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

December 15, 2020, 1:00 – 2:30 pm
WebEx

Welcome –

FDA MDUFA Performance — Actions through September 30, 2020

- Report on decision goals for 4th Quarter FY 2020
- Shared outcome goals

Guidance Development

Registration and Listing

Qualitative Update on Finances – 4th Quarter FY 2020

- User fee receipts through the 4th Quarter FY 2020
- How funding is being used to enhance scientific review capacity
- Reviewer to Manager Ratio

Quality Management Update

- Summary of FY 2020 activities
- Planning for FY 2021 audits
- Independent Assessment Update

Report on implementation of deficiency performance improvements

Report on ASCA program

CDRH Training Update

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Quarterly Update on
Medical Device Performance Goals
MDUFA IV CDRH Performance Data ---
Action through 30 September 2020---

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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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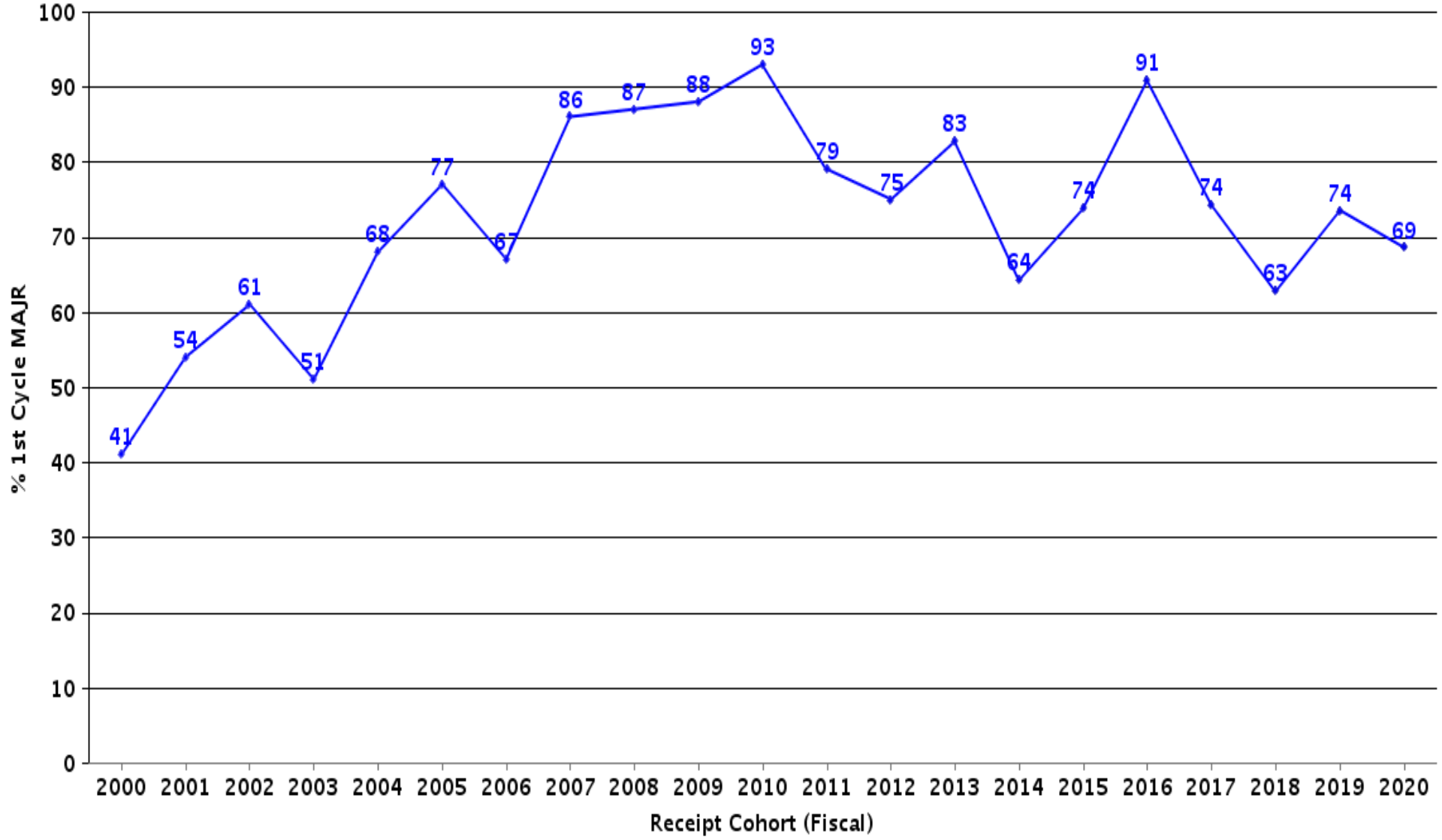
PMAs

Q4FY2020

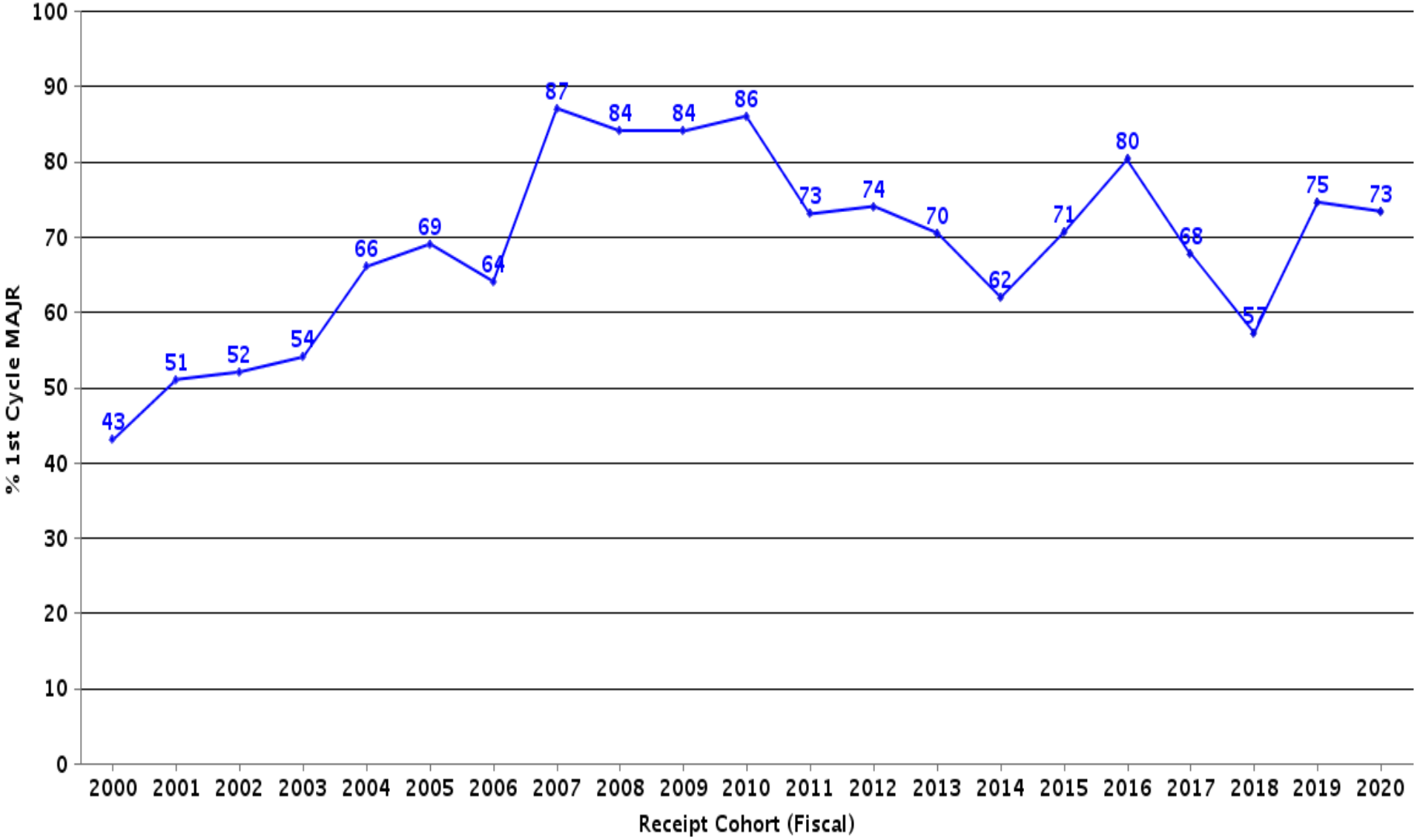
PMA Originals Filed As Of 6/30/20: 1st Cycle Major Deficiency Rate as of 9/30/20



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 6/30/20. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

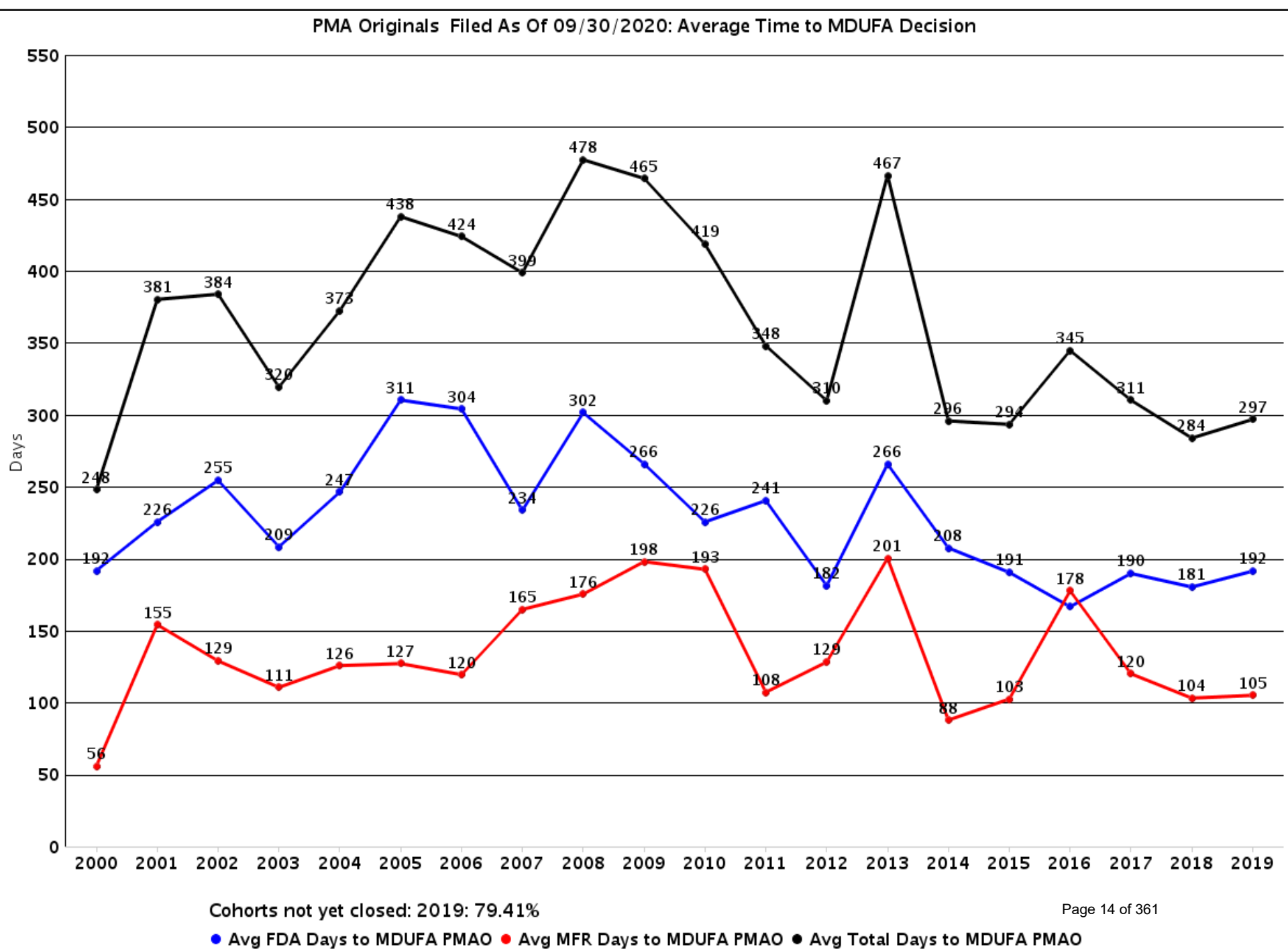
◆ % 1st Cycle MAJR PMAO

PMA Originals and Panel Track Supplements Filed As Of 6/30/20: 1st Cycle Major Deficiency Rate as of 9/30/20

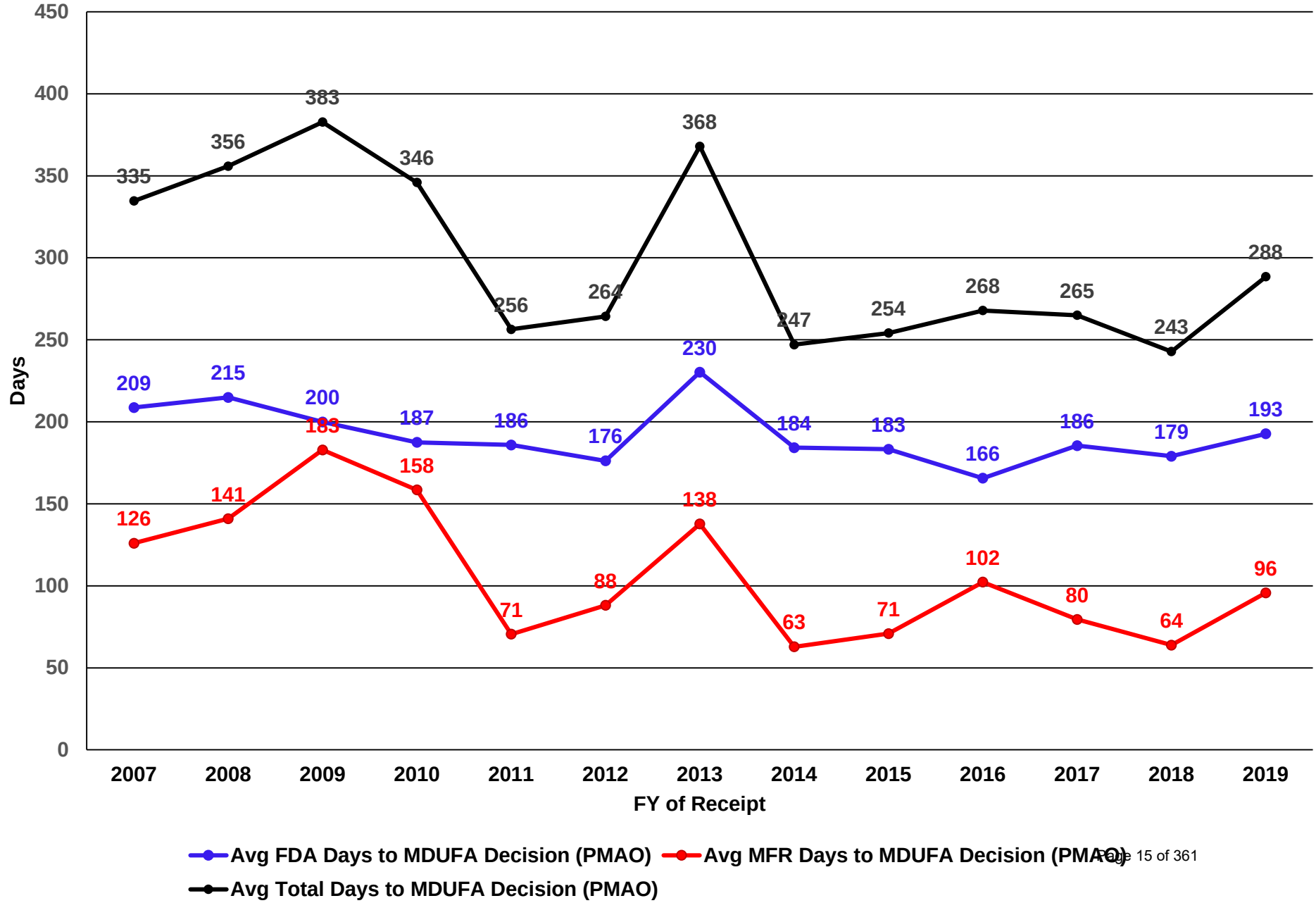


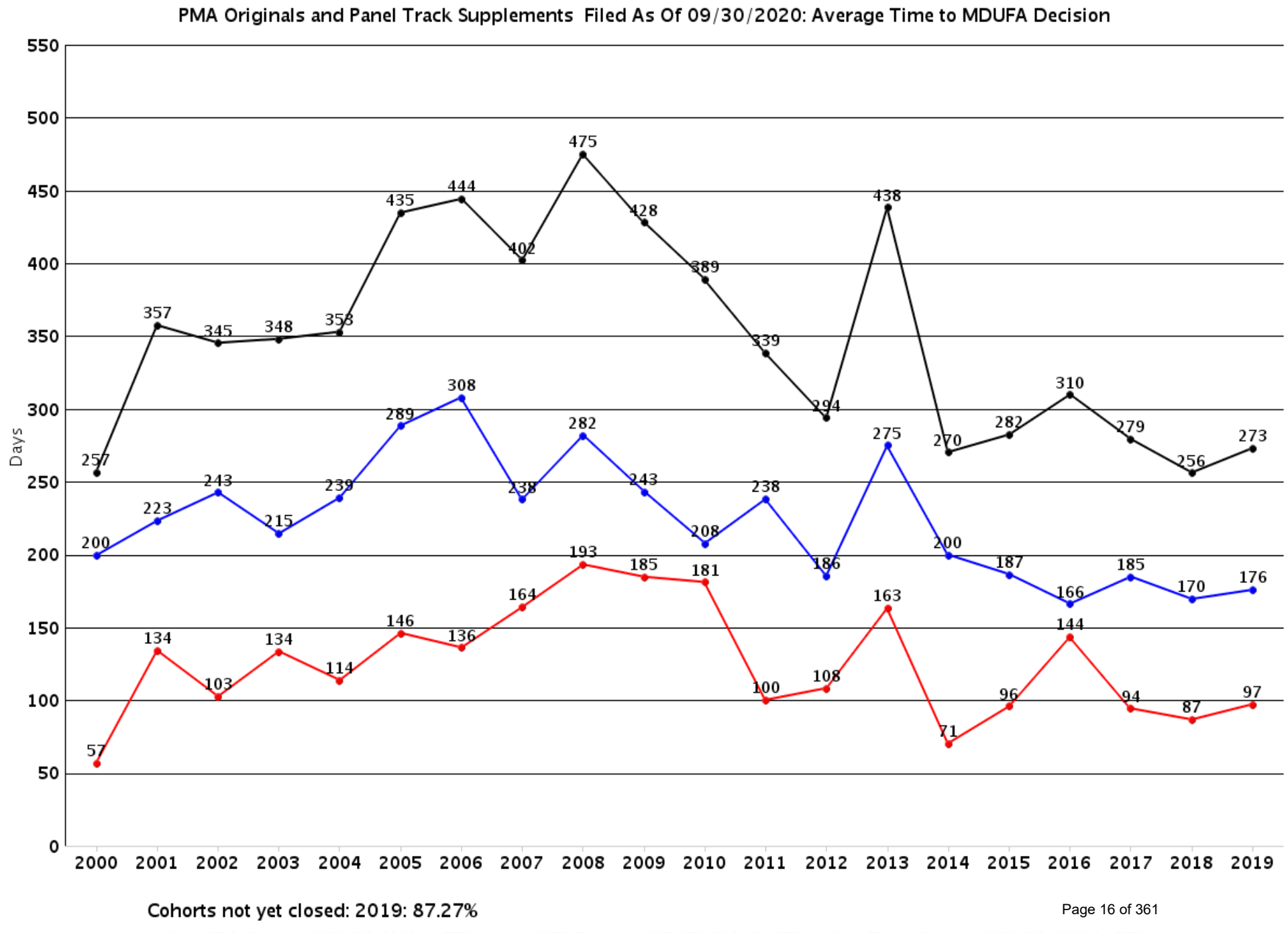
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/20. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

♦ % 1st Cycle MAJR PMAO/PTS

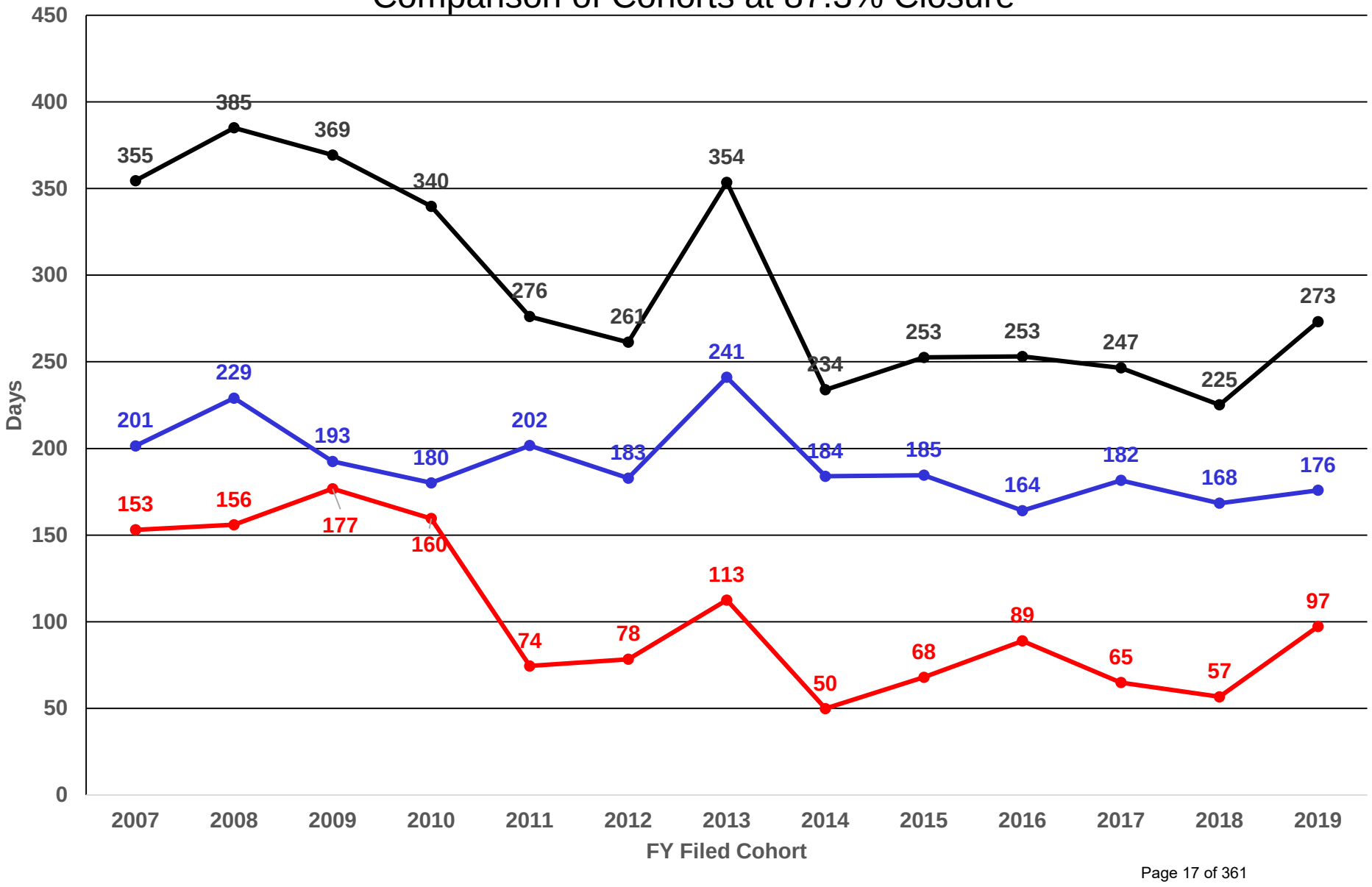

PMA Originals Filed As Of 09/30/2020: Average Time to MDUFA Decision
Days
550
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019
248 381 384 320 373 438 424 399 478 465 419 348 310 467 296 294 345 311 284 297
192 226 255 209 247 311 304 234 302 266 226 241 182 266 208 191 178 190 181 192
56 155 129 111 126 127 120 165 176 198 193 108 129 201 88 103 178 120 104 105
Cohorts not yet closed: 2019: 79.41%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO

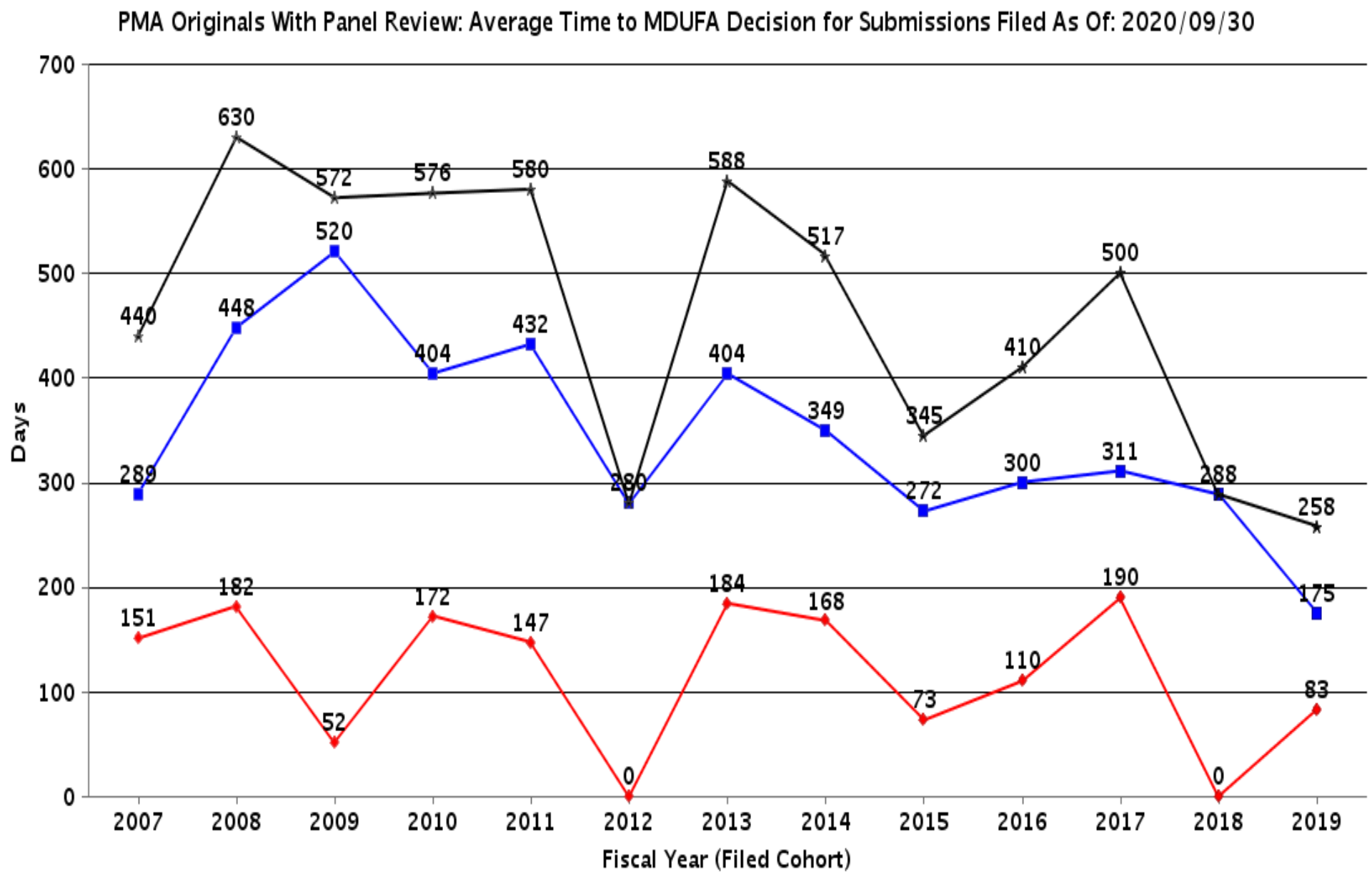
PMA Originals Filed as of 9/30/2020: Average Time to MDUFA Decision
Comparison of Cohorts at 79.4% Closure




PMA Originals and Panel Track Supplements Filed As Of 09/30/2020: 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
257 357 345 348 353 435 444 402 475 428 389 339 294 438 270 282 310 279 256 273
200 223 243 215 239 289 308 238 282 243 208 238 186 275 200 187 166 185 170 176
57 134 103 134 114 146 136 164 193 185 181 100 108 163 71 96 144 94 87 97
Cohorts not yet closed: 2019: 87.27%
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 9/30/2020: Average Time to MDUFA Decision
Comparison of Cohorts at 87.3% Closure

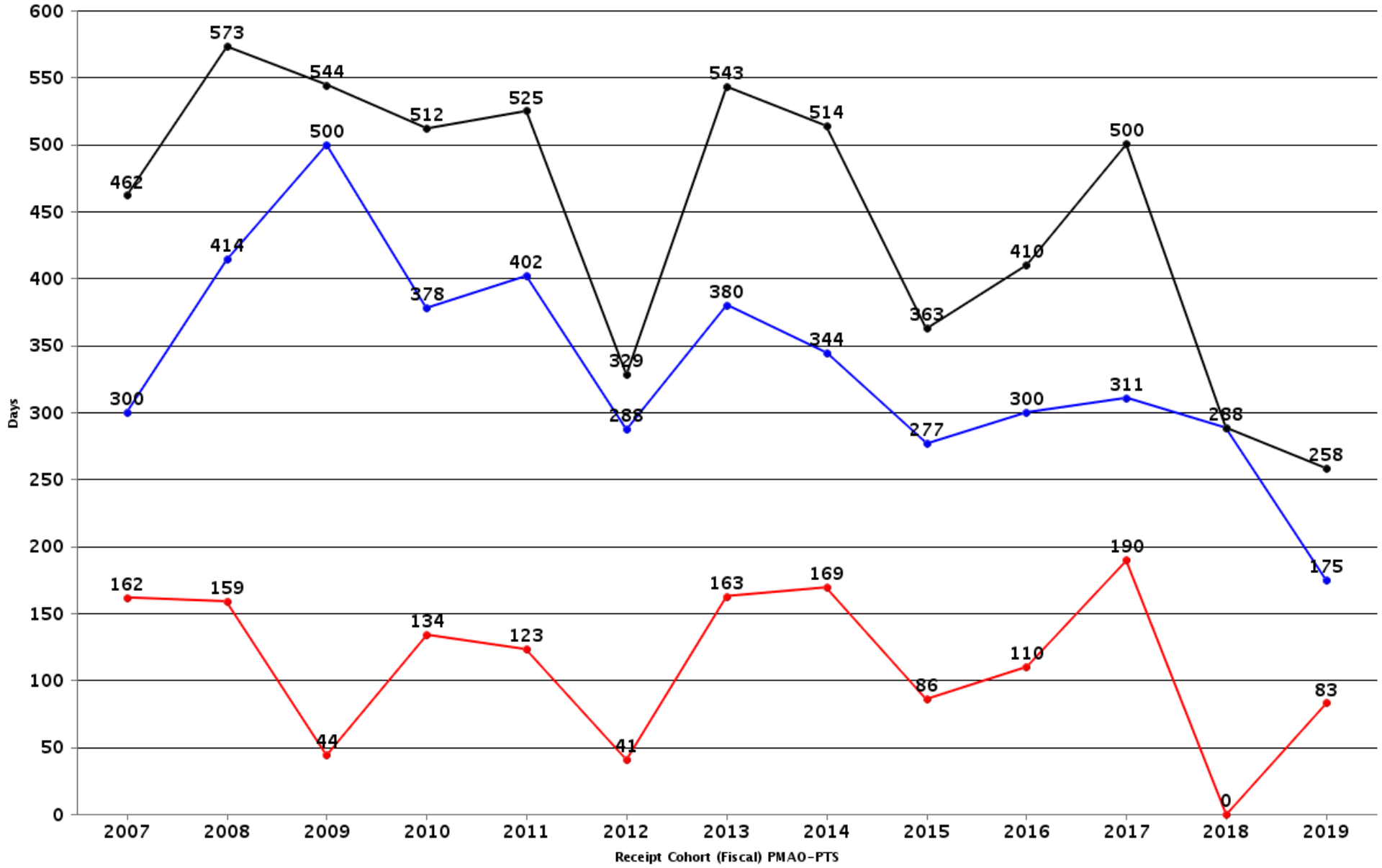




Numbers Filed: 2007 = 7; 2008 = 7; 2009 = 6; 2010 = 7; 2011 = 11; 2012 = 1; 2013 = 11; 2014 = 5; 2015 = 5; 2016 = 1; 2017 = 5; 2018 = 45; 2019 = 2

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

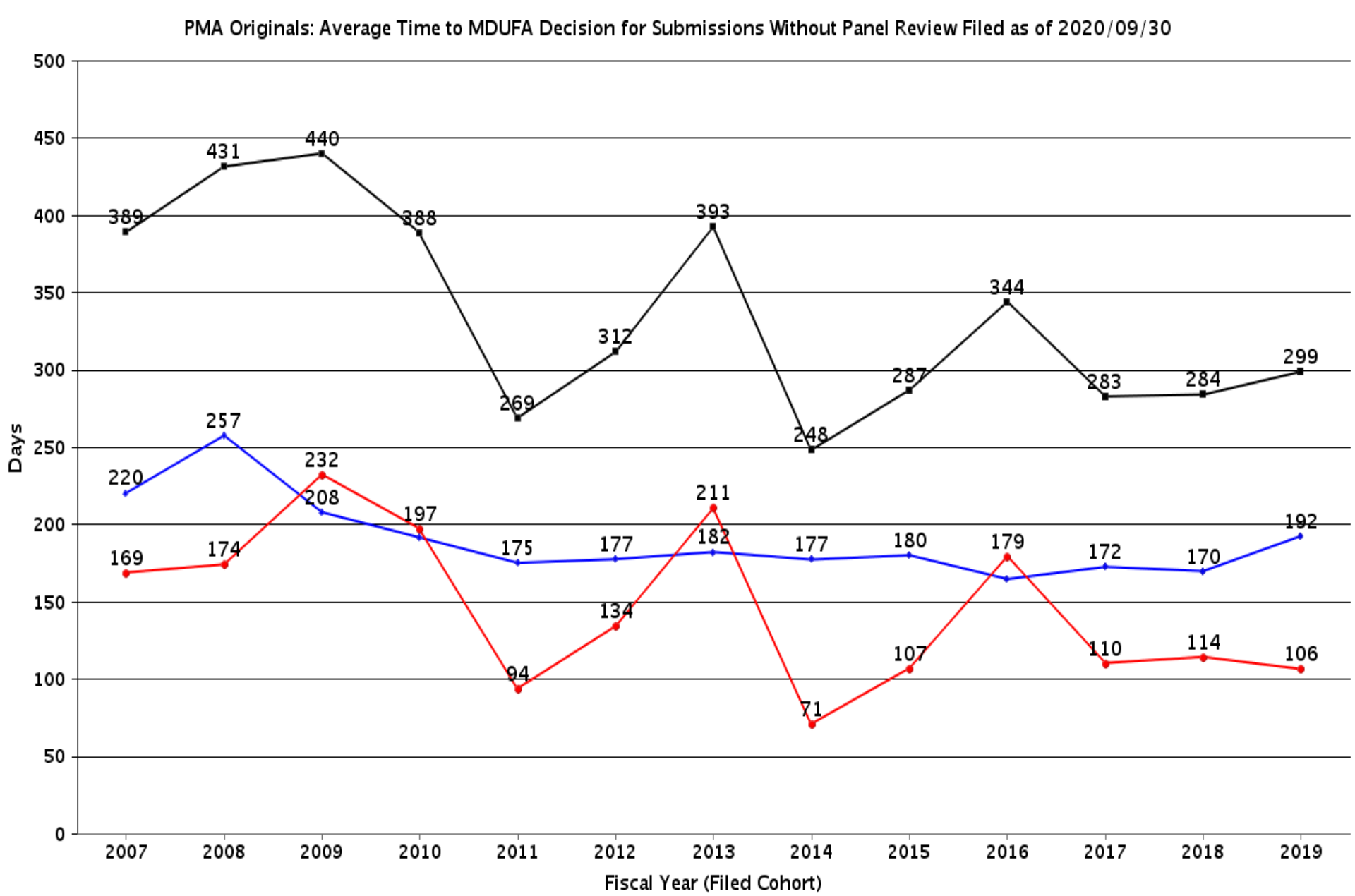
PMA Originals and Panel Track Supplements With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2020/09/30



Numbers Filed: 2007 = 8; 2008 = 8; 2009 = 7; 2010 = 9; 2011 = 14; 2012 = 2; 2013 = 17; 2014 = 6; 2015 = 6; 2016 = 1; 2017 = 5; 2018 = 4; 2019 = 2

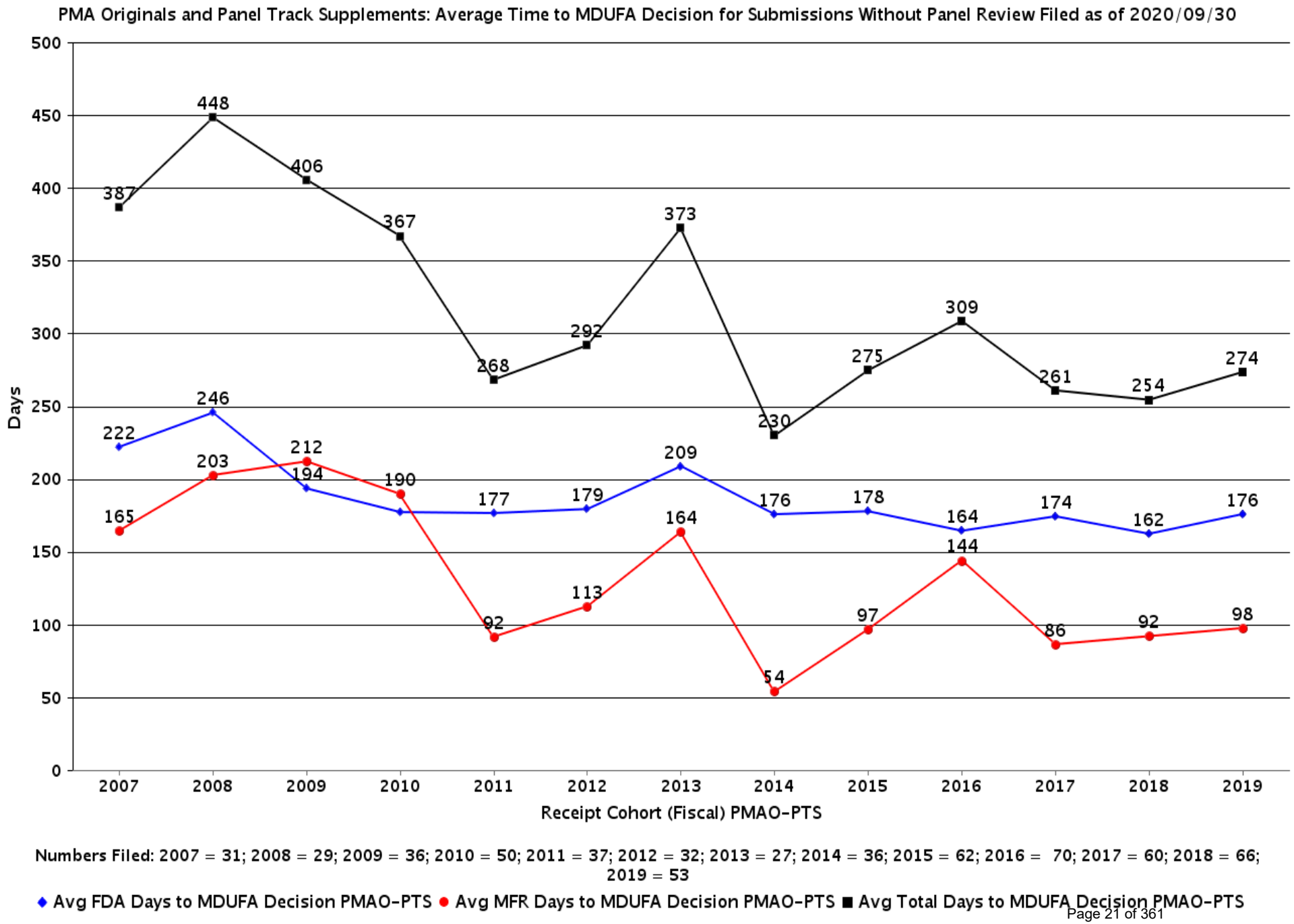
● Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ● Avg Total Days to MDUFA Decision PMAO-PTS

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



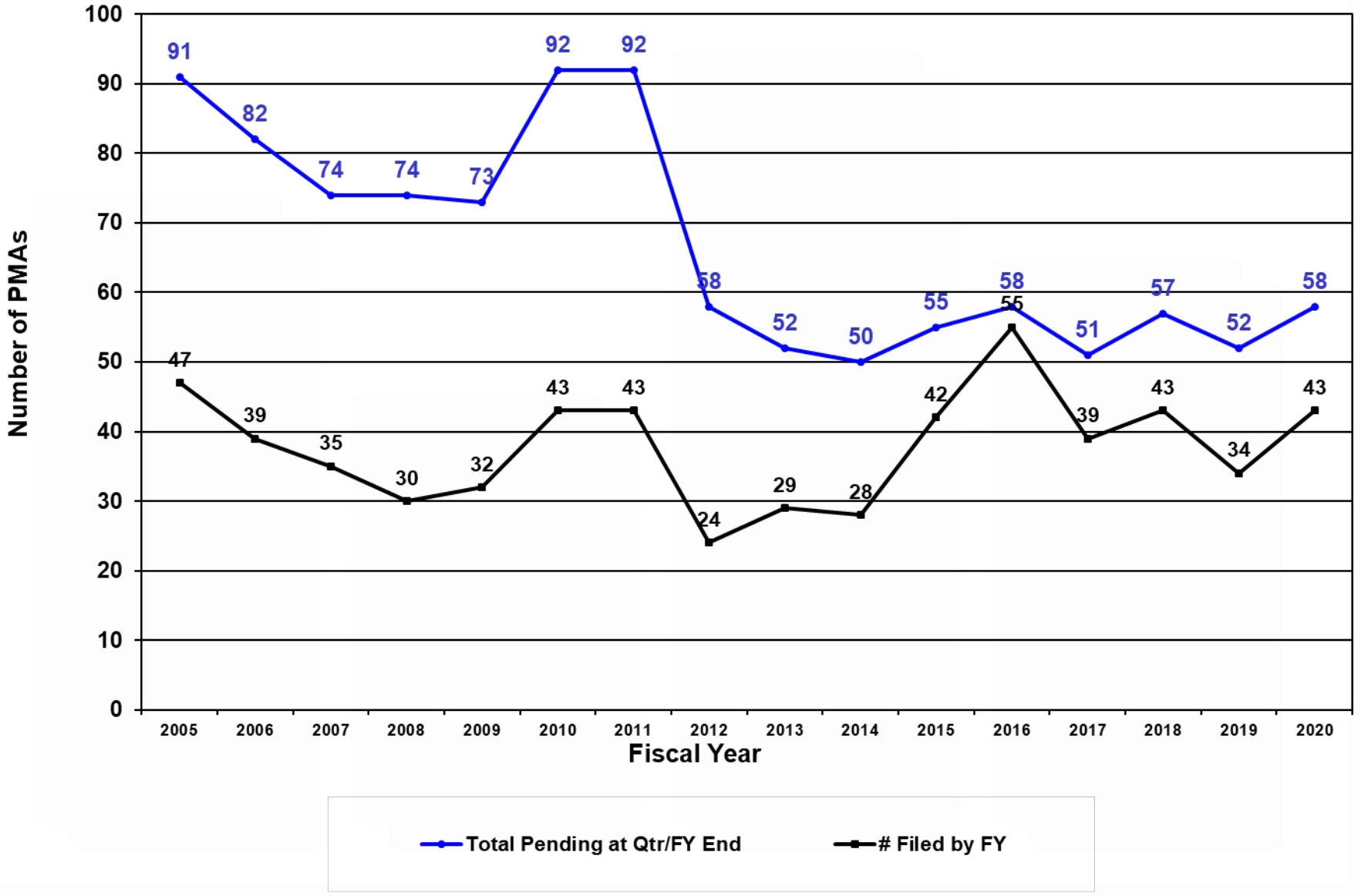
Submissions Filed: 2007 = 28; 2008 = 23; 2009 = 26; 2010 = 36; 2011 = 32; 2012 = 23; 2013 = 18; 2014 = 23; 2015 = 37; 2016 = 54; 2017 = 34; 2018 = 39; 2019 = 32

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



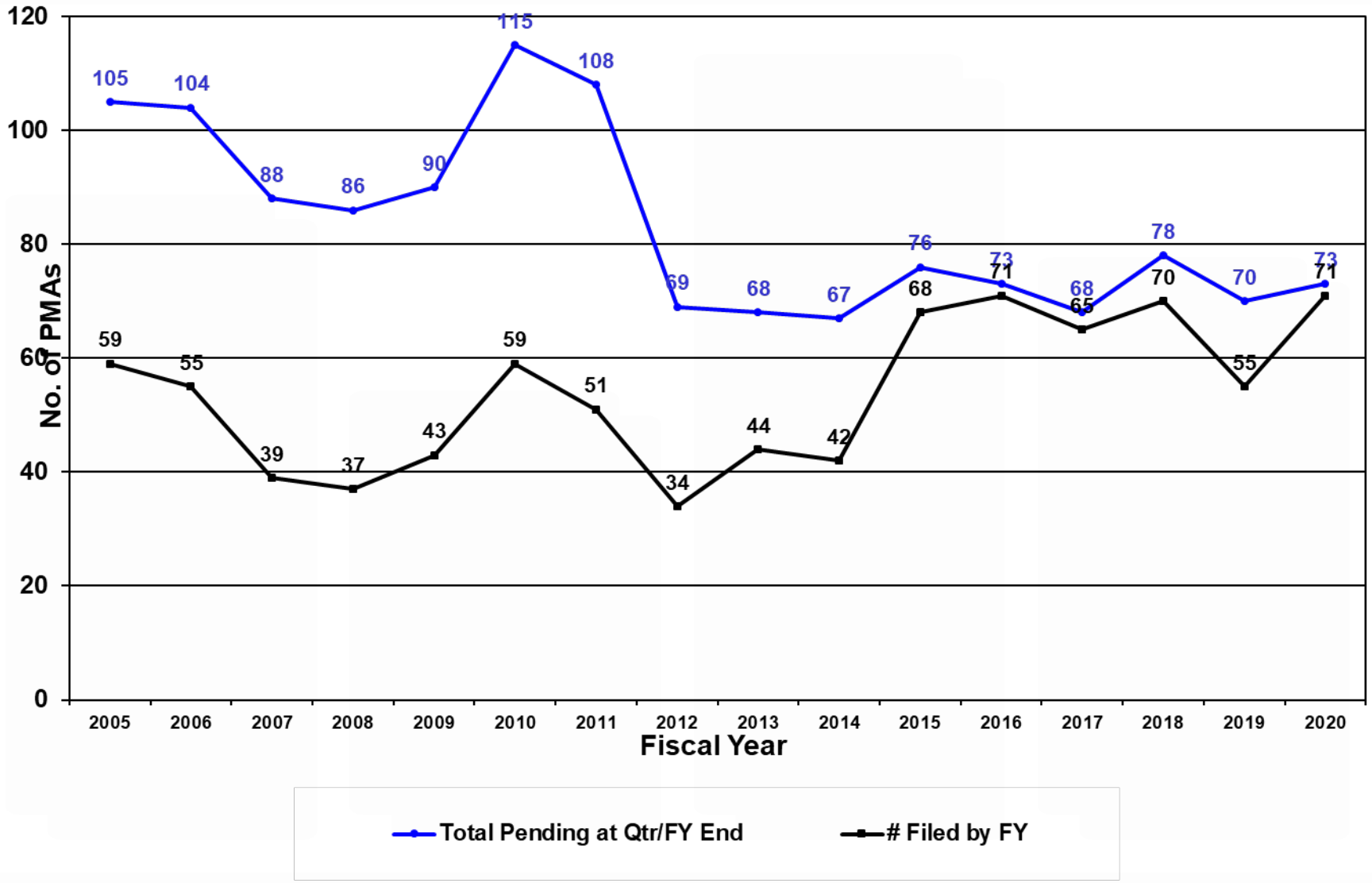
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

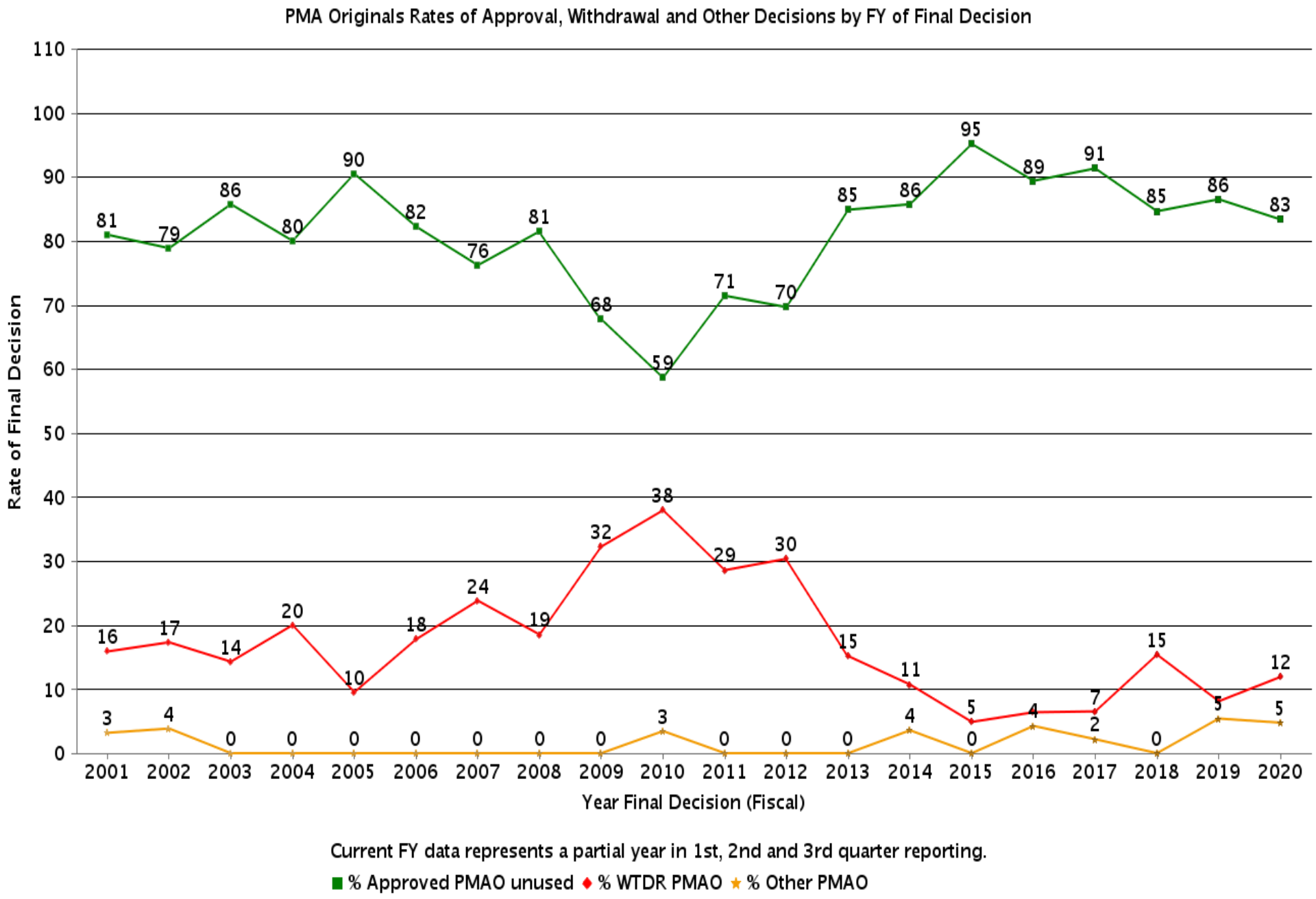


***Original PMAs under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.**

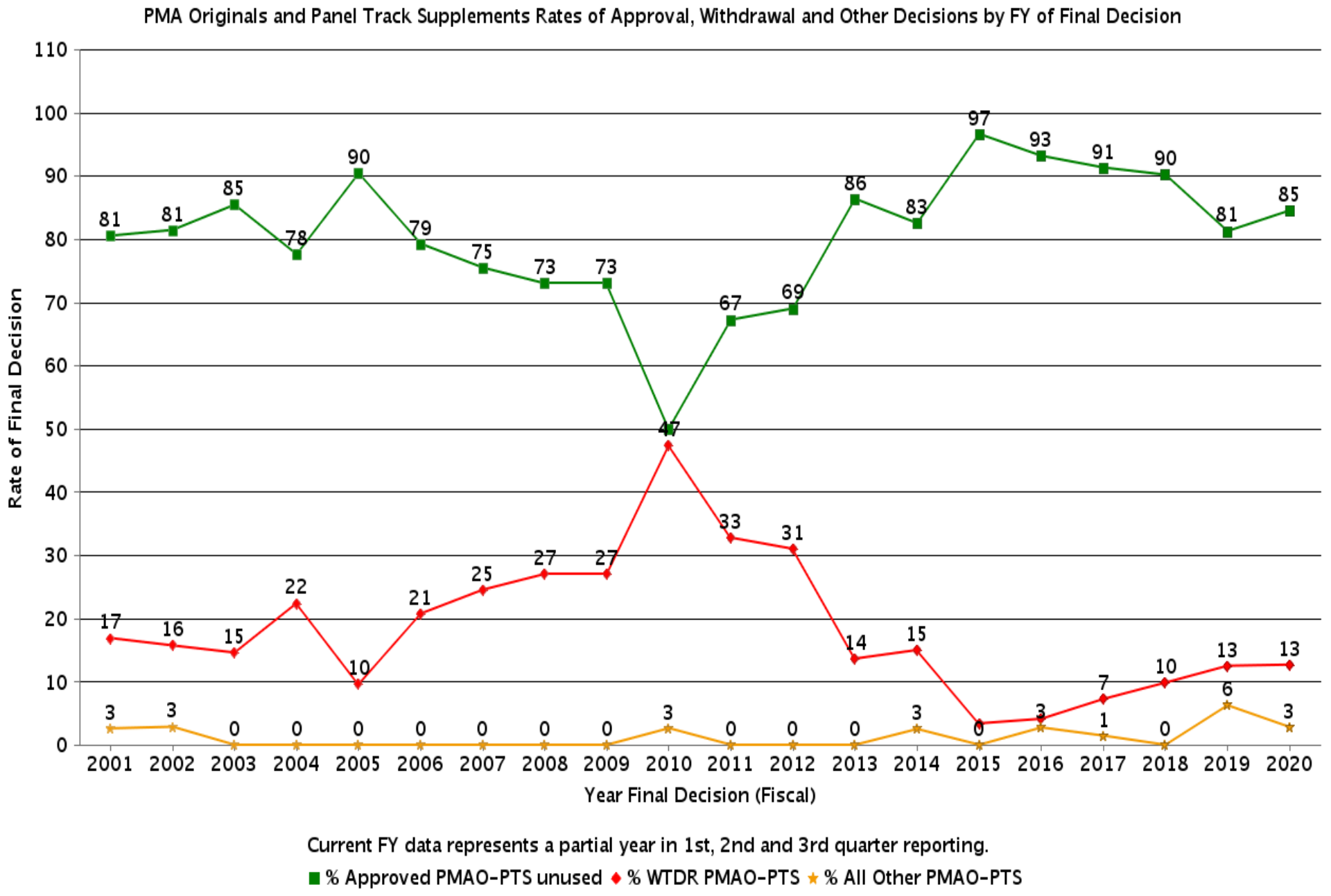
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



***Original PMAs/PTS 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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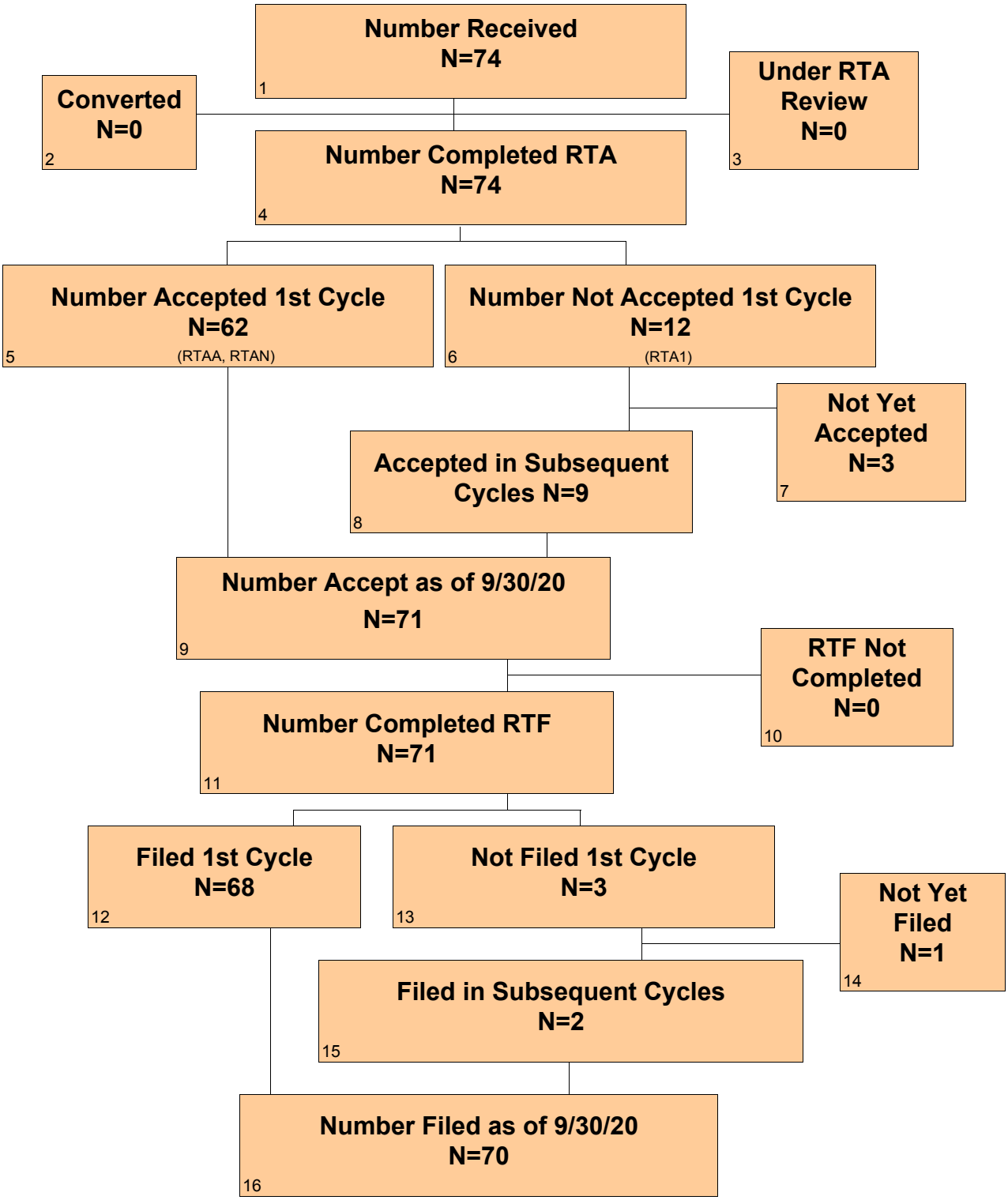
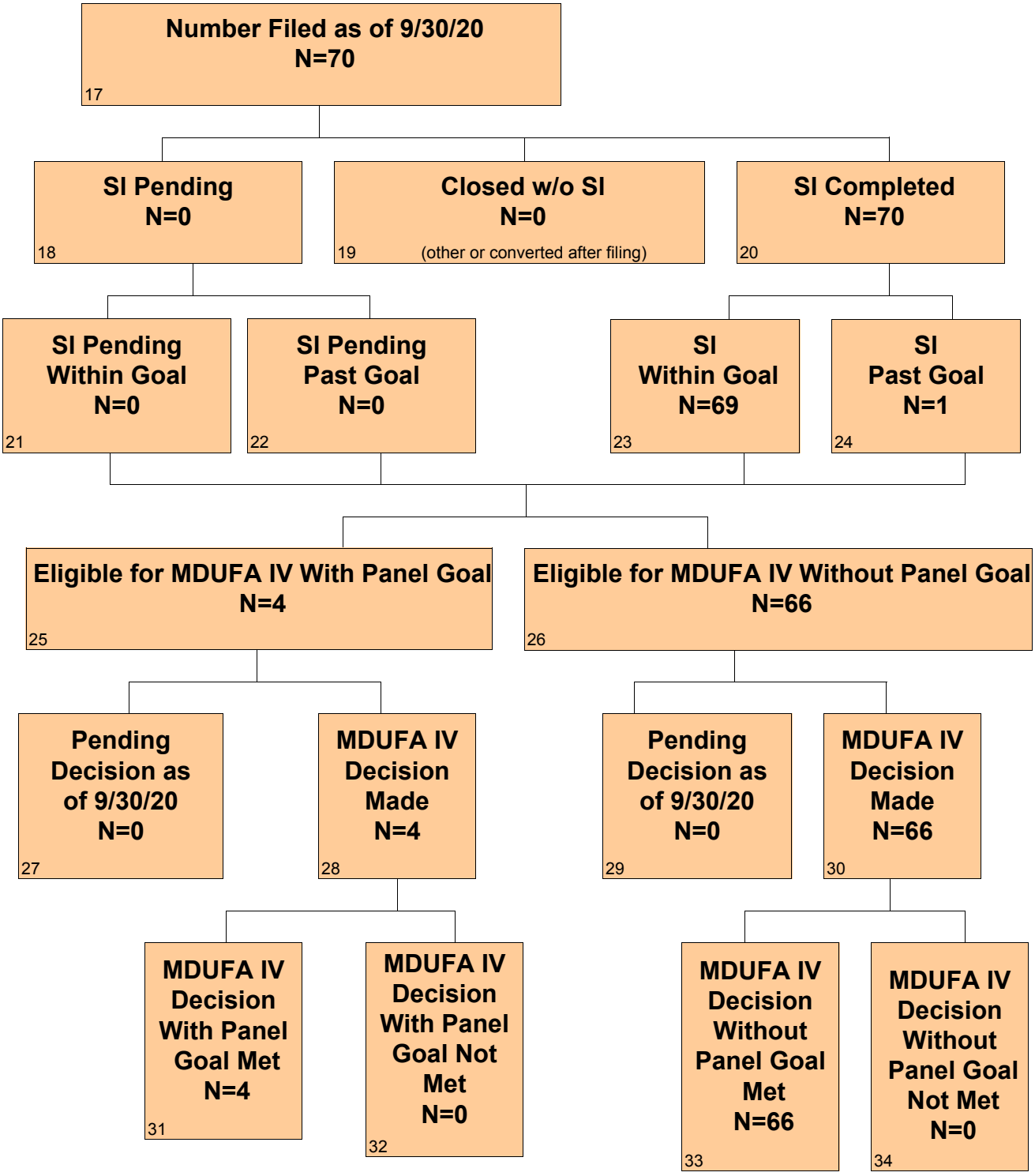
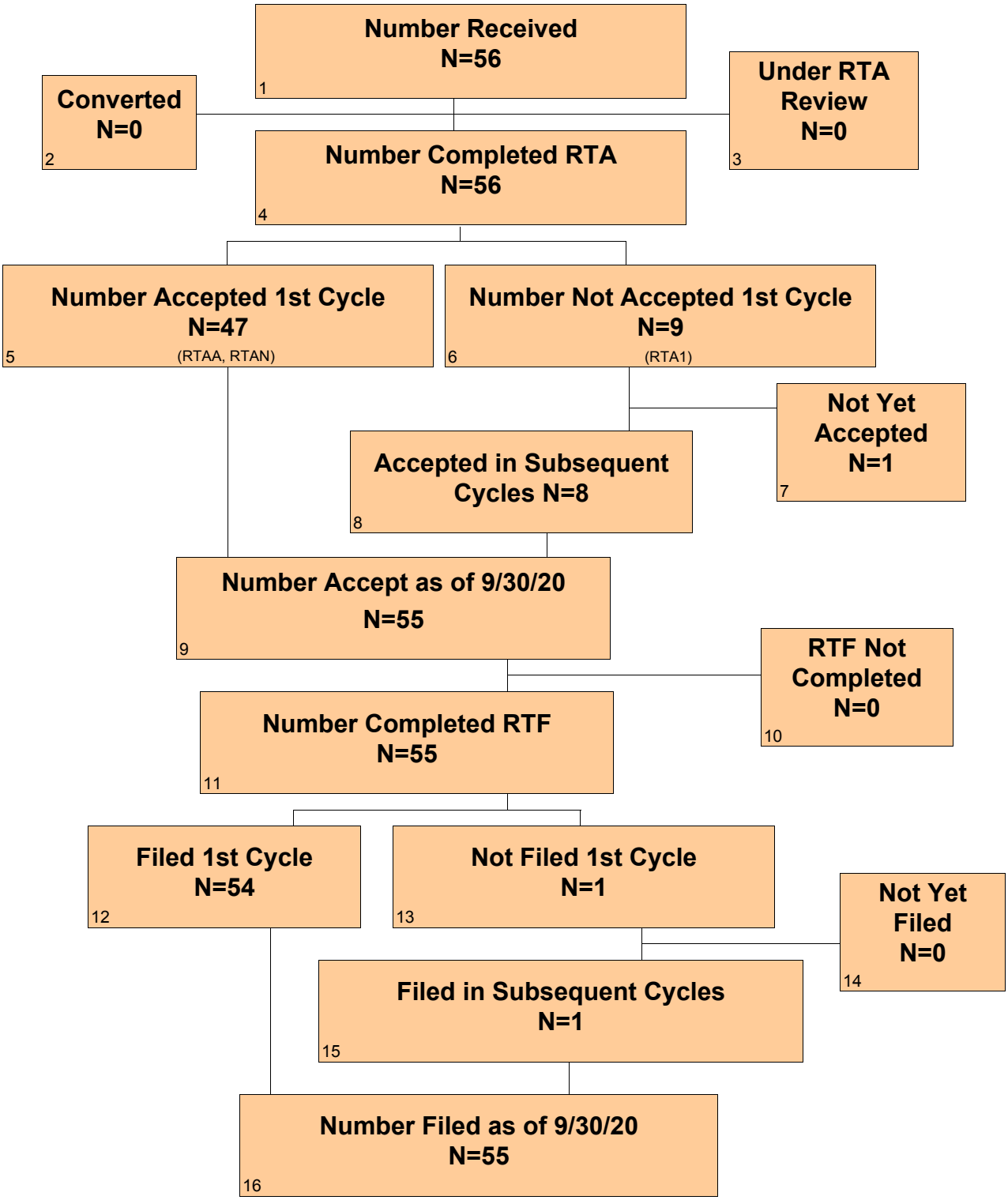
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/20



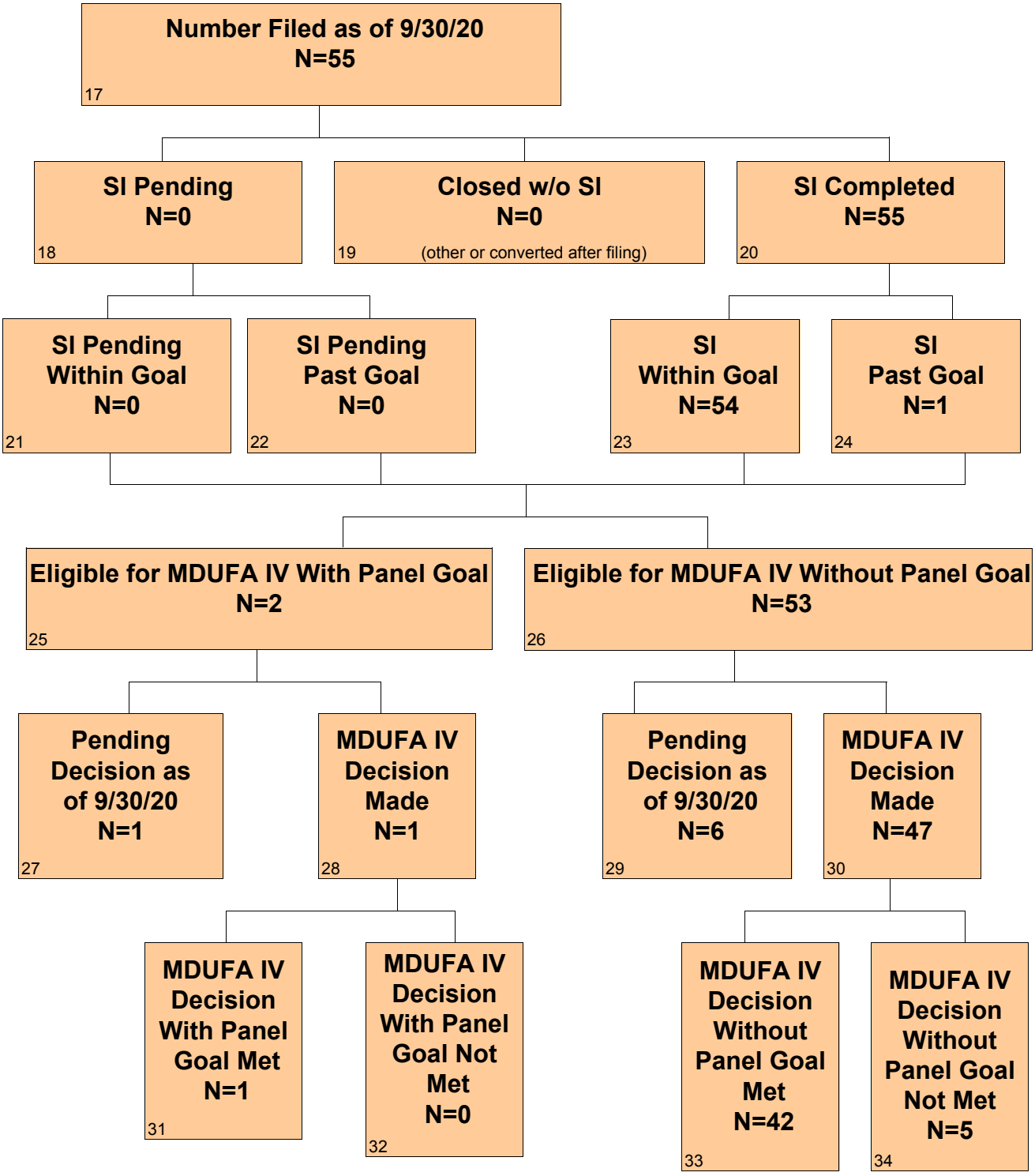
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/20 Continued



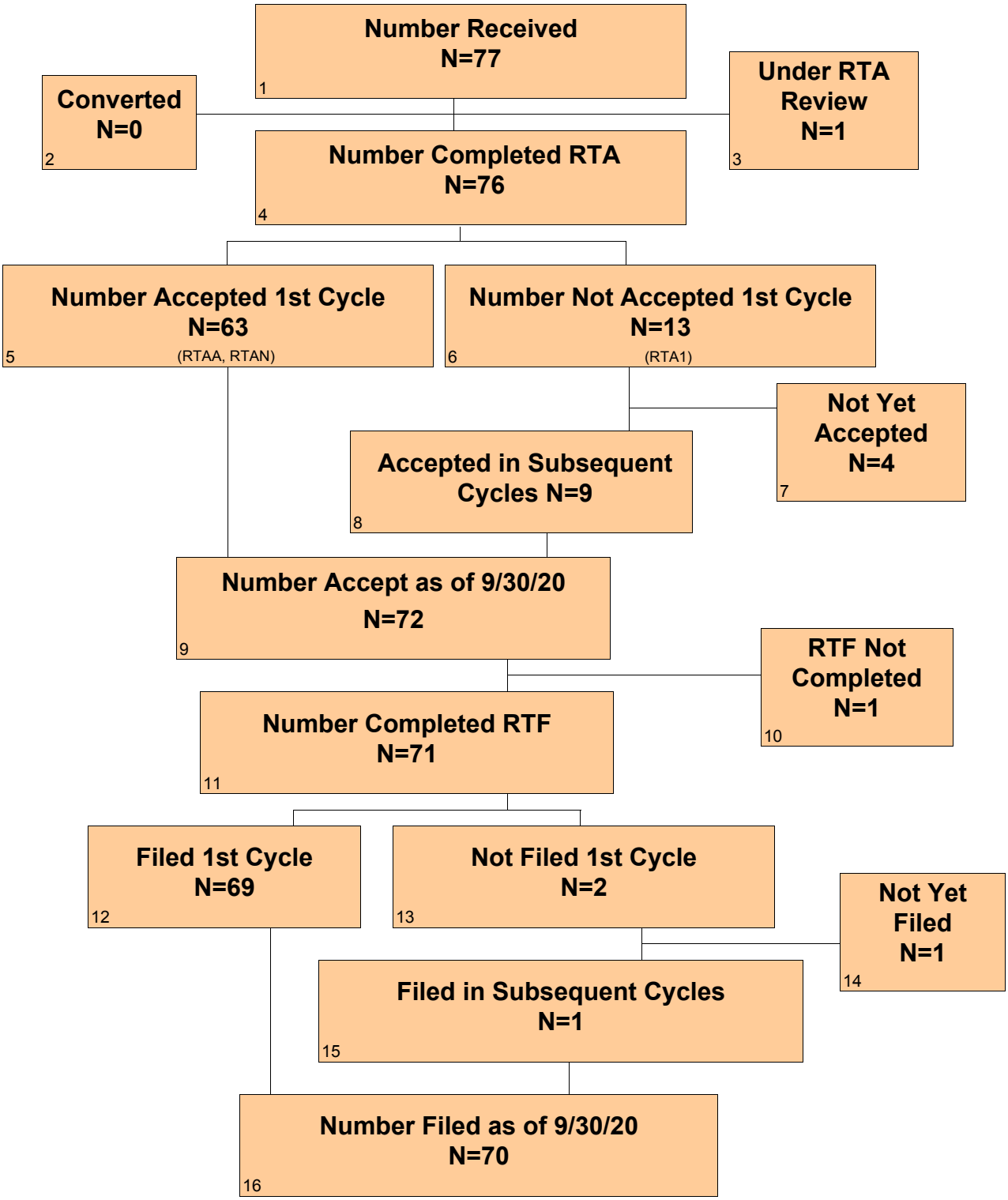
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/20



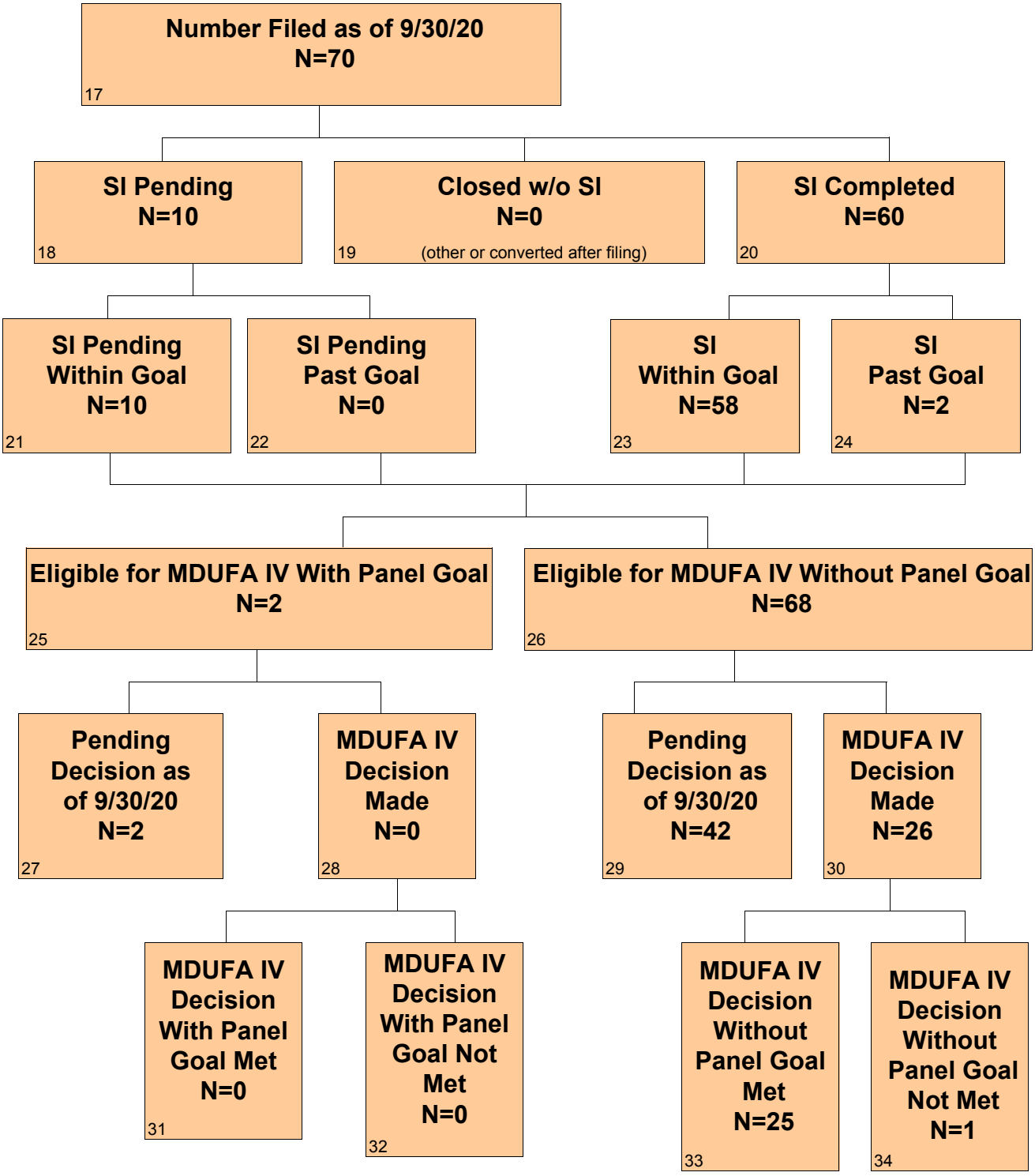
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/20 Continued



CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/20



CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/20 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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	62	46	62		
Number Without a RTA Review and > 15 Days Since Date Received	0	1	1		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted for Filing Review	12	9	13		
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	17.11%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	74	56	77		
Number Accepted	62	47	63		
Completed RTF	71	55	71		
Number Not Filed	3	1	2		
Rate of Submissions Not Filed	4.23%	1.82%	2.82%		

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	70	55	70		
SI Goal Met	69	54	58		
SI Goal Not Met	1	1	2		
SI Pending Within Goal	0	0	10		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	98.57%	98.18%	96.67%		

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	70	55	60		
Average Number of FDA Days to Substantive Interaction	86.86	89.95	88.47		
20th Percentile FDA Days to Substantive Interaction	84	87	88		
40th Percentile FDA Days to Substantive Interaction	88	88	88		
60th Percentile FDA Days to Substantive Interaction	90	89	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	178	246	135		

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	68		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	66	47	26		
MDUFA IV Decision Goal Met	66	42	25		
PMAs Pending MDUFA IV Decision	0	6	42		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	89.36%	96.15%		

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	4	2	2		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	4	1	0		
MDUFA IV Decision Goal Met	4	1	0		
PMAs Pending MDUFA IV Decision	0	1	2		
PMAs Pending MDUFA IV Decision Past Goal	0	1	0		
Current Performance Percent Goal Met*	100%	50%	N/A		

* Per agreement in the MDUFA IV commitment letter, if in any one fiscal year the MDUFA Cohort for this goal is less than 10 submissions, FDA can calculate performance by combining with other fiscal year cohorts until there is a combined cohort of at least 10 submissions. When FDA calculates the final performance in this way, it will be clearly annotated in the MDUFA Annual Performance Report to Congress.

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	66	47	26		
Average FDA Days to MDUFA IV Decision	162.36	175.89	161.27		
20th Percentile FDA Days to MDUFA IV Decision	146	140	149		
40th Percentile FDA Days to MDUFA IV Decision	176	177	179		
60th Percentile FDA Days to MDUFA IV Decision	178	180	180		
80th Percentile FDA Days to MDUFA IV Decision	180	180	180		
Maximum FDA Days to MDUFA IV Decision	279	338	183		
Average Industry Days to MDUFA IV Decision	93.21	97.62	28.85		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	26	20	0		
60th Percentile Industry Days to MDUFA IV Decision	90	79	22		
80th Percentile Industry Days to MDUFA IV Decision	162	176	62		
Maximum Industry Days to MDUFA IV Decision	360	360	127		
Average Total Days to MDUFA IV Decision	255.58	273.51	190.12		
20th Percentile Total Days to MDUFA IV Decision	168	173	169		
40th Percentile Total Days to MDUFA IV Decision	180	200	179		
60th Percentile Total Days to MDUFA IV Decision	258	263	201		
80th Percentile Total Days to MDUFA IV Decision	340	357	238		
Maximum Total Days to MDUFA IV Decision	540	632	307		

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	4	1	0		
Average FDA Days to MDUFA IV Decision	288.25	175.00	0.00		
20th Percentile FDA Days to MDUFA IV Decision	267	175	0		
40th Percentile FDA Days to MDUFA IV Decision	315	175	0		
60th Percentile FDA Days to MDUFA IV Decision	319	175	0		
80th Percentile FDA Days to MDUFA IV Decision	321	175	0		
Maximum FDA Days to MDUFA IV Decision	322	175	0		
Average Industry Days to MDUFA IV Decision	0.00	83.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	83	0		
40th Percentile Industry Days to MDUFA IV Decision	0	83	0		
60th Percentile Industry Days to MDUFA IV Decision	0	83	0		
80th Percentile Industry Days to MDUFA IV Decision	0	83	0		
Maximum Industry Days to MDUFA IV Decision	0	83	0		
Average Total Days to MDUFA IV Decision	288.25	258.00	0.00		
20th Percentile Total Days to MDUFA IV Decision	267	258	0		
40th Percentile Total Days to MDUFA IV Decision	315	258	0		
60th Percentile Total Days to MDUFA IV Decision	319	258	0		
80th Percentile Total Days to MDUFA IV Decision	321	258	0		
Maximum Total Days to MDUFA IV Decision	322	258	0		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	66	53	68		
Number with MDUFA IV Decision	66	47	26		
Number of Withdrawal	6	3	1		
Number of Not Approvable	9	6	1		
Number of Deleted	0	0	0		
Rate of Withdrawal	9.09%	6.38%	3.85%		
Rate of Not Approvable	13.64%	12.77%	3.85%		

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	4	2	2		
Number With MDUFA IV Decision	4	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	3	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	75.00%	100.00%	N/A		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	5	1		
Mean FDA Days for Submissions that Missed the Goal	0.00	266.60	183.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	235.00	0.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	457.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	4	11		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	1	3	6		
MDUFA IV Decision Goal Met	1	3	6		
PMAs Pending MDUFA IV Decision	0	1	5		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met**	100.00%	100.00%	100.00%		

***Includes submission that went to panel**

** Per agreement in the MDUFA IV commitment letter, if in any one fiscal year the MDUFA Cohort for this goal is less than 10 submissions, FDA can calculate performance by combining with other fiscal year cohorts until there is a combined cohort of at least 10 submissions. When FDA calculates the final performance in this way, it will be clearly annotated in the MDUFA Annual Performance Report to Congress.

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	14		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	15	16	8		
MDUFA IV Decision Goal Met	15	12	7		
PMAs Pending MDUFA IV Decision	0	1	6		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	75.00%	87.50%		

***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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	11	6	4		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	5	1	2		
Rate of Submissions Not Accepted for Filing Review	31.25%	14.29%	33.33%		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	16	7	6		
Average Number of FDA Days to Substantive Interaction	87.13	88.86	88.00		
20th Percentile FDA Days to Substantive Interaction	86	88	87		
40th Percentile FDA Days to Substantive Interaction	87	89	88		
60th Percentile FDA Days to Substantive Interaction	90	90	88		
80th Percentile FDA Days to Substantive Interaction	90	90	88		
Maximum FDA Days to Substantive Interaction	90	90	90		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	16	7	6		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	16	7	0		
MDUFA IV Decision Goal Met	16	7	0		
PMAs Pending MDUFA IV Decision	0	0	6		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

Table 1.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	16	7	0		
Average FDA Days to MDUFA IV Decision	177.25	179.14	0.00		
20th Percentile FDA Days to MDUFA IV Decision	176	179	0		
40th Percentile FDA Days to MDUFA IV Decision	177	180	0		
60th Percentile FDA Days to MDUFA IV Decision	179	180	0		
80th Percentile FDA Days to MDUFA IV Decision	180	180	0		
Maximum FDA Days to MDUFA IV Decision	180	180	0		
Average Industry Days to MDUFA IV Decision	128.69	65.43	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	4	0		
40th Percentile Industry Days to MDUFA IV Decision	86	20	0		
60th Percentile Industry Days to MDUFA IV Decision	119	50	0		
80th Percentile Industry Days to MDUFA IV Decision	272	148	0		
Maximum Industry Days to MDUFA IV Decision	360	180	0		
Average Total Days to MDUFA IV Decision	305.94	244.57	0.00		
20th Percentile Total Days to MDUFA IV Decision	178	184	0		
40th Percentile Total Days to MDUFA IV Decision	266	200	0		
60th Percentile Total Days to MDUFA IV Decision	299	230	0		
80th Percentile Total Days to MDUFA IV Decision	444	328	0		
Maximum Total Days to MDUFA IV Decision	528	359	0		

Table 1.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	0		
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA IV Decision	0	0	0		
40th Percentile FDA Days to MDUFA IV Decision	0	0	0		
60th Percentile FDA Days to MDUFA IV Decision	0	0	0		
80th Percentile FDA Days to MDUFA IV Decision	0	0	0		
Maximum FDA Days to MDUFA IV Decision	0	0	0		
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	0	0		
60th Percentile Industry Days to MDUFA IV Decision	0	0	0		
80th Percentile Industry Days to MDUFA IV Decision	0	0	0		
Maximum Industry Days to MDUFA IV Decision	0	0	0		
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile Total Days to MDUFA IV Decision	0	0	0		
40th Percentile Total Days to MDUFA IV Decision	0	0	0		
60th Percentile Total Days to MDUFA IV Decision	0	0	0		
80th Percentile Total Days to MDUFA IV Decision	0	0	0		
Maximum Total Days to MDUFA IV Decision	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	16	7	6		
Number with MDUFA IV Decision	16	7	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	5	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	31.25%	14.29%	N/A		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0		
Number With MDUFA IV Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	20	11	21		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	3	3	2		
Rate of Submissions Not Accepted for Filing Review	13.04%	21.43%	8.70%		

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		
Number Accepted	20	11	21		
Completed RTF	22	14	22		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	4.55%	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	22		
SI Goal Met	22	14	18		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	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	18		
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.33		
20th Percentile FDA Days to Substantive Interaction	84	85	88		
40th Percentile FDA Days to Substantive Interaction	87	88	88		
60th Percentile FDA Days to Substantive Interaction	89	89	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	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	20		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	21	10	10		
MDUFA IV Decision Goal Met	21	10	10		
PMAs Pending MDUFA IV Decision	0	2	10		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	2		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	1	1	0		
MDUFA IV Decision Goal Met	1	1	0		
PMAs Pending MDUFA IV Decision	0	1	2		
PMAs Pending MDUFA IV Decision Past Goal	0	1	0		
Current Performance Percent Goal Met	100.00%	50.00%	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	10	10		
Average FDA Days to MDUFA IV Decision	174.00	167.20	178.50		
20th Percentile FDA Days to MDUFA IV Decision	161	151	177		
40th Percentile FDA Days to MDUFA IV Decision	178	178	179		
60th Percentile FDA Days to MDUFA IV Decision	179	178	179		
80th Percentile FDA Days to MDUFA IV Decision	180	180	180		
Maximum FDA Days to MDUFA IV Decision	279	180	180		
Average Industry Days to MDUFA IV Decision	51.48	98.80	39.10		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	57	18		
60th Percentile Industry Days to MDUFA IV Decision	45	93	46		
80th Percentile Industry Days to MDUFA IV Decision	91	174	64		
Maximum Industry Days to MDUFA IV Decision	162	322	127		
Average Total Days to MDUFA IV Decision	225.48	266.00	217.60		
20th Percentile Total Days to MDUFA IV Decision	168	151	179		
40th Percentile Total Days to MDUFA IV Decision	180	236	197		
60th Percentile Total Days to MDUFA IV Decision	229	272	225		
80th Percentile Total Days to MDUFA IV Decision	324	353	243		
Maximum Total Days to MDUFA IV Decision	340	501	307		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	1	0		
Average FDA Days to MDUFA IV Decision	197.00	175.00	0.00		
20th Percentile FDA Days to MDUFA IV Decision	197	175	0		
40th Percentile FDA Days to MDUFA IV Decision	197	175	0		
60th Percentile FDA Days to MDUFA IV Decision	197	175	0		
80th Percentile FDA Days to MDUFA IV Decision	197	175	0		
Maximum FDA Days to MDUFA IV Decision	197	175	0		
Average Industry Days to MDUFA IV Decision	0.00	83.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	83	0		
40th Percentile Industry Days to MDUFA IV Decision	0	83	0		
60th Percentile Industry Days to MDUFA IV Decision	0	83	0		
80th Percentile Industry Days to MDUFA IV Decision	0	83	0		
Maximum Industry Days to MDUFA IV Decision	0	83	0		
Average Total Days to MDUFA IV Decision	197.00	258.00	0.00		
20th Percentile Total Days to MDUFA IV Decision	197	258	0		
40th Percentile Total Days to MDUFA IV Decision	197	258	0		
60th Percentile Total Days to MDUFA IV Decision	197	258	0		
80th Percentile Total Days to MDUFA IV Decision	197	258	0		
Maximum Total Days to MDUFA IV Decision	197	258	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	20		
Number with MDUFA IV Decision	21	10	10		
Number of Withdrawal	0	0	1		
Number of Not Approvable	1	1	1		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	10.00%		
Rate of Not Approvable	4.76%	10.00%	10.00%		

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	2		
Number With MDUFA IV Decision	1	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	0.00%	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	457.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	8	3	6		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	1		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	0	0		
Rate of Submissions Not Accepted for Filing Review	11.11%	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		
Number Accepted	8	3	7		
Completed RTF	9	3	7		
Number Not Filed	1	0	1		
Rate of Submissions Not Filed	11.11%	0.00%	14.29%		

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		
SI Goal Met	8	3	4		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	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	4		
Average Number of FDA Days to Substantive Interaction	99.50	139.67	89.25		
20th Percentile FDA Days to Substantive Interaction	87	86	89		
40th Percentile FDA Days to Substantive Interaction	88	87	89		
60th Percentile FDA Days to Substantive Interaction	90	119	90		
80th Percentile FDA Days to Substantive Interaction	91	182	90		
Maximum FDA Days to Substantive Interaction	178	246	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	6		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	5	3	0		
MDUFA IV Decision Goal Met	5	3	0		
PMAs Pending MDUFA IV Decision	0	0	6		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	3	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	3	0	0		
MDUFA IV Decision Goal Met	3	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	N/A		

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	3	6		
Number with MDUFA IV Decision	5	3	0		
Number of Withdrawal	1	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	20.00%	0.00%	N/A		
Rate of Not Approvable	0.00%	33.33%	N/A		

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	0.00%	0.00%	0.00%		

***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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	1	1	2		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted for Filing Review	2	1	2		
Rate of Submissions Not Accepted for Filing Review	66.67%	50.00%	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		
Number Accepted	1	1	2		
Completed RTF	1	2	3		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	2	3		
SI Goal Met	1	2	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	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	1	2	3		
Average Number of FDA Days to Substantive Interaction	88.00	90.00	89.33		
20th Percentile FDA Days to Substantive Interaction	88	90	89		
40th Percentile FDA Days to Substantive Interaction	88	90	90		
60th Percentile FDA Days to Substantive Interaction	88	90	90		
80th Percentile FDA Days to Substantive Interaction	88	90	90		
Maximum FDA Days to Substantive Interaction	88	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	1	2	3		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	1	2	1		
MDUFA IV Decision Goal Met	1	1	1		
PMAs Pending MDUFA IV Decision	0	0	2		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	50.00%	100.00%		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	2	1		
Average FDA Days to MDUFA IV Decision	159.00	181.00	180.00		
20th Percentile FDA Days to MDUFA IV Decision	159	179	180		
40th Percentile FDA Days to MDUFA IV Decision	159	180	180		
60th Percentile FDA Days to MDUFA IV Decision	159	182	180		
80th Percentile FDA Days to MDUFA IV Decision	159	183	180		
Maximum FDA Days to MDUFA IV Decision	159	184	180		
Average Industry Days to MDUFA IV Decision	6.00	90.00	33.00		
20th Percentile Industry Days to MDUFA IV Decision	6	49	33		
40th Percentile Industry Days to MDUFA IV Decision	6	76	33		
60th Percentile Industry Days to MDUFA IV Decision	6	104	33		
80th Percentile Industry Days to MDUFA IV Decision	6	131	33		
Maximum Industry Days to MDUFA IV Decision	6	159	33		
Average Total Days to MDUFA IV Decision	165.00	271.00	213.00		
20th Percentile Total Days to MDUFA IV Decision	165	231	213		
40th Percentile Total Days to MDUFA IV Decision	165	258	213		
60th Percentile Total Days to MDUFA IV Decision	165	284	213		
80th Percentile Total Days to MDUFA IV Decision	165	311	213		
Maximum Total Days to MDUFA IV Decision	165	337	213		

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

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	3	4	1		
Number Without a RTA Review and > 15 Days Since Date Received	0	1	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	1	0	3		
Rate of Submissions Not Accepted for Filing Review	25.00%	0.00%	75.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5	4		
Number Accepted	3	5	1		
Completed RTF	4	5	3		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	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		
SI Goal Met	3	5	1		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	75.00%	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	1		
Average Number of FDA Days to Substantive Interaction	90.50	84.80	90.00		
20th Percentile FDA Days to Substantive Interaction	90	84	90		
40th Percentile FDA Days to Substantive Interaction	90	90	90		
60th Percentile FDA Days to Substantive Interaction	90	90	90		
80th Percentile FDA Days to Substantive Interaction	91	90	90		
Maximum FDA Days to Substantive Interaction	92	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	3		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	4	4	0		
MDUFA IV Decision Goal Met	4	4	0		
PMAs Pending MDUFA IV Decision	0	1	3		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	4	0		
Average FDA Days to MDUFA IV Decision	180.00	157.50	0.00		
20th Percentile FDA Days to MDUFA IV Decision	180	144	0		
40th Percentile FDA Days to MDUFA IV Decision	180	180	0		
60th Percentile FDA Days to MDUFA IV Decision	180	180	0		
80th Percentile FDA Days to MDUFA IV Decision	180	180	0		
Maximum FDA Days to MDUFA IV Decision	180	180	0		
Average Industry Days to MDUFA IV Decision	186.75	129.25	0.00		
20th Percentile Industry Days to MDUFA IV Decision	56	81	0		
40th Percentile Industry Days to MDUFA IV Decision	134	125	0		
60th Percentile Industry Days to MDUFA IV Decision	253	164	0		
80th Percentile Industry Days to MDUFA IV Decision	320	184	0		
Maximum Industry Days to MDUFA IV Decision	360	194	0		
Average Total Days to MDUFA IV Decision	366.75	286.75	0.00		
20th Percentile Total Days to MDUFA IV Decision	236	246	0		
40th Percentile Total Days to MDUFA IV Decision	314	272	0		
60th Percentile Total Days to MDUFA IV Decision	433	287	0		
80th Percentile Total Days to MDUFA IV Decision	500	325	0		
Maximum Total Days to MDUFA IV Decision	540	374	0		

Table 1.8 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0	0		
Number With MDUFA IV Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	2	2	2		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	2	0		
Rate of Submissions Not Accepted for Filing Review	0.00%	50.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4	2		
Number Accepted	2	2	2		
Completed RTF	2	3	2		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	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		
SI Goal Met	2	3	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	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		
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50		
20th Percentile FDA Days to Substantive Interaction	84	88	88		
40th Percentile FDA Days to Substantive Interaction	86	89	88		
60th Percentile FDA Days to Substantive Interaction	87	89	89		
80th Percentile FDA Days to Substantive Interaction	89	90	89		
Maximum FDA Days to Substantive Interaction	90	90	89		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	2	3	2		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	2	2	1		
MDUFA IV Decision Goal Met	2	2	1		
PMAs Pending MDUFA IV Decision	0	1	1		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	2	1		
Average FDA Days to MDUFA IV Decision	180.00	133.00	177.00		
20th Percentile FDA Days to MDUFA IV Decision	180	105	177		
40th Percentile FDA Days to MDUFA IV Decision	180	124	177		
60th Percentile FDA Days to MDUFA IV Decision	180	142	177		
80th Percentile FDA Days to MDUFA IV Decision	180	161	177		
Maximum FDA Days to MDUFA IV Decision	180	179	177		
Average Industry Days to MDUFA IV Decision	141.50	80.50	0.00		
20th Percentile Industry Days to MDUFA IV Decision	57	39	0		
40th Percentile Industry Days to MDUFA IV Decision	113	67	0		
60th Percentile Industry Days to MDUFA IV Decision	170	94	0		
80th Percentile Industry Days to MDUFA IV Decision	226	122	0		
Maximum Industry Days to MDUFA IV Decision	283	149	0		
Average Total Days to MDUFA IV Decision	321.50	213.50	177.00		
20th Percentile Total Days to MDUFA IV Decision	237	145	177		
40th Percentile Total Days to MDUFA IV Decision	293	191	177		
60th Percentile Total Days to MDUFA IV Decision	350	236	177		
80th Percentile Total Days to MDUFA IV Decision	406	282	177		
Maximum Total Days to MDUFA IV Decision	463	328	177		

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		
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA IV Decision	0	0	0		
40th Percentile FDA Days to MDUFA IV Decision	0	0	0		
60th Percentile FDA Days to MDUFA IV Decision	0	0	0		
80th Percentile FDA Days to MDUFA IV Decision	0	0	0		
Maximum FDA Days to MDUFA IV Decision	0	0	0		
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	0	0		
60th Percentile Industry Days to MDUFA IV Decision	0	0	0		
80th Percentile Industry Days to MDUFA IV Decision	0	0	0		
Maximum Industry Days to MDUFA IV Decision	0	0	0		
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile Total Days to MDUFA IV Decision	0	0	0		
40th Percentile Total Days to MDUFA IV Decision	0	0	0		
60th Percentile Total Days to MDUFA IV Decision	0	0	0		
80th Percentile Total Days to MDUFA IV Decision	0	0	0		
Maximum Total Days to MDUFA IV Decision	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		
Number with MDUFA IV Decision	2	2	1		
Number of Withdrawal	0	1	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	50.00%	0.00%		
Rate of Not Approvable	0.00%	50.00%	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		
Number With MDUFA IV Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	17	19	26		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	2	4		
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	13.33%		

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		
Number Accepted	17	19	26		
Completed RTF	17	21	28		
Number Not Filed	0	0	1		
Rate of Submissions Not Filed	0.00%	0.00%	3.57%		

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	17	21	28		
SI Goal Met	17	20	24		
SI Goal Not Met	0	1	2		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	95.24%	92.31%		

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	26		
Average Number of FDA Days to Substantive Interaction	84.29	87.76	88.38		
20th Percentile FDA Days to Substantive Interaction	84	87	86		
40th Percentile FDA Days to Substantive Interaction	87	88	88		
60th Percentile FDA Days to Substantive Interaction	89	89	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	90	91	135		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	17	21	28		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	17	19	14		
MDUFA IV Decision Goal Met	17	15	13		
PMAs Pending MDUFA IV Decision	0	2	14		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	78.95%	92.86%		

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

Table 1.7 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	17	19	14		
Average FDA Days to MDUFA IV Decision	123.35	178.84	146.50		
20th Percentile FDA Days to MDUFA IV Decision	90	131	107		
40th Percentile FDA Days to MDUFA IV Decision	99	159	155		
60th Percentile FDA Days to MDUFA IV Decision	141	177	180		
80th Percentile FDA Days to MDUFA IV Decision	174	214	180		
Maximum FDA Days to MDUFA IV Decision	180	299	183		
Average Industry Days to MDUFA IV Decision	86.18	101.11	23.29		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	3	0		
60th Percentile Industry Days to MDUFA IV Decision	75	62	21		
80th Percentile Industry Days to MDUFA IV Decision	149	234	36		
Maximum Industry Days to MDUFA IV Decision	336	360	124		
Average Total Days to MDUFA IV Decision	209.53	279.95	169.79		
20th Percentile Total Days to MDUFA IV Decision	90	155	136		
40th Percentile Total Days to MDUFA IV Decision	139	177	171		
60th Percentile Total Days to MDUFA IV Decision	213	200	180		
80th Percentile Total Days to MDUFA IV Decision	266	436	204		
Maximum Total Days to MDUFA IV Decision	511	632	304		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	17	21	28		
Number with MDUFA IV Decision	17	19	14		
Number of Withdrawal	5	1	0		
Number of Not Approvable	2	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	29.41%	5.26%	0.00%		
Rate of Not Approvable	11.76%	5.26%	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		
Number With MDUFA IV Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

Table 1.11 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	1		
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	183.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	288.50	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	1	3	6		
MDUFA IV Decision Goal Met	1	3	6		
PMAs Pending MDUFA IV Decision	0	1	5		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

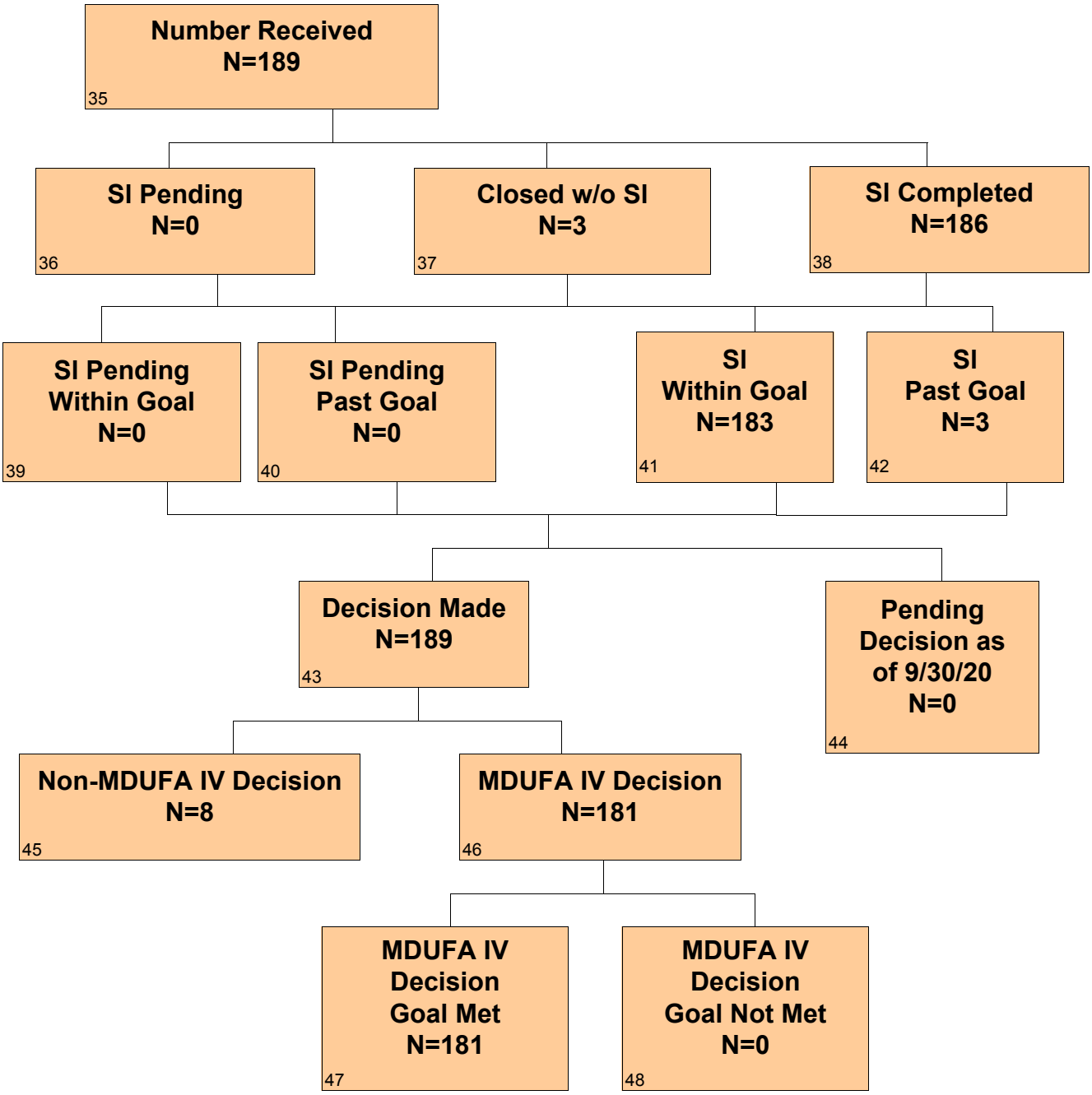
***Includes submission that went to panel**

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

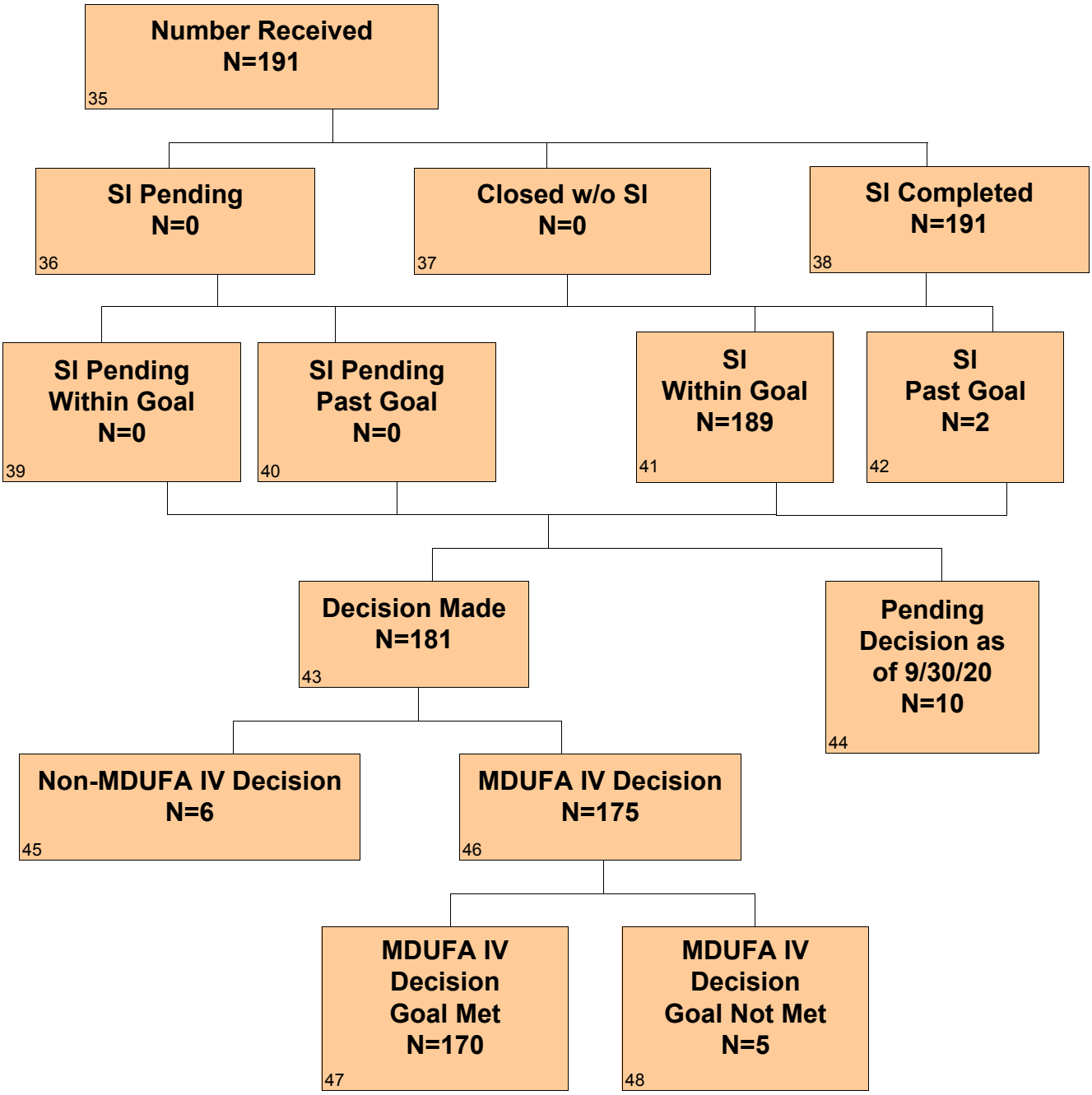
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	14		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	15	16	8		
MDUFA IV Decision Goal Met	15	12	7		
PMAs Pending MDUFA IV Decision	0	1	6		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	75.00%	87.50%		

***Includes submission that went to panel**

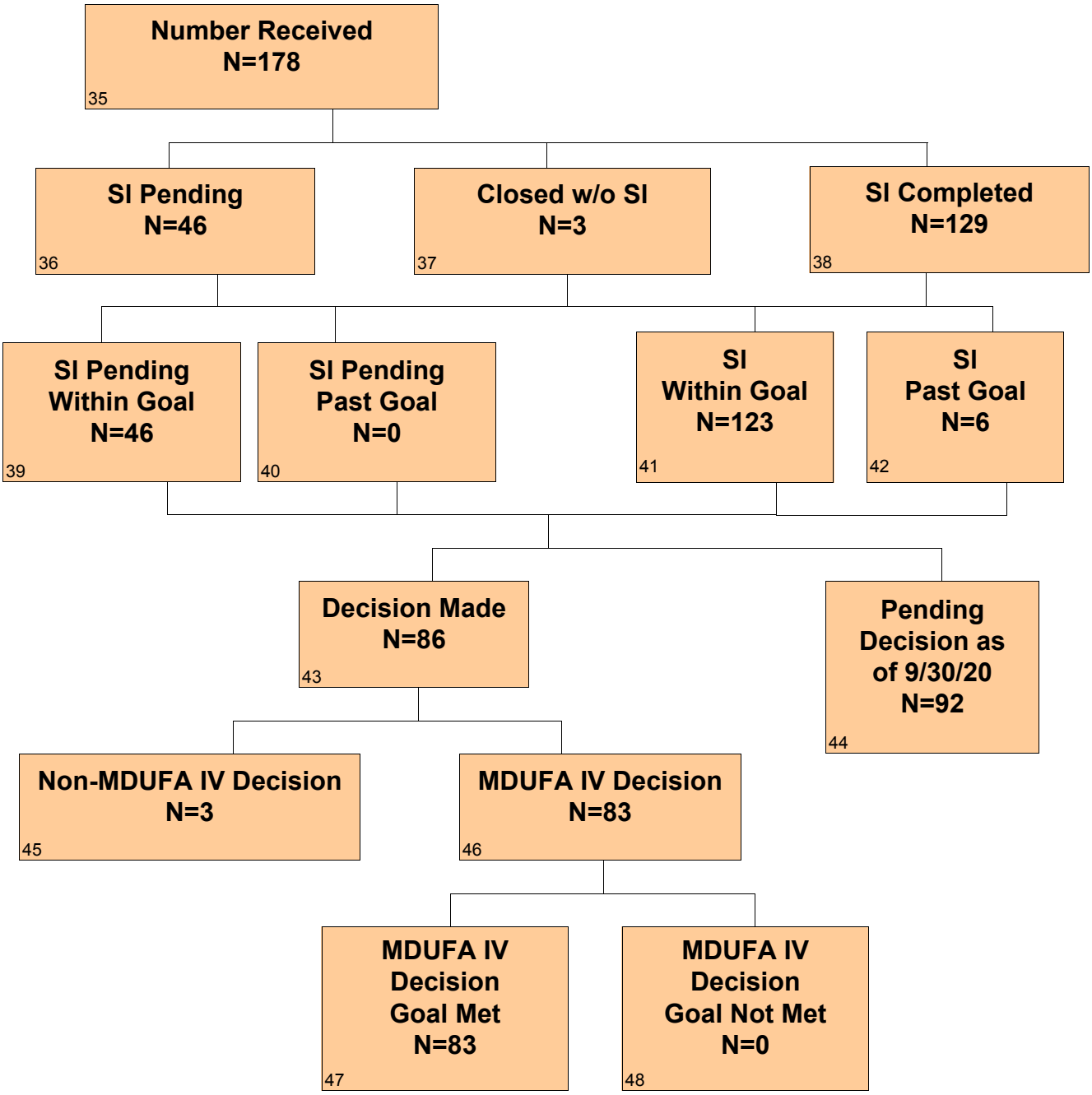
CDRH PMA 180 Day Supplements - FY 2018 as of 9/30/20



CDRH PMA 180 Day Supplements - FY 2019 as of 9/30/20



CDRH PMA 180 Day Supplements - FY 2020 as of 9/30/20



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Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	189	191	178		
SI Goal Met	183	189	123		
SI Goal Not Met	3	2	6		
SI Pending Within Goal	0	0	46		
SI Pending Past Goal	0	0	0		
Closed Without SI	3	0	3		
Current SI Performance Percent Goal Met	98.39%	98.95%	95.35%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	189	191	178		
Non-MDUFA IV Decision	8	6	3		
MDUFA IV Decision	181	175	83		
MDUFA IV Decision Goal Met	181	170	83		
Supplements Pending MDUFA IV Decision	0	10	92		
Supplements Pending MDUFA IV Decision Past Goal	0	0	1		
Current Performance Percent Goal Met	100.00%	97.14%	98.81%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	189	191	178		
Number with MDUFA IV Decision	181	175	83		
Number of Not Approvable	13	8	3		
Rate of Not Approvable	7.18%	4.57%	3.61%		

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	5	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	228.40	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	10.80	0.00		

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	20	36	29		
SI Goal Met	20	36	21		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	8		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	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	29		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	20	30	14		
MDUFA IV Decision Goal Met	20	29	14		
Supplements Pending MDUFA IV Decision	0	6	15		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	96.67%	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	29		
Number with MDUFA IV Decision	20	30	14		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	5.00%	0.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	302.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	41.00	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		
SI Goal Met	91	81	52		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	17		
SI Pending Past Goal	0	0	0		
Closed Without SI	2	0	0		
Current SI Performance Percent Goal Met	98.91%	100.00%	98.11%		

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		
Non-MDUFA IV Decision	2	3	0		
MDUFA IV Decision	92	78	30		
MDUFA IV Decision Goal Met	92	78	30		
Supplements Pending MDUFA IV Decision	0	0	40		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number with MDUFA IV Decision	92	78	30		
Number of Not Approvable	6	6	0		
Rate of Not Approvable	6.52%	7.69%	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	14	15	11		
SI Goal Not Met	1	1	0		
SI Pending Within Goal	0	0	5		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	3		
Current SI Performance Percent Goal Met	93.33%	93.75%	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		
Non-MDUFA IV Decision	0	2	3		
MDUFA IV Decision	15	13	8		
MDUFA IV Decision Goal Met	15	13	8		
Supplements Pending MDUFA IV Decision	0	1	8		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number with MDUFA IV Decision	15	13	8		
Number of Not Approvable	0	1	2		
Rate of Not Approvable	0.00%	7.69%	25.00%		

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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	9	9	5		
SI Goal Not Met	0	1	1		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	90.00%	83.33%		

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		
Non-MDUFA IV Decision	1	1	0		
MDUFA IV Decision	8	8	4		
MDUFA IV Decision Goal Met	8	5	4		
Supplements Pending MDUFA IV Decision	0	1	3		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	62.50%	100.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	10	7		
Number with MDUFA IV Decision	8	8	4		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	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	3	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	198.67	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	16	24		
SI Goal Met	12	16	14		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	10		
SI Pending Past Goal	0	0	0		
Closed Without SI	1	0	0		
Current SI Performance Percent Goal Met	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	24		
Non-MDUFA IV Decision	2	0	0		
MDUFA IV Decision	11	15	8		
MDUFA IV Decision Goal Met	11	14	8		
Supplements Pending MDUFA IV Decision	0	1	16		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	93.33%	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	24		
Number with MDUFA IV Decision	11	15	8		
Number of Not Approvable	2	0	1		
Rate of Not Approvable	18.18%	0.00%	12.50%		

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

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

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	6	2		
SI Goal Met	1	6	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	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	1	6	2		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	1	6	0		
MDUFA IV Decision Goal Met	1	6	0		
Supplements Pending MDUFA IV Decision	0	0	2		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	0.00%		

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	1	6	2		
Number with MDUFA IV Decision	1	6	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	N/A		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	36	26	19		
SI Goal Not Met	1	0	4		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	97.30%	100.00%	82.61%		

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		
Non-MDUFA IV Decision	3	0	0		
MDUFA IV Decision	34	25	19		
MDUFA IV Decision Goal Met	34	25	19		
Supplements Pending MDUFA IV Decision	0	1	8		
Supplements Pending MDUFA IV Decision Past Goal	0	0	1		
Current Performance Percent Goal Met	100.00%	100.00%	95.00%		

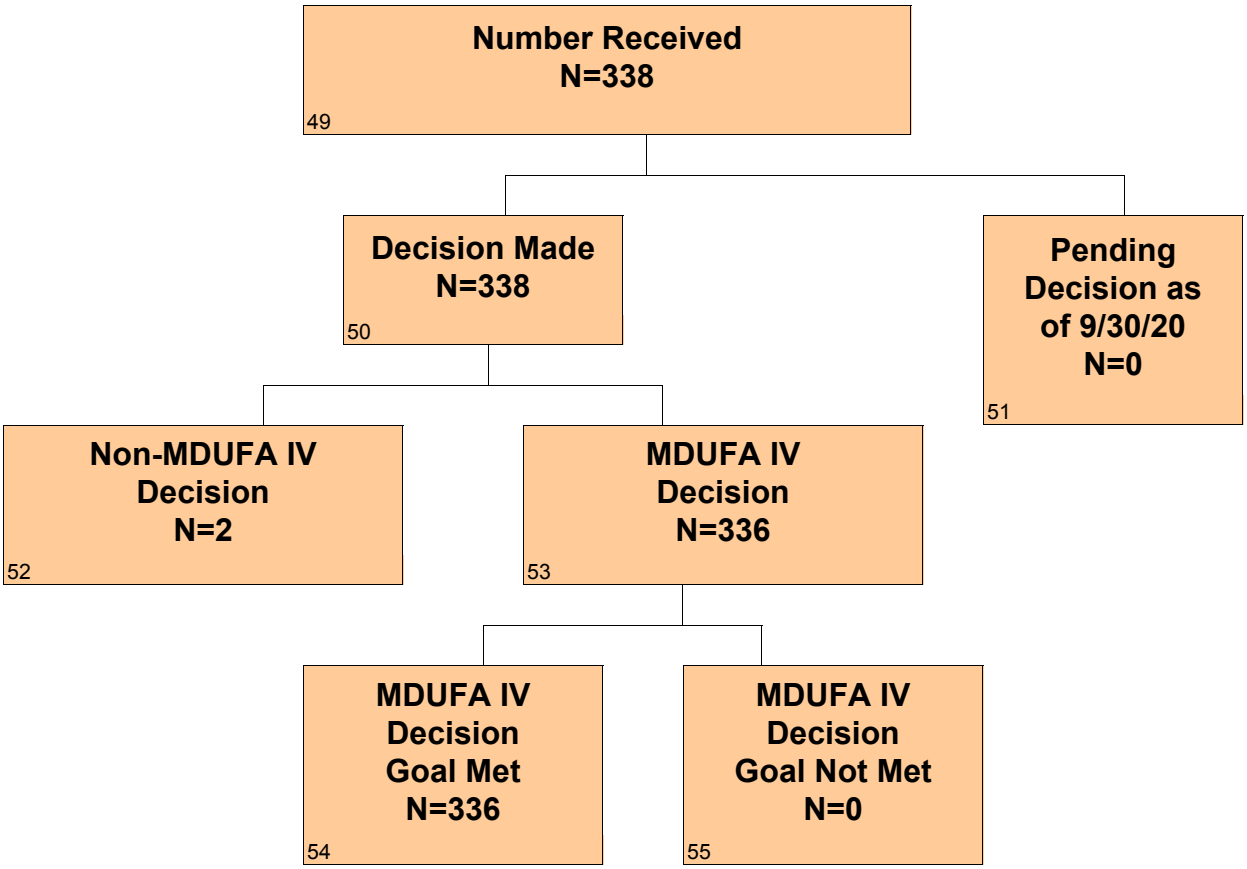
Table 2.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	26	27		
Number with MDUFA IV Decision	34	25	19		
Number of Not Approvable	4	1	0		
Rate of Not Approvable	11.76%	4.00%	0.00%		

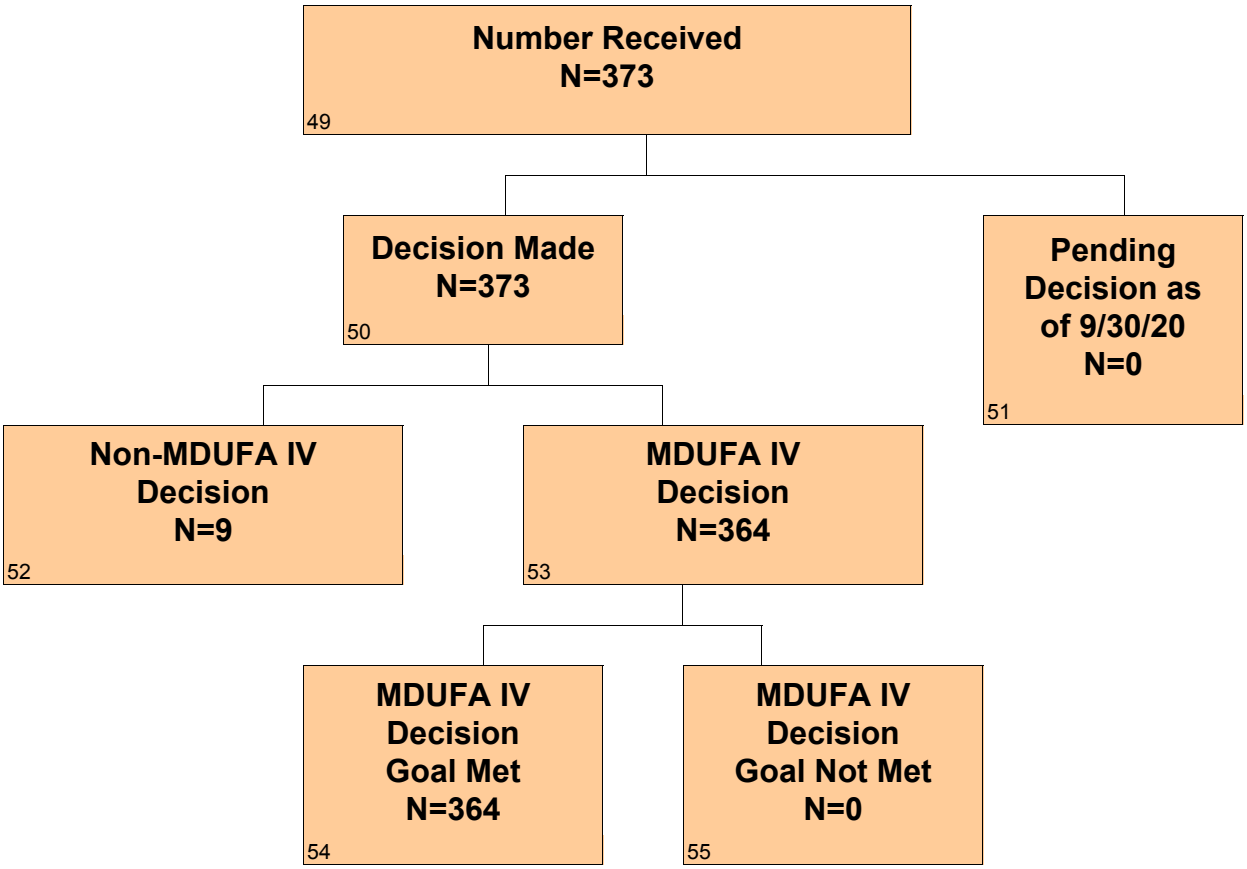
Table 2.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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

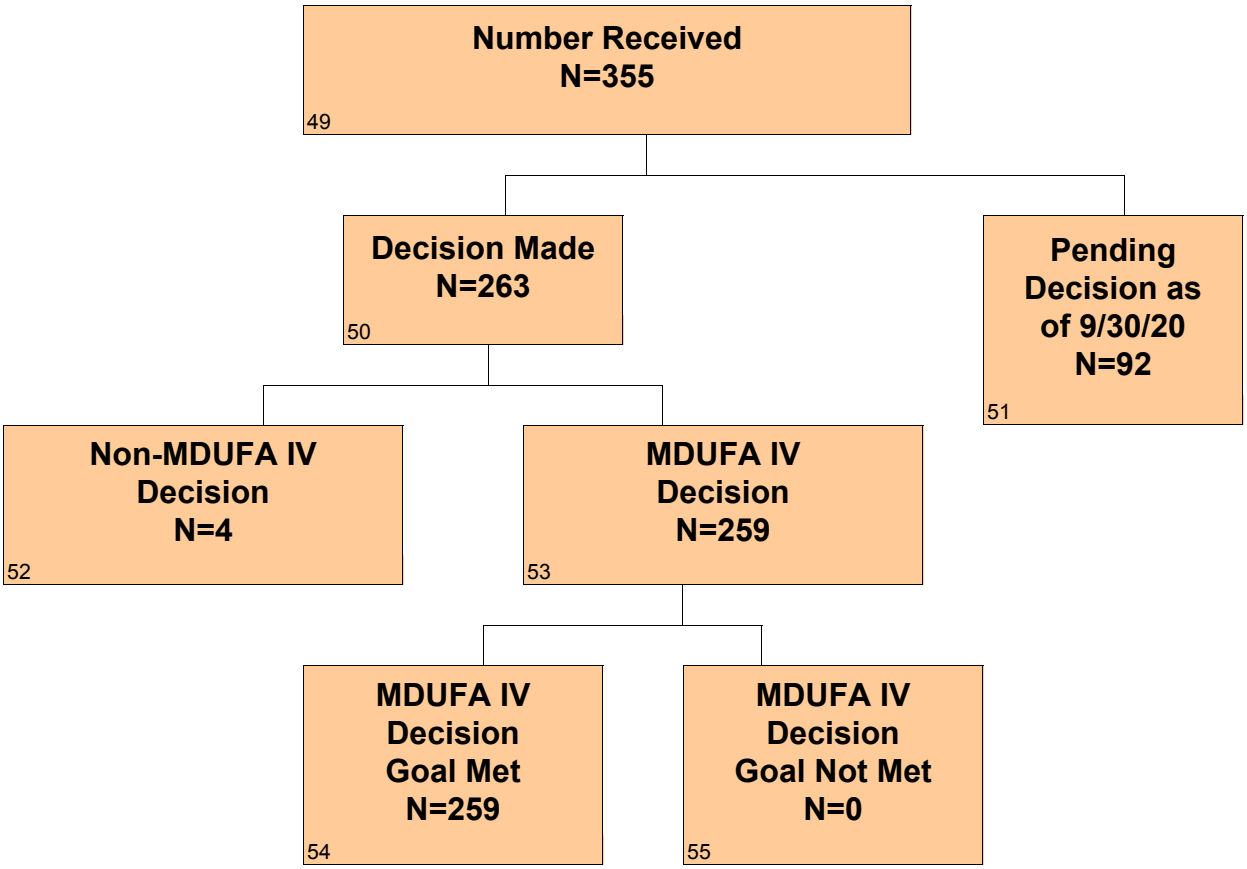
CDRH PMA Real Time Supplements - FY 2018 as of 9/30/20



CDRH PMA Real Time Supplements - FY 2019 as of 9/30/20



CDRH PMA Real Time Supplements - FY 2020 as of 9/30/20



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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	355		
Non-MDUFA IV Decision	2	9	4		
MDUFA IV Decision	336	364	259		
MDUFA IV Decision Goal Met	336	364	259		
Supplements Pending MDUFA IV Decision	0	0	92		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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	355		
Number With MDUFA IV Decision	336	364	259		
Number of Not Approvable	20	29	6		
Rate of Not Approvable	5.95%	7.97%	2.32%		

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	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	2	1		
MDUFA IV Decision	23	38	12		
MDUFA IV Decision Goal Met	23	38	12		
Supplements Pending MDUFA IV Decision	0	0	3		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number With MDUFA IV Decision	23	38	12		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	4.35%	2.63%	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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	194		
Non-MDUFA IV Decision	0	3	2		
MDUFA IV Decision	154	170	149		
MDUFA IV Decision Goal Met	154	170	149		
Supplements Pending MDUFA IV Decision	0	0	43		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	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	194		
Number With MDUFA IV Decision	154	170	149		
Number of Not Approvable	12	15	1		
Rate of Not Approvable	7.79%	8.82%	0.67%		

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	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	1	0		
MDUFA IV Decision	20	38	25		
MDUFA IV Decision Goal Met	20	38	25		
Supplements Pending MDUFA IV Decision	0	0	11		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number with MDUFA IV Decision	20	38	25		
Number of Not Approvable	1	8	1		
Rate of Not Approvable	5.00%	21.05%	4.00%		

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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	1	0	0		
MDUFA IV Decision	12	18	10		
MDUFA IV Decision Goal Met	12	18	10		
Supplements Pending MDUFA IV Decision	0	0	3		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	18	13		
Number with MDUFA IV Decision	12	18	10		
Number of Not Approvable	4	0	0		
Rate of Not Approvable	33.33%	0.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	16	32	22		
MDUFA IV Decision Goal Met	16	32	22		
Supplements Pending MDUFA IV Decision	0	0	2		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number with MDUFA IV Decision	16	32	22		
Number of Not Approvable	0	2	3		
Rate of Not Approvable	0.00%	6.25%	13.64%		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	17	22	10		
Non-MDUFA IV Decision	0	0	1		
MDUFA IV Decision	17	22	6		
MDUFA IV Decision Goal Met	17	22	6		
Supplements Pending MDUFA IV Decision	0	0	3		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	22	10		
Number with MDUFA IV Decision	17	22	6		
Number of Not Approvable	2	2	1		
Rate of Not Approvable	11.76%	9.09%	16.67%		

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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	1	3	0		
MDUFA IV Decision	94	46	35		
MDUFA IV Decision Goal Met	94	46	35		
Supplements Pending MDUFA IV Decision	0	0	27		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	95	49	62		
Number with MDUFA IV Decision	94	46	35		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	2.17%	0.00%		

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

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

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2019 and September 30, 2020.

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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	6	0	
Original PMAs (Panel) - Non-Breakthrough Device	3	2	1	0	
Original PMAs (No Panel) - Non-Breakthrough Device	39	31	40	0	
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	0	0	
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	26	21	28	0	
PMA Modules	64	73	70	0	
180-Day Supplements	189	191	178	0	
Real-Time Supplements	338	373	355	0	

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	70	55	70	0	
Number With a Decision (MDUFA or Non-MDUFA)	70	48	27	0	
% of FY Closed	100.00%	87.27%	36.84%	0.00%	

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 395 FDA Days	3 Year Cohort 395 FDA Days	3 Year Cohort 395 FDA Days	3 Year Cohort 395 FDA Days	3 Year Cohort 395 FDA Days
Number With a MDUFA Decision	197	177	142	0	
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	177	159	128	0	
Three-year Rolling Average Total Time to MDUFA Decision	262.32	N/A	N/A	0.00	

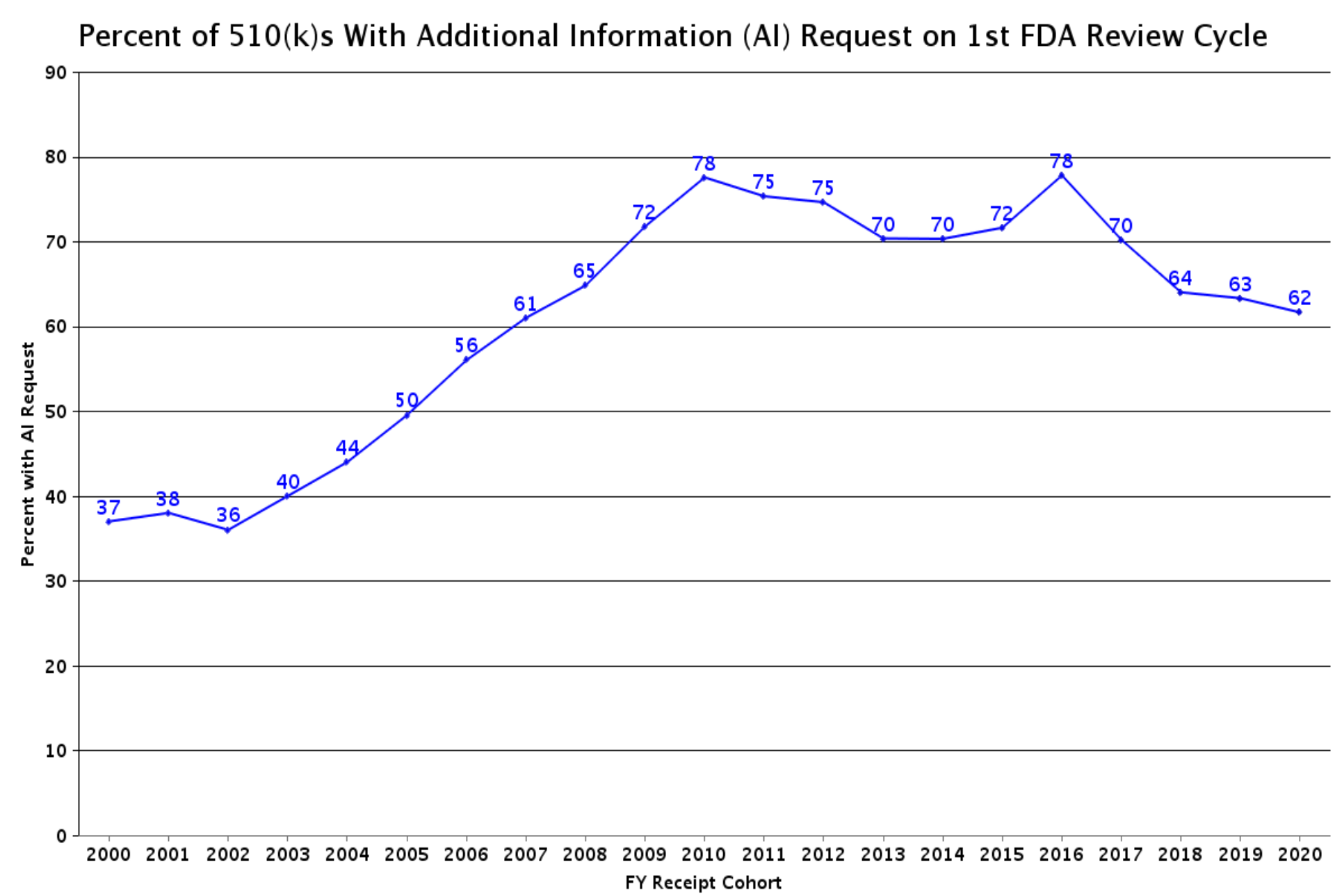
PM Originals and Panel Track Supplements			
Amendment Type	**FY2018**	**FY2019**	**FY2020**
MAJR - Response to MAJR Deficiency Letter	37	39	32
ADEF - Response to Approvable Pending Deficiency Letter	0	0	0
NOAP - Response to Not Approvable Deficiency Letter	5	4	0
UMAJ - Unsolicited Major Amendment	5	5	1
UMIN - Unsolicited Minor Amendment	64	47	62

PM 180-Day Supplements			
Amendment Type	**FY2018**	**FY2019**	**FY2020**
MAJR - Response to MAJR Deficiency Letter	92	86	52
ADEF - Response to Approvable Pending Deficiency Letter	2	2	1
NOAP - Response to Not Approvable Deficiency Letter	14	6	2
UMAJ - Unsolicited Major Amendment	0	0	0
UMIN - Unsolicited Minor Amendment	32	62	34

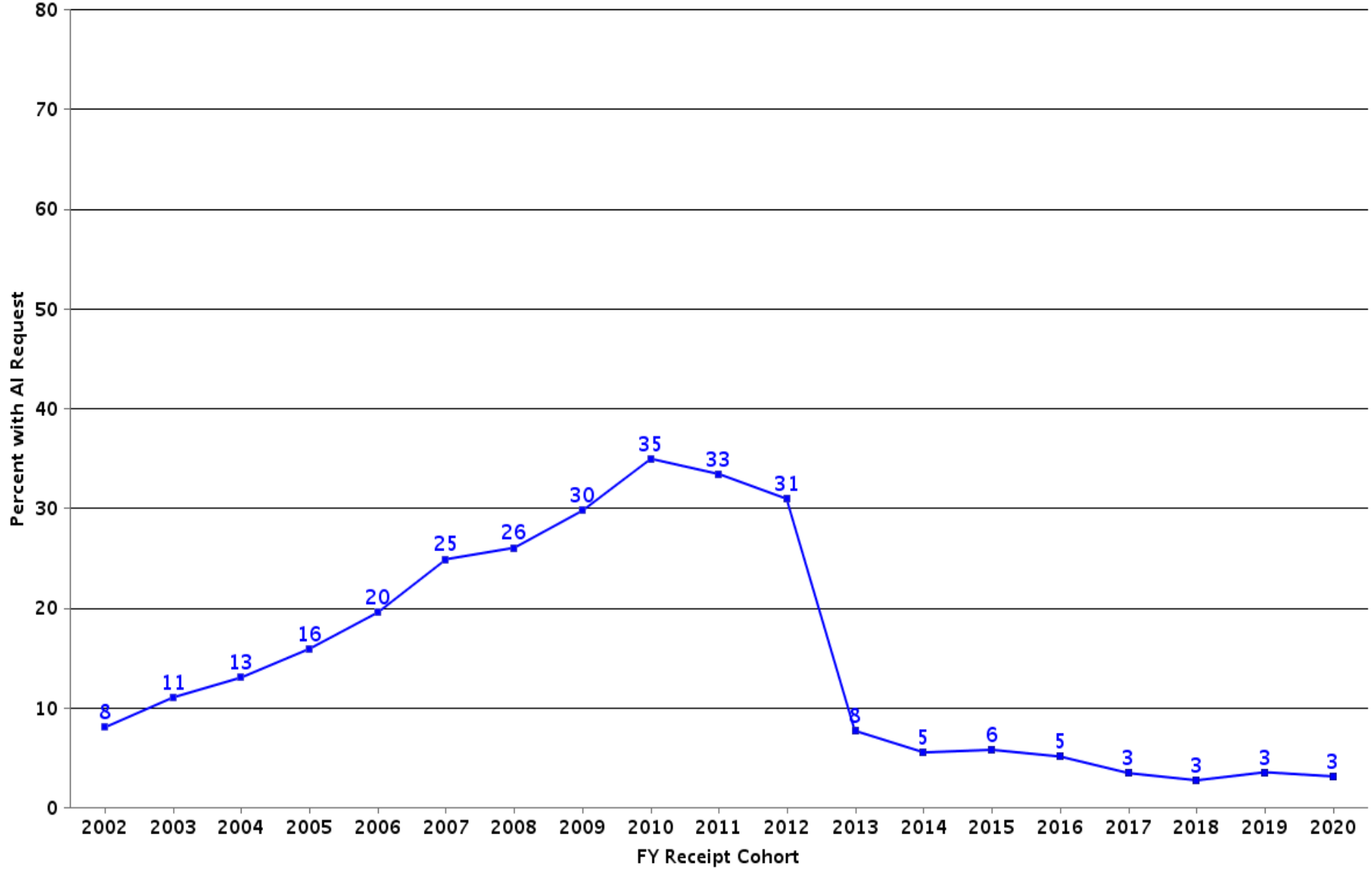
PM Real-Time Supplements			
Amendment Type	**FY2018**	**FY2019**	**FY2020**
MAJR - Response to MAJR Deficiency Letter	0	0	0
ADEF - Response to Approvable Pending Deficiency Letter	3	8	0
NOAP - Response to Not Approvable Deficiency Letter	8	26	3
UMAJ - Unsolicited Major Amendment	0	0	0
UMIN - Unsolicited Minor Amendment	11	39	24

510(k)s

Q4FY2020

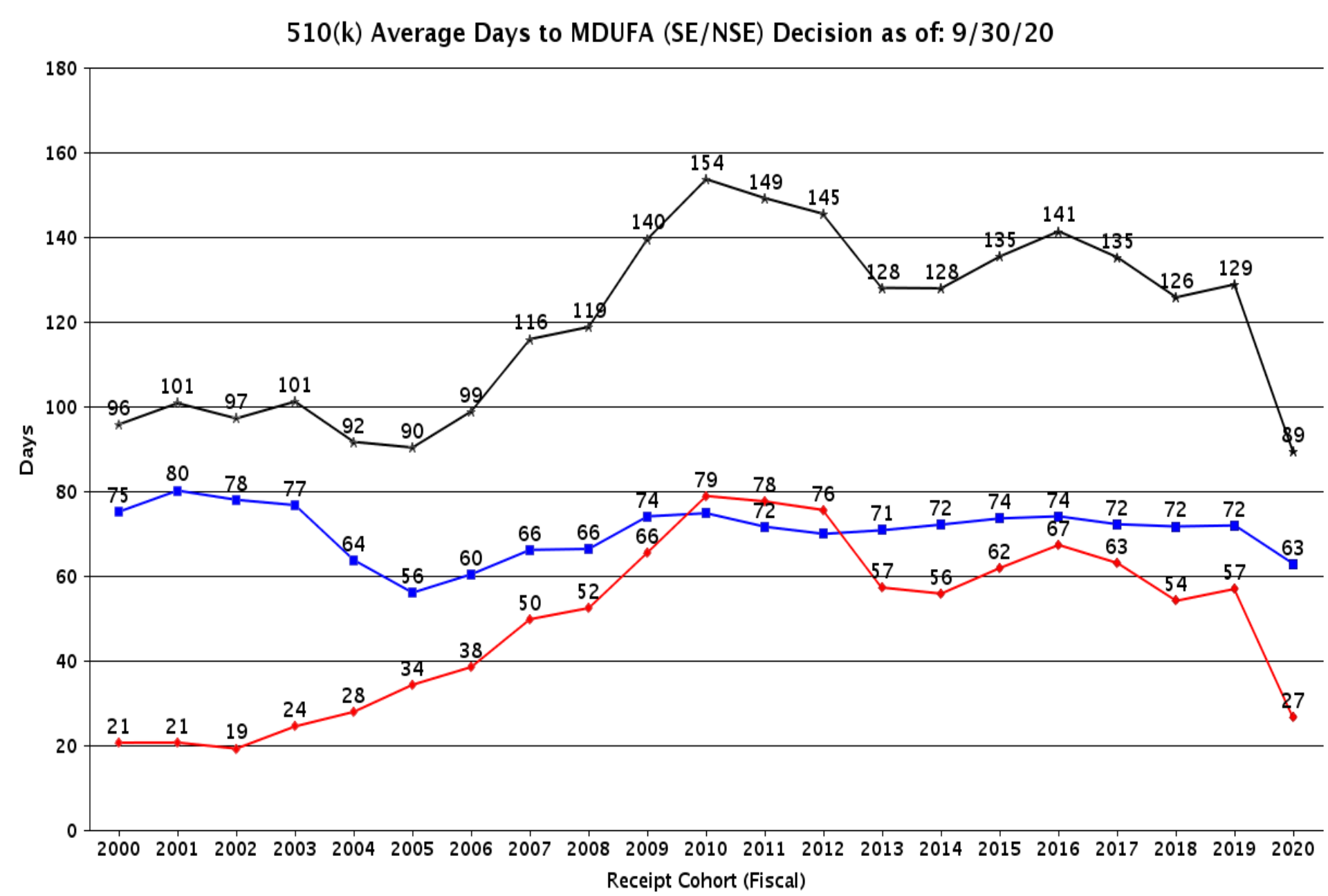

Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle
Percent with AI Request
90
80
70
60
50
40
30
20
10
0
37
38
36
40
44
50
56
61
65
72
78
75
75
70
70
72
78
70
64
63
62
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020
FY Receipt Cohort
AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/20
% with 1st Cycle AI Request

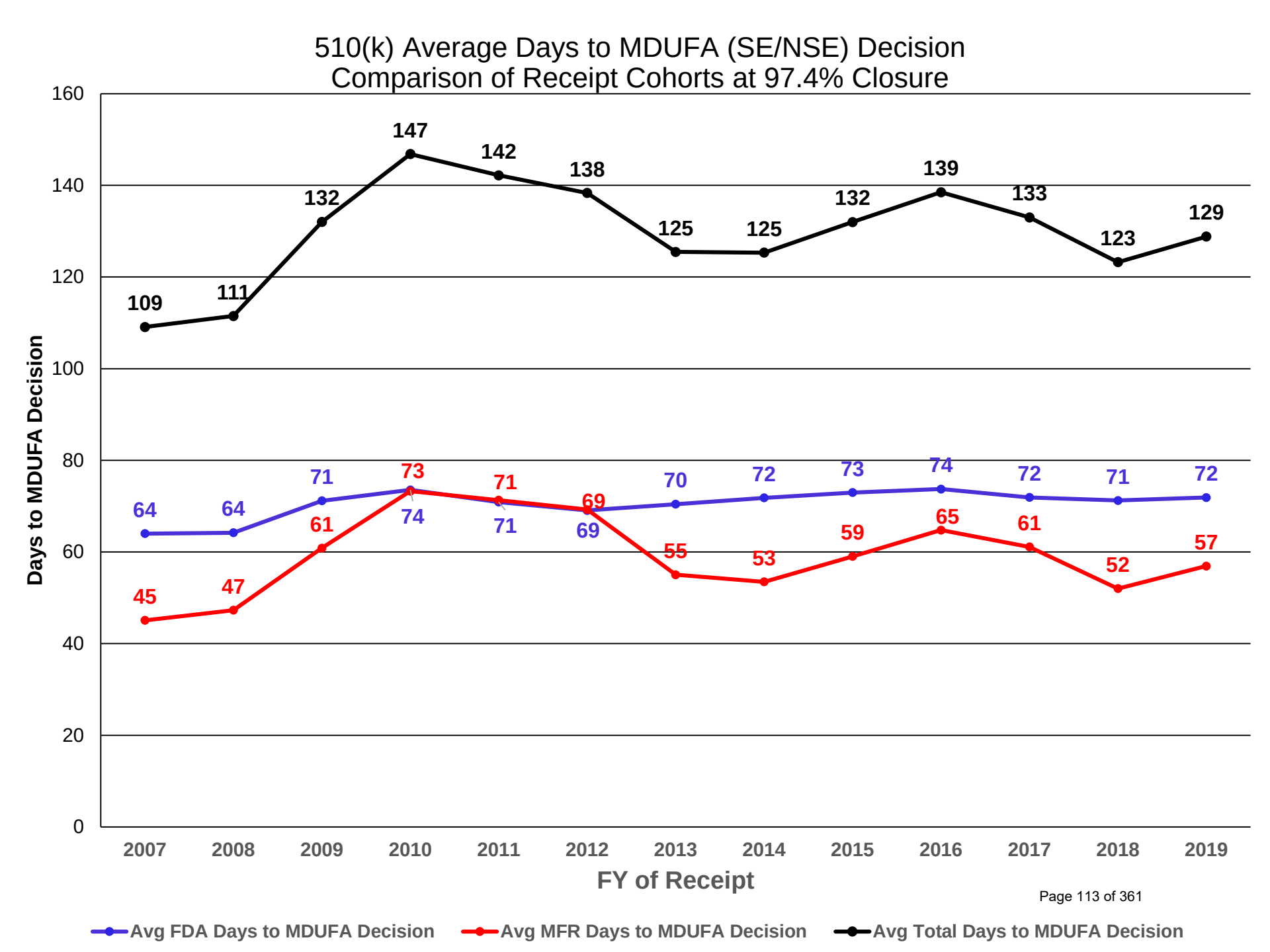
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

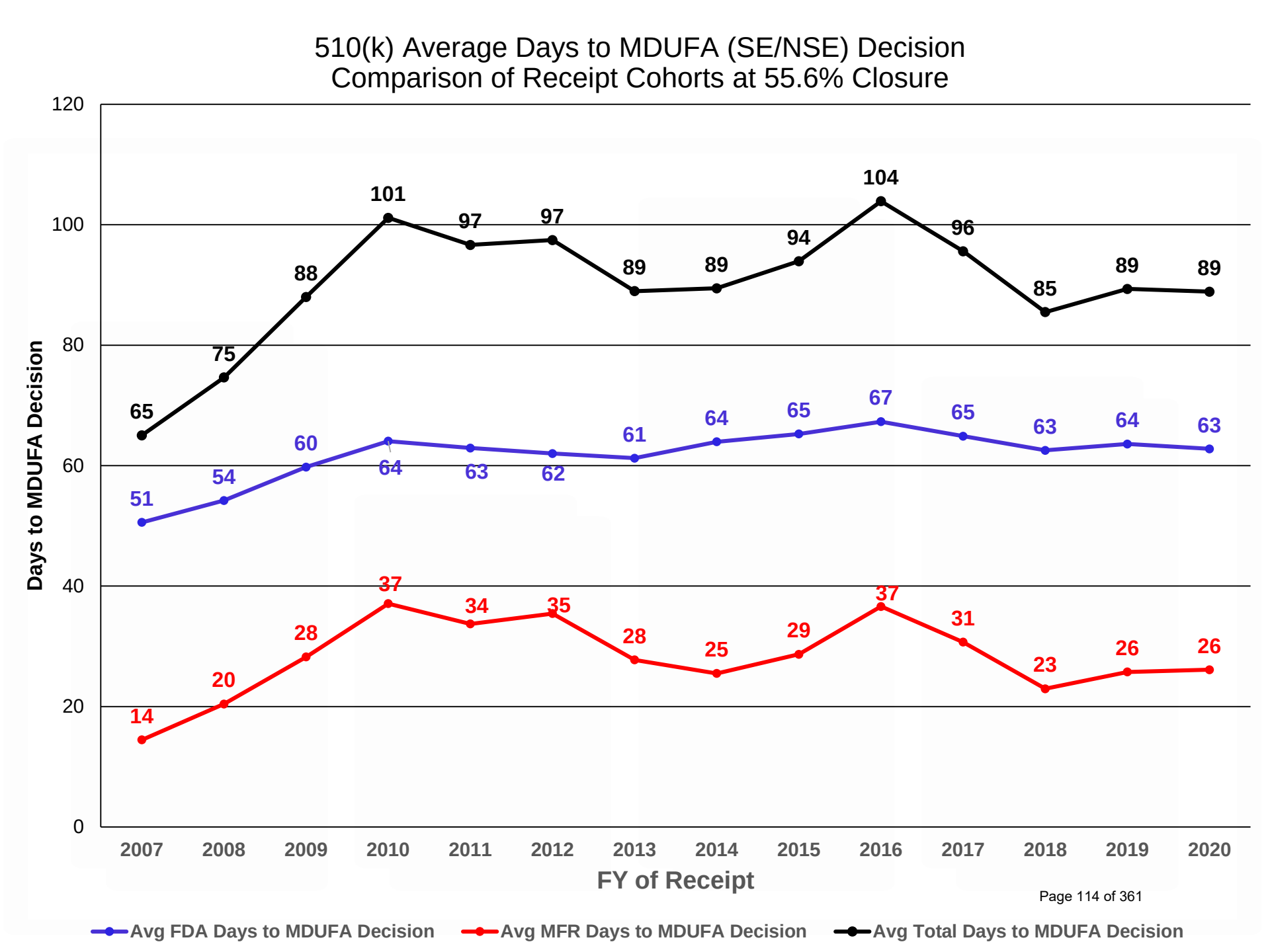


AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 2/29/20

■ % with 2nd Cycle AI Request

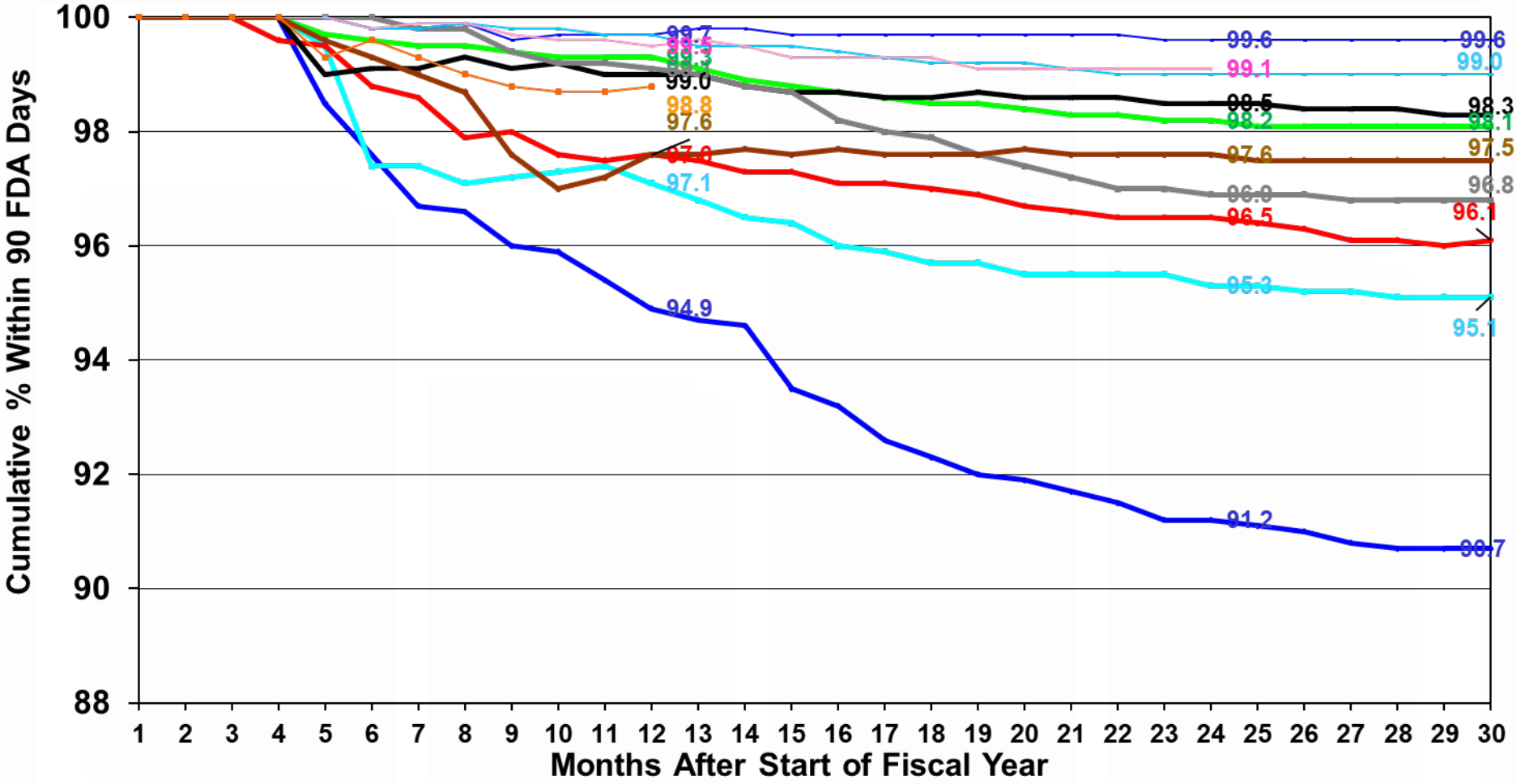

510(k) Average Days to MDUFA (SE/NSE) Decision as of: 9/30/20
Days
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2018: 99.87%; 2019: 97.35%; 2020: 55.6%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision


510(k) Average Days to MDUFA (SE/NSE) Decision
Comparison of Receipt Cohorts at 97.4% Closure
Days to MDUFA Decision
160
140
120
100
80
60
40
20
0
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
FY of Receipt
109
111
132
147
142
138
125
125
132
139
133
123
129
64
64
71
73
71
69
70
72
73
74
72
71
72
45
47
61
74
71
69
55
53
59
65
61
52
57
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

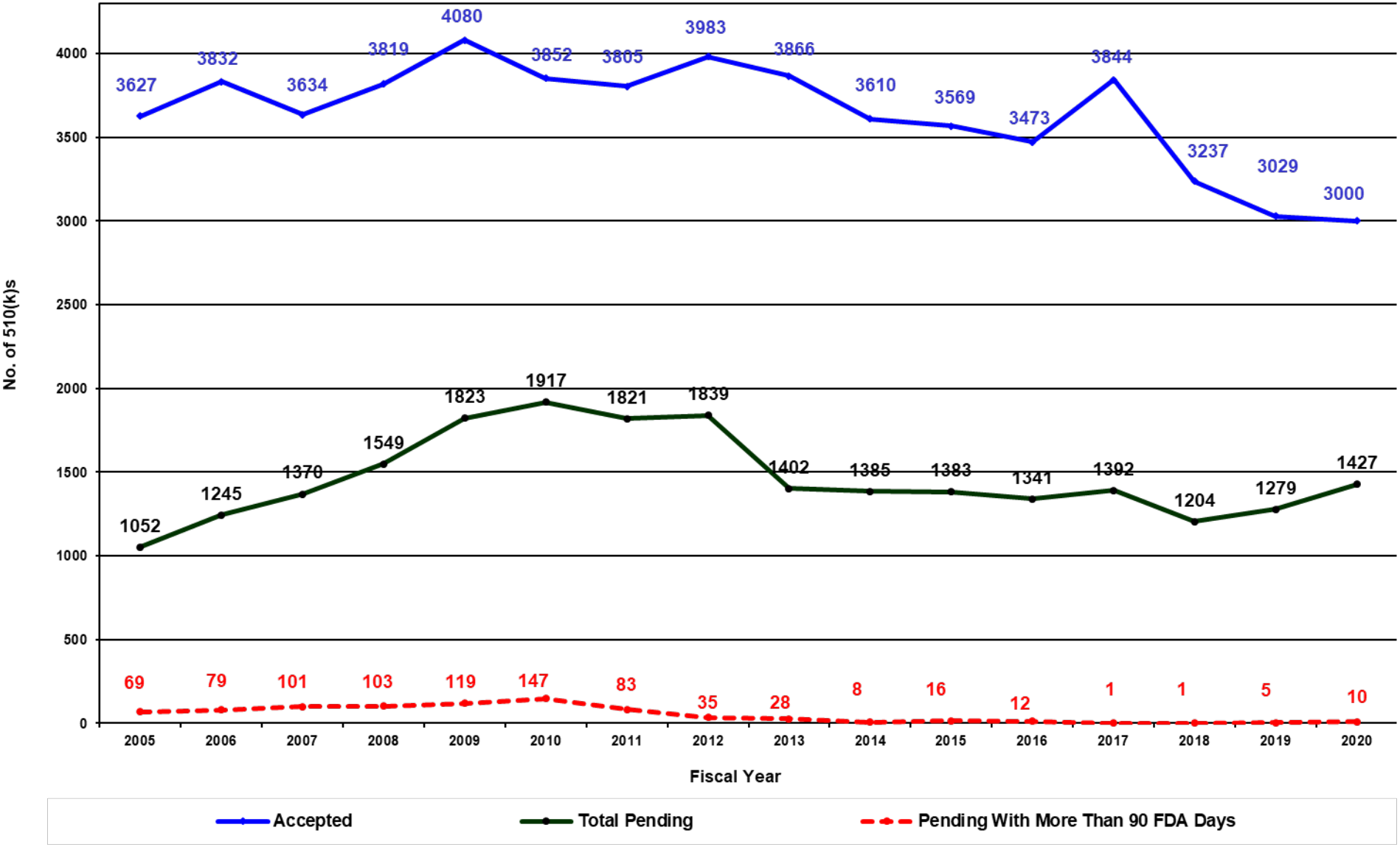

510(k) Average Days to MDUFA (SE/NSE) Decision
Comparison of Receipt Cohorts at 55.6% Closure
Days to MDUFA Decision
120
100
80
60
40
20
0
65
75
88
101
97
97
89
89
94
104
96
85
89
89
51
54
60
64
63
62
61
64
65
67
65
63
64
63
14
20
28
37
34
35
28
25
29
37
31
23
26
26
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
FY of Receipt
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

Trend in 510(k) MDUFA Decision Goal Performance

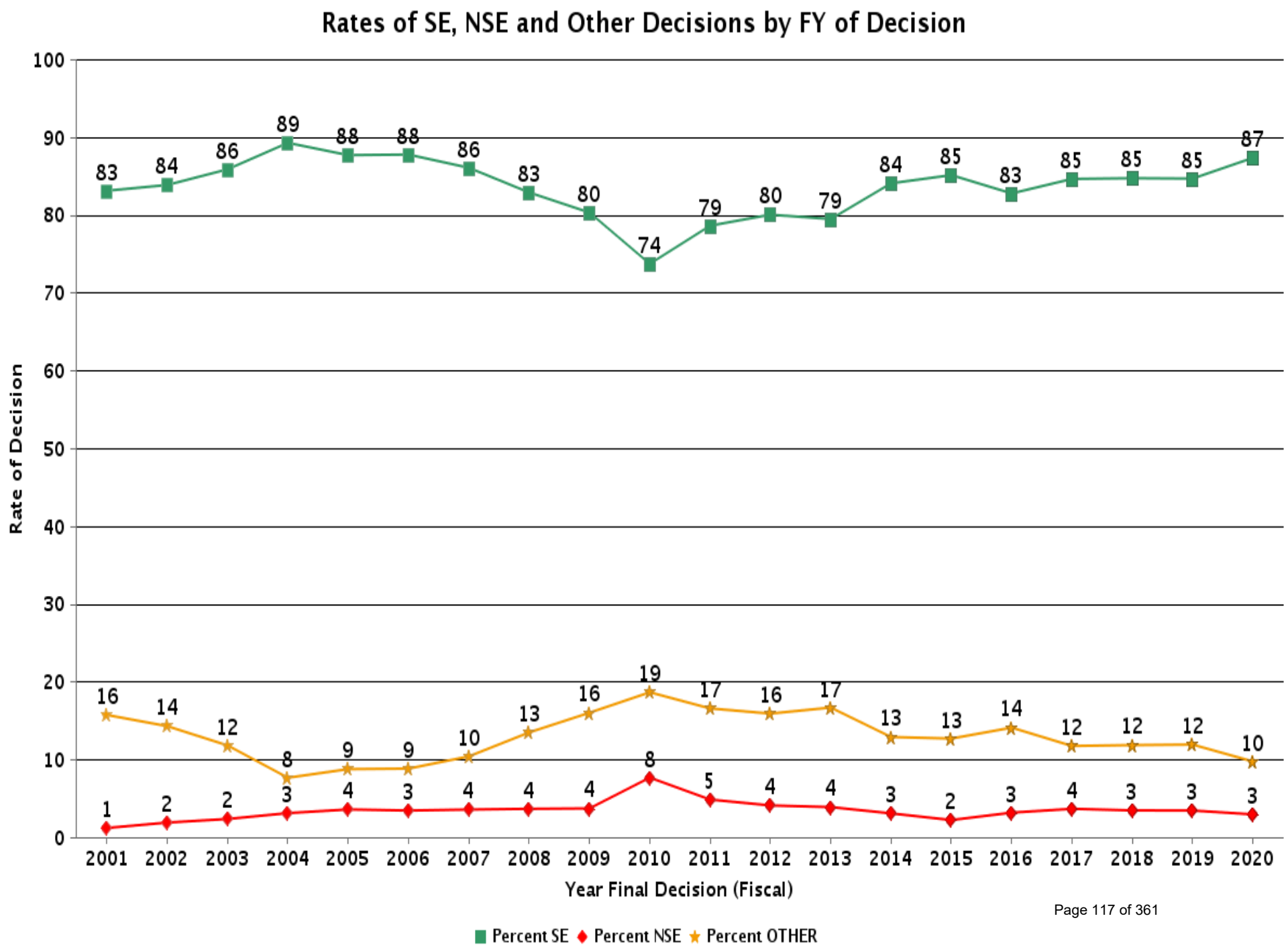
Comparison of FY10 – FY20 Receipt Cohorts



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

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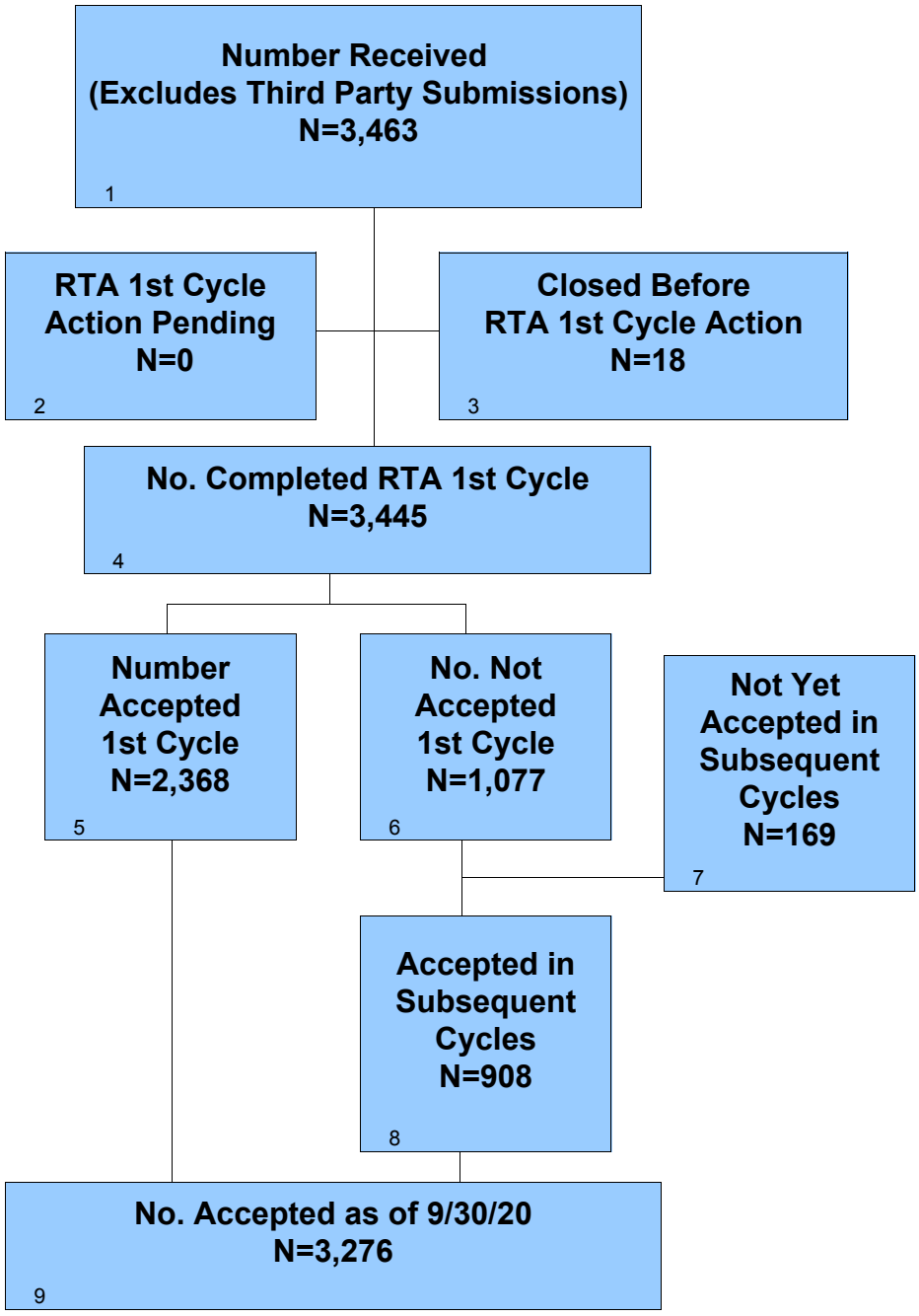
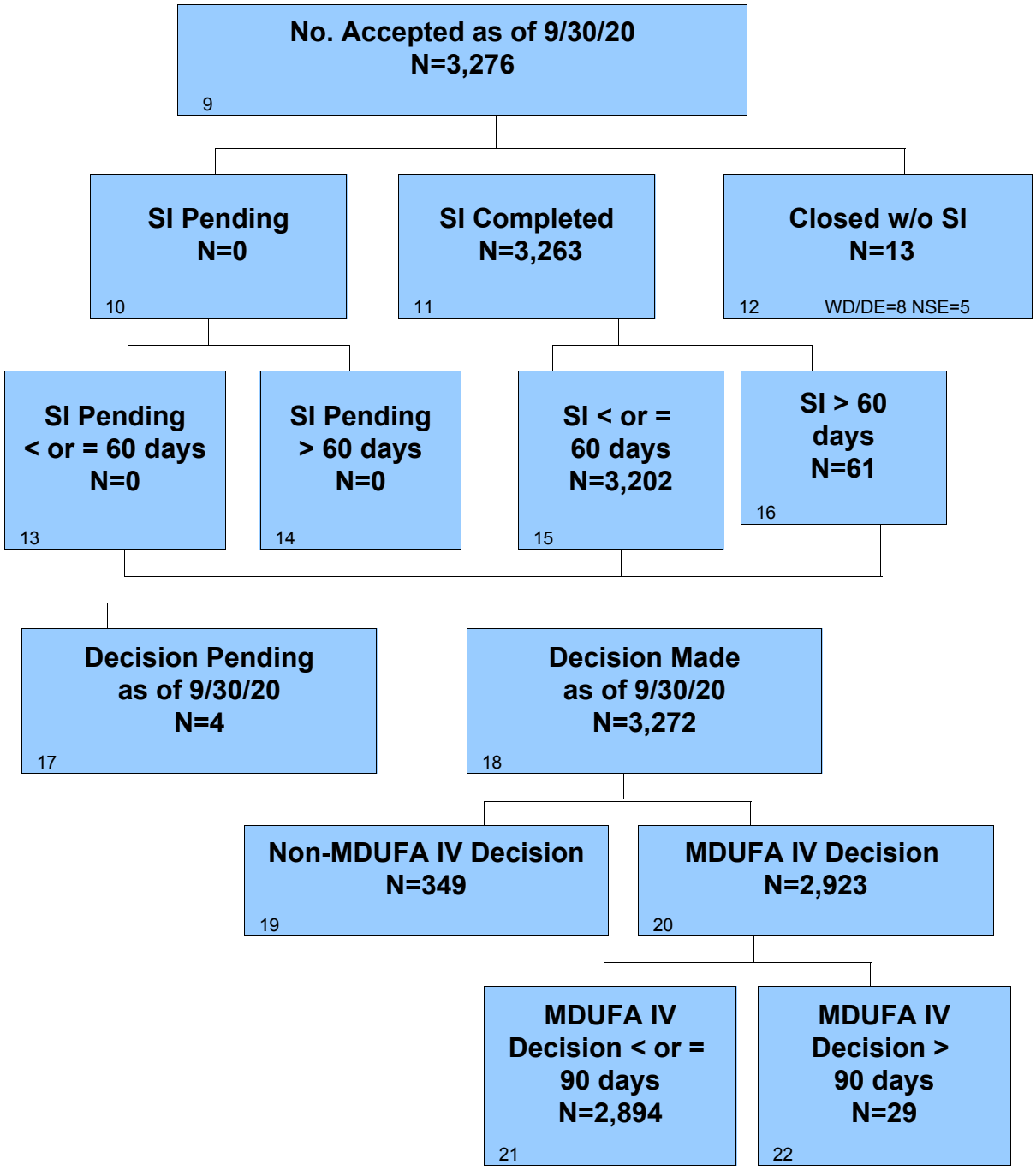
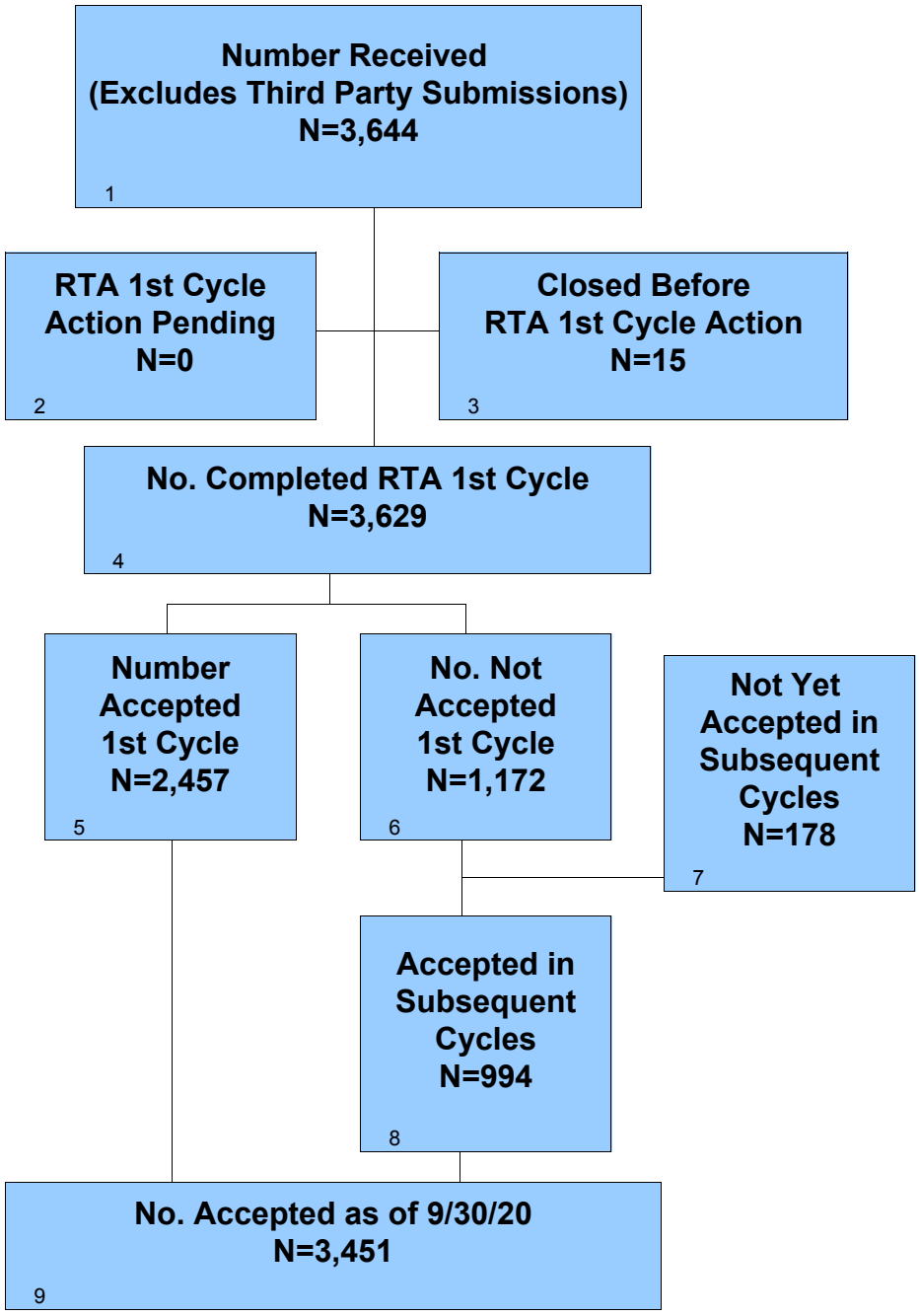
CDRH 510(k)s - FY 2018
as of 9/30/20



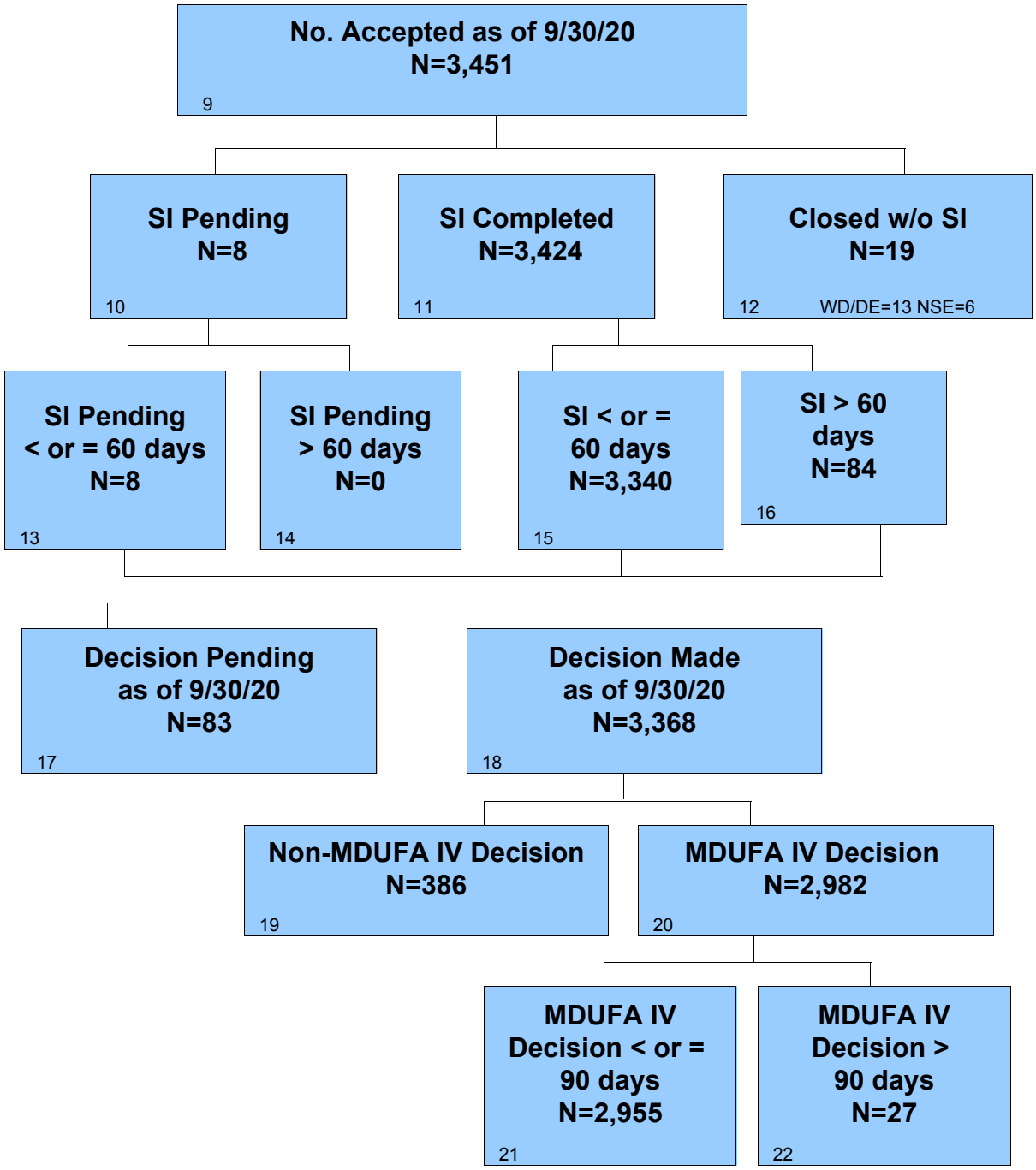
CDRH 510(k)s - FY 2018 as of 9/30/20 Continued



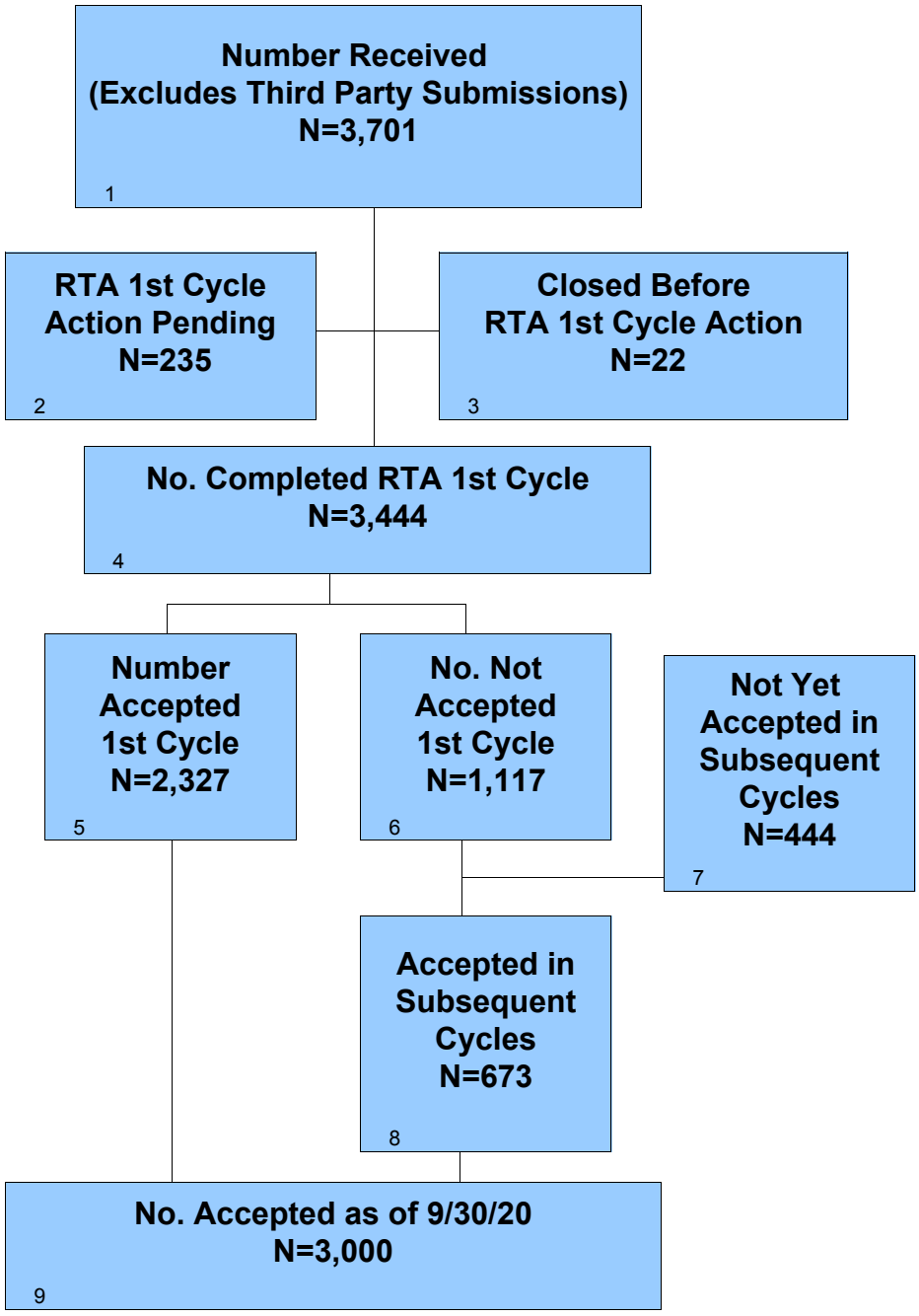
CDRH 510(k)s - FY 2019
as of 9/30/20



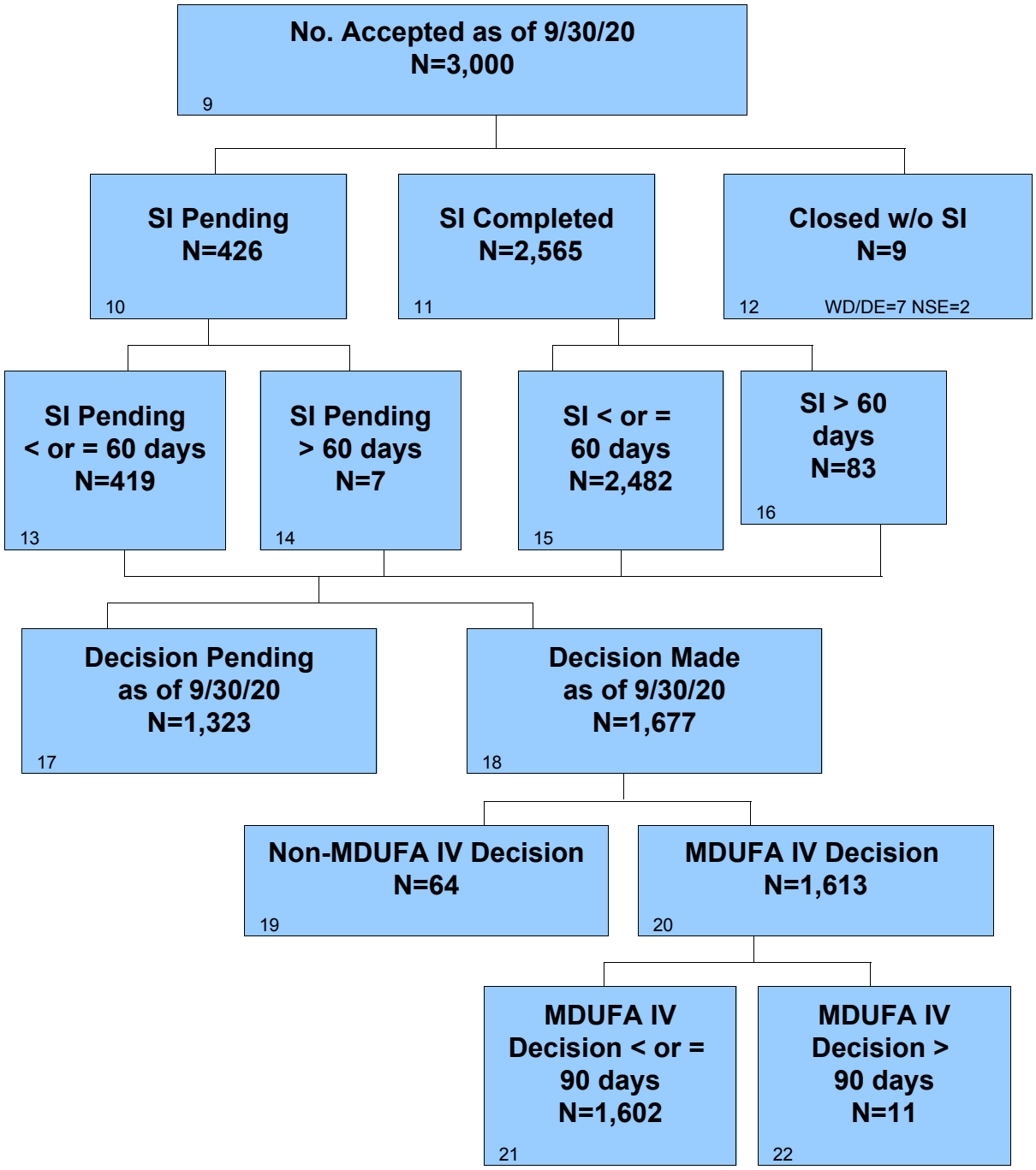
CDRH 510(k)s - FY 2019 as of 9/30/20 Continued



CDRH 510(k)s - FY 2020
as of 9/30/20



CDRH 510(k)s - FY 2020
as of 9/30/20 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	3,701		
Closed Before RTA Action	18	15	22		
Number Accepted	2,353	2,403	2,286		
Number Without a RTA Review and > 15 Days Since Date Received	15	54	41		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	235		
Number Not Accepted	1,077	1,172	1,117		
Rate of Submissions Not Accepted for Review	31.26%	32.30%	32.43%		

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	3,451	3,000		
Deleted or Withdrawn Prior to SI	8	13	7		
SI Within 60 FDA Days	3,202	3,340	2,482		
SI Over 60 FDA Days	61	84	83		
SI Pending Within 60 FDA Days	0	8	419		
SI Pending Over 60 FDA Days	0	0	7		
510(k)s NSE Without SI	5	6	2		
Current SI Performance Percent Within 60 FDA Days	97.98%	97.38%	96.43%		

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	3,424	2,565		
Average Number of FDA Days to Substantive Interaction	51.04	51.37	50.59		
20th Percentile FDA Days to Substantive Interaction	43	42	31		
40th Percentile FDA Days to Substantive Interaction	55	56	56		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	86	90	101		

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	3,451	3,000		
Non-MDUFA IV Decision	349	386	64		
MDUFA IV Decision (SE/NSE)	2,923	2,982	1,613		
MDUFA IV Decision Within 90 FDA Days	2,894	2,955	1,602		
510(k)s Pending MDUFA IV Decision	4	83	1,323		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	9		
Current Performance Percent Within 90 FDA Days	99.01%	99.06%	98.77%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	2	2	1		
Number With MDUFA IV Decision	2,923	2,982	1,613		
Average Number of FDA Days to MDUFA IV Decision	72.61	72.89	64.31		
20th Percentile FDA Days to MDUFA IV Decision	54	54	30		
40th Percentile FDA Days to MDUFA IV Decision	79	82	59		
60th Percentile FDA Days to MDUFA IV Decision	87	88	85		
80th Percentile FDA Days to MDUFA IV Decision	89	90	89		
Maximum FDA Days to MDUFA IV Decision	220	207	133		
Average Number of Industry Days to MDUFA IV Decision	54.54	57.73	27.15		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	5	0	0		
60th Percentile Industry Days to MDUFA IV Decision	44	47	7		
80th Percentile Industry Days to MDUFA IV Decision	127	132	51		
Maximum Industry Days to MDUFA IV Decision	563	444	250		
Average Number of Total Days to MDUFA IV Decision	127.15	130.62	91.46		
20th Percentile Total Days to MDUFA IV Decision	57	57	30		
40th Percentile Total Days to MDUFA IV Decision	89	90	60		
60th Percentile Total Days to MDUFA IV Decision	128	130	90		
80th Percentile Total Days to MDUFA IV Decision	212	218	135		
Maximum Total Days to MDUFA IV Decision	783	543	339		

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	3,451	3,000		
Number With MDUFA IV Decision	2,923	2,982	1,613		
Number of SE Decision	2,807	2,878	1,596		
Number of NSE Decision	116	104	17		
Number of Withdrawal	184	204	54		
Number of Deleted	156	164	7		
Rate of SE Decision	96.03%	96.51%	98.95%		
Rate of NSE Decision	3.97%	3.49%	1.05%		
Rate of Withdrawal	5.62%	5.91%	1.80%		
Rate of Deleted	4.76%	4.75%	0.23%		

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	27	11		
Mean FDA Days for Submissions that Missed the Goal	111.38	111.70	98.73		
Mean Industry Days for Submissions that Missed the Goal	136.24	170.59	45.73		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	272	278	227		
Non-MDUFA IV Decision	41	34	9		
MDUFA IV Decision (SE/NSE)	231	236	107		
MDUFA IV Decision Within 90 FDA Days	230	236	107		
510(k)s Pending MDUFA IV Decision	0	8	111		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	8		
Current Performance Percent Within 90 FDA Days	99.57%	99.58%	93.04%		

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	537		
Closed Before RTA Action	1	1	0		
Number Accepted	208	207	212		
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	43		
Number Not Accepted	343	373	274		
Rate of Submissions Not Accepted for Review	62.25%	63.01%	55.47%		

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	408		
Deleted or Withdrawn Prior to SI	2	6	0		
SI Within 60 FDA Days	477	486	293		
SI Over 60 FDA Days	14	53	56		
SI Pending Within 60 FDA Days	0	4	57		
SI Pending Over 60 FDA Days	0	0	2		
510(k)s NSE Without SI	1	1	0		
Current SI Performance Percent Within 60 FDA Days	96.95%	90.00%	83.48%		

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	539	349		
Average Number of FDA Days to Substantive Interaction	55.63	55.98	54.50		
20th Percentile FDA Days to Substantive Interaction	54	54	51		
40th Percentile FDA Days to Substantive Interaction	58	58	57		
60th Percentile FDA Days to Substantive Interaction	59	59	60		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	78	87	83		

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	408		
Non-MDUFA IV Decision	73	69	5		
MDUFA IV Decision (SE/NSE)	418	451	205		
MDUFA IV Decision Within 90 FDA Days	415	450	202		
510(k)s Pending MDUFA IV Decision	3	30	198		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	99.28%	99.78%	98.54%		

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	1.68	1.57		
Number With MDUFA IV Decision	418	451	205		
Average Number of FDA Days to MDUFA IV Decision	81.02	82.16	74.93		
20th Percentile FDA Days to MDUFA IV Decision	77	84	56		
40th Percentile FDA Days to MDUFA IV Decision	87	88	85		
60th Percentile FDA Days to MDUFA IV Decision	89	89	88		
80th Percentile FDA Days to MDUFA IV Decision	90	90	90		
Maximum FDA Days to MDUFA IV Decision	148	153	101		
Average Number of Industry Days to MDUFA IV Decision	64.78	64.56	31.75		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	17	17	0		
60th Percentile Industry Days to MDUFA IV Decision	63	63	21		
80th Percentile Industry Days to MDUFA IV Decision	151	141	62		
Maximum Industry Days to MDUFA IV Decision	389	284	246		
Average Number of Total Days to MDUFA IV Decision	145.79	146.73	106.68		
20th Percentile Total Days to MDUFA IV Decision	78	88	60		
40th Percentile Total Days to MDUFA IV Decision	102	103	90		
60th Percentile Total Days to MDUFA IV Decision	148	149	105		
80th Percentile Total Days to MDUFA IV Decision	239	229	147		
Maximum Total Days to MDUFA IV Decision	479	401	336		

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	408		
Number With MDUFA IV Decision	418	451	205		
Number of SE Decision	400	432	200		
Number of NSE Decision	18	19	5		
Number of Withdrawal	34	44	5		
Number of Deleted	39	22	0		
Rate of SE Decision	95.69%	95.79%	97.56%		
Rate of NSE Decision	4.31%	4.21%	2.44%		
Rate of Withdrawal	6.88%	8.00%	1.23%		
Rate of Deleted	7.89%	4.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	3	1	3		
Mean FDA Days for Submissions that Missed the Goal	115.33	153.00	96.67		
Mean Industry Days for Submissions that Missed the Goal	107.67	248.00	107.33		

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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Closed Before RTA Action	4	2	1		
Number Accepted	237	266	265		
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	23		
Number Not Accepted	114	100	87		
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.44%		

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	332		
Deleted or Withdrawn Prior to SI	4	0	1		
SI Within 60 FDA Days	324	358	284		
SI Over 60 FDA Days	13	8	7		
SI Pending Within 60 FDA Days	0	0	39		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	1		
Current SI Performance Percent Within 60 FDA Days	96.14%	97.81%	97.26%		

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	291		
Average Number of FDA Days to Substantive Interaction	49.74	50.76	50.72		
20th Percentile FDA Days to Substantive Interaction	30	30	30		
40th Percentile FDA Days to Substantive Interaction	53	56	56		
60th Percentile FDA Days to Substantive Interaction	58	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	83	71	101		

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	332		
Non-MDUFA IV Decision	32	51	5		
MDUFA IV Decision (SE/NSE)	309	312	180		
MDUFA IV Decision Within 90 FDA Days	303	302	178		
510(k)s Pending MDUFA IV Decision	0	3	147		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1		
Current Performance Percent Within 90 FDA Days	98.06%	96.79%	98.34%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	2	2	2		
Number With MDUFA IV Decision	309	312	180		
Average Number of FDA Days to MDUFA IV Decision	71.68	71.23	65.56		
20th Percentile FDA Days to MDUFA IV Decision	50	49	30		
40th Percentile FDA Days to MDUFA IV Decision	80	80	59		
60th Percentile FDA Days to MDUFA IV Decision	88	88	87		
80th Percentile FDA Days to MDUFA IV Decision	90	90	90		
Maximum FDA Days to MDUFA IV Decision	159	117	101		
Average Number of Industry Days to MDUFA IV Decision	64.80	65.24	39.18		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	19	20	0		
60th Percentile Industry Days to MDUFA IV Decision	65	67	28		
80th Percentile Industry Days to MDUFA IV Decision	146	139	81		
Maximum Industry Days to MDUFA IV Decision	292	359	249		
Average Number of Total Days to MDUFA IV Decision	136.48	136.46	104.73		
20th Percentile Total Days to MDUFA IV Decision	55	50	30		
40th Percentile Total Days to MDUFA IV Decision	102	97	70		
60th Percentile Total Days to MDUFA IV Decision	150	147	115		
80th Percentile Total Days to MDUFA IV Decision	228	225	166		
Maximum Total Days to MDUFA IV Decision	370	447	339		

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	332		
Number With MDUFA IV Decision	309	312	180		
Number of SE Decision	291	289	178		
Number of NSE Decision	18	23	2		
Number of Withdrawal	20	30	5		
Number of Deleted	10	20	0		
Rate of SE Decision	94.17%	92.63%	98.89%		
Rate of NSE Decision	5.83%	7.37%	1.11%		
Rate of Withdrawal	5.87%	8.20%	1.51%		
Rate of Deleted	2.93%	5.46%	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	10	2		
Mean FDA Days for Submissions that Missed the Goal	107.17	100.10	100.00		
Mean Industry Days for Submissions that Missed the Goal	131.50	156.90	59.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	440		
Closed Before RTA Action	3	4	4		
Number Accepted	333	349	275		
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	25		
Number Not Accepted	116	117	134		
Rate of Submissions Not Accepted for Review	25.72%	24.79%	32.60%		

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	346		
Deleted or Withdrawn Prior to SI	0	1	0		
SI Within 60 FDA Days	426	447	302		
SI Over 60 FDA Days	6	4	5		
SI Pending Within 60 FDA Days	0	0	39		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	3	1	0		
Current SI Performance Percent Within 60 FDA Days	97.93%	98.89%	98.37%		

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	307		
Average Number of FDA Days to Substantive Interaction	51.16	52.58	52.43		
20th Percentile FDA Days to Substantive Interaction	44	48	49		
40th Percentile FDA Days to Substantive Interaction	55	57	57		
60th Percentile FDA Days to Substantive Interaction	58	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	67	78	68		

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	346		
Non-MDUFA IV Decision	50	73	12		
MDUFA IV Decision (SE/NSE)	385	370	144		
MDUFA IV Decision Within 90 FDA Days	381	366	142		
510(k)s Pending MDUFA IV Decision	0	10	190		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	98.96%	98.92%	98.61%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.74	1.84	1.58		
Number With MDUFA IV Decision	385	370	144		
Average Number of FDA Days to MDUFA IV Decision	75.81	78.02	69.34		
20th Percentile FDA Days to MDUFA IV Decision	58	60	30		
40th Percentile FDA Days to MDUFA IV Decision	84	86	78		
60th Percentile FDA Days to MDUFA IV Decision	88	88	87		
80th Percentile FDA Days to MDUFA IV Decision	89	90	89		
Maximum FDA Days to MDUFA IV Decision	118	150	133		
Average Number of Industry Days to MDUFA IV Decision	75.12	93.95	48.63		
20th Percentile Industry Days to MDUFA IV Decision	0	5	0		
40th Percentile Industry Days to MDUFA IV Decision	30	53	0		
60th Percentile Industry Days to MDUFA IV Decision	94	117	35		
80th Percentile Industry Days to MDUFA IV Decision	165	174	111		
Maximum Industry Days to MDUFA IV Decision	214	444	230		
Average Number of Total Days to MDUFA IV Decision	150.94	171.97	117.97		
20th Percentile Total Days to MDUFA IV Decision	65	86	30		
40th Percentile Total Days to MDUFA IV Decision	113	137	87		
60th Percentile Total Days to MDUFA IV Decision	177	203	118		
80th Percentile Total Days to MDUFA IV Decision	248	260	194		
Maximum Total Days to MDUFA IV Decision	304	540	319		

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	346		
Number With MDUFA IV Decision	385	370	144		
Number of SE Decision	360	348	141		
Number of NSE Decision	25	22	3		
Number of Withdrawal	20	30	10		
Number of Deleted	30	41	2		
Rate of SE Decision	93.51%	94.05%	97.92%		
Rate of NSE Decision	6.49%	5.95%	2.08%		
Rate of Withdrawal	4.60%	6.62%	2.89%		
Rate of Deleted	6.90%	9.05%	0.58%		

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	4	2		
Mean FDA Days for Submissions that Missed the Goal	100.00	112.75	112.00		
Mean Industry Days for Submissions that Missed the Goal	117.00	306.75	21.00		

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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Closed Before RTA Action	2	0	4		
Number Accepted	369	392	423		
Number Without a RTA Review and > 15 Days Since Date Received	6	7	1		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	65		
Number Not Accepted	176	205	227		
Rate of Submissions Not Accepted for Review	31.94%	33.94%	34.87%		

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	557	528		
Deleted or Withdrawn Prior to SI	0	3	2		
SI Within 60 FDA Days	513	540	409		
SI Over 60 FDA Days	4	12	7		
SI Pending Within 60 FDA Days	0	1	108		
SI Pending Over 60 FDA Days	0	0	1		
510(k)s NSE Without SI	0	1	1		
Current SI Performance Percent Within 60 FDA Days	99.23%	97.65%	97.85%		

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	552	416		
Average Number of FDA Days to Substantive Interaction	52.55	52.17	51.93		
20th Percentile FDA Days to Substantive Interaction	49	48	48		
40th Percentile FDA Days to Substantive Interaction	56	56	56		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	69	90	64		

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	557	528		
Non-MDUFA IV Decision	68	65	14		
MDUFA IV Decision (SE/NSE)	448	479	253		
MDUFA IV Decision Within 90 FDA Days	440	475	250		
510(k)s Pending MDUFA IV Decision	1	13	261		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	98.21%	99.16%	98.81%		

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	1.57	1.36		
Number With MDUFA IV Decision	448	479	253		
Average Number of FDA Days to MDUFA IV Decision	73.73	72.94	66.30		
20th Percentile FDA Days to MDUFA IV Decision	56	55	44		
40th Percentile FDA Days to MDUFA IV Decision	79	81	59		
60th Percentile FDA Days to MDUFA IV Decision	87	86	85		
80th Percentile FDA Days to MDUFA IV Decision	89	89	88		
Maximum FDA Days to MDUFA IV Decision	220	207	99		
Average Number of Industry Days to MDUFA IV Decision	48.58	53.77	21.55		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	0	0		
60th Percentile Industry Days to MDUFA IV Decision	31	41	0		
80th Percentile Industry Days to MDUFA IV Decision	108	124	36		
Maximum Industry Days to MDUFA IV Decision	563	355	245		
Average Number of Total Days to MDUFA IV Decision	122.31	126.71	87.85		
20th Percentile Total Days to MDUFA IV Decision	58	57	50		
40th Percentile Total Days to MDUFA IV Decision	88	87	60		
60th Percentile Total Days to MDUFA IV Decision	109	124	88		
80th Percentile Total Days to MDUFA IV Decision	191	208	118		
Maximum Total Days to MDUFA IV Decision	783	511	333		

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	557	528		
Number With MDUFA IV Decision	448	479	253		
Number of SE Decision	437	465	249		
Number of NSE Decision	11	14	4		
Number of Withdrawal	36	35	12		
Number of Deleted	31	28	1		
Rate of SE Decision	97.54%	97.08%	98.42%		
Rate of NSE Decision	2.46%	2.92%	1.58%		
Rate of Withdrawal	6.96%	6.28%	2.27%		
Rate of Deleted	6.00%	5.03%	0.19%		

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	3		
Mean FDA Days for Submissions that Missed the Goal	119.50	121.00	93.67		
Mean Industry Days for Submissions that Missed the Goal	168.63	132.50	7.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	262		
Closed Before RTA Action	3	0	3		
Number Accepted	147	156	102		
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	17		
Number Not Accepted	107	112	135		
Rate of Submissions Not Accepted for Review	41.63%	40.73%	55.79%		

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	251	173		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	232	246	136		
SI Over 60 FDA Days	4	2	2		
SI Pending Within 60 FDA Days	0	3	35		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	98.31%	99.19%	98.55%		

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	248	138		
Average Number of FDA Days to Substantive Interaction	53.91	54.39	50.70		
20th Percentile FDA Days to Substantive Interaction	53	54	30		
40th Percentile FDA Days to Substantive Interaction	58	58	58		
60th Percentile FDA Days to Substantive Interaction	60	60	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	86	63	62		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	236	251	173		
Non-MDUFA IV Decision	30	29	6		
MDUFA IV Decision (SE/NSE)	206	216	88		
MDUFA IV Decision Within 90 FDA Days	201	209	88		
510(k)s Pending MDUFA IV Decision	0	6	79		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	97.57%	96.76%	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	1.19		
Number With MDUFA IV Decision	206	216	88		
Average Number of FDA Days to MDUFA IV Decision	76.47	80.06	62.27		
20th Percentile FDA Days to MDUFA IV Decision	60	67	29		
40th Percentile FDA Days to MDUFA IV Decision	86	88	45		
60th Percentile FDA Days to MDUFA IV Decision	89	90	87		
80th Percentile FDA Days to MDUFA IV Decision	90	90	90		
Maximum FDA Days to MDUFA IV Decision	170	152	90		
Average Number of Industry Days to MDUFA IV Decision	42.60	51.90	12.86		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	0	0		
60th Percentile Industry Days to MDUFA IV Decision	38	37	0		
80th Percentile Industry Days to MDUFA IV Decision	84	118	0		
Maximum Industry Days to MDUFA IV Decision	187	391	165		
Average Number of Total Days to MDUFA IV Decision	119.07	131.96	75.14		
20th Percentile Total Days to MDUFA IV Decision	61	81	29		
40th Percentile Total Days to MDUFA IV Decision	89	90	45		
60th Percentile Total Days to MDUFA IV Decision	117	123	89		
80th Percentile Total Days to MDUFA IV Decision	171	208	90		
Maximum Total Days to MDUFA IV Decision	346	543	245		

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	251	173		
Number With MDUFA IV Decision	206	216	88		
Number of SE Decision	198	209	87		
Number of NSE Decision	8	7	1		
Number of Withdrawal	17	16	6		
Number of Deleted	10	12	0		
Rate of SE Decision	96.12%	96.76%	98.86%		
Rate of NSE Decision	3.88%	3.24%	1.14%		
Rate of Withdrawal	7.20%	6.37%	3.47%		
Rate of Deleted	4.24%	4.78%	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		
Mean FDA Days for Submissions that Missed the Goal	111.40	119.43	0.00		
Mean Industry Days for Submissions that Missed the Goal	80.60	110.29	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Closed Before RTA Action	2	4	5		
Number Accepted	466	489	471		
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	33		
Number Not Accepted	138	136	140		
Rate of Submissions Not Accepted for Review	22.85%	21.59%	22.69%		

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	587		
Deleted or Withdrawn Prior to SI	0	2	2		
SI Within 60 FDA Days	575	617	513		
SI Over 60 FDA Days	19	3	1		
SI Pending Within 60 FDA Days	0	0	71		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	96.80%	99.52%	99.81%		

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	514		
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.14		
20th Percentile FDA Days to Substantive Interaction	39	30	30		
40th Percentile FDA Days to Substantive Interaction	55	56	55		
60th Percentile FDA Days to Substantive Interaction	57	58	58		
80th Percentile FDA Days to Substantive Interaction	59	60	60		
Maximum FDA Days to Substantive Interaction	78	64	61		

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	587		
Non-MDUFA IV Decision	40	43	9		
MDUFA IV Decision (SE/NSE)	554	568	362		
MDUFA IV Decision Within 90 FDA Days	552	567	362		
510(k)s Pending MDUFA IV Decision	0	11	216		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	99.64%	99.82%	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	1.61	1.35		
Number With MDUFA IV Decision	554	568	362		
Average Number of FDA Days to MDUFA IV Decision	71.36	70.35	60.80		
20th Percentile FDA Days to MDUFA IV Decision	52	51	30		
40th Percentile FDA Days to MDUFA IV Decision	74	76	57		
60th Percentile FDA Days to MDUFA IV Decision	86	87	76		
80th Percentile FDA Days to MDUFA IV Decision	89	89	88		
Maximum FDA Days to MDUFA IV Decision	135	91	90		
Average Number of Industry Days to MDUFA IV Decision	48.84	48.06	19.62		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	10	0	0		
60th Percentile Industry Days to MDUFA IV Decision	34	28	-		
80th Percentile Industry Days to MDUFA IV Decision	103	97	33		
Maximum Industry Days to MDUFA IV Decision	340	423	208		
Average Number of Total Days to MDUFA IV Decision	120.19	118.41	80.43		
20th Percentile Total Days to MDUFA IV Decision	57	56	30		
40th Percentile Total Days to MDUFA IV Decision	86	87	57		
60th Percentile Total Days to MDUFA IV Decision	115	110	86		
80th Percentile Total Days to MDUFA IV Decision	189	178	117		
Maximum Total Days to MDUFA IV Decision	430	510	295		

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	587		
Number With MDUFA IV Decision	554	568	362		
Number of SE Decision	540	558	361		
Number of NSE Decision	14	10	1		
Number of Withdrawal	24	28	8		
Number of Deleted	16	15	1		
Rate of SE Decision	97.47%	98.24%	99.72%		
Rate of NSE Decision	2.53%	1.76%	0.28%		
Rate of Withdrawal	4.04%	4.50%	1.36%		
Rate of Deleted	2.69%	2.41%	0.17%		

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		
Mean FDA Days for Submissions that Missed the Goal	117.50	91.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	208.50	260.00	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	707		
Closed Before RTA Action	3	4	5		
Number Accepted	593	544	538		
Number Without a RTA Review and > 15 Days Since Date Received	2	7	15		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	29		
Number Not Accepted	83	129	120		
Rate of Submissions Not Accepted for Review	12.24%	18.97%	17.83%		

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	626		
Deleted or Withdrawn Prior to SI	2	1	2		
SI Within 60 FDA Days	655	646	545		
SI Over 60 FDA Days	1	2	5		
SI Pending Within 60 FDA Days	0	0	70		
SI Pending Over 60 FDA Days	0	0	4		
510(k)s NSE Without SI	1	3	0		
Current SI Performance Percent Within 60 FDA Days	99.70%	99.23%	98.38%		

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	550		
Average Number of FDA Days to Substantive Interaction	46.54	46.73	47.32		
20th Percentile FDA Days to Substantive Interaction	30	29	29		
40th Percentile FDA Days to Substantive Interaction	48	49	49		
60th Percentile FDA Days to Substantive Interaction	56	56	56		
80th Percentile FDA Days to Substantive Interaction	58	59	59		
Maximum FDA Days to Substantive Interaction	61	61	97		

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	626		
Non-MDUFA IV Decision	56	56	13		
MDUFA IV Decision (SE/NSE)	603	586	381		
MDUFA IV Decision Within 90 FDA Days	602	586	380		
510(k)s Pending MDUFA IV Decision	0	10	232		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	8		
Current Performance Percent Within 90 FDA Days	99.83%	99.83%	97.69%		

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	1.43	1.38		
Number With MDUFA IV Decision	603	586	381		
Average Number of FDA Days to MDUFA IV Decision	64.21	63.16	58.56		
20th Percentile FDA Days to MDUFA IV Decision	30	30	28		
40th Percentile FDA Days to MDUFA IV Decision	59	59	53		
60th Percentile FDA Days to MDUFA IV Decision	81	81	73		
80th Percentile FDA Days to MDUFA IV Decision	88	88	87		
Maximum FDA Days to MDUFA IV Decision	93	90	91		
Average Number of Industry Days to MDUFA IV Decision	42.78	40.38	25.06		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	0	0		
60th Percentile Industry Days to MDUFA IV Decision	25	12	0		
80th Percentile Industry Days to MDUFA IV Decision	91	84	46		
Maximum Industry Days to MDUFA IV Decision	231	353	250		
Average Number of Total Days to MDUFA IV Decision	106.99	103.54	83.62		
20th Percentile Total Days to MDUFA IV Decision	30	30	28		
40th Percentile Total Days to MDUFA IV Decision	72	60	54		
60th Percentile Total Days to MDUFA IV Decision	104	90	87		
80th Percentile Total Days to MDUFA IV Decision	177	169	123		
Maximum Total Days to MDUFA IV Decision	321	443	310		

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	227		
Non-MDUFA IV Decision	41	34	9		
MDUFA IV Decision (SE/NSE)	231	236	107		
MDUFA IV Decision Within 90 FDA Days	230	236	107		
510(k)s Pending MDUFA IV Decision	0	8	111		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1	8		
Current Performance Percent Within 90 FDA Days	99.57%	99.58%	93.04%		

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	626		
Number With MDUFA IV Decision	603	586	381		
Number of SE Decision	581	577	380		
Number of NSE Decision	22	9	1		
Number of Withdrawal	33	21	8		
Number of Deleted	20	26	3		
Rate of SE Decision	96.35%	98.46%	99.74%		
Rate of NSE Decision	3.65%	1.54%	0.26%		
Rate of Withdrawal	5.01%	3.22%	1.28%		
Rate of Deleted	3.03%	3.99%	0.48%		

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	0	1		
Mean FDA Days for Submissions that Missed the Goal	93.00	0.00	91.00		
Mean Industry Days for Submissions that Missed the Goal	202.00	0.00	0.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	2	1	4		
Non-MDUFA IV Decision	1	0	0		
MDUFA IV Decision (SE/NSE)	1	1	2		
MDUFA IV Decision Within 90 FDA Days	1	1	1		
510(k)s Pending MDUFA IV Decision	0	0	2		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%		

Section 7 510(k) Annual General Metrics

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

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	3,351	3,529	3,085	0	
Number of Traditional Submissions	2,789	2,894	2,451	0	
Number of Special Submissions	419	493	486	0	
Number of Abbreviated Submissions	68	64	63	0	
Average Number of Days to Accept/Refuse to Accept	10.58	11.19	11.20	0.00	
Number of Third Party Submissions	75	78	85	0	

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	3,529	3,085	0	
Currently Under Review	4	83	1,340	0	
Number With Non-MDUFA IV Decision	354	393	67	0	
Number With MDUFA IV Decision	2,993	3,053	1,678	0	
Percent of Cohort Closed	99.87%	97.35%	55.60%	0.00%	
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	2,851	N/A	N/A	0	
Average Total Time to MDUFA IV Decision	123.40	N/A	N/A	0	

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	0	
90th Percentile FDA Days to MDUFA IV Decision	55.40	52.00	30.00	0.00	

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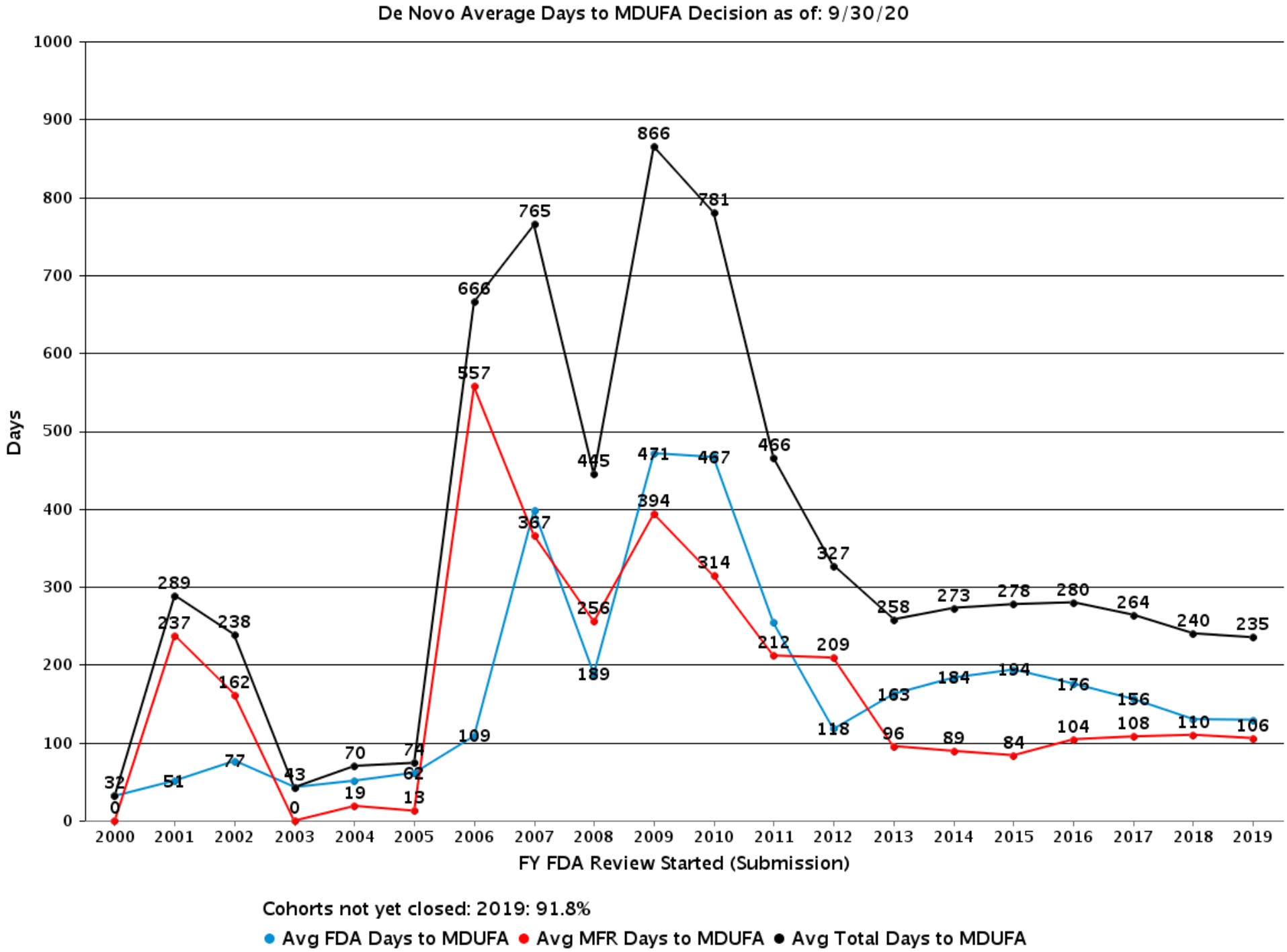
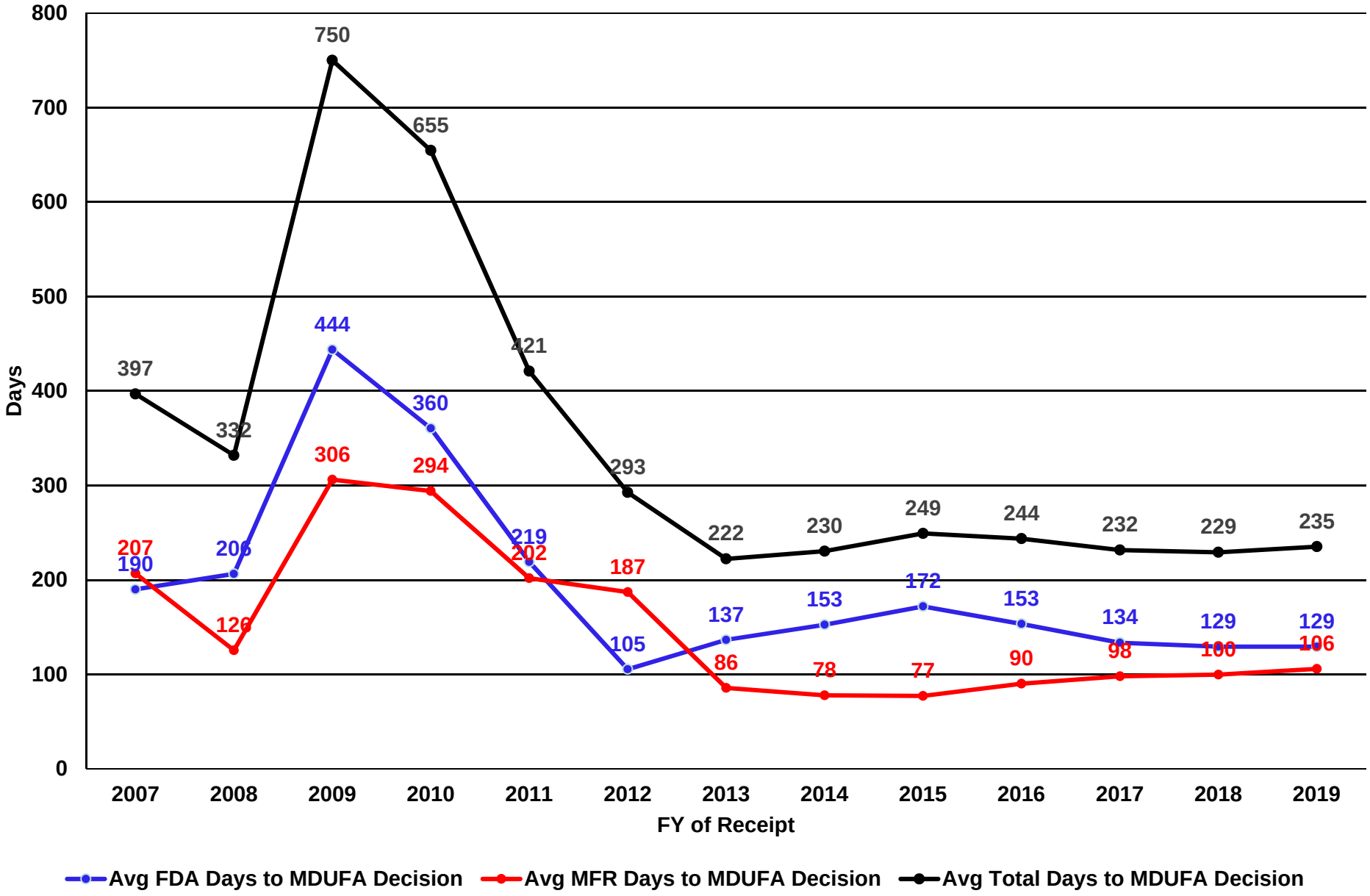
De Novos

Q4FY2020


De Novo Average Days to MDUFA Decision as of: 9/30/20
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2019: 91.8%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos*

(91.8% closure comparison)



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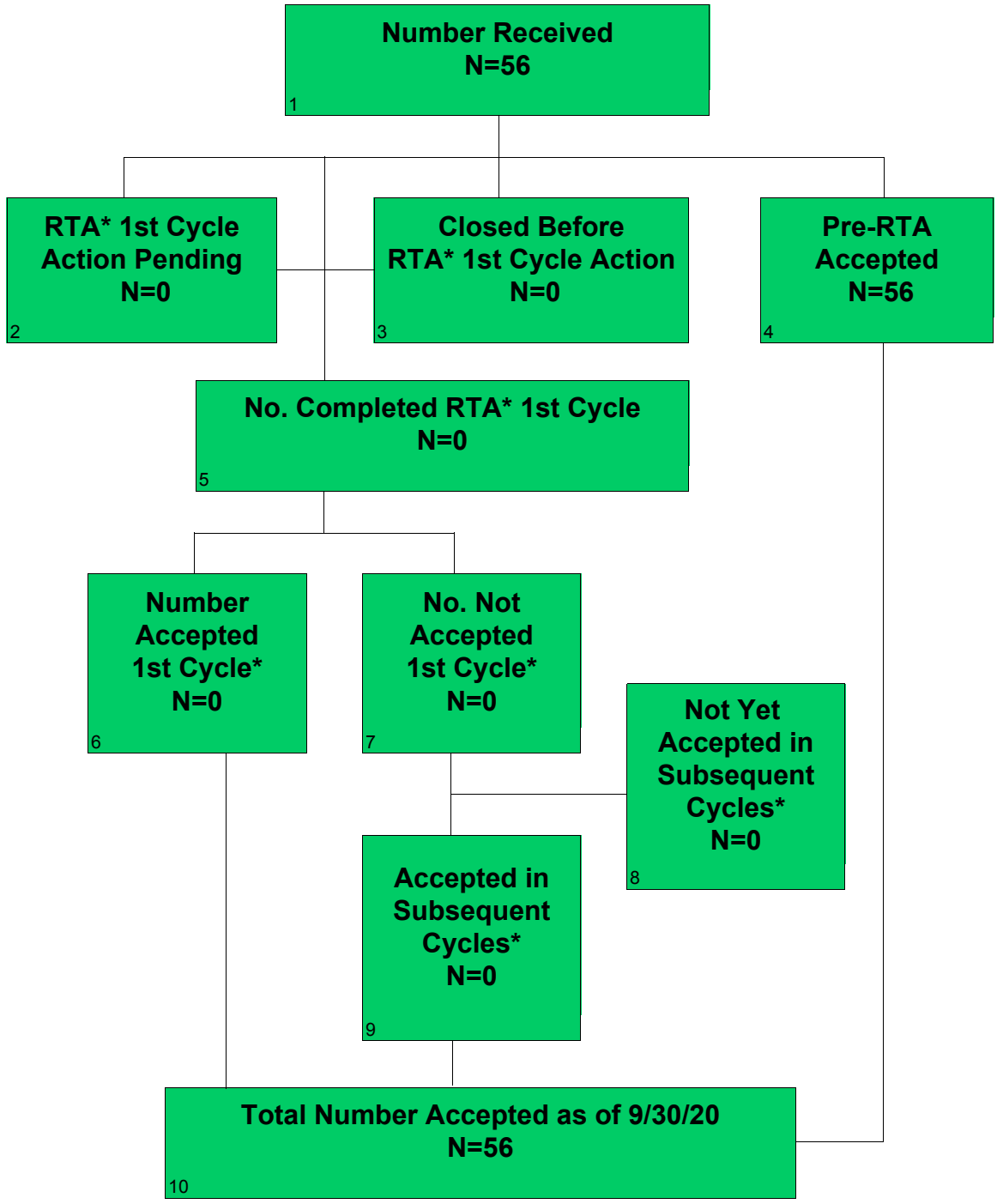
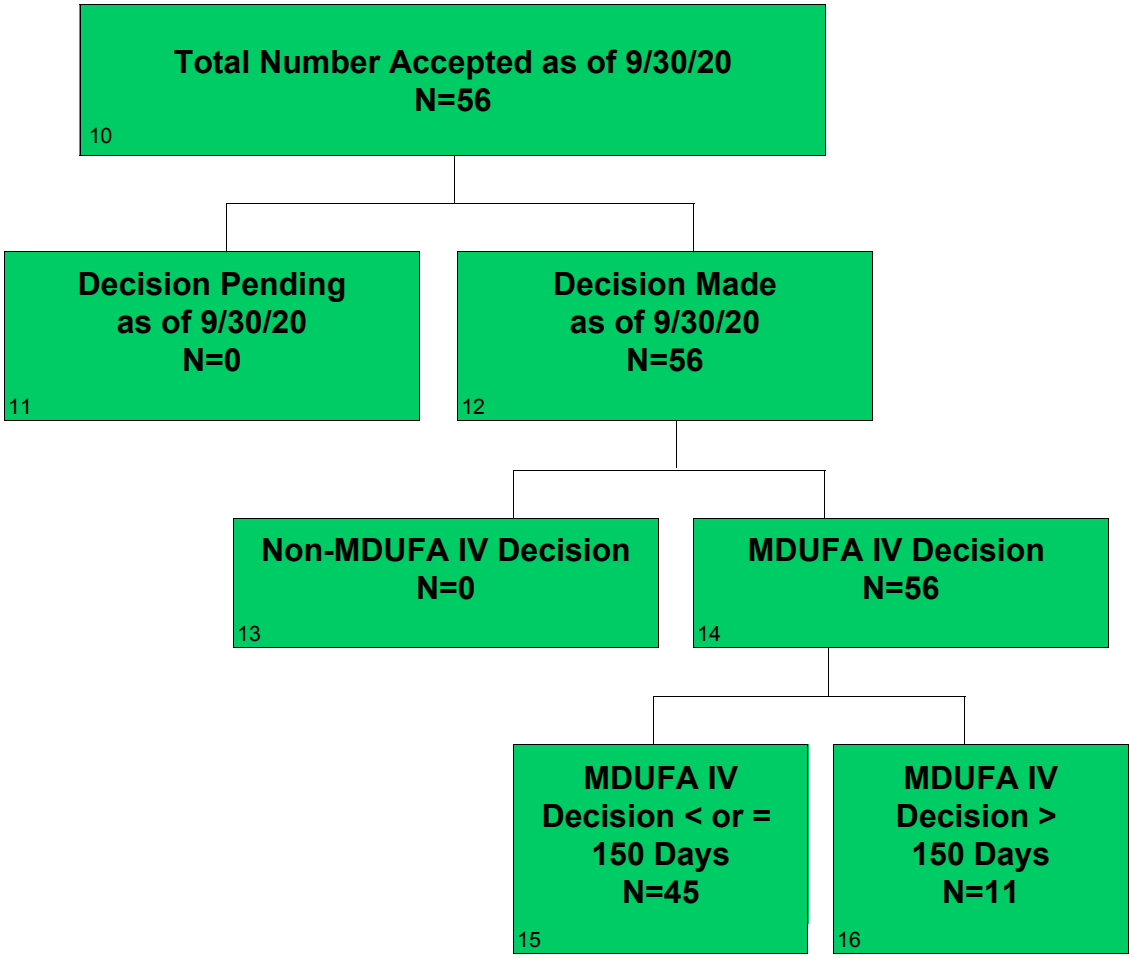
CDRH De Novo - FY 2018
as of 9/30/20

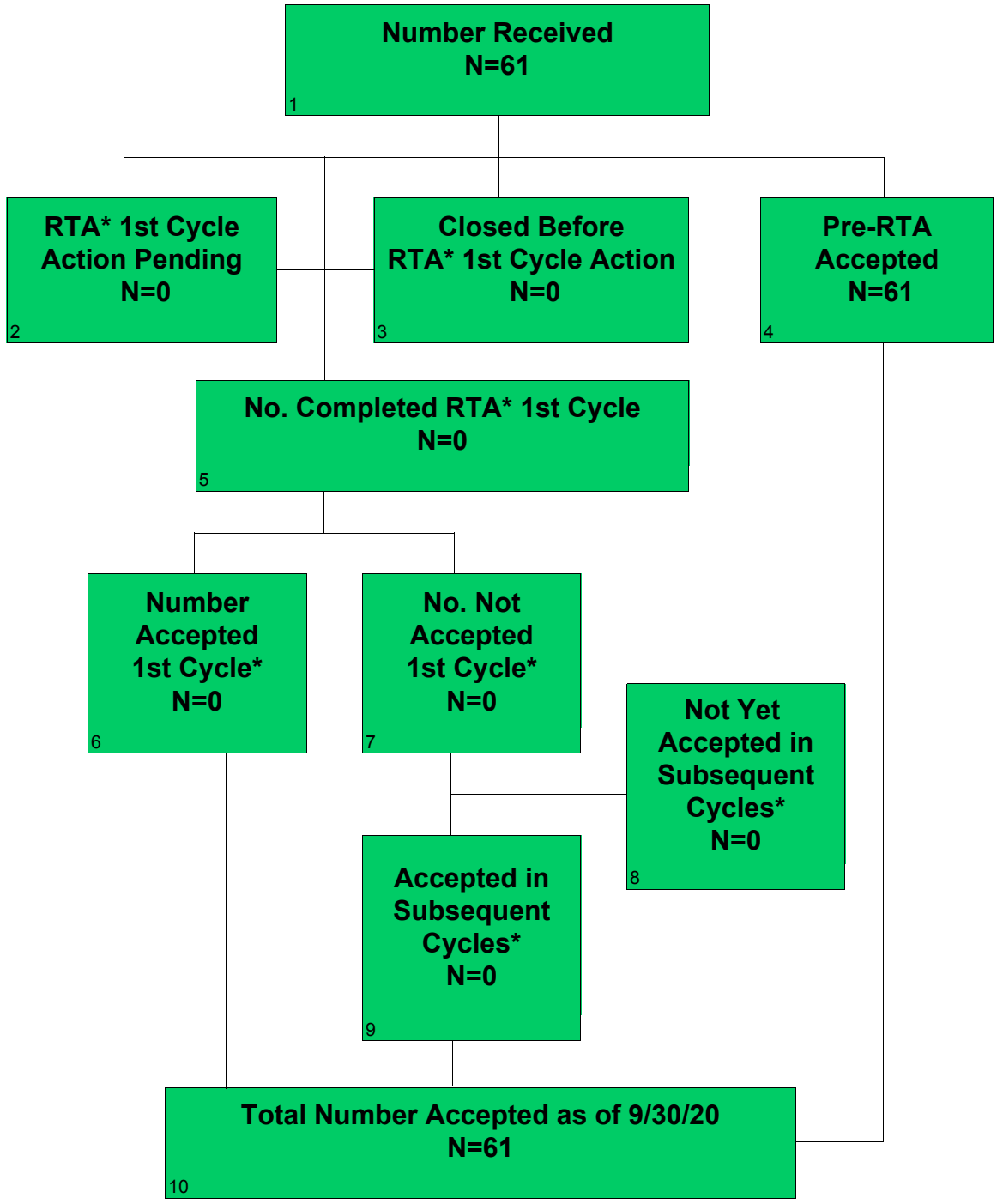


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018
as of 9/30/20 Continued

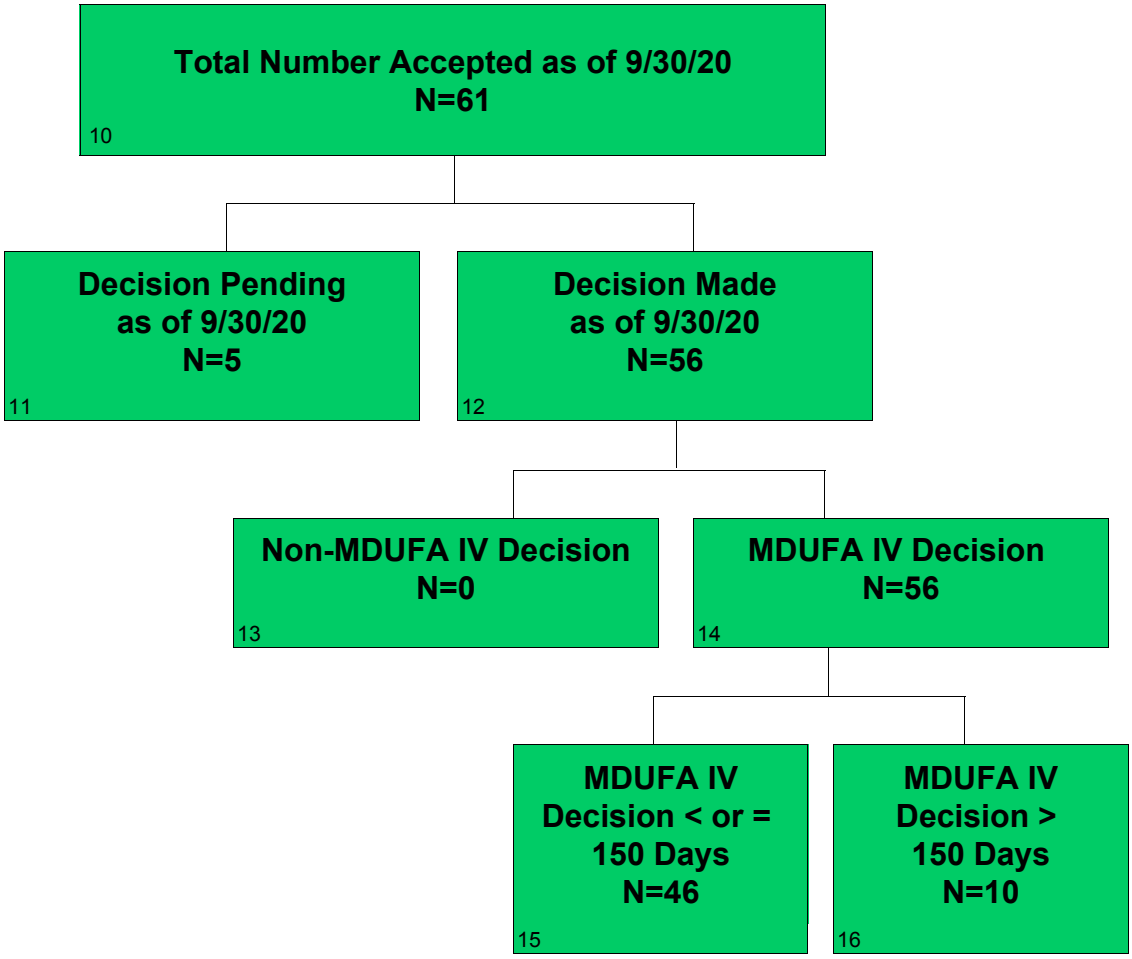


CDRH De Novo - FY 2019
as of 9/30/20

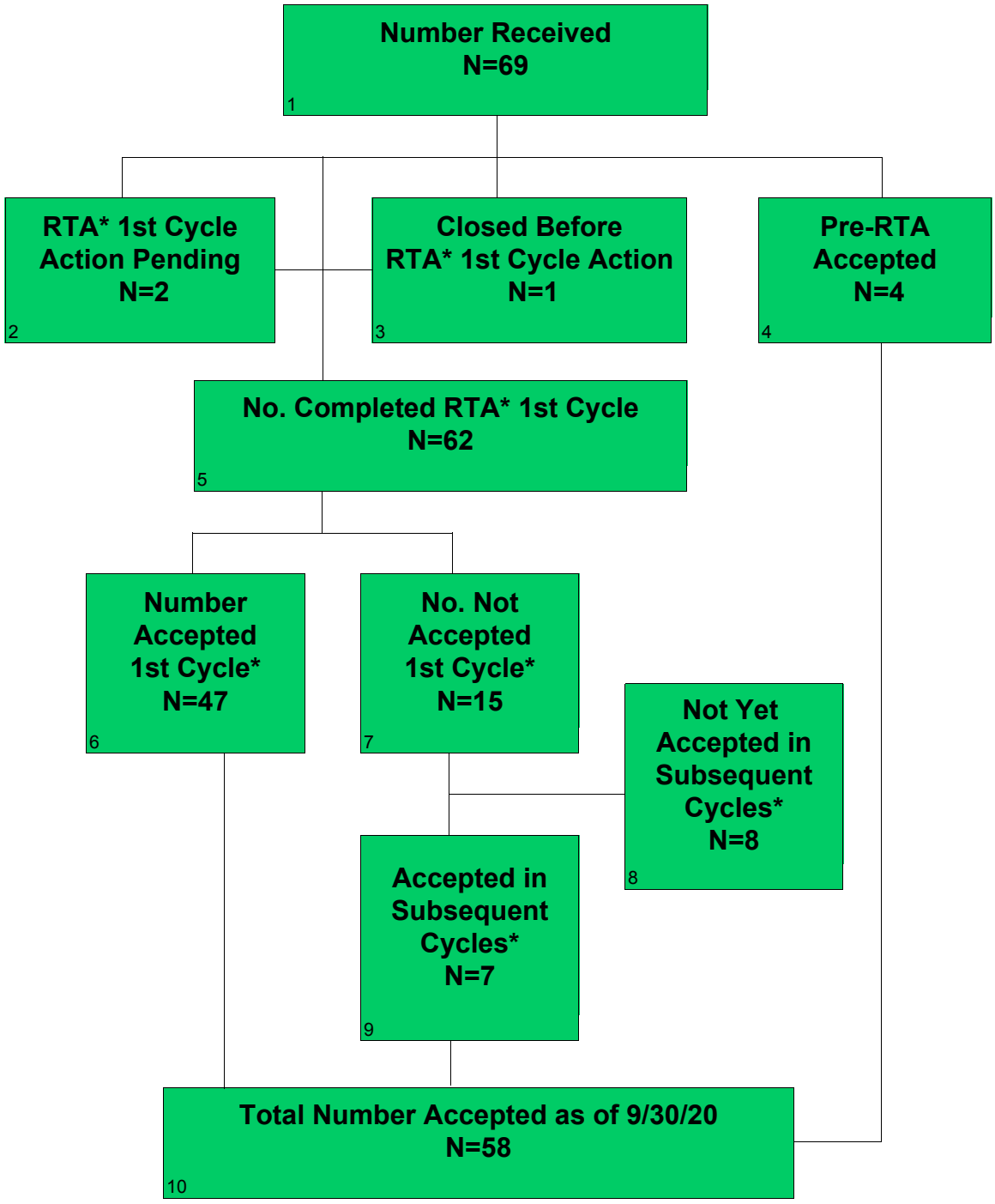


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019
as of 9/30/20 Continued

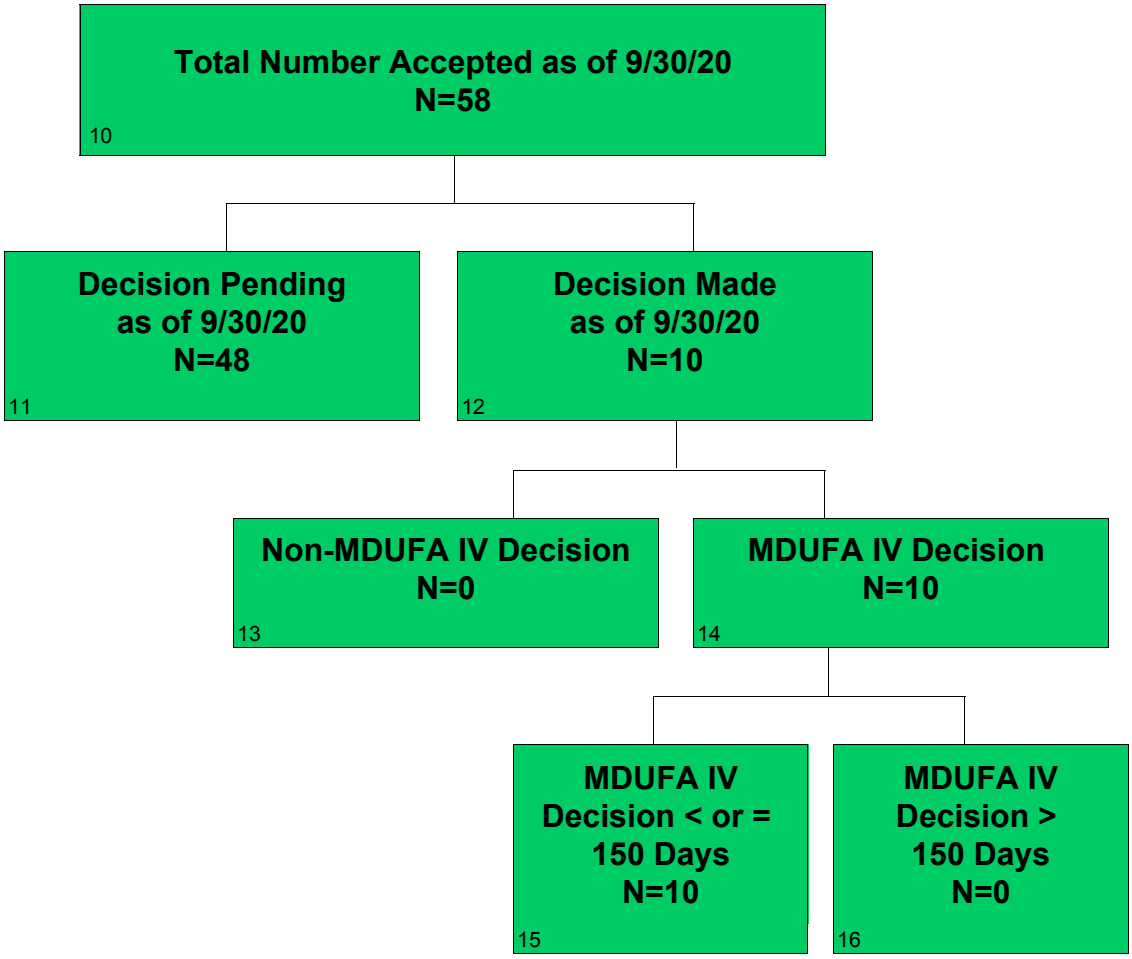


CDRH De Novo - FY 2020
as of 9/30/20



***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 9/30/20 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		
Closed Before RTA Action	0	0	1		
Number Accepted First RTA Cycle	0	0	44		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	3		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	2		
Number Not Accepted	0	0	15		
Rate of Submissions Not Accepted for Review	N/A	N/A	24.19%		

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

Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	56	61	58		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	56	56	10		
MDUFA IV Decisions Within 150 FDA Days	45	46	10		
De Novos Pending MDUFA IV Decision	0	5	48		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	3	4		
Current Performance Percent Within 150 FDA Days	80.36%	77.97%	71.43%		

Table 8.3 CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.57	1.55	1.50		
Number With MDUFA IV Decision	56	56	10		
Average FDA Days to MDUFA IV Decision	130.13	129.38	111.90		
20th Percentile FDA Days to MDUFA IV Decision	75	75	64		
40th Percentile FDA Days to MDUFA IV Decision	145	127	107		
60th Percentile FDA Days to MDUFA IV Decision	150	148	143		
80th Percentile FDA Days to MDUFA IV Decision	150	150	149		
Maximum FDA Days to MDUFA IV Decision	254	327	150		
Average Industry Days to MDUFA IV Decision	110.13	105.88	26.00		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	89	0	0		
60th Percentile Industry Days to MDUFA IV Decision	166	174	8		
80th Percentile Industry Days to MDUFA IV Decision	180	188	65		
Maximum Industry Days to MDUFA IV Decision	389	373	105		
Average Total Days to MDUFA IV Decision	240.25	235.25	137.90		
20th Percentile Total Days to MDUFA IV Decision	145	99	64		
40th Percentile Total Days to MDUFA IV Decision	251	150	107		
60th Percentile Total Days to MDUFA IV Decision	292	283	158		
80th Percentile Total Days to MDUFA IV Decision	324	347	210		
Maximum Total Days to MDUFA IV Decision	463	609	253		

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	58		
Number With MDUFA IV Decisions	56	56	10		
Number With Granted Decisions	25	24	5		
Number With Declined Decisions	15	14	2		
Number of Withdrawals	10	13	3		
Number Deleted	6	5	0		
Rate of Granted Decisions	44.64%	42.86%	50.00%		
Rate of Declined Decisions	26.79%	25.00%	20.00%		
Rate of Withdrawals	17.86%	23.21%	30.00%		
Rate of Deleted	10.71%	8.93%	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	10	0		
Mean FDA Days for Submissions that Missed the Goal	192.45	212.10	0.00		
Mean Industry Days for Submissions that Missed the Goal	127.27	208.40	0.00		

Table 8.6 CDRH - LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5	1		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	1	4	0		
MDUFA IV Decisions Within 150 FDA Days	1	2	0		
De Novos Pending MDUFA IV Decision	0	1	1		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	0		
Current Performance Percent Within 150 FDA Days	100.00%	40.00%	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	15		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	15	14	3		
MDUFA IV Decisions Within 150 FDA Days	15	14	3		
De Novos Pending MDUFA IV Decision	0	0	12		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

Table 8.8 CDRH - De Novo Annual General Metrics*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted First RTA Cycle	56	61	58		
Average Number of Days to Accept / Refuse to Accept*	0.00	0.00	11.50		

*** RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. 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		
Closed Before RTA Action	0	0	0		
Number Accepted First RTA Cycle	0	0	10		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted	0	0	2		
Rate of Submissions Not Accepted for Review	0.00	0.00	16.67%		

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

Table 8.2 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	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	8	5	12		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	8	5	2		
MDUFA IV Decisions Within 150 FDA Days	5	4	2		
De Novos Pending MDUFA IV Decision	0	0	10		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1		
Current Performance Percent Within 150 FDA Days	62.50%	80.00%	66.67%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.63	1.80	1.50		
Number With MDUFA IV Decision	8	5	2		
Average FDA Days to MDUFA IV Decision	141.25	124.80	106.50		
20th Percentile FDA Days to MDUFA IV Decision	110	75	82		
40th Percentile FDA Days to MDUFA IV Decision	149	119	98		
60th Percentile FDA Days to MDUFA IV Decision	153	148	115		
80th Percentile FDA Days to MDUFA IV Decision	165	154	131		
Maximum FDA Days to MDUFA IV Decision	194	180	148		
Average Industry Days to MDUFA IV Decision	106.13	195.20	52.50		
20th Percentile Industry Days to MDUFA IV Decision	9	185	21		
40th Percentile Industry Days to MDUFA IV Decision	45	192	42		
60th Percentile Industry Days to MDUFA IV Decision	75	199	63		
80th Percentile Industry Days to MDUFA IV Decision	167	206	84		
Maximum Industry Days to MDUFA IV Decision	389	212	105		
Average Total Days to MDUFA IV Decision	247.38	320.00	159.00		
20th Percentile Total Days to MDUFA IV Decision	157	268	103		
40th Percentile Total Days to MDUFA IV Decision	199	304	140		
60th Percentile Total Days to MDUFA IV Decision	260	336	178		
80th Percentile Total Days to MDUFA IV Decision	332	360	215		
Maximum Total Days to MDUFA IV Decision	463	392	253		

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	12		
Number With MDUFA IV Decisions	8	5	2		
Number With Granted Decisions	5	2	1		
Number With Declined Decisions	2	1	1		
Number of Withdrawals	0	0	0		
Number Deleted	1	2	0		
Rate of Granted Decisions	62.50%	40.00%	50.00%		
Rate of Declined Decisions	25.00%	20.00%	50.00%		
Rate of Withdrawals	0.00%	0.00%	0.00%		
Rate of Deleted	12.50%	40.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	3	1	0		
Mean FDA Days for Submissions that Missed the Goal	174.67	180.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	127.00	212.00	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Closed Before RTA Action	0	0	0		
Number Accepted First RTA Cycle	0	0	6		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted	0	0	1		
Rate of Submissions Not Accepted for Review	N/A	N/A	14.29%		

***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	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	9	8		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	5	8	1		
MDUFA IV Decisions Within 150 FDA Days	5	8	1		
De Novos Pending MDUFA IV Decision	0	1	7		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	2		
Current Performance Percent Within 150 FDA Days	100.00%	88.89%	33.33%		

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	1.38	1.00		
Number With MDUFA IV Decision	5	8	1		
Average FDA Days to MDUFA IV Decision	74.00	118.50	73.00		
20th Percentile FDA Days to MDUFA IV Decision	32	80	73		
40th Percentile FDA Days to MDUFA IV Decision	58	123	73		
60th Percentile FDA Days to MDUFA IV Decision	79	146	73		
80th Percentile FDA Days to MDUFA IV Decision	98	149	73		
Maximum FDA Days to MDUFA IV Decision	148	150	73		
Average Industry Days to MDUFA IV Decision	112.40	57.75	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	98	0	0		
60th Percentile Industry Days to MDUFA IV Decision	171	38	0		
80th Percentile Industry Days to MDUFA IV Decision	188	121	0		
Maximum Industry Days to MDUFA IV Decision	217	207	0		
Average Total Days to MDUFA IV Decision	186.40	176.25	73.00		
20th Percentile Total Days to MDUFA IV Decision	32	111	73		
40th Percentile Total Days to MDUFA IV Decision	173	143	73		
60th Percentile Total Days to MDUFA IV Decision	277	187	73		
80th Percentile Total Days to MDUFA IV Decision	296	248	73		
Maximum Total Days to MDUFA IV Decision	312	303	73		

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		
Number With MDUFA IV Decisions	5	8	1		
Number With Granted Decisions	3	1	0		
Number With Declined Decisions	0	5	0		
Number of Withdrawals	0	1	1		
Number Deleted	2	1	0		
Rate of Granted Decisions	60.00%	12.50%	0.00%		
Rate of Declined Decisions	0.00%	62.50%	0.00%		
Rate of Withdrawals	0.00%	12.50%	100.00%		
Rate of Deleted	40.00%	12.50%	0.00%		

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Closed Before RTA Action	0	0	0		
Number Accepted First RTA Cycle	0	0	4		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted	0	0	2		
Rate of Submissions Not Accepted for Review	N/A	N/A	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 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	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	11	6		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	4	9	1		
MDUFA IV Decisions Within 150 FDA Days	3	4	1		
De Novos Pending MDUFA IV Decision	0	2	5		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1		
Current Performance Percent Within 150 FDA Days	75.00%	44.44%	50.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.78	2.00		
Number With MDUFA IV Decision	4	9	1		
Average FDA Days to MDUFA IV Decision	100.00	180.33	150.00		
20th Percentile FDA Days to MDUFA IV Decision	57	148	150		
40th Percentile FDA Days to MDUFA IV Decision	97	157	150		
60th Percentile FDA Days to MDUFA IV Decision	135	189	150		
80th Percentile FDA Days to MDUFA IV Decision	149	199	150		
Maximum FDA Days to MDUFA IV Decision	151	327	150		
Average Industry Days to MDUFA IV Decision	136.75	138.78	21.00		
20th Percentile Industry Days to MDUFA IV Decision	100	82	21		
40th Percentile Industry Days to MDUFA IV Decision	169	166	21		
60th Percentile Industry Days to MDUFA IV Decision	175	177	21		
80th Percentile Industry Days to MDUFA IV Decision	187	178	21		
Maximum Industry Days to MDUFA IV Decision	203	241	21		
Average Total Days to MDUFA IV Decision	236.75	319.11	171.00		
20th Percentile Total Days to MDUFA IV Decision	179	229	171		
40th Percentile Total Days to MDUFA IV Decision	293	333	171		
60th Percentile Total Days to MDUFA IV Decision	312	362	171		
80th Percentile Total Days to MDUFA IV Decision	321	376	171		
Maximum Total Days to MDUFA IV Decision	325	568	171		

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		
Number With MDUFA IV Decisions	4	9	1		
Number With Granted Decisions	0	7	0		
Number With Declined Decisions	3	2	1		
Number of Withdrawals	0	0	0		
Number Deleted	1	0	0		
Rate of Granted Decisions	0.00%	77.78%	0.00%		
Rate of Declined Decisions	75.00%	22.22%	100.00%		
Rate of Withdrawals	0.00%	0.00%	0.00%		
Rate of Deleted	25.00%	0.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	5	0		
Mean FDA Days for Submissions that Missed the Goal	151.00	220.60	0.00		
Mean Industry Days for Submissions that Missed the Goal	167.00	186.80	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Closed Before RTA Action	0	0	0		
Number Accepted First RTA Cycle	0	0	2		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	1		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted	0	0	3		
Rate of Submissions Not Accepted for Review	N/A	N/A	50.00%		

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

Table 8.2 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	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	6	4		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	5	5	1		
MDUFA IV Decisions Within 150 FDA Days	3	4	1		
De Novos Pending MDUFA IV Decision	0	1	3		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	0		
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	100.00%		

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	1.40	1.00		
Number With MDUFA IV Decision	5	5	1		
Average FDA Days to MDUFA IV Decision	147.40	122.00	56.00		
20th Percentile FDA Days to MDUFA IV Decision	133	90	56		
40th Percentile FDA Days to MDUFA IV Decision	150	96	56		
60th Percentile FDA Days to MDUFA IV Decision	151	102	56		
80th Percentile FDA Days to MDUFA IV Decision	167	133	56		
Maximum FDA Days to MDUFA IV Decision	221	236	56		
Average Industry Days to MDUFA IV Decision	90.80	112.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	12	0	0		
40th Percentile Industry Days to MDUFA IV Decision	65	0	0		
60th Percentile Industry Days to MDUFA IV Decision	124	75	0		
80th Percentile Industry Days to MDUFA IV Decision	165	224	0		
Maximum Industry Days to MDUFA IV Decision	179	373	0		
Average Total Days to MDUFA IV Decision	238.20	234.00	56.00		
20th Percentile Total Days to MDUFA IV Decision	145	90	56		
40th Percentile Total Days to MDUFA IV Decision	215	101	56		
60th Percentile Total Days to MDUFA IV Decision	275	178	56		
80th Percentile Total Days to MDUFA IV Decision	332	350	56		
Maximum Total Days to MDUFA IV Decision	400	609	56		

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	4		
Number With MDUFA IV Decisions	5	5	1		
Number With Granted Decisions	3	0	0		
Number With Declined Decisions	1	3	0		
Number of Withdrawals	1	1	1		
Number Deleted	0	1	0		
Rate of Granted Decisions	60.00%	0.00%	0.00%		
Rate of Declined Decisions	20.00%	60.00%	0.00%		
Rate of Withdrawals	20.00%	20.00%	100.00%		
Rate of Deleted	0.00%	20.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	1	0		
Mean FDA Days for Submissions that Missed the Goal	187.00	236.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	170.50	373.00	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Closed Before RTA Action	0	0	0		
Number Accepted First RTA Cycle	0	0	5		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted	0	0	2		
Rate of Submissions Not Accepted for Review	N/A	N/A	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 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	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	6	6		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	13	6	1		
MDUFA IV Decisions Within 150 FDA Days	9	6	1		
De Novos Pending MDUFA IV Decision	0	0	5		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	69.23%	100.00%	100.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.77	1.33	1.00		
Number With MDUFA IV Decision	13	6	1		
Average FDA Days to MDUFA IV Decision	153.00	113.33	59.00		
20th Percentile FDA Days to MDUFA IV Decision	104	76	59		
40th Percentile FDA Days to MDUFA IV Decision	148	127	59		
60th Percentile FDA Days to MDUFA IV Decision	150	136	59		
80th Percentile FDA Days to MDUFA IV Decision	219	149	59		
Maximum FDA Days to MDUFA IV Decision	254	150	59		
Average Industry Days to MDUFA IV Decision	106.08	20.17	0.00		
20th Percentile Industry Days to MDUFA IV Decision	39	0	0		
40th Percentile Industry Days to MDUFA IV Decision	82	0	0		
60th Percentile Industry Days to MDUFA IV Decision	164	0	0		
80th Percentile Industry Days to MDUFA IV Decision	174	45	0		
Maximum Industry Days to MDUFA IV Decision	183	76	0		
Average Total Days to MDUFA IV Decision	259.08	133.50	59.00		
20th Percentile Total Days to MDUFA IV Decision	226	76	59		
40th Percentile Total Days to MDUFA IV Decision	266	127	59		
60th Percentile Total Days to MDUFA IV Decision	316	136	59		
80th Percentile Total Days to MDUFA IV Decision	323	195	59		
Maximum Total Days to MDUFA IV Decision	371	225	59		

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		
Number With MDUFA IV Decisions	13	6	1		
Number With Granted Decisions	3	2	1		
Number With Declined Decisions	7	0	0		
Number of Withdrawals	3	4	0		
Number Deleted	0	0	0		
Rate of Granted Decisions	23.08%	33.33%	100.00%		
Rate of Declined Decisions	53.85%	0.00%	0.00%		
Rate of Withdrawals	23.08%	66.67%	0.00%		
Rate of Deleted	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	0		
Mean FDA Days for Submissions that Missed the Goal	229.25	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	82.75	0.00	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Closed Before RTA Action	0	0	0		
Number Accepted First RTA Cycle	0	0	5		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted	0	0	0		
Rate of Submissions Not Accepted for Review	N/A	N/A	N/A		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	4	5		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	4	4	1		
MDUFA IV Decisions Within 150 FDA Days	3	3	1		
De Novos Pending MDUFA IV Decision	0	0	4		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	75.00%	75.00%	100.00%		

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		
Number With MDUFA IV Decision	4	4	1		
Average FDA Days to MDUFA IV Decision	133.25	144.75	149.00		
20th Percentile FDA Days to MDUFA IV Decision	122	116	149		
40th Percentile FDA Days to MDUFA IV Decision	148	143	149		
60th Percentile FDA Days to MDUFA IV Decision	150	144	149		
80th Percentile FDA Days to MDUFA IV Decision	150	173	149		
Maximum FDA Days to MDUFA IV Decision	151	217	149		
Average Industry Days to MDUFA IV Decision	161.00	178.50	63.00		
20th Percentile Industry Days to MDUFA IV Decision	149	104	63		
40th Percentile Industry Days to MDUFA IV Decision	179	175	63		
60th Percentile Industry Days to MDUFA IV Decision	180	177	63		
80th Percentile Industry Days to MDUFA IV Decision	180	252	63		
Maximum Industry Days to MDUFA IV Decision	181	362	63		
Average Total Days to MDUFA IV Decision	294.25	323.25	212.00		
20th Percentile Total Days to MDUFA IV Decision	260	221	212		
40th Percentile Total Days to MDUFA IV Decision	278	333	212		
60th Percentile Total Days to MDUFA IV Decision	316	380	212		
80th Percentile Total Days to MDUFA IV Decision	330	439	212		
Maximum Total Days to MDUFA IV Decision	331	505	212		

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Closed Before RTA Action	0	0	1		
Number Accepted First RTA Cycle	0	0	12		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	2		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted	0	0	5		
Rate of Submissions Not Accepted for Review	N/A	N/A	26.32%		

***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	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	17	20	17		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	17	19	3		
MDUFA IV Decisions Within 150 FDA Days	17	17	3		
De Novos Pending MDUFA IV Decision	0	1	14		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	0		
Current Performance Percent Within 150 FDA Days	100.00%	85.00%	100.00%		

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	1.53	1.67		
Number With MDUFA IV Decision	17	19	3		
Average FDA Days to MDUFA IV Decision	125.18	114.79	139.67		
20th Percentile FDA Days to MDUFA IV Decision	108	69	134		
40th Percentile FDA Days to MDUFA IV Decision	127	118	137		
60th Percentile FDA Days to MDUFA IV Decision	146	148	141		
80th Percentile FDA Days to MDUFA IV Decision	150	150	146		
Maximum FDA Days to MDUFA IV Decision	150	223	150		
Average Industry Days to MDUFA IV Decision	101.88	97.21	23.67		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	84	0	0		
60th Percentile Industry Days to MDUFA IV Decision	169	154	14		
80th Percentile Industry Days to MDUFA IV Decision	179	200	43		
Maximum Industry Days to MDUFA IV Decision	189	276	71		
Average Total Days to MDUFA IV Decision	227.06	212.00	163.33		
20th Percentile Total Days to MDUFA IV Decision	137	90	138		
40th Percentile Total Days to MDUFA IV Decision	183	150	146		
60th Percentile Total Days to MDUFA IV Decision	277	261	162		
80th Percentile Total Days to MDUFA IV Decision	313	331	186		
Maximum Total Days to MDUFA IV Decision	327	450	210		

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	17		
Number With MDUFA IV Decisions	17	19	3		
Number With Granted Decisions	10	11	2		
Number With Declined Decisions	1	0	0		
Number of Withdrawals	5	7	1		
Number Deleted	1	1	0		
Rate of Granted Decisions	58.82%	57.89%	66.67%		
Rate of Declined Decisions	5.88%	0.00%	0.00%		
Rate of Withdrawals	29.41%	36.84%	33.33%		
Rate of Deleted	5.88%	5.26%	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	2	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	192.50	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	193.50	0.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5	1		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	1	4	0		
MDUFA IV Decisions Within 150 FDA Days	1	2	0		
De Novos Pending MDUFA IV Decision	0	1	1		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	1	0		
Current Performance Percent Within 150 FDA Days	100.00%	40.00%	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	15		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	15	14	3		
MDUFA IV Decisions Within 150 FDA Days	15	14	3		
De Novos Pending MDUFA IV Decision	0	0	12		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

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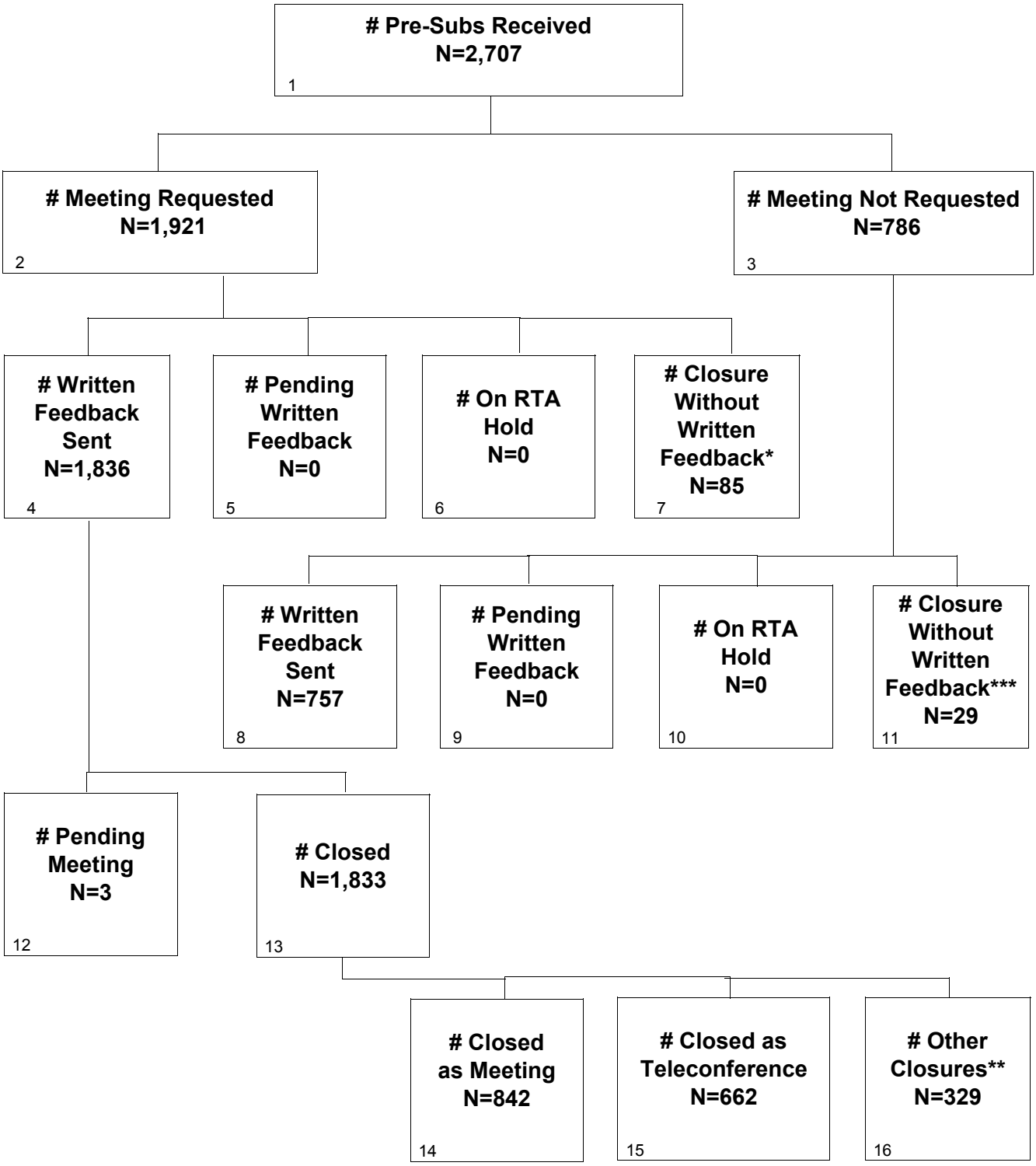
CDRH Pre-Sub - FY 2018
as of 9/30/20



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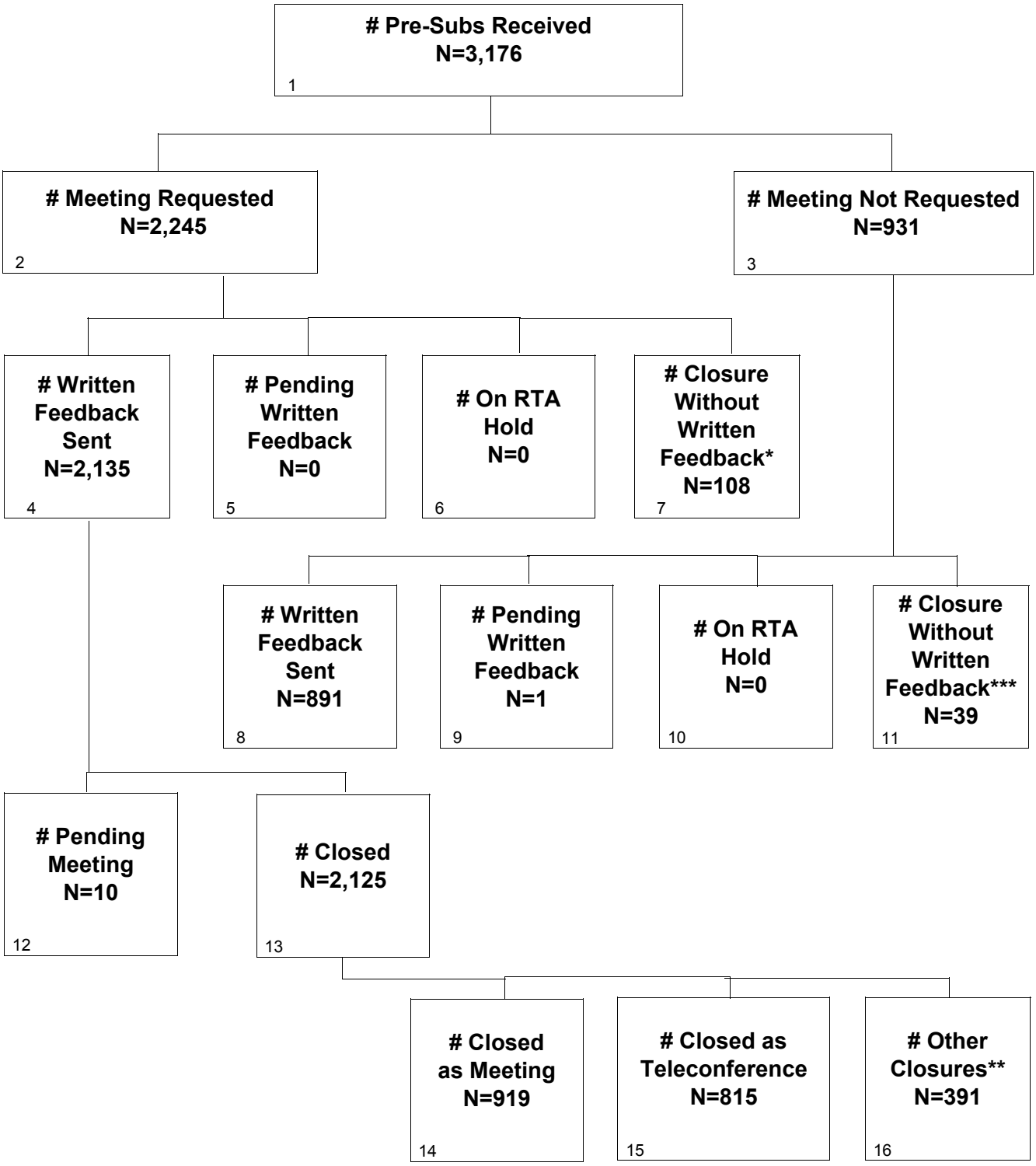
CDRH Pre-Sub - FY 2019
as of 9/30/20



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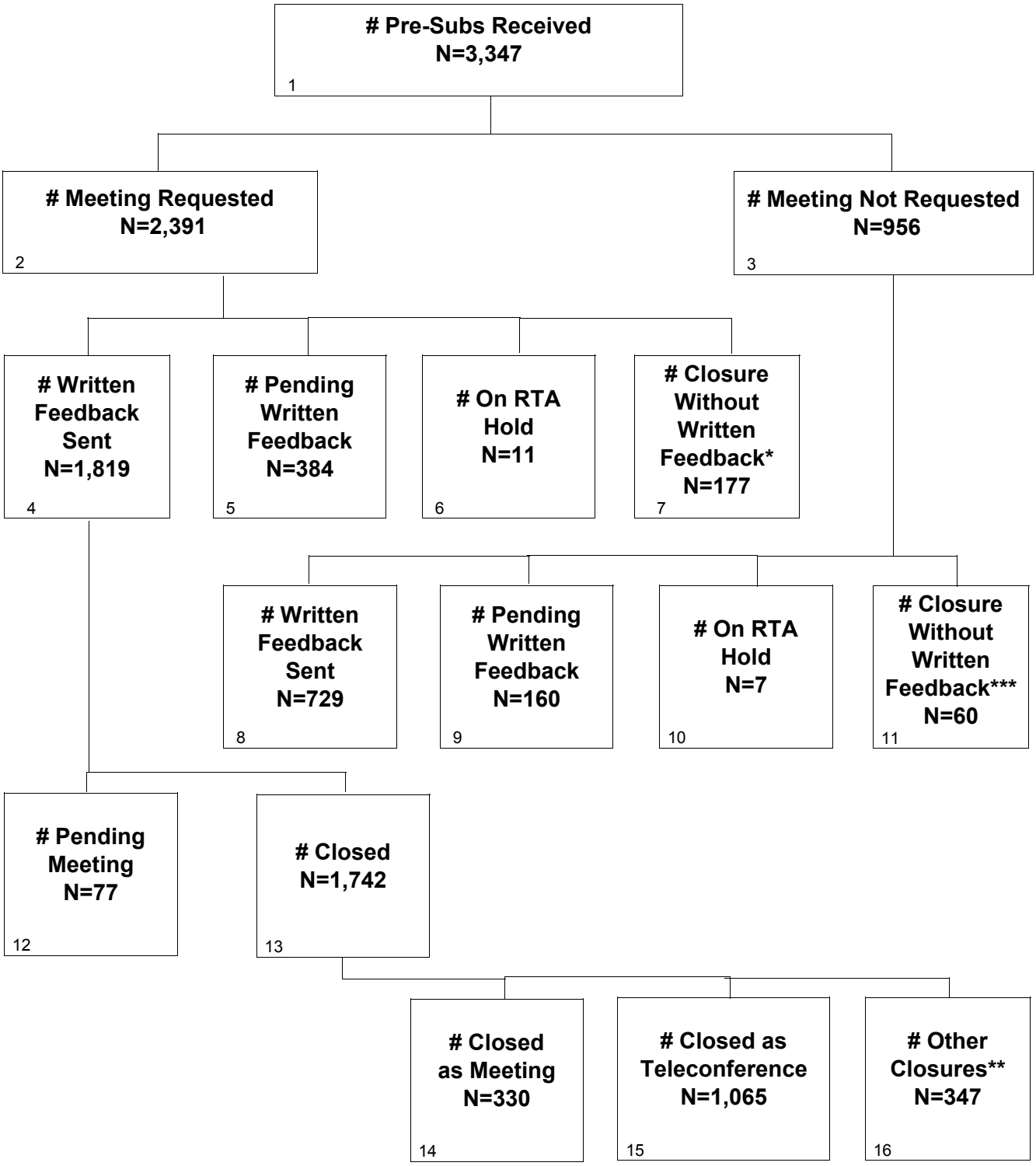
CDRH Pre-Sub - FY 2020
as of 9/30/20



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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	3,347		
Closed Before RTA Action	27	41	107		
Number Accepted First RTA Cycle	2,565	3,004	2,974		
Number Without a RTA Review and > 15 Days Since Date Received	49	71	139		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	88		
Number Not Accepted	66	60	39		
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.24%		

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	2,548		
Written Feedback Provided Within MDUFA IV Goal	2,439	2,847	2,288		

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	2,548		
Average FDA Days to Written Feedback	58.86	59.93	61.62		
20th Percentile FDA Days to Written Feedback	49	49	51		
40th Percentile FDA Days to Written Feedback	59	60	61		
60th Percentile FDA Days to Written Feedback	65	65	66		
80th Percentile FDA Days to Written Feedback	69	70	70		
Maximum FDA Days to Written Feedback	172	397	290		

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	28		
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	39.46		

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	1,504	1,736	1,395		
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,110	875		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	59		
Meeting Minutes Past 15 Days of Meeting	481	556	386		
Meeting Minutes Not Submitted and >15 Days Since Meeting	52	70	75		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.56%	63.94%	65.49%		

Section 9 Pre-Sub Office Level Metrics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	318	393	429		
Closed Before RTA Action	0	6	5		
Number Accepted First RTA Cycle	283	363	392		
Number Without a RTA Review and > 15 Days Since Date Received	8	9	10		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	14		
Number Not Accepted	27	15	8		
Rate of Submissions Not Accepted for Review	8.49%	3.88%	1.95%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	297	363	318		
Written Feedback Provided Within MDUFA IV Goal	256	317	231		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	297	363	318		
Average FDA Days to Written Feedback	64.23	64.17	69.08		
20th Percentile FDA Days to Written Feedback	56	57	61		
40th Percentile FDA Days to Written Feedback	64	65	65		
60th Percentile FDA Days to Written Feedback	69	69	70		
80th Percentile FDA Days to Written Feedback	70	70	73		
Maximum FDA Days to Written Feedback	168	119	188		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	5	10		
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	33.40	42.40		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	182	227	188		
Meeting Minutes Submitted Within 15 Days of Meeting	125	154	115		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	10		
Meeting Minutes Past 15 Days of Meeting	50	68	52		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	11		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.68%	67.84%	64.61%		

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	529	581	674		
Closed Before RTA Action	6	7	4		
Number Accepted First RTA Cycle	505	554	627		
Number Without a RTA Review and > 15 Days Since Date Received	12	14	11		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	23		
Number Not Accepted	6	6	9		
Rate of Submissions Not Accepted for Review	1.15%	1.05%	1.39%		

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	511	562	544		
Written Feedback Provided Within MDUFA IV Goal	481	534	508		

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	511	562	544		
Average FDA Days to Written Feedback	53.00	55.49	55.71		
20th Percentile FDA Days to Written Feedback	39	44	44		
40th Percentile FDA Days to Written Feedback	50	53	54		
60th Percentile FDA Days to Written Feedback	59	63	63		
80th Percentile FDA Days to Written Feedback	67	69	69		
Maximum FDA Days to Written Feedback	91	115	115		

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

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	310	320	277		
Meeting Minutes Submitted Within 15 Days of Meeting	183	197	157		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	12		
Meeting Minutes Past 15 Days of Meeting	117	103	89		
Meeting Minutes Not Submitted and >15 Days Since Meeting	10	20	19		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	59.03%	61.56%	59.25%		

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	335	380	398		
Closed Before RTA Action	5	7	11		
Number Accepted First RTA Cycle	308	357	358		
Number Without a RTA Review and > 15 Days Since Date Received	11	7	3		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	17		
Number Not Accepted	11	9	9		
Rate of Submissions Not Accepted for Review	3.33%	2.41%	2.43%		

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	314	352	301		
Written Feedback Provided Within MDUFA IV Goal	301	343	292		

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	314	352	301		
Average FDA Days to Written Feedback	60.53	60.76	60.35		
20th Percentile FDA Days to Written Feedback	53	53	51		
40th Percentile FDA Days to Written Feedback	61	61	60		
60th Percentile FDA Days to Written Feedback	65	66	66		
80th Percentile FDA Days to Written Feedback	69	69	70		
Maximum FDA Days to Written Feedback	156	148	98		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	7	1		
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	37.71	36.00		

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	179	203	165		
Meeting Minutes Submitted Within 15 Days of Meeting	113	125	114		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	11		
Meeting Minutes Past 15 Days of Meeting	64	72	37		
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.13%	61.58%	74.03%		

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	252	278	339		
Closed Before RTA Action	4	5	21		
Number Accepted First RTA Cycle	235	253	301		
Number Without a RTA Review and > 15 Days Since Date Received	6	11	8		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	5		
Number Not Accepted	7	9	4		
Rate of Submissions Not Accepted for Review	2.82%	3.30%	1.28%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	256	259		
Written Feedback Provided Within MDUFA IV Goal	215	224	235		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	256	259		
Average FDA Days to Written Feedback	60.68	62.62	61.57		
20th Percentile FDA Days to Written Feedback	52	55	56		
40th Percentile FDA Days to Written Feedback	59	63	62		
60th Percentile FDA Days to Written Feedback	65	66	65		
80th Percentile FDA Days to Written Feedback	69	70	69		
Maximum FDA Days to Written Feedback	121	106	131		

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	4		
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	32.75		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	125	142	157		
Meeting Minutes Submitted Within 15 Days of Meeting	92	95	102		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	26	42	38		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	12		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.60%	66.90%	67.11%		

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	275	309		
Closed Before RTA Action	3	2	2		
Number Accepted First RTA Cycle	232	251	280		
Number Without a RTA Review and > 15 Days Since Date Received	7	10	16		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	7		
Number Not Accepted	7	12	4		
Rate of Submissions Not Accepted for Review	2.85%	4.40%	1.33%		

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	258	232		
Written Feedback Provided Within MDUFA IV Goal	202	217	149		

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	258	232		
Average FDA Days to Written Feedback	64.72	72.88	76.89		
20th Percentile FDA Days to Written Feedback	58	63	64		
40th Percentile FDA Days to Written Feedback	65	68	70		
60th Percentile FDA Days to Written Feedback	69	70	70		
80th Percentile FDA Days to Written Feedback	70	70	82		
Maximum FDA Days to Written Feedback	172	397	290		

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

Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	155	167	128		
Meeting Minutes Submitted Within 15 Days of Meeting	99	99	80		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	3		
Meeting Minutes Past 15 Days of Meeting	50	57	38		
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	11	7		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.87%	59.28%	64.00%		

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		
Closed Before RTA Action	1	3	1		
Number Accepted First RTA Cycle	127	160	167		
Number Without a RTA Review and > 15 Days Since Date Received	5	6	7		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted	0	2	3		
Rate of Submissions Not Accepted for Review	0.00%	1.19%	1.69%		

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	151		
Written Feedback Provided Within MDUFA IV Goal	115	151	147		

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	151		
Average FDA Days to Written Feedback	61.91	61.14	62.15		
20th Percentile FDA Days to Written Feedback	52	55	56		
40th Percentile FDA Days to Written Feedback	62	63	63		
60th Percentile FDA Days to Written Feedback	67	66	69		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	106	92	105		

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

Table 9.5 OHT6 - Office of Orthopedic Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	77	87	62		
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	46		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	3		
Meeting Minutes Past 15 Days of Meeting	19	29	11		
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.97%		

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	1019		
Closed Before RTA Action	8	11	63		
Number Accepted First RTA Cycle	875	1066	849		
Number Without a RTA Review and > 15 Days Since Date Received	0	14	84		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	21		
Number Not Accepted	8	7	2		
Rate of Submissions Not Accepted for Review	0.91%	0.64%	0.21%		

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	743		
Written Feedback Provided Within MDUFA IV Goal	869	1,061	726		

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	743		
Average FDA Days to Written Feedback	57.35	56.61	58.40		
20th Percentile FDA Days to Written Feedback	48	45	50		
40th Percentile FDA Days to Written Feedback	57	57	58		
60th Percentile FDA Days to Written Feedback	63	63	64		
80th Percentile FDA Days to Written Feedback	68	68	68		
Maximum FDA Days to Written Feedback	85	307	142		

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	5		
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	35.60	41.80		

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	418		
Meeting Minutes Submitted Within 15 Days of Meeting	304	387	261		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	15		
Meeting Minutes Past 15 Days of Meeting	155	185	121		
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	18	21		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.87%	65.59%	64.76%		

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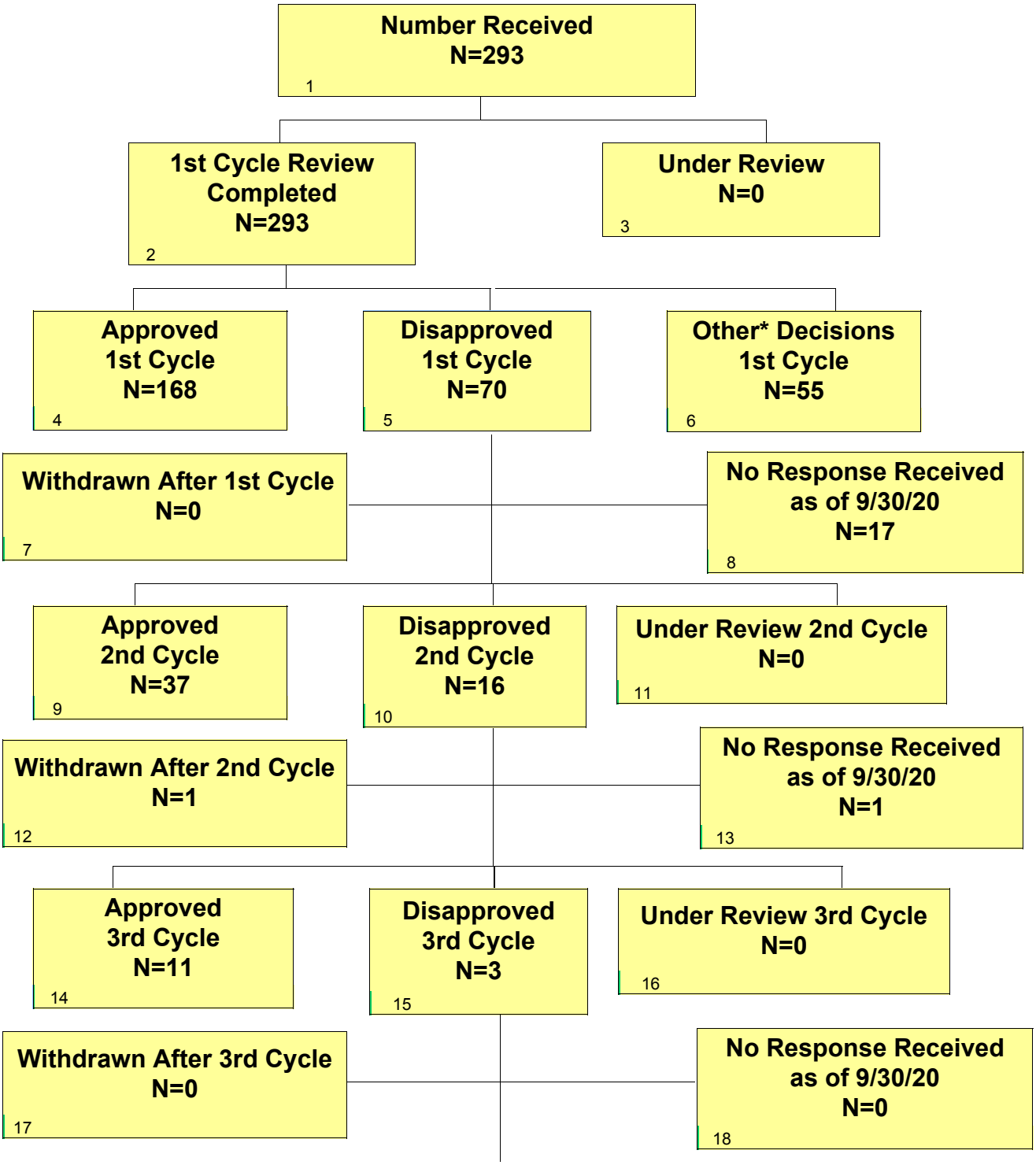
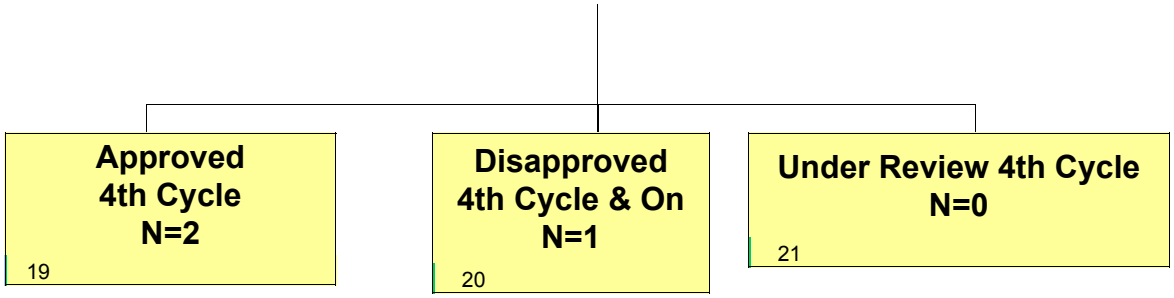
CDRH IDEs - FY 2018
as of 9/30/20

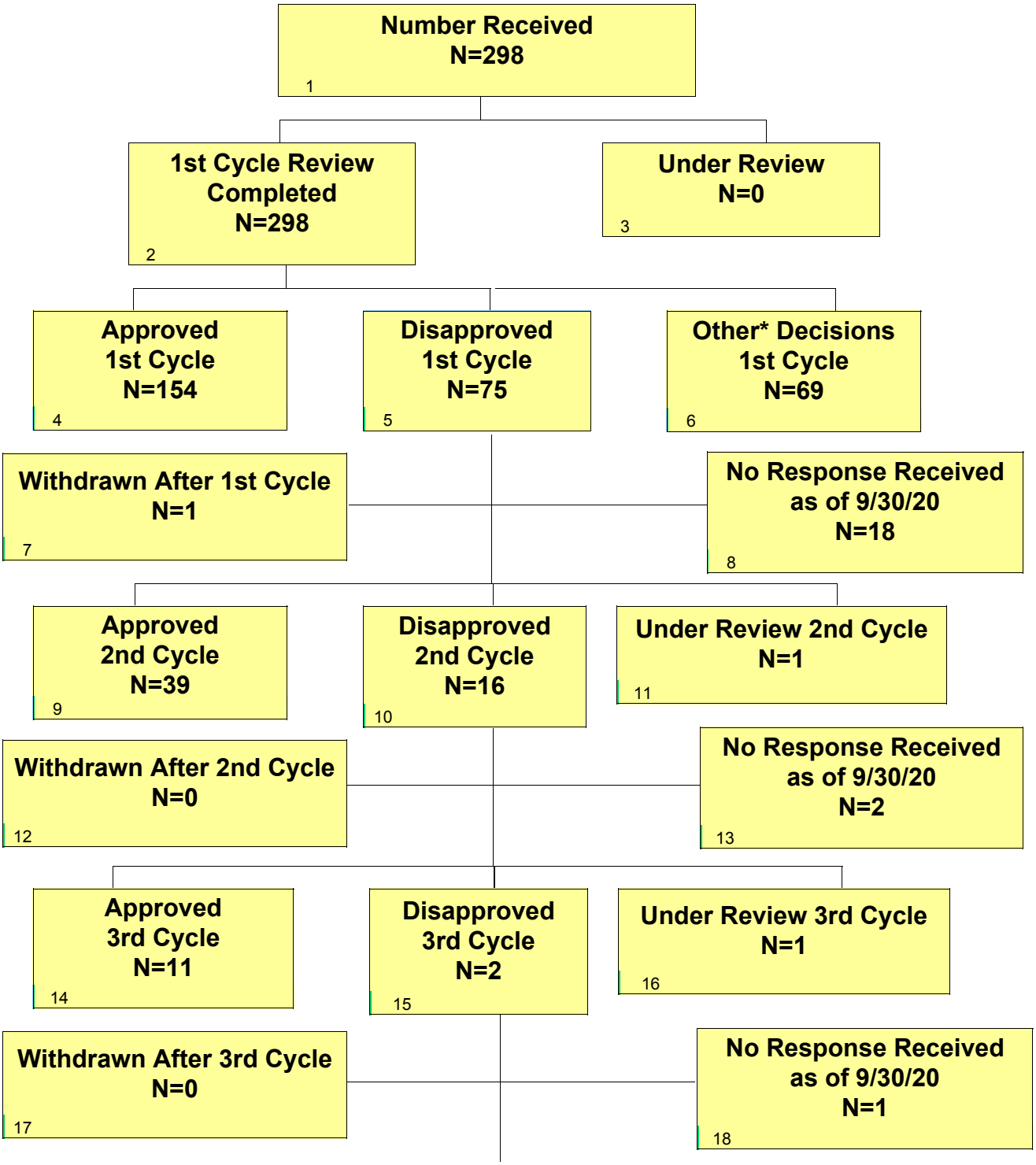


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2018
as of 9/30/20

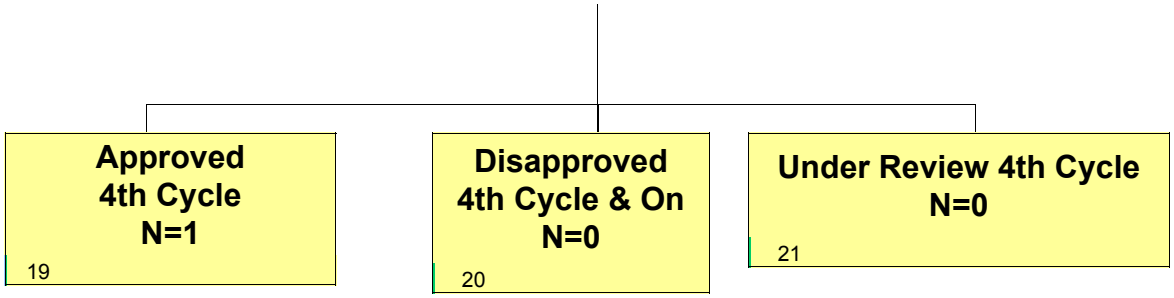


CDRH IDEs - FY 2019
as of 9/30/20

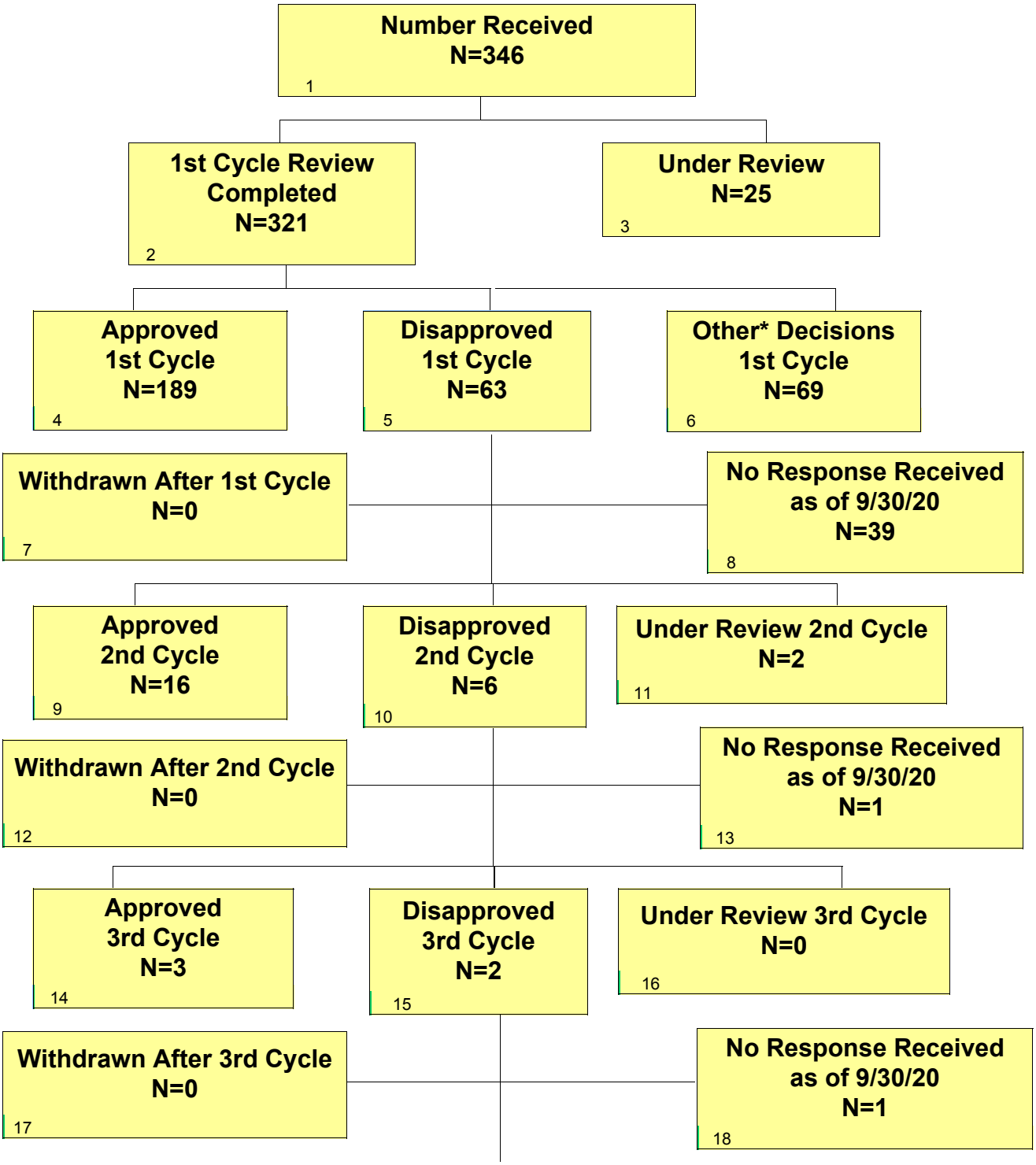


*** Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2019
as of 9/30/20

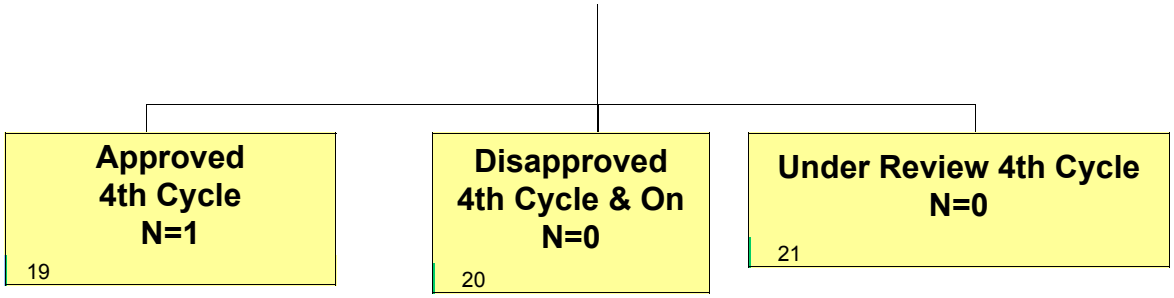


CDRH IDEs - FY 2020
as of 9/30/20



*** Other decisions include withdrawn (N=12), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=14), 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 9/30/20



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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.31	1.12		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.31	0.12		

Section 10 IDE - Office Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	44	35	41		
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.26	1.10		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.26	0.10		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.41	1.22		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.41	0.22		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.60	1.39	1.39		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.60	0.39	0.39		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.03		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.03		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.03		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.03		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.20	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.20	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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.03	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.03	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	1		
Withdrawn prior to SI	0	1	0		
SI within 90 FDA days	4	7	0		
SI over 90 FDA days	0	0	0		
SI pending within 90 FDA days	0	0	0		
SI pending over 90 FDA days	0	0	1		
Denial without SI	0	0	0		
Current SI Performance Percent within 90 FDA days*	100.00%	100.00%	91.67%		

* Per agreement in the MDUFA IV commitment letter, if in any one fiscal year the MDUFA Cohort for this goal is less than 10 submissions, FDA can calculate performance by combining with other fiscal year cohorts until there is a combined cohort of at least 10 submissions. When FDA calculates the final performance in this way, it will be clearly annotated in the MDUFA Annual Performance Report to Congress.

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		
Average number of FDA days to Substantive Interaction	59.50	59.86	0.00		
20th Percentile FDA days to Substantive Interaction	39	49	0		
40th Percentile FDA days to Substantive Interaction	48	55	0		
60th Percentile FDA days to Substantive Interaction	67	65	0		
80th Percentile FDA days to Substantive Interaction	79	84	0		
Maximum FDA days to Substantive Interaction	88	90	0		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	4	8	1		
Non-MDUFA IV Decisions	0	1	0		
MDUFA IV Decisions	4	7	0		
MDUFA IV Decisions within 150 FDA Days	4	7	0		
CLIA Waiver Applications pending MDUFA IV Decision	0	1	1		
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0	0	1		
Current Performance Percent within 150 FDA Days*	100.00%	100.00%	91.67%		

* Per agreement in the MDUFA IV commitment letter, if in any one fiscal year the MDUFA Cohort for this goal is less than 10 submissions, FDA can calculate performance by combining with other fiscal year cohorts until there is a combined cohort of at least 10 submissions. When FDA calculates the final performance in this way, it will be clearly annotated in the MDUFA Annual Performance Report to Congress.

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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions within 320 FDA Days	0	0	0		
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0		
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0		
Current Performance Percent within 320 FDA Days*	N/A	N/A	N/A		

* Per agreement in the MDUFA IV commitment letter, if in any one fiscal year the MDUFA Cohort for this goal is less than 10 submissions, FDA can calculate performance by combining with other fiscal year cohorts until there is a combined cohort of at least 10 submissions. When FDA calculates the final performance in this way, it will be clearly annotated in the MDUFA Annual Performance Report to Congress.

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	7	0		
Average FDA days to MDUFA IV decision	119.50	53.86	0.00		
20th Percentile FDA days to MDUFA IV decision	102	47	0		
40th Percentile FDA days to MDUFA IV decision	143	49	0		
60th Percentile FDA days to MDUFA IV decision	145	58	0		
80th Percentile FDA days to MDUFA IV decision	147	65	0		
Maximum FDA days to MDUFA IV decision	148	90	0		
Average Industry days to MDUFA IV decision	150.50	101.86	0.00		
20th Percentile Industry days to MDUFA IV decision	86	0	0		
40th Percentile Industry days to MDUFA IV decision	151	69	0		
60th Percentile Industry days to MDUFA IV decision	173	177	0		
80th Percentile Industry days to MDUFA IV decision	219	180	0		
Maximum Industry days to MDUFA IV decision	278	180	0		
Average Total days to MDUFA IV decision	270.00	155.71	0.00		
20th Percentile Total days to MDUFA IV decision	192	52	0		
40th Percentile Total days to MDUFA IV decision	236	115	0		
60th Percentile Total days to MDUFA IV decision	276	211	0		
80th Percentile Total days to MDUFA IV decision	342	241	0		
Maximum Total days to MDUFA IV decision	420	270	0		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA decision	0	0	0		
Average FDA days to MDUFA IV decision	0.00	0.00	0.00		
20th Percentile FDA days to MDUFA IV decision	0	0	0		
40th Percentile FDA days to MDUFA IV decision	0	0	0		
60th Percentile FDA days to MDUFA IV decision	0	0	0		
80th Percentile FDA days to MDUFA IV decision	0	0	0		
Maximum FDA days to MDUFA IV decision	0	0	0		
Average Industry days to MDUFA IV decision	0.00	0.00	0.00		
20th Percentile Industry days to MDUFA IV decision	0	0	0		
40th Percentile Industry days to MDUFA IV decision	0	0	0		
60th Percentile Industry days to MDUFA IV decision	0	0	0		
80th Percentile Industry days to MDUFA IV decision	0	0	0		
Maximum Industry days to MDUFA IV decision	0	0	0		
Average Total days to MDUFA IV decision	0.00	0.00	0.00		
20th Percentile Total days to MDUFA IV decision	0	0	0		
40th Percentile Total days to MDUFA IV decision	0	0	0		
60th Percentile Total days to MDUFA IV decision	0	0	0		
80th Percentile Total days to MDUFA IV decision	0	0	0		
Maximum Total days to MDUFA IV decision	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		
Withdrawn prior to SI	0	0	0		
SI within 90 FDA days	11	5	6		
SI over 90 FDA days	0	0	0		
SI pending within 90 FDA days	0	0	0		
SI pending over 90 FDA days	0	0	0		
Denial without SI	0	0	0		
Current SI Performance Percent within 90 FDA days	100.00%	100.00%	100.00%		

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		
Average number of FDA days to Substantive Interaction	85.18	86.60	85.00		
20th Percentile FDA days to Substantive Interaction	84	87	82		
40th Percentile FDA days to Substantive Interaction	87	88	86		
60th Percentile FDA days to Substantive Interaction	87	88	88		
80th Percentile FDA days to Substantive Interaction	88	88	90		
Maximum FDA days to Substantive Interaction	90	88	90		

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		
Non-MDUFA IV Decisions	0	1	0		
MDUFA IV Decisions	11	5	1		
MDUFA IV Decisions within 180 FDA Days	11	4	1		
CLIA Waiver Applications pending MDUFA IV Decision	0	0	5		
CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	0	0	0		
Current Performance Percent within 180 FDA Days	100.00%	93.75%	83.33%		

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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions with in 320 FDA Days	0	0	0		
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0		
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0		
Current Performance Percent within 320 FDA Days	N/A	N/A	N/A		

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	1		
Average FDA days to MDUFA IV decision	139.64	142.60	82.00		
20th Percentile FDA days to MDUFA IV decision	87	88	82		
40th Percentile FDA days to MDUFA IV decision	140	137	82		
60th Percentile FDA days to MDUFA IV decision	176	173	82		
80th Percentile FDA days to MDUFA IV decision	180	180	82		
Maximum FDA days to MDUFA IV decision	180	190	82		
Average Industry days to MDUFA IV decision	42.18	142.20	144.00		
20th Percentile Industry days to MDUFA IV decision	0	69	144		
40th Percentile Industry days to MDUFA IV decision	0	139	144		
60th Percentile Industry days to MDUFA IV decision	0	177	144		
80th Percentile Industry days to MDUFA IV decision	110	198	144		
Maximum Industry days to MDUFA IV decision	180	270	144		
Average Total days to MDUFA IV decision	181.82	284.80	226.00		
20th Percentile Total days to MDUFA IV decision	87	243	226		
40th Percentile Total days to MDUFA IV decision	155	263	226		
60th Percentile Total days to MDUFA IV decision	177	302	226		
80th Percentile Total days to MDUFA IV decision	270	353	226		
Maximum Total days to MDUFA IV decision	354	358	226		

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		
Average FDA days to MDUFA IV decision	0.00	0.00	0.00		
20th Percentile FDA days to MDUFA IV decision	0	0	0		
40th Percentile FDA days to MDUFA IV decision	0	0	0		
60th Percentile FDA days to MDUFA IV decision	0	0	0		
80th Percentile FDA days to MDUFA IV decision	0	0	0		
Maximum FDA days to MDUFA IV decision	0	0	0		
Average Industry days to MDUFA IV decision	0.00	0.00	0.00		
20th Percentile Industry days to MDUFA IV decision	0	0	0		
40th Percentile Industry days to MDUFA IV decision	0	0	0		
60th Percentile Industry days to MDUFA IV decision	0	0	0		
80th Percentile Industry days to MDUFA IV decision	0	0	0		
Maximum Industry days to MDUFA IV decision	0	0	0		
Average Total days to MDUFA IV decision	0.00	0.00	0.00		
20th Percentile Total days to MDUFA IV decision	0	0	0		
40th Percentile Total days to MDUFA IV decision	0	0	0		
60th Percentile Total days to MDUFA IV decision	0	0	0		
80th Percentile Total days to MDUFA IV decision	0	0	0		
Maximum Total days to MDUFA IV decision	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 (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

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

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

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

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

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

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

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

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

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

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

*Includes submissions that went to panel

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

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

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

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

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

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

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

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

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

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

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

Section 3 PMA Real Time Supplements

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

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

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

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

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

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

Section 5 PMA Annual Metrics and Goals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 De Novo MDUFA IV Performance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

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

Section 9 Pre-Submissions

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

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

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

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

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

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

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

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

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

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Quarterly Update on
Medical Device Performance Goals
----MDUFA IV CBER Performance Data ----
Actions through 30 Sep 2020

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3	3		
Number Accepted	1	2	3		
Completed RTF	3	3	3		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	33.33%	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		
SI Goal Met	2	3	2		
SI Goal Not Met	0	0	1		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	66.67%		

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		
Average Number of FDA Days to Substantive Interaction	69.00	85.33	91.33		
20th Percentile FDA Days to Substantive Interaction	50.00	82.00	81.00		
40th Percentile FDA Days to Substantive Interaction	50.00	84.00	89.00		
60th Percentile FDA Days to Substantive Interaction	88.00	84.00	89.00		
80th Percentile FDA Days to Substantive Interaction	88.00	90.00	104.00		
Maximum FDA Days to Substantive Interaction	88.00	90.00	104.00		

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	1		
Average FDA Days to MDUFA IV Decision	164.50	162.33	150.00		
20th Percentile FDA Days to MDUFA IV Decision	156.00	140.00	150.00		
40th Percentile FDA Days to MDUFA IV Decision	156.00	171.00	150.00		
60th Percentile FDA Days to MDUFA IV Decision	173.00	171.00	150.00		
80th Percentile FDA Days to MDUFA IV Decision	173.00	176.00	150.00		
Maximum FDA Days to MDUFA IV Decision	173.00	176.00	150.00		
Average Industry Days to MDUFA IV Decision	319.50	161.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	105.00	56.00	0.00		
40th Percentile Industry Days to MDUFA IV Decision	105.00	177.00	0.00		
60th Percentile Industry Days to MDUFA IV Decision	534.00	177.00	0.00		
80th Percentile Industry Days to MDUFA IV Decision	534.00	250.00	0.00		
Maximum Industry Days to MDUFA IV Decision	534.00	250.00	0.00		
Average Total Days to MDUFA IV Decision	484.00	323.33	150.00		
20th Percentile Total Days to MDUFA IV Decision	261.00	196.00	150.00		
40th Percentile Total Days to MDUFA IV Decision	261.00	348.00	150.00		
60th Percentile Total Days to MDUFA IV Decision	707.00	348.00	150.00		
80th Percentile Total Days to MDUFA IV Decision	707.00	426.00	150.00		
Maximum Total Days to MDUFA IV Decision	707.00	426.00	150.00		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0	0		
Average FDA Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA IV Decision	0	0	0		
40th Percentile FDA Days to MDUFA IV Decision	0	0	0		
60th Percentile FDA Days to MDUFA IV Decision	0	0	0		
80th Percentile FDA Days to MDUFA IV Decision	0	0	0		
Maximum FDA Days to MDUFA IV Decision	0	0	0		
Average Industry Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	0	0		
40th Percentile Industry Days to MDUFA IV Decision	0	0	0		
60th Percentile Industry Days to MDUFA IV Decision	0	0	0		
80th Percentile Industry Days to MDUFA IV Decision	0	0	0		
Maximum Industry Days to MDUFA IV Decision	0	0	0		
Average Total Days to MDUFA IV Decision	0.00	0.00	0.00		
20th Percentile Total Days to MDUFA IV Decision	0	0	0		
40th Percentile Total Days to MDUFA IV Decision	0	0	0		
60th Percentile Total Days to MDUFA IV Decision	0	0	0		
80th Percentile Total Days to MDUFA IV Decision	0	0	0		
Maximum Total Days to MDUFA IV Decision	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		
Number with MDUFA IV Decision	2	3	1		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	50%	33%	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		
Number With MDUFA IV Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	0	0	0		
MDUFA IV Decision Goal Met	0	0	0		
PMAs Pending MDUFA IV Decision	0	0	0		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	1	2	1		
MDUFA IV Decision Goal Met	1	2	1		
PMAs Pending MDUFA IV Decision	0	0	1		
PMAs Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	50.00%		

***Includes submission that went to panel**

Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	5	8		
SI Goal Met	8	5	5		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100%	100%	100%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	5	8		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	8	5	4		
MDUFA IV Decision Goal Met	8	5	4		
Supplements Pending MDUFA IV Decision	0	0	4		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number with MDUFA IV Decision	8	5	4		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision	3	2	3		
MDUFA IV Decision Goal Met	3	2	3		
Supplements Pending MDUFA IV Decision	0	0	2		
Supplements Pending MDUFA IV Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

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

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

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

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

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	54	50		
Closed Before RTA Action	0	0	0		
Number Accepted	40	38	33		
Number Without a RTA Review and > 15 Days Since Date Received	2	1	1		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	4		
Number Not Accepted	11	15	12		
Rate of Submissions Not Accepted for Review	20.75%	27.78%	26.09%		

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	41		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	49	51	33		
SI Over 60 FDA Days	0	0	0		
SI Pending Within 60 FDA Days	0	0	8		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100%	100%	100%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	49	51	33		
Average Number of FDA Days to Substantive Interaction	50.60	45.27	46.50		
20th Percentile FDA Days to Substantive Interaction	43	21	21		
40th Percentile FDA Days to Substantive Interaction	57	53	54		
60th Percentile FDA Days to Substantive Interaction	59	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	60	60	60		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	49	51	41		
Non-MDUFA IV Decision	6	4	1		
MDUFA IV Decision (SE/NSE)	43	45	24		
MDUFA IV Decision Within 90 FDA Days	43	45	24		
510(k)s Pending MDUFA IV Decision	0	2	16		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100%	100%	100%		

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.30	1.47	1.21		
Number With MDUFA IV Decision	43	45	24		
Average Number of FDA Days to MDUFA IV Decision	75.12	67.00	56.08		
20th Percentile FDA Days to MDUFA IV Decision	65	28	28		
40th Percentile FDA Days to MDUFA IV Decision	85	72	30		
60th Percentile FDA Days to MDUFA IV Decision	87	86	78		
80th Percentile FDA Days to MDUFA IV Decision	90	88	88		
Maximum FDA Days to MDUFA IV Decision	90	206	90		
Average Number of Industry Days to MDUFA IV Decision	25.23	73.60	11.04		
20th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00		
40th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00		
60th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00		
80th Percentile Industry Days to MDUFA IV Decision	59.00	58.00	17.00		
Maximum Industry Days to MDUFA IV Decision	178.00	389.00	104.00		
Average Number of Total Days to MDUFA IV Decision	100.37	140.60	67.17		
20th Percentile Total Days to MDUFA IV Decision	76	30	28		
40th Percentile Total Days to MDUFA IV Decision	86	85	45		
60th Percentile Total Days to MDUFA IV Decision	90	93	78		
80th Percentile Total Days to MDUFA IV Decision	147	257	89		
Maximum Total Days to MDUFA IV Decision	268	463	192		

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	41		
Number With MDUFA IV Decision	43	45	24		
Number of SE Decision	43	43	24		
Number of NSE Decision	0	2	0		
Number of Withdrawal	2	3	1		
Number of Deleted	3	1	0		
Rate of SE Decision	100%	96%	100%		
Rate of NSE Decision	0%	4%	0%		
Rate of Withdrawal	4%	6%	2%		
Rate of Deleted	6%	2%	0%		

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0	0		
Non-MDUFA IV Decision	0	0	0		
MDUFA IV Decision (SE/NSE)	0	0	0		
MDUFA IV Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA IV Decision	0	0	0		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	16	6		
Non-MDUFA IV Decision	0	1	0		
MDUFA IV Decision (SE/NSE)	15	15	4		
MDUFA IV Decision Within 90 FDA Days	15	15	4		
510(k)s Pending MDUFA IV Decision	0	0	2		
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision*

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

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

Table 8.2 CBER - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	0	1	0		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	1	0		
MDUFA IV Decisions Within 150 FDA Days	0	1	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

Table 8.3 CBER - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00	2	0.00		
Number With MDUFA IV Decision	0	1	0		
Average FDA Days to MDUFA IV Decision	0.00	150	0.00		
20th Percentile FDA Days to MDUFA IV Decision	0	150	0		
40th Percentile FDA Days to MDUFA IV Decision	0	150	0		
60th Percentile FDA Days to MDUFA IV Decision	0	150	0		
80th Percentile FDA Days to MDUFA IV Decision	0	150	0		
Maximum FDA Days to MDUFA IV Decision	0	150	0		
Average Industry Days to MDUFA IV Decision	0.00	81	0.00		
20th Percentile Industry Days to MDUFA IV Decision	0	81	0		
40th Percentile Industry Days to MDUFA IV Decision	0	81	0		
60th Percentile Industry Days to MDUFA IV Decision	0	81	0		
80th Percentile Industry Days to MDUFA IV Decision	0	81	0		
Maximum Industry Days to MDUFA IV Decision	0	81	0		
Average Total Days to MDUFA IV Decision	0.00	231	0.00		
20th Percentile Total Days to MDUFA IV Decision	0	231	0		
40th Percentile Total Days to MDUFA IV Decision	0	231	0		
60th Percentile Total Days to MDUFA IV Decision	0	231	0		
80th Percentile Total Days to MDUFA IV Decision	0	231	0		
Maximum Total Days to MDUFA IV Decision	0	231	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		
Number With MDUFA IV Decisions	0	1	0		
Number With Granted Decisions	0	1	0		
Number With Declined Decisions	0	0	0		
Number of Withdrawals	0	0	0		
Number Deleted	0	0	0		
Rate of Granted Decisions	N/A	1	N/A		
Rate of Declined Decisions	N/A	N/A	N/A		
Rate of Withdrawals	N/A	N/A	N/A		
Rate of Deleted	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA IV Decisions	0	0	0		
MDUFA IV Decisions	0	1	0		
MDUFA IV Decisions Within 150 FDA Days	0	1	0		
De Novos Pending MDUFA IV Decision	0	0	0		
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	100%	N/A		

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	76	77	77		
Closed Before RTA Action	5	3	10		
Number Accepted First RTA Cycle	69	70	63		
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	2		
Number Not Accepted	1	1	1		
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.54%		

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	58		
Written Feedback Provided Within MDUFA IV Goal	68	71	53		

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	58		
Average FDA Days to Written Feedback	57.86	61.00	56.15		
20th Percentile FDA Days to Written Feedback	47	55	40		
40th Percentile FDA Days to Written Feedback	58	60	58		
60th Percentile FDA Days to Written Feedback	64	63	64		
80th Percentile FDA Days to Written Feedback	67	68	68		
Maximum FDA Days to Written Feedback	72	75	77		

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		
Average Days to Scheduling for Meetings Scheduled After Day 30	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	23		
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	22		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0		
Meeting Minutes Past 15 Days of Meeting	9	2	1		
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	90.91%	95.65%		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.63	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.63	0.00		

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		
Number of Standard BLA First Actions less than or equal to 10 months	14	4	0		
Number of Standard BLA Frist Actions greater than 10 months	0	0	0		
Number of Standard BLAs Pending	0	0	0		
Number of Priority BLA Filed	0	0	0		
Number of Priority BLA First Actions less than or equal to 10 months	0	0	0		
Number of Priority BLA Frist Actions greater than 10 months	0	0	0		
Number of Priority BLAs Pending	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		
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	8	2	0		
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0	0	0		
Number of Standard Efficacy Supplements Pending	0	0	0		
Number of Priority Efficacy Supplements Filed	0	0	0		
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0	0		
Number of Priority Efficacy Supplements Frist Actions greater than 10 months	0	0	0		
Number of Priority Efficacy Supplements Pending	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	81		
Number of Standard PAS Supplements First Actions less than or equal to 4months	94	53	79		
Number of Standard PAS Supplements First Actions greater than 4 months	0	1	0		
Number of Standard PAS Supplements Pending	0	0	2		

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		
Number of Class 1 Resubmission Actions less than or equal to 2 months	1	17	0		
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0		
Number of Class 1 Resbumssions Pending	0	0	0		
Number of Class 2 Resubmissions Received	7	0	1		
Number of Class 2 Resubmission Actions less than or equal to 6 months	7	0	1		
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0		
Number of Class 2 Resubmissions Pending	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, 2020 is shown in **bold** text.

As of September 30, 2020, the 510(k) and PMA cohorts for FY 2018 have met the decision threshold to calculate the average TTD and both cohorts met the goal.

As of September 30, 2020, neither the 510(k) nor the PMA cohorts for FY 2019 or FY 2020 have met the decision threshold to calculate the average TTD. FDA will report the average TTD for FY 2019 and FY 2020 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	*	*		
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
Current Performance (Days)	123	*	*		

* As of September 30, 2020, fiscal year cohort has not met the decision threshold to calculate performance.

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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 2020

#	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	Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/intravascular-catheters-wires-and-delivery-systems-lubricious-coatings-labeling-considerations	10/10/2019	Yes	No	N/A	No
2	Q1	Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling www.fda.gov/regulatory-information/search-fda-guidance-documents/coronary-peripheral-and-neurovascular-guidewires-performance-tests-and-recommended-labeling	10/10/2019	Yes	No	N/A	No
3	Q1	Breast Implants - Certain Labeling Recommendations to Improve Patient Communication www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication	10/24/2019	Yes	No	N/A	A-List

[1] www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf; see section VI (Performance Reports)
[2] CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.
[3] www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2020-fy-2020

#	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	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	11/14/2019	No	Yes	Sec. 704 of the FDA Reauthorization Act of 2017	A-List
5	Q1	Certificates of Confidentiality www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	11/25/2019	No	No	N/A	No
6	Q1	Magnetic Resonance (MR) Coil - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/magnetic-resonance-mr-coil-performance-criteria-safety-and-performance-based-pathway	12/9/2019	Yes	No	N/A	A-List
7	Q1	[4]Real-Time Premarket Approval Application (PMA) Supplements www.fda.gov/regulatory-information/search-fda-guidance-documents/real-time-premarket-approval-application-pma-supplements	12/16/2019	Yes	No	N/A	No
8	Q1	[4]FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic	12/16/2019	Yes	No	N/A	No
9	Q1	[4]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions	12/16/2019	Yes	No	N/A	No
10	Q1	[4]Annual Reports for Approved Premarket Approval Applications (PMA) www.fda.gov/regulatory-information/search-fda-guidance-documents/annual-reports-approved-premarket-approval-applications-pma	12/16/2019	Yes	No	N/A	No
11	Q1	[4]Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas	12/16/2019	Yes	No	N/A	No

[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q1	[4]30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes www.fda.gov/regulatory-information/search-fda-guidance-documents/30-day-notices-135-day-premarket-approval-pma-supplements-and-75-day-humanitarian-device-exemption	12/16/2019	Yes	No	N/A	No
13	Q1	Bridging for Drug-Device and Biologic-Device Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/bridging-drug-device-and-biologic-device-combination-products	12/19/2019	No	No	N/A	No
14	Q1	[4]Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket	12/20/2019	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	12/26/2019	Yes	Yes	Sec. 3038 of the 21st Century Cures Act	No
16	Q2	Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-percutaneous-transluminal-angioplasty-pta-and-specialty-catheters-premarket-notification	1/13/2020	Yes	No	N/A	No
17	Q2	[4]Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-performance-assessment-considerations-computer-assisted-detection-devices-applied-radiology	1/22/2020	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
18	Q2	Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/arthroscopy-pump-tubing-sets-intended-multiple-patient-use-premarket-notification-510k-submissions	1/28/2020	Yes	No	N/A	No
19	Q2	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	2/13/2020	Yes	No	N/A	No
20	Q2	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-dual-510k-and-clia-waiver-application-studies	2/26/2020	Yes	No	N/A	A-List
21	Q2	Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-clinical-laboratory-improvement-amendments-1988-clia-waiver-applications	2/26/2020	No	Yes	Sec. 3057 of the 21st Century Cures Act	A-List
22	Q2	Product Labeling for Laparoscopic Power Morcellators www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators	2/26/2020	Yes	No	N/A	No
23	Q2	[5]Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency	2/29/2020	No	No	N/A	No
24	Q2	Bone Anchors - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/bone-anchors-premarket-notification-510k-submissions	3/3/2020	Yes	No	N/A	No

[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic 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
25	Q2	Soft (Hydrophilic) Daily Wear Contact Lenses - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/soft-hydrophilic-daily-wear-contact-lenses-performance-criteria-safety-and-performance-based-pathway	3/4/2020	Yes	No	N/A	A-List
26	Q2	[4]Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-510k-submissions-electrosurgical-devices-general-surgery	3/9/2020	Yes	No	N/A	No
27	Q2	510(k) Third Party Review Program www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program	3/12/2020	Yes	Yes	Sec. 206 of the FDA Reauthorization Act of 2017	A-List
28	Q2	[5]Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency	3/16/2020	No	No	N/A	No
29	Q2	Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/restricted-delivery-systems-flow-restrictors-oral-liquid-drug-products-guidance-industry	3/17/2020	No	No	N/A	No
30	Q2	[5]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	3/18/2020	Yes	No	N/A	No
31	Q2	[5]Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic	3/19/2020	No	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
32	Q2	[5]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during	3/20/2020	Yes	No	N/A	No
33	Q2	[5]Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus	3/22/2020	Yes	No	N/A	No
34	Q2	[5]Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health	3/25/2020	Yes	No	N/A	No
35	Q2	[5]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	3/27/2020	Yes	No	N/A	No
36	Q2	[4]Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a	3/27/2020	No	No	N/A	No
37	Q2	[5]Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease	3/29/2020	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
38	Q2	[5]Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health	3/30/2020	Yes	No	N/A	No
39	Q3	[5]Enforcement Policy for Face 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-and-respirators-during-coronavirus-disease-covid-19-public-health	4/2/2020	Yes	No	N/A	No
40	Q3	[5]Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public	4/4/2020	Yes	No	N/A	No
41	Q3	[5]Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public	4/5/2020	Yes	No	N/A	No
42	Q3	[5]Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease	4/6/2020	Yes	No	N/A	No
43	Q3	[5]Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during	4/6/2020	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
44	Q3	Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-labeling-vitro-companion-diagnostic-devices-specific-group-oncology-therapeutic	4/14/2020	Yes	No	N/A	No
45	Q3	[5]Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease	4/14/2020	Yes	No	N/A	No
46	Q3	[5]Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health	4/16/2020	Yes	No	N/A	No
47	Q3	Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda	4/22/2020	Yes	No	N/A	No
48	Q3	Nonbinding Feedback After Certain FDA Inspections of Device Establishments www.fda.gov/regulatory-information/search-fda-guidance-documents/nonbinding-feedback-after-certain-fda-inspections-device-establishments	4/22/2020	No	Yes	Sec. 702 of the FDA Reauthorization Act of 2017	A-List
49	Q3	[5]Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient	4/23/2020	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
50	Q3	[5]Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency	4/23/2020	Yes	No	N/A	No
51	Q3	[5]Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-digital-pathology-devices-during-coronavirus-disease-2019-covid-19-public	4/24/2020	Yes	No	N/A	No
52	Q3	[4]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health	4/27/2020	Yes	No	N/A	No
53	Q3	Classification of Posterior Cervical Screw Systems: Small Entity Compliance Guide www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-posterior-cervical-screw-systems-small-entity-compliance-guide	5/4/2020	Yes	Yes	Sec. 212 of the Small Business Regulatory Enforcement Fairness Act	No
54	Q3	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	5/4/2020	No	No	N/A	No
55	Q3	[5]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 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	5/6/2020	No	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
56	Q3	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	5/11/2020	No	No	N/A	No
57	Q3	[5]Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic	5/11/2020	No	No	N/A	No
58	Q3	[5]Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/supplements-approved-premarket-approval-pma-or-humanitarian-device-exemption-hde-submissions-during	5/21/2020	Yes	No	N/A	No
59	Q3	[5]Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks	5/26/2020	No	No	N/A	No
60	Q3	[5]Enforcement Policy for Face 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-and-respirators-during-coronavirus-disease-covid-19-public-health	5/26/2020	Yes	No	N/A	No
61	Q3	[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	6/5/2020	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
62	Q3	[5]Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-considerations-clinical-trials-during-covid-19-public-health-emergency-guidance-industry	6/16/2020	Yes	No	N/A	No
63	Q3	[5]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	6/19/2020	No	No	N/A	No
64	Q3	[5]Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices	6/22/2020	Yes	No	N/A	No
65	Q3	Review and Update of Device Establishment Inspection Processes and Standards www.fda.gov/regulatory-information/search-fda-guidance-documents/review-and-update-device-establishment-inspection-processes-and-standards	6/29/2020	No	Yes	Sec. 702 of the FDA Reauthorization Act of 2017	N/A
66	Q4	[5]Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and	7/1/2020	No	No	N/A	No
67	Q4	[5]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-pandemic	7/2/2020	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
68	Q4	Select Updates for Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-peripheral-vascular-atherectomy-devices-premarket-notification-510k-submissions	7/13/2020	Yes	No	N/A	No
69	Q4	Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign	7/14/2020	Yes	No	N/A	No
70	Q4	Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab	7/15/2020	Yes	Yes	Sec. 207 of the FDA Reauthorization Act of 2017	N/A
71	Q4	Clinical Investigations for Prostate Tissue Ablation Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-investigations-prostate-tissue-ablation-devices	7/15/2020	Yes	No	N/A	No
72	Q4	[5]Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health	7/20/2020	Yes	No	N/A	No
73	Q4	Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal	7/21/2020	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
74	Q4	Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions	7/21/2020	No	No	N/A	No
75	Q4	Multiple Function Device Products: Policy and Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations	7/29/2020	Yes	No	N/A	A-List
76	Q4	Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/cutaneous-electrodes-recording-purposes-performance-criteria-safety-and-performance-based-pathway	8/14/2020	Yes	No	N/A	A-List
77	Q4	Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/conventional-foley-catheters-performance-criteria-safety-and-performance-based-pathway	8/14/2020	Yes	No	N/A	A-List
78	Q4	Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank www.fda.gov/regulatory-information/search-fda-guidance-documents/civil-money-penalties-relating-clinicaltrialsgov-data-bank	8/17/2020	No	No	N/A	No
79	Q4	Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use	8/31/2020	Yes	Yes	MDUFA Commitment Letter IV.F.3.a	A-List
80	Q4	[4]Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and	9/4/2020	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
81	Q4	Recognition and Withdrawal of Voluntary Consensus Standards www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards	9/15/2020	Yes	No	N/A	A-List
82	Q4	[5]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	9/21/2020	Yes	No	N/A	No
83	Q4	The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program	9/25/2020	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017; MDUFA Commitment Letter IV.D.	A-List
84	Q4	Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme	9/25/2020	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017; MDUFA Commitment Letter IV.D.	A-List
85	Q4	Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and	9/25/2020	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017; MDUFA Commitment Letter IV.D.	A-List
86	Q4	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use	9/29/2020	Yes	No	N/A	B-List
87	Q4	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use	9/29/2020	Yes	No	N/A	B-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
88	Q4	Breast Implants - Certain Labeling Recommendations to Improve Patient Communication www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication	9/29/2020	Yes	No	N/A	No
89	Q4	[4]Saline, Silicone Gel, and Alternative Breast Implants www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants	9/29/2020	Yes	No	N/A	No

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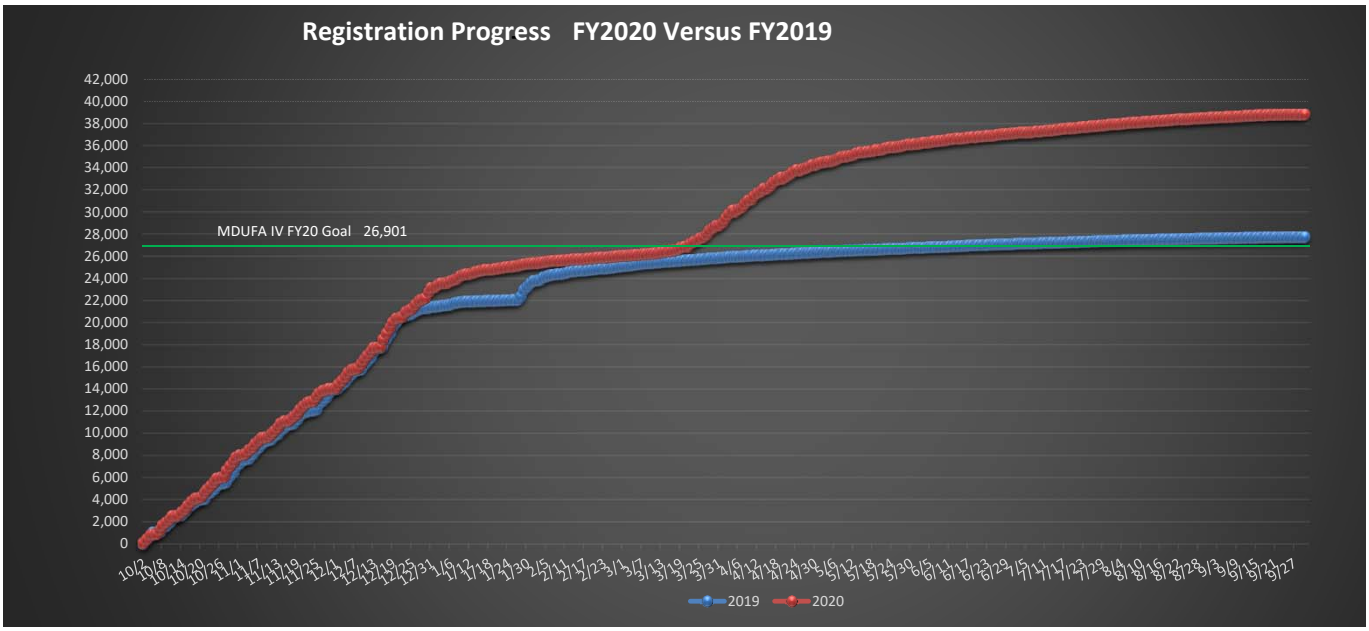
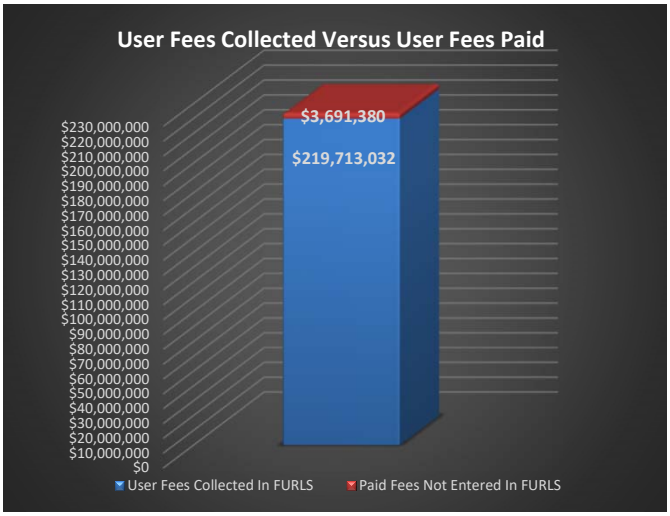
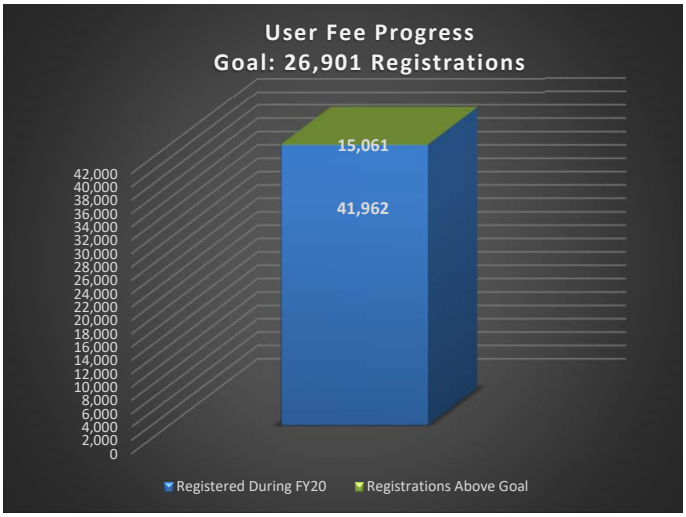
MDUFA IV Registrations - 4th Quarter Summary FY2020*

Current Active Registrations by Type	FY20 Q4			FY19 Year End Active Totals			FY20 vs End FY19
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,750	21,519	28,269	6,266	10,241	16,507	171.25%
Contract Manufacturer	1,186	1,707	2,892	1,121	1,598	2,719	106.36%
Contract Sterilizer	62	143	205	70	138	208	98.56%
Specification Developer	1,784	579	2,363	1,711	540	2,251	104.98%
Reprocessor of Single Use Devices	34	6	40	24	2	26	153.85%
U.S. Manufacturer of Export Only Devices	127	0	127	123	0	123	103.25%
Repackager/Relabeler	1,232	235	1,467	1,136	191	1,327	110.55%
Remanufacturer	19	8	27	19	9	28	96.43%
Foreign Exporter/Private Label Distributor	1	1,203	1,204		1,033	1,032	116.67%
Initial Importer	4,768		4,768	3,255		3,255	146.48%
Unknown	6	40	46	1	1	2	2300.00%
Total:	**15,969**	**25,440**	**41,409**	**13,726**	**13,753**	**27,479**	**150.69%**

*Note: This data is current as of 10/1/2020







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FY 2020 Medical Device User Fee Collections as of September 30th, 2020 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$222,743,379	$714,780	$222,028,599		
Application Fees	$70,251,179	$3,126,601	$67,124,578		
Total	**$292,994,558**	**$3,841,381**	**$289,153,177**	**$220,142,000**	**131%**

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	$31,728,269	$34,417,751	$28,031,569
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,714,015	$57,560,249	$63,948,268	$70,153,462	$65,829,332
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,276,798	$121,138,355	$134,515,320	$146,291,737	$136,822,621
	FY 2018	**FY 2019**	**FY 2020**		
MD IV	$189,228,240	$201,564,870	$289,153,177		

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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 2020 by Submission type	# Waived	# Reduced
Full Fee applications[2/]		
PMA	9	4
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
Panel Track Supplements	1	7
De Novo Classification	2	47
180-Day Supplements	1	20
Real-Time Supplements	1	30
510(k)s	32	1668
30-day Notices	7	106
513(g)s	0	57
PMA Annual Report	0	68
Total	**53**	**2,007**

[1/] User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter is a small business submitting their first premarket approval application or premarket report. User fees are reduced for small businesses. 510(k)s reviewed through the Third Party Review program are not included because FDA does not collect user fees for 510(k)s reviewed through that program. Counts are cumulative for the Fiscal Year.

[2/] As specified in the MDUFA 4 Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually. CBER counts are included in 180 Day Supplements (5 reduced), 510(k)s (15 reduced), 30-day Notices (16 reduced), 513(g)s (1 reduced) and PMA Annual Reports (8 reduced).

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CDRH Quality Management and Organizational Excellence (QMOE) Program

FY 2020 Summary

A. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2020 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 within 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, ISO 17025:2015 Trained 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; 20/02/2016
[2] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; pages 10-11; 20/02/2016

1.4. CDRH QMOE Program Services. QMOE staff manage the CDRH QMS and all its components. They ensure the QMS is functioning, identify issues and improvements to the CDRH QMS and work with staff providing services that inform and improve review staff activities, including:

- Management internal responses to process-related external assessments
- Creating, formatting, or publishing documents in SWIFT Docs, Pilot Docs, or CDRH Docs
- Creating custom reports (e.g. Customer Service, FEEDBACK-CDRH reports, audits)
- Developing or analyzing customized surveys
- Providing ASQ quality training and certification/re-certification opportunities
- Addressing data analytics and visualization needs
- Designing or revising flowcharts and process maps
- Continual improvement projects facilitation
- Creating reports, replying to data calls related to operational excellence activities
- Developing or executing internal audits/assessments
- Developing performance metrics
- Facilitating implementation and use improvement and assessment methodologies, including Lean Six Sigma (process improvement) and Kirkpatrick (training assessment)

2. Quality Management Training

2.1. To support the adoption of quality management across CDRH, the following training was provided in FY 2020:

- ISO 9001:2015 Requirements from A-Z
- ASQ Six Sigma Yellow Belt

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, source management, lifecycle management, and quality system evaluation…"

1. ISO 9001:2015 Certification

1.1. On November 15, 2019, 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.

[3] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; pages 10-11; 20/02/2016

1.2. As of September 30, 2020, the team was preparing for the required yearly surveillance audit, scheduled for October 30th, 2020.[4]

2. Voice of the Customer (VOC)

2.1. **VOC - Feedback✓CDRH – FY 2020 Improvements.** The system was updated in March 2020. The updates allow for a more efficient processing of feedback and better tracing to the related QMS systems areas.

2.2. **Customer Service Survey.** The CDRH customer satisfaction survey is available through the FDA.gov and is included in all CDRH staff email correspondence. Overall, industry satisfaction with CDRH increased to 95 percent in FY 2020 from 92 percent in FY 2019. The industry submitters continue to positively comment on their satisfaction with the premarket review process.

2.3. **VOC QM Staff Role.** QM staff manage the VOC system and oversee resolution of VOC tasks. Staff conduct additional investigations as needed, work with SMEs developing solutions and ensure issues are suggestions are addressed with established timelines.

3. Document Control

3.1. **Document Control System (DCS) – FY 2020 Improvements.** The system is under a business process improvement project to improve and simplify the experience of document developers.

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 900 operating procedures, work instructions, forms and templates. 79 percent of the CDRH controlled documentation pertains to OPEQ core processes, including those associated with premarket review.

3.4. **DCS QM Staff Role.** QM staff manage CDRH's documented information using DCS. QM staff prepare documents for distribution, help develop documents, ensure DCS practices are followed and help a large network or staff across that work on developing and improving CDRH review process documentation. Additional services include end to end SOP update and development, flowcharting, SOP writing and bulk documentation uploads.

[4] ISO 9001:2015 surveillance audit successfully completed 10/30/2020. No nonconformities found.

4. Internal Audits

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

…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 QM Staff Role. QM at OCD staff manage the Internal Audit Program. To maintain impartiality, all audits designated as internal audits are conducted by QM staff at the Office of the Center Director. OCD QM staff work with SMEs developing the audit goals and protocols and execute audit independently. In support of internal audits, staff conduct a variety of activities depending on the purpose and scope of the audit:

- Desk Audits (review of documented information)
- Customer Service inquiries
- Process owners and users' interviews
- Review of records
- Data collection and data analytics
- Effectiveness checks (data checks and/or follow up audits)

4.2. Audit Schedule FY 2021. Data call for FY 2021 internal audit schedule is planned for FY 2021 Q1. The following internal audits are already on the FY 2021 schedule:

- Withdrawal
- Least Burdensome
- ISO 9001:2015 (External Audit)
- CDRH QMS Core Processes

[5] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 11; 20/02/2016

4.3. FY 2020 Audits (Final Schedule)

Title	Purpose	Findings
External	ISO 9001:2015 Surveillance Audit	No Nonconformities. The QM Unit QMS continues to be ISO 9001:2015 certified.
AF-2019-00001	Assess Biocompatibility Focal Point Program process	No Nonconformities
AF-2019-00002	Assess use of "Four-Part Harmony" (meets MDUFA commitment for FY 2020 "Deficiency Letter" audit[6])	Follow-up to AF-2018-00003. Established baseline using OPEQ revised four-part harmony criteria. Audited SMART Template stock deficiencies.
AF-2020-00001	Internal quality audit; verifying the Document Control System to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00002	Internal quality audit; verifying the Design and Development Verification and Validation system to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00003	Internal quality audit; verifying the Audit Management system to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00005	Internal quality audit; verifying the Quality Management Review system to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00006	Internal quality audit; verifying the Risk/ Non-Conformance / Corrective Action systems to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00007	Internal quality audit; verifying the QMS Training system to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00008	Assess use of "Four-Part Harmony" (meets MDUFA commitment for FY 2020 "Deficiency Letter" audit[7]) (Follow-up to AF-2018-00003; Follow-up)	Implementation of actions to resolve logged nonconformity from AF-2018-00003 appear to be effective when compared to the AF-2019-0002 baseline audit.
AF-2020-00009	Pre-submissions (MDUFA Required)	No Nonconformities
AF-2020-00012	Internal quality audit; verifying the Feedback✓CDRH system to ISO 9001:2015 requirements	No Nonconformities
AF-2020-00013	Internal quality audit; verifying the Tools and Services Requests system to ISO 9001:2015 requirements	No Nonconformities

CDRH QMS: In summary for CDRH QMS Processes, no nonconformities were found. We identified six opportunities for improvement and eight best practices.

[6] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 11; 20/02/2016
[7] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 11; 20/02/2016

4.4. AF-2019-00001: Assess Biocompatibility Focal Point Program process

- **Purpose:** Determine adherence to "Focal Point Program: Review of Biocompatibility Information in Regulatory Submissions" procedures, including escalation procedures for cases were specialized expertise was requested.
- **Findings:** 86 percent of the records examined were executed in accordance to the established procedures. Findings were stratified by office (OHT) and delivered to OPEQ to better inform future actions. 97 percent of the records examined followed established escalation procedures.
- No Nonconformities were identified.

4.5. AF-2019-00002 and AF-2020-00008: Assess use of "Four-Part Harmony"

- **Purpose**: AF-2019-00002 internal audit re-assessed the FY 2019 audit dataset applying the clarified criteria for Part 3 and later in the year AF-2020-00008 audit assessed of the impact of FDA CAPA actions.
- **Four Part Harmony:** In the 2017 revision of the 2000 Guidance document Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions Section B. "Suggested content and format for deficiencies" describes four elements deficiencies should include, also known as four-part harmony (4PH). The update further incorporated least burdensome provisions and agreed upon MDUFA IV commitments.

Four-part harmony (4PH) Abbreviated Description	2017 Guidance document Section B Language
Part 1. What was provided?	1. Acknowledgment of the information submitted by the applicant, including references to sections, page numbers, or tables where appropriate.
Part 2. Why not adequate?	2. Explanation of why the current information does not adequately address the issue (i.e., what is deficient).
Part 3. Why important – Reference and Relevance?	3. Explanation of the request's **relevance** to the PMA RASE determination, 510(k) SE determination, HDE safety and probable benefit determination, or De Novo classification determination, including, where appropriate, reference to an applicable section of a final rule, final guidance, and/or an FDA-recognized standard (unless the entire or most of the document is applicable). *When the deficiency cannot be traced in the manner above* and relates to a scientific or regulatory issue pertinent to the determination, FDA will *cite the specific scientific issue and* the **information to support** its position.
Part 4. What to provide?	4. Explicit request for the additional information needed to address the issue and potential alternate ways of satisfying the issue, if applicable.

- **AF-2018-00003**: In FY 2019, internal audit AF-2018-00003 found variable interpretations for Part 3 and was unable to determine presence of that component. FDA logged a nonconformity and clarified Part 3.

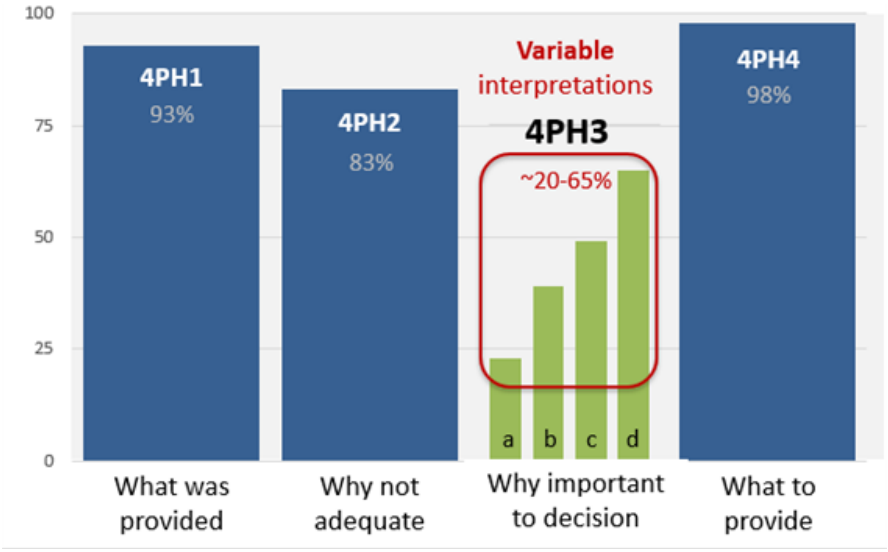

Figure 1. FY 2019 AF-2018-00003 Results sowed variable interpretation of Part 3.

- **Clarified Part 3. Why important**: The MDUFA V commitment letter focuses on "Part 3." Part 3 has two components—reference and relevance. Internal audits AF-2019-00002 and AF-2020-00008 examined adherence to FDA's current interpretation of Part 3 criteria, as described below:

    - 3a**. Reference:** Statement of basis for the deficiencies that includes a specific reference to (a) applicable section of a final rule, regulation, or statute, (b) applicable section of a final guidance or an FDA-recognized standard (unless the entire or most of the document is applicable), and/or (c) specific scientific, clinical, or regulatory issue.
    - **3b. Relevance:** For specific references (b) or (c), the deficiency should also include information to support FDA's position. Supportive information are explanations that cite one or more of the following:
        - Relevance to the regulatory decision
        - Relevance to understanding device's benefit-risk profile
        - Relevance to safe and effective use of device
        - Regulatory precedent (such as in 510(k) predicate)

- **AF-2019-00002 (Baseline) and AF-2020-00008 (Follow-up) Findings**: Findings suggest that FDA's CAPA plan is addressing the nonconformity. (Effectiveness Check)

    - FDA's current interpretation of Part 3 (above) exceeds the MDUFA 4 requirement.
    - The percentage of samples will all four-part present increased from 24 percent to 43 percent
    - In the AF-2020-0008 sample, three out of four parts of the harmony are present over 90 percent of the time—Part 1 (what was provided, 93 percent), Part 2(why not adequate;

increased from 83 percent to 92 percent) and Part 4 (what to provide; 98 percent).

- Presence of Part 3 increased to 50 percent overall. Presence of the two components of Part 3 also increased—from 34 percent to 64 percent for reference and 62 percent to 74 percent for the explanation or relevance.

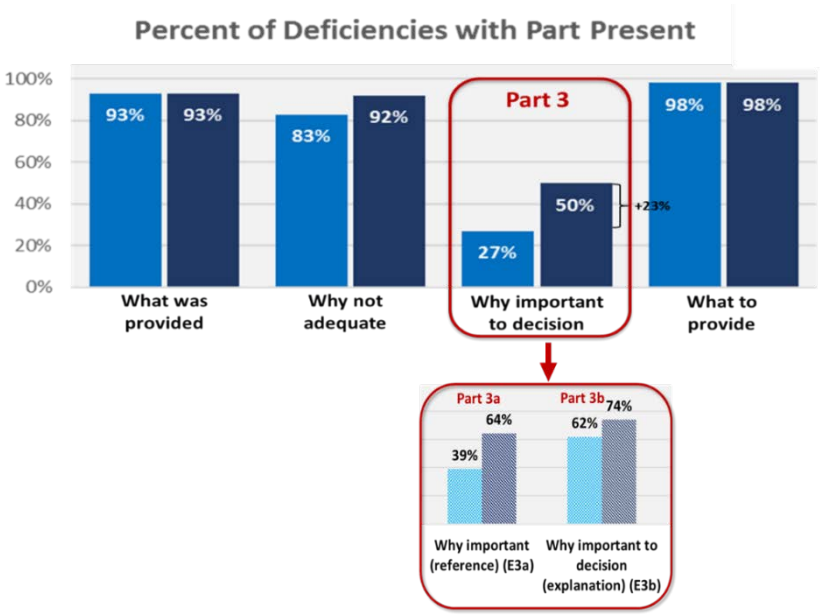

Figure 2. Comparison between AF-2019-0002 (baseline) and AF-2020-0008 (follow-up) results

- **No additional nonconformities logged**: FDA will continue to address deficiency letter improvement actions under the existing nonconformity and has taken actions beyond those included in the initial CAPA plan.
- Follow-up audit recommended.

4.6. AF-2020-00009: Pre-submissions (MDUFA Required)

The audit was completed 9/29/2020 and CDRH Audit Team is currently preparing the report. Findings will be shared at an upcoming FY 2021 Performance Review meeting.

5. Continual Improvement.

5.1. Business Process Improvement (BPI; ongoing). In support of CDRH's 2018-2020 Simplicity Strategic Priority and Digital Transformation Initiative, this project aims to lean CDRH core businesses processes. Effort objectives include:

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

5.2. Continual Improvement QM Staff Role. QM staff manage the CDRH BPI program offering a variety of continual improvement services. Staff:

- lead and facilitate end-to end BPI project execution
- provide lean six sigma (LSS), data and project management expertise
- assist with the documentation of nonconformities
- enable collection of data for improvement exercises
- help develop and implement solutions and control plans

5.3. Training Improvement. In FY2020 QM assisted the OCE on the development of Kirkpatrick metrics for the assessment of the effectiveness of the premarket Reviewer Certification Program.

5.4. BPI: Document Control System (DCS; ongoing)

CDRH recently completed an effort to optimize performance of its Document Control System (DCS). The DCS serves as the Center's central repository for controlled documents and effectively using the system is vital to ensuring that staff have access to resources that enable effective and repeatable processes. At the outset of the business process improvement initiate, leadership gathered data to identify specific pain points and opportunities for improvement. Most notably, there was variation in the quality and level of detail of documents across the various program areas of the Center. The project team developed a redesigned template for creation of controlled documents, to include clear and concise guidance, as well as relevant examples to aid in creation of new documents within DCS. Furthermore, the project team established a new cover page for a structured and standardized collection of metadata to enable an optimized search functionality. Lastly, a holistic user guide was created to provide step-by-step instruction on completion of the template, as well as supporting materials to facilitate a consistent tone and style for the creation of new documents.

5.5. BPI: CDRH QM Framework (CDRH QMS; ongoing)

Currently, all CDRH programs are conforming to the QM Program ISO 9001:2015 certified Quality Management System (QMS), The QMS infrastructure and QMS staff services is used broadly across all Programs throughout the Center. The goal of the project is to move CDRH process from conformity to the CDRH cohesive ISO 9001:2015 certified Quality Management System (QMS) to certification.

5.6. BPI: Premarket Harmonization

Within key premarket processes in OPEQ, there are high-level activities and processes that require similar actions across various application types. Thus, the BPI program sought to simplify the Staff experience by developing a harmonized, high-level Premarket Review Process that addressed major steps, which are common across many premarket reviews. Scalability, adaptability, and portability of training materials would allow reviewers to learn from one work stream and carry it over into others. The team designed an efficient, high-level premarket review process that addressed and simplified major steps, which were common across all types of premarket reviews. In addition, the group harmonized the taxonomy / vocabulary of the artifacts produced from the premarket review process to have generic names / terms that apply to all submissions and platforms.

5.7. BPI: Team Review

Prior to embarking on an improvement journey, the approach to conducting a consult review was overburdensome and very formal in nature, making way for an opportunity to improve review efficiency and relieve the strain on CDRH staff's time and quality of life, brought on by the increasing volume and complexity of premarket reviews. Improving efficiency would reduce staff burden, increase internal and

external customer satisfaction, and reduce the time to bring new products to the U.S market. The goal was to identify a future, long term strategic vision for simplifying and harmonizing how teams incorporate, evaluate, and communicate information into premarket reviews. Once a future vision and high-level process was developed, the team identified and initiated short-term improvements to decrease staff burden and move closer to the future vision.

5.8. Innovative Technological Improvements: eSTAR Submission Tool

In FY 2019 and FY 2020, 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 pilot of the **e**lectronic **S**ubmission **T**emplate **a**nd **R**esource (eSTAR) project. 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 program began as a pilot to help pilot participants through the process to prepare a 510(k) medical device submission in February 2020. 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 2020, we've received 14 eSTAR submissions. Positive sentiments were received from 14 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.

- The eSTAR program expanded to include all non-In Vitro Diagnostics (nIVD) and In Vitro Diagnostic (IVD) devices that are not combination products on September 8th, 2020.
- De Novo content of both eSTARs is done and internally approved. A nine-submission pilot is forthcoming.
- Final Third eSTAR for 513(g), IDE, and Q-Sub in development.

The content of eSTAR mirrors the SMART review template that reviewers use when reviewing the submission content.

5.9. 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 Summer 2020 and began a sequential deployment to the OHTs soon afterward. All OHTs are expected to be using the IDE smart template by the end of 2020 or early 2021. A PMA smart template began construction in Summer 2020 and continues internal review by the Tools and Templates Committee before the end of 2020. We expect it to be fully deployed to all OHTs in Spring 2021. An IVD specific De Novo smart template (the nIVD De Novo smart template has been in use since 2016) will begin our internal Tools and Templates Committee review by the end of 2020. Of the main premarket submission types, only an HDE smart template, and an IVD specific PMA smart template have yet to be developed.

- IDE SMART is now available for all to use - Once two more OHTs are trained by the end of 2020, all will be required for use by all OHTs
- PMA SMART is complete and currently undergoing our Tools and Templates Committee review – expect to be in full use by all OHTs in Spring 2021

6. Independent Assessment of Review Process.

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:[8]

> *"…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*."

[8] MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, https://www.fda.gov/media/102699/download; page 11; 20/02/2016

6.1. Progress

- **FY2020 Q1:** N/A
- **FY2020 Q2**: In January of FY 2020, FDA awarded a contract for the execution of the Phase 2 independent Third-Party assessment, led by the FDA Office of the Commissioner. During Q2 an evaluation framework was developed and initial meetings with all CDRH leads were conducted.
- **FY2020 Q3**: The following assessments began during Q3
    - Premarket efficiencies that should be realized as a result of the process improvements and investments under MDUFA III and IV
    - Premarket review program infrastructure and allocation of FTEs
    - Quality Management
    - Digital Health
- **FY2020 Q4**: The following assessments began during Q4
    - Patient Science and Engagement
    - Third Party
    - Training and Alignment
    - Deficiencies

D. Presentation Slides

Ongoing Commitment to Quality

- We are dedicated to providing **QM and operational excellence** (QMOE) services and tools that meet or exceed customer requirements and support quality assurance, continuous process improvement and operational excellence across CDRH.
- The Program embraces the core values and concepts of the ISO9001:2015 and is **ISO 9001:2015** Certified for provision of quality management (QM) and operational excellence (OE)
  - ISO certification demonstrates that CDRH has implemented a quality management system which meets the requirements of the applicable Standard(s).

QM Professionals

- 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
- ISO 17025:2015 Trained
- Bronze Level Kirkpatrick Evaluation Certification Program

Over 20 FTEs, including 14 MDUFA FTEs

2

CDRH Quality Management Program

FEEDBACK✓CDRH

- One Stop Shop for submitting ideas, suggestions and issues.

CDRH Docs
CDRH Pilots

- **CDRH Docs:** All CDRH processes documents available in one place
- **CDRH Pilots:** all pilot process documentation in one place
- QM Program can help with:
  - Document development assistance and mentoring—process documentation planning, document logic model
  - Flowcharts
  - Writing
  - Multi-Office Clearance

Training

- Recertification Opportunities
- CDRH QMS & Quality Training
- Kirkpatrick Metrics

CDRH Continual Improvement (CPI)

- Mentoring staff
- Risk Management
- Facilitating and coordinating continual improvement and quality activities
- Providing organizational QM and process improvement knowledge

CDRH Metrics

- Performance metrics and data science
- Dashboards
- Surveys
- Reports and Analyses

Customer Service

- Customer Service feedback from external and internal customers—CDRH Customer Service Survey

CDRH Audits

- Internal audit and evaluations
- Nonconformity and CAPA

3

Ongoing Commitment to Quality

Key Tenets of CDRH Quality

95%
CDRH Customer Service Rating

27%
Feedback✓CDRH about premarket

900+
Documents managed via DCS

79%
OPEQ, including premarket

200+
Staff certified by ASQ

20+
Audits, including process audits

80+%
CDRH core review, regulatory, and administrative processes improved within three years

Premarket
PMA, 510(k), 513g, CLIA, Premarket Harmonization, Team Review, eSTAR, SMART

CDRH Internal Audit Program

2021

The following internal audits are already on the FY 2021 schedule:

- Withdrawal
- Least Burdensome
- ISO 9001:2015 (External Audit)
- CDRH QMS Core Processes

Due: End of January 2021

Title	Purpose
External	ISO 9001:2015 Surveillance Audit
AF-2019-00001	Assess Biocompatibility Focal Point Program process
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6

CDRH Internal Audit Program

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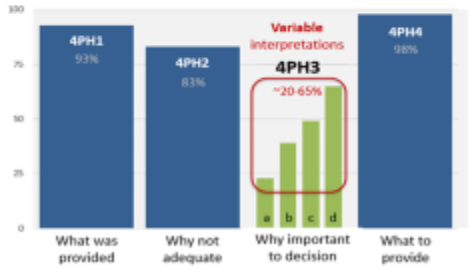
Part 2. Why not adequate?
Part 3. Why important – Reference and Relevance?
Part 4. What to provide?



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CDRH Internal Audit Program

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- FDA's current interpretation of Part 3 exceeds the MDUFA 4 requirement.
- The percentage of samples will all four-part present increased from 24 percent to 43 percent
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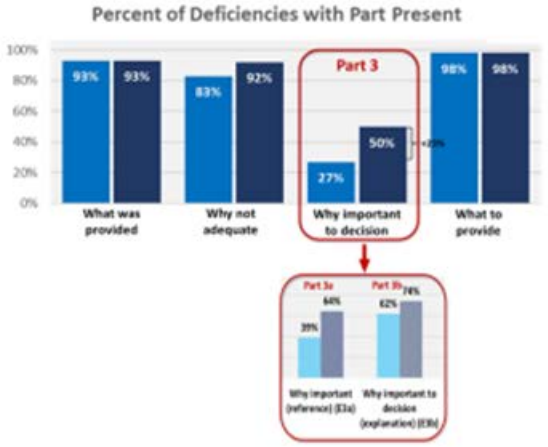


Business Process Improvement (BPI) Outcomes

Selected Improvements

Team Review

- Future, long term strategic model for how teams incorporate, evaluate, and communicate information into premarket reviews

eSTAR

- Ongoing Pilot; positive initial feedback from participants

SMART

- IDE SMART available; PMA SMART under development

Business Process Improvement (BPI) Outcomes

Selected Improvements

Premarket Harmonization

- Modular and harmonized review

De Novo

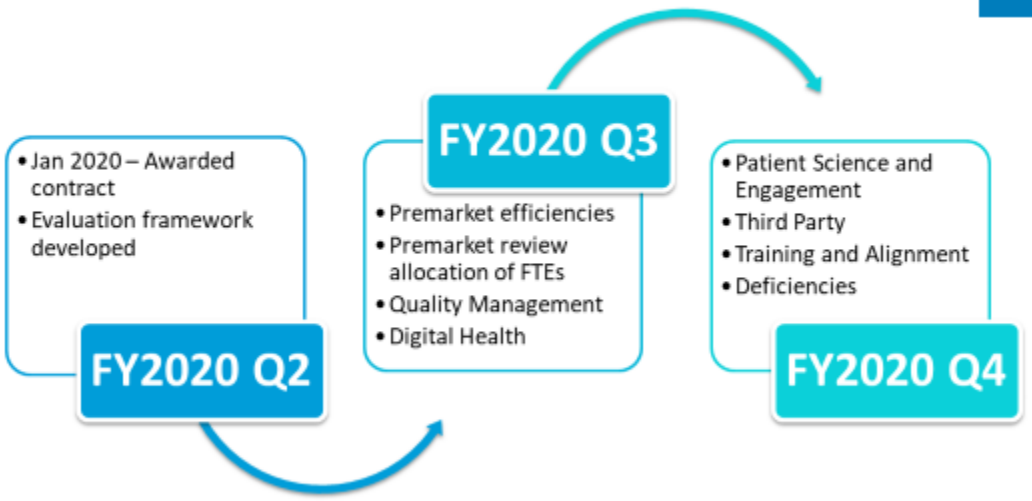
- 20% reduction of process steps

Clinical Laboratory Improvement Amendments (CLIA)

- Number of submissions reviewed over 30 FDA days reduced to 6% (pilot results)

10

Independent Assessment of Review Process



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ASCA

Accreditation Scheme for Conformity Assessment

Guidance Publication

Nine months post-docket:

- Evaluated and addressed comments
- Reorganized the draft guidance into three documents (one program guidance and two standards-specific guidances to facilitate ease of understanding and navigation)
- Added example summary test reports
- Cleared and published

Implementation: Outreach

- Public webinar with ~500 participants
- Two national Regulatory Affairs Professionals Society (RAPS) presentations
  - How to Use Standards and Declarations of Conformity in Device Submissions with ~120 attendees
  - Putting Standards to Work in Device Submissions: the ASCA Pilot with ~ 200 attendees
- Industry association roundtable
- Accreditation body training (mandatory) with 99 technical assessors
- Accreditation body kick-off teleconference with all five ASCA-recognized accreditation bodies
- Test lab training (non-mandatory)
  - Basic safety and essential performance with ~ 92 attendees
  - Biocompatibility with ~ 64 attendees
- Internal awareness-raising among review staff and management

Implementation: Quality Management System

- Developed a quality management framework that leverages
  - Core values and concepts in ISO 9001
  - CDRH Quality Management Program tools
- Created and implemented:
  - Standard operating procedures
  - Work instructions
  - Templates

Implementation: Document Management

ASCA premarket submissions need to be compatible with electronic systems utilized in routine device review. The ASCA team has:

- Created, tested and implemented infrastructure to flag and route ASCA device submissions
- Updated SMART templates for premarket submissions to include checks for ASCA Pilot files
- Developed checklists to mirror the sample test report summaries in the standards-specific guidance documents

Outcome: an Out of the Gate Start

- Five accreditation bodies met the deadline for an ‘initial list’ of ASCA-recognized accreditation bodies.
- FDA evaluated and accepted all five and the list published on November 25, 2020.
- This expedited start ensures that testing laboratories can also apply quickly and appear on an ‘initial list’ of ASCA-accredited test labs.
- Manufacturers may choose an ASCA-accredited lab to perform ASCA Pilot testing as soon as April 12, 2021.

Center for Devices and Radiological Health Internal Training Summary Report

Q4 FY20

October 2019 – September 2020

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

As of: 11/12/2020

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, 2019 and September 30, 2020. DETD offered 505 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 – FY20 CDRH Internal Training Conducted by DETD:

October 1, 2019 and September 30, 2020

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA IV	5	1187	952
	ELP	5	93	1272
	Least Burdensome (Refresher)	3	5742	2101
	Other LAW	310	22193	17592
	LAW Subtotal:	*323*	*29215*	*21917*
Leadership Development Training (LED)	LEAD: Leadership for Managers	43	486	1951
	Leadership for Non-Managers	7	89	530
	Other LED	10	116	324
	LED Subtotal:	*60*	*691*	*2805*
Professional Development (PRO) Training	New Employee Orientation (NEO)	3	191	796
	Other PRO	56	918	3771
	PRO Subtotal:	*59*	*1109*	*4567*
Center-Specific Information Technology (CIT) Training	Premarket IT	6	633	639
	Other CIT	4	25	15
	CIT Subtotal:	*10*	*658*	*654*
Science (SCI) Training	All SCI	53	1087	3807
	SCI Subtotal:	*53*	*1087*	*3807*
	Grand Total:	**505**	**32760**	**33750**

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
Total:	**346**	**8217**	**22680**

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, 2019 and September 30, 2020*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 1 2019 Cohort	13	18	OPEQ	28	544	726
			OSEL	5	70	94
			Subtotal:	***33***	***614***	***820***
Fall 2 2019 Cohort	13	18	OCD	1	15	21
			OCE	1	28	38
			OPEQ	26	680	875
			OSEL	2	26	31
			Subtotal:	***30***	***749***	***965***
Spring 1 2020 Cohort	13	18	OCE	1	19	28
			OM	2	27	38
			OPEQ	26	666	858
			OST	1	15	19
			Subtotal:	***30***	***727***	***943***
Spring 2 2020 Cohort	13	18	OCE	1	29	39
			OPEQ	26	727	937
			OST	3	47	62
			Subtotal:	***30***	***803***	***1038***
Summer 1 2020 Cohort	13	18	OCE	1	31	39
			OPEQ	45	1208	1532
			OSEL	2	60	77
			Subtotal:	***48***	***1299***	***1648***
Summer 2 2020 Cohort	13	18	OCD	1	30	41
			OPEQ	38	1041	1326
			OSEL	7	187	241
			Subtotal:	***46***	***1258***	***1608***
Total:	**78**	**108**	**-**	**217**	**5450**	**7022**

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, 2019 and September 30, 2020*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
5	93	1272	• Innovation • Surgical Devices • Clinical Application of Proton Therapy • Clinical Trials • Digital Health: AI Machine Learning

ELP Training Completed by Office: *October 1, 2019 and September 30, 2020*

Office	Total # of Attendees	Total Training Hours
OP	1	8
OPEQ	82	1104
OSEL	3	48
OST	7	112
Total:	**93**	**1272**

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, 2019 and September 30, 2020*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	43	486	1951	• Behaviorial Based Interviewing • Managing Change • Leadership Communication • Creating and Maintaining a Collaborative Department • Managing the Mid-Year Performance Review • Guiding Principles Implementation: Over for Managers

LEAD Training Completed by OPEQ: *October 1, 2019 and September 30, 2020*

Office	Total # of Managers/Supervisors*	# of Training Participants	Training Hours Required**	% of Required Training Hours Completed
OPEQ	137	66	2192	33%

*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 FY20.

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.
Master Four-Part Harmony	This course provides instruction for writing deficiencies that are clear, concise, and in the appropriate format.
Master Technical Writing	This course teaches the basic techniques for writing in plain language and how they are used to write clear and succinct technical documents.
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.
Effective Communication Skills for Technical and Scientific Professionals	This course addresses real-world communication strategies for scientific and technical professionals.
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 how to find 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.