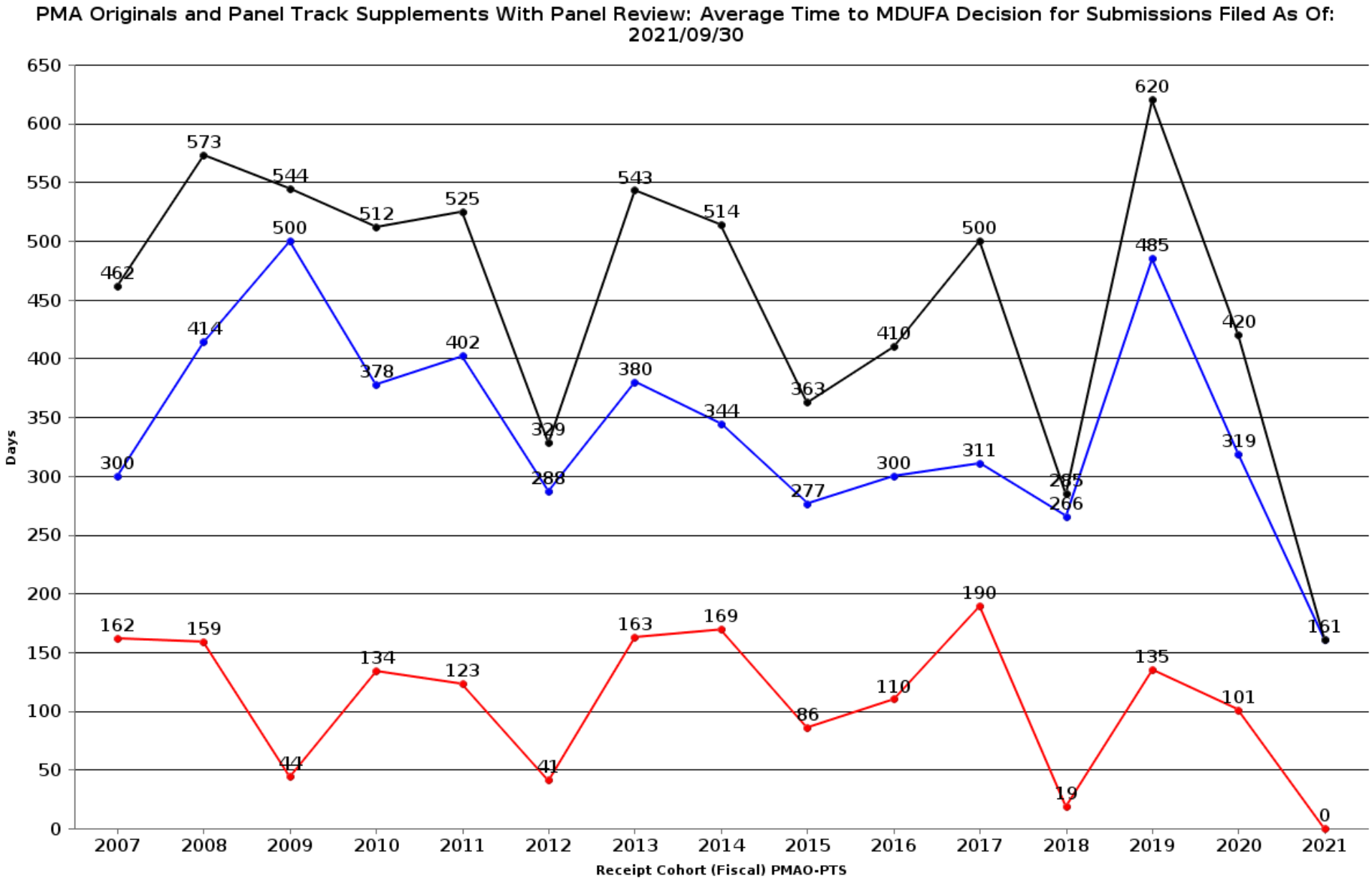
PMA Originals and Panel Track Supplements Filed as of 9/30/2021: Average Time to MDUFA Decision
Comparison of Cohorts at 82.2% Closure



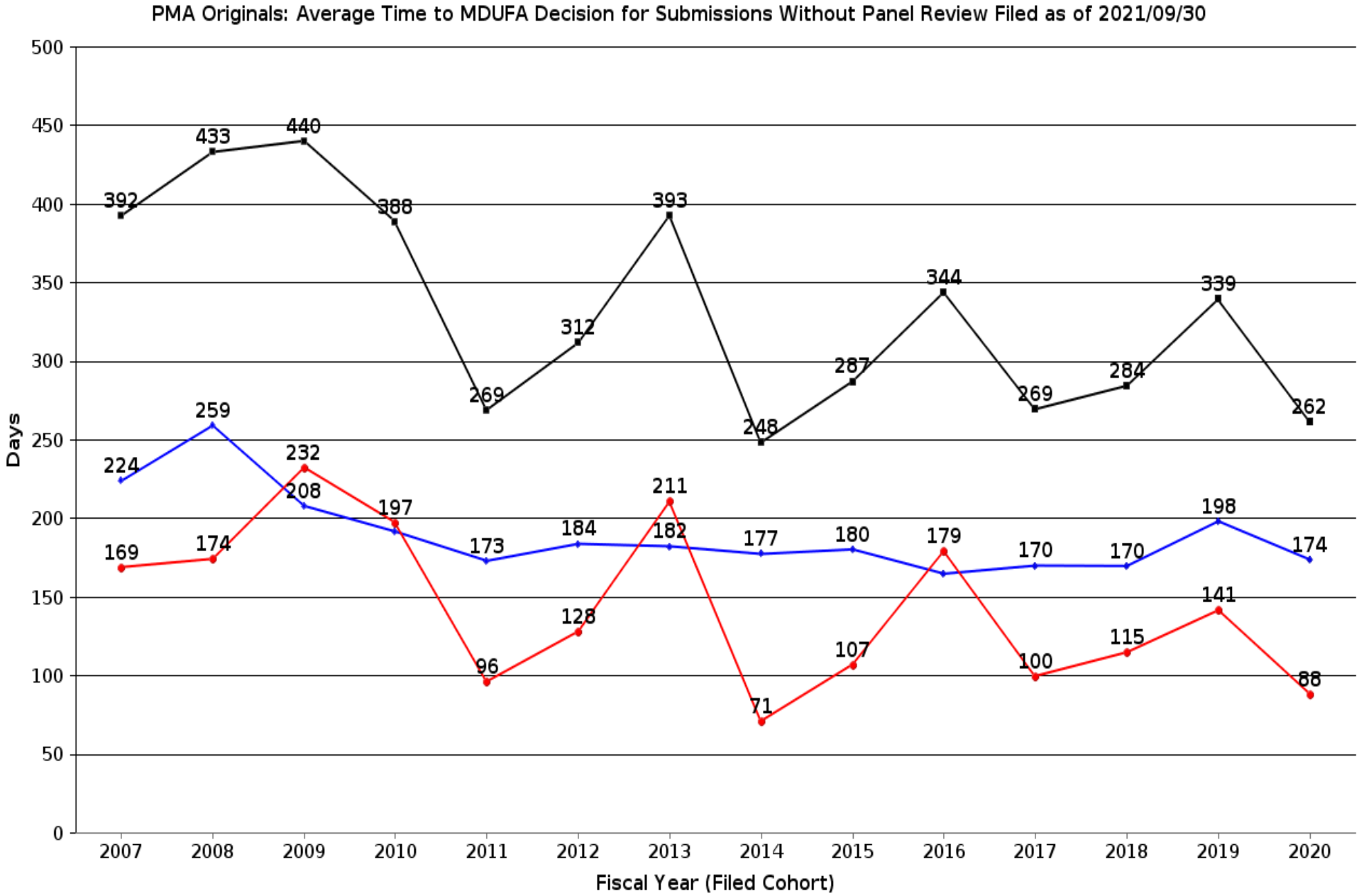


Numbers Filed/Closed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/2

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



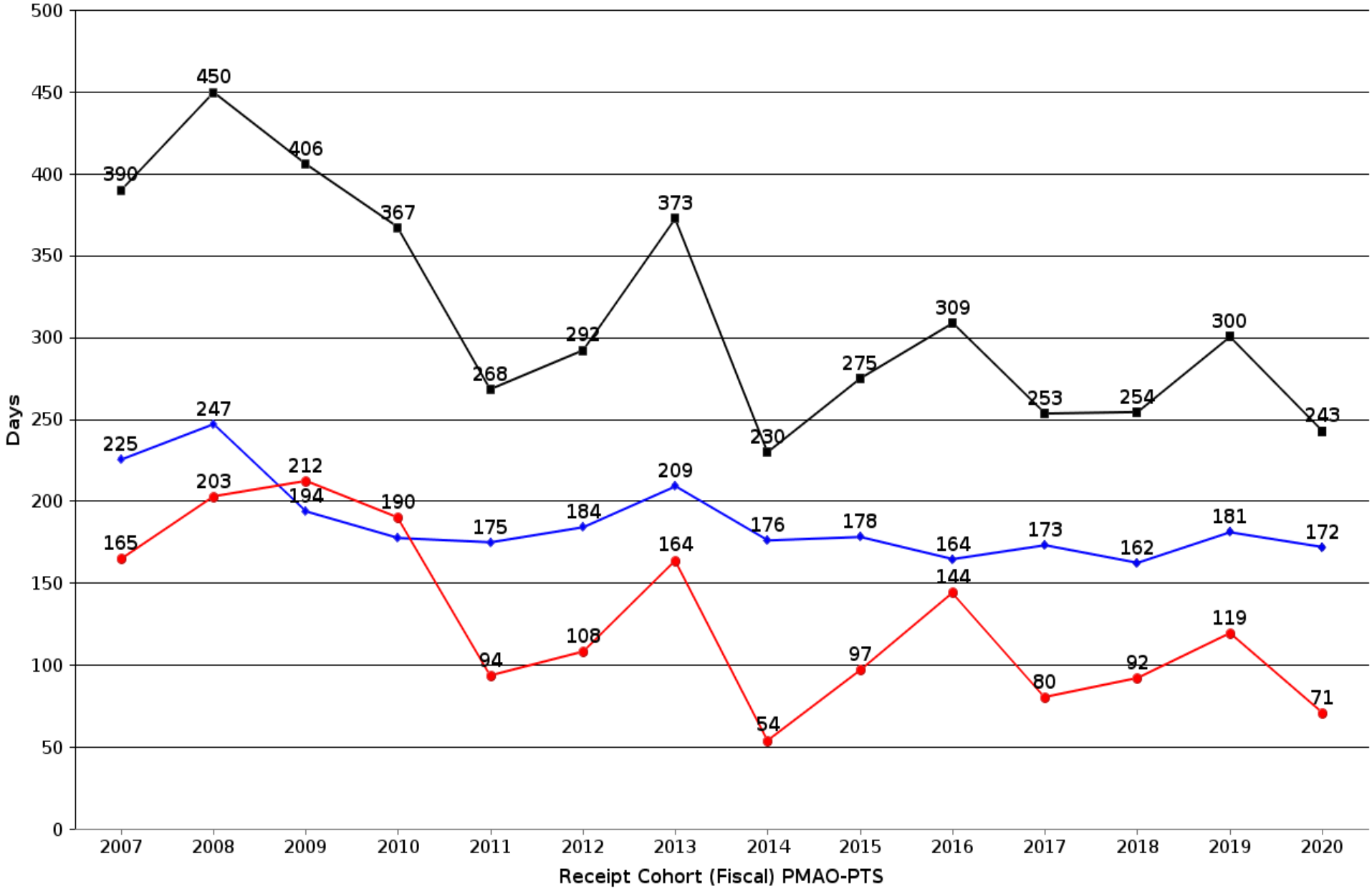
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.



Numbers Filed/Closed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/31; 2020 = 42/32; 2021 = /

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

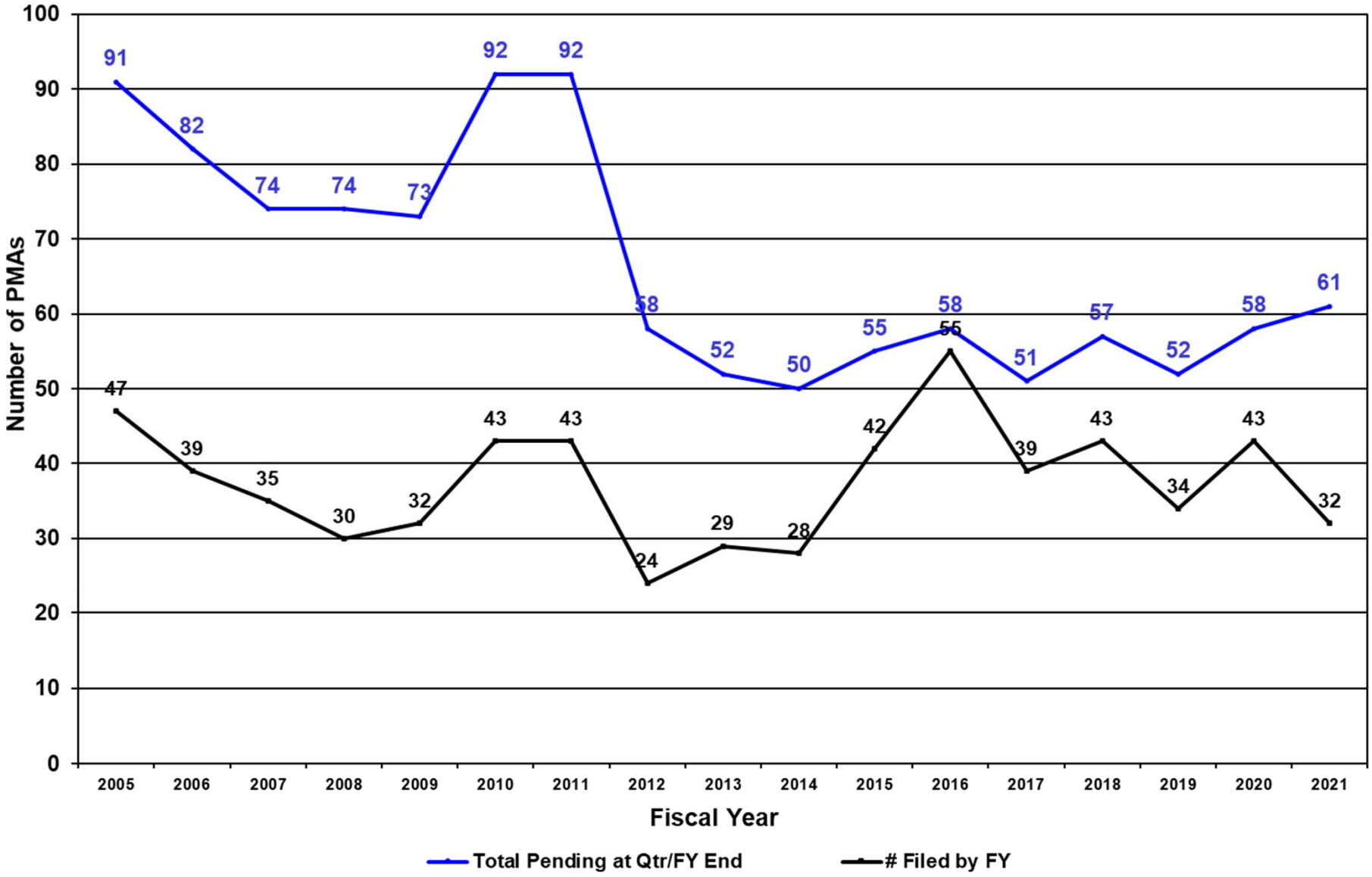
PMA Originals and Panel Track Supplements: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2021/09/30



Numbers Filed/Closed: 2007 = 31/31; 2008 = 29/29; 2009 = 36/36; 2010 = 50/50; 2011 = 37/37; 2012 = 32/32; 2013 = 27/27; 2014 = 36/36; 2015 = 62/62; 2016 = 70/70; 2017 = 60/60; 2018 = 66/65; 2019 = 53/52; 2020 = 69/57; 2021 = /

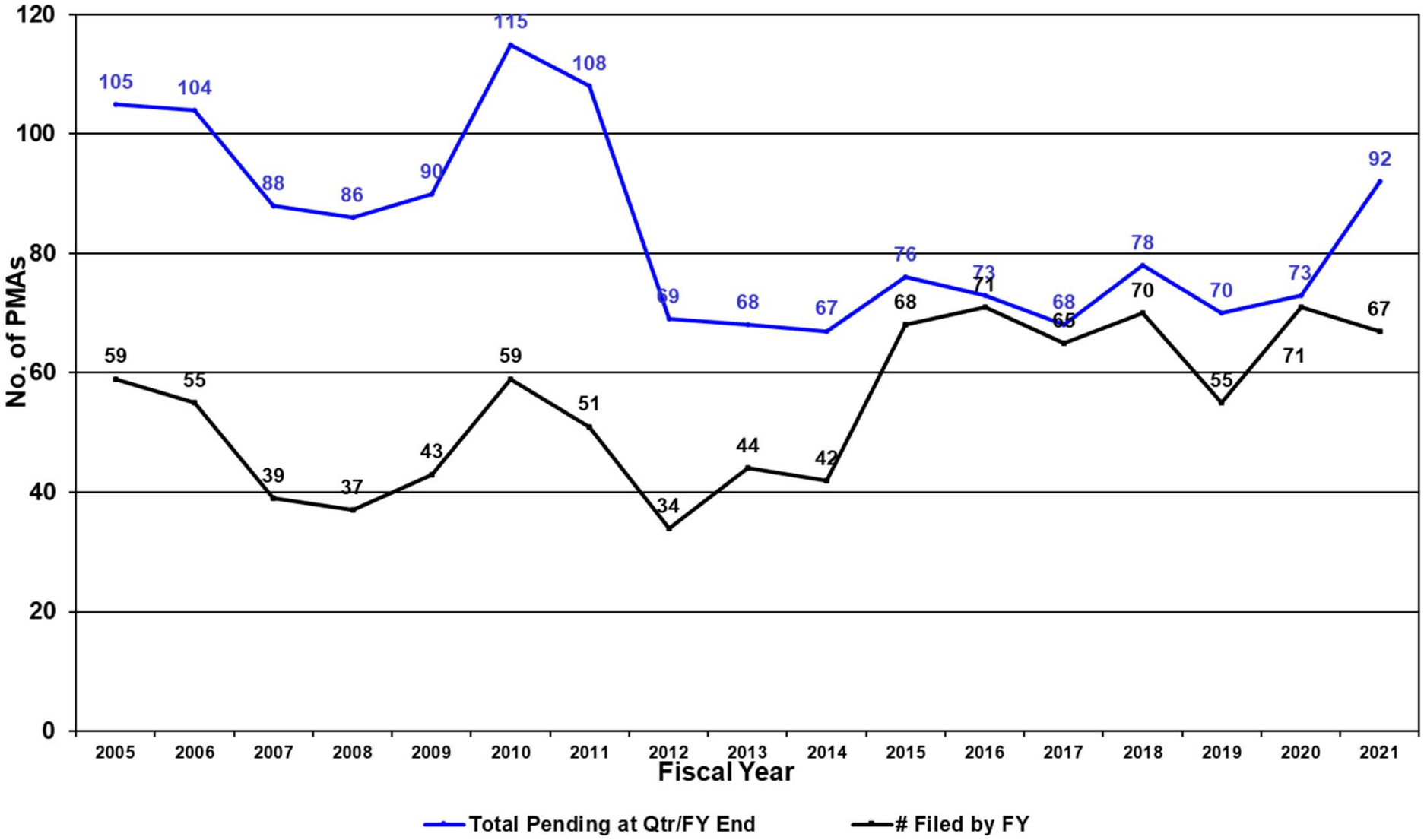
◆ Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ■ Avg Total Days to MDUFA Decision PMAO-PTS

PMA Originals Pending* at End of Quarter/Year

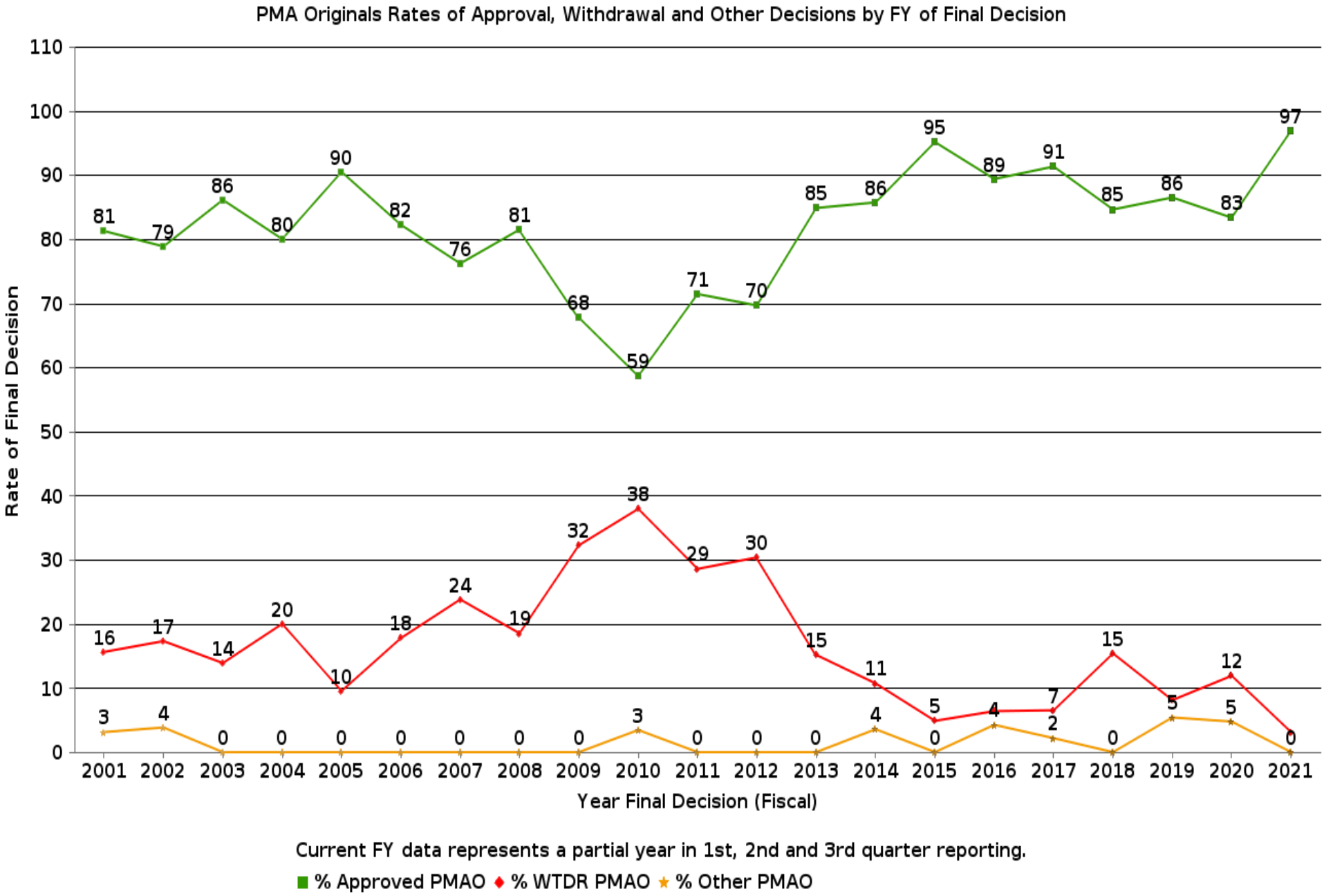


***Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.**

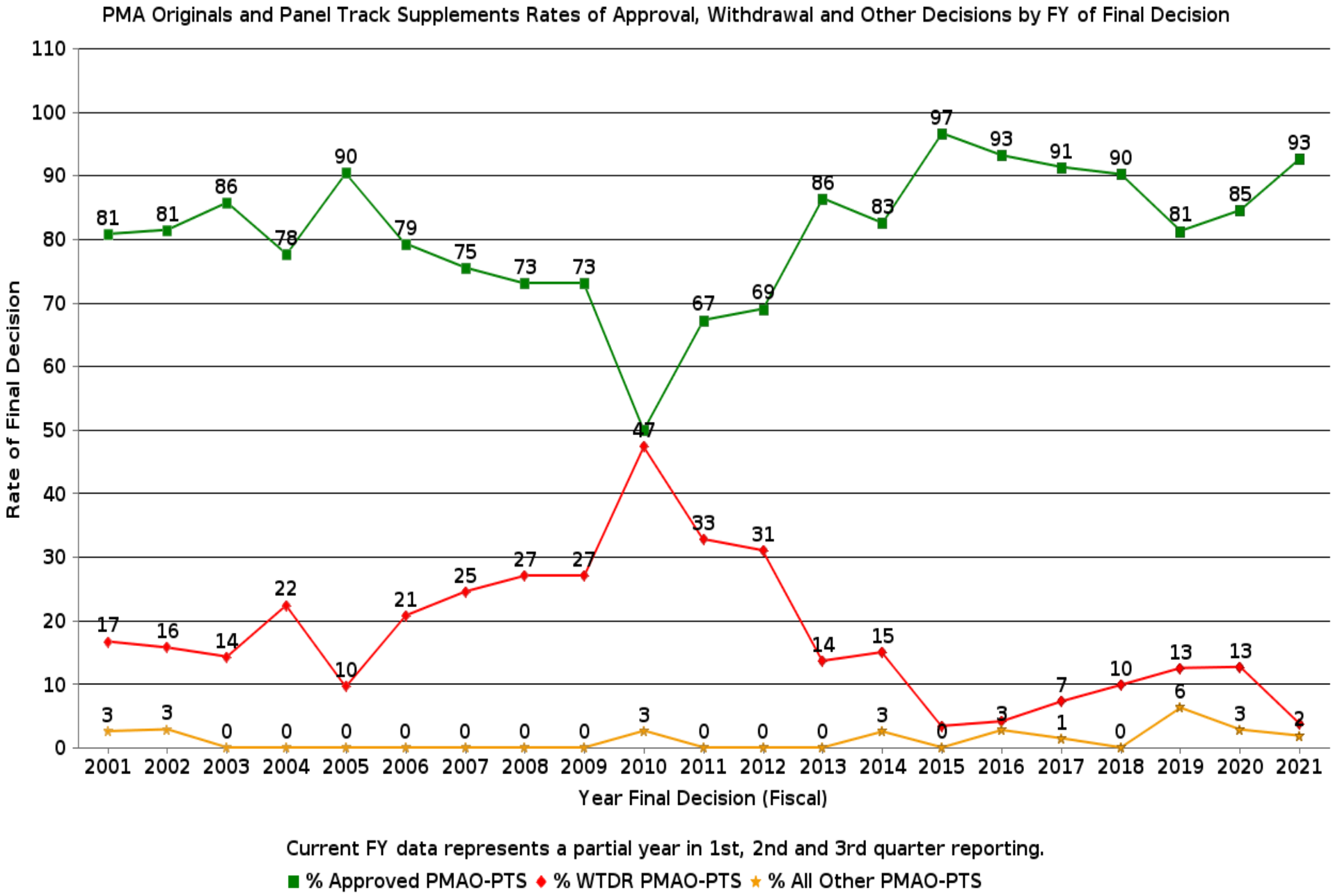
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



***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



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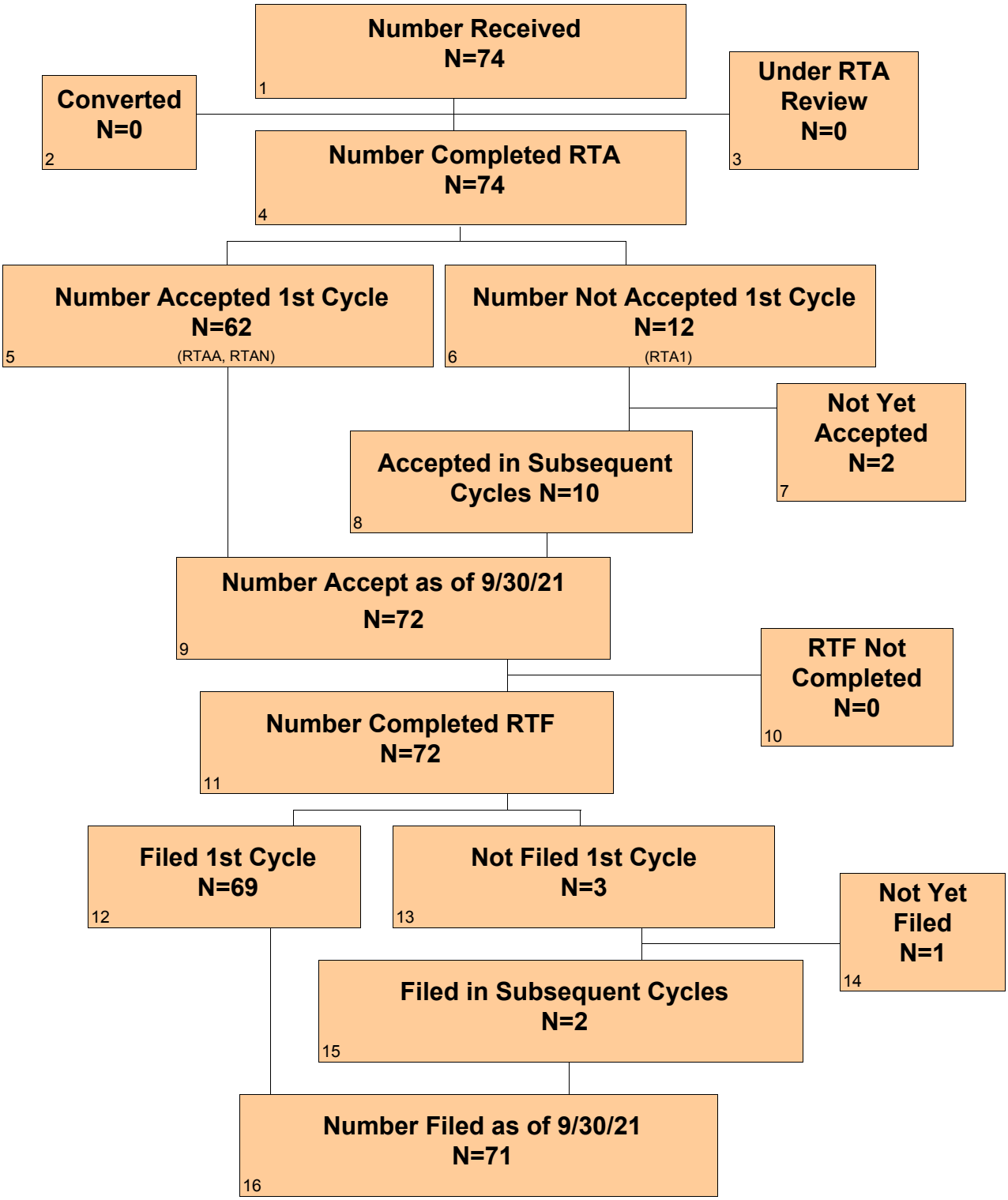
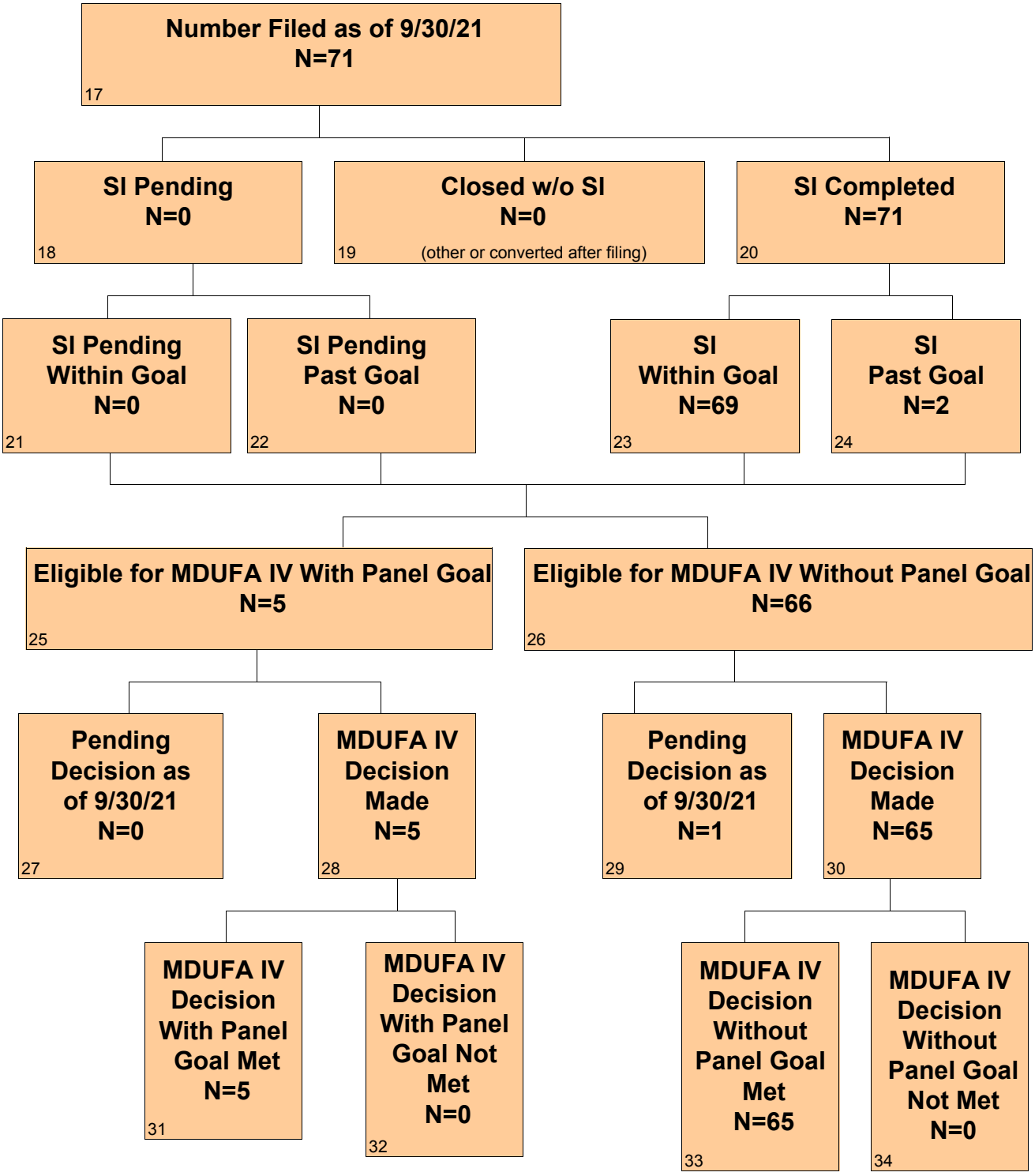
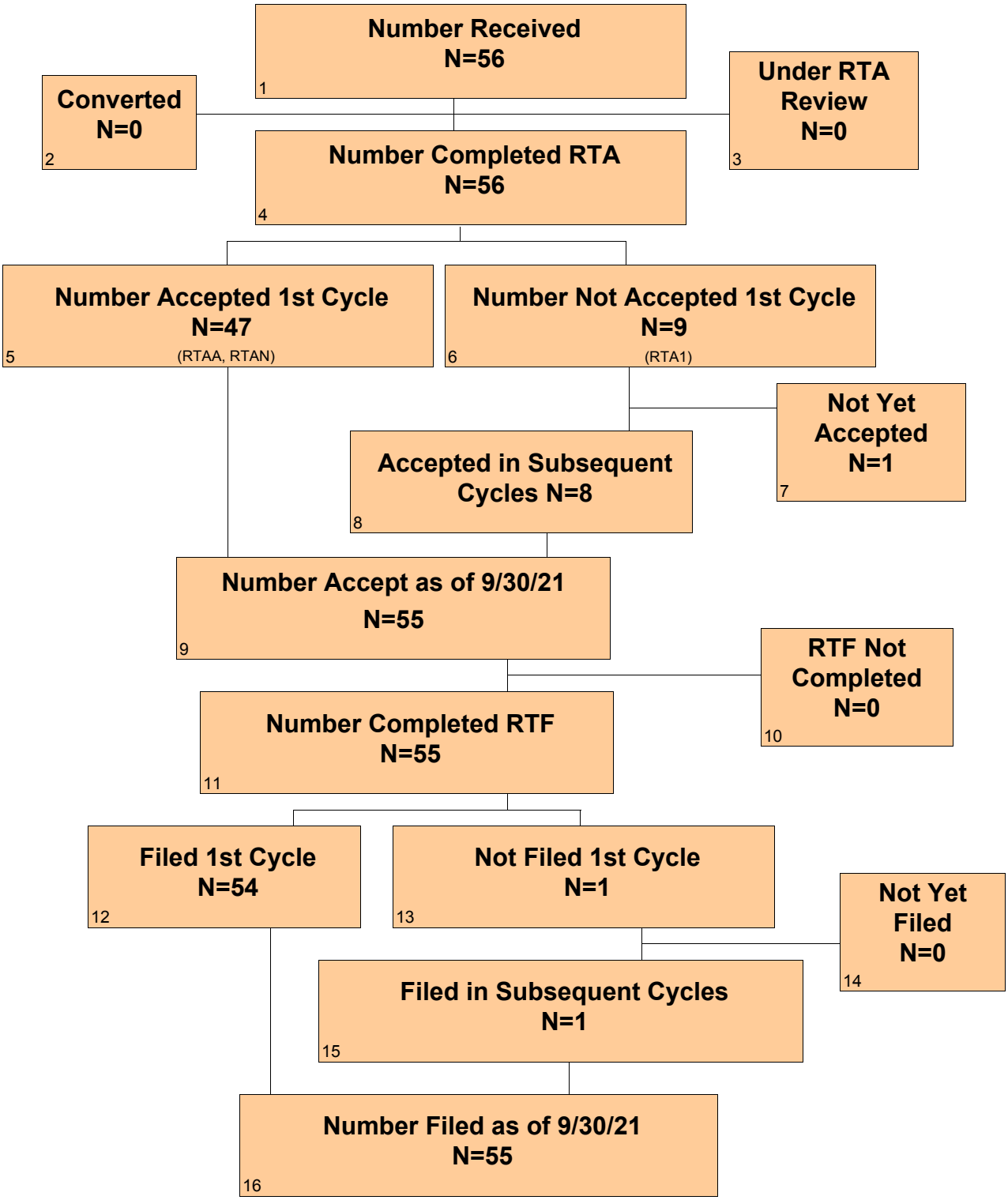
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/21



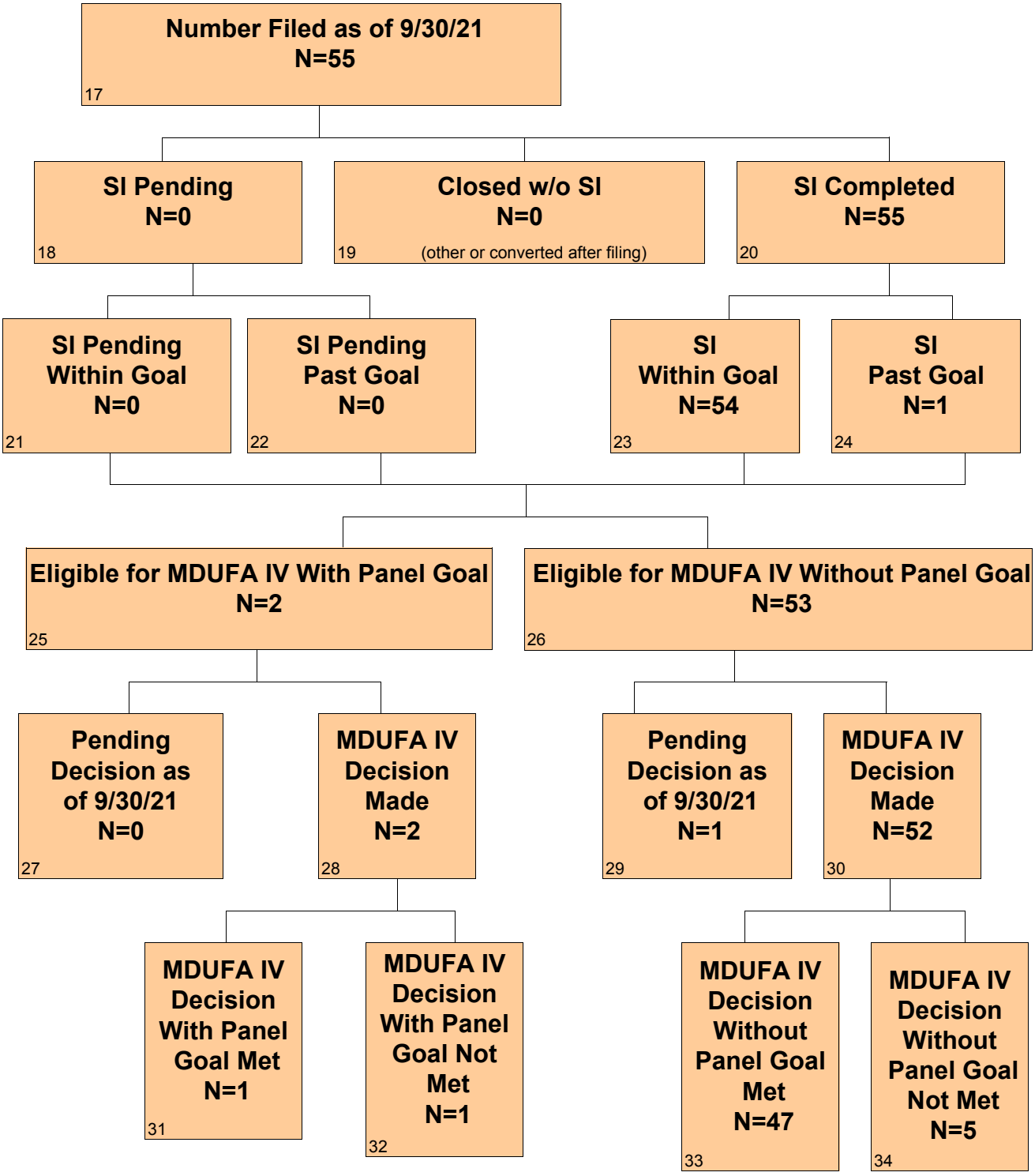
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/21 Continued



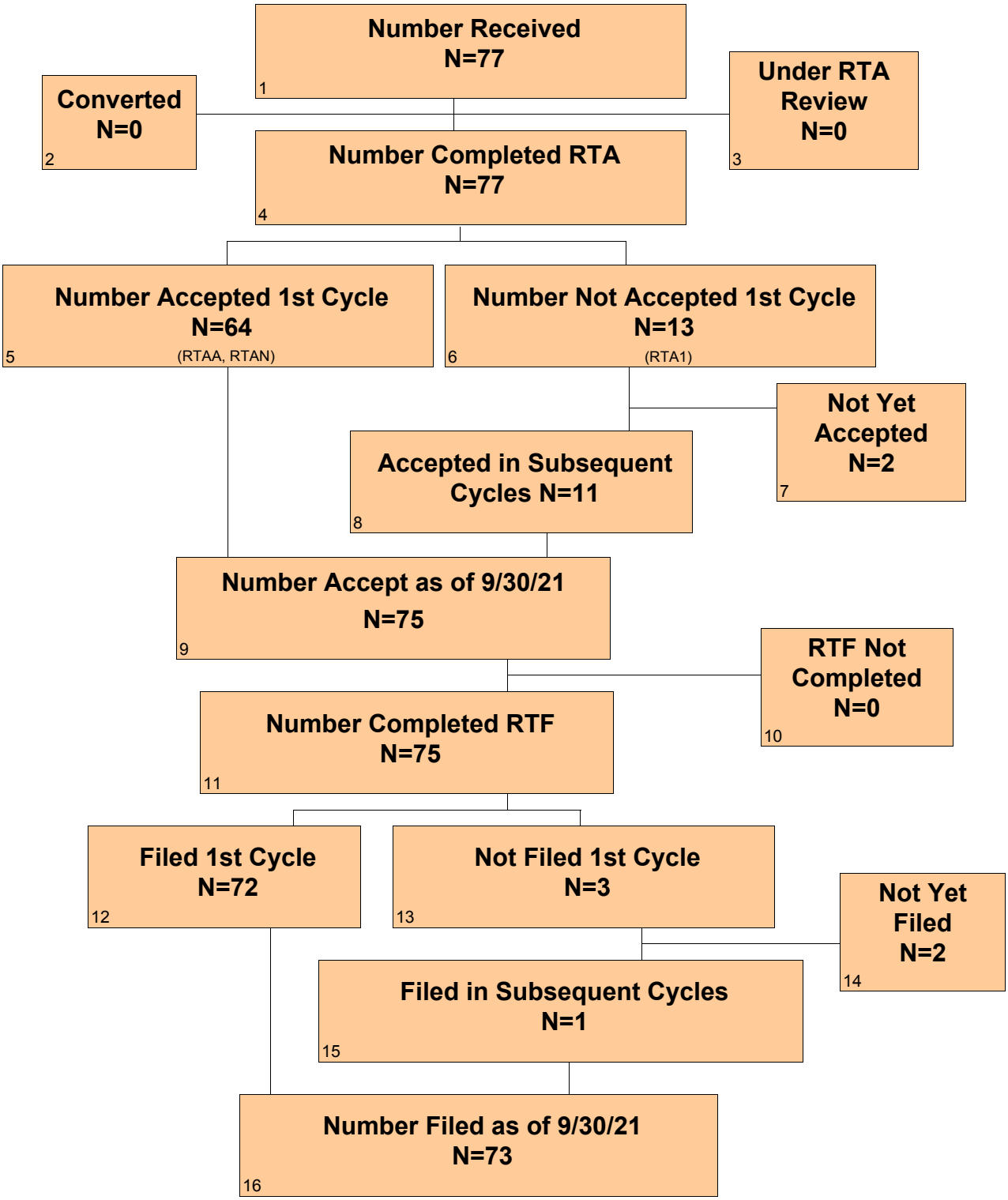
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/21



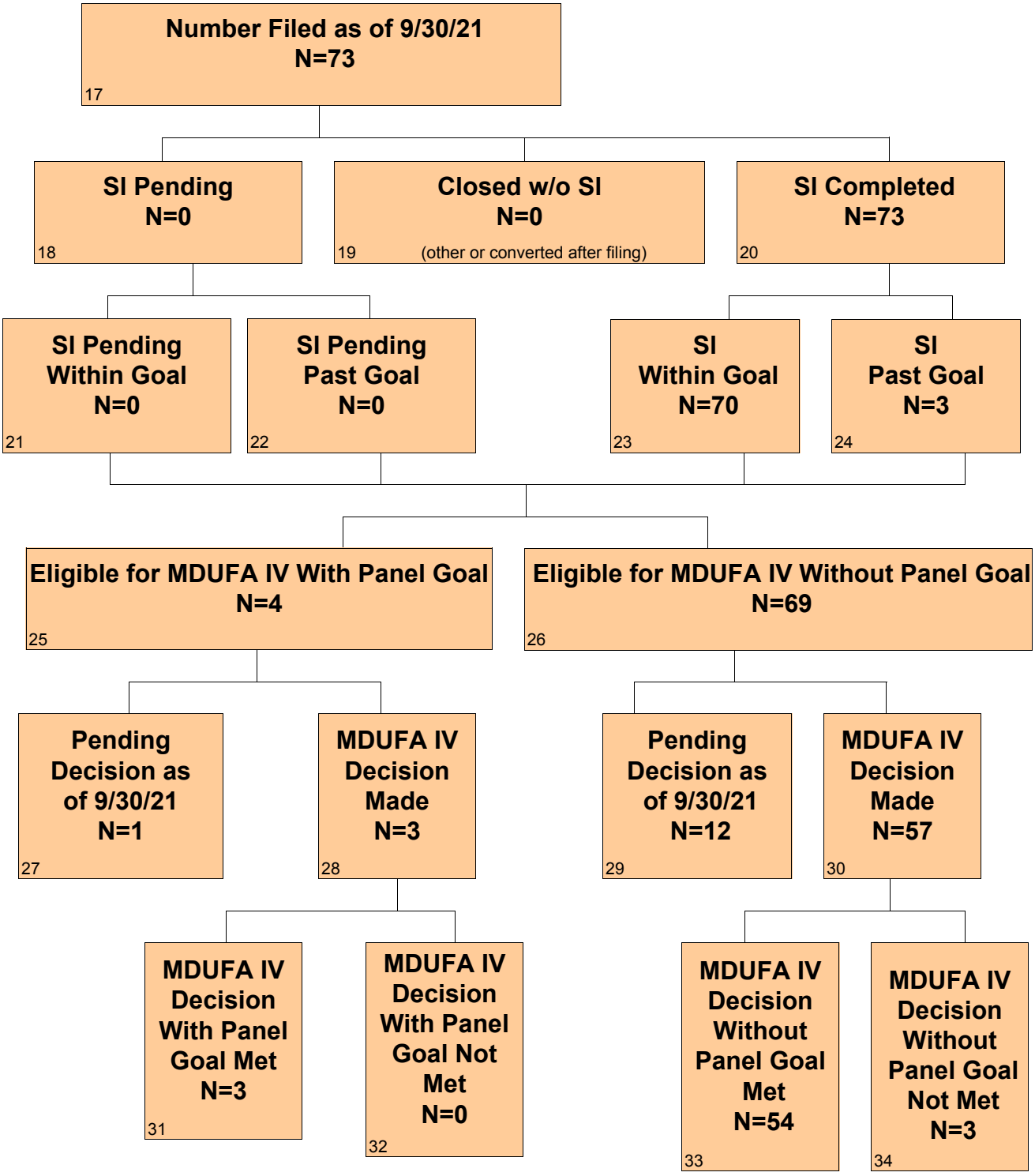
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/21 Continued



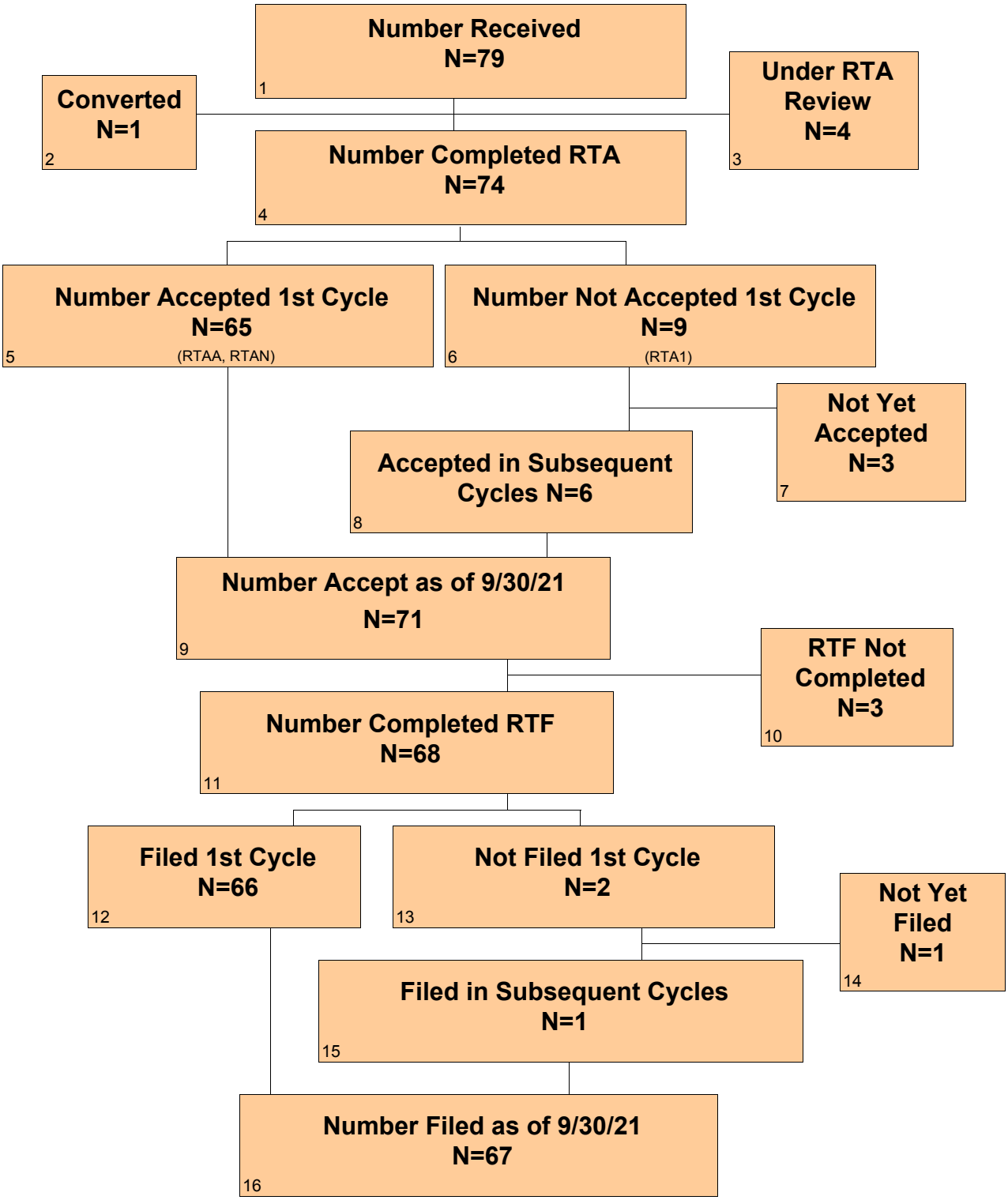
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/21



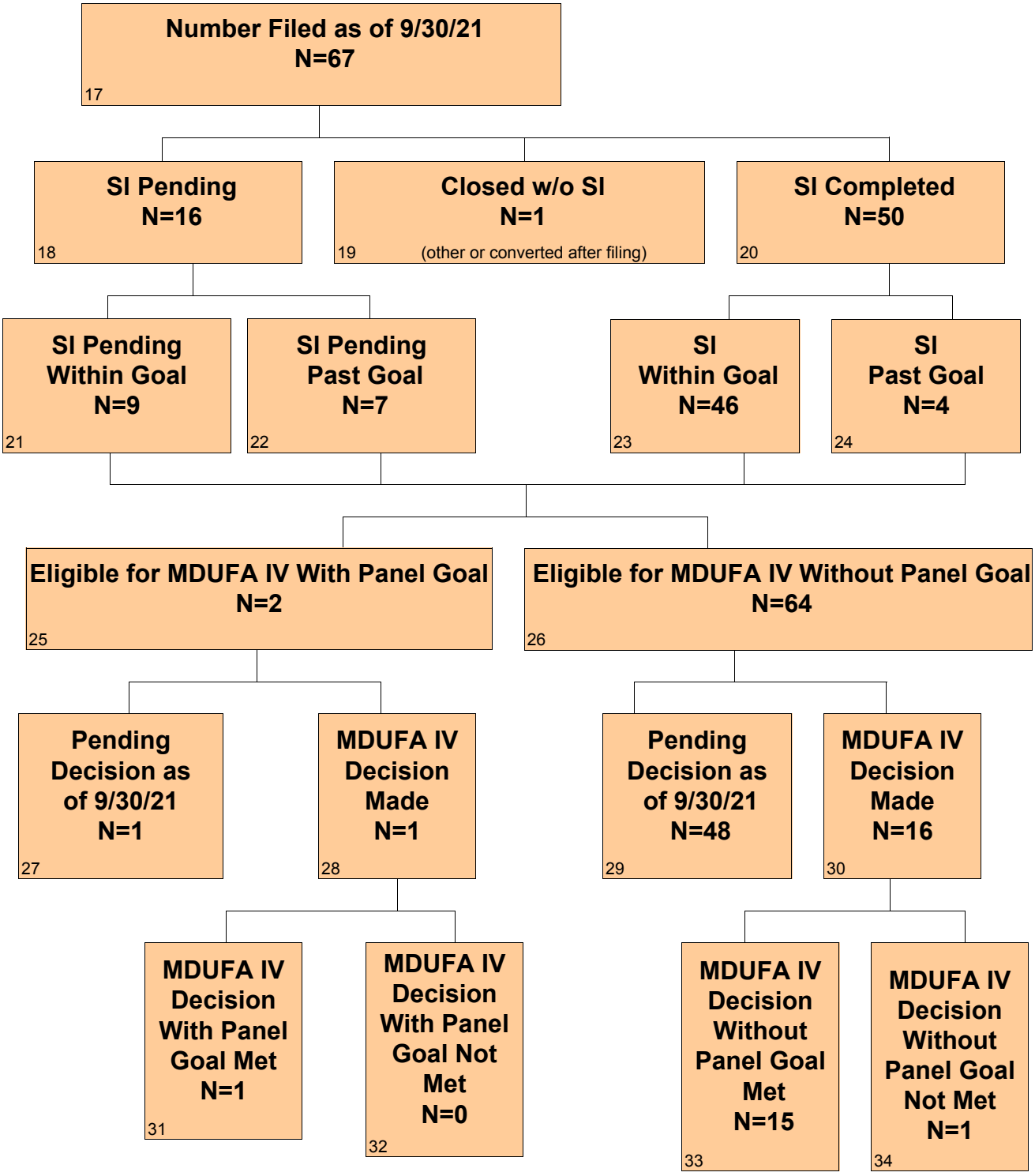
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/21 Continued



CDRH PMA Original and Panel Track Supplements - FY 2021 as of 9/30/21



CDRH PMA Original and Panel Track Supplements - FY 2021 as of 9/30/21 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	79	
Closed Before RTA Action	0	0	0	1	
Number with Accepted RTA Review	62	46	63	56	
Number Without a RTA Review and > 15 Days Since Date Received	0	1	1	9	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	4	
Number Not Accepted for Filing Review	12	9	13	9	
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	16.88%	12.16%	

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	79	
Number Accepted	62	47	64	65	
Completed RTF	72	55	75	68	
Number Not Filed	3	1	3	2	
Rate of Submissions Not Filed	4.17%	1.82%	4.00%	2.94%	

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	71	55	73	67	
SI Goal Met	69	54	70	46	
SI Goal Not Met	2	1	3	4	
SI Pending Within Goal	0	0	0	9	
SI Pending Past Goal	0	0	0	7	
Closed Without SI	0	0	0	1	
Current SI Performance Percent Goal Met	97.18%	98.18%	95.89%	80.70%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	71	55	73	50	
Average Number of FDA Days to Substantive Interaction	87.03	89.95	91.74	92.86	
20th Percentile FDA Days to Substantive Interaction	84	87	88	87	
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	325	250	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	66	53	69	65	
Non-MDUFA IV Decision	0	0	0	1	
MDUFA IV Decision	65	52	57	16	
MDUFA IV Decision Goal Met	65	47	54	15	
PMAs Pending MDUFA IV Decision	1	1	12	48	
PMAs Pending MDUFA IV Decision Past Goal	0	0	2	4	
Current Performance Percent Goal Met	100.00%	90.38%	91.53%	75.00%	

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	4	2	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	5	2	3	1	
MDUFA IV Decision Goal Met	5	1	3	1	
PMAs Pending MDUFA IV Decision	0	0	1	1	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	50.00%	100.00%	100.00%	

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	57	16	
Average FDA Days to MDUFA IV Decision	162.15	180.79	171.79	156.56	
20th Percentile FDA Days to MDUFA IV Decision	144	145	175	128	
40th Percentile FDA Days to MDUFA IV Decision	177	177	179	156	
60th Percentile FDA Days to MDUFA IV Decision	178	180	180	178	
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	179	
Maximum FDA Days to MDUFA IV Decision	279	338	406	226	
Average Industry Days to MDUFA IV Decision	93.18	119.35	70.81	30.81	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	18	26	25	0	
60th Percentile Industry Days to MDUFA IV Decision	88	122	63	33	
80th Percentile Industry Days to MDUFA IV Decision	162	186	121	53	
Maximum Industry Days to MDUFA IV Decision	360	529	424	110	
Average Total Days to MDUFA IV Decision	255.34	300.13	242.60	187.38	
20th Percentile Total Days to MDUFA IV Decision	167	175	176	156	
40th Percentile Total Days to MDUFA IV Decision	180	203	201	178	
60th Percentile Total Days to MDUFA IV Decision	257	302	242	200	
80th Percentile Total Days to MDUFA IV Decision	342	417	301	226	
Maximum Total Days to MDUFA IV Decision	540	705	604	258	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	2	3	1	
Average FDA Days to MDUFA IV Decision	265.80	485.00	319.00	161.00	
20th Percentile FDA Days to MDUFA IV Decision	193	299	318	161	
40th Percentile FDA Days to MDUFA IV Decision	267	423	319	161	
60th Percentile FDA Days to MDUFA IV Decision	316	547	319	161	
80th Percentile FDA Days to MDUFA IV Decision	320	671	320	161	
Maximum FDA Days to MDUFA IV Decision	322	795	320	161	
Average Industry Days to MDUFA IV Decision	19.00	135.00	101.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	104	79	0	
40th Percentile Industry Days to MDUFA IV Decision	0	125	96	0	
60th Percentile Industry Days to MDUFA IV Decision	0	145	110	0	
80th Percentile Industry Days to MDUFA IV Decision	19	166	123	0	
Maximum Industry Days to MDUFA IV Decision	95	187	136	0	
Average Total Days to MDUFA IV Decision	284.80	620.00	420.00	161.00	
20th Percentile Total Days to MDUFA IV Decision	256	403	398	161	
40th Percentile Total Days to MDUFA IV Decision	297	548	415	161	
60th Percentile Total Days to MDUFA IV Decision	316	692	430	161	
80th Percentile Total Days to MDUFA IV Decision	320	837	443	161	
Maximum Total Days to MDUFA IV Decision	322	982	455	161	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	66	53	69	65	
Number with MDUFA IV Decision	65	52	57	16	
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%	5.26%	0.00%	
Rate of Not Approvable	12.31%	13.46%	7.02%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	2	4	2	
Number With MDUFA IV Decision	5	2	3	1	
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%	0.00%	
Rate of Not Approvable	80.00%	50.00%	33.33%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	5	5	5	
Mean FDA Days for Submissions that Missed the Goal	0.00	266.60	232.60	253.60	
Mean Industry Days for Submissions that Missed the Goal	0.00	235.00	18.40	5.20	

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	795.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	187.00	0.00	0.00	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	4	11	5	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	3	11	2	
MDUFA IV Decision Goal Met	1	3	11	2	
PMAs Pending MDUFA IV Decision	0	1	0	3	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	1	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	66.67%	

***Includes submission that went to panel**

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	15	18	
Non-MDUFA IV Decision	0	0	0	1	
MDUFA IV Decision	15	17	13	4	
MDUFA IV Decision Goal Met	15	13	12	4	
PMAs Pending MDUFA IV Decision	0	0	2	14	
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	2	
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	66.67%	

***Includes submission that went to panel**

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	8	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	11	6	4	6	
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	2	
Rate of Submissions Not Accepted for Filing Review	31.25%	14.29%	33.33%	25.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	8	
Number Accepted	11	6	4	6	
Completed RTF	16	7	6	7	
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	7	
SI Goal Met	16	7	6	5	
SI Goal Not Met	0	0	0	1	
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%	83.33%	

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	6	
Average Number of FDA Days to Substantive Interaction	87.13	88.86	88.00	100.17	
20th Percentile FDA Days to Substantive Interaction	86	88	87	89	
40th Percentile FDA Days to Substantive Interaction	87	89	88	90	
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	154	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	15	7	6	7	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	15	7	5	1	
MDUFA IV Decision Goal Met	15	7	5	1	
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%	100.00%	100.00%	100.00%	

Table 1.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (with Panel Review) MDUFA 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	5	1	
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	180.00	
20th Percentile FDA Days to MDUFA IV Decision	176	179	180	180	
40th Percentile FDA Days to MDUFA IV Decision	178	180	180	180	
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	180	
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	
Maximum FDA Days to MDUFA IV Decision	180	180	180	180	
Average Industry Days to MDUFA IV Decision	130.93	65.43	112.20	28.00	
20th Percentile Industry Days to MDUFA IV Decision	0	4	60	28	
40th Percentile Industry Days to MDUFA IV Decision	52	20	76	28	
60th Percentile Industry Days to MDUFA IV Decision	141	50	92	28	
80th Percentile Industry Days to MDUFA IV Decision	278	148	142	28	
Maximum Industry Days to MDUFA IV Decision	360	180	277	28	
Average Total Days to MDUFA IV Decision	308.27	244.57	292.20	208.00	
20th Percentile Total Days to MDUFA IV Decision	178	184	240	208	
40th Percentile Total Days to MDUFA IV Decision	232	200	256	208	
60th Percentile Total Days to MDUFA IV Decision	321	230	272	208	
80th Percentile Total Days to MDUFA IV Decision	450	328	322	208	
Maximum Total Days to MDUFA IV Decision	528	359	457	208	

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	7	
Number with MDUFA IV Decision	15	7	5	1	
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%	0.00%	
Rate of Not Approvable	26.67%	14.29%	40.00%	0.00%	

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	19	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	20	11	21	17	
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	3	3	2	1	
Rate of Submissions Not Accepted for Filing Review	13.04%	21.43%	8.70%	5.56%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14	23	19	
Number Accepted	20	11	21	17	
Completed RTF	22	14	23	18	
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	18	
SI Goal Met	22	14	23	15	
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 1.4 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	22	14	23	15	
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.26	88.93	
20th Percentile FDA Days to Substantive Interaction	84	85	87	88	
40th Percentile FDA Days to Substantive Interaction	87	88	88	89	
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	18	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	21	12	18	6	
MDUFA IV Decision Goal Met	21	12	18	6	
PMAs Pending MDUFA IV Decision	0	0	4	12	
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	2	1	0	
MDUFA IV Decision Goal Met	1	1	1	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%	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	18	6	
Average FDA Days to MDUFA IV Decision	174.00	178.92	178.22	170.00	
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	176	
40th Percentile FDA Days to MDUFA IV Decision	178	178	179	178	
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	179	
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	179	
Maximum FDA Days to MDUFA IV Decision	279	295	180	180	
Average Industry Days to MDUFA IV Decision	51.48	107.00	70.44	29.67	
20th Percentile Industry Days to MDUFA IV Decision	0	10	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	67	10	0	
60th Percentile Industry Days to MDUFA IV Decision	45	122	50	47	
80th Percentile Industry Days to MDUFA IV Decision	91	171	90	53	
Maximum Industry Days to MDUFA IV Decision	162	322	424	78	
Average Total Days to MDUFA IV Decision	225.48	285.92	248.67	199.67	
20th Percentile Total Days to MDUFA IV Decision	168	170	177	176	
40th Percentile Total Days to MDUFA IV Decision	180	245	189	179	
60th Percentile Total Days to MDUFA IV Decision	229	302	229	226	
80th Percentile Total Days to MDUFA IV Decision	324	363	270	231	
Maximum Total Days to MDUFA IV Decision	340	501	604	258	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	2	1	0	
Average FDA Days to MDUFA IV Decision	197.00	485.00	318.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	197	299	318	0	
40th Percentile FDA Days to MDUFA IV Decision	197	423	318	0	
60th Percentile FDA Days to MDUFA IV Decision	197	547	318	0	
80th Percentile FDA Days to MDUFA IV Decision	197	671	318	0	
Maximum FDA Days to MDUFA IV Decision	197	795	318	0	
Average Industry Days to MDUFA IV Decision	0.00	135.00	63.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	104	63	0	
40th Percentile Industry Days to MDUFA IV Decision	0	125	63	0	
60th Percentile Industry Days to MDUFA IV Decision	0	145	63	0	
80th Percentile Industry Days to MDUFA IV Decision	0	166	63	0	
Maximum Industry Days to MDUFA IV Decision	0	187	63	0	
Average Total Days to MDUFA IV Decision	197.00	620.00	381.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	197	403	381	0	
40th Percentile Total Days to MDUFA IV Decision	197	548	381	0	
60th Percentile Total Days to MDUFA IV Decision	197	692	381	0	
80th Percentile Total Days to MDUFA IV Decision	197	837	381	0	
Maximum Total Days to MDUFA IV Decision	197	982	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	18	
Number with MDUFA IV Decision	21	12	18	6	
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%	5.56%	0.00%	
Rate of Not Approvable	4.76%	8.33%	5.56%	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	2	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%	50.00%	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	795.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	187.00	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	4	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	8	3	6	4	
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	4	
Number Accepted	8	3	7	4	
Completed RTF	9	3	7	4	
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	4	
SI Goal Met	8	3	6	4	
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	4	
Average Number of FDA Days to Substantive Interaction	99.50	139.67	89.17	88.25	
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	89	
Maximum FDA Days to Substantive Interaction	178	246	90	90	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	5	3	5	4	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	5	3	1	0	
MDUFA IV Decision Goal Met	5	3	1	0	
PMAs Pending MDUFA IV Decision	0	0	4	4	
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	100.00%	100.00%	50.00%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	3	0	1	0	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	3	0	1	0	
MDUFA IV Decision Goal Met	3	0	1	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	100.00%	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	1	0	
Average FDA Days to MDUFA IV Decision	178.00	228.33	180.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	159	172	180	0	
40th Percentile FDA Days to MDUFA IV Decision	177	177	180	0	
60th Percentile FDA Days to MDUFA IV Decision	179	212	180	0	
80th Percentile FDA Days to MDUFA IV Decision	197	275	180	0	
Maximum FDA Days to MDUFA IV Decision	266	338	180	0	
Average Industry Days to MDUFA IV Decision	102.20	121.00	177.00	0.00	
20th Percentile Industry Days to MDUFA IV Decision	77	2	177	0	
40th Percentile Industry Days to MDUFA IV Decision	97	5	177	0	
60th Percentile Industry Days to MDUFA IV Decision	108	76	177	0	
80th Percentile Industry Days to MDUFA IV Decision	122	217	177	0	
Maximum Industry Days to MDUFA IV Decision	163	357	177	0	
Average Total Days to MDUFA IV Decision	280.20	349.33	357.00	0.00	
20th Percentile Total Days to MDUFA IV Decision	248	247	357	0	
40th Percentile Total Days to MDUFA IV Decision	270	308	357	0	
60th Percentile Total Days to MDUFA IV Decision	285	375	357	0	
80th Percentile Total Days to MDUFA IV Decision	302	450	357	0	
Maximum Total Days to MDUFA IV Decision	350	524	357	0	

Table 1.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	3	0	1	0	
Number With MDUFA IV Decision	3	0	1	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	0.00%	N/A	
Rate of Not Approvable	100.00%	N/A	0.00%	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	239.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 1.12 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	
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	6	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	1	1	3	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 for Filing Review	2	1	2	3	
Rate of Submissions Not Accepted for Filing Review	66.67%	50.00%	40.00%	50.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2	5	6	
Number Accepted	1	1	3	3	
Completed RTF	2	2	4	6	
Number Not Filed	0	0	0	1	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	16.67%	

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	2	4	5	
SI Goal Met	1	2	4	3	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	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	3	
Average Number of FDA Days to Substantive Interaction	93.50	90.00	89.25	88.67	
20th Percentile FDA Days to Substantive Interaction	90	90	89	88	
40th Percentile FDA Days to Substantive Interaction	92	90	89	89	
60th Percentile FDA Days to Substantive Interaction	95	90	90	90	
80th Percentile FDA Days to Substantive Interaction	97	90	90	90	
Maximum FDA Days to Substantive Interaction	99	90	90	90	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	2	2	3	4	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	2	3	1	
MDUFA IV Decision Goal Met	1	1	1	0	
PMAs Pending MDUFA IV Decision	1	0	0	3	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	50.00%	33.33%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	1	1	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	0	1	0	
MDUFA IV Decision Goal Met	0	0	1	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	100.00%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	2	3	1	
Average FDA Days to MDUFA IV Decision	159.00	181.00	198.67	226.00	
20th Percentile FDA Days to MDUFA IV Decision	159	179	189	226	
40th Percentile FDA Days to MDUFA IV Decision	159	180	198	226	
60th Percentile FDA Days to MDUFA IV Decision	159	182	204	226	
80th Percentile FDA Days to MDUFA IV Decision	159	183	209	226	
Maximum FDA Days to MDUFA IV Decision	159	184	214	226	
Average Industry Days to MDUFA IV Decision	6.00	90.00	41.67	26.00	
20th Percentile Industry Days to MDUFA IV Decision	6	49	27	26	
40th Percentile Industry Days to MDUFA IV Decision	6	76	31	26	
60th Percentile Industry Days to MDUFA IV Decision	6	104	40	26	
80th Percentile Industry Days to MDUFA IV Decision	6	131	55	26	
Maximum Industry Days to MDUFA IV Decision	6	159	69	26	
Average Total Days to MDUFA IV Decision	165.00	271.00	240.33	252.00	
20th Percentile Total Days to MDUFA IV Decision	165	231	218	252	
40th Percentile Total Days to MDUFA IV Decision	165	258	223	252	
60th Percentile Total Days to MDUFA IV Decision	165	284	237	252	
80th Percentile Total Days to MDUFA IV Decision	165	311	260	252	
Maximum Total Days to MDUFA IV Decision	165	337	283	252	

Table 1.8 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	2	1	
Mean FDA Days for Submissions that Missed the Goal	0.00	184.00	208.00	226.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	21.00	46.00	26.00	

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	9	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	3	4	1	8	
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	0	
Number Not Accepted for Filing Review	1	0	3	1	
Rate of Submissions Not Accepted for Filing Review	25.00%	0.00%	75.00%	11.11%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5	4	9	
Number Accepted	3	5	1	8	
Completed RTF	4	5	3	8	
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	8	
SI Goal Met	3	5	3	6	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	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	6	
Average Number of FDA Days to Substantive Interaction	90.50	84.80	90.00	86.67	
20th Percentile FDA Days to Substantive Interaction	90	84	90	84	
40th Percentile FDA Days to Substantive Interaction	90	90	90	86	
60th Percentile FDA Days to Substantive Interaction	90	90	90	87	
80th Percentile FDA Days to Substantive Interaction	91	90	90	89	
Maximum FDA Days to Substantive Interaction	92	90	90	90	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	4	5	2	8	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	4	5	2	2	
MDUFA IV Decision Goal Met	4	5	2	2	
PMAs Pending MDUFA IV Decision	0	0	0	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 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	1	0	
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 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	2	
Average FDA Days to MDUFA IV Decision	180.00	188.00	132.50	172.50	
20th Percentile FDA Days to MDUFA IV Decision	180	162	107	169	
40th Percentile FDA Days to MDUFA IV Decision	180	180	124	171	
60th Percentile FDA Days to MDUFA IV Decision	180	180	141	174	
80th Percentile FDA Days to MDUFA IV Decision	180	206	158	176	
Maximum FDA Days to MDUFA IV Decision	180	310	175	178	
Average Industry Days to MDUFA IV Decision	186.75	172.00	32.00	16.50	
20th Percentile Industry Days to MDUFA IV Decision	56	96	13	7	
40th Percentile Industry Days to MDUFA IV Decision	134	151	26	13	
60th Percentile Industry Days to MDUFA IV Decision	253	184	38	20	
80th Percentile Industry Days to MDUFA IV Decision	320	224	51	26	
Maximum Industry Days to MDUFA IV Decision	360	343	64	33	
Average Total Days to MDUFA IV Decision	366.75	360.00	164.50	189.00	
20th Percentile Total Days to MDUFA IV Decision	236	256	158	182	
40th Percentile Total Days to MDUFA IV Decision	314	282	162	187	
60th Percentile Total Days to MDUFA IV Decision	433	325	167	191	
80th Percentile Total Days to MDUFA IV Decision	500	430	171	196	
Maximum Total Days to MDUFA IV Decision	540	653	175	200	

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	2	8	
Number with MDUFA IV Decision	4	5	2	2	
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%	0.00%	
Rate of Not Approvable	0.00%	40.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	1	0	
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	4	
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	1	
Number Not Accepted for Filing Review	0	2	0	1	
Rate of Submissions Not Accepted for Filing Review	0.00%	50.00%	0.00%	33.33%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4	2	4	
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	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 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	2	
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50	85.00	
20th Percentile FDA Days to Substantive Interaction	84	88	88	82	
40th Percentile FDA Days to Substantive Interaction	86	89	88	84	
60th Percentile FDA Days to Substantive Interaction	87	89	89	86	
80th Percentile FDA Days to Substantive Interaction	89	90	89	88	
Maximum FDA Days to Substantive Interaction	90	90	89	90	

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	1	
MDUFA IV Decision Goal Met	2	3	2	1	
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%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
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	1	
Average FDA Days to MDUFA IV Decision	180.00	146.33	178.50	156.00	
20th Percentile FDA Days to MDUFA IV Decision	180	121	178	156	
40th Percentile FDA Days to MDUFA IV Decision	180	156	178	156	
60th Percentile FDA Days to MDUFA IV Decision	180	174	179	156	
80th Percentile FDA Days to MDUFA IV Decision	180	177	179	156	
Maximum FDA Days to MDUFA IV Decision	180	179	180	156	
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	156.00	
20th Percentile Total Days to MDUFA IV Decision	237	191	219	156	
40th Percentile Total Days to MDUFA IV Decision	293	282	261	156	
60th Percentile Total Days to MDUFA IV Decision	350	387	303	156	
80th Percentile Total Days to MDUFA IV Decision	406	505	345	156	
Maximum Total Days to MDUFA IV Decision	463	623	387	156	

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	1	
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%	0.00%	
Rate of Not Approvable	0.00%	33.33%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0	0	
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	29	
Closed Before RTA Action	0	0	0	1	
Number with Accepted RTA Review	17	19	26	16	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	9	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted for Filing Review	0	2	4	1	
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	13.33%	3.85%	

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	29	
Number Accepted	17	19	26	25	
Completed RTF	17	21	30	23	
Number Not Filed	0	0	2	1	
Rate of Submissions Not Filed	0.00%	0.00%	6.67%	4.35%	

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	29	23	
SI Goal Met	17	20	26	11	
SI Goal Not Met	0	1	3	3	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	7	
Closed Without SI	0	0	0	1	
Current SI Performance Percent Goal Met	100.00%	95.24%	89.66%	52.38%	

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	29	14	
Average Number of FDA Days to Substantive Interaction	84.29	87.76	96.55	99.93	
20th Percentile FDA Days to Substantive Interaction	84	87	87	86	
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	325	250	

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	29	22	
Non-MDUFA IV Decision	0	0	0	1	
MDUFA IV Decision	17	20	26	5	
MDUFA IV Decision Goal Met	17	16	25	5	
PMAs Pending MDUFA IV Decision	0	1	3	16	
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	4	
Current Performance Percent Goal Met	100.00%	80.00%	92.59%	55.56%	

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	1	
MDUFA IV Decision Goal Met	0	0	0	1	
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	100.00%	

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	26	5	
Average FDA Days to MDUFA IV Decision	123.35	178.70	164.85	115.60	
20th Percentile FDA Days to MDUFA IV Decision	90	133	134	96	
40th Percentile FDA Days to MDUFA IV Decision	99	166	179	103	
60th Percentile FDA Days to MDUFA IV Decision	141	176	180	118	
80th Percentile FDA Days to MDUFA IV Decision	174	197	180	137	
Maximum FDA Days to MDUFA IV Decision	180	299	406	149	
Average Industry Days to MDUFA IV Decision	86.18	122.50	62.85	45.60	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	10	22	20	
60th Percentile Industry Days to MDUFA IV Decision	75	71	62	54	
80th Percentile Industry Days to MDUFA IV Decision	149	323	124	90	
Maximum Industry Days to MDUFA IV Decision	336	529	257	110	
Average Total Days to MDUFA IV Decision	209.53	301.20	227.69	161.20	
20th Percentile Total Days to MDUFA IV Decision	90	155	156	129	
40th Percentile Total Days to MDUFA IV Decision	139	178	183	159	
60th Percentile Total Days to MDUFA IV Decision	213	223	242	178	
80th Percentile Total Days to MDUFA IV Decision	266	482	304	187	
Maximum Total Days to MDUFA IV Decision	511	705	458	207	

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	1	
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00	161.00	
20th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	
40th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	
60th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	
80th Percentile FDA Days to MDUFA IV Decision	0	0	0	161	
Maximum FDA Days to MDUFA IV Decision	0	0	0	161	
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	161.00	
20th Percentile Total Days to MDUFA IV Decision	0	0	0	161	
40th Percentile Total Days to MDUFA IV Decision	0	0	0	161	
60th Percentile Total Days to MDUFA IV Decision	0	0	0	161	
80th Percentile Total Days to MDUFA IV Decision	0	0	0	161	
Maximum Total Days to MDUFA IV Decision	0	0	0	161	

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	29	22	
Number with MDUFA IV Decision	17	20	26	5	
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%	3.85%	0.00%	
Rate of Not Approvable	11.76%	5.00%	3.85%	0.00%	

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	1	
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	0.00%	
Rate of Not Approvable	N/A	N/A	N/A	0.00%	

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	2	4	
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	254.00	260.50	
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	5	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	1	3	11	2	
MDUFA IV Decision Goal Met	1	3	11	2	
PMAs Pending MDUFA IV Decision	0	1	0	3	
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	1	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	66.67%	

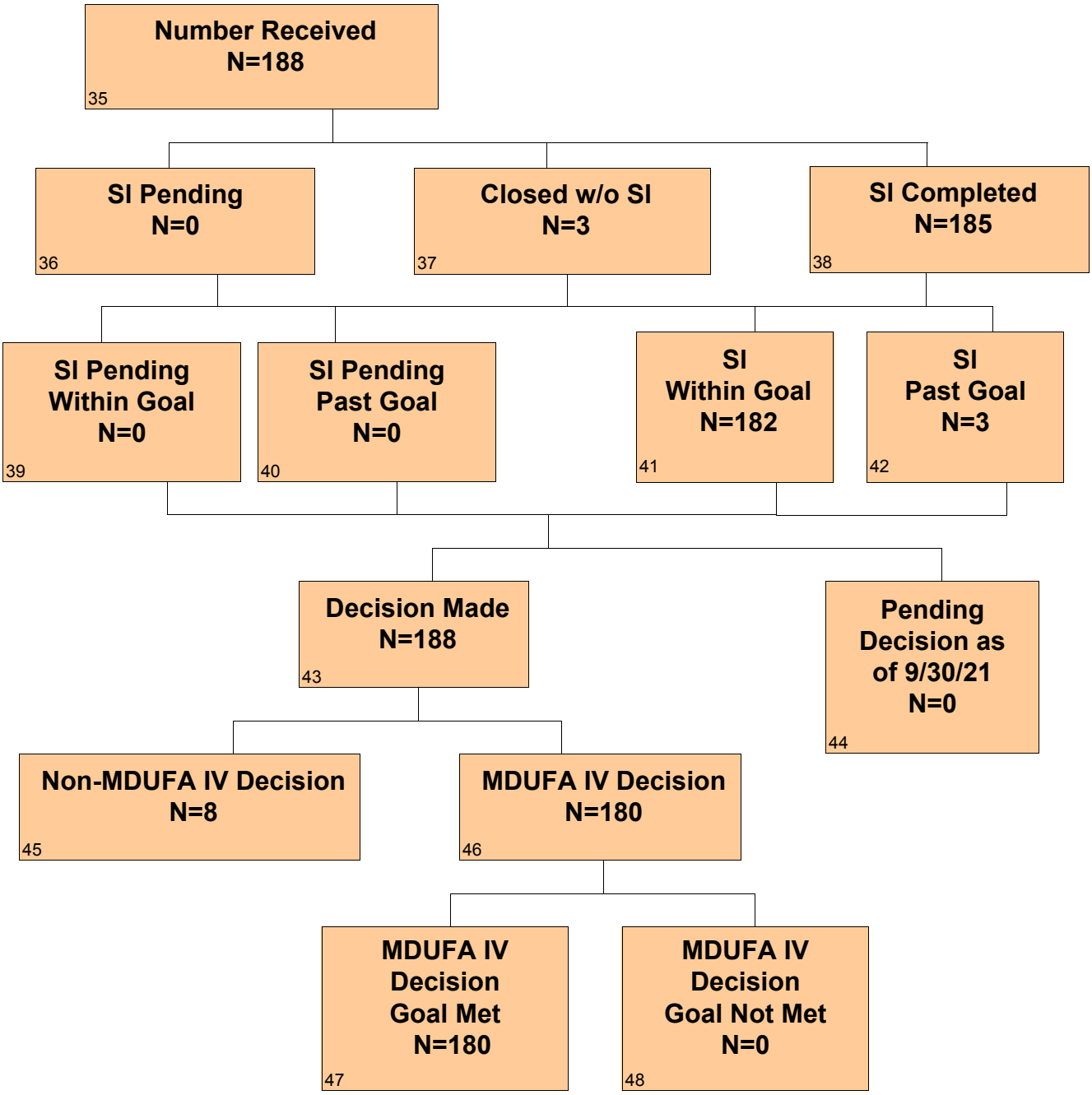
***Includes submission that went to panel**

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

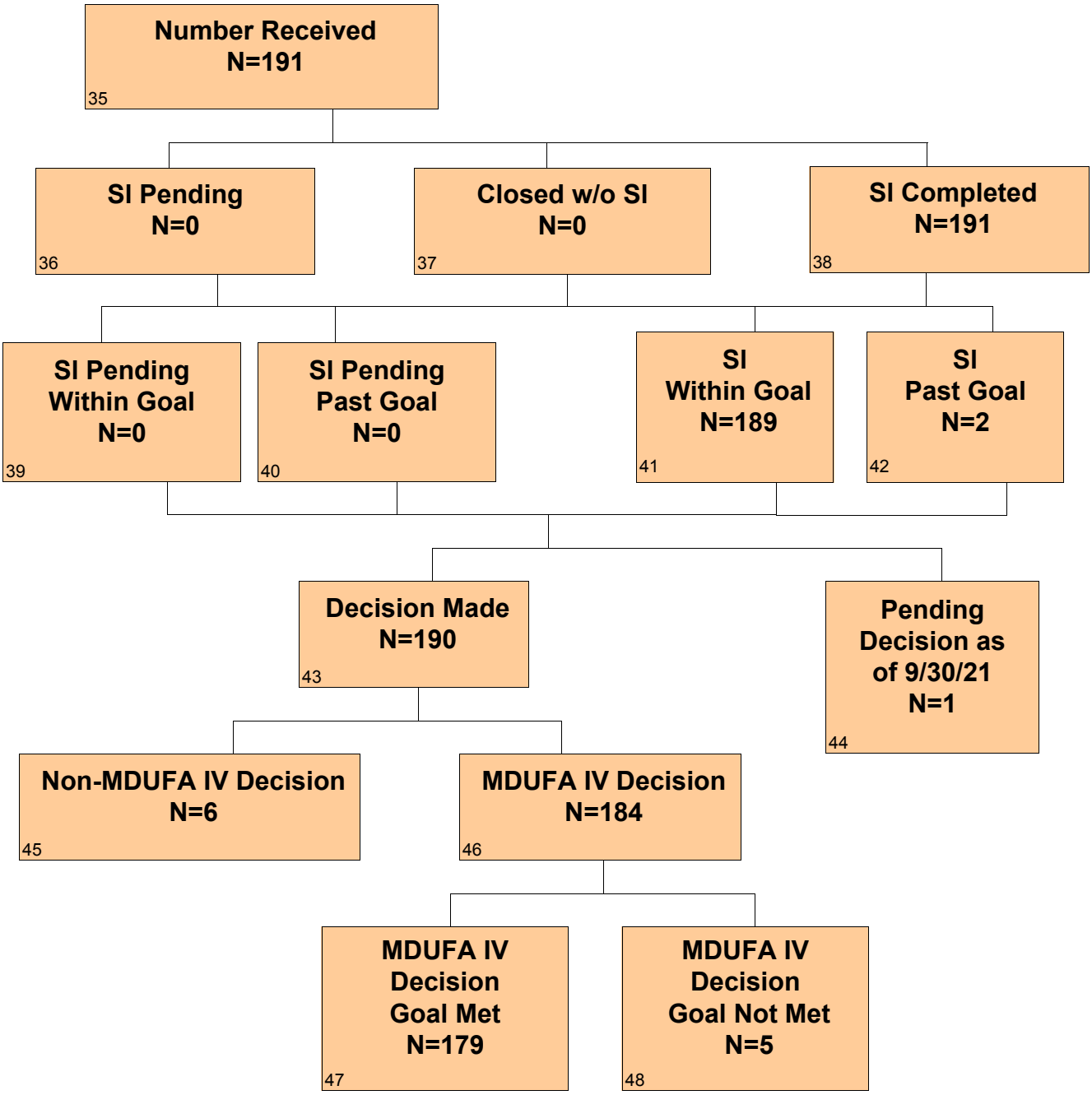
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	15	18	
Non-MDUFA IV Decision	0	0	0	1	
MDUFA IV Decision	15	17	13	4	
MDUFA IV Decision Goal Met	15	13	12	4	
PMAs Pending MDUFA IV Decision	0	0	2	14	
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	2	
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	66.67%	

***Includes submission that went to panel**

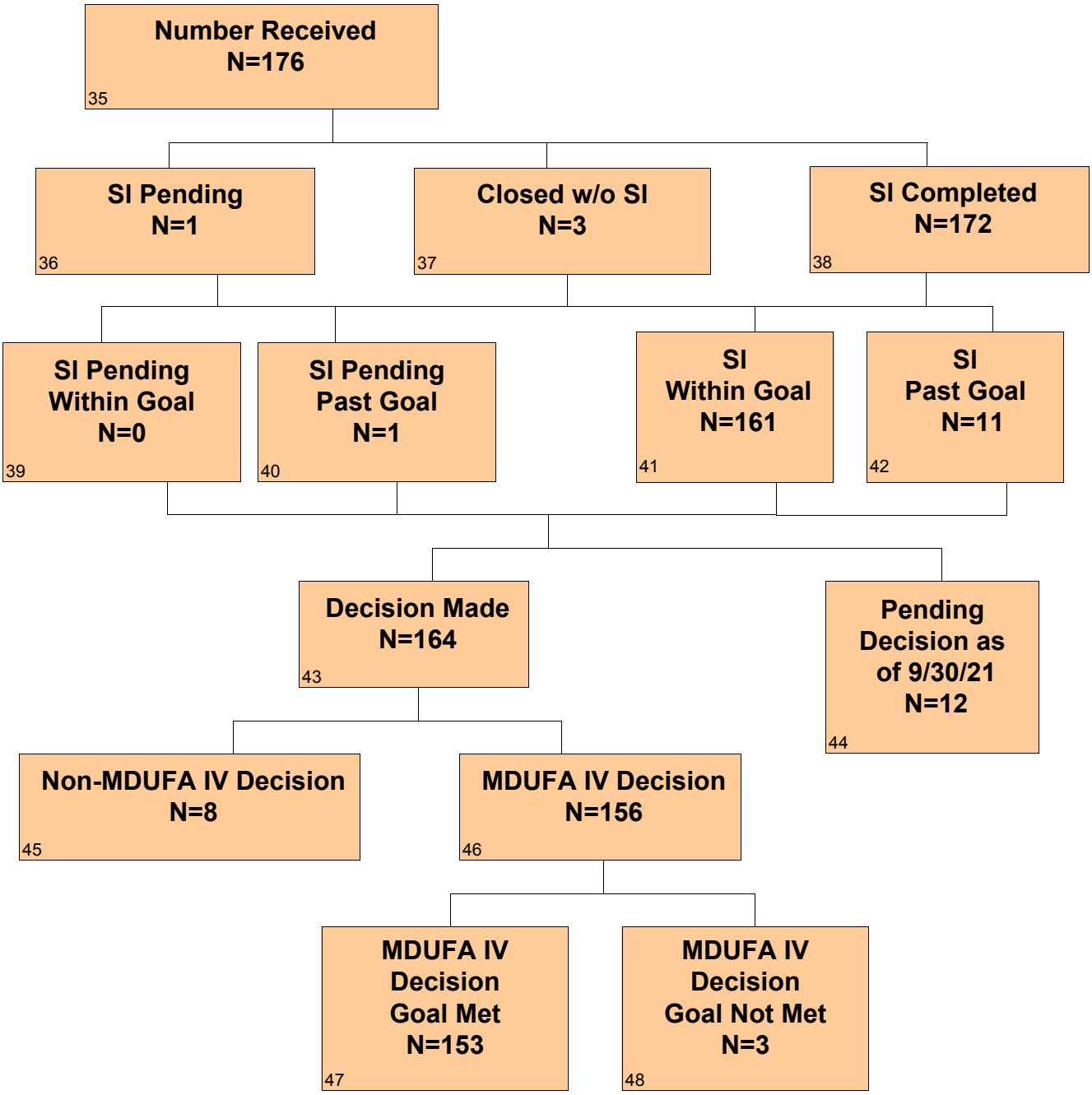
CDRH PMA 180 Day Supplements - FY 2018 as of 9/30/21



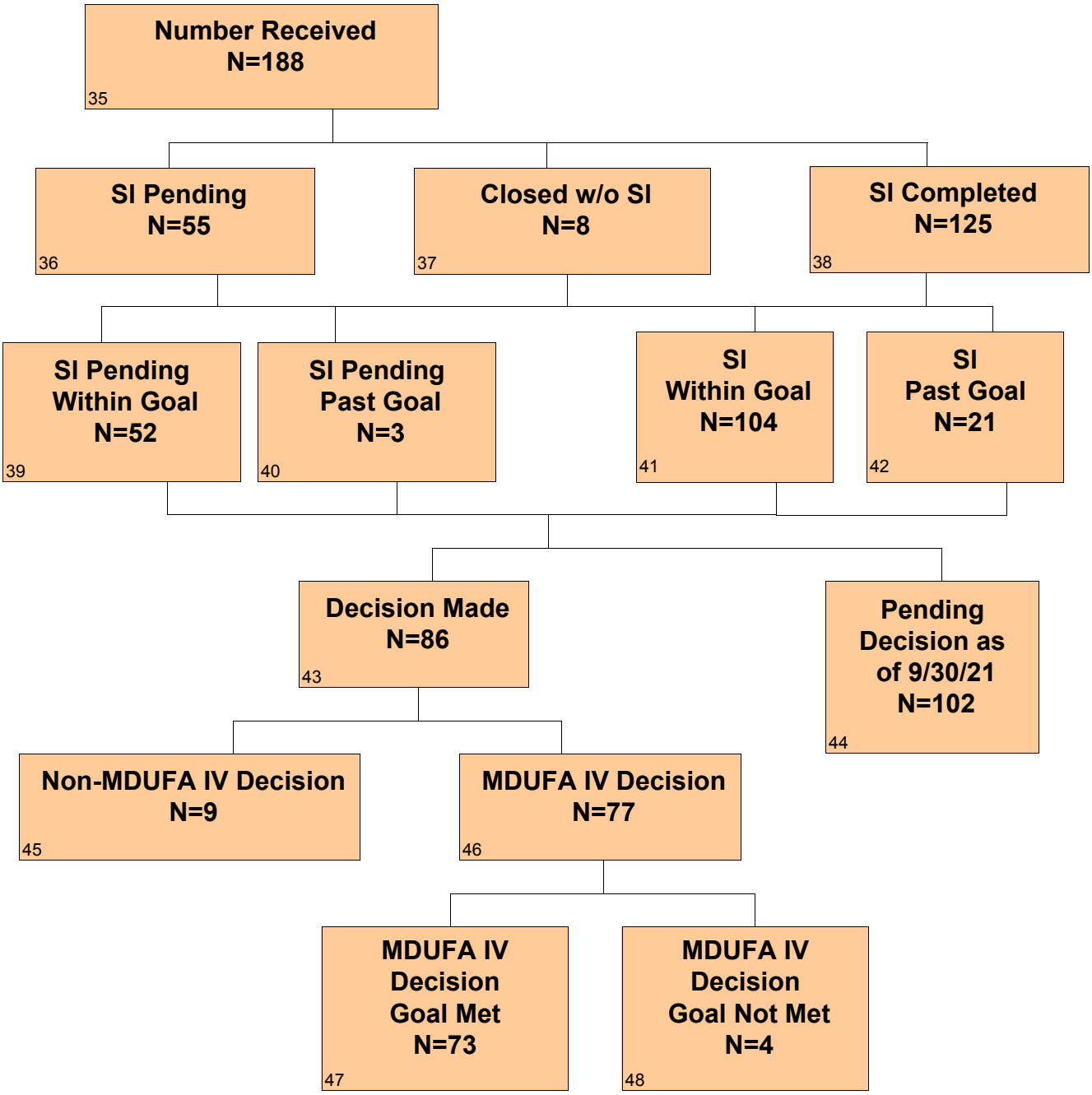
CDRH PMA 180 Day Supplements - FY 2019 as of 9/30/21



CDRH PMA 180 Day Supplements - FY 2020 as of 9/30/21



CDRH PMA 180 Day Supplements - FY 2021 as of 9/30/21



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	188	191	176	188	
SI Goal Met	182	189	161	104	
SI Goal Not Met	3	2	11	21	
SI Pending Within Goal	0	0	0	52	
SI Pending Past Goal	0	0	1	3	
Closed Without SI	3	0	3	8	
Current SI Performance Percent Goal Met	98.38%	98.95%	93.06%	81.25%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	188	191	176	188	
Non-MDUFA IV Decision	8	6	8	9	
MDUFA IV Decision	180	184	156	77	
MDUFA IV Decision Goal Met	180	179	153	73	
Supplements Pending MDUFA IV Decision	0	1	12	102	
Supplements Pending MDUFA IV Decision Past Goal	0	1	2	6	
Current Performance Percent Goal Met	100.00%	96.76%	96.84%	87.95%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	188	191	176	188	
Number with MDUFA IV Decision	180	184	156	77	
Number of Not Approvable	13	10	8	0	
Rate of Not Approvable	7.22%	5.43%	5.13%	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	5	10	
Mean FDA Days for Submissions that Missed the Goal	0.00	251.50	310.40	221.20	
Mean Industry Days for Submissions that Missed the Goal	0.00	9.00	60.40	11.90	

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	14	
SI Goal Met	20	36	28	11	
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	14	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	20	36	28	6	
MDUFA IV Decision Goal Met	20	35	28	6	
Supplements Pending MDUFA IV Decision	0	0	0	8	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	97.22%	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	14	
Number with MDUFA IV Decision	20	36	28	6	
Number of Not Approvable	1	1	1	0	
Rate of Not Approvable	5.00%	2.78%	3.57%	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	95	
SI Goal Met	91	81	66	52	
SI Goal Not Met	1	0	4	7	
SI Pending Within Goal	0	0	0	28	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	2	0	0	8	
Current SI Performance Percent Goal Met	98.91%	100.00%	94.29%	88.14%	

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	95	
Non-MDUFA IV Decision	2	3	0	8	
MDUFA IV Decision	92	78	63	44	
MDUFA IV Decision Goal Met	92	78	63	44	
Supplements Pending MDUFA IV Decision	0	0	7	43	
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	95	
Number with MDUFA IV Decision	92	78	63	44	
Number of Not Approvable	6	6	4	0	
Rate of Not Approvable	6.52%	7.69%	6.35%	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	19	
SI Goal Met	14	15	16	10	
SI Goal Not Met	1	1	0	0	
SI Pending Within Goal	0	0	0	9	
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	19	
Non-MDUFA IV Decision	0	2	6	1	
MDUFA IV Decision	15	14	11	6	
MDUFA IV Decision Goal Met	15	14	11	6	
Supplements Pending MDUFA IV Decision	0	0	2	12	
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 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	16	19	19	
Number with MDUFA IV Decision	15	14	11	6	
Number of Not Approvable	0	2	2	0	
Rate of Not Approvable	0.00%	14.29%	18.18%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	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	15	
SI Goal Met	9	9	6	5	
SI Goal Not Met	0	1	1	8	
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%	90.00%	85.71%	35.71%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	9	10	7	15	
Non-MDUFA IV Decision	1	1	0	0	
MDUFA IV Decision	8	8	6	4	
MDUFA IV Decision Goal Met	8	5	6	2	
Supplements Pending MDUFA IV Decision	0	1	1	11	
Supplements Pending MDUFA IV Decision Past Goal	0	1	1	2	
Current Performance Percent Goal Met	100.00%	55.56%	85.71%	33.33%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	10	7	15	
Number with MDUFA IV Decision	8	8	6	4	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	1	4	
Mean FDA Days for Submissions that Missed the Goal	0.00	240.75	186.00	200.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	177.00	15.00	

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	16	23	20	
SI Goal Met	12	16	23	15	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	5	
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	20	
Non-MDUFA IV Decision	2	0	2	0	
MDUFA IV Decision	11	16	21	11	
MDUFA IV Decision Goal Met	11	15	21	11	
Supplements Pending MDUFA IV Decision	0	0	0	9	
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	20	
Number with MDUFA IV Decision	11	16	21	11	
Number of Not Approvable	2	0	1	0	
Rate of Not Approvable	18.18%	0.00%	4.76%	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	0	6	2	4	
SI Goal Met	0	6	2	4	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	N/A	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	0	6	2	4	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	0	6	1	1	
MDUFA IV Decision Goal Met	0	6	1	1	
Supplements Pending MDUFA IV Decision	0	0	1	3	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	100.00%	100.00%	100.00%	

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

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

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

Performance Metric	FY 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	21	
SI Goal Met	36	26	20	7	
SI Goal Not Met	1	0	6	6	
SI Pending Within Goal	0	0	0	6	
SI Pending Past Goal	0	0	1	2	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	97.30%	100.00%	74.07%	46.67%	

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	21	
Non-MDUFA IV Decision	3	0	0	0	
MDUFA IV Decision	34	26	26	5	
MDUFA IV Decision Goal Met	34	26	23	3	
Supplements Pending MDUFA IV Decision	0	0	1	16	
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	4	
Current Performance Percent Goal Met	100.00%	100.00%	85.19%	33.33%	

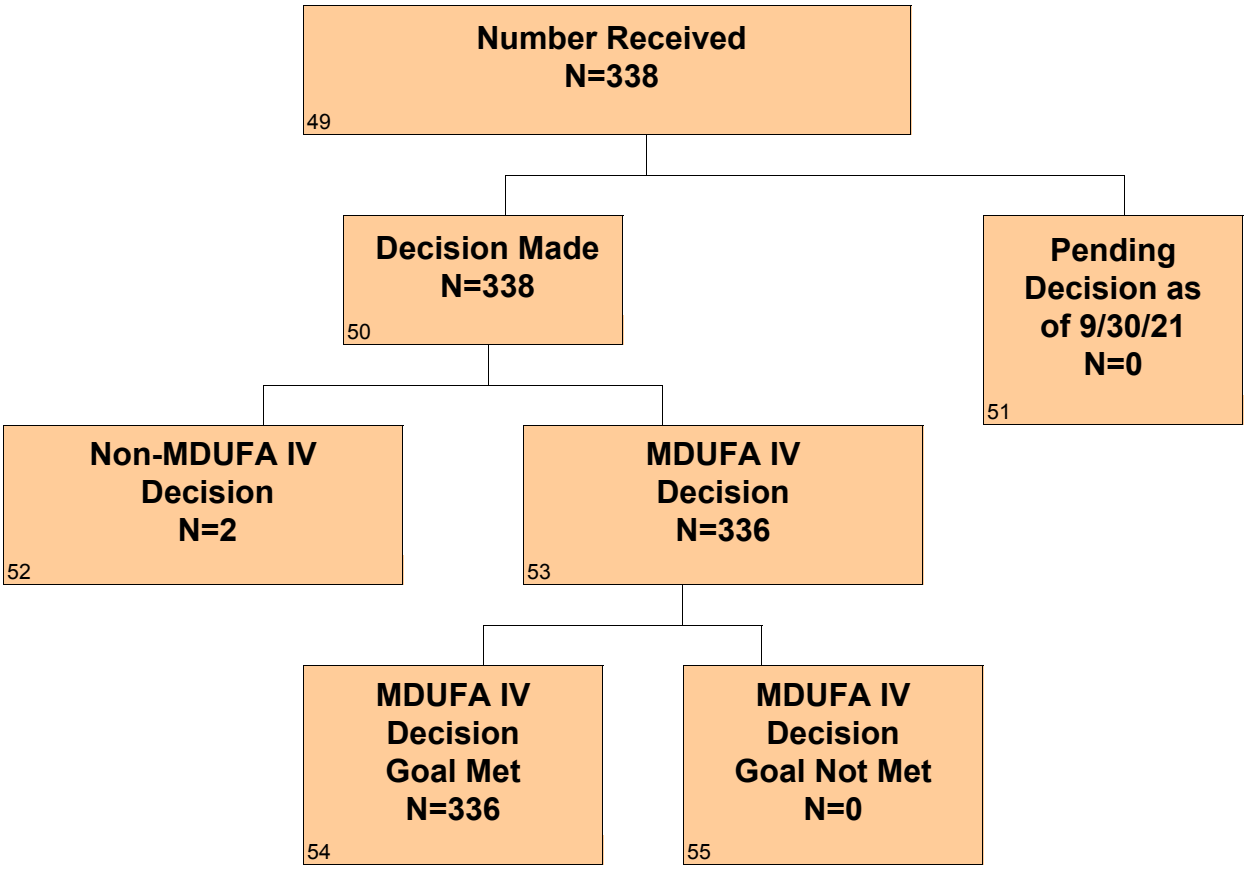
Table 2.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	26	27	21	
Number with MDUFA IV Decision	34	26	26	5	
Number of Not Approvable	4	1	0	0	
Rate of Not Approvable	11.76%	3.85%	0.00%	0.00%	

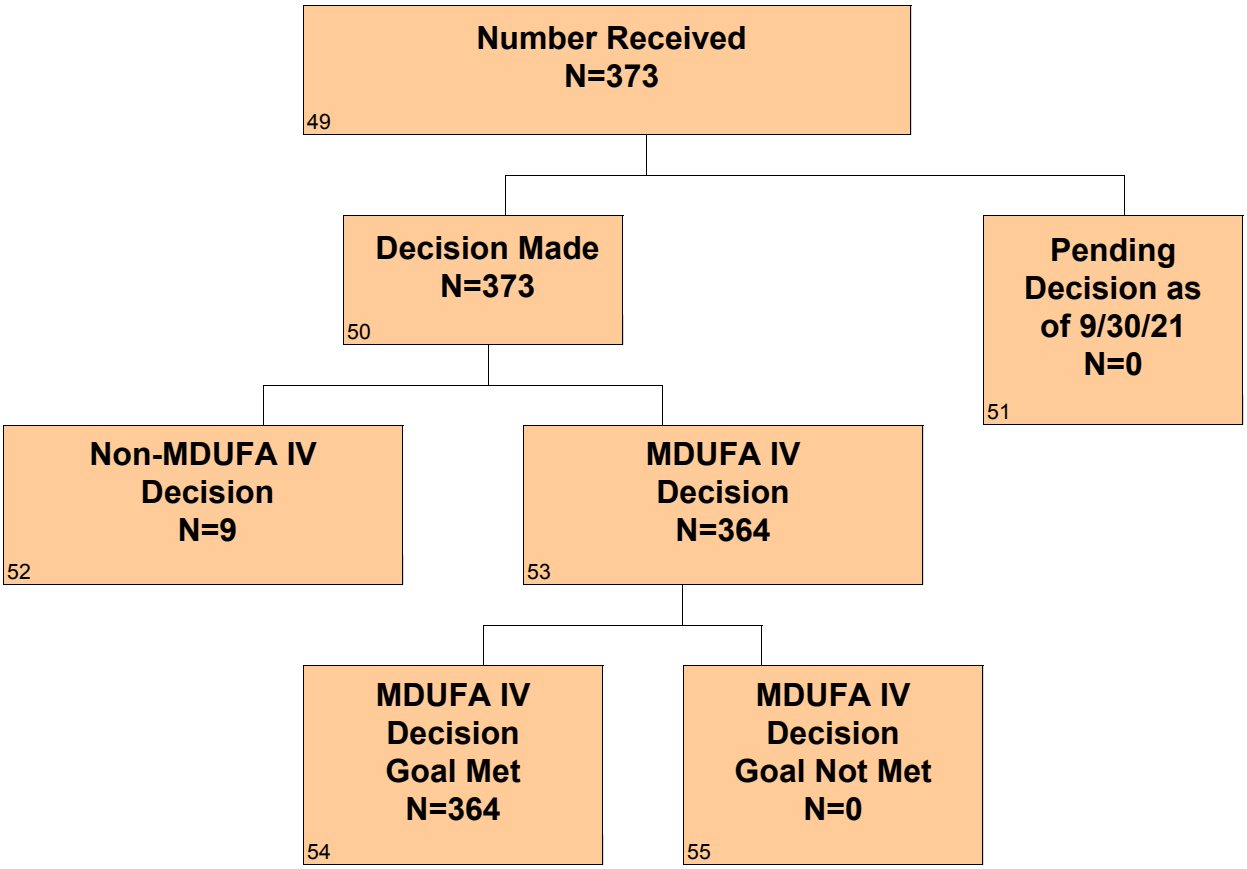
Table 2.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	6	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	341.50	235.33	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	31.25	9.83	

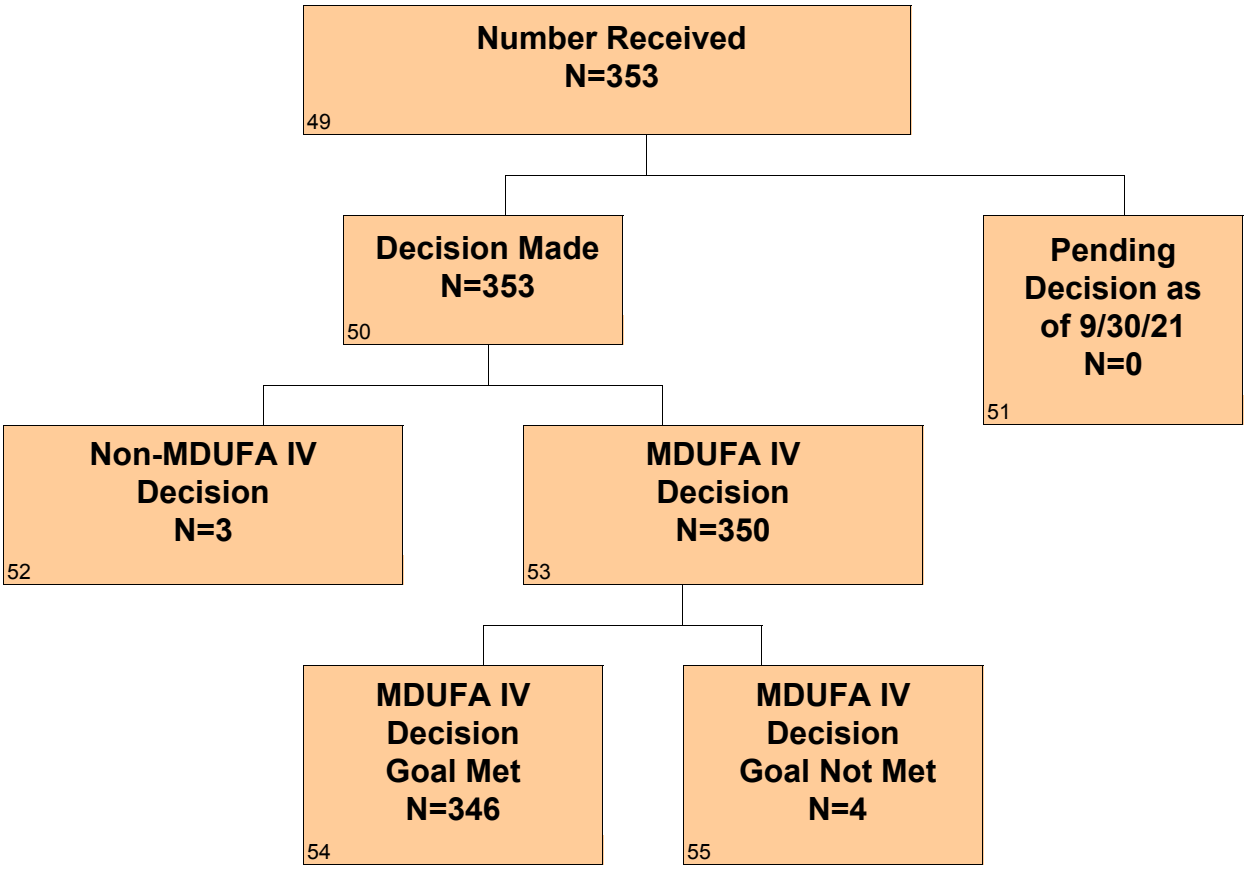
CDRH PMA Real Time Supplements - FY 2018 as of 9/30/21



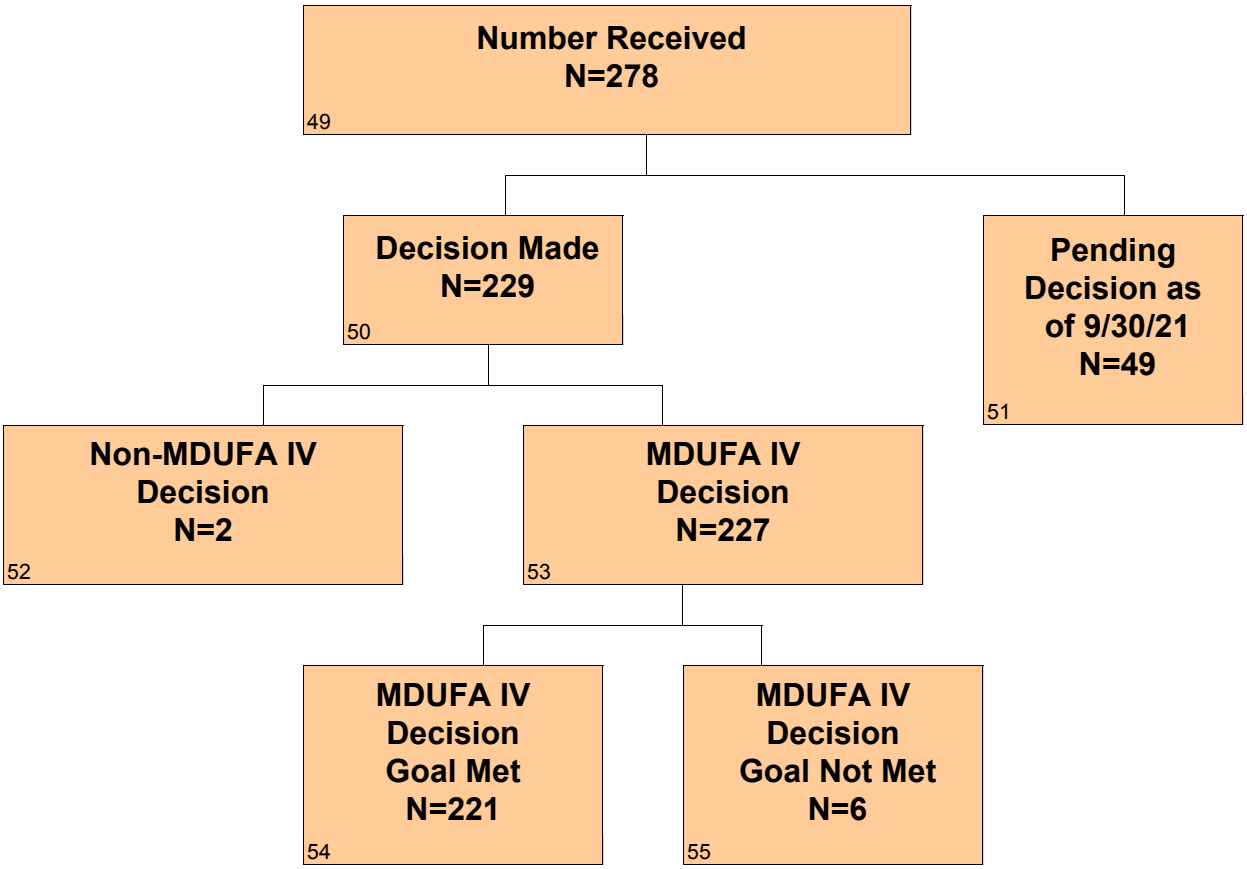
CDRH PMA Real Time Supplements - FY 2019 as of 9/30/21



CDRH PMA Real Time Supplements - FY 2020 as of 9/30/21



CDRH PMA Real Time Supplements - FY 2021 as of 9/30/21



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	353	278	
Non-MDUFA IV Decision	2	9	3	2	
MDUFA IV Decision	336	364	350	227	
MDUFA IV Decision Goal Met	336	364	346	221	
Supplements Pending MDUFA IV Decision	0	0	0	49	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	98.86%	97.36%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	338	373	353	278	
Number With MDUFA IV Decision	336	364	350	227	
Number of Not Approvable	20	29	6	9	
Rate of Not Approvable	5.95%	7.97%	1.71%	3.96%	

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	6	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.25	183.33	
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	21	
Non-MDUFA IV Decision	0	2	1	0	
MDUFA IV Decision	23	38	15	16	
MDUFA IV Decision Goal Met	23	38	15	16	
Supplements Pending MDUFA IV Decision	0	0	0	5	
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	21	
Number With MDUFA IV Decision	23	38	15	16	
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	147	
Non-MDUFA IV Decision	0	3	2	0	
MDUFA IV Decision	154	170	191	122	
MDUFA IV Decision Goal Met	154	170	190	122	
Supplements Pending MDUFA IV Decision	0	0	0	25	
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	147	
Number With MDUFA IV Decision	154	170	191	122	
Number of Not Approvable	12	15	1	2	
Rate of Not Approvable	7.79%	8.82%	0.52%	1.64%	

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	16	
Non-MDUFA IV Decision	0	1	0	2	
MDUFA IV Decision	20	38	36	12	
MDUFA IV Decision Goal Met	20	38	36	12	
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 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	20	39	36	16	
Number with MDUFA IV Decision	20	38	36	12	
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	13	
Non-MDUFA IV Decision	1	0	0	0	
MDUFA IV Decision	12	18	13	5	
MDUFA IV Decision Goal Met	12	18	13	4	
Supplements Pending MDUFA IV Decision	0	0	0	8	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	80.00%	

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	13	
Number with MDUFA IV Decision	12	18	13	5	
Number of Not Approvable	4	0	0	1	
Rate of Not Approvable	33.33%	0.00%	0.00%	20.00%	

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	1	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	134.00	
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	22	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	16	32	24	19	
MDUFA IV Decision Goal Met	16	32	24	19	
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	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	32	24	22	
Number with MDUFA IV Decision	16	32	24	19	
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	9	3	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	17	22	9	2	
MDUFA IV Decision Goal Met	17	22	9	2	
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	9	3	
Number with MDUFA IV Decision	17	22	9	2	
Number of Not Approvable	2	2	1	1	
Rate of Not Approvable	11.76%	9.09%	11.11%	50.00%	

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	56	
Non-MDUFA IV Decision	1	3	0	0	
MDUFA IV Decision	94	46	62	51	
MDUFA IV Decision Goal Met	94	46	59	46	
Supplements Pending MDUFA IV Decision	0	0	0	5	
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	95.16%	90.20%	

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	56	
Number with MDUFA IV Decision	94	46	62	51	
Number of Not Approvable	0	1	0	5	
Rate of Not Approvable	0.00%	2.17%	0.00%	9.80%	

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	5	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.00	193.80	
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 October 1, 2020 and September 30, 2021.

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Section 5 PMA Annual General Metrics

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

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0	0	0	
Original PMAs (Panel) - Breakthrough Device	1	0	1	0	
Original PMAs (No Panel) - Breakthrough Device	3	2	4	5	
Original PMAs (Panel) - Non-Breakthrough Device	4	2	2	1	
Original PMAs (No Panel) - Non-Breakthrough Device	38	31	41	34	
Panel-Tracked Supplements (Panel) - Breakthrough Device	0	0	0	0	
Panel-Tracked Supplements (No Panel) - Breakthrough Device	2	0	1	0	
Panel-Tracked Supplements (Panel) - Non-Breakthrough Device	0	0	1	1	
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	26	21	27	38	
PMA Modules	63	73	70	73	
180-Day Supplements	188	191	176	189	
Real-Time Supplements	338	373	353	278	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	71	55	73	67	
Number With a Decision (MDUFA or Non-MDUFA)	70	54	60	17	
% of FY Closed	98.59%	98.18%	82.19%	25.37%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	3 Year Cohort 320 FDA Days	3 Year Cohort 315 FDA Days	3 Year Cohort 310 FDA Days	3 Year Cohort 300 FDA Days	3 Year Cohort 290 FDA Days
Number With a MDUFA Decision	198	182	183	133	
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	180	164	165	119	
Three-year Rolling Average Total Time to MDUFA Decision	264.04	264.41	N/A	N/A	

PMA Originals and Panel Track Supplements (as of September 20, 2021)				
Amendment Type	**FY2018**	**FY2019**	**FY2020**	**FY2021**
MAJR - Response to MAJR Deficiency Letter	37	40	32	22
ADEF - Response to Approvable Pending Deficiency Letter	0	0	0	0
NOAP - Response to Not Approvable Deficiency Letter	6	7	0	1
UMAJ - Unsolicited Major Amendment	5	5	1	0
UMIN - Unsolicited Minor Amendment	64	54	62	37

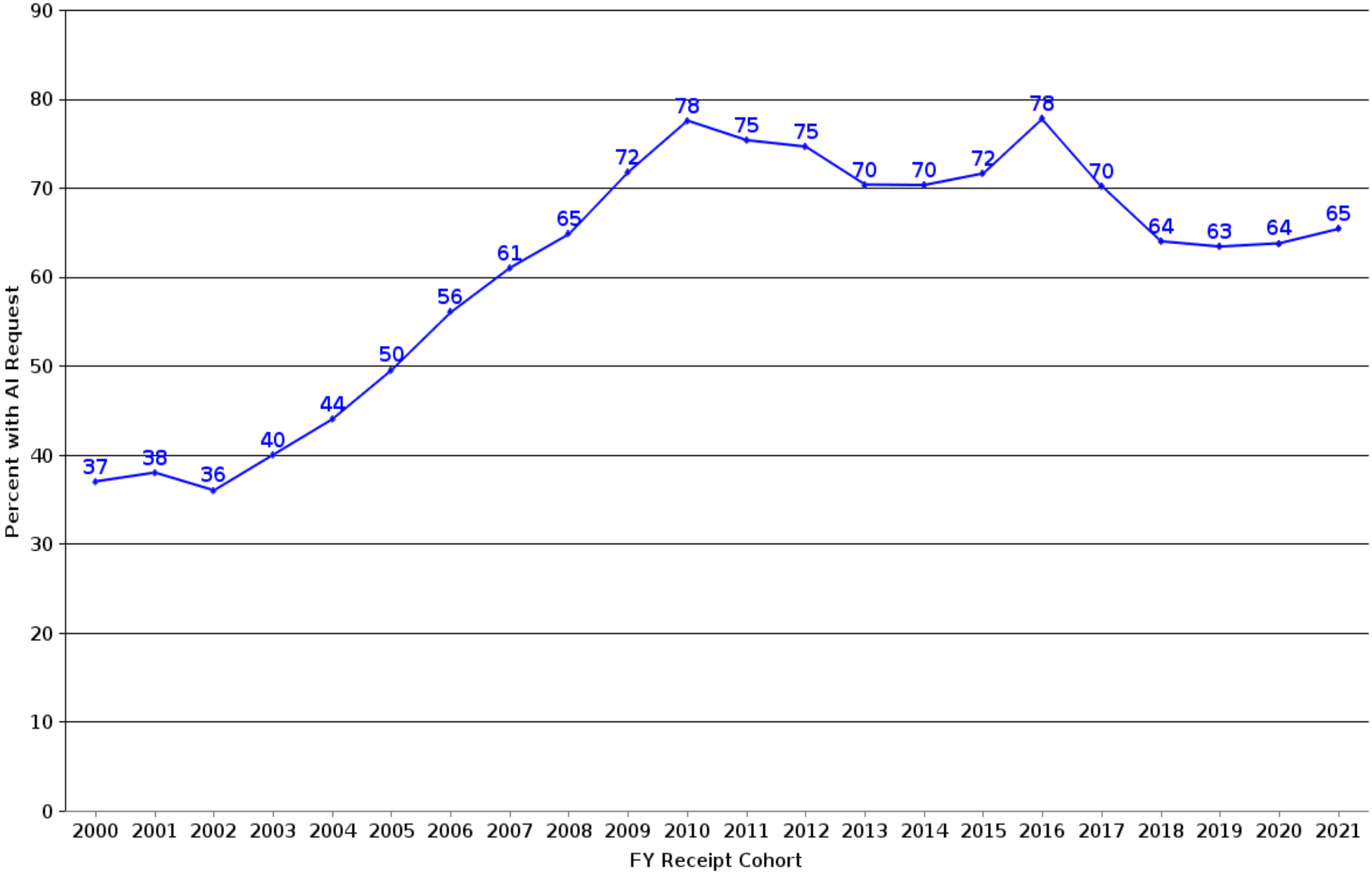
PMA 180-Day Supplements (as of September 30, 2021)				
Amendment Type	**FY2018**	**FY2019**	**FY2020**	**FY2021**
MAJR - Response to MAJR Deficiency Letter	92	92	90	54
ADEF - Response to Approvable Pending Deficiency Letter	2	2	1	0
NOAP - Response to Not Approvable Deficiency Letter	14	8	2	0
UMAJ - Unsolicited Major Amendment	0	0	0	0
UMIN - Unsolicited Minor Amendment	34	62	42	13

PMA Real-Time Supplements (as of September 30, 2021)				
Amendment Type	**FY2018**	**FY2019**	**FY2020**	**FY2021**
MAJR - Response to MAJR Deficiency Letter	3	8	0	2
ADEF - Response to Approvable Pending Deficiency Letter	3	8	0	2
NOAP - Response to Not Approvable Deficiency Letter	8	26	4	3
UMAJ - Unsolicited Major Amendment	0	0	0	0
UMIN - Unsolicited Minor Amendment	11	39	25	17

510(k)s

Q4FY2021

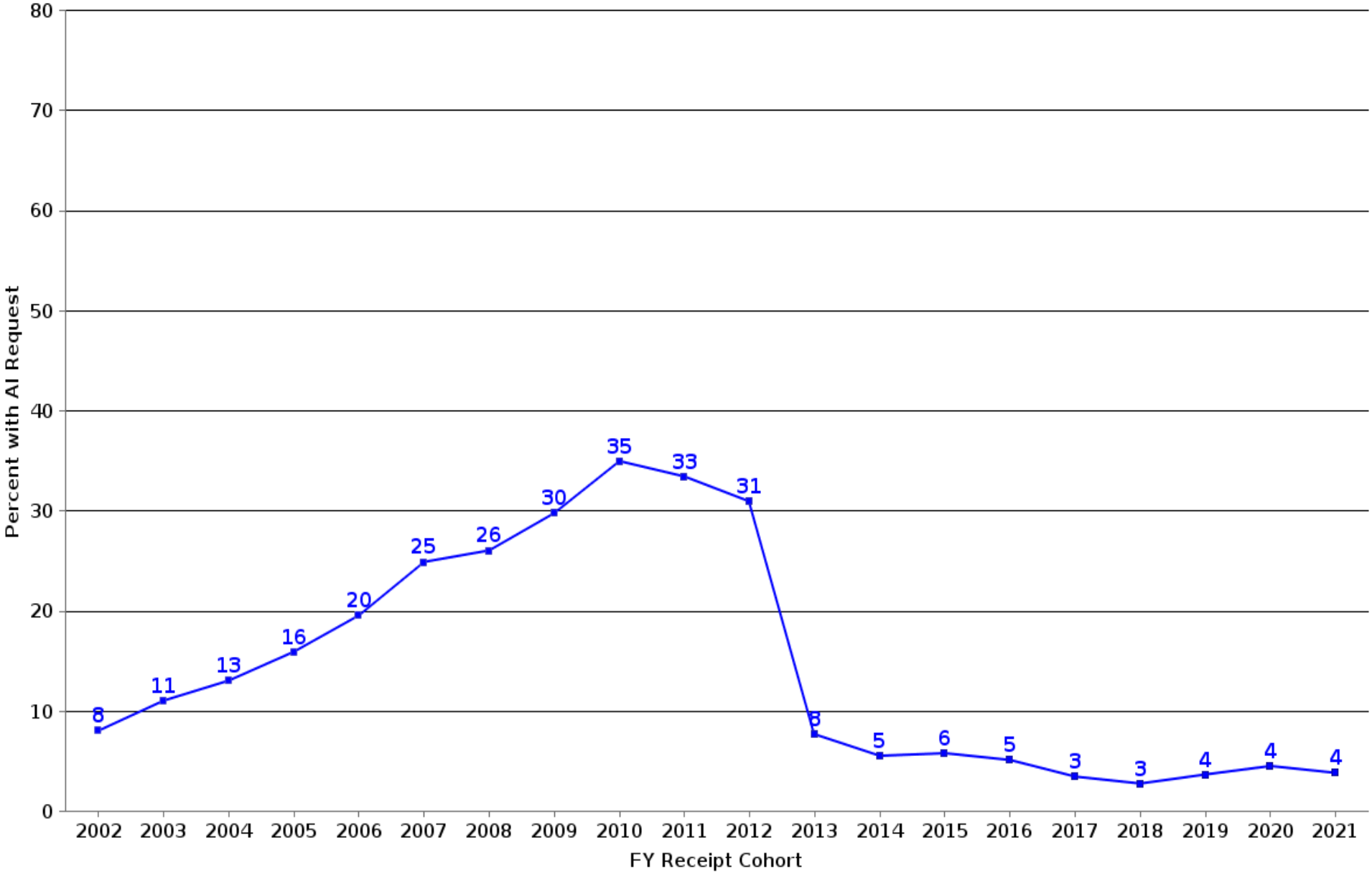
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/21

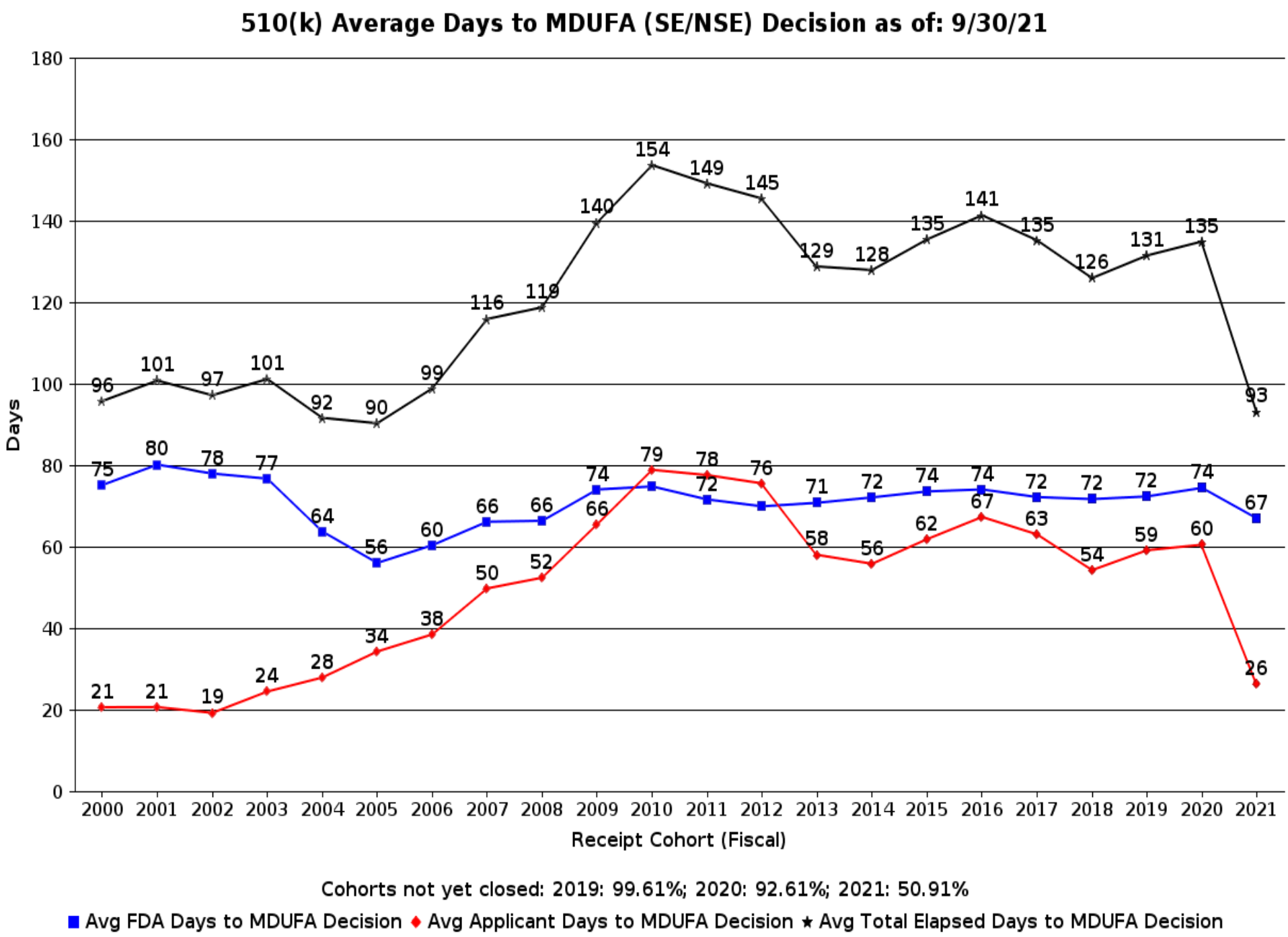
◆ % with 1st Cycle AI Request

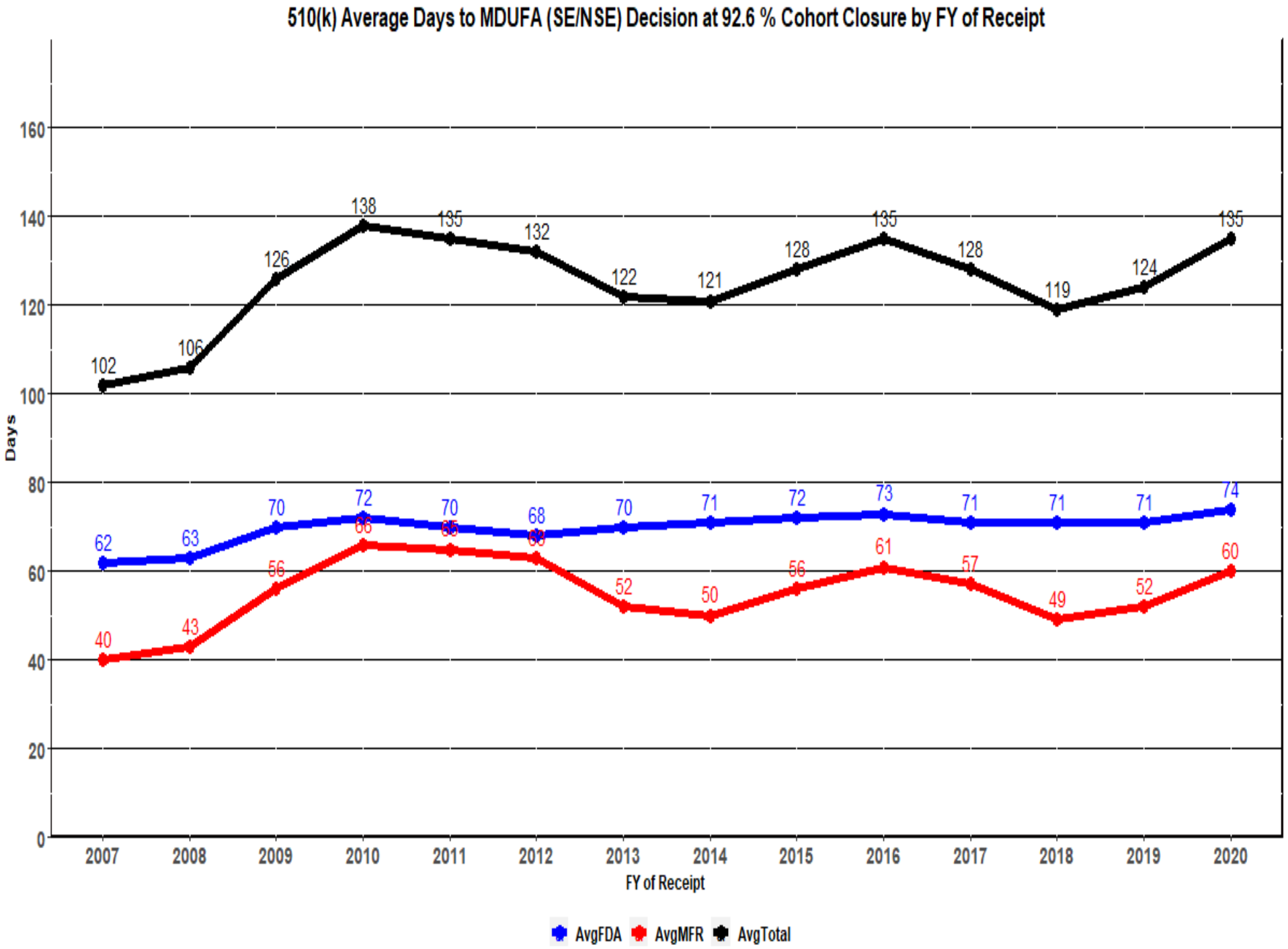
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

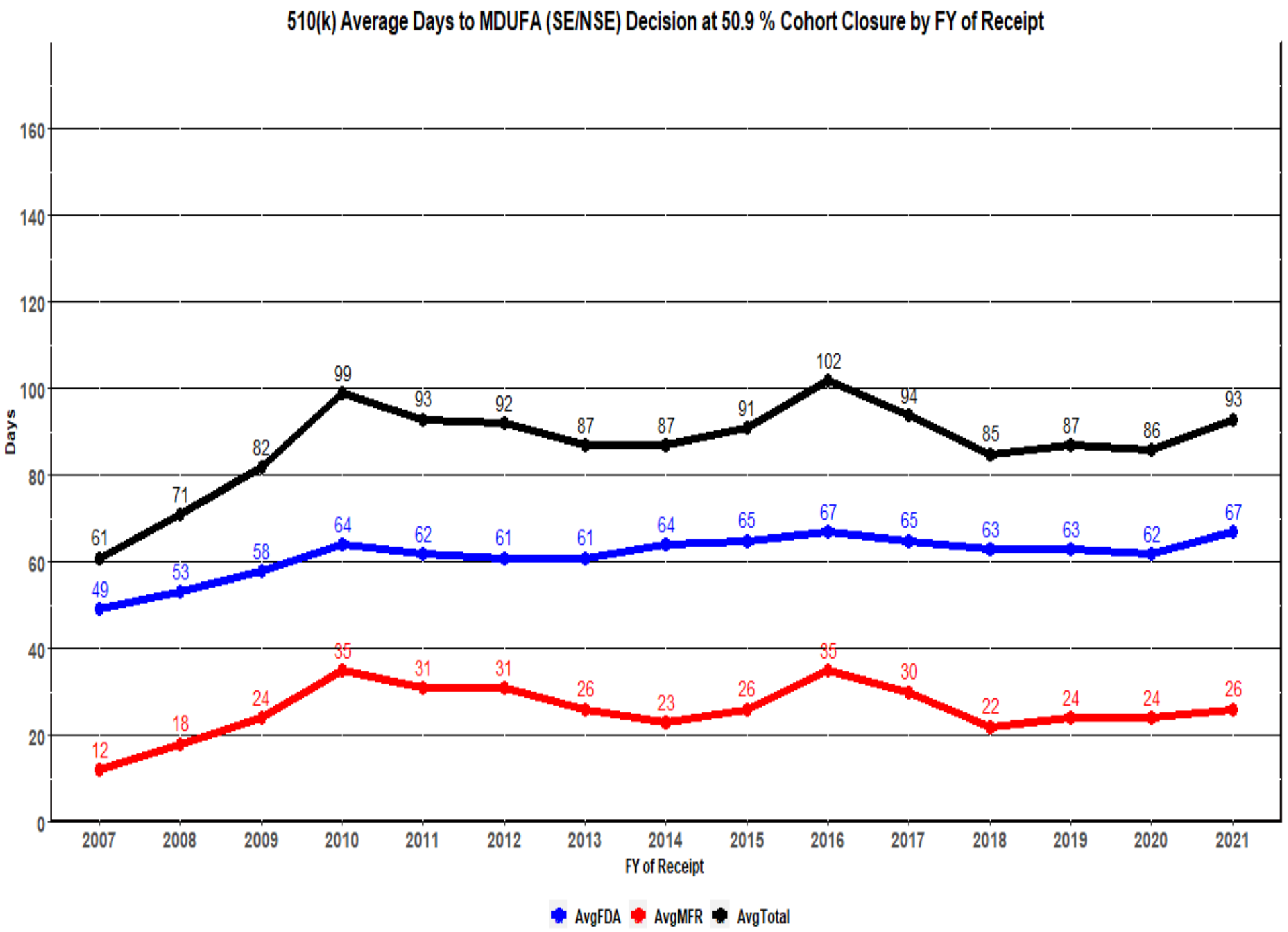


AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 2/28/21

■ % with 2nd Cycle AI Request

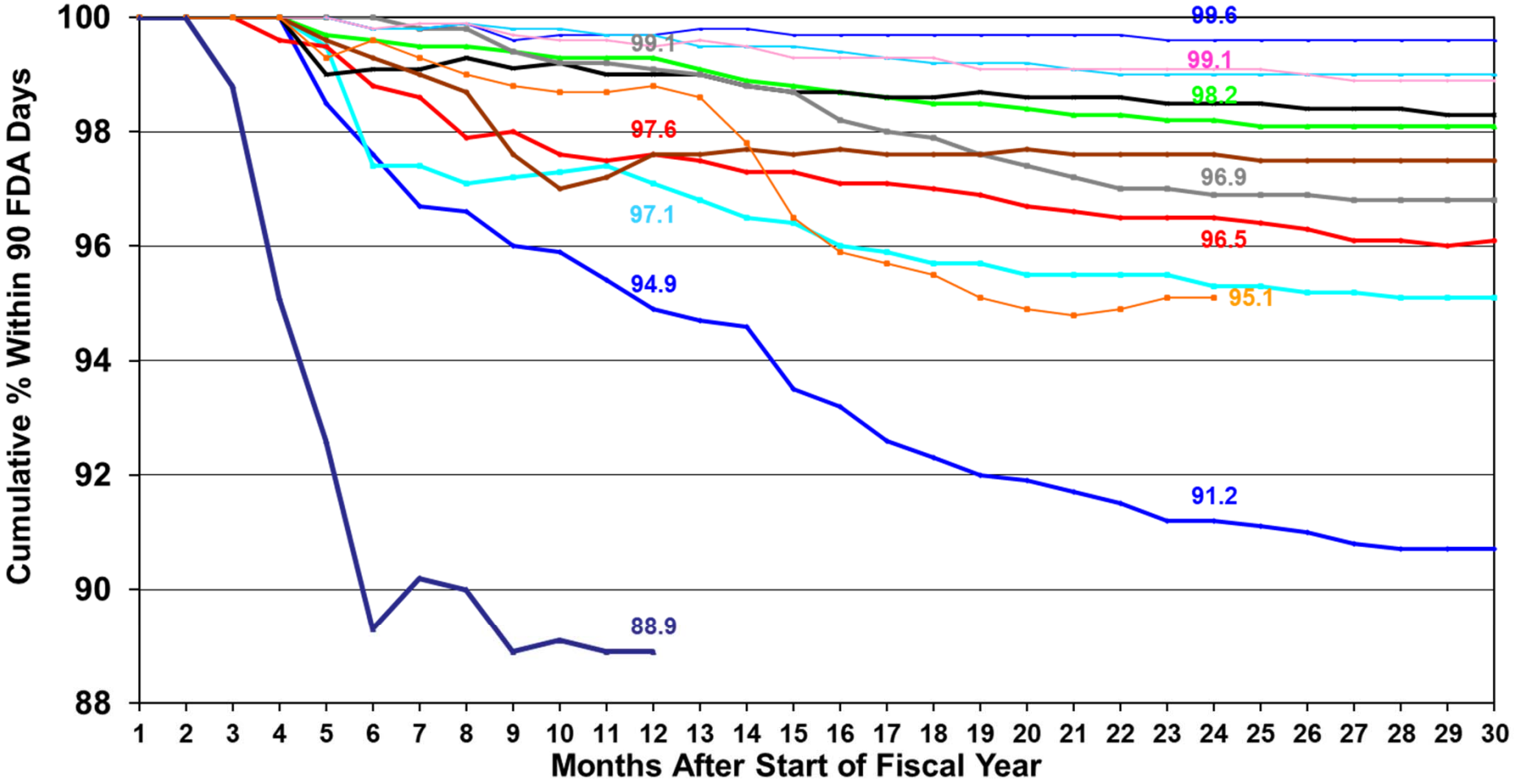

510(k) Average Days to MDUFA (SE/NSE) Decision as of: 9/30/21
Days
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2019: 99.61%; 2020: 92.61%; 2021: 50.91%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision


510(k) Average Days to MDUFA (SE/NSE) Decision at 92.6 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
AvgFDA
AvgMFR
AvgTotal

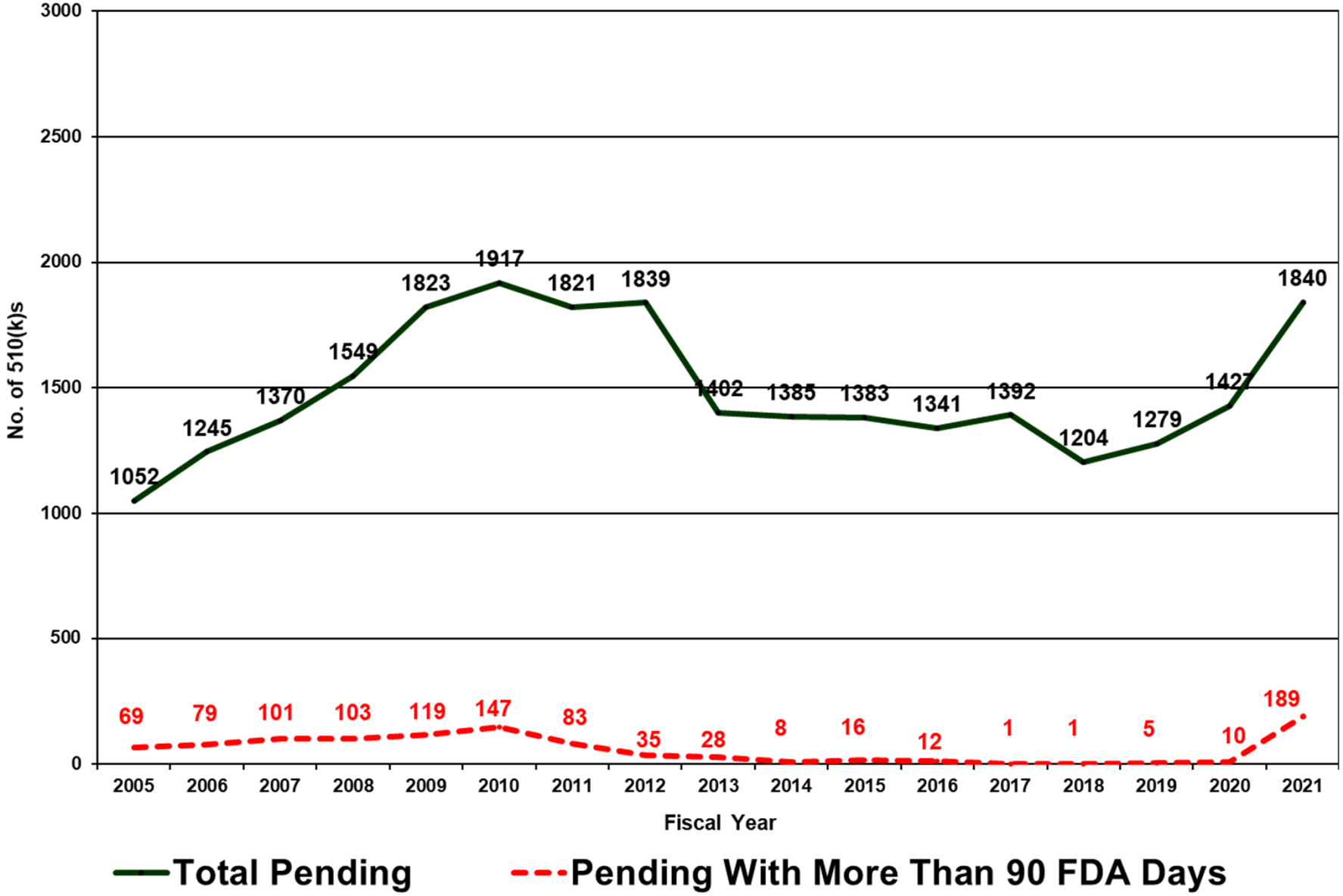

510(k) Average Days to MDUFA (SE/NSE) Decision at 50.9 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
FY of Receipt
61
71
82
99
93
92
87
87
91
102
94
85
87
86
93
49
53
58
64
62
61
61
64
65
67
65
63
63
62
67
12
18
24
35
31
31
26
23
26
35
30
22
24
24
26
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

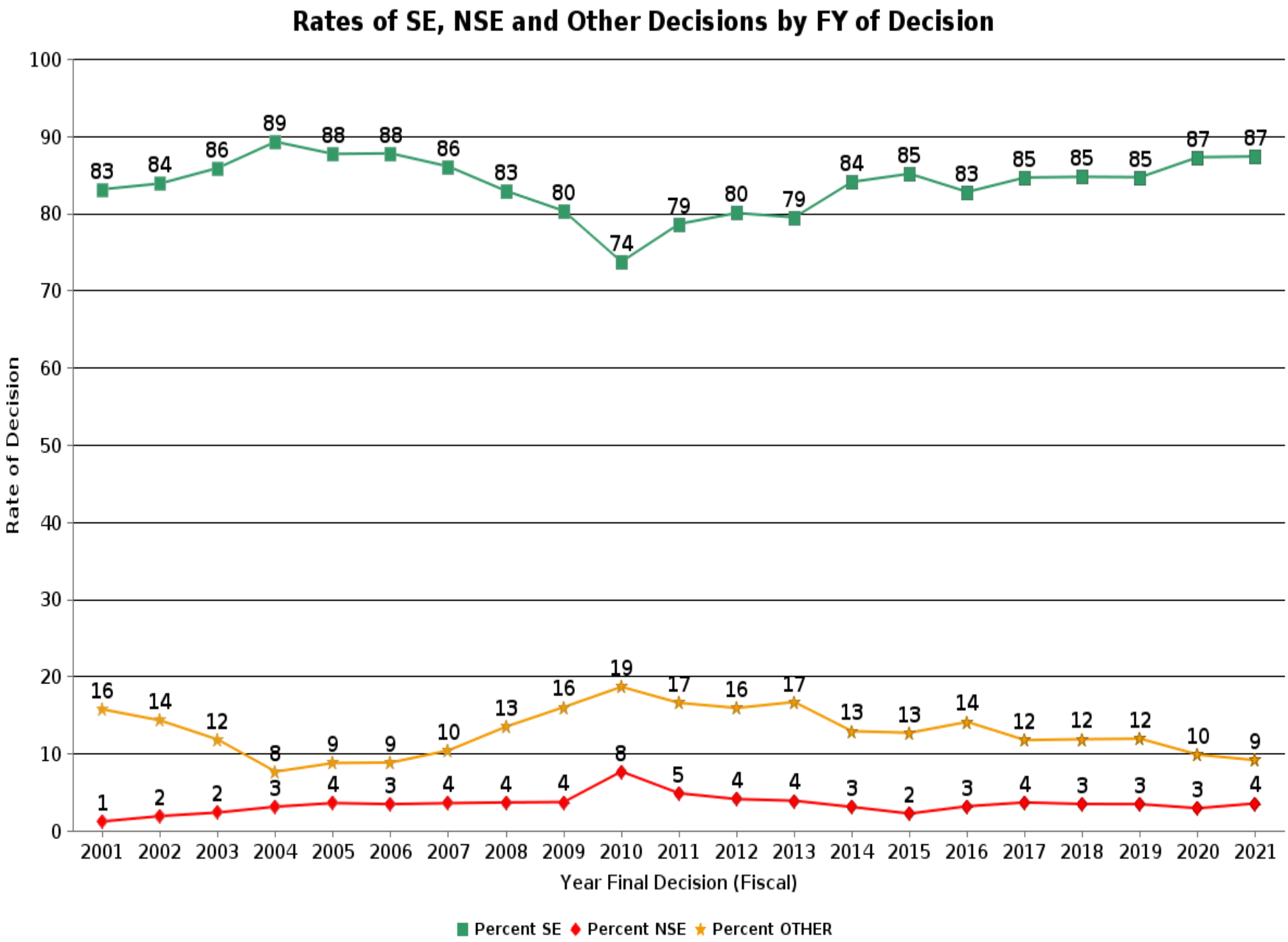
Comparison of FY10 – FY21 Receipt Cohorts



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 87
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9
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

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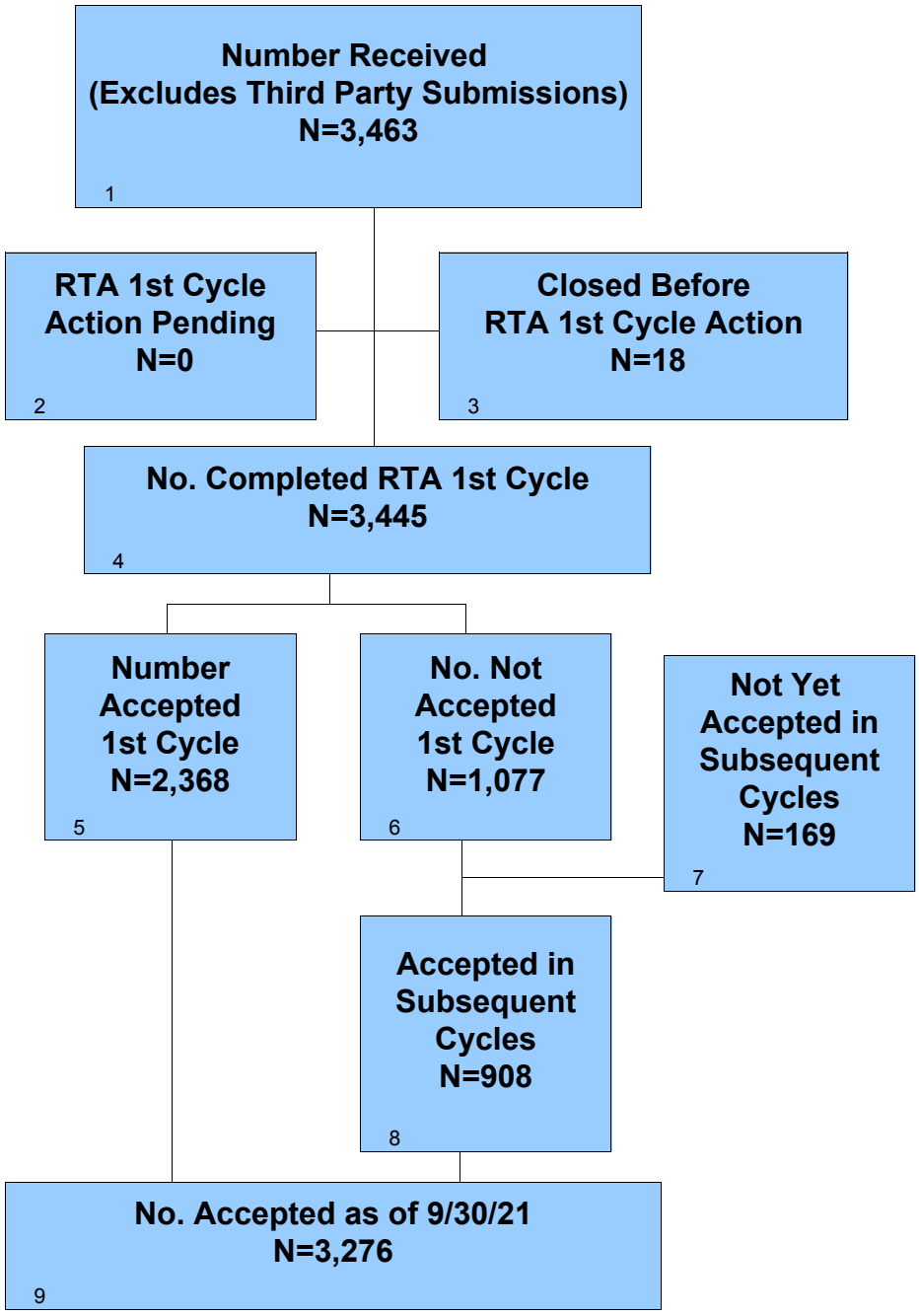
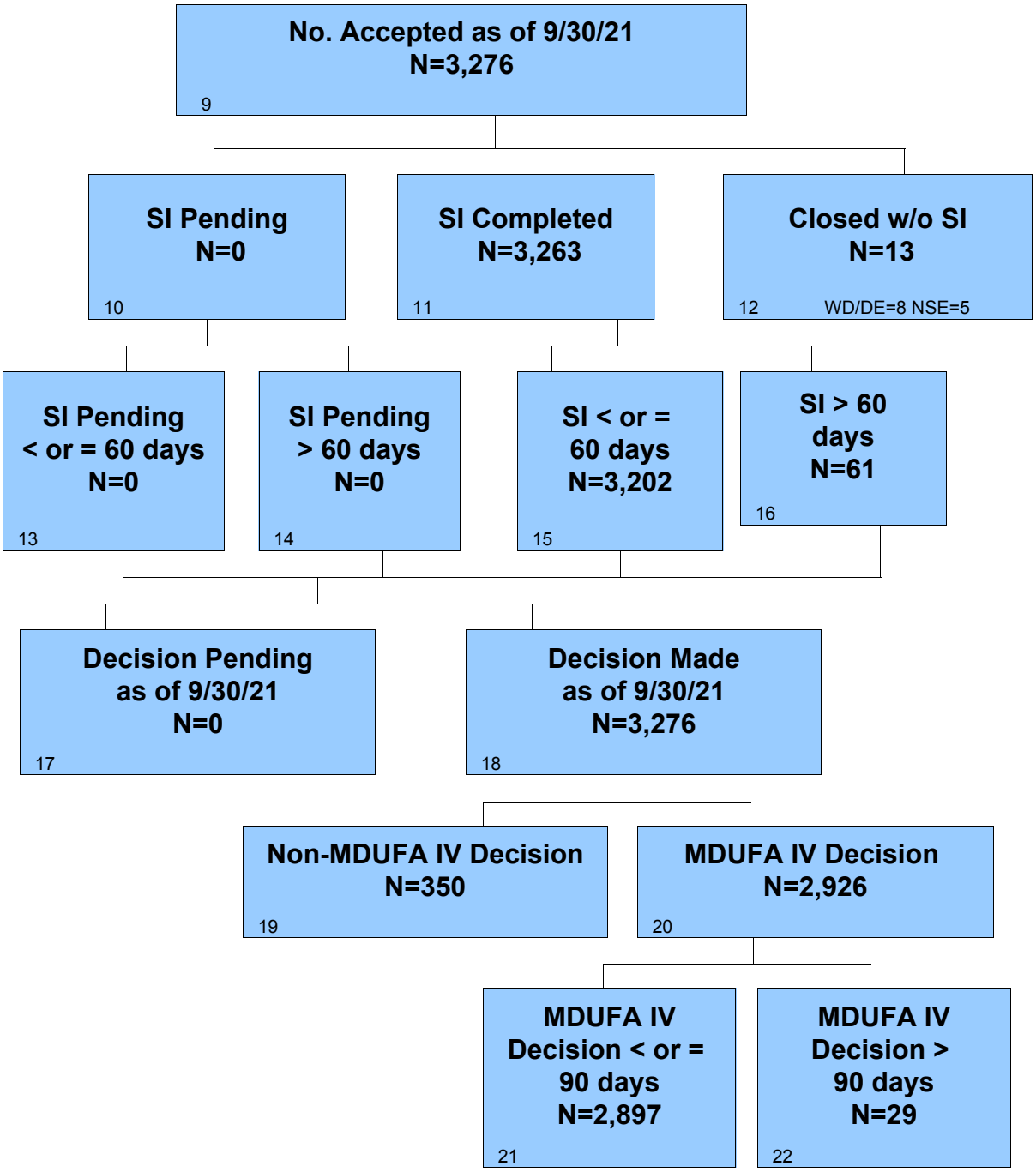
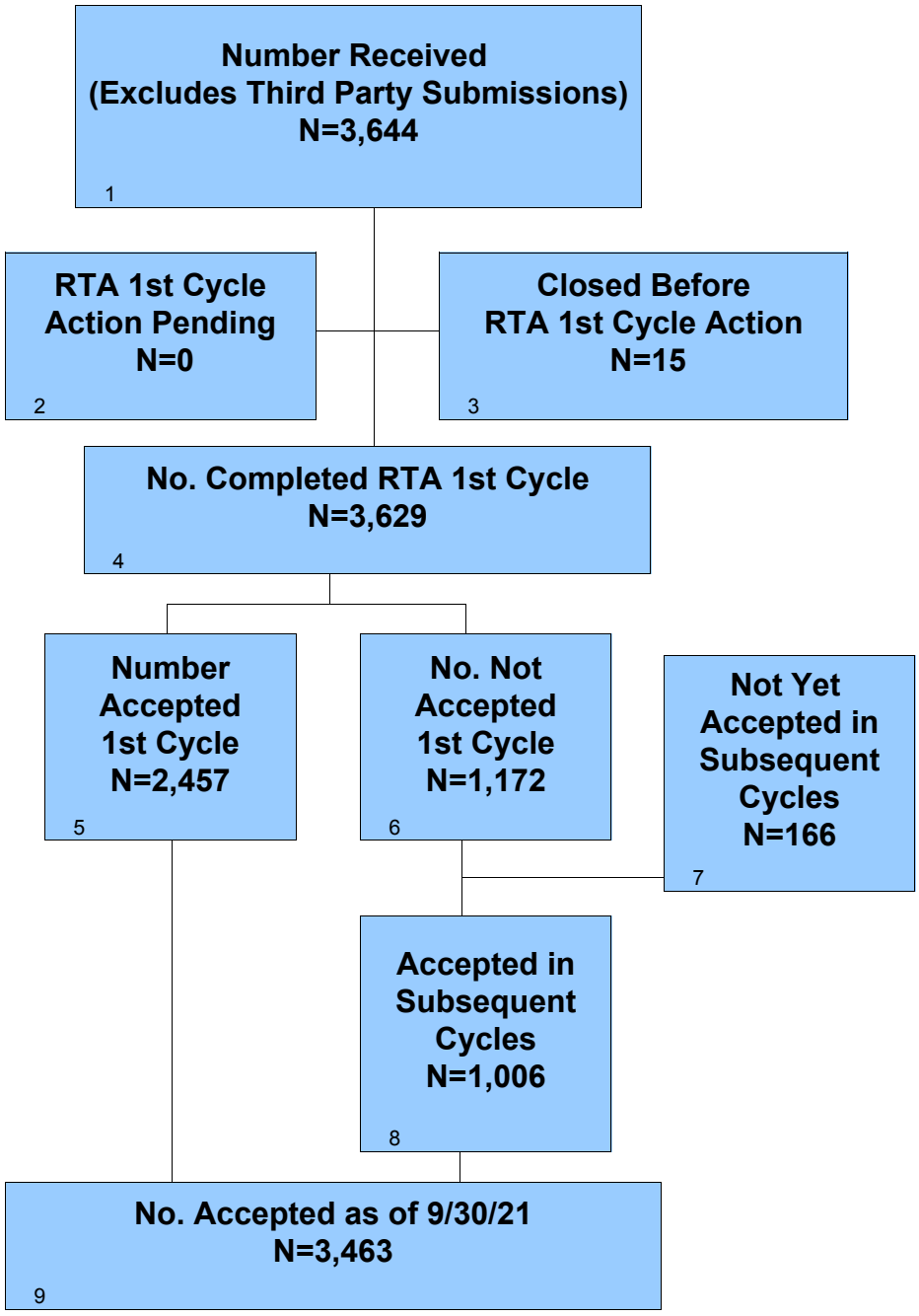
CDRH 510(k)s - FY 2018
as of 9/30/21



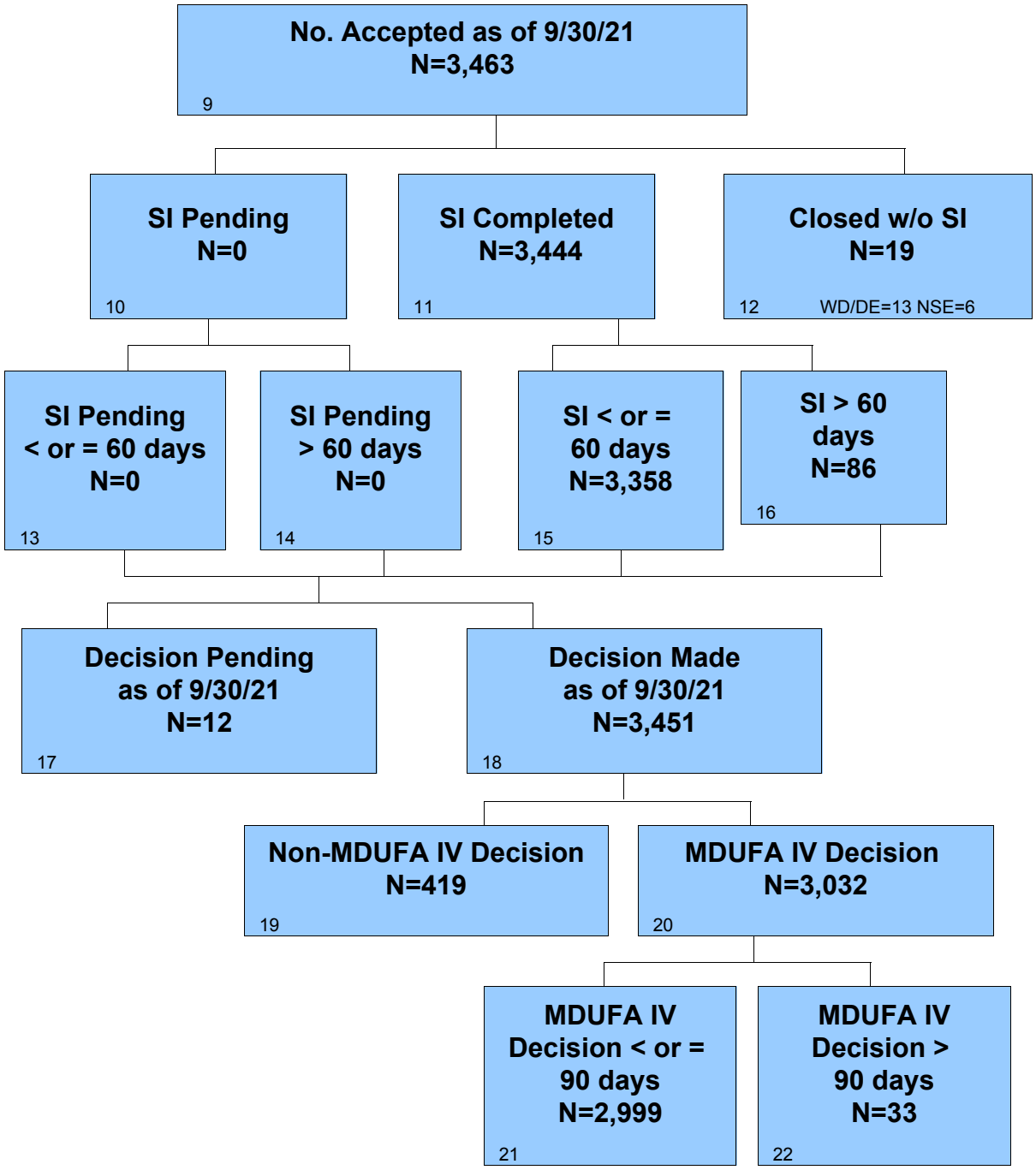
CDRH 510(k)s - FY 2018 as of 9/30/21 Continued



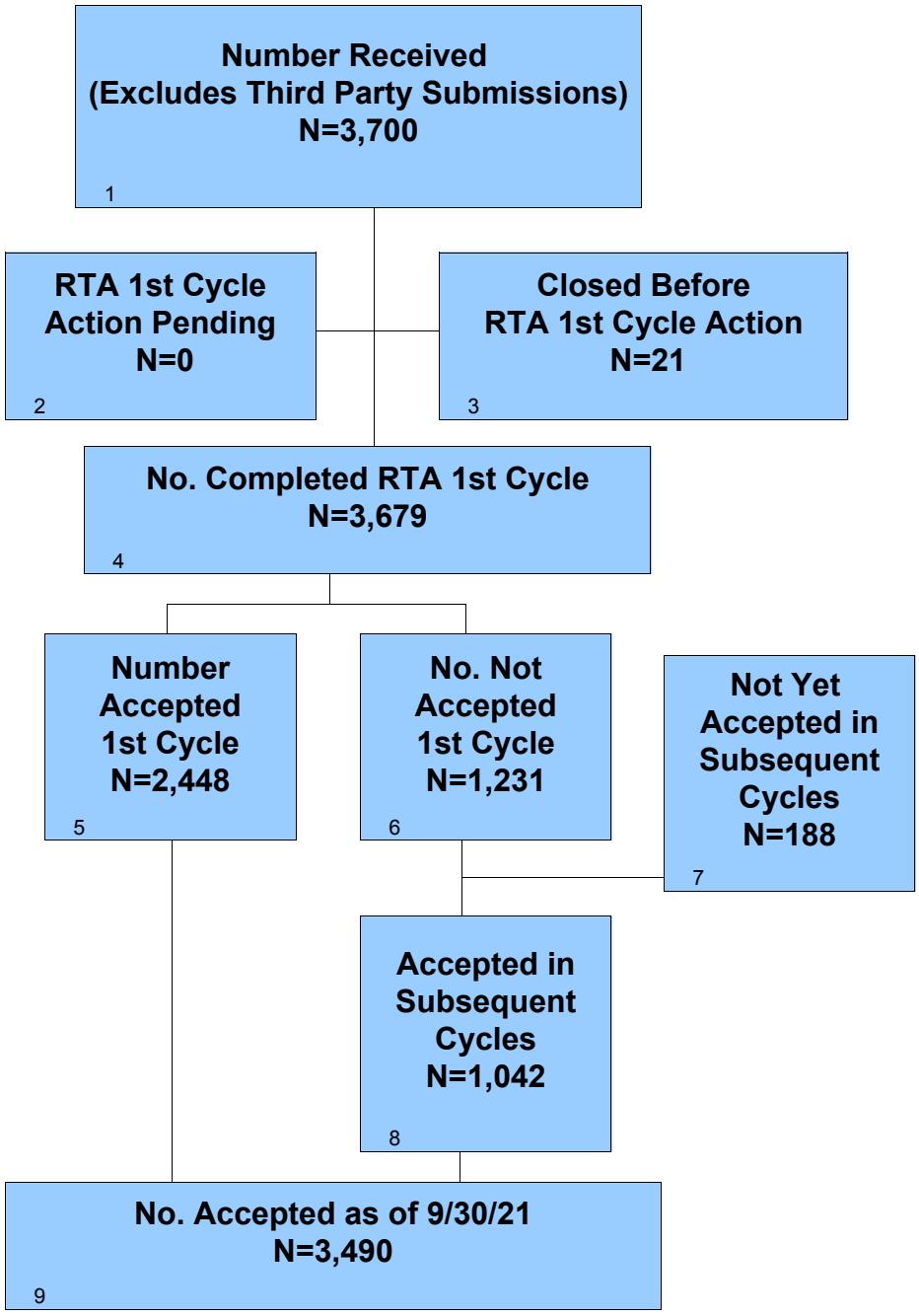
CDRH 510(k)s - FY 2019
as of 9/30/21



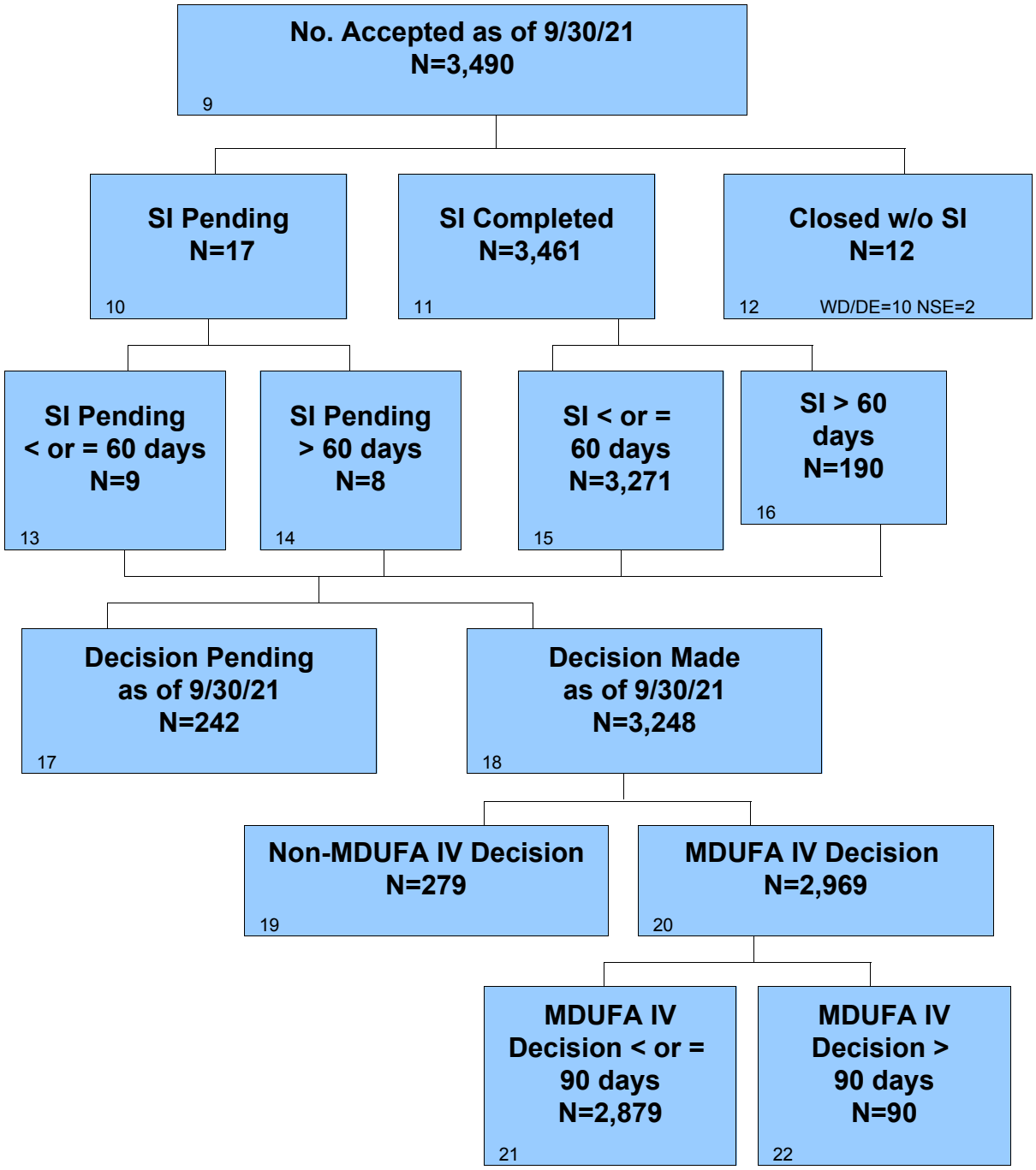
CDRH 510(k)s - FY 2019 as of 9/30/21 Continued



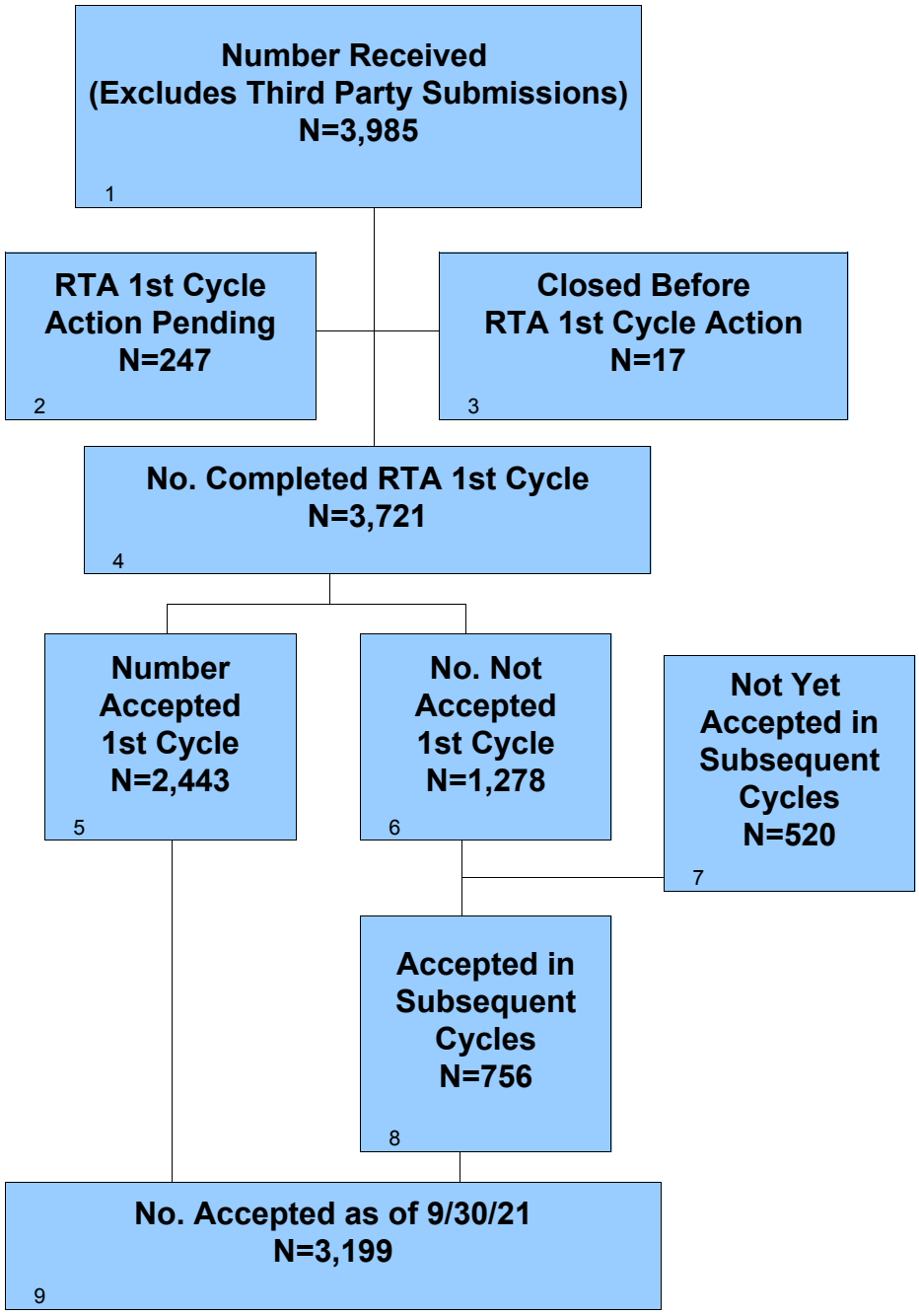
CDRH 510(k)s - FY 2020
as of 9/30/21



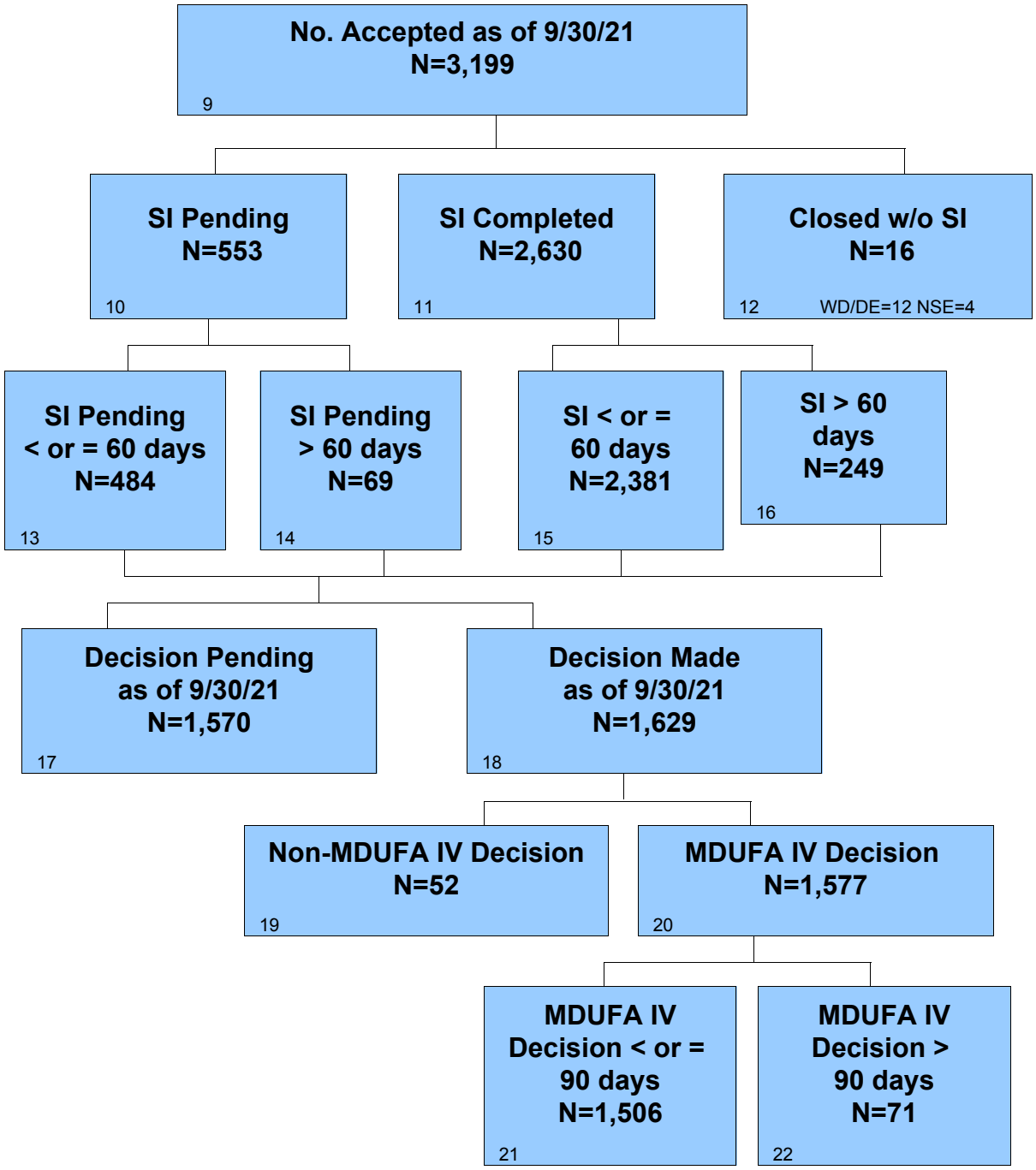
CDRH 510(k)s - FY 2020 as of 9/30/21 Continued



CDRH 510(k)s - FY 2021
as of 9/30/21



CDRH 510(k)s - FY 2021
as of 9/30/21 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	3,985	
Closed Before RTA Action	18	15	21	17	
Number Accepted	2,353	2,403	2,399	2,230	
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	213	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	247	
Number Not Accepted	1,077	1,172	1,231	1,278	
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.46%	34.35%	

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	3,463	3,490	3,199	
Deleted or Withdrawn Prior to SI	8	13	10	12	
SI Within 60 FDA Days	3,202	3,358	3,271	2,381	
SI Over 60 FDA Days	61	86	190	249	
SI Pending Within 60 FDA Days	0	0	9	484	
SI Pending Over 60 FDA Days	0	0	8	69	
510(k)s NSE Without SI	5	6	2	4	
Current SI Performance Percent Within 60 FDA Days	97.98%	97.33%	94.24%	88.09%	

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	3,444	3,461	2,630	
Average Number of FDA Days to Substantive Interaction	51.04	51.42	54.45	56.36	
20th Percentile FDA Days to Substantive Interaction	43	43	45	46	
40th Percentile FDA Days to Substantive Interaction	55	56	56	56	
60th Percentile FDA Days to Substantive Interaction	58	58	59	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	86	90	496	331	

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	3,463	3,490	3,199	
Non-MDUFA IV Decision	350	419	279	52	
MDUFA IV Decision (SE/NSE)	2,926	3,032	2,969	1,577	
MDUFA IV Decision Within 90 FDA Days	2,897	2,999	2,879	1,506	
510(k)s Pending MDUFA IV Decision	0	12	242	1,570	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	61	127	
Current Performance Percent Within 90 FDA Days	99.01%	98.88%	95.02%	88.38%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.62	1.62	1.62	1.45	
Number With MDUFA IV Decision	2,926	3,032	2,969	1,577	
Average Number of FDA Days to MDUFA IV Decision	72.62	73.32	75.60	68.54	
20th Percentile FDA Days to MDUFA IV Decision	54	55	54	35	
40th Percentile FDA Days to MDUFA IV Decision	79	82	83	60	
60th Percentile FDA Days to MDUFA IV Decision	87	88	88	86	
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	89	
Maximum FDA Days to MDUFA IV Decision	220	423	432	290	
Average Number of Industry Days to MDUFA IV Decision	54.69	59.97	61.20	26.61	
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	48	11	
80th Percentile Industry Days to MDUFA IV Decision	127	138	131	52	
Maximum Industry Days to MDUFA IV Decision	563	448	402	205	
Average Number of Total Days to MDUFA IV Decision	127.31	133.29	136.79	95.14	
20th Percentile Total Days to MDUFA IV Decision	57	57	56	40	
40th Percentile Total Days to MDUFA IV Decision	89	90	90	68	
60th Percentile Total Days to MDUFA IV Decision	128	133	133	93	
80th Percentile Total Days to MDUFA IV Decision	212	224	222	141	
Maximum Total Days to MDUFA IV Decision	783	871	607	308	

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	3,463	3,490	3,199	
Number With MDUFA IV Decision	2,926	3,032	2,969	1,577	
Number of SE Decision	2,810	2,918	2,879	1,545	
Number of NSE Decision	116	114	90	32	
Number of Withdrawal	185	213	180	50	
Number of Deleted	156	188	95	0	
Rate of SE Decision	96.04%	96.24%	96.97%	97.97%	
Rate of NSE Decision	3.96%	3.76%	3.03%	2.03%	
Rate of Withdrawal	5.65%	6.15%	5.16%	1.56%	
Rate of Deleted	4.76%	5.43%	2.72%	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	33	90	71	
Mean FDA Days for Submissions that Missed the Goal	111.38	125.97	190.56	130.87	
Mean Industry Days for Submissions that Missed the Goal	136.24	193.39	117.03	30.92	

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	4	0	
MDUFA IV Decision Within 90 FDA Days	1	1	2	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	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	253	179	
Non-MDUFA IV Decision	41	37	32	6	
MDUFA IV Decision (SE/NSE)	231	240	169	40	
MDUFA IV Decision Within 90 FDA Days	230	237	122	11	
510(k)s Pending MDUFA IV Decision	0	1	52	133	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	47	98	
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	56.48%	7.97%	

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

Table 6.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	552	593	536	533	
Closed Before RTA Action	1	1	0	0	
Number Accepted	208	207	226	191	
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8	10	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	45	
Number Not Accepted	343	373	302	287	
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	58.81%	

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	499	374	
Deleted or Withdrawn Prior to SI	2	6	0	0	
SI Within 60 FDA Days	477	489	405	276	
SI Over 60 FDA Days	14	54	89	41	
SI Pending Within 60 FDA Days	0	0	5	56	
SI Pending Over 60 FDA Days	0	0	0	1	
510(k)s NSE Without SI	1	1	0	0	
Current SI Performance Percent Within 60 FDA Days	96.95%	89.89%	81.98%	86.79%	

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	494	317	
Average Number of FDA Days to Substantive Interaction	55.63	56.03	55.32	55.37	
20th Percentile FDA Days to Substantive Interaction	54	54	51	53	
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	499	374	
Non-MDUFA IV Decision	74	83	42	15	
MDUFA IV Decision (SE/NSE)	420	464	421	171	
MDUFA IV Decision Within 90 FDA Days	417	462	417	171	
510(k)s Pending MDUFA IV Decision	0	3	36	188	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	1	
Current Performance Percent Within 90 FDA Days	99.29%	99.57%	99.05%	99.42%	

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	1.69	1.52	
Number With MDUFA IV Decision	420	464	421	171	
Average Number of FDA Days to MDUFA IV Decision	81.05	82.37	79.70	74.13	
20th Percentile FDA Days to MDUFA IV Decision	77	84	76	57	
40th Percentile FDA Days to MDUFA IV Decision	87	88	87	82	
60th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	89	
Maximum FDA Days to MDUFA IV Decision	148	153	115	90	
Average Number of Industry Days to MDUFA IV Decision	65.45	68.02	67.51	33.13	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	18	19	15	0	
60th Percentile Industry Days to MDUFA IV Decision	63	67	58	23	
80th Percentile Industry Days to MDUFA IV Decision	152	153	144	65	
Maximum Industry Days to MDUFA IV Decision	389	284	382	180	
Average Number of Total Days to MDUFA IV Decision	146.51	150.39	147.21	107.26	
20th Percentile Total Days to MDUFA IV Decision	79	88	83	57	
40th Percentile Total Days to MDUFA IV Decision	103	106	98	86	
60th Percentile Total Days to MDUFA IV Decision	148	153	143	107	
80th Percentile Total Days to MDUFA IV Decision	241	239	233	153	
Maximum Total Days to MDUFA IV Decision	479	401	472	270	

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	499	374	
Number With MDUFA IV Decision	420	464	421	171	
Number of SE Decision	402	442	409	167	
Number of NSE Decision	18	22	12	4	
Number of Withdrawal	35	48	31	13	
Number of Deleted	39	32	11	-	
Rate of SE Decision	95.71%	95.26%	97.15%	97.66%	
Rate of NSE Decision	4.29%	4.74%	2.85%	2.34%	
Rate of Withdrawal	7.09%	8.73%	6.21%	3.48%	
Rate of Deleted	7.89%	5.82%	2.20%	0.00%	

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

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

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	0.00%	0.00%	0.00%	0.00%	

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	392	
Closed Before RTA Action	4	2	1	2	
Number Accepted	237	266	282	263	
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	17	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	21	
Number Not Accepted	114	100	93	89	
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.54%	24.12%	

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	370	339	
Deleted or Withdrawn Prior to SI	4	0	1	1	
SI Within 60 FDA Days	324	358	354	276	
SI Over 60 FDA Days	13	8	12	15	
SI Pending Within 60 FDA Days	0	0	1	39	
SI Pending Over 60 FDA Days	0	0	1	7	
510(k)s NSE Without SI	0	0	1	1	
Current SI Performance Percent Within 60 FDA Days	96.14%	97.81%	96.20%	92.31%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	337	366	366	291	
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.58	49.91	
20th Percentile FDA Days to Substantive Interaction	30	30	36	30	
40th Percentile FDA Days to Substantive Interaction	53	56	57	56	
60th Percentile FDA Days to Substantive Interaction	58	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	83	71	101	89	

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	370	339	
Non-MDUFA IV Decision	32	52	25	2	
MDUFA IV Decision (SE/NSE)	309	314	323	158	
MDUFA IV Decision Within 90 FDA Days	303	303	313	156	
510(k)s Pending MDUFA IV Decision	0	0	22	179	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	5	5	
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	95.43%	95.71%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.71	1.70	1.79	1.54	
Number With MDUFA IV Decision	309	314	323	158	
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	74.26	61.97	
20th Percentile FDA Days to MDUFA IV Decision	50	49	54	29	
40th Percentile FDA Days to MDUFA IV Decision	80	80	86	57	
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	86	
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	89	
Maximum FDA Days to MDUFA IV Decision	159	117	245	99	
Average Number of Industry Days to MDUFA IV Decision	64.80	66.25	76.92	34.25	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	19	20	27	0	
60th Percentile Industry Days to MDUFA IV Decision	65	68	73	30	
80th Percentile Industry Days to MDUFA IV Decision	146	140	148	63	
Maximum Industry Days to MDUFA IV Decision	292	359	372	181	
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	151.18	96.22	
20th Percentile Total Days to MDUFA IV Decision	55	51	55	29	
40th Percentile Total Days to MDUFA IV Decision	102	98	115	59	
60th Percentile Total Days to MDUFA IV Decision	150	148	155	110	
80th Percentile Total Days to MDUFA IV Decision	228	227	239	147	
Maximum Total Days to MDUFA IV Decision	370	447	462	270	

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	370	339	
Number With MDUFA IV Decision	309	314	323	158	
Number of SE Decision	291	289	299	149	
Number of NSE Decision	18	25	24	9	
Number of Withdrawal	20	31	16	2	
Number of Deleted	10	20	9	0	
Rate of SE Decision	94.17%	92.04%	92.57%	94.30%	
Rate of NSE Decision	5.83%	7.96%	7.43%	5.70%	
Rate of Withdrawal	5.87%	8.47%	4.32%	0.59%	
Rate of Deleted	2.93%	5.46%	2.43%	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	10	2	
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	111.60	95.00	
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	152.70	130.50	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	454	476	443	518	
Closed Before RTA Action	3	4	4	6	
Number Accepted	333	349	289	272	
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2	14	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	40	
Number Not Accepted	116	117	148	186	
Rate of Submissions Not Accepted for Review	25.72%	24.79%	33.71%	39.41%	

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	417	381	
Deleted or Withdrawn Prior to SI	0	1	1	2	
SI Within 60 FDA Days	426	447	401	303	
SI Over 60 FDA Days	6	4	13	13	
SI Pending Within 60 FDA Days	0	0	1	57	
SI Pending Over 60 FDA Days	0	0	1	5	
510(k)s NSE Without SI	3	1	0	1	
Current SI Performance Percent Within 60 FDA Days	97.93%	98.89%	96.63%	94.10%	

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	414	316	
Average Number of FDA Days to Substantive Interaction	51.16	52.58	53.35	53.16	
20th Percentile FDA Days to Substantive Interaction	44	48	51	51	
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	73	

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	417	381	
Non-MDUFA IV Decision	50	77	41	8	
MDUFA IV Decision (SE/NSE)	385	376	339	162	
MDUFA IV Decision Within 90 FDA Days	381	371	332	162	
510(k)s Pending MDUFA IV Decision	0	0	37	211	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	5	5	
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	96.51%	97.01%	

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	1.81	1.61	
Number With MDUFA IV Decision	385	376	339	162	
Average Number of FDA Days to MDUFA IV Decision	75.81	78.15	78.13	72.10	
20th Percentile FDA Days to MDUFA IV Decision	58	60	60	44	
40th Percentile FDA Days to MDUFA IV Decision	84	87	87	84	
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	89	
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	
Maximum FDA Days to MDUFA IV Decision	118	150	135	90	
Average Number of Industry Days to MDUFA IV Decision	75.12	95.90	95.59	48.82	
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	0	
40th Percentile Industry Days to MDUFA IV Decision	30	54	49	5	
60th Percentile Industry Days to MDUFA IV Decision	94	118	117	52	
80th Percentile Industry Days to MDUFA IV Decision	165	174	175	101	
Maximum Industry Days to MDUFA IV Decision	214	444	360	183	
Average Number of Total Days to MDUFA IV Decision	150.94	174.06	173.72	120.92	
20th Percentile Total Days to MDUFA IV Decision	65	87	85	49	
40th Percentile Total Days to MDUFA IV Decision	113	140	133	90	
60th Percentile Total Days to MDUFA IV Decision	177	205	202	141	
80th Percentile Total Days to MDUFA IV Decision	248	261	262	189	
Maximum Total Days to MDUFA IV Decision	304	540	449	273	

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	417	381	
Number With MDUFA IV Decision	385	376	339	162	
Number of SE Decision	360	353	320	155	
Number of NSE Decision	25	23	19	7	
Number of Withdrawal	20	31	22	8	
Number of Deleted	30	44	18	0	
Rate of SE Decision	93.51%	93.88%	94.40%	95.68%	
Rate of NSE Decision	6.49%	6.12%	5.60%	4.32%	
Rate of Withdrawal	4.60%	6.84%	5.28%	2.10%	
Rate of Deleted	6.90%	9.71%	4.32%	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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	553	604	720	1,031	
Closed Before RTA Action	2	0	3	4	
Number Accepted	369	392	447	563	
Number Without a RTA Review and > 15 Days Since Date Received	6	7	5	33	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	57	
Number Not Accepted	176	205	265	374	
Rate of Submissions Not Accepted for Review	31.94%	33.94%	36.96%	38.56%	

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	650	801	
Deleted or Withdrawn Prior to SI	0	3	2	3	
SI Within 60 FDA Days	513	543	624	546	
SI Over 60 FDA Days	4	12	23	90	
SI Pending Within 60 FDA Days	0	0	0	157	
SI Pending Over 60 FDA Days	0	0	0	5	
510(k)s NSE Without SI	0	1	1	0	
Current SI Performance Percent Within 60 FDA Days	99.23%	97.66%	96.30%	85.18%	

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	647	636	
Average Number of FDA Days to Substantive Interaction	52.55	52.19	53.92	55.27	
20th Percentile FDA Days to Substantive Interaction	49	48	52	52	
40th Percentile FDA Days to Substantive Interaction	56	56	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	69	90	91	106	

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	650	801	
Non-MDUFA IV Decision	68	71	58	8	
MDUFA IV Decision (SE/NSE)	449	484	544	357	
MDUFA IV Decision Within 90 FDA Days	441	480	524	317	
510(k)s Pending MDUFA IV Decision	0	4	48	436	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	4	18	
Current Performance Percent Within 90 FDA Days	98.22%	99.17%	95.62%	84.53%	

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	1.66	1.51	
Number With MDUFA IV Decision	449	484	544	357	
Average Number of FDA Days to MDUFA IV Decision	73.76	73.11	75.86	74.04	
20th Percentile FDA Days to MDUFA IV Decision	57	55	58	56	
40th Percentile FDA Days to MDUFA IV Decision	79	81	84	80	
60th Percentile FDA Days to MDUFA IV Decision	87	87	87	87	
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	90	
Maximum FDA Days to MDUFA IV Decision	220	207	179	143	
Average Number of Industry Days to MDUFA IV Decision	48.88	54.82	59.97	25.32	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA IV Decision	0	0	8	0	
60th Percentile Industry Days to MDUFA IV Decision	31	41	56	13	
80th Percentile Industry Days to MDUFA IV Decision	110	128	128	48	
Maximum Industry Days to MDUFA IV Decision	563	355	331	205	
Average Number of Total Days to MDUFA IV Decision	122.64	127.93	135.83	99.36	
20th Percentile Total Days to MDUFA IV Decision	59	57	59	56	
40th Percentile Total Days to MDUFA IV Decision	88	87	90	85	
60th Percentile Total Days to MDUFA IV Decision	110	125	138	99	
80th Percentile Total Days to MDUFA IV Decision	193	210	217	136	
Maximum Total Days to MDUFA IV Decision	783	511	389	300	

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	650	801	
Number With MDUFA IV Decision	449	484	544	357	
Number of SE Decision	438	470	532	355	
Number of NSE Decision	11	14	12	2	
Number of Withdrawal	36	37	36	8	
Number of Deleted	31	32	21	0	
Rate of SE Decision	97.55%	97.11%	97.79%	99.44%	
Rate of NSE Decision	2.45%	2.89%	2.21%	0.56%	
Rate of Withdrawal	6.96%	6.62%	5.54%	1.00%	
Rate of Deleted	6.00%	5.72%	3.23%	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	20	40	
Mean FDA Days for Submissions that Missed the Goal	119.50	121.00	101.40	96.60	
Mean Industry Days for Submissions that Missed the Goal	168.63	132.50	105.50	44.65	

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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	260	275	261	278	
Closed Before RTA Action	3	0	3	1	
Number Accepted	147	156	110	126	
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5	8	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	20	
Number Not Accepted	107	112	143	123	
Rate of Submissions Not Accepted for Review	41.63%	40.73%	55.43%	47.86%	

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	261	237	213	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	232	258	227	174	
SI Over 60 FDA Days	4	3	9	2	
SI Pending Within 60 FDA Days	0	0	1	37	
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%	98.85%	96.19%	98.86%	

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	261	236	176	
Average Number of FDA Days to Substantive Interaction	53.91	54.56	53.48	52.27	
20th Percentile FDA Days to Substantive Interaction	53	54	50	44	
40th Percentile FDA Days to Substantive Interaction	58	58	58	58	
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	261	237	213	
Non-MDUFA IV Decision	30	30	13	4	
MDUFA IV Decision (SE/NSE)	206	227	204	100	
MDUFA IV Decision Within 90 FDA Days	201	220	204	100	
510(k)s Pending MDUFA IV Decision	0	4	20	109	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	97.57%	96.92%	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	1.42	1.31	
Number With MDUFA IV Decision	206	227	204	100	
Average Number of FDA Days to MDUFA IV Decision	76.47	80.29	74.83	66.08	
20th Percentile FDA Days to MDUFA IV Decision	60	68	45	30	
40th Percentile FDA Days to MDUFA IV Decision	86	88	86	65	
60th Percentile FDA Days to MDUFA IV Decision	89	90	89	86	
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	54.10	46.92	19.32	
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	38	11	0	
80th Percentile Industry Days to MDUFA IV Decision	84	124	98	29	
Maximum Industry Days to MDUFA IV Decision	187	391	354	177	
Average Number of Total Days to MDUFA IV Decision	119.07	134.39	121.75	85.40	
20th Percentile Total Days to MDUFA IV Decision	61	82	45	30	
40th Percentile Total Days to MDUFA IV Decision	89	90	88	76	
60th Percentile Total Days to MDUFA IV Decision	117	124	100	88	
80th Percentile Total Days to MDUFA IV Decision	171	216	188	105	
Maximum Total Days to MDUFA IV Decision	346	543	442	266	

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	261	237	213	
Number With MDUFA IV Decision	206	227	204	100	
Number of SE Decision	198	220	194	99	
Number of NSE Decision	8	7	10	1	
Number of Withdrawal	17	16	11	4	
Number of Deleted	10	13	2	0	
Rate of SE Decision	96.12%	96.92%	95.10%	99.00%	
Rate of NSE Decision	3.88%	3.08%	4.90%	1.00%	
Rate of Withdrawal	7.20%	6.13%	4.64%	1.88%	
Rate of Deleted	4.24%	4.98%	0.84%	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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	634	655	575	
Closed Before RTA Action	2	4	5	2	
Number Accepted	466	489	493	416	
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6	6	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	32	
Number Not Accepted	138	136	151	119	
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.23%	22.00%	

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	594	622	638	508	
Deleted or Withdrawn Prior to SI	0	2	3	1	
SI Within 60 FDA Days	575	617	634	436	
SI Over 60 FDA Days	19	3	1	0	
SI Pending Within 60 FDA Days	0	0	0	71	
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	635	436	
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.83	48.86	
20th Percentile FDA Days to Substantive Interaction	39	30	30	30	
40th Percentile FDA Days to Substantive Interaction	55	56	56	54	
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	638	508	
Non-MDUFA IV Decision	40	47	51	7	
MDUFA IV Decision (SE/NSE)	554	575	566	329	
MDUFA IV Decision Within 90 FDA Days	552	574	566	329	
510(k)s Pending MDUFA IV Decision	0	0	21	172	
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	1.50	1.35	
Number With MDUFA IV Decision	554	575	566	329	
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	66.57	58.65	
20th Percentile FDA Days to MDUFA IV Decision	52	51	35	30	
40th Percentile FDA Days to MDUFA IV Decision	74	76	60	55	
60th Percentile FDA Days to MDUFA IV Decision	86	87	86	67	
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	87	
Maximum FDA Days to MDUFA IV Decision	135	91	90	90	
Average Number of Industry Days to MDUFA IV Decision	48.84	50.98	47.05	19.53	
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	18	0	
80th Percentile Industry Days to MDUFA IV Decision	103	103	91	35	
Maximum Industry Days to MDUFA IV Decision	340	444	402	180	
Average Number of Total Days to MDUFA IV Decision	120.19	121.55	113.62	78.17	
20th Percentile Total Days to MDUFA IV Decision	57	56	35	30	
40th Percentile Total Days to MDUFA IV Decision	86	87	65	56	
60th Percentile Total Days to MDUFA IV Decision	115	111	101	82	
80th Percentile Total Days to MDUFA IV Decision	189	185	180	113	
Maximum Total Days to MDUFA IV Decision	430	533	491	268	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	594	622	638	508	
Number With MDUFA IV Decision	554	575	566	329	
Number of SE Decision	540	563	562	326	
Number of NSE Decision	14	12	4	3	
Number of Withdrawal	24	28	34	7	
Number of Deleted	16	19	17	0	
Rate of SE Decision	97.47%	97.91%	99.29%	99.09%	
Rate of NSE Decision	2.53%	2.09%	0.71%	0.91%	
Rate of Withdrawal	4.04%	4.50%	5.33%	1.38%	
Rate of Deleted	2.69%	3.05%	2.66%	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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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	658	
Closed Before RTA Action	3	4	5	2	
Number Accepted	593	544	552	399	
Number Without a RTA Review and > 15 Days Since Date Received	2	7	19	125	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	32	
Number Not Accepted	83	129	129	100	
Rate of Submissions Not Accepted for Review	12.24%	18.97%	18.43%	16.03%	

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	679	583	
Deleted or Withdrawn Prior to SI	2	1	3	5	
SI Within 60 FDA Days	655	646	626	370	
SI Over 60 FDA Days	1	2	43	88	
SI Pending Within 60 FDA Days	0	0	1	67	
SI Pending Over 60 FDA Days	0	0	6	51	
510(k)s NSE Without SI	1	3	0	2	
Current SI Performance Percent Within 60 FDA Days	99.70%	99.23%	92.74%	72.41%	

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	669	458	
Average Number of FDA Days to Substantive Interaction	46.54	46.73	61.32	73.60	
20th Percentile FDA Days to Substantive Interaction	30	29	30	40	
40th Percentile FDA Days to Substantive Interaction	48	49	51	54	
60th Percentile FDA Days to Substantive Interaction	56	56	57	58	
80th Percentile FDA Days to Substantive Interaction	58	59	59	60	
Maximum FDA Days to Substantive Interaction	61	61	496	331	

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	679	583	
Non-MDUFA IV Decision	56	59	49	8	
MDUFA IV Decision (SE/NSE)	603	592	572	300	
MDUFA IV Decision Within 90 FDA Days	602	589	523	271	
510(k)s Pending MDUFA IV Decision	0	1	58	275	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	47	98	
Current Performance Percent Within 90 FDA Days	99.83%	99.33%	84.49%	68.09%	

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	1.52	1.36	
Number With MDUFA IV Decision	603	592	572	300	
Average Number of FDA Days to MDUFA IV Decision	64.21	64.36	80.78	72.00	
20th Percentile FDA Days to MDUFA IV Decision	30	30	30	30	
40th Percentile FDA Days to MDUFA IV Decision	59	59	63	59	
60th Percentile FDA Days to MDUFA IV Decision	81	81	85	80	
80th Percentile FDA Days to MDUFA IV Decision	88	88	89	88	
Maximum FDA Days to MDUFA IV Decision	93	423	432	290	
Average Number of Industry Days to MDUFA IV Decision	42.78	42.71	47.54	18.59	
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	33	0	
80th Percentile Industry Days to MDUFA IV Decision	91	89	99	36	
Maximum Industry Days to MDUFA IV Decision	231	448	357	179	
Average Number of Total Days to MDUFA IV Decision	106.99	107.06	128.32	90.59	
20th Percentile Total Days to MDUFA IV Decision	30	30	30	30	
40th Percentile Total Days to MDUFA IV Decision	72	60	74	59	
60th Percentile Total Days to MDUFA IV Decision	104	90	119	92	
80th Percentile Total Days to MDUFA IV Decision	177	172	202	135	
Maximum Total Days to MDUFA IV Decision	321	871	607	308	

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	679	583	
Number With MDUFA IV Decision	603	592	572	300	
Number of SE Decision	581	581	563	294	
Number of NSE Decision	22	11	9	6	
Number of Withdrawal	33	22	30	8	
Number of Deleted	20	28	17	0	
Rate of SE Decision	96.35%	98.14%	98.43%	98.00%	
Rate of NSE Decision	3.65%	1.86%	1.57%	2.00%	
Rate of Withdrawal	5.01%	3.37%	4.42%	1.37%	
Rate of Deleted	3.03%	4.29%	2.50%	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	3	49	29	
Mean FDA Days for Submissions that Missed the Goal	93.00	275.00	262.06	180.62	
Mean Industry Days for Submissions that Missed the Goal	202.00	297.67	106.33	5.10	

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	4	0	
MDUFA IV Decision Within 90 FDA Days	1	1	2	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	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	253	179	
Non-MDUFA IV Decision	41	37	32	6	
MDUFA IV Decision (SE/NSE)	231	240	169	40	
MDUFA IV Decision Within 90 FDA Days	230	237	122	11	
510(k)s Pending MDUFA IV Decision	0	1	52	133	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	47	98	
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	56.48%	7.97%	

Section 7 510(k) Annual General Metrics

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	3,351	3,541	3,575	3,289	
Number of Traditional Submissions	2,789	2,906	2,898	2,700	
Number of Special Submissions	419	493	517	430	
Number of Abbreviated Submissions	68	64	75	69	
Average Number of Days to Accept/Refuse to Accept	10.58	11.20	11.43	11.63	
Number of Third Party Submissions	75	78	85	90	

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	124 Days	120 Days	116 Days	112 Days	108 Days
Number Accepted	3,351	3,541	3,575	3,289	
Currently Under Review	0	12	243	1,585	
Number With Non-MDUFA IV Decision	355	426	285	60	
Number With MDUFA IV Decision	2,996	3,103	3,047	1,644	
Percent of Cohort Closed	100.00%	99.61%	92.61%	50.91%	
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	2,851	2,977	NA	NA	
Average Total Time to MDUFA IV Decision	123.40	127.98	NA	NA	

Table 7.3 CDRH - 510(k) Third Party Performance

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	75	78	85	90	
90th Percentile FDA Days to MDUFA IV Decision	55.40	52.00	33.10	38.00	

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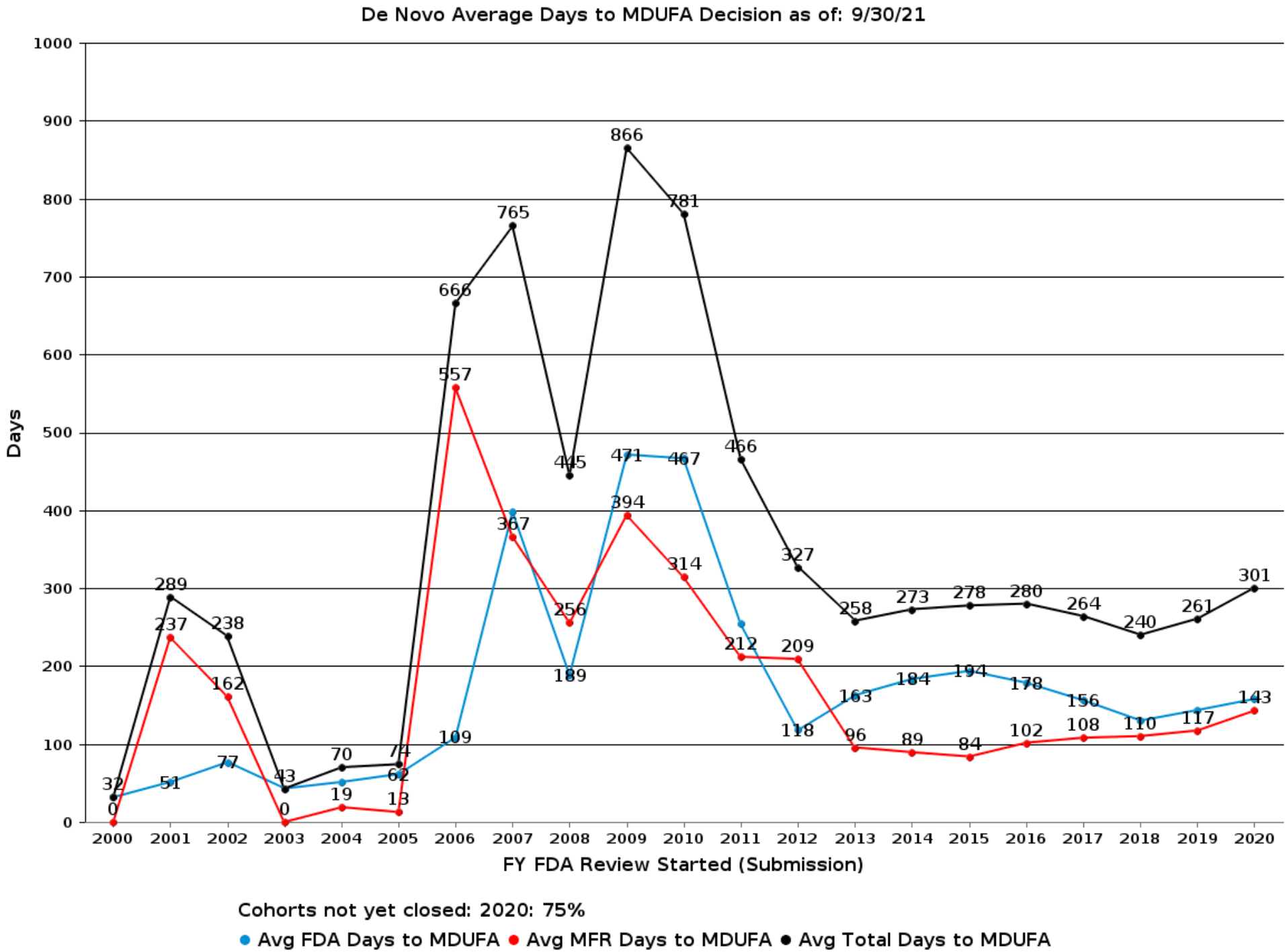
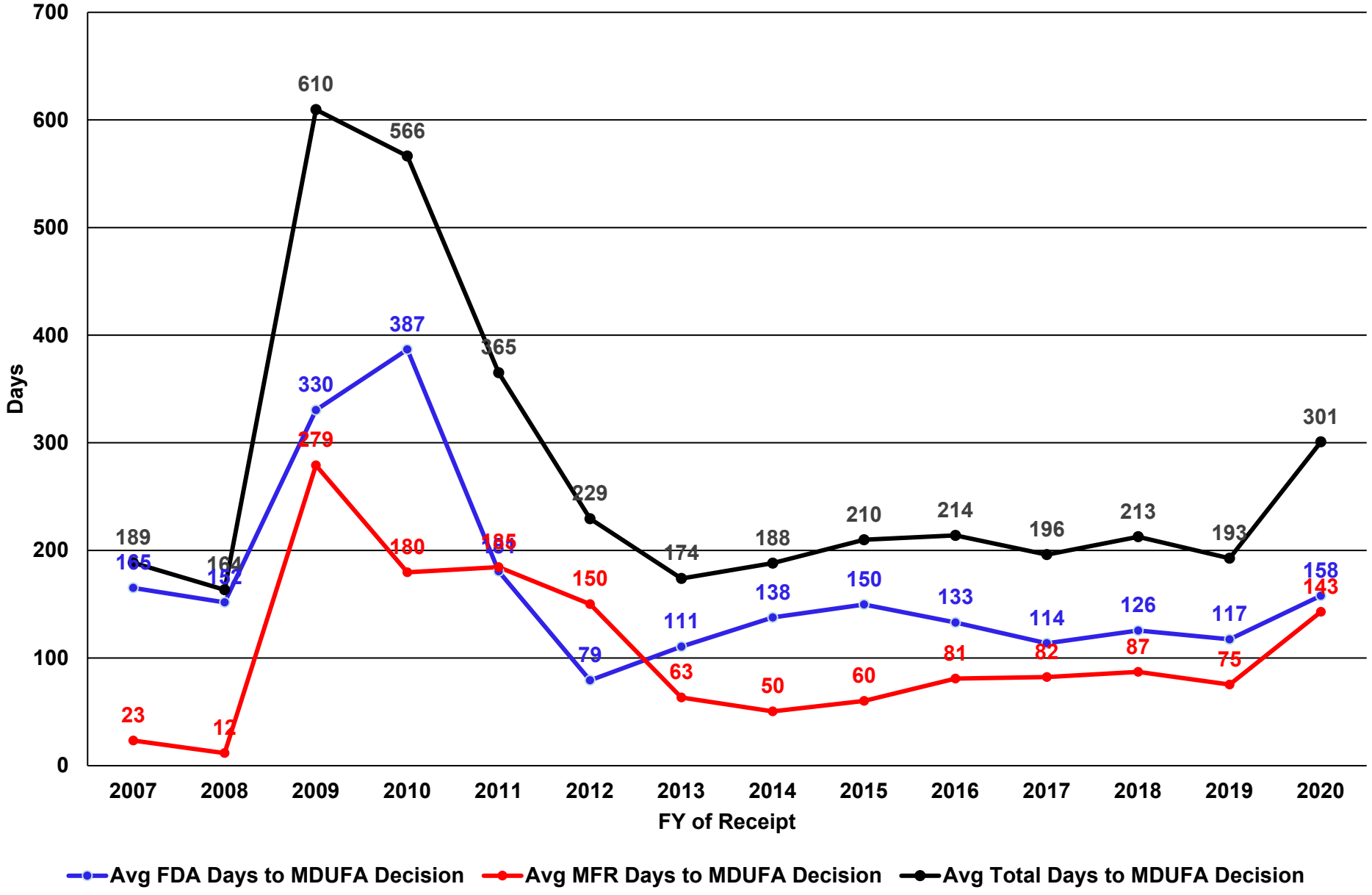
De Novos

Q4FY2021


De Novo Average Days to MDUFA Decision as of: 9/30/21
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2020: 75%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos*

(75% closure comparison)



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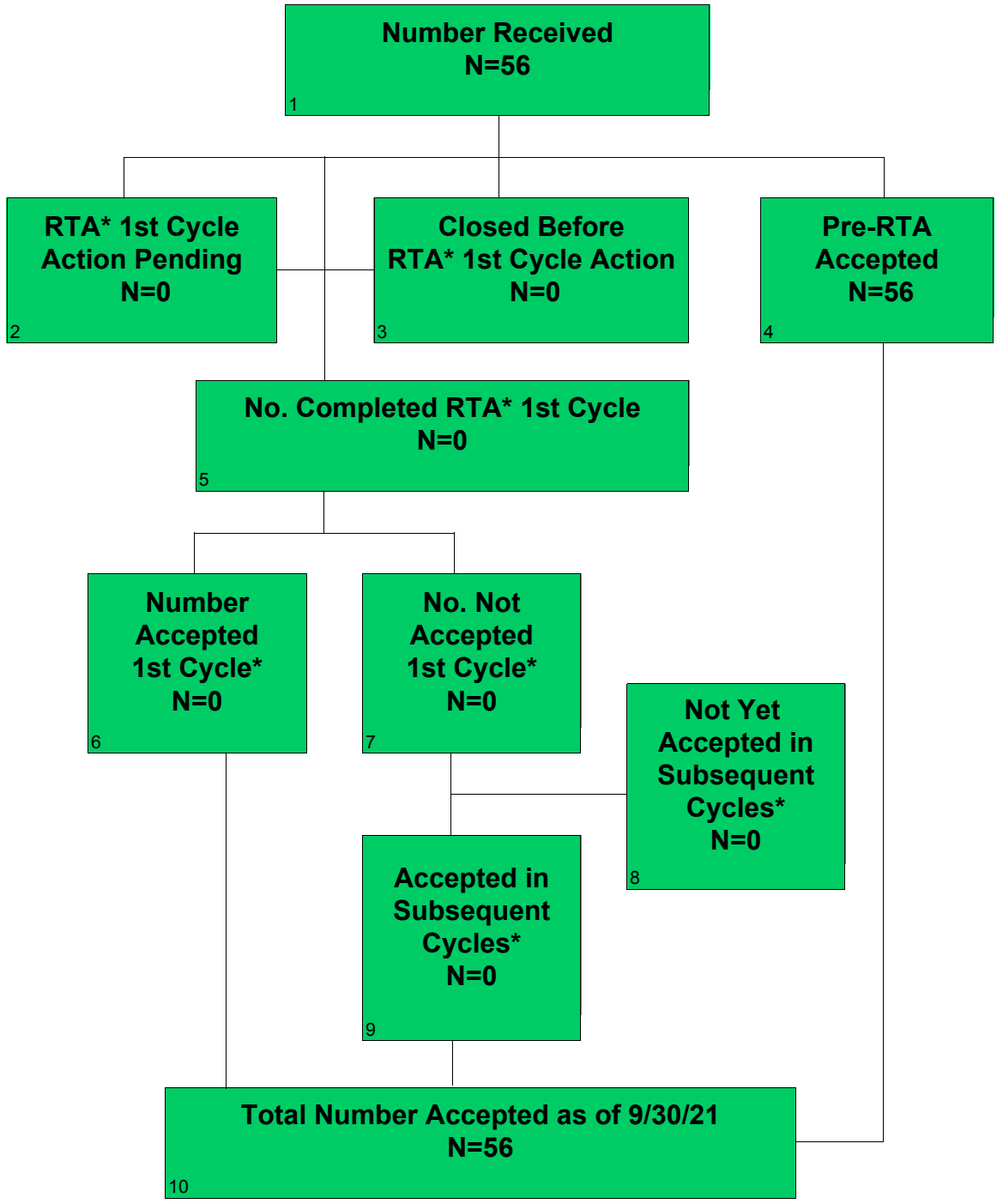
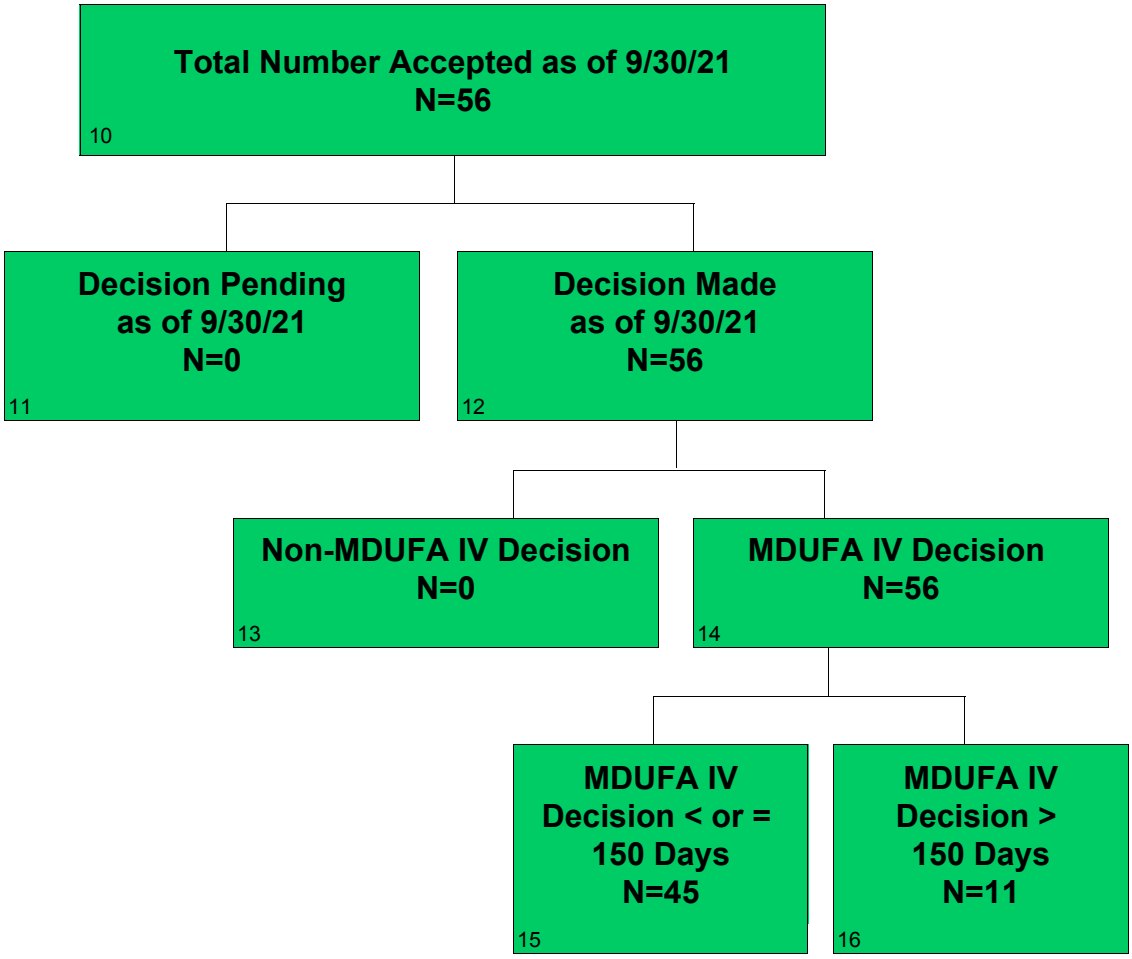
CDRH De Novo - FY 2018
as of 9/30/21

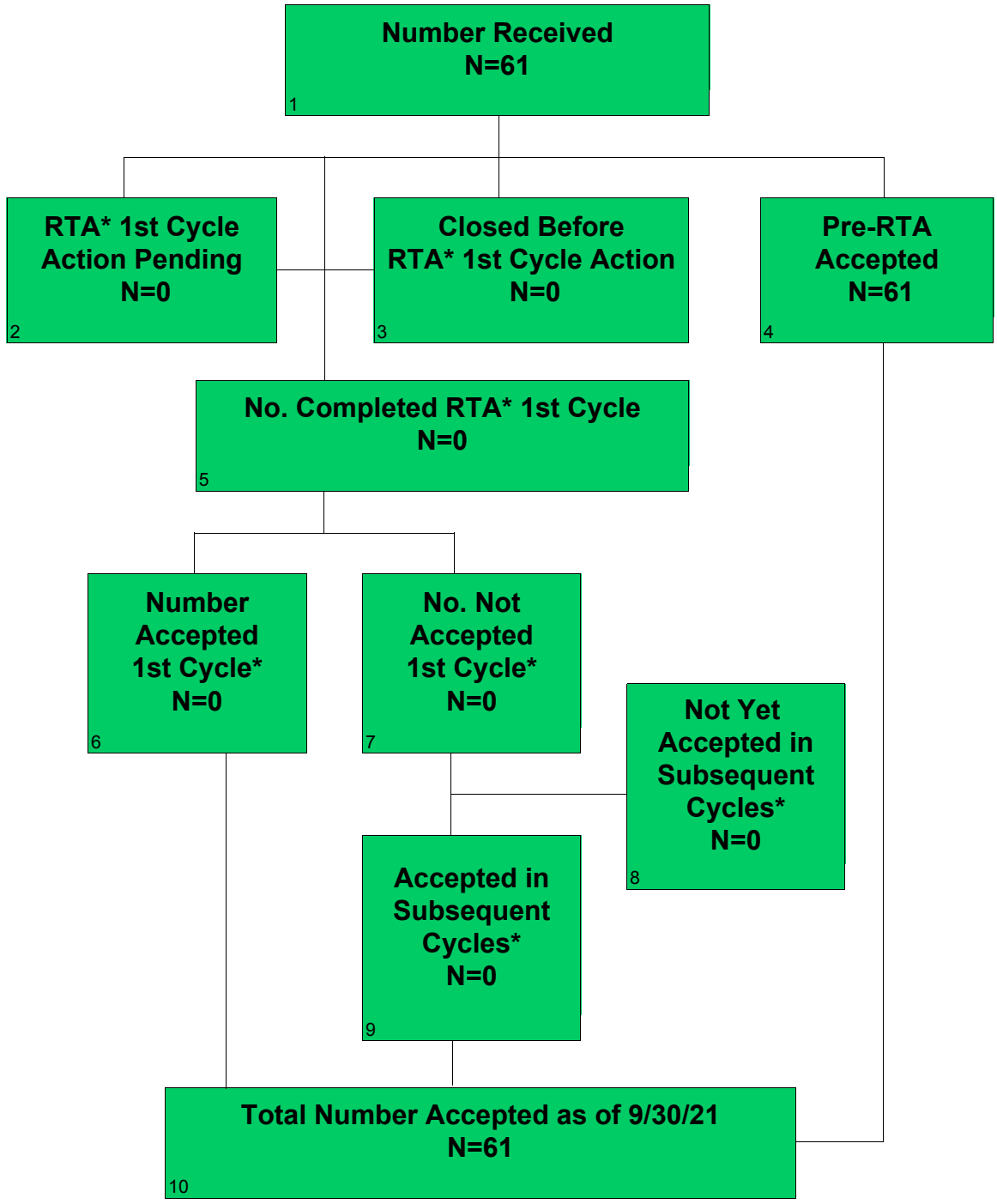


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018
as of 9/30/21 Continued

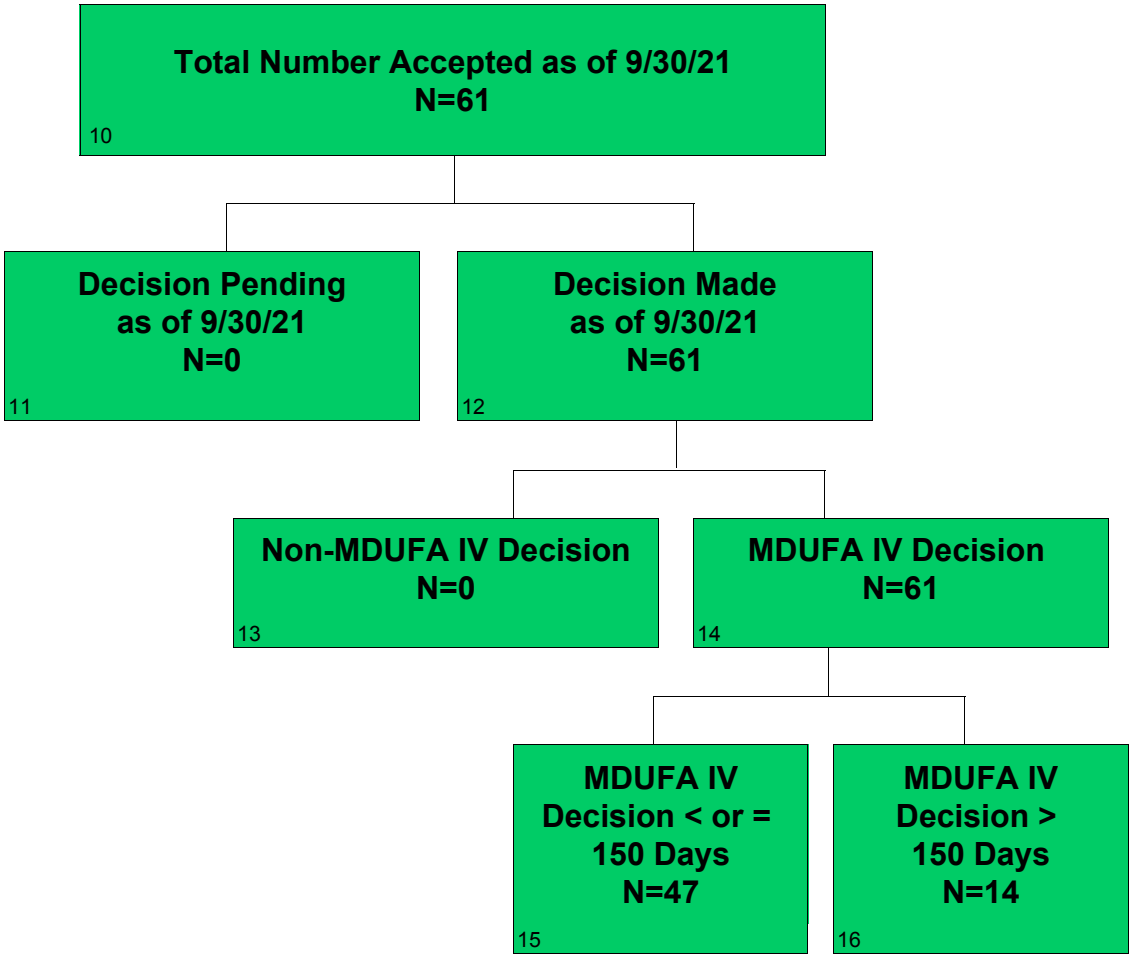


CDRH De Novo - FY 2019
as of 9/30/21

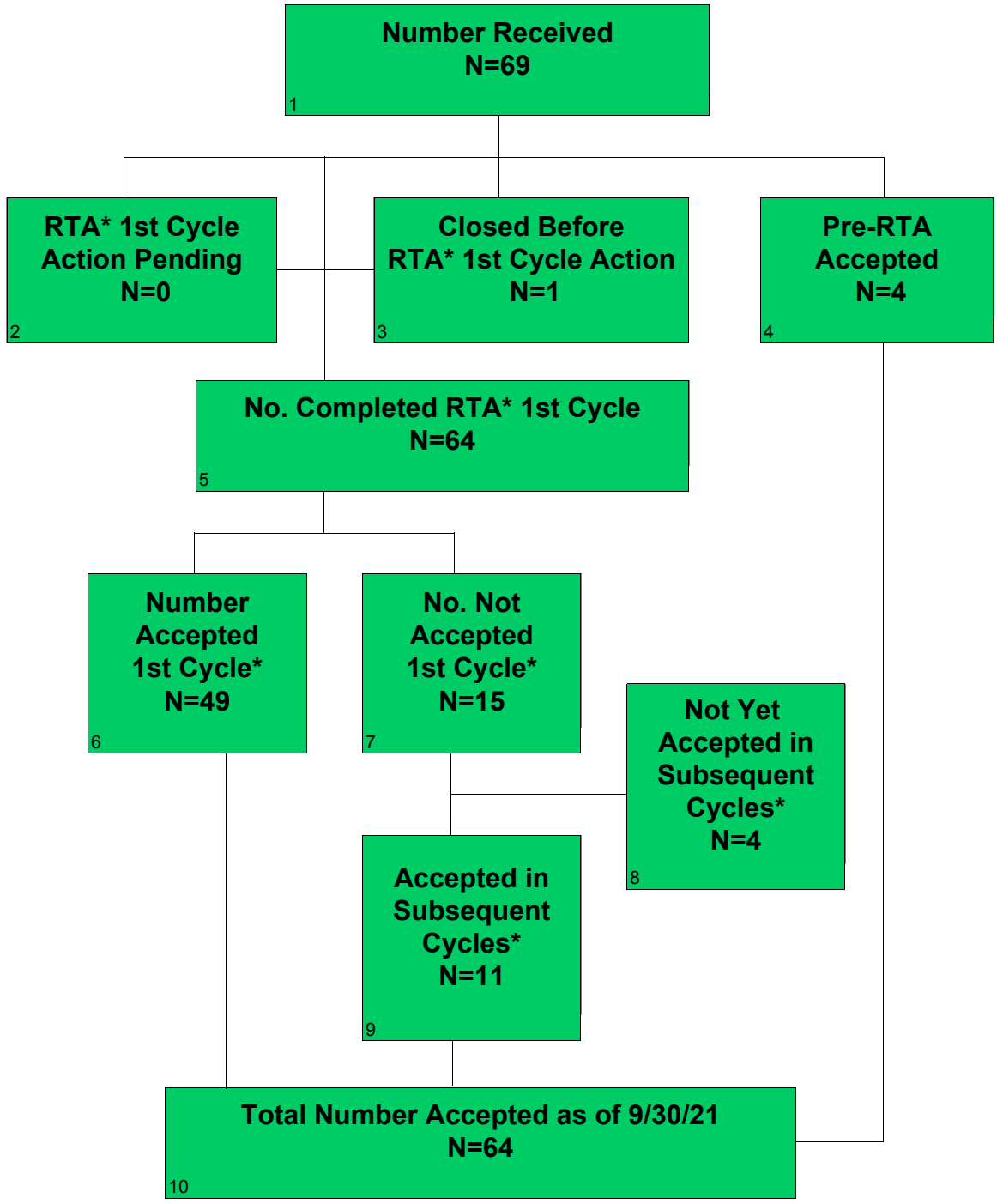


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019
as of 9/30/21 Continued

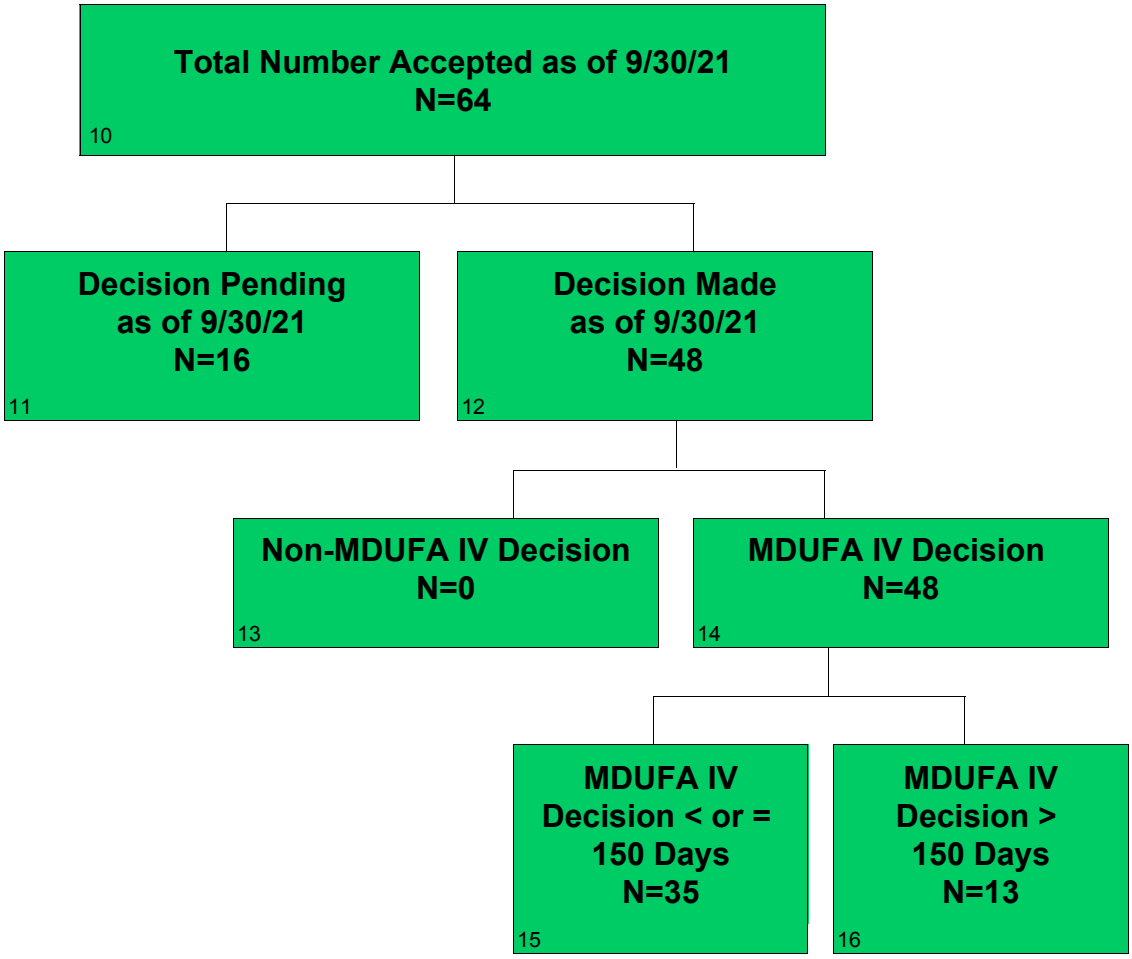


CDRH De Novo - FY 2020
as of 9/30/21

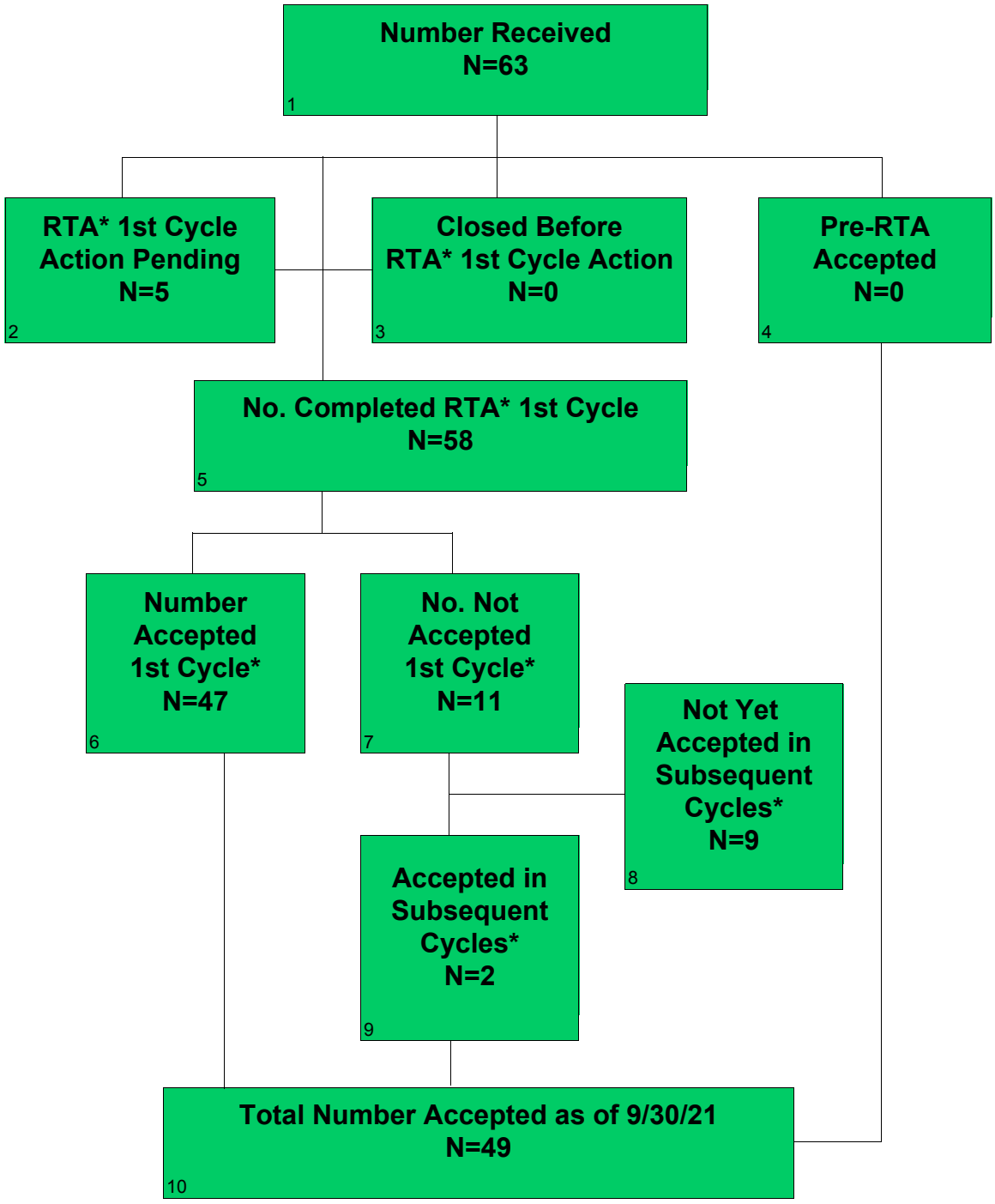


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020
as of 9/30/21 Continued

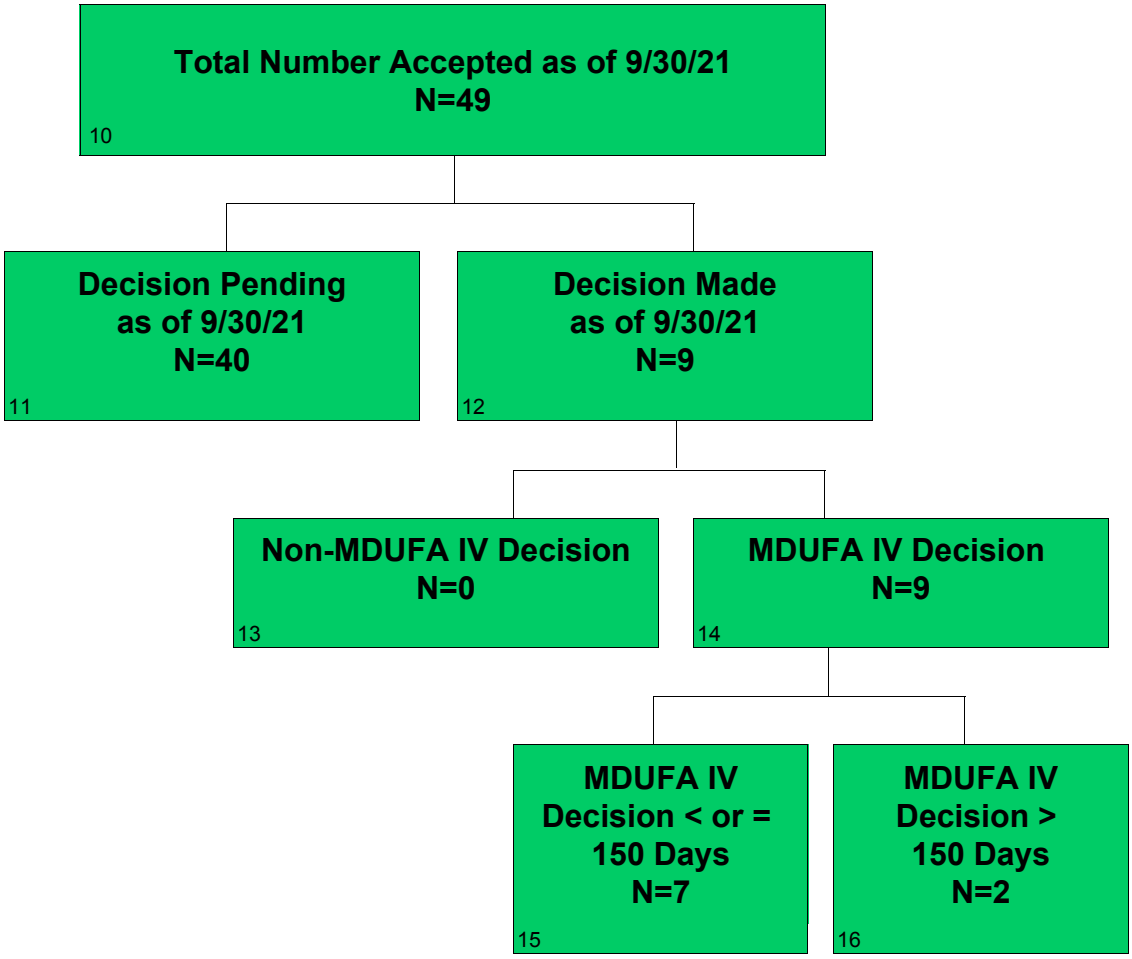


CDRH De Novo - FY 2021
as of 9/30/21



*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 9/30/21 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	63	
Closed Before RTA Action	0	0	1	0	
Number Accepted First RTA Cycle	0	0	46	39	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	3	8	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	5	
Number Not Accepted	0	0	15	11	
Rate of Submissions Not Accepted for Review	N/A	N/A	23.44%	18.97%	

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

Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	56	61	64	49	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	56	61	48	9	
MDUFA IV Decisions Within 150 FDA Days	45	47	35	7	
De Novos Pending MDUFA IV Decision	0	0	16	40	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	7	8	
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	63.64%	41.18%	

Table 8.3 CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.57	1.61	1.77	1.67	
Number With MDUFA IV Decision	56	61	48	9	
Average FDA Days to MDUFA IV Decision	130.13	143.57	157.90	150.56	
20th Percentile FDA Days to MDUFA IV Decision	75	76	97	133	
40th Percentile FDA Days to MDUFA IV Decision	145	130	149	148	
60th Percentile FDA Days to MDUFA IV Decision	150	148	150	149	
80th Percentile FDA Days to MDUFA IV Decision	150	180	189	172	
Maximum FDA Days to MDUFA IV Decision	254	485	403	223	
Average Industry Days to MDUFA IV Decision	110.13	117.44	142.96	52.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	12	0	
40th Percentile Industry Days to MDUFA IV Decision	89	29	94	43	
60th Percentile Industry Days to MDUFA IV Decision	166	177	160	60	
80th Percentile Industry Days to MDUFA IV Decision	180	204	246	84	
Maximum Industry Days to MDUFA IV Decision	389	373	427	141	
Average Total Days to MDUFA IV Decision	240.25	261.02	300.85	202.56	
20th Percentile Total Days to MDUFA IV Decision	145	107	181	133	
40th Percentile Total Days to MDUFA IV Decision	251	179	273	203	
60th Percentile Total Days to MDUFA IV Decision	292	304	334	221	
80th Percentile Total Days to MDUFA IV Decision	324	388	402	274	
Maximum Total Days to MDUFA IV Decision	463	680	651	302	

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	49	
Number With MDUFA IV Decisions	56	61	48	9	
Number With Granted Decisions	25	28	25	5	
Number With Declined Decisions	15	15	13	2	
Number of Withdrawals	10	13	6	2	
Number Deleted	6	5	4	0	
Rate of Granted Decisions	44.64%	45.90%	52.08%	55.56%	
Rate of Declined Decisions	26.79%	24.59%	27.08%	22.22%	
Rate of Withdrawals	17.86%	21.31%	12.50%	22.22%	
Rate of Deleted	10.71%	8.20%	8.33%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	11	14	13	2	
Mean FDA Days for Submissions that Missed the Goal	192.45	248.29	247.77	213.50	
Mean Industry Days for Submissions that Missed the Goal	127.27	218.64	139.38	69.50	

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	13	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	15	14	11	2	
MDUFA IV Decisions Within 150 FDA Days	15	14	8	1	
De Novos Pending MDUFA IV Decision	0	0	6	11	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	4	6	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	53.33%	12.50%	

Table 8.8 CDRH - De Novo Annual General Metrics*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted First RTA Cycle	56	61	64	49	
Average Number of Days to Accept / Refuse to Accept*	0.00	0.00	11.61	12.47	

***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.**

Section 8 De Novo Office Level Metrics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5	13	11	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	10	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	0	0	2	3	
Rate of Submissions Not Accepted for Review	0.00%	0.00%	16.67%	27.27%	

***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	8	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	8	5	9	1	
MDUFA IV Decisions Within 150 FDA Days	5	4	8	1	
De Novos Pending MDUFA IV Decision	0	0	4	7	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	0	
Current Performance Percent Within 150 FDA Days	62.50%	80.00%	72.73%	100.00%	

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	1.78	2.00	
Number With MDUFA IV Decision	8	5	9	1	
Average FDA Days to MDUFA IV Decision	141.25	124.80	127.44	149.00	
20th Percentile FDA Days to MDUFA IV Decision	110	75	70	149	
40th Percentile FDA Days to MDUFA IV Decision	149	119	148	149	
60th Percentile FDA Days to MDUFA IV Decision	153	148	149	149	
80th Percentile FDA Days to MDUFA IV Decision	165	154	150	149	
Maximum FDA Days to MDUFA IV Decision	194	180	199	149	
Average Industry Days to MDUFA IV Decision	106.13	195.20	151.00	75.00	
20th Percentile Industry Days to MDUFA IV Decision	9	185	63	75	
40th Percentile Industry Days to MDUFA IV Decision	45	192	125	75	
60th Percentile Industry Days to MDUFA IV Decision	75	199	157	75	
80th Percentile Industry Days to MDUFA IV Decision	167	206	251	75	
Maximum Industry Days to MDUFA IV Decision	389	212	318	75	
Average Total Days to MDUFA IV Decision	247.38	320.00	278.44	224.00	
20th Percentile Total Days to MDUFA IV Decision	157	268	178	224	
40th Percentile Total Days to MDUFA IV Decision	199	304	300	224	
60th Percentile Total Days to MDUFA IV Decision	260	336	316	224	
80th Percentile Total Days to MDUFA IV Decision	332	360	363	224	
Maximum Total Days to MDUFA IV Decision	463	392	466	224	

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	8	
Number With MDUFA IV Decisions	8	5	9	1	
Number With Granted Decisions	5	2	4	0	
Number With Declined Decisions	2	1	3	1	
Number of Withdrawals	0	0	1	0	
Number Deleted	1	2	1	0	
Rate of Granted Decisions	62.50%	40.00%	44.44%	0.00%	
Rate of Declined Decisions	25.00%	20.00%	33.33%	100.00%	
Rate of Withdrawals	0.00%	0.00%	11.11%	0.00%	
Rate of Deleted	12.50%	40.00%	11.11%	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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	
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	0.00%	0.00%	0.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	9	8	6	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	6	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	0	0	1	2	
Rate of Submissions Not Accepted for Review	0.00%	0.00%	14.29%	33.33%	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	9	8	5	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	5	9	8	0	
MDUFA IV Decisions Within 150 FDA Days	5	8	3	0	
De Novos Pending MDUFA IV Decision	0	0	0	5	
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%	37.50%	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	2.00	0.00	
Number With MDUFA IV Decision	5	9	8	0	
Average FDA Days to MDUFA IV Decision	74.00	144.00	200.50	0.00	
20th Percentile FDA Days to MDUFA IV Decision	32	86	150	0	
40th Percentile FDA Days to MDUFA IV Decision	58	132	162	0	
60th Percentile FDA Days to MDUFA IV Decision	79	148	214	0	
80th Percentile FDA Days to MDUFA IV Decision	98	150	253	0	
Maximum FDA Days to MDUFA IV Decision	148	348	357	0	
Average Industry Days to MDUFA IV Decision	112.40	71.11	161.75	0.00	
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	0	
40th Percentile Industry Days to MDUFA IV Decision	98	6	96	0	
60th Percentile Industry Days to MDUFA IV Decision	171	64	177	0	
80th Percentile Industry Days to MDUFA IV Decision	188	163	279	0	
Maximum Industry Days to MDUFA IV Decision	217	207	427	0	
Average Total Days to MDUFA IV Decision	186.40	215.11	362.25	0.00	
20th Percentile Total Days to MDUFA IV Decision	32	117	286	0	
40th Percentile Total Days to MDUFA IV Decision	173	153	350	0	
60th Percentile Total Days to MDUFA IV Decision	277	213	363	0	
80th Percentile Total Days to MDUFA IV Decision	296	281	448	0	
Maximum Total Days to MDUFA IV Decision	312	526	651	0	

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	
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	6	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	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	2	
Number Not Accepted	0	0	2	0	
Rate of Submissions Not Accepted for Review	0.00%	0.00%	33.33%	0.00%	

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

Table 8.2 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	4	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	4	11	6	0	
MDUFA IV Decisions Within 150 FDA Days	3	5	4	0	
De Novos Pending MDUFA IV Decision	0	0	0	4	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	75.00%	45.45%	66.67%	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	1.82	1.83	0.00	
Number With MDUFA IV Decision	4	11	6	0	
Average FDA Days to MDUFA IV Decision	100.00	186.55	161.50	0.00	
20th Percentile FDA Days to MDUFA IV Decision	57	148	148	0	
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	0	
60th Percentile FDA Days to MDUFA IV Decision	135	191	150	0	
80th Percentile FDA Days to MDUFA IV Decision	149	211	203	0	
Maximum FDA Days to MDUFA IV Decision	151	327	243	0	
Average Industry Days to MDUFA IV Decision	136.75	168.45	116.83	0.00	
20th Percentile Industry Days to MDUFA IV Decision	100	136	21	0	
40th Percentile Industry Days to MDUFA IV Decision	169	175	24	0	
60th Percentile Industry Days to MDUFA IV Decision	175	177	61	0	
80th Percentile Industry Days to MDUFA IV Decision	187	241	222	0	
Maximum Industry Days to MDUFA IV Decision	203	338	363	0	
Average Total Days to MDUFA IV Decision	236.75	355.00	278.33	0.00	
20th Percentile Total Days to MDUFA IV Decision	179	283	209	0	
40th Percentile Total Days to MDUFA IV Decision	293	347	213	0	
60th Percentile Total Days to MDUFA IV Decision	312	368	267	0	
80th Percentile Total Days to MDUFA IV Decision	321	416	372	0	
Maximum Total Days to MDUFA IV Decision	325	617	438	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	4	
Number With MDUFA IV Decisions	4	11	6	0	
Number With Granted Decisions	0	8	3	0	
Number With Declined Decisions	3	3	2	0	
Number of Withdrawals	0	0	0	0	
Number Deleted	1	0	1	0	
Rate of Granted Decisions	0.00%	72.73%	50.00%	N/A	
Rate of Declined Decisions	75.00%	27.27%	33.33%	N/A	
Rate of Withdrawals	0.00%	0.00%	0.00%	N/A	
Rate of Deleted	25.00%	0.00%	16.67%	N/A	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	6	2	0	
Mean FDA Days for Submissions that Missed the Goal	151.00	230.33	223.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	167.00	212.00	17.00	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	8	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	3	4	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	1	1	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted	0	0	3	2	
Rate of Submissions Not Accepted for Review	0.00%	0.00%	42.86%	28.57%	

***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	5	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	5	6	4	0	
MDUFA IV Decisions Within 150 FDA Days	3	4	3	0	
De Novos Pending MDUFA IV Decision	0	0	3	5	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	1	
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	75.00%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.80	1.50	1.50	0.00	
Number With MDUFA IV Decision	5	6	4	0	
Average FDA Days to MDUFA IV Decision	147.40	182.50	126.00	0.00	
20th Percentile FDA Days to MDUFA IV Decision	133	93	100	0	
40th Percentile FDA Days to MDUFA IV Decision	150	98	133	0	
60th Percentile FDA Days to MDUFA IV Decision	151	107	143	0	
80th Percentile FDA Days to MDUFA IV Decision	167	236	157	0	
Maximum FDA Days to MDUFA IV Decision	221	485	172	0	
Average Industry Days to MDUFA IV Decision	90.80	125.83	189.75	0.00	
20th Percentile Industry Days to MDUFA IV Decision	12	0	85	0	
40th Percentile Industry Days to MDUFA IV Decision	65	0	167	0	
60th Percentile Industry Days to MDUFA IV Decision	124	187	247	0	
80th Percentile Industry Days to MDUFA IV Decision	165	195	302	0	
Maximum Industry Days to MDUFA IV Decision	179	373	345	0	
Average Total Days to MDUFA IV Decision	238.20	308.33	315.75	0.00	
20th Percentile Total Days to MDUFA IV Decision	145	93	210	0	
40th Percentile Total Days to MDUFA IV Decision	215	107	331	0	
60th Percentile Total Days to MDUFA IV Decision	275	285	384	0	
80th Percentile Total Days to MDUFA IV Decision	332	609	438	0	
Maximum Total Days to MDUFA IV Decision	400	680	492	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	5	
Number With MDUFA IV Decisions	5	6	4	0	
Number With Granted Decisions	3	1	0	0	
Number With Declined Decisions	1	3	2	0	
Number of Withdrawals	1	1	2	0	
Number Deleted	0	1	0	0	
Rate of Granted Decisions	60.00%	16.67%	0.00%	N/A	
Rate of Declined Decisions	20.00%	50.00%	50.00%	N/A	
Rate of Withdrawals	20.00%	16.67%	50.00%	N/A	
Rate of Deleted	0.00%	16.67%	0.00%	N/A	

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	1	0	
Mean FDA Days for Submissions that Missed the Goal	187.00	360.50	172.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	170.50	284.00	141.00	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	9	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	5	7	
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	2	
Rate of Submissions Not Accepted for Review	0.00%	0.00%	28.57%	22.22%	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	6	6	7	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	13	6	5	4	
MDUFA IV Decisions Within 150 FDA Days	9	6	4	4	
De Novos Pending MDUFA IV Decision	0	0	1	3	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	1	
Current Performance Percent Within 150 FDA Days	69.23%	100.00%	80.00%	80.00%	

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	1.80	1.75	
Number With MDUFA IV Decision	13	6	5	4	
Average FDA Days to MDUFA IV Decision	153.00	113.33	136.40	129.50	
20th Percentile FDA Days to MDUFA IV Decision	104	76	131	117	
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	148	
60th Percentile FDA Days to MDUFA IV Decision	150	136	149	149	
80th Percentile FDA Days to MDUFA IV Decision	219	149	155	149	
Maximum FDA Days to MDUFA IV Decision	254	150	175	150	
Average Industry Days to MDUFA IV Decision	106.08	20.17	78.40	63.50	
20th Percentile Industry Days to MDUFA IV Decision	39	0	11	31	
40th Percentile Industry Days to MDUFA IV Decision	82	0	56	53	
60th Percentile Industry Days to MDUFA IV Decision	164	0	100	60	
80th Percentile Industry Days to MDUFA IV Decision	174	45	134	94	
Maximum Industry Days to MDUFA IV Decision	183	76	169	141	
Average Total Days to MDUFA IV Decision	259.08	133.50	214.80	193.00	
20th Percentile Total Days to MDUFA IV Decision	226	76	142	149	
40th Percentile Total Days to MDUFA IV Decision	266	127	206	203	
60th Percentile Total Days to MDUFA IV Decision	316	136	250	209	
80th Percentile Total Days to MDUFA IV Decision	323	195	288	242	
Maximum Total Days to MDUFA IV Decision	371	225	344	289	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	13	6	6	7	
Number With MDUFA IV Decisions	13	6	5	4	
Number With Granted Decisions	3	2	5	2	
Number With Declined Decisions	7	0	0	1	
Number of Withdrawals	3	4	0	1	
Number Deleted	0	0	0	0	
Rate of Granted Decisions	23.08%	33.33%	100.00%	50.00%	
Rate of Declined Decisions	53.85%	0.00%	0.00%	25.00%	
Rate of Withdrawals	23.08%	66.67%	0.00%	25.00%	
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	6	
Closed Before RTA Action	0	0	0	0	
Number Accepted First RTA Cycle	0	0	5	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	1	
Number Not Accepted	0	0	0	1	
Rate of Submissions Not Accepted for Review	0.00%	0.00%	0.00%	20.00%	

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

Table 8.2 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	5	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	4	4	5	2	
MDUFA IV Decisions Within 150 FDA Days	3	3	5	1	
De Novos Pending MDUFA IV Decision	0	0	0	3	
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%	50.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.75	2.00	1.50	
Number With MDUFA IV Decision	4	4	5	2	
Average FDA Days to MDUFA IV Decision	133.25	144.75	147.40	172.50	
20th Percentile FDA Days to MDUFA IV Decision	122	116	147	154	
40th Percentile FDA Days to MDUFA IV Decision	148	143	150	166	
60th Percentile FDA Days to MDUFA IV Decision	150	144	150	179	
80th Percentile FDA Days to MDUFA IV Decision	150	173	150	191	
Maximum FDA Days to MDUFA IV Decision	151	217	150	204	
Average Industry Days to MDUFA IV Decision	161.00	178.50	132.60	49.00	
20th Percentile Industry Days to MDUFA IV Decision	149	104	62	20	
40th Percentile Industry Days to MDUFA IV Decision	179	175	107	39	
60th Percentile Industry Days to MDUFA IV Decision	180	177	146	59	
80th Percentile Industry Days to MDUFA IV Decision	180	252	179	78	
Maximum Industry Days to MDUFA IV Decision	181	362	245	98	
Average Total Days to MDUFA IV Decision	294.25	323.25	280.00	221.50	
20th Percentile Total Days to MDUFA IV Decision	260	221	209	173	
40th Percentile Total Days to MDUFA IV Decision	278	333	256	205	
60th Percentile Total Days to MDUFA IV Decision	316	380	296	238	
80th Percentile Total Days to MDUFA IV Decision	330	439	329	270	
Maximum Total Days to MDUFA IV Decision	331	505	395	302	

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	5	
Number With MDUFA IV Decisions	4	4	5	2	
Number With Granted Decisions	1	1	3	2	
Number With Declined Decisions	1	3	2	0	
Number of Withdrawals	1	0	0	0	
Number Deleted	1	0	0	0	
Rate of Granted Decisions	25.00%	25.00%	60.00%	100.00%	
Rate of Declined Decisions	25.00%	75.00%	40.00%	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	1	
Mean FDA Days for Submissions that Missed the Goal	151.00	217.00	0.00	204.00	
Mean Industry Days for Submissions that Missed the Goal	180.00	178.00	0.00	98.00	

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	17	
Closed Before RTA Action	0	0	1	0	
Number Accepted First RTA Cycle	0	0	13	8	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	2	7	
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%	6.25%	

***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	15	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	17	20	11	2	
MDUFA IV Decisions Within 150 FDA Days	17	17	8	1	
De Novos Pending MDUFA IV Decision	0	0	8	13	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	5	6	
Current Performance Percent Within 150 FDA Days	100.00%	85.00%	50.00%	12.50%	

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	1.60	1.55	1.50	
Number With MDUFA IV Decision	17	20	11	2	
Average FDA Days to MDUFA IV Decision	125.18	121.60	176.00	171.50	
20th Percentile FDA Days to MDUFA IV Decision	108	73	75	141	
40th Percentile FDA Days to MDUFA IV Decision	127	121	139	161	
60th Percentile FDA Days to MDUFA IV Decision	146	148	150	182	
80th Percentile FDA Days to MDUFA IV Decision	150	150	231	202	
Maximum FDA Days to MDUFA IV Decision	150	243	403	223	
Average Industry Days to MDUFA IV Decision	101.88	105.25	154.00	20.50	
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	8	
40th Percentile Industry Days to MDUFA IV Decision	84	0	96	16	
60th Percentile Industry Days to MDUFA IV Decision	169	168	171	25	
80th Percentile Industry Days to MDUFA IV Decision	179	220	247	33	
Maximum Industry Days to MDUFA IV Decision	189	276	364	41	
Average Total Days to MDUFA IV Decision	227.06	226.85	330.00	192.00	
20th Percentile Total Days to MDUFA IV Decision	137	99	150	149	
40th Percentile Total Days to MDUFA IV Decision	183	150	302	178	
60th Percentile Total Days to MDUFA IV Decision	277	278	402	206	
80th Percentile Total Days to MDUFA IV Decision	313	337	439	235	
Maximum Total Days to MDUFA IV Decision	327	509	596	264	

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	15	
Number With MDUFA IV Decisions	17	20	11	2	
Number With Granted Decisions	10	12	5	1	
Number With Declined Decisions	1	0	2	0	
Number of Withdrawals	5	7	2	1	
Number Deleted	1	1	2	0	
Rate of Granted Decisions	58.82%	60.00%	45.45%	50.00%	
Rate of Declined Decisions	5.88%	0.00%	18.18%	0.00%	
Rate of Withdrawals	29.41%	35.00%	18.18%	50.00%	
Rate of Deleted	5.88%	5.00%	18.18%	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	3	1	
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	332.67	223.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	166.33	41.00	

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	13	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	15	14	11	2	
MDUFA IV Decisions Within 150 FDA Days	15	14	8	1	
De Novos Pending MDUFA IV Decision	0	0	6	11	
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	4	6	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	53.33%	12.50%	

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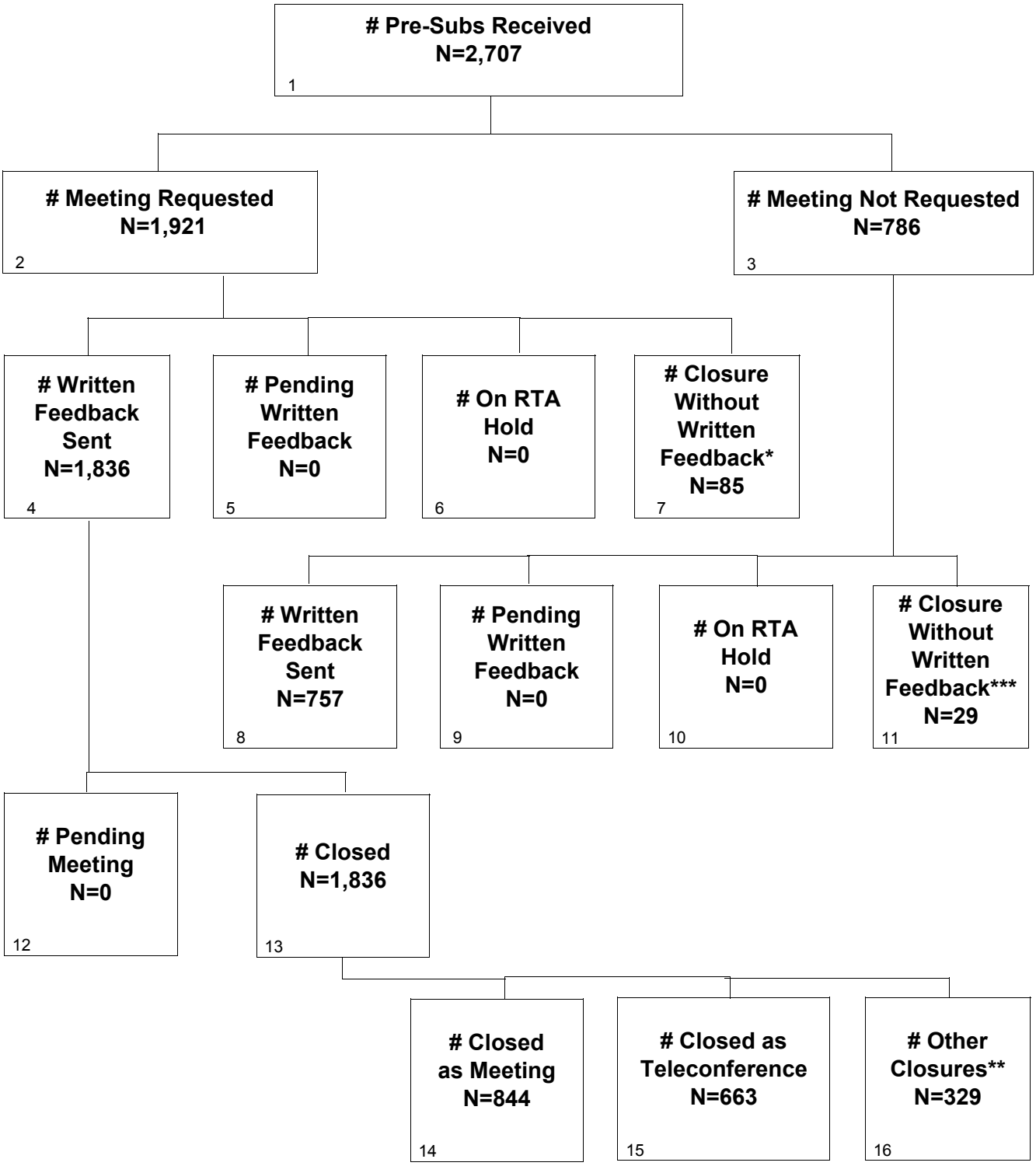
CDRH Pre-Sub - FY 2018
as of 9/30/21



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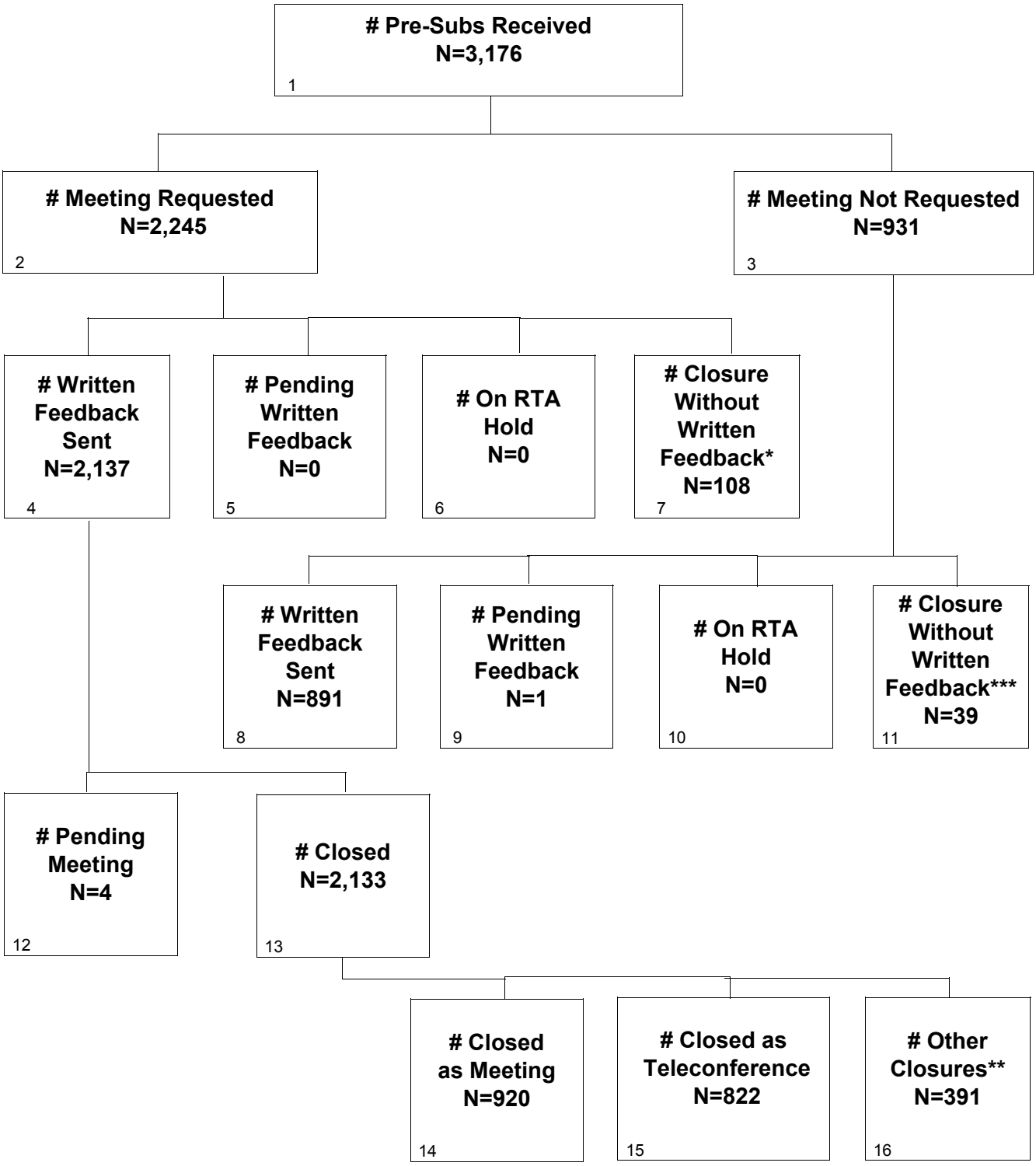
CDRH Pre-Sub - FY 2019
as of 9/30/21



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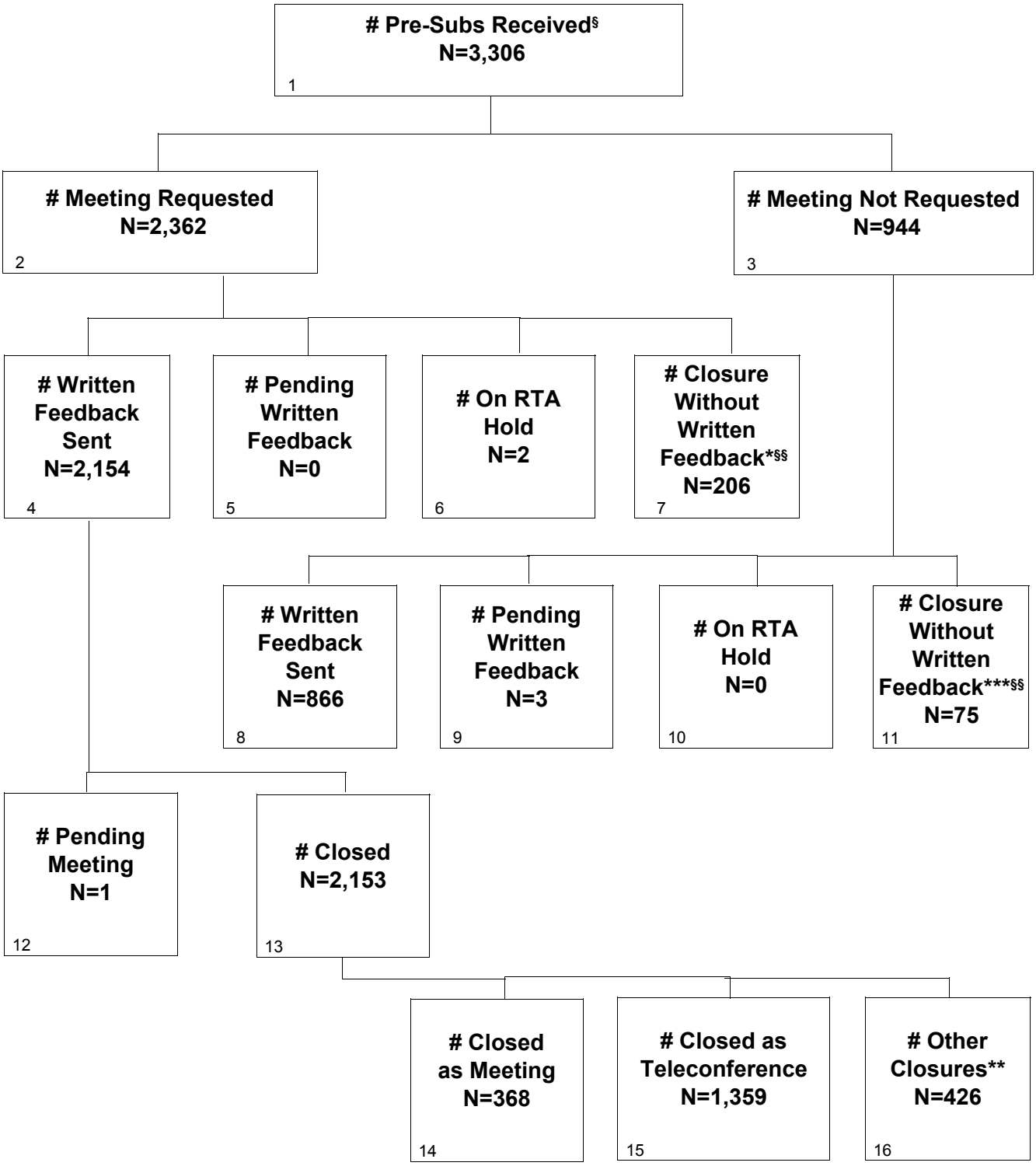
CDRH Pre-Sub - FY 2020
as of 9/30/21



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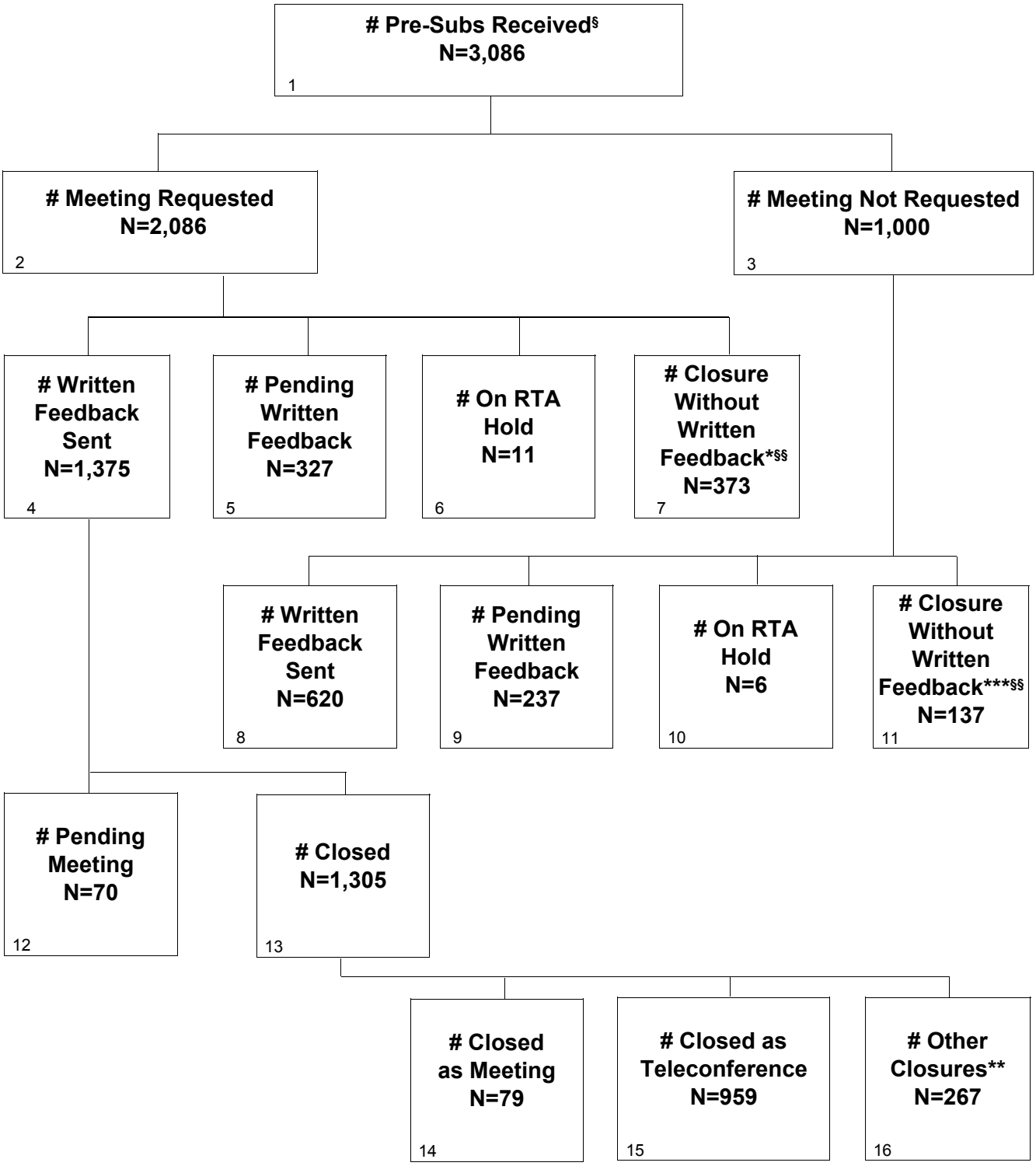
§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.
§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

CDRH Pre-Sub - FY 2021
as of 9/30/21



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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	3,176	3,306	3,086	
Closed Before RTA Action**	27	41	109	385	
Number Accepted First RTA Cycle**	2,565	3,004	3,035	2,388	
Number Without a RTA Review and > 15 Days Since Date Received	49	71	121	213	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	71	
Number Not Accepted	66	60	41	29	
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.28%	1.10%	

***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	3,020	1,995	
Written Feedback Provided Within MDUFA IV Goal	2,439	2,848	2,652	1,651	

***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	3,020	1,995	
Average FDA Days to Written Feedback	58.86	59.93	63.26	64.06	
20th Percentile FDA Days to Written Feedback	49	49	52	50	
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	389	307	

***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	81	
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	43.33	47.04	

***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	1,742	1,727	1,038	
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,113	1,110	666	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	41	
Meeting Minutes Past 15 Days of Meeting	483	559	539	285	
Meeting Minutes Not Submitted and >15 Days Since Meeting	53	70	78	46	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	63.89%	64.27%	66.80%	

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

Section 9 Pre-Sub Office Level Metrics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	319	389	429	400	
Closed Before RTA Action	0	6	5	8	
Number Accepted First RTA Cycle	284	359	406	366	
Number Without a RTA Review and > 15 Days Since Date Received	8	9	10	12	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	10	
Number Not Accepted	27	15	8	4	
Rate of Submissions Not Accepted for Review	8.46%	3.92%	1.89%	1.05%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	298	359	401	310	
Written Feedback Provided Within MDUFA IV Goal	256	314	279	195	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	298	359	401	310	
Average FDA Days to Written Feedback	64.18	64.05	73.33	71.59	
20th Percentile FDA Days to Written Feedback	56	57	62	63	
40th Percentile FDA Days to Written Feedback	64	65	66	67	
60th Percentile FDA Days to Written Feedback	69	69	70	70	
80th Percentile FDA Days to Written Feedback	70	70	74	77	
Maximum FDA Days to Written Feedback	168	119	389	219	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	4	10	17	
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	34.00	42.40	61.94	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	183	224	242	174	
Meeting Minutes Submitted Within 15 Days of Meeting	126	151	151	108	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	8	
Meeting Minutes Past 15 Days of Meeting	50	68	80	50	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	11	8	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.85%	67.41%	62.40%	65.06%	

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	772	
Closed Before RTA Action	6	7	4	7	
Number Accepted First RTA Cycle	506	555	648	720	
Number Without a RTA Review and > 15 Days Since Date Received	12	14	14	23	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	18	
Number Not Accepted	6	6	9	4	
Rate of Submissions Not Accepted for Review	1.15%	1.04%	1.34%	0.54%	

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	613	
Written Feedback Provided Within MDUFA IV Goal	482	535	610	560	

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	613	
Average FDA Days to Written Feedback	53.02	55.51	56.20	57.65	
20th Percentile FDA Days to Written Feedback	39	44	44	45	
40th Percentile FDA Days to Written Feedback	50	53	55	56	
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	190	

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

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

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	324	357	301	
Meeting Minutes Submitted Within 15 Days of Meeting	183	199	212	194	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	6	
Meeting Minutes Past 15 Days of Meeting	119	105	123	87	
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	20	22	14	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	58.47%	61.42%	59.38%	65.76%	

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	381	399	379	
Closed Before RTA Action	5	7	11	30	
Number Accepted First RTA Cycle	307	358	376	318	
Number Without a RTA Review and > 15 Days Since Date Received	11	7	3	16	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	10	
Number Not Accepted	11	9	9	5	
Rate of Submissions Not Accepted for Review	3.34%	2.41%	2.32%	1.47%	

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	353	372	265	
Written Feedback Provided Within MDUFA IV Goal	300	343	352	232	

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	353	372	265	
Average FDA Days to Written Feedback	60.53	60.84	61.36	65.63	
20th Percentile FDA Days to Written Feedback	53	53	51	57	
40th Percentile FDA Days to Written Feedback	61	61	61	64	
60th Percentile FDA Days to Written Feedback	65	66	66	67	
80th Percentile FDA Days to Written Feedback	69	69	70	70	
Maximum FDA Days to Written Feedback	156	148	168	204	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	8	1	8	
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	36.88	36.00	54.00	

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	203	220	150	
Meeting Minutes Submitted Within 15 Days of Meeting	112	125	156	103	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	7	
Meeting Minutes Past 15 Days of Meeting	64	72	61	36	
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	4	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.58%	70.91%	72.03%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	251	278	337	313	
Closed Before RTA Action	4	5	21	119	
Number Accepted First RTA Cycle	234	253	304	160	
Number Without a RTA Review and > 15 Days Since Date Received	6	11	7	27	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	4	
Number Not Accepted	7	9	5	3	
Rate of Submissions Not Accepted for Review	2.83%	3.30%	1.58%	1.58%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	234	256	300	122	
Written Feedback Provided Within MDUFA IV Goal	215	224	264	87	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	234	256	300	122	
Average FDA Days to Written Feedback	60.70	62.62	63.10	65.36	
20th Percentile FDA Days to Written Feedback	52	55	56	51	
40th Percentile FDA Days to Written Feedback	59	63	62	62	
60th Percentile FDA Days to Written Feedback	65	66	66	66	
80th Percentile FDA Days to Written Feedback	69	70	70	71	
Maximum FDA Days to Written Feedback	121	106	268	139	

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	15	
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	42.80	41.73	

Table 9.5 OHT4 - Office of Surgical and Infection Control Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	124	142	180	67	
Meeting Minutes Submitted Within 15 Days of Meeting	92	95	118	45	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	4	
Meeting Minutes Past 15 Days of Meeting	26	42	50	14	
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5	12	4	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.19%	66.90%	65.56%	71.43%	

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	337	
Closed Before RTA Action	3	2	2	1	
Number Accepted First RTA Cycle	232	253	285	303	
Number Without a RTA Review and > 15 Days Since Date Received	7	10	16	14	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	11	
Number Not Accepted	7	12	5	8	
Rate of Submissions Not Accepted for Review	2.85%	4.36%	1.63%	2.46%	

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	297	245	
Written Feedback Provided Within MDUFA IV Goal	202	219	184	170	

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	297	245	
Average FDA Days to Written Feedback	64.73	72.86	80.73	75.12	
20th Percentile FDA Days to Written Feedback	58	63	65	64	
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	84	78	
Maximum FDA Days to Written Feedback	172	397	385	307	

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	14	
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00	37.50	37.79	

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	172	176	126	
Meeting Minutes Submitted Within 15 Days of Meeting	99	103	107	77	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	6	
Meeting Minutes Past 15 Days of Meeting	50	58	62	37	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	11	7	6	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.46%	59.88%	60.80%	64.17%	

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	239	
Closed Before RTA Action	1	3	1	2	
Number Accepted First RTA Cycle	127	160	168	224	
Number Without a RTA Review and > 15 Days Since Date Received	5	6	7	5	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	5	
Number Not Accepted	0	2	3	3	
Rate of Submissions Not Accepted for Review	0.00%	1.19%	1.69%	1.29%	

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	188	
Written Feedback Provided Within MDUFA IV Goal	115	152	169	185	

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	188	
Average FDA Days to Written Feedback	61.91	61.14	62.34	58.96	
20th Percentile FDA Days to Written Feedback	52	55	57	44	
40th Percentile FDA Days to Written Feedback	62	63	63	60	
60th Percentile FDA Days to Written Feedback	67	66	69	65	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	106	92	105	78	

Table 9.4 OHT6 - Office of Orthopedic Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	4	0	2	
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	43.75	0.00	31.00	

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	82	
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	61	51	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	2	
Meeting Minutes Past 15 Days of Meeting	19	29	15	26	
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	3	3	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.22%	63.75%	

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	1098	979	646	
Closed Before RTA Action	8	11	65	218	
Number Accepted First RTA Cycle	875	1066	848	297	
Number Without a RTA Review and > 15 Days Since Date Received	0	14	64	116	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	13	
Number Not Accepted	8	7	2	2	
Rate of Submissions Not Accepted for Review	0.91%	0.64%	0.22%	0.48%	

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	252	
Written Feedback Provided Within MDUFA IV Goal	869	1,061	794	222	

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	1072	817	252	
Average FDA Days to Written Feedback	57.35	56.61	58.79	61.20	
20th Percentile FDA Days to Written Feedback	48	45	50	46	
40th Percentile FDA Days to Written Feedback	57	56	58	56	
60th Percentile FDA Days to Written Feedback	63	63	64	63	
80th Percentile FDA Days to Written Feedback	68	68	69	68	
Maximum FDA Days to Written Feedback	85	307	190	295	

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	5	
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	35.60	53.50	57.60	

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	138	
Meeting Minutes Submitted Within 15 Days of Meeting	304	387	305	88	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	8	
Meeting Minutes Past 15 Days of Meeting	155	185	148	35	
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	18	20	7	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.87%	65.59%	64.48%	67.69%	

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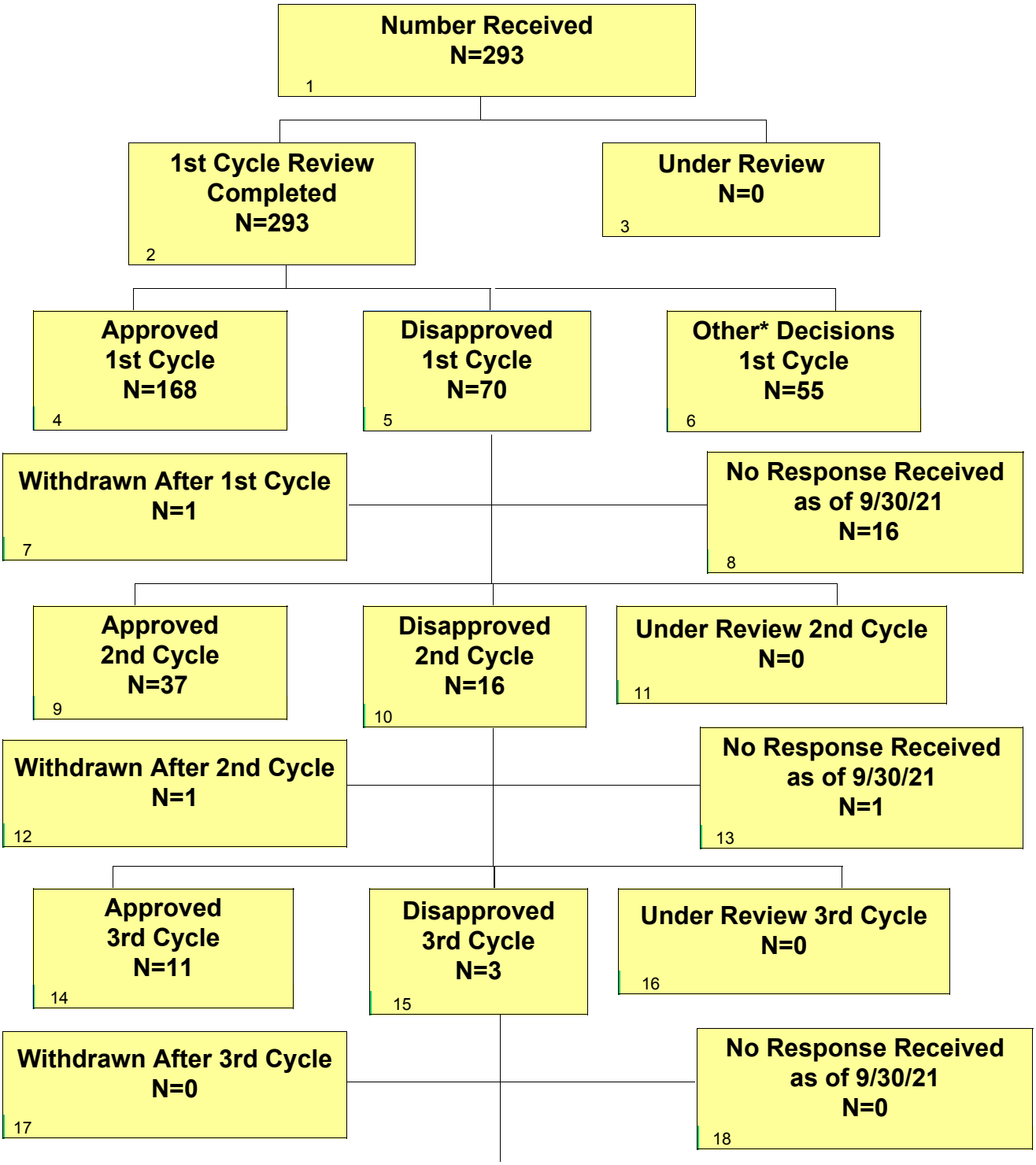
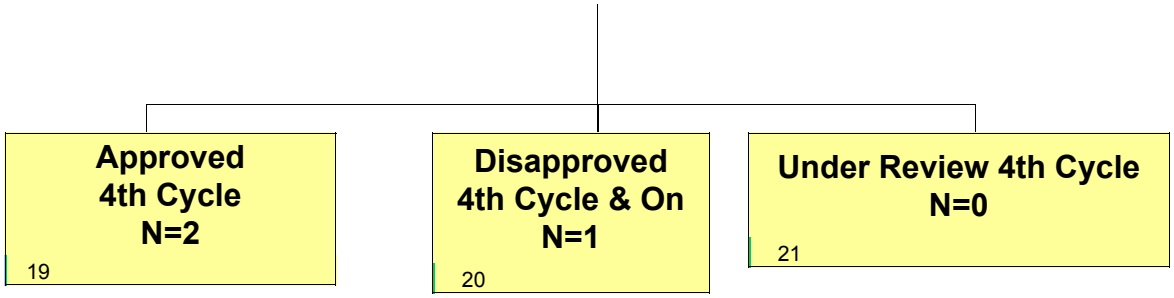
CDRH IDEs - FY 2018
as of 9/30/21

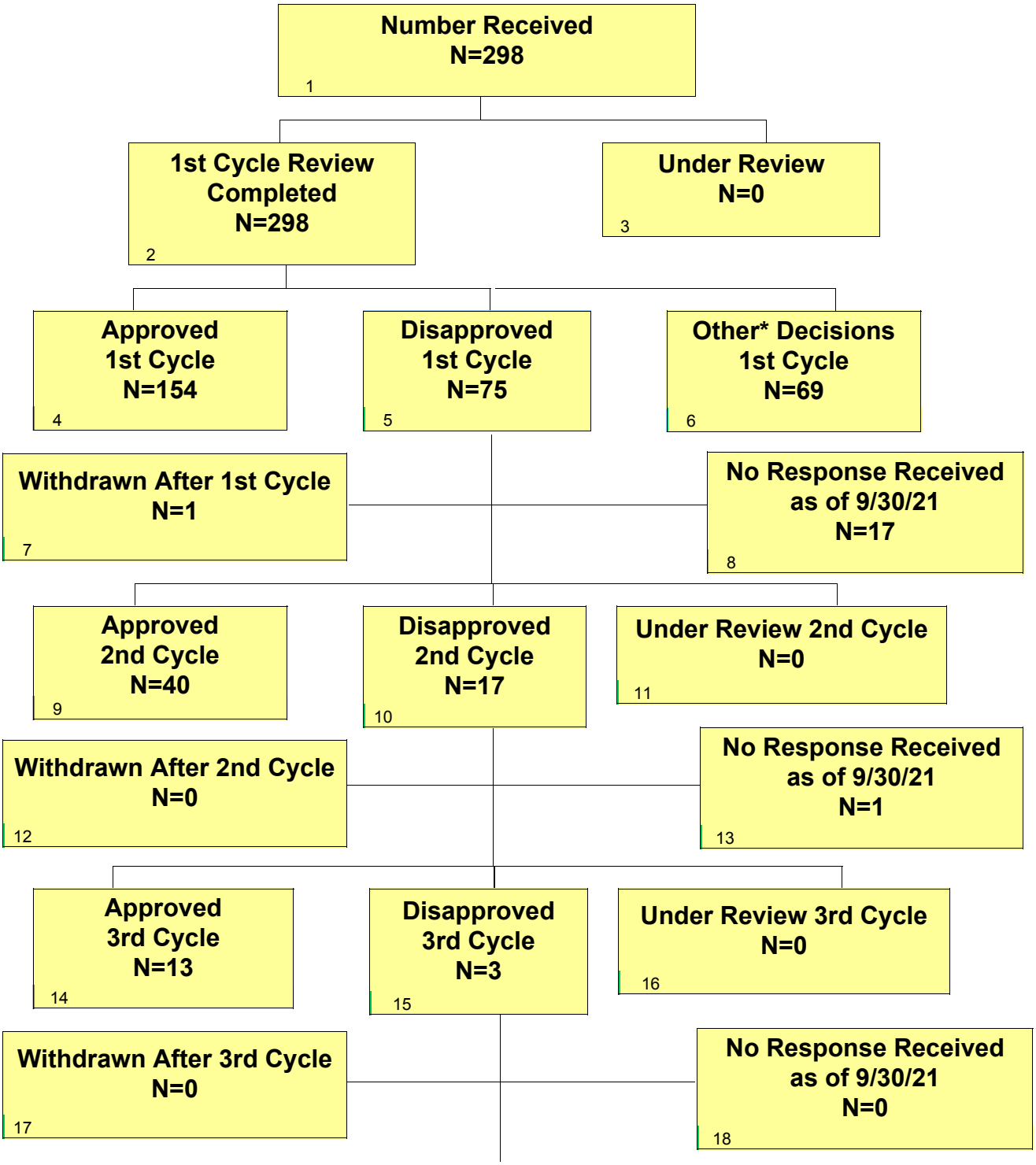


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2018
as of 9/30/21

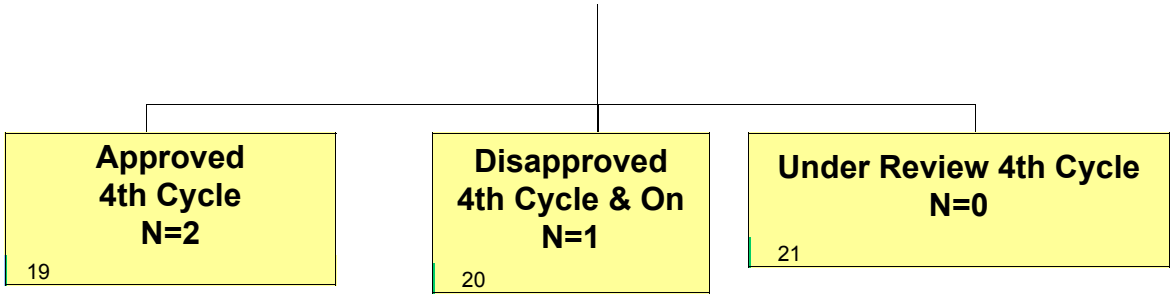


CDRH IDEs - FY 2019
as of 9/30/21

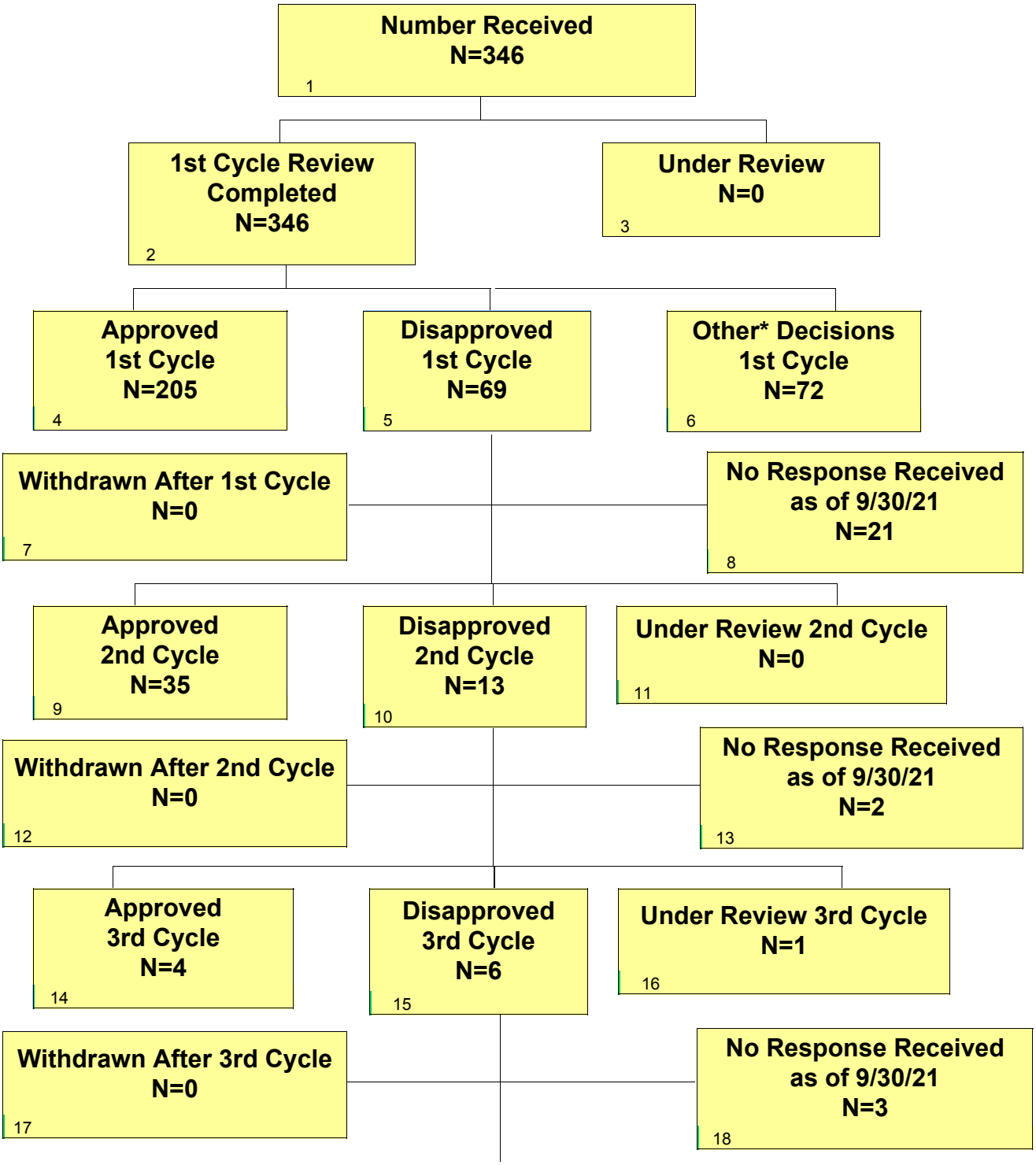


*** Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2019
as of 9/30/21

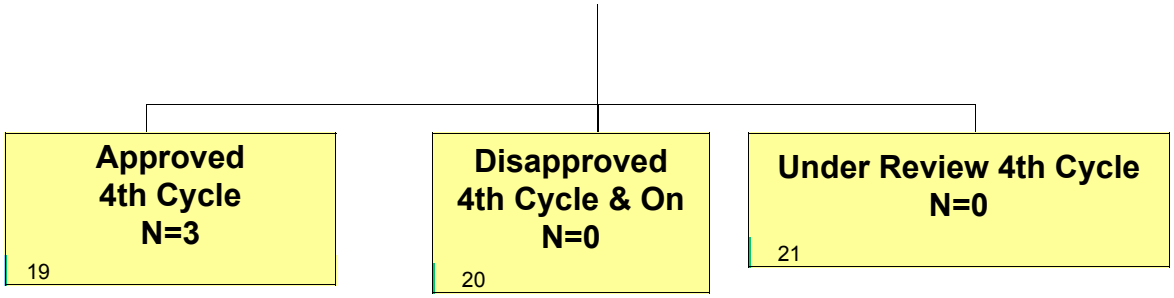


CDRH IDEs - FY 2020
as of 9/30/21

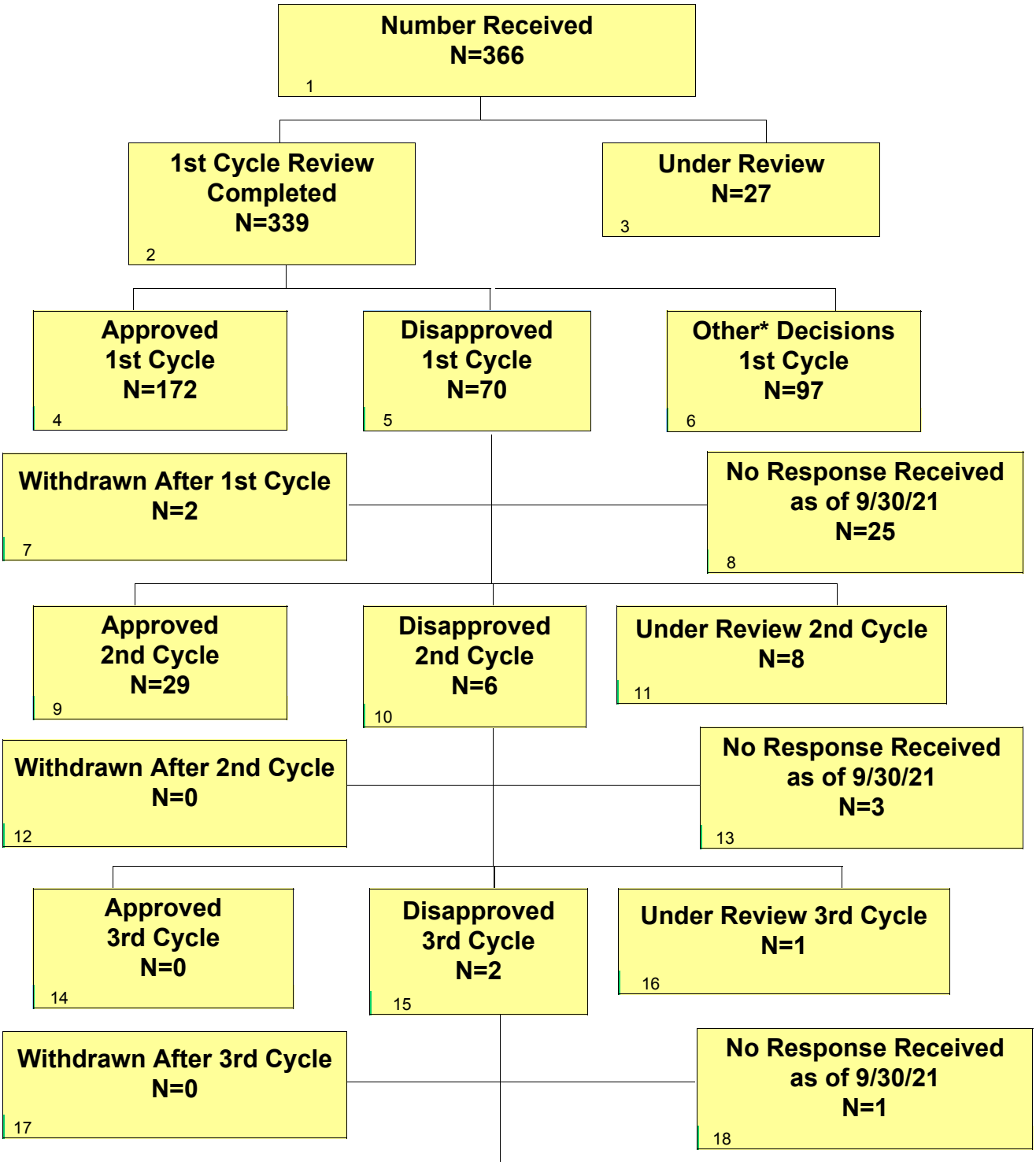


*** Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2020
as of 9/30/21



CDRH IDEs - FY 2021
as of 9/30/21



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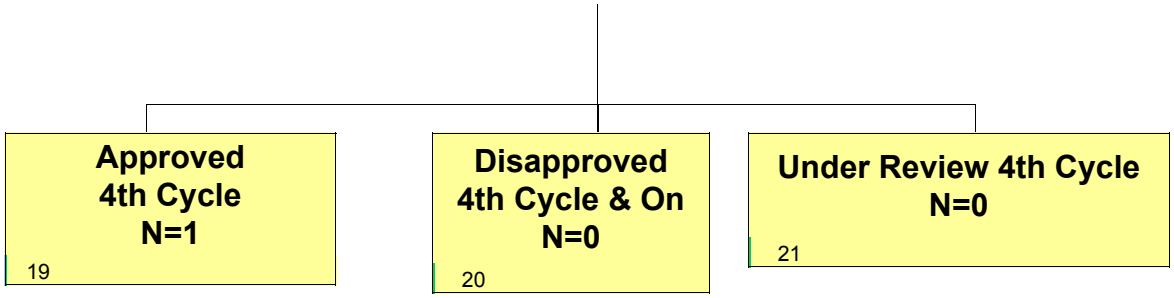
CDRH IDEs - FY 2021
as of 9/30/21



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	366	
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.34	1.21	1.16	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.34	0.21	0.16	

Section 10 IDE - Office Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	44	35	41	37	
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.36	1.21	1.29	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.36	0.21	0.29	

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	76	
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.43	1.41	1.29	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.43	0.41	0.29	

Table 10.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	33	43	47	47	
Average Number of Cycles to IDE Approval or Conditional Approval	1.60	1.50	1.45	1.36	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.60	0.50	0.45	0.36	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	29	32	42	42	
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.11	1.04	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.11	0.04	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	62	70	66	59	
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.11	1.10	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.11	0.10	

Table 10.1 OHT6 - Office of Orthopedic Devices
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	16	11	17	19	
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	86	
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	

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Section 11 CLIA Waiver Annual Metrics

Table 11.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	4	8 (12)	1	3 (4)	
Withdrawn prior to SI	0	1 (1)	0	0 (0)	
SI within 90 FDA days	4	7 (11)	0	0 (0)	
SI over 90 FDA days	0	0 (0)	0	3 (3)	
SI pending within 90 FDA days	0	0 (0)	0	0 (0)	
SI pending over 90 FDA days	0	0 (0)	0	0 (0)	
Denial without SI	0	0 (0)	1	0 (1)	
Current SI Performance Percent within 90 FDA days	N/A*	100.00%	N/A*	N/A*	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	7	0	3	
Average number of FDA days to Substantive Interaction	59.50	59.86	0.00	177.67	
20th Percentile FDA days to Substantive Interaction	39	49	0	145	
40th Percentile FDA days to Substantive Interaction	48	55	0	180	
60th Percentile FDA days to Substantive Interaction	67	65	0	203	
80th Percentile FDA days to Substantive Interaction	79	84	0	214	
Maximum FDA days to Substantive Interaction	88	90	0	225	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	4	8 (12)	1	3 (4)	
Non-MDUFA IV Decisions	0	1 (1)	0	0 (0)	
MDUFA IV Decisions	4	8 (12)	1	1 (2)	
MDUFA IV Decisions within 150 FDA Days	4	7 (11)	0	1 (1)	
CLIA Waiver Applications pending MDUFA IV Decision	0	0 (0)	0	2 (2)	
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0	0 (0)	0	2 (2)	
Current Performance Percent within 150 FDA Days	N/A*	91.67%	N/A*	N/A*	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decisions	0	0	0	0	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions within 320 FDA Days	0	0	0	0	
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0	0	
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0	0	
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*	N/A*	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA decision	4	8	1	1	
Average FDA days to MDUFA IV decision	119.50	82.25	462.00	111.00	
20th Percentile FDA days to MDUFA IV decision	102	47	462	111	
40th Percentile FDA days to MDUFA IV decision	143	50	462	111	
60th Percentile FDA days to MDUFA IV decision	145	64	462	111	
80th Percentile FDA days to MDUFA IV decision	147	80	462	111	
Maximum FDA days to MDUFA IV decision	148	281	462	111	
Average Industry days to MDUFA IV decision	150.50	145.38	0.00	0.00	
20th Percentile Industry days to MDUFA IV decision	86	0	0	0	
40th Percentile Industry days to MDUFA IV decision	151	138	0	0	
60th Percentile Industry days to MDUFA IV decision	173	180	0	0	
80th Percentile Industry days to MDUFA IV decision	219	180	0	0	
Maximum Industry days to MDUFA IV decision	278	450	0	0	
Average Total days to MDUFA IV decision	270.00	227.63	462.00	111.00	
20th Percentile Total days to MDUFA IV decision	192	55	462	111	
40th Percentile Total days to MDUFA IV decision	236	167	462	111	
60th Percentile Total days to MDUFA IV decision	276	228	462	111	
80th Percentile Total days to MDUFA IV decision	342	260	462	111	
Maximum Total days to MDUFA IV decision	420	731	462	111	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA decision	0	0	0	0	
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	

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

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

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	11	5	6 (11)	4	
Withdrawn prior to SI	0	0	0	0	
SI within 90 FDA days	11	5	6 (11)	0	
SI over 90 FDA days	0	0	0	1	
SI pending within 90 FDA days	0	0	0	0	
SI pending over 90 FDA days	0	0	0	3	
Denial without SI	0	0	0	0	
Current SI Performance Percent within 90 FDA days*	100.00%	N/A*	100.00%	N/A*	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	11	5	6	1	
Average number of FDA days to Substantive Interaction	85.18	86.60	85.00	92.00	
20th Percentile FDA days to Substantive Interaction	84	87	82	92	
40th Percentile FDA days to Substantive Interaction	87	88	86	92	
60th Percentile FDA days to Substantive Interaction	87	88	88	92	
80th Percentile FDA days to Substantive Interaction	88	88	90	92	
Maximum FDA days to Substantive Interaction	90	88	90	92	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Eligible for MDUFA IV Decision	11	5	6 (11)	4	
Non-MDUFA IV Decisions	0	1	0 (1)	0	
MDUFA IV Decisions	11	5	4 (9)	1	
MDUFA IV Decisions within 180 FDA Days	11	4	4 (8)	1	
CLIA Waiver Applications pending MDUFA IV Decision	0	0	2 (2)	3	
CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	0	0	2 (2)	3	
Current Performance Percent within 180 FDA Days*	100.00%	N/A*	72.73%	N/A*	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decision	0	0	0	0	
Non-MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions	0	0	0	0	
MDUFA IV Decisions with in 320 FDA Days	0	0	0	0	
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0	0	
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0	0	
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*	N/A*	

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV decision	11	5	4	1	
Average FDA days to MDUFA IV decision	139.64	142.60	121.00	92.00	
20th Percentile FDA days to MDUFA IV decision	87	88	79	92	
40th Percentile FDA days to MDUFA IV decision	140	137	95	92	
60th Percentile FDA days to MDUFA IV decision	176	173	135	92	
80th Percentile FDA days to MDUFA IV decision	180	180	161	92	
Maximum FDA days to MDUFA IV decision	180	190	180	92	
Average Industry days to MDUFA IV decision	42.18	142.20	223.25	178.00	
20th Percentile Industry days to MDUFA IV decision	0	69	86	178	
40th Percentile Industry days to MDUFA IV decision	0	139	190	178	
60th Percentile Industry days to MDUFA IV decision	0	177	327	178	
80th Percentile Industry days to MDUFA IV decision	110	198	374	178	
Maximum Industry days to MDUFA IV decision	180	270	376	178	
Average Total days to MDUFA IV decision	181.82	284.80	344.25	270.00	
20th Percentile Total days to MDUFA IV decision	87	243	208	270	
40th Percentile Total days to MDUFA IV decision	155	263	271	270	
60th Percentile Total days to MDUFA IV decision	177	302	405	270	
80th Percentile Total days to MDUFA IV decision	270	353	478	270	
Maximum Total days to MDUFA IV decision	354	358	521	270	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV decision	0	0	0	0	
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	

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

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

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

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

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

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

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

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

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

Tables 1.5 and Tables 1.5.x PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals - Definitions

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

Table 1.6 and Tables 1.6.x PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals - Definitions

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

Table 1.7 and Tables 1.7.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions

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

Table 1.8 and Tables 1.8.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions

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

Table 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions

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

Table 1.10 and Tables 1.10.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions

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

Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions

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

Tables 1.13 and Tables 1.13.x LDT PMA Originals & Panel-Track Supplements Metric* MDUFA Decision Performance Goals - Definitions

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

*Includes submissions that went to panel

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

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

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

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

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

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

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

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

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

Table 2.4 and Tables 2.4.x PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions

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

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions

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

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

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

Table 3.3 and Tables 3.3.x Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions

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

Section 5 PMA Annual Metrics and Goals

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

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

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

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

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

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

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

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

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision in the first RTA review cycle.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that received a "Did not perform RTA" (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15th day of that cycle..
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage of the sum of the Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

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

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

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

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

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

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

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

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

Table 6.6 and Tables 6.6.x 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decision – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 De Novo MDUFA IV Performance

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

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage the sum of the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

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

Tables 8.2 and Tables 8.2.x De Novo MDUFA IV Decision Performance Goals – Definitions

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

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

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

Table 8.4 and Tables 8.4.x De Novo Performance Metrics – Rate of Grant, Decline, Withdrawal and Delete Decisions – Definitions

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

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

#	Measure	Description
1	Number of Submissions that Mssed the Goal	Number of De Novo submissions accepted in this fiscal year that had a MDUFA IV decision with more than 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

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

Section 9 Pre-Submissions

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

#	Measure	Description
1	Number Received	Number of Pre-Subs submissions received in this fiscal year.
2	Closed before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days Since Date Received	Number Received (line 1) that had "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review.
5	Number Without a RTA Review and <= 15 days Since Date Received	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that had "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Written Feedback Provided Within MDUFA IV Goal	Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request).

Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions

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

Table 9.4 and Tables 9.4.x Pre-Submissions Performance Metrics Meeting Scheduling-Definitions

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

Table 9.5 and Tables 9.5.x Pre-Submissions Performance Metrics Meeting Minutes- Definitions

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CBER Performance Data ----
Actions through 30 Sep 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	66.67%	33.33%	0.00%	0.00%	

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	82	81	86	
40th Percentile FDA Days to Substantive Interaction	50	84	89	86	
60th Percentile FDA Days to Substantive Interaction	88	84	89	86	
80th Percentile FDA Days to Substantive Interaction	88	90	104	86	
Maximum FDA Days to Substantive Interaction	88	90	104	86	

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	1	
MDUFA IV Decision Goal Met	2	3	3	1	
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%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
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	1	
Average FDA Days to MDUFA IV Decision	164.50	162.33	164.67	177.00	
20th Percentile FDA Days to MDUFA IV Decision	156	140	150	177	
40th Percentile FDA Days to MDUFA IV Decision	156	171	169	177	
60th Percentile FDA Days to MDUFA IV Decision	173	171	169	177	
80th Percentile FDA Days to MDUFA IV Decision	173	176	175	177	
Maximum FDA Days to MDUFA IV Decision	173	176	175	177	
Average Industry Days to MDUFA IV Decision	319.50	161.00	55.33	0.00	
20th Percentile Industry Days to MDUFA IV Decision	105	56	166	0	
40th Percentile Industry Days to MDUFA IV Decision	105	177	166	0	
60th Percentile Industry Days to MDUFA IV Decision	534	177	166	0	
80th Percentile Industry Days to MDUFA IV Decision	534	250	166	0	
Maximum Industry Days to MDUFA IV Decision	534	250	166	0	
Average Total Days to MDUFA IV Decision	484.00	323.33	220.00	177.00	
20th Percentile Total Days to MDUFA IV Decision	261	196	150	177	
40th Percentile Total Days to MDUFA IV Decision	261	348	169	177	
60th Percentile Total Days to MDUFA IV Decision	707	348	169	177	
80th Percentile Total Days to MDUFA IV Decision	707	426	341	177	
Maximum Total Days to MDUFA IV Decision	707	426	341	177	

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	1	
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	50.00%	33.33%	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	7	
SI Goal Met	8	5	8	3	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	4	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	5	8	7	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	8	5	8	1	
MDUFA IV Decision Goal Met	8	5	8	1	
Supplements Pending MDUFA IV Decision	0	0	0	6	
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 CBER - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5	8	7	
Number with MDUFA IV Decision	8	5	8	1	
Number of Not Approvable	0	0	1	0	
Rate of Not Approvable	0.00%	0.00%	12.50%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	
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	9	
Non-MDUFA IV Decision	0	0	0	0	
MDUFA IV Decision	3	2	5	9	
MDUFA IV Decision Goal Met	3	2	5	9	
Supplements Pending MDUFA IV Decision	0	0	0	0	
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 CBER - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2	5	9	
Number With MDUFA IV Decision	3	2	5	9	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	0.00%	

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 5 PMA Annual Metrics and Goals

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

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0	0	0	
Original PMAs (Panel) – Priority	0	0	0	0	
Original PMAs (No Panel) – Priority	0	0	0	0	
Original PMAs (Panel) – Non-Priority	0	0	0	0	
Original PMAs (No Panel) – Non-Priority	3	3	2	0	
Panel-Tracked Supplements (Panel) – Priority	0	0	0	0	
Panel-Tracked Supplements (No Panel) – Priority	0	0	0	0	
Panel-Tracked Supplements (Panel) – Non-Priority	0	0	0	0	
Panel-Tracked Supplements (No Panel) – Non-Priority	0	0	1	1	
PMA Modules	7	1	0	0	
180-Day Supplements	8	5	8	7	
Real-Time Supplements	3	2	5	9	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	3	1	
Number with a decision (MDUFA or Non-MDUFA)	2	3	3	1	
% of FY closed	100.00%	100.00%	100.00%	100.00%	

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	54	50	45	
Closed Before RTA Action	0	0	1	1	
Number Accepted	40	38	34	35	
Number Without a RTA Review and > 15 Days Since Date Received	2	1	1	3	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted	11	15	14	5	
Rate of Submissions Not Accepted for Review	20.75%	27.78%	28.57%	11.63%	

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	39	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	49	51	43	35	
SI Over 60 FDA Days	0	0	1	0	
SI Pending Within 60 FDA Days	0	0	0	4	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	97.73%	100.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	49	51	44	35	
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.98	52.80	
20th Percentile FDA Days to Substantive Interaction	43	21	21	55	
40th Percentile FDA Days to Substantive Interaction	57	53	55	58	
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	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	39	
Non-MDUFA IV Decision	6	5	5	0	
MDUFA IV Decision (SE/NSE)	43	46	37	21	
MDUFA IV Decision Within 90 FDA Days	43	46	37	21	
510(k)s Pending MDUFA IV Decision	0	0	2	18	
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%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.30	1.48	1.24	1.09	
Number With MDUFA IV Decision	43	46	37	21	
Average Number of FDA Days to MDUFA IV Decision	75.58	67.48	64.08	68.57	
20th Percentile FDA Days to MDUFA IV Decision	65	28	30	30	
40th Percentile FDA Days to MDUFA IV Decision	85	77	65	79	
60th Percentile FDA Days to MDUFA IV Decision	88	87	82	81	
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	25.26	75.76	16.95	1.81	
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	78	0	0	
80th Percentile Industry Days to MDUFA IV Decision	59	179	29	0	
Maximum Industry Days to MDUFA IV Decision	178	389	199	25	
Average Number of Total Days to MDUFA IV Decision	100.84	143.24	81.05	70.38	
20th Percentile Total Days to MDUFA IV Decision	76	59	30	30	
40th Percentile Total Days to MDUFA IV Decision	86	87	65	79	
60th Percentile Total Days to MDUFA IV Decision	90	141	82	81	
80th Percentile Total Days to MDUFA IV Decision	147	269	105	89	
Maximum Total Days to MDUFA IV Decision	268	463	287	114	

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	39	
Number With MDUFA IV Decision	43	46	37	21	
Number of SE Decision	43	43	35	21	
Number of NSE Decision	0	3	2	0	
Number of Withdrawal	2	4	4	0	
Number of Deleted	3	1	1	0	
Rate of SE Decision	100.00%	93.48%	94.59%	100.00%	
Rate of NSE Decision	0.00%	6.52%	5.41%	0.00%	
Rate of Withdrawal	4.08%	7.84%	9.09%	0.00%	
Rate of Deleted	6.12%	1.96%	2.27%	0.00%	

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	
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 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	18	
Non-MDUFA IV Decision	0	1	0	0	
MDUFA IV Decision (SE/NSE)	15	16	7	8	
MDUFA IV Decision Within 90 FDA Days	15	16	7	8	
510(k)s Pending MDUFA IV Decision	0	0	0	10	
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%	

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	49	51	44	39	
Number of Traditional Submissions	41	35	34	35	
Number of Special Submissions	8	16	10	6	
Number of Abbreviated Submissions	0	0	0	0	
Average Number of Days to Accept/Refuse to Accept	12.69	12.57	12.57	11.67	
Number of Third Party Submissions	0	0	0	0	

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	124 Days	120 Days	116 Days	112 Days	108 Days
Number Accepted	49	51	44	39	
Currently Under Review	-	0	2	18	
Number With Non-MDUFA IV Decision	6	5	5	0	
Number With MDUFA IV Decision	43	46	37	21	
Percent of Cohort Closed	100.00%	100.00%	94.87%	53.85%	
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	41	44	35	19	
Average Total Time to MDUFA IV Decision	100.84	143.24	81.05	70.38	

Table 7.3 CBER - 510(k) Third Party Performance

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	0	0	0	0	
90th Percentile FDA Days to MDUFA IV Decision	0	0	0	0	

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 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 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	100%	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	2.00	0.00	0.00	
Number With MDUFA IV Decision	0	1	0	0	
Average FDA Days to MDUFA IV Decision	0.00	150.00	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	81.00	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	231.00	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	100.00%	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	100.00%	N/A	N/A	

Table 8.8 CBER - De Novo Annual General Metrics*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted First RTA Cycle	N/A	N/A	0	0	
Average Number of Days to Accept / Refuse to Accept*	N/A	N/A	0	0	

***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.**

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	76	77	77	80	
Closed Before RTA Action	5	3	10	6	
Number Accepted First RTA Cycle	69	70	65	64	
Number Without a RTA Review and > 15 Days Since Date Received**	1	3	1	6	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	3	
Number Not Accepted	1	1	1	1	
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.49%	1.41%	

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	59	
Written Feedback Provided Within MDUFA IV Goal	68	71	63	57	

*** Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have resulted in missed MDUFA goals.**

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	59	
Average FDA Days to Written Feedback	57.86	61.00	56.70	59.80	
20th Percentile FDA Days to Written Feedback	47	55	48	53	
40th Percentile FDA Days to Written Feedback	58	60	58	62	
60th Percentile FDA Days to Written Feedback	64	63	64	64	
80th Percentile FDA Days to Written Feedback	67	68	68	66	
Maximum FDA Days to Written Feedback	72	75	77	123	

*** Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have resulted in missed MDUFA goals.**

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	28	
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	26	21	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	9	2	1	6	
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%	77.78%	

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	15	21	20	
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.63	1.07	1.25	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.63	0.07	0.25	

BLA
CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard BLAs Filed	14	4	0	1	
Number of Standard BLA First Actions less than or equal to 10 months	14	4	0	0	
Number of Standard BLA Frist Actions greater than 10 months	0	0	0	0	
Number of Standard BLAs Pending	0	0	0	1	
Number of Priority BLA Filed	0	0	0	0	
Number of Priority BLA First Actions less than or equal to 10 months	0	0	0	0	
Number of Priority BLA Frist Actions greater than 10 months	0	0	0	0	
Number of Priority BLAs Pending	0	0	0	0	

BLA Efficacy Supplements
CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard Efficacy Supplements Filed	8	2	0	0	
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	8	2	0	0	
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0	0	0	0	
Number of Standard Efficacy Supplements Pending	0	0	0	0	
Number of Priority Efficacy Supplements Filed	0	0	0	0	
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0	0	0	
Number of Priority Efficacy Supplements Frist Actions greater than 10 months	0	0	0	0	
Number of Priority Efficacy Supplements Pending	0	0	0	0	

BLA Prior Approval Manufacturing Supplements
CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard PAS Supplements Filed	94	54	92	52	
Number of Standard PAS Supplements First Actions less than or equal to 4months	94	53	92	49	
Number of Standard PAS Supplements First Actions greater than 4 months	0	1	0	0	
Number of Standard PAS Supplements Pending	0	0	0	3	

BLA/BLA Resubmissions
CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Class 1 Resubmissions Received	1	17	0	0	
Number of Class 1 Resubmission Actions less than or equal to 2 months	1	17	0	0	
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0	0	
Number of Class 1 Resbumssions Pending	0	0	0	0	
Number of Class 2 Resubmissions Received	7	0	1	0	
Number of Class 2 Resubmission Actions less than or equal to 6 months	7	0	1	0	
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0	0	
Number of Class 2 Resubmissions Pending	0	0	0	0	

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Shared Outcome Goals (FY 2018 through FY 2022)

FDA has two shared outcome goals each fiscal year, one for Original PMAs and Panel-Track Supplements and one for 510(k)s. FDA committed to report the average TTD within a closed cohort and based on the methodology prescribed in the MDUFA IV commitment letter. A PMA cohort is considered closed when 95 percent of applications have reached a decision. A 510(k) cohort is considered closed when 99 percent of accepted submissions have reached a decision. Both the 510(k) and PMA cohorts include submissions reviewed in CDRH and CBER. Performance for submission types that are meeting or exceeding the goal as of September 30, 2021 is shown in **bold** text.

As of September 30, 2021, the 510(k) and PMA cohorts for FY 2018 and FY 2019 have met the decision threshold to calculate the average TTD.

As of September 30, 2021, neither the 510(k) nor the PMA cohorts for FY 2020 or FY 2021 have met the decision threshold to calculate the average TTD. FDA will report the average TTD for FY 2020 and FY 2021 in future reports once the cohorts have met the decision threshold.

MDUFA IV Shared Outcome Goals

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs and Panel Track PMA Supplements					
TTD Goal (Days)	320	315	310	300	290
Current Performance (Days)	**272**	**267**	*	*	
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
Current Performance (Days)	**123**	128	*	*	

* As of September 30, 2021, fiscal year cohort has not met the decision threshold to calculate performance.

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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-2021-fy-2021.
[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	[4,6]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 wayback.archive-it.org/7993/20201218040833/https://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

[6] This guidance was withdrawn on 6/30/2021 because it no longer represents FDA's current thinking. Please see the Withdrawn Guidance webpage for information on withdrawn guidance presented for historical purposes only: www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/withdrawn-guidance.

#	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
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
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

#	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
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
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 (Revised) 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
28	Q3	Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus www.fda.gov/regulatory-information/search-fda-guidance-documents/feasibility-and-early-feasibility-clinical-studies-certain-medical-devices-intended-therapeutically	5/20/2021	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
29	Q3	Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-vascular-atherectomy-devices-premarket-notification-510k-submissions	5/20/2021	Yes	No	N/A	No
30	Q3	Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/implanted-brain-computer-interface-bci-devices-patients-paralysis-or-amputation-non-clinical-testing	5/20/2021	Yes	No	N/A	B-List
31	Q3	Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment	5/20/2021	Yes	No	N/A	B-List
32	Q3	ICH Q12: Implementation Considerations for FDA-Regulated Products www.fda.gov/regulatory-information/search-fda-guidance-documents/ich-q12-implementation-considerations-fda-regulated-products	5/20/2021	No	No	N/A	No
33	Q3	[4]Enforcement Policy Regarding Use of National Health Related Item Code and National Drug Code Numbers on Device Labels and Packages www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-regarding-use-national-health-related-item-code-and-national-drug-code-numbers	5/21/2021	No	No	N/A	No
34	Q3	Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act-0	5/27/2021	Yes	No	N/A	A-List
35	Q3	Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-handling-post-approval-studies-imposed-premarket-approval-application-order	5/27/2021	Yes	No	N/A	A-List

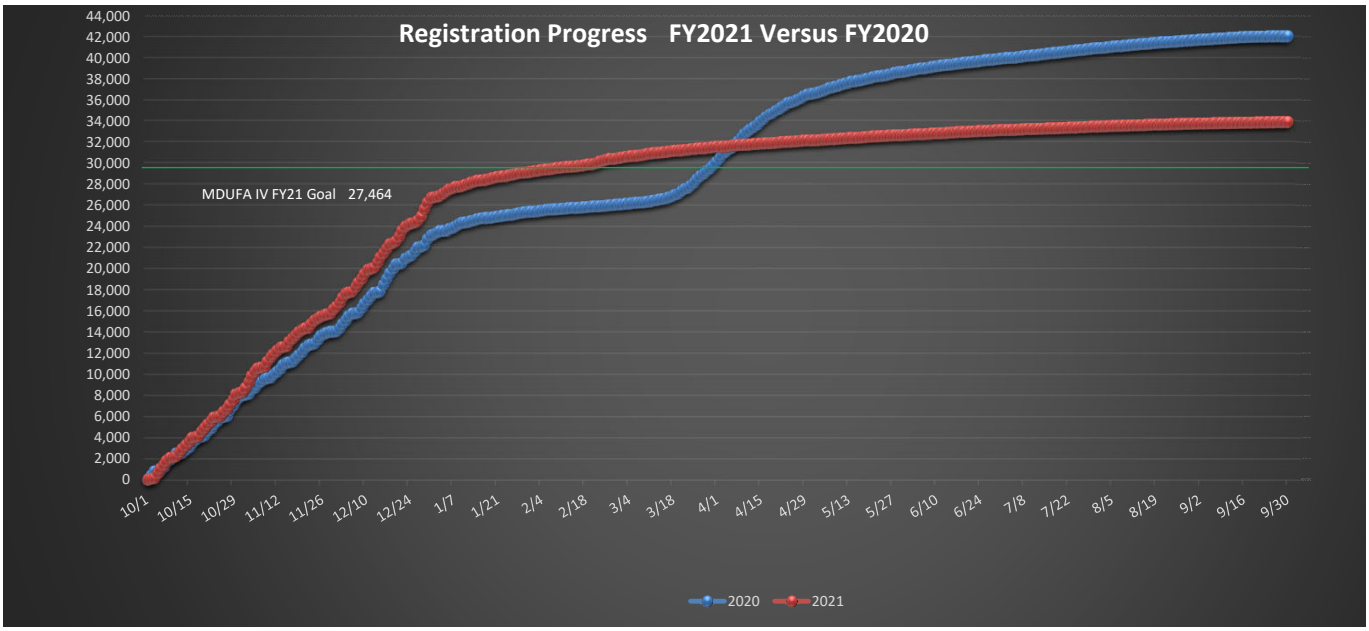
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
36	Q3	Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/oral-drug-products-administered-enteral-feeding-tube-in-vitro-testing-and-labeling-recommendations	6/3/2021	Yes	No	N/A	No
37	Q3	Remanufacturing of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices	6/24/2021	Yes	No	N/A	A-List
38	Q4	Unique Device Identification Systems: Form and Content of the Unique Device Identifier (UDI) www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-system-form-and-content-unique-device-identifier-udi	7/7/2021	No	No	N/A	B-List
39	Q4	[5]Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-non-clinical-assessment-medical-devices-containing-nitinol	7/9/2021	Yes	No	N/A	No
40	Q4	[5]FDA Export Certification Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification	8/20/2021	No	No	N/A	No
41	Q4	[4]FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	8/30/2021	Yes	No	N/A	No
42	Q4	Facet Screw Systems – Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/facet-screw-systems-performance-criteria-safety-and-performance-based-pathway	8/30/2021	Yes	No	N/A	A-List

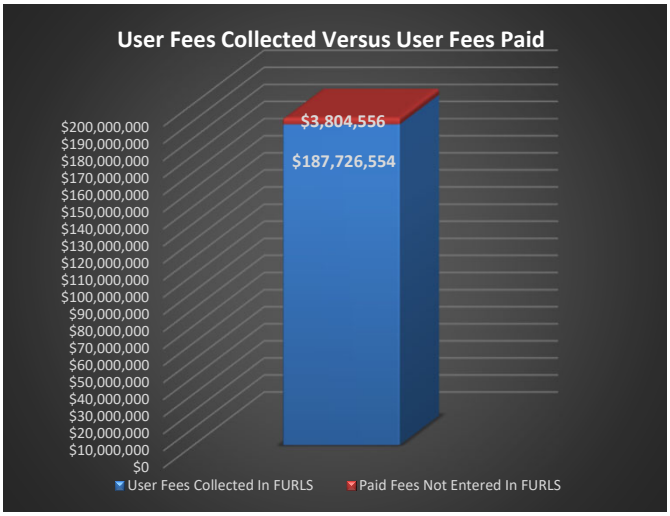
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
43	Q4	Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/denture-base-resins-performance-criteria-safety-and-performance-based-pathway	8/30/2021	Yes	No	N/A	A-List
44	Q4	[4]Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-face-shields-surgical-masks-and-respirators	9/15/2021	Yes	No	N/A	No
45	Q4	Electronic Submission Template for Medical Device 510(k) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions	9/29/2021	Yes	Yes	N/A	A-List
46	Q4	Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	9/30/2021	Yes	No	N/A	No

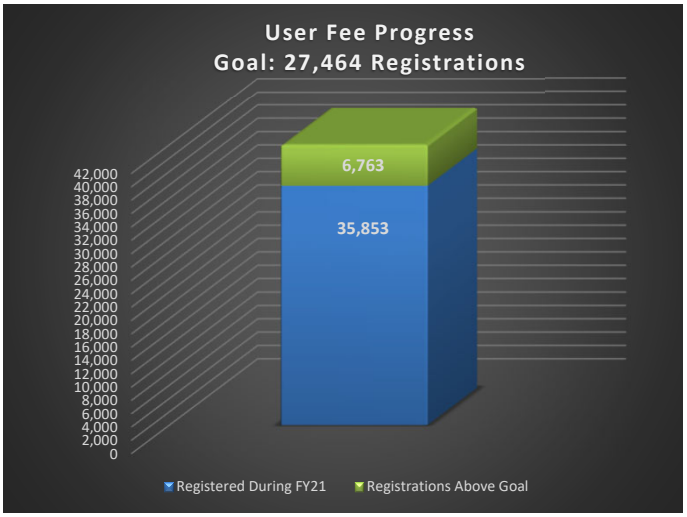
MDUFA IV Registrations - 4th Quarter Summary FY2021*

Current Active Registrations by Type	FY21 Q4			FY20 Year End Active Totals			FY21 vs End FY20
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,899	14,017	20,916	6,750	21,519	28,269	73.99%
Contract Manufacturer	1,213	1,745	2,958	1,186	1,707	2,892	102.28%
Contract Sterilizer	70	156	226	62	143	205	110.24%
Specification Developer	1,785	594	2,379	1,784	579	2,363	100.68%
Reprocessor of Single Use Devices	30	8	38	34	6	40	95.00%
U.S. Manufacturer of Export Only Devices	133	0	133	127	0	127	104.72%
Repackager/Relabeler	1,186	230	1,416	1,232	235	1,467	96.52%
Remanufacturer	17	11	28	19	8	27	103.70%
Foreign Exporter/Private Label Distributor		1,179	1,179	1	1,203	1,204	97.92%
Initial Importer	4,125		4,125	4,768		4,768	86.51%
Unknown	4	5	9	6	40	46	19.57%
Total:	**15,462**	**17,945**	**33,407**	**15,969**	**25,440**	**41,409**	**80.68%**

*Note: This data is current as of 10/01/2021







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FY 2021 4th QUARTER COLLECTION TABLE

FY 2021 Medical Device User Fee Collections as of September 30th, 2021 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$188,126,294	$604,219	$187,522,075		
Application Fees	$76,590,612	$1,764,584	$74,826,028		
Total	**$264,716,906**	**$2,368,803**	**$262,348,103**	**$236,059,000**	**111%**
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	$47,796,525	$56,962,601	$63,699,312	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,055,950	$122,346,416	$136,096,316	$147,161,472	$137,778,305
	FY 2018	**FY 2019**	**FY 2020**	**FY2021**	
MD IV	$193,470,728	$197,050,081	$290,391,803	$262,348,103	

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

CDRH and CBER Combined Data 4th Quarter FY 2021 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	9	2
PMA	9	2
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
Panel Track Supplements	3	6
De Novo Classification	21	42
180-Day Supplements	0	36
Real-Time Supplements	0	22
510(k)s	40	1,847
30-day Notices	10	27
513(g)s	0	53
PMA Annual Report	0	60
Total	**83**	**2,095**

[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 Panel Track Supplements (1 reduced), 180 Day Supplements (6 reduced), Real-Time Supplements (2 reduced), 510(k)s (14 reduced), 30-day Notices (9 reduced), and PMA Annual Reports (7 reduced).

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CDRH Quality Management and Organizational Excellence (QMOE) Program

FY 2021 Summary

A. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2021 Summary meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[1]

> *"VI. Performance Reports…3. In addition, the Agency will provide the following information on an annual basis… 3.14. Report on quality management program 3.15. Summary of quality system audits…"*

B. CDRH Quality Management Program

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[2]

> *"...The Agency will establish a dedicated Quality Management (QM) Unit that reports directly to the CDRH Director or Deputy Director..."*

1. Quality Management Unit Expertise

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

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

1.3. ISO and Quality Credentials. Collectively, CDRH QM staff hold one or more of the following quality-related credentials: ASQ Certified Quality Improvement Associate (CQIA); ASQ Certified Quality Auditor (CQA); ASQ Certified Quality Engineer (CQE); ASQ Certified Manager of Quality and Operational Excellence (CMQOE); ASQ Certified Lean Six Sigma Yellow Belt (CLSSYB); ASQ Certified Lean Six Sigma Green Belt (CLSSGB); Lean Six Sigma Master Black Belt (LSSMBB); ISO 13485:2013 Lead Auditor; ISO 9001:2015 Lead Auditor; and Bronze Level Kirkpatrick Evaluation Certification.

[1] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 23; 12/02/2016

[2] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; pages 10-11; 12/02/2016

2. Quality Management Training

2.1. To support the adoption of quality management across CDRH, the following training was provided in FY 2021:

- ISO 9001:2015 Requirements from A-Z
- ISO 9001:2015 Executive Training

C. CDRH Quality Management System (QMS)

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[3]

> *"…and establish a quality management framework for the premarket submission process in CDRH. The Framework will include infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation…"*

1. ISO 9001:2015 Certification

1.1. On October 30, 2020, the CDRH QMOE Program at the Office of the Center Director successfully completed a required ISO 9001:2015 surveillance audit (no nonconformities were found). The program has been ISO 9001:2015 certified for the provision of quality management and organizational excellence tools, services, and training since late 2018.

1.2. As of September 30, 2021, the team was preparing for the required recertification audit, scheduled for October 21-22, 2021.

2. Voice of the Customer (VOC)

2.1. Customer Service Survey. The CDRH customer satisfaction survey is available through FDA.gov and is included in all CDRH staff email correspondence. Overall, industry continued to be highly satisfied with CDRH. Industry's customer service satisfaction rate with CDRH was 96 percent in FY 2021. Industry respondents continued to comment positively about their satisfaction with the premarket review process.

2.2. Feedback✓CDRH. Feedback✓CDRH is the internal system used to collect internal staff input. The input is assigned to offices who determine whether actions need to be taken. After feedback is addressed, a summary of actions taken is made available to all CDRH staff. In FY 2021, over 50 percent of the feedback received was about OPEQ processes and procedures, with 46 percent of that feedback related to premarket review. All feedback was examined and addressed within the established CDRH timelines.

[3] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; pages 10-11; 12/02/2016

3. Document Control

3.1. Document Control System (DCS) – FY 2020 Improvements. The system went through a business process improvement project to improve and simplify the experience of document developers. Improvements will be implemented when the system is moved to SharePoint Online in 2022.

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

3.3. Conforming Offices Documentation. All documents related to the management and execution of the premarket review program processes are controlled using the CDRH DCS. The system houses over 1140 operating procedures, work instructions, forms and templates. 86 percent of the CDRH controlled documentation pertains to OPEQ core processes, including those associated with premarket review.

4. Internal Audits

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[4]

> *"…At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's Corrective and Preventive Action (CAPA) process. FDA will expand the scope of its annual audits as it implements and builds up its auditing capability. As part of these ongoing audits, high-performing premarket review processes utilized in one division will be identified and shared accordingly with other divisions to improve efficiencies and effectiveness. At a minimum, FDA audits in the following areas will be completed by the end of FY 2020: Deficiency Letters and Pre-Submissions. Additional audits in the following areas will be completed by the end of FY 2022: Submission Issue Meetings, Interactive Review, Withdrawals and Special 510(k) conversions…"*

4.1. Audit Schedule FY 2022. A data call for the FY 2022 internal audit schedule is planned for FY 2022 Q1. The following internal audits are already on the FY 2022 schedule:

- Withdrawal
- ISO 9001:2015 (External Audit)
- CDRH QMS Core Processes
- Submission Issue Meeting
- Interactive Review
- Special 510(k) conversions

[4] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 11; 12/02/2016

4.2. FY 2021 Audits (Final Schedule)

Title	Purpose	Findings
AF-2021-00011	Least Burdensome Training Audit	No findings
AF-2021-00014	Document Control System (DCS)	Internal audit, No Findings
AF-2021-00015	Design Development Verification and Validation System (DDVV)	Internal audit, No Findings
AF-2021-00016 **AF-2021-00017**	Pre-submissions Audit, Expanded Search and Validation	Continuation of Pre-sub audit from FY20, no findings
AF-2021-00018	Risk/Nonconformance/Corrective Actions	Internal audit, No Findings
AF-2021-00020	QMOE Tools and Services (TSR)	Internal audit, No Findings
AF-2021-00021	Quality Management Review (QMR)	Internal audit, No Findings
AF-2021-00022	Training and Competence	Internal audit, No Findings
AF-2021-00023	Feedback✓CDRH	Internal audit, No Findings
AF-2021-00024	Audit Management System (AMS)	Internal audit, No Findings

4.3. CDRH QMS Audits (AF-2021-00014; AF-2021-00015; AF-2021-00018; AF-2021-00020; AF-2021-00021; AF-2021-00022; AF-2021-00024): No nonconformities found; six opportunities for improvement and two best practices were identified.

4.4. AF-2020-00011: Least Burdensome Training Audit

- **Purpose:** To assess the effectiveness of training and actions taken in support the least burdensome provisions.
- **Findings:**
  - In 2020, the CDRH LB training module was revised and CDRH staff were again required to take the LB training. Kirkpatrick Level 2 results, which compare knowledge before and after the training, showed a 19% increase in knowledge acquired for CDRH's Office of Product Evaluation and Quality (OPEQ) staff and managers. Overall, at the Center level a knowledge gain of 20% was observed.
  - CDRH periodically reaches out to industry to assess our implementation of the LB provisions. Compared to the feedback received in calendar year 2018, 2020 industry respondents indicated increased satisfaction with CDRH's implementation of the LB provisions.
  - No Nonconformities were logged

4.5. AF-2021-00016 and AF-2021-00017: Pre-Submission Program Audit

AF-2021-00016

- **Purpose:** To assess the use of the Pre-Submission program and the use of FDA feedback.
- **Findings:**
  - Most Pre-Subs are related to one submission: 65% of manually matched Pre-Subs were matched to only one application
  - Most applications were received within two years of the Pre-Sub feedback provided date: 90% of the manually matched were submitted within two years of the Pre-Sub feedback provided date
  - No Nonconformities were logged.

AF-2021-00017

- **Purpose:** Compare Pre-Submission feedback letters to requests for additional information in 510(k) submissions
- **Findings:**
  - Using the AF-2021-00016 sample, auditors were able to associate 102 Pre-Submissions to 510(k)s
    - 55 of those associated 510(k) had AINN decision codes and an AI letter
    - AI rate for audit sample, 55/102 (54%), was 10% below the overall CDRH 510(k) AI rate (64%)
  - Letter pairs (AI and Pre-submission letter) were further examined to identity similar subjects.
    - 104 similar subjects were found in 14 of the 55 letter pairs
    - When similar subjects were compared, feedback in the pre-submission and AI letter were consistent.
  - No Nonconformities were logged.

5. Continual Improvement.

5.1. Business Process Improvement (BPI; ongoing).

CDRH's Simplicity Strategic Priority and Digital Transformation Initiatives continued through FY 2021. CDRH continues to lean CDRH core businesses processes. BPI objectives include:

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

5.2. Innovative Technological Improvements: eSTAR Submission Tool

In 2021, CDRH continued to advance innovative technologies and meet the MDUFA IV commitment to develop electronic submission templates to improve the sponsor submission process through the **e**lectronic **S**ubmission **T**emplate **a**nd **R**esource (eSTAR) pilot. eSTAR began as a voluntary alternate method for industry to submit submissions in an effort to develop resources to aid sponsors in providing structured electronic submissions. The eSTAR pilot began in February, 2020, to help participants use eSTAR to prepare 510(k) medical device submissions.

The eSTAR template contains:

- automation, content, and structure similar to interview review templates,
- integration of guidance, databases and other resources,
- instructions for each section, and
- automatic verification.

As of October 25, 2021, CDRH received 127 eSTAR submissions, with 47 SE, 2 NSE, and 8 WTDR decisions. Positive sentiments were received from 23 unique firms, with no negative sentiments received. The pilot is ongoing, and updates to the eSTARs are being made based on user input and utilization analysis.

On September 8, 2020, the eSTAR program expanded to include all non-In Vitro Diagnostics (nIVD) and In Vitro Diagnostic (IVD) devices that are not combination products. De Novo content of both these eSTARs has been completed and internally approved, and deployment is on schedule for November, 2021. eSTARs for 513(g)s, IDEs, and Q-Subs are in development.

5.3. Innovative Technological Improvements: Submission Memo and Review Template (SMART) Development

Another innovative technological solution is the continued development of smart review templates to increase consistency and efficiency for FDA review staff.

An IDE SMART template was internally approved by OPEQ's Tool and Templates Committee in January 2020. Sequential deployment to the OHTs began on February 2020, and the IDE SMART template was fully deployed to all OHTs by March 9, 2021.

A PMA SMART templates began construction in Summer 2020 and received approval by the Tools and Templates Committee in Summer 2021. Sequential deployment to the OHTs began on July 1, 2021, and PMA SMART templates for Originals, Panel Track Supplements, 180 day, and Real Time supplements were deployed to all OHTs on October 1, 2021.

The nIVD De Novo SMART template has been in use since 2016, and an IVD specific De Novo SMART template was approved by the Tools and Templates Committee in Summer 2021. The Do Novo SMART template was deployed for use by OHT7 IVD divisions on July 1, 2021.

Mandated Studies and EIR SMART templates are under development. Sequential deployment is planned to begin in October, 2021.

Of the main premarket submission types, only an HDE SMART template and an IVD specific PMA SMART template have yet to be developed.

5.4. BPI: CDRH QM Integration (CDRH QMS; ongoing)

Through this integrated quality management program, CDRH has established a mature Quality Management Framework that surpasses our commitment to industry and has been ISO 9001:2015 certified since 2018.

This effort intends to expand QMOE's centralized cohesive ISO 9001:2015 certified Quality Management System (QMS) to include all Center products and services. The goal of the project is to move all CDRH processes to full ISO 9001:2015 compliance and certification.

6. Independent Assessment of Review Process.

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[5]

"…For Phase 2 of the independent assessment, FDA will award the contract no later than 3/31/2020. However, the contractor would not begin the audit of deficiency letters and Pre-Submissions before 10/1/2020. The contractor will publish comprehensive findings and recommendations within 1 year.

For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable. FDA will incorporate findings and recommendations, as appropriate, into its management of the premarket review program. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness.

During the second phase, the contractor will:

1. *Evaluate FDA's premarket review program to identify efficiencies that should be realized as a result of the process improvements and investments under MDUFA III and IV;*
2. *Evaluate premarket review program infrastructure and allocation of FTEs;*
3. *Assess the alignment of resource needs with the training and expertise of hires;*
4. *Identify and share best practices across branches in ODE and OIR;*
5. *Assess the effectiveness of programs targeted for improvement under this agreement, including the:*
    a. *Quality Management program,*
    b. *Proportion of deficiencies in which FDA references the basis for the deficiency determination,*
    c. *Pre-Submission program (assess whether (a) CDRH is providing guidance specific to the questions being asked; (b) CDRH is using Pre-Submissions appropriately; and (c) CDRH and Industry are adhering to the procedural aspects as set forth in this agreement),*
    d. *Third Party Review program (assess efficiency of program and suggest process improvements),*
    e. *Digital Health program,*
    f. *Patient Engagement program, and*
    g. *Real World Evidence program;*
6. *Analyze conversions of Special 510(k)s to Traditional 510(k)s; and*
7. *Assess other key areas identified by FDA and industry as resources permit."*

[5] DELIVERABLE 12: MDUFA IV INDEPENDENT ASSESSMENT – FINAL REPORT, Section 4.5.2.2, Audit Results. https://www.fda.gov/media/152594/download; 09/30/2021.

6.1. Progress

FY2021 Q1-Q2

- The following assessments were completed:
  - Patient Science and Engagement
  - Third Party
  - Training and Alignment
  - Deficiencies
- The following assessments began:
  - Real World Evidence
  - 510(k) conversions
  - Pre-Submission

FY2021 Q3-Q4

- The following assessments were completed:
  - Real World Evidence
  - 510(k) conversions
  - Pre-Submission

- The independent assessment has concluded.
- The Assessment Report[6] was published on September 30, 2021.

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Center for Devices and Radiological Health Internal Training Summary Report

Q4 FY21

October 2020 – September 2021

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

As of: 10/28/2021

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 September 30, 2021. DETD offered 640 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.

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Table X – FY21 CDRH Internal Training Conducted by DETD:

October 1, 2020 and September 30, 2021

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA IV	5	917	751
	ELP	8	292	4342
	Least Burdensome (Refresher)	3	580	215
	Other LAW	300	16344	15571
	LAW Subtotal:	*316*	*18133*	*20879*
Leadership Development Training (LED)	LEAD: Leadership for Managers	43	1024	2894
	Leadership for Non-Managers	4	39	344
	Other LED	14	339	7865
	LED Subtotal:	*61*	*1402*	*11103*
Professional Development (PRO) Training	All PRO	*161*	*8482*	*7409*
	PRO Subtotal:	*161*	*8482*	*7409*
Center-Specific Information Technology (CIT) Training	Premarket IT	6	315	315
	Other CIT	6	266	266
	CIT Subtotal:	*12*	*581*	*581*
Science (SCI) Training	All SCI	90	4450	7628
	SCI Subtotal:	90	4450	7628
		640	**33048**	**47600**

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	99	2879	3398
Total:	**445**	**11096**	**26078**

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 September 30, 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***
Spring 2 2021 Cohort	13	18	*OCD*	*1*	*16*	*19*
			OSEL	*1*	*30*	*39*
			OPEQ	*21*	*589*	*753*
			Subtotal:	***23***	***635***	***811***
Summer 1 2021 Cohort	13	18	*OSEL*	*2*	*60*	*76*
			OPEQ	*12*	*321*	*413*
			Subtotal:	***14***	***381***	***489***
Summer 2 2021 Cohort	13	18	*OST*	*5*	*105*	*138*
			OSEL	*2*	*41*	*55*
			OPEQ	*18*	*414*	*530*
			Subtotal:	***25***	***560***	***723***
Total:	**78**	**108**	**-**	**194**	**4997**	**6344**

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 September 30, 2021*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
8	292	4342	• Innovation • Digital Health

ELP Training Completed by Office: *October 1, 2020 and September 30, 2021*

Office	Total # of Completions	Total Training Hours
OCD	1	24
OP	4	43
OPEQ	242	3948
OSEL	29	221
OST	16	106
Total:	**292**	**4342**

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 September 30, 2021*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	43	1024	2894	• 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 September 30, 2021*

Office	Total # of Managers/Supervisors*	# of Training Participants	Training Hours Required**	% of Required Training Hours Completed
OPEQ	166	138	2656	46%

*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.

FY21 MDUFA Reporting – CDRH Training

Summary of Training Opportunities for Reviewers

CDRH provides employees involved in medical device and radiological product review with a Comprehensive Reviewer Training curriculum through multiple programs and supporting components. This document provides brief summaries for each of these programs and components.

Reviewer Certification Program (RCP) and Advanced RCP:

The RCP has continued to evolve since its initial launch nearly 10 years ago. It was designed to address the baseline learning needs of new staff involved in medical device regulation. The program is offered during six cohorts per fiscal year and provides training in a blended-learning format with a focus on the basic core competencies for review staff in the Office of Product Evaluation and Quality (OPEQ) and the Office of Science and Engineering Laboratories (OSEL). There are two parts to the program: RCP Core and RCP Advanced. The RCP Core contains 30 courses (14 classroom, 16 online) over 38.5 hours of training addressing review topics including 510K and the Smart Template. The RCP Advanced consists of eight additional courses that are taken after RCP Core completion. Examples of advanced course topics include Medical Device Law and Mastering Four Part Harmony. With the establishment of the TPLC structure, the OPEQ Professional Development staff in collaboration with the Office of Communication and Education, identified gaps in the program content to support staff who previously worked on Postmarket functions. As such, training content addressing topics such as EIRs and Allegations have been added to the program. The program has also been restructured to condense the learning content. Overall training days have been reduced from 10 to 6 day per cohort and classroom trainings have been converted to online learning to support 24x7 access.

Additions and Updates to the RCP Curriculum

- During the pandemic, all courses were moved to virtual training (March 2020).
- An "attendance optional" meet and greet event was added to the curriculum
  - Participants to ask questions post orientation
  - Networking opportunity for new hires involved in medical device regulation
- Content modifications include:

Content Added to RCP in 2019		
Courses and Length	**Description**	**Status**
General Biocompatibility Guidance (4.0)	Goal is to provide clarity and update on evaluation and testing within a risk management process.	Course originated to RCP online (2019)
Medical Device Corrections & Removals (Recalls) (1.5)	Introduces definitions, regulations, and overall review process, including responsibilities of the different entities for Medical Device recalls.	Course originated to RCP online (2019), Module updated in 2021
OPEQ: Establishment Inspection Report & Potential Outcomes (EIR/PO) (1.0)	Provides an understanding of Establishment Inspection Report.	Course originated to RCP online (2019), Module updated in 2021

OPEQ: Allegations (1.0)	Describes what Allegations are, where they come from and how they are received, including how to approach Allegation assignments.	Course originated to RCP online (2019) - *Formerly Allegations & Promotions, Advertising & Labeling Review,* Module updated in 2021

Content Added to RCP in 2021		
Quality Compliance Program (1.0)	Broad overview of compliance and quality, and how it relates to the CDRH mission	New course developed 2021

Content Updated 2019 - 2021		
Courses and Length	**Description**	**Status**
Basic Clinical Trials & IDEs (1.0)	Provides an overview of clinical review process including Investigational Device Exemptions	Module updated in 2019
Q-Subs & the Pre-submission Program (1.0)	Provides an overview of the Pre-submission process	Module updated in 2019
Least Burdensome Provision & Principles: Finding a Balance (0.25)	General overview of Least Burdensome	Module updated in 2020
Basics of Four-Part Harmony in Lead & Consult Reviews (1.0)	Applying four-part Harmony when writing deficiencies; Identifying two different audiences of all deficiencies and how to write for both audiences.	Module updated in 2020
Basics of Standards in Premarket Review (1.0)	Discussion of how standards became integral to the CDRH mission and how they are used	Module updated in 2021
OPEQ: Promotions Advertising & Labeling (.30)	Introduces concepts central to labeling and advertising that are shared across all FDA medical product centers.	Module updated in 2021
Standards Overview (1.0)	Define standards and how they are applied, including difference between horizontal and vertical standards.	Module updated in 2021
Standards Resources and Premarket Use (1.0)	Provide resources on how to find recognized standards and discusses how standards are used in premarket submissions	Module updated in 2021

Experiential Learning Program (ELP):

The ELP launched in FY12 and was designed to create a platform for review staff to encounter emerging devices and innovative technology through experiential learning experiences (site visits) offered by the medical device industry. The purpose of the ELP is to provide a collaborative approach to closing the knowledge gap between CDRH and medical device industry and the review of the resulting medical devices. Specifically, providing awareness and understanding of medical device technology while improving communication, critical thinking and problem solving. As participants in the ELP, CDRH employees involved in medical device regulation are provided with real-world knowledge of products by learning from the medical device industry, the clinical community and academic stakeholders during site visits. The site visits support the reviewers understanding of how medical devices are developed, clinically tested, manufactured, and utilized. Currently, CDRH conducts physical and virtual site visits due to the existing travel limitations. CDRH intends to expand the use of virtual site visits in FY22 and beyond.

Scientific and Regulatory Training

In addition to the Review Training component, CDRH continues to ensure that new and existing staff involved in medical device review are properly training and prepared. Specifically, CDRH's Scientific and Regulatory training focuses on a reviewer's abilities to ensure review efficiency, consistency, predictability and reduced total time to decision. Training is offered to staff involved in medical device regulation through instructor-led classroom training and online modules. The following section provides a basic overview of the Scientific and Regulatory training component.

CDRH's Scientific and Regulatory Training continues to be modified based on new guidance and policies and to meet the need of employees through the offering of trainings that are condensed in length and when applicable available 24X7 in an online learning format. OCE frequently works with Subject Matter Experts (SMEs) to initially provide mandatory training in a classroom format and then will convert the training to an online module. Examples of CDRH's Scientific and Regulatory Training include.

- **Grand Rounds:** Another method of delivering Scientific and Regulatory training is through a "Rounds" system of delivery. The "Rounds" system is designed for experts of different scientific and technical disciplines to provide concise, targeted and engaging training in a short time (1 hour or less-condensed length of time) with content easily adaptive immediate implementation by review staff. CDRH currently conducts two "Rounds" systems; the Total Product Life Cycle (TPLC) Grand Rounds and the OPEQ Rounds (addressed in the On-the-Job Component section). The TPLC Grand Rounds provides a venue for employees to share interesting and challenging issues related to CDRH activities or occurrences across the total product life cycle with CDRH senior management and the Center staff. The purpose of the TPLC Rounds is to connect and engage staff regarding cross-cutting issues, innovative device technologies and challenging regulatory issues.

- **Guidance Training:** CDRH conducts guidance training for all final guidance. The classroom training is provided in a briefing format with the purpose and high-level process requirements discussed. The online training is provided via webinar and the target audience consists of both internal staff and external stakeholders.

- **AdHoc Training:** CDRH delivers AdHoc training to provide general awareness of specialized topics. These trainings are typically conducted as one-time events or briefings. The training varies in length and is often delivered to augment other training courses.

On-the-Job Training

Another component of CDRH's Comprehensive Reviewer Training curriculum, is On-the-Job training. This training is provided for staff and managers at the "local levels," meaning within their Office, Division or Branch levels. Training topics are more specific to the perspective organization and may include device specific scientific and regulatory discussions. Specifically, Office or Division meetings provide updates on guidance, Office Meetings – Office meetings provide updates to managers and staff about legislation, policy and process changes and

Division Meetings provide training on specific devices or technologies through instruction conducted by the organization's managers, team leads or experienced staff. In addition to didactic learning, On-the-Job training is also delivered through 1x1 engagement between new review staff and a Technical Mentor. CDRH has also implemented an extensive Quality Management System to support the achievement of the Center's mission and vision. Additional information regarding CDRH's On-the-Job Training component is provided below.

- **Office, Division and Branch Level Training:** The OPEQ Rounds are an example of On-the-Job training and development featuring interactive sessions derived from staff input, management observations, and the effort for continuous process improvement within OPEQ. The purpose is to connect and engage staff for more device specific and emerging technology training opportunities. Topics addressed during the Rounds include policies, processes, work instructions, tools and templates.

- **Mentoring:** New staff involved in medical device regulation are provided with a technical mentor during the onboarding process to provide on-the-job training support. Technical Mentors open the pathways of communication and education for new staff during their most critical development phase. The mentors are selected by the new reviewer's supervisor based on their relevant technical expertise. They are assigned to help new review staff understand legislation and office policies and processes. OPEQ offices handle mentoring differently, and to varying degrees of interaction, assigning technical mentors for new staff conducting reviews (OHTs), assignment of clinical evidence program mentors (for OCEA), or regulatory program/policy mentors (for ORP). The progress for the Technical mentor/new reviewer relationship is closely monitored by the new reviewer's supervisor.

- **Quality Management:** The availability of the CDRH Document Control System (DOCS) provides CDRH staff and managers involved in medical device regulation with ongoing access to a quality management system that includes Working Instructions, Templates, Forms, Flowcharts, Process Maps and SOPs. The Quality Management system monitors Center performance relative to quality objectives; and makes timely adjustments as required to fulfill the needs and expectations of our customers and stakeholders. The DOCS are used throughout the review process to ensure that employees have the steps to follow when conducting reviews and are appropriately completing those steps with an emphasis on quality and consistency.

Professional Development

In addition to training specific to the regulatory review process, CDRH provides professional development training for employees. Specific program components include training targeting new and existing supervisory and management staff, staff who are aspiring to leadership positions in the future and leadership skills for staff at all levels in the organization. Except for the Leadership Readiness Program, employees who are involved in medical device regulation can participate during professional development training as their schedule permits.

- **Supervisory Training:** CDRH offers two programs that support supervisory training. The New Manager Academy (NMA) which targets new supervisors to the Center and offers cohort-based training and 6-months of mentoring from a seasoned CDRH supervisory. The Leadership Enhancement and Development (LEAD) program provides training courses for existing supervisors. Both programs support the federal supervisory training competencies and requirements as indicated in the regulation 5 CFR 412.

- **Leadership Readiness Program:** The Leadership Readiness Program is a one-year learning opportunity for employees interested in a management or leadership career path. The Program provides participants with experiences in mentoring, classroom-based learning, self-assessment, and experiential activities. The selection process is competitive and requires completion of an application, statement of interest and interviews of the most qualified candidates. Selected participants remain in their current position throughout program the year and participate in the LRP as an additional activity.

- **Leadership for Non-Managers:** The Leadership for Non-Managers program provides leadership training for staff at any level in the organization. The training address topics such as *Leading Without Authority*, *Managing Up* and *Project Management.*