Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance

November 5, 2013
10:00 A.M.

Welcome. *Barbara Zimmerman, CDRH-ODE*.

Guidance Development

- FDA issued 10 medical device guidance documents during the 4th quarter. *Barbara Zimmerman, CDRH-ODE*; *Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIR, Philip Desjardins, CDRH-OCD.*

FDA MDUFA Performance — Actions through September 30, 2013

- Report on decisions goals for 4th quarter of FY 2013.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

Qualitative Update on Finances – 4th Quarter of FY 2013

- User fee receipts through the 4th quarter of FY 2013. *David Miller,* FDA-OFM.

CDRH Registration and Listing

- Report on registration and listing- Dave Gartner, CDRH- OC.

Independent Assessment

- Progress and update- Amber Sligar, FDA-OC.

CDRH Staff Training Update

- Report on CDRH staff training- Jacqueline Woodard, CDRH-OCER.

Discussion

- DSMICA 510(k) Status Request Function- Elias Mallis, CDRH-OCER.

Set date for next meeting, following close of Q1. Target Date: Tuesday 1/28/14 at 10:00 am.

Medical Device Guidance Documents

Issued in FY 2013

(July 1, 2013 thru September 30, 2013)

1. Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff (09/25/2013)
2. Global Unique Device Identification Database (GUDID) - Draft Guidance for Industry (9/24/2013)
3. Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems - Draft Guidance for Industry and Food and Drug Administration Staff (8/30/2013)
4. The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions and Answers - Draft Guidance for Industry and Food and Drug Administration Staff (08/28/2013)
5. IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed (08/27/2013)
6. Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (08/14/2013)
7. Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Approach to Monitoring (08/06/2013)
8. Minimizing Risk for Children's Toy Laser Products - Draft Guidance for Industry and Food and Drug Administration Staff (08/07/2013)
9. Guidance for Industry and Food and Drug Administration Staff and Foreign Governments - FY 2014 Medical Device User Fee Small Business Qualification and Certification (08/02/2013)
10. Draft Guidance for Industry and Food and Drug Administration Staff - Medical Device Reporting for Manufacturers (07/09/2013)

(April 1, 2013 thru June 30, 2013)

11. Guidance for Industry: Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality (June 2013)

12. Implanted Blood Access Devices for Hemodialysis - Draft Guidance for Industry and Food and Drug Administration Staff (6/28/2013)
13. Draft Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens (6/19/2013)
14. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (6/14/2013)
15. Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff - FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations (PDF) (PDF - 564KB) (6/14/2013)
16. Guidance for Industry and Food and Drug Administration Staff - Priority Review of Premarket Submissions for Devices (5/17/2013)
17. Center for Devices and Radiological Health Appeals Processes - Guidance for Industry and Food and Drug Administration Staff (5/17/2013)
18. Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A - Draft Guidance for Industry and Food and Drug Administration Staff (5/17/2013)
19. Assay Migration Studies for In Vitro Diagnostic Devices - Guidance for Industry and FDA Staff (PDF - 1.2MB) (4/25/2013)
20. Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" - Draft Guidance for Industry and Food and Drug Administration Staff (PDF - 522KB) (4/23/2013)
21. Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff (4/11/2013)
22. Molecular Diagnostic Instruments with Combined Functions - Draft Guidance for Industry and Food and Drug Administration Staff (4/09/2013)
23. Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications (4/02/2013)
24. Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s) (4/02/2013)

(January 1, 2013 thru March 31, 2013)

25. Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi (3/28/2013)

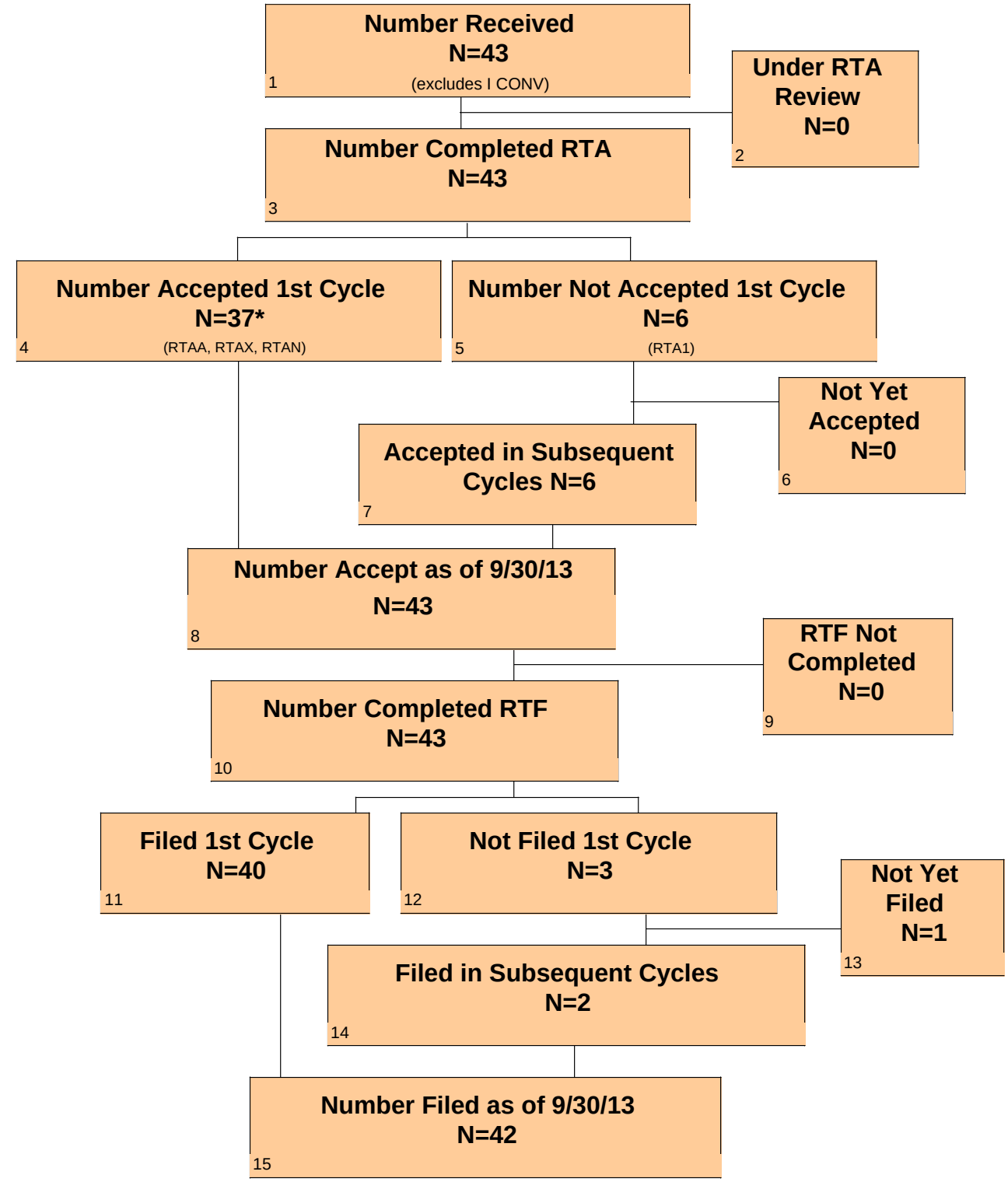
26. Draft Guidance for Industry and Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex (3/11/2013)
27. Guidance for Industry and FDA Staff - Investigational Device Exemption (IDE) Guidance for Retinal Prostheses (3/6/2013)
28. Types of Communication During the Review of Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff (3/5/2013)
29. Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (3/4/2013)
30. Financial Disclosure by Clinical Investigators- Guidance for Clinical Investigators , Industry, and FDA Staff (PDF - 165KB) (February 2013)
31. Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements - Draft Guidance for Industry and Food and Drug Administration Staff (2/22/2013)
32. Draft Guidance for Industry and Food and Drug Administration Staff - Providing Information about Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act (2/19/2013)
33. Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I - Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers (2/15/2013)
34. Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation - Guidance for Industry and Food and Drug Administration Staff (2/15/2013)
35. Draft Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate (2/7/2013
36. Guidance for Industry and FDA Staff - HUD Designations (PDF - 92KB) (1/24/2013)

(October 1, 2012 thru December 31, 2013)

37. Guidance for Industry and Food and Drug Administration Staff - Refuse to Accept Policy for 510(k)s (12/31/2012)
38. Guidance for Industry and Food and Drug Administration Staff - Acceptance and Filing Review for Premarket Approval Applications (PMAs) (12/31/2012)
39. Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions (12/31/2012)
40. Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use (12/12/2012)
41. IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed (11/20/2012)

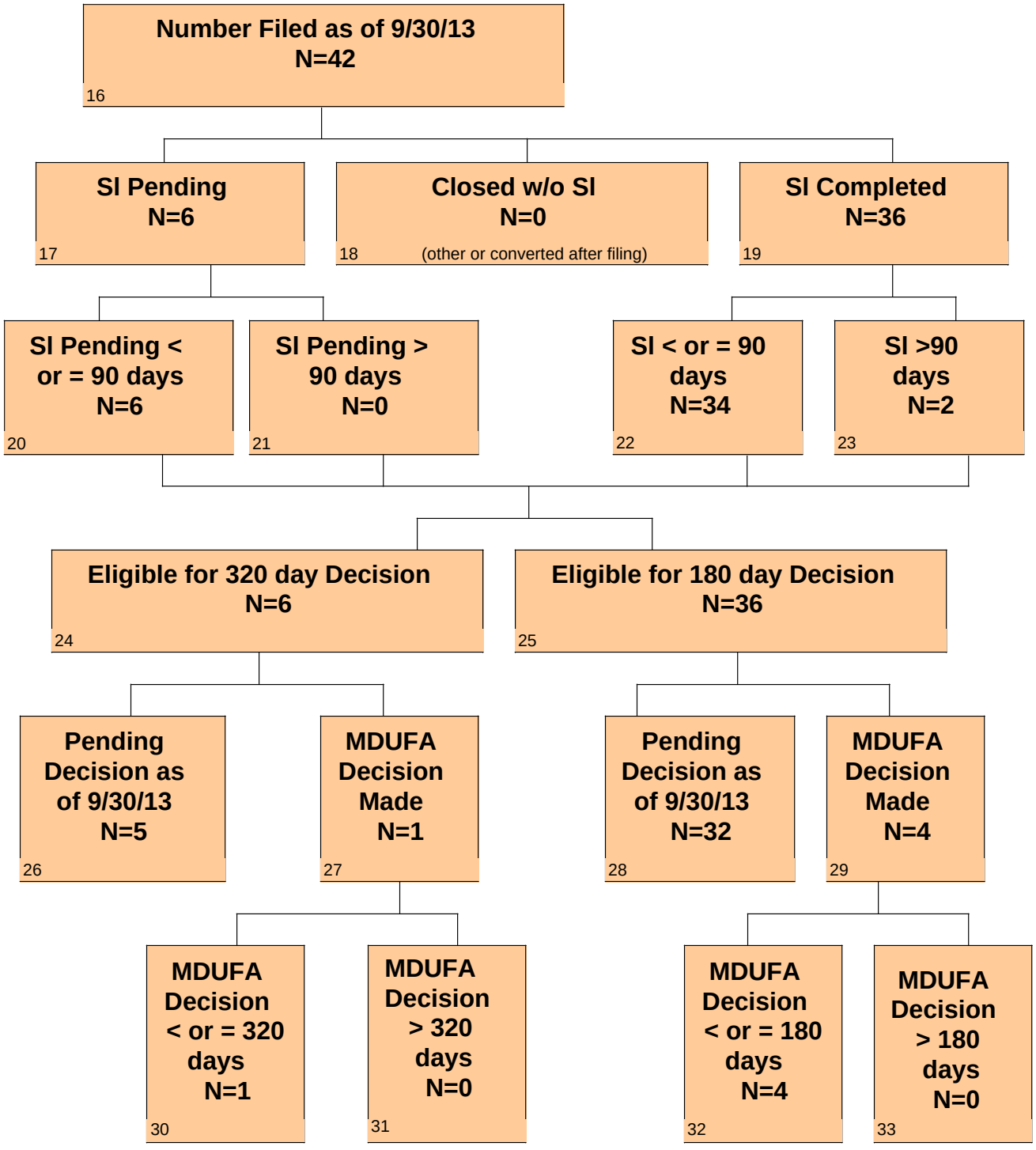
42. Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems (11/09/2012)
43. Draft Guidance for Industry and Food and Drug Administration Staff - Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices (11/09/2012)
44. Draft Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions (10/17/2012)
45. Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals (10/15/2012)
46. Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals (10/15/2012)

CDRH PMA Original and Panel Track Supplements(10/01/12-9/30/13)



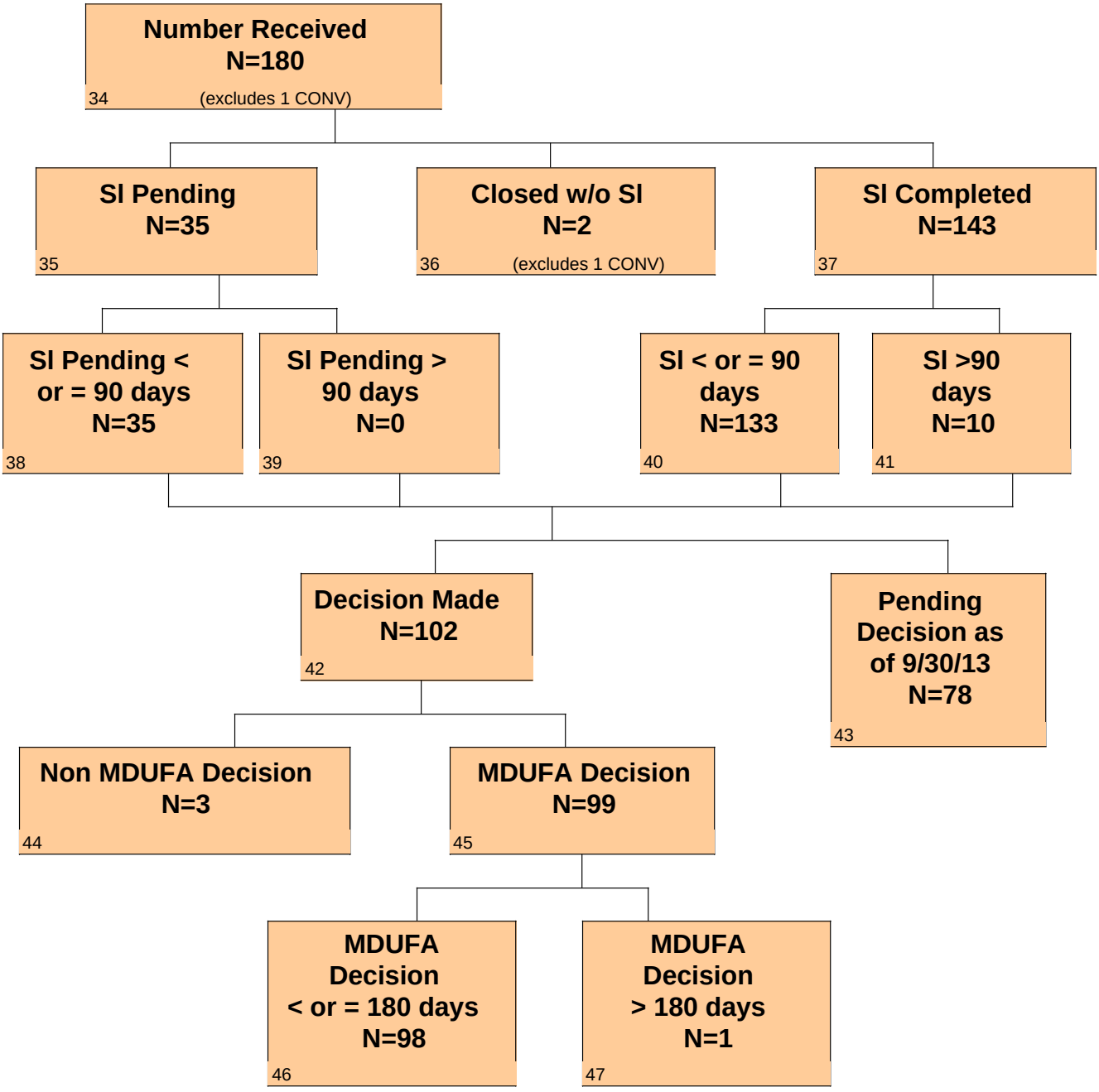
* Includes 10 accepted 1st Quarter, prior to implementation of RTA refusal

CDRH PMA Original and Panel Track Supplements(10/01/12-9/30/13)Con't

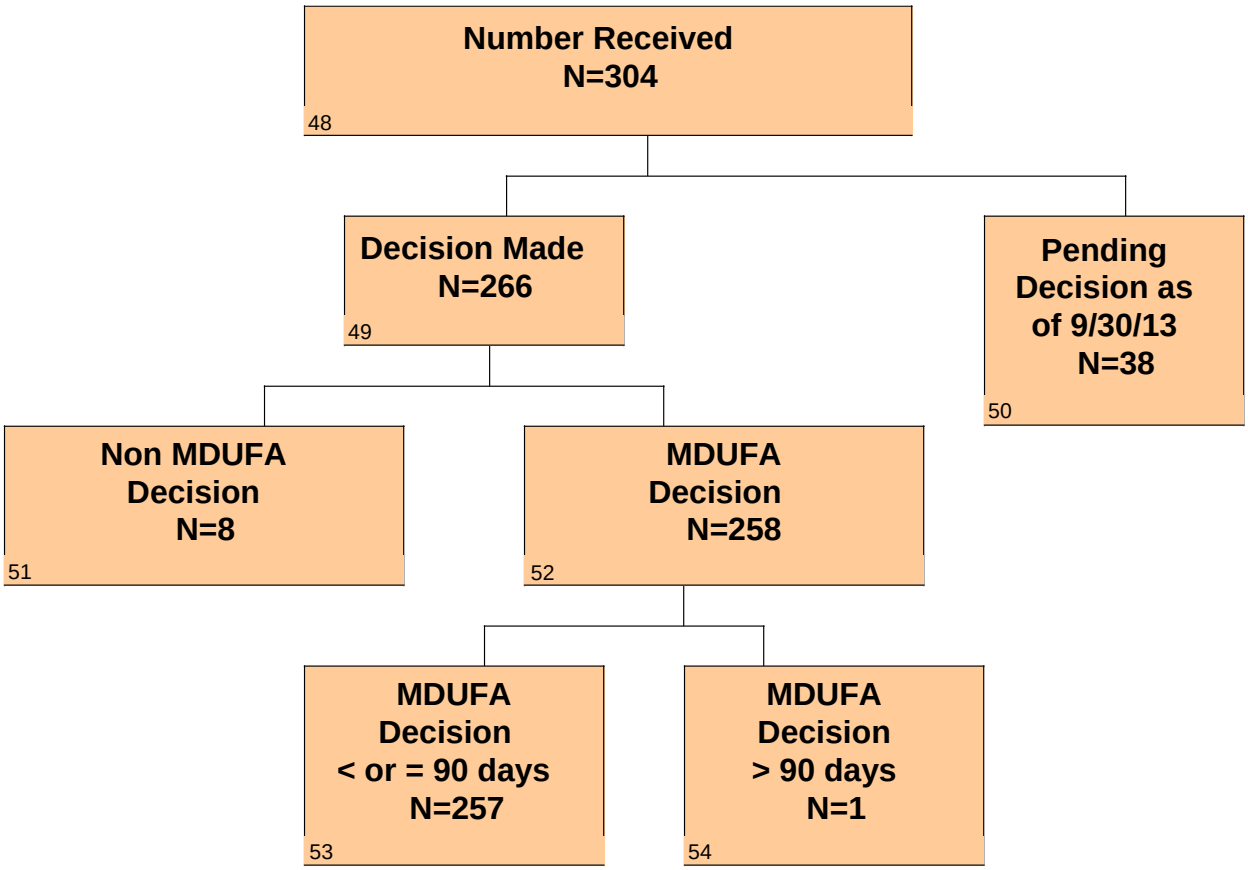


[#] Submission of an unsolicited major amendment will extend the SI and MDUFA goals.

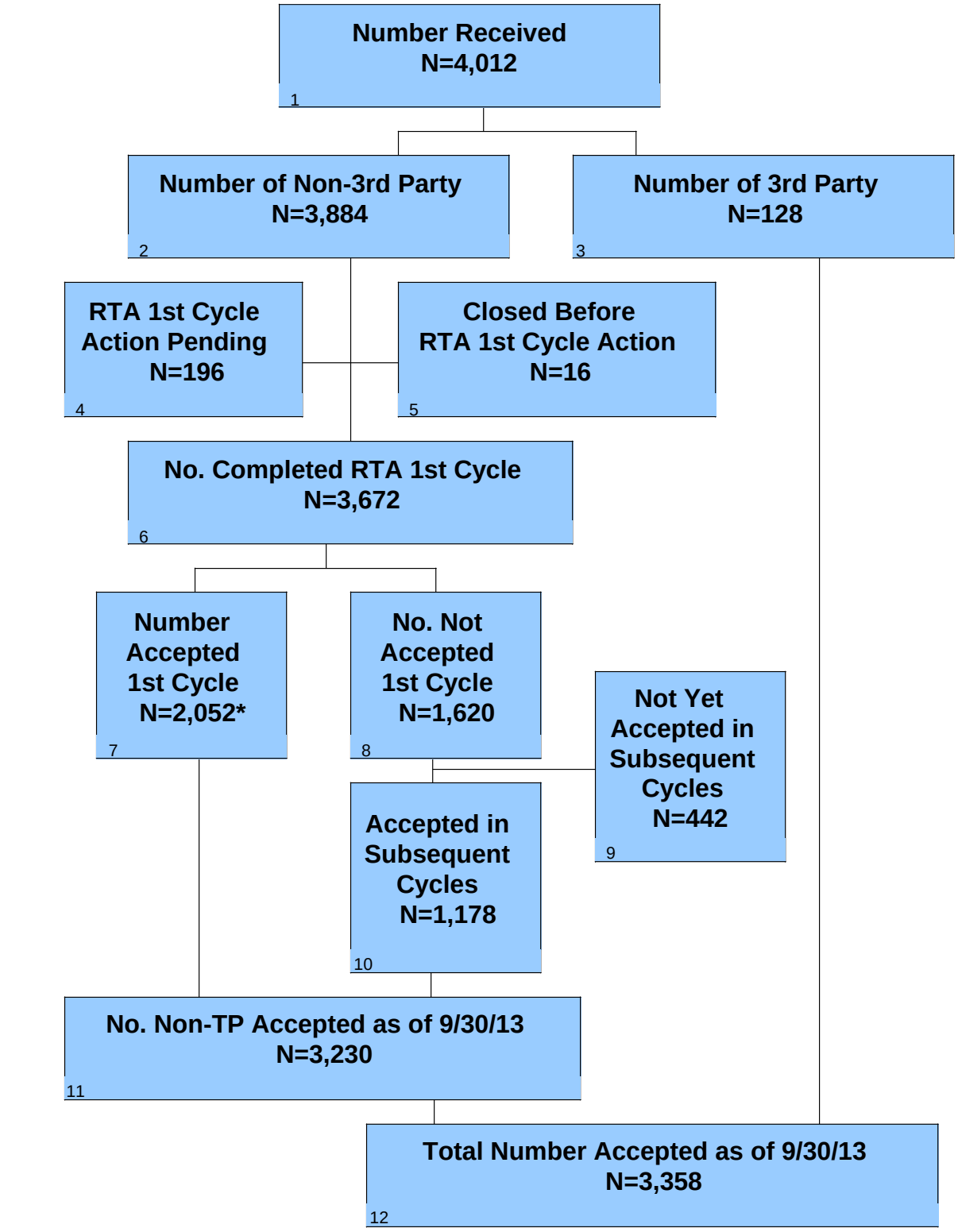
CDRH PMA 180 Day Supplements (10/01/12-9/30/13)



CDRH PMA Real Time Supplements (10/01/12-9/30/13)

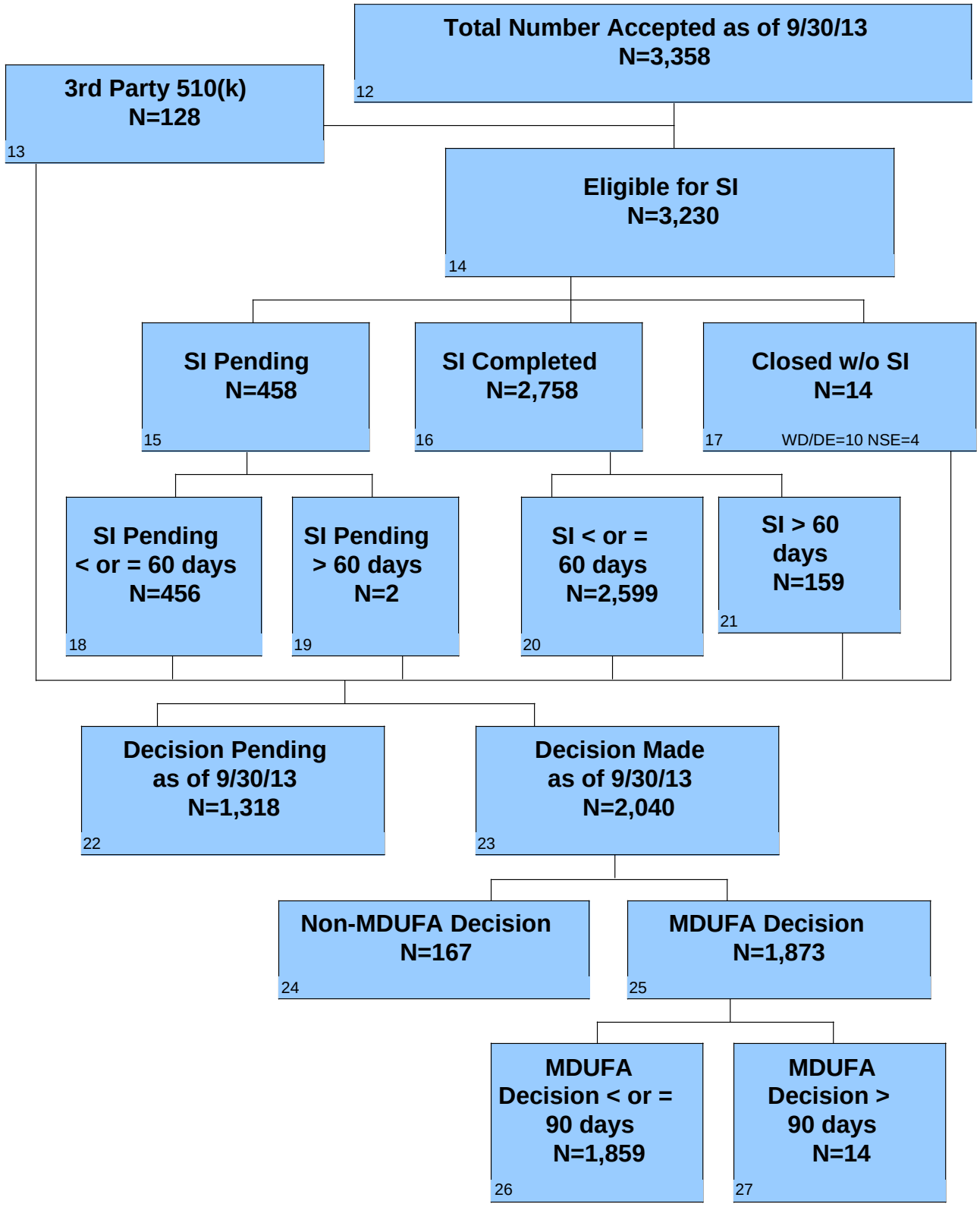


CDRH510(k)s(10/01/12-9/30/13)

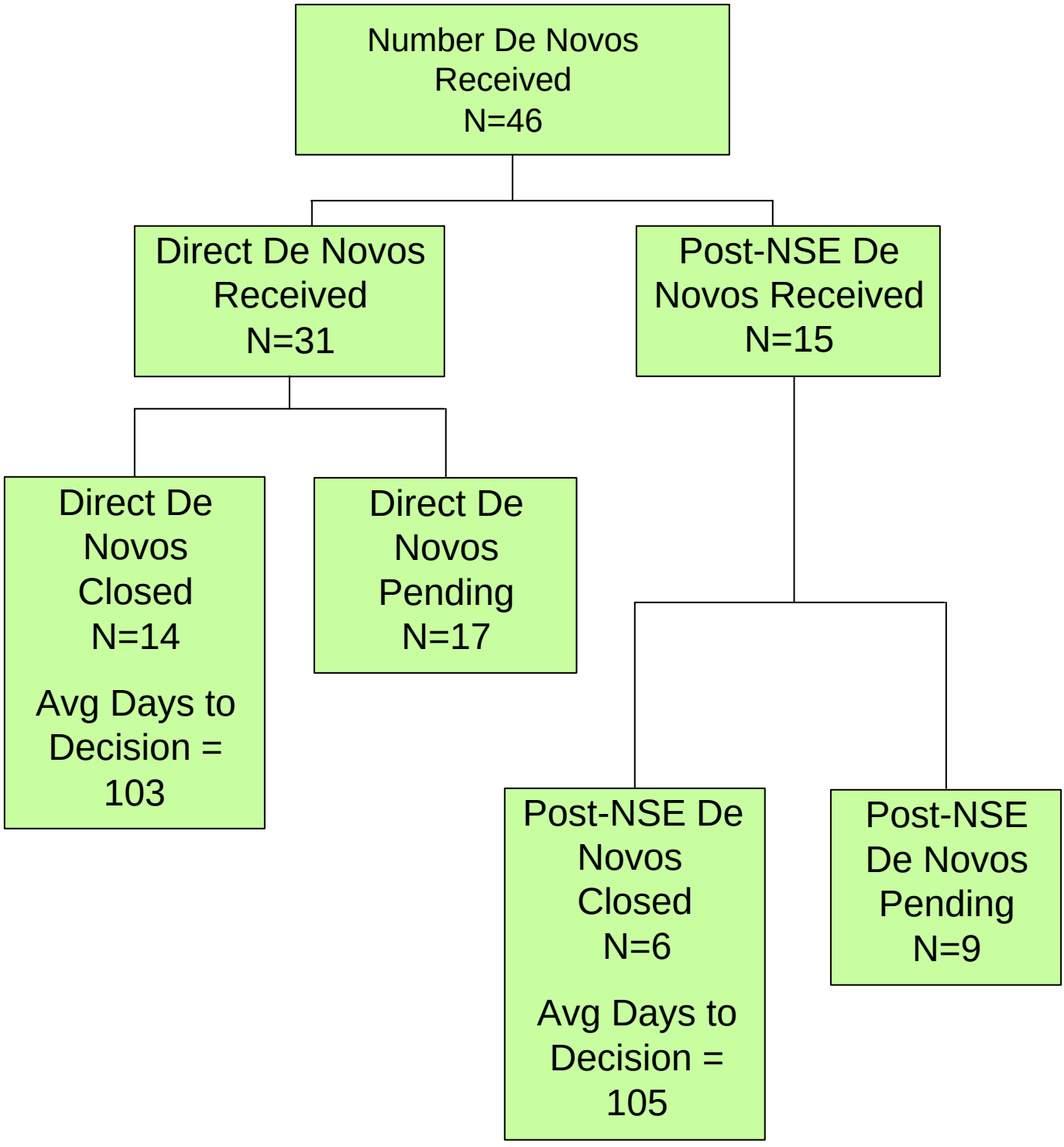


* Includes 919 accepted 1st Quarter, prior to implementation of RTA refusal

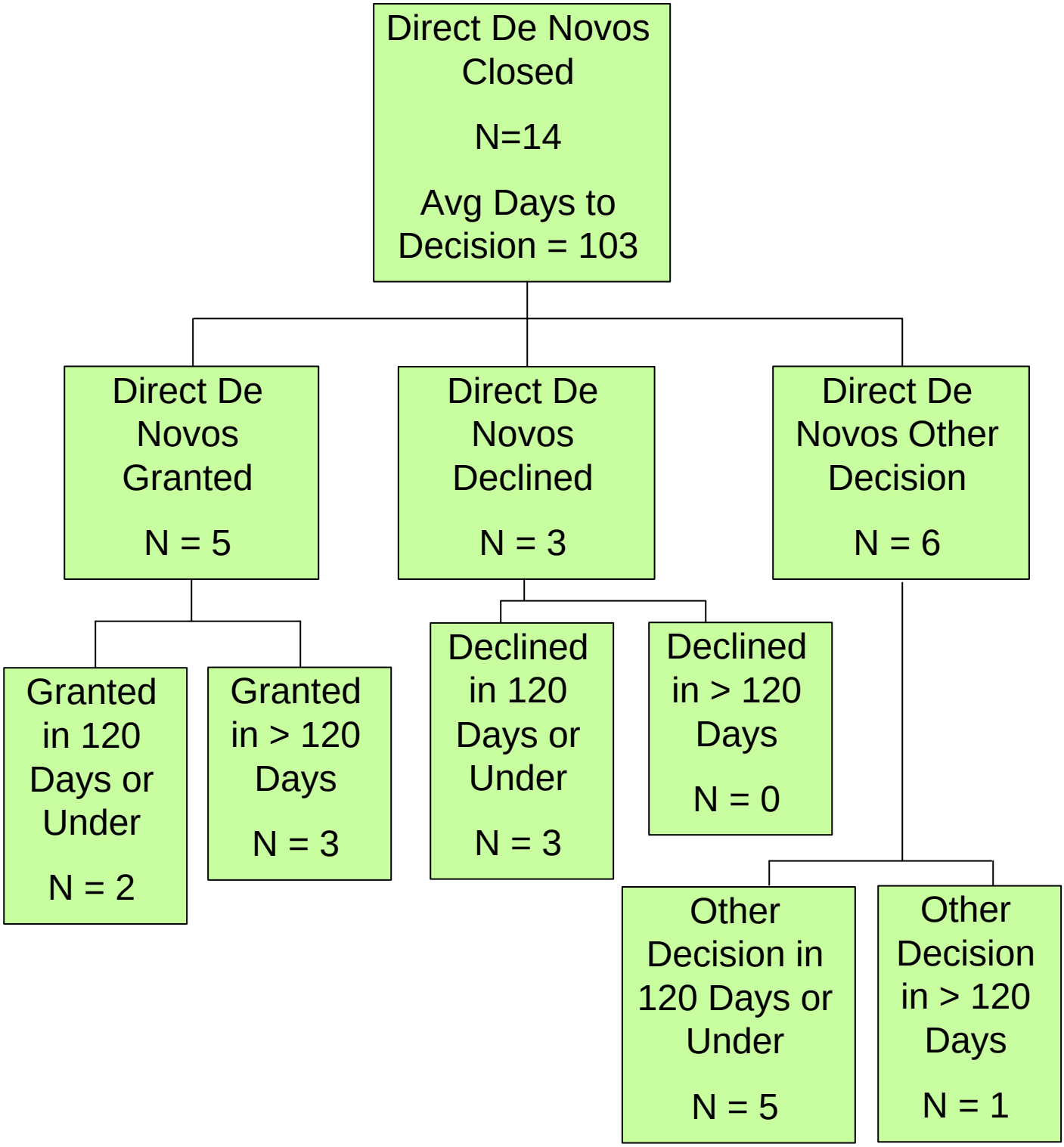
CDRH 510(k)s (10/01/12 - 9/30/13) Con't



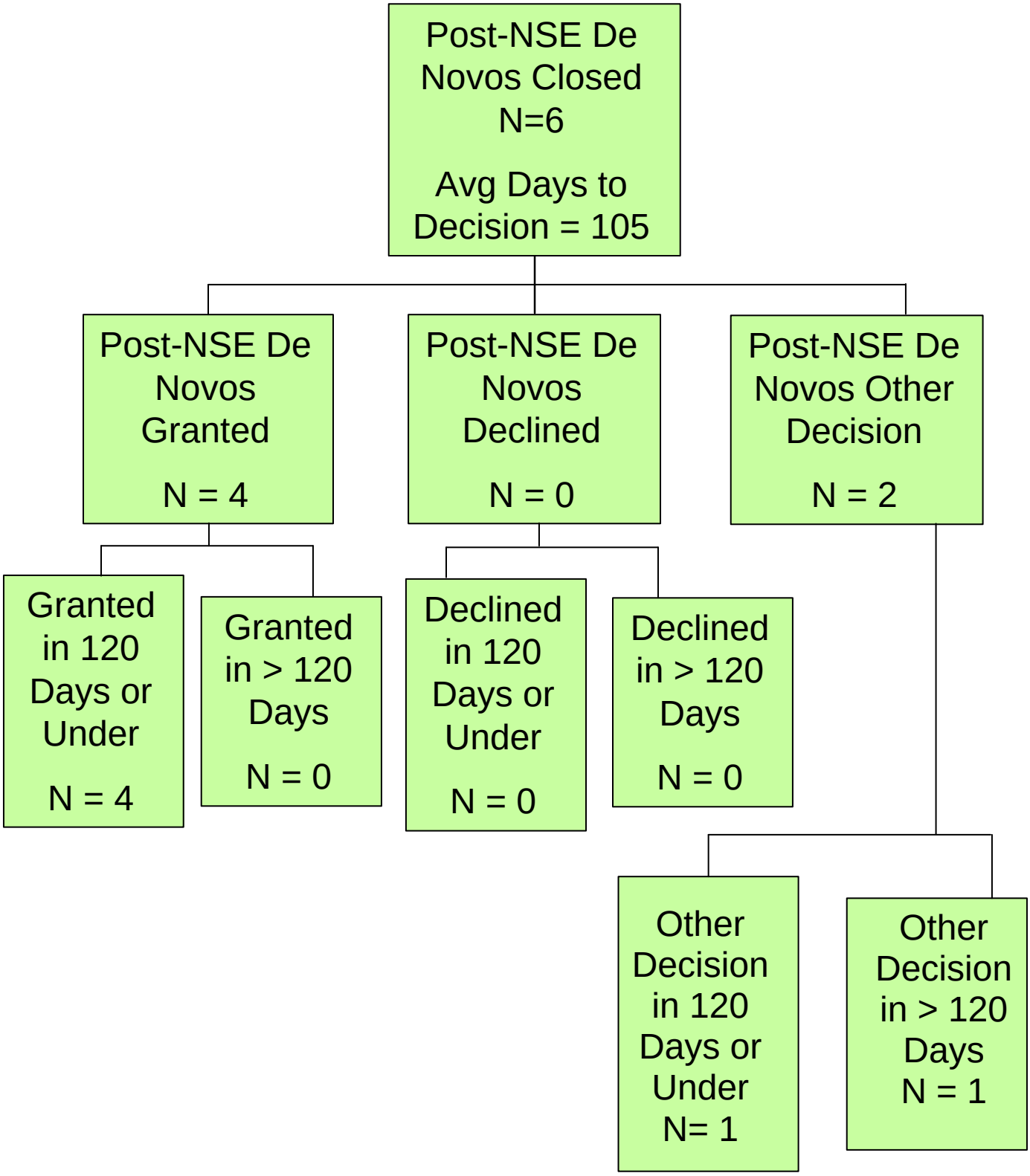
CDRH De Novos (10/1/12 – 9/30/13)



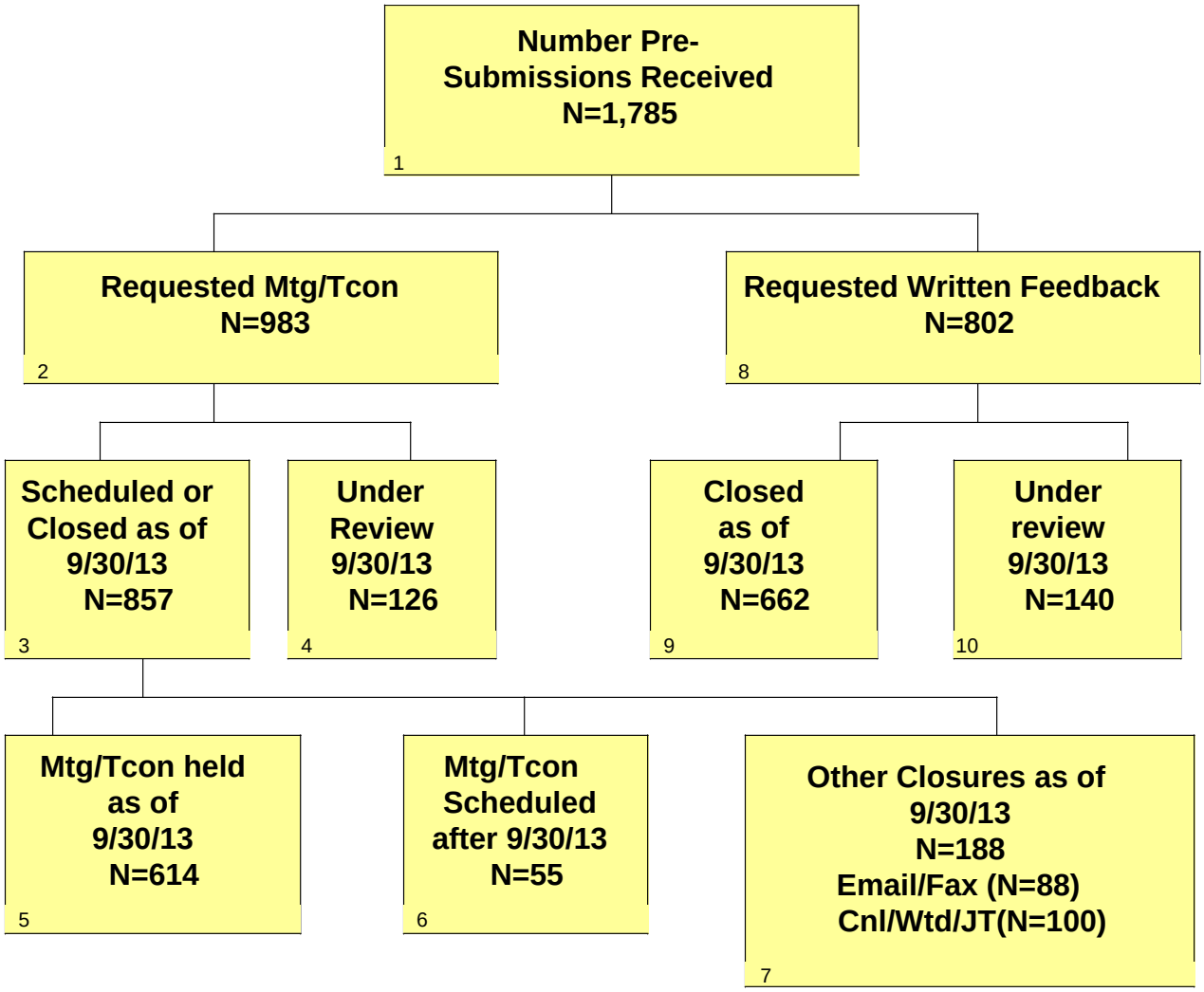
CDRH De Novos (10/1/12 – 9/30/13) Con't



CDRH De Novos (10/1/12 – 9/30/13) Con't



Pre-Submissions (10/1/12 - 9/30/13)



Annual Update on
Medical Device Performance Goals
MDUFA III Performance Data

October 1, 2012 – September 30, 2013

Report prepared by Ellen Pinnow and the MDUFA III Performance Goal Report Team

PMA
Wanda Sawyer-Major
Nicole Wolanski

510(k)
Margaret McCabe-Janicki
Eric Rechen
Marjorie Shulman

Pre-Submission
Ellen Pinnow

CLIA Waiver/OIR
Jean Cooper
Elizabeth Hillebrenner

Edaptive Systems
Victor Kuttikattu
Jerry Logue
Arkady Soldatov
Steven Stone

Updated: 10/28/2013

Table of Contents

Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Act
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DRH	Division of Radiological Health
DNPMD	Division of Neurological and Physical Medicine Devices
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose and Throat Devices
DRGUD	Division of Reproductive, Gastro-Renal, and Urological Devices
DSD	Division of Surgical Devices
IDE	Investigational Device Exemption
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

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

Section 1 PMA Originals and Panel Track Supplements

PMA Originals and Panel Track Supplements – Center Level

Table 1.1 CDRH – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34				
Closed before RTA action	1				
Number with accepted RTA review	26				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	6				
Rate of submissions not accepted for filing review	18%				

*** RTA was not in place 1st quarter, thus data in Table 1.1 for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	44				
Number Accepted[#]	37				
Completed RTF	43				
Number Not Filed[@]	3				
Rate of submissions Not Filed	7%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

Table 1.3 CDRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	42				
SI within 90 FDA days	34*				
SI over 90 FDA days	2				
SI pending within 90 FDA days	6				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	94%*				

* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

Table 1.4 CDRH – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	36				
Average number of FDA days to Substantive Interaction	88				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	88				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	117				

Table 1.5 CDRH – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	36				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
PMAs pending MDUFA III Decision	32				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6 CDRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	6				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 320 FDA Days	1				
PMAs pending MDUFA III Decision	5				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	100%				

Table 1.7 CDRH – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	4				
Average FDA days to MDUFA III decision	143				
20th Percentile FDA days to MDUFA III decision	109				
40th Percentile FDA days to MDUFA III decision	128				
60th Percentile FDA days to MDUFA III decision	165				
80th Percentile FDA days to MDUFA III decision	178				
Maximum FDA days to MDUFA III decision	180				
Average Industry days to MDUFA III decision	47				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	14				
60th Percentile Industry days to MDUFA III decision	57				
80th Percentile Industry days to MDUFA III decision	90				
Maximum Industry days to MDUFA III decision	118				
Average Total days to MDUFA III decision	190				
20th Percentile Total days to MDUFA III decision	179				
40th Percentile Total days to MDUFA III decision	181				
60th Percentile Total days to MDUFA III decision	186				
80th Percentile Total days to MDUFA III decision	199				
Maximum Total days to MDUFA III decision	217				

Table 1.8 CDRH – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	206				
20th Percentile FDA days to MDUFA III decision	206				
40th Percentile FDA days to MDUFA III decision	206				
60th Percentile FDA days to MDUFA III decision	206				
80th Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	206				
20th Percentile Total days to MDUFA III decision	206				
40th Percentile Total days to MDUFA III decision	206				
60th Percentile Total days to MDUFA III decision	206				
80th Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

Table 1.9 CDRH – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	36				
Number with MDUFA decision	4				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

Table 1.10 CDRH – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	6				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

Table 1.11 CDRH – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12 CDRH – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

PMA Originals and Panel Track Supplements – Office Level

Table 1.1.ODE ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	27				
Closed before RTA action	1				
Number with accepted RTA review	19				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	6				
Rate of submissions not accepted for filing review	23%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.ODE for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.ODE ODE – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34				
Number Accepted[#]	27				
Completed RTF	33				
Number Not Filed[@]	3				
Rate of submissions Not Filed	9%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

Table 1.3.ODE ODE – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	32				
SI within 90 FDA days	25				
SI over 90 FDA days	2				
SI pending within 90 FDA days	5				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	93%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	27				
Average number of FDA days to Substantive Interaction	88				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	87				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	117				

Table 1.5.ODE ODE - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	28				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	2				
MDUFA III Decisions within 180 FDA Days	2				
PMAs pending MDUFA III Decision	26				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6.ODE ODE – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	4				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	2				
Average FDA days to MDUFA III decision	179				
20th Percentile FDA days to MDUFA III decision	178				
40th Percentile FDA days to MDUFA III decision	178				
60th Percentile FDA days to MDUFA III decision	179				
80th Percentile FDA days to MDUFA III decision	179				
Maximum FDA days to MDUFA III decision	180				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	179				
20th Percentile Total days to MDUFA III decision	178				
40th Percentile Total days to MDUFA III decision	178				
60th Percentile Total days to MDUFA III decision	179				
80th Percentile Total days to MDUFA III decision	179				
Maximum Total days to MDUFA III decision	180				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	28				
Number with MDUFA decision	2				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.ODE ODE – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.OIR OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7				
Closed before RTA action	0				
Number with accepted RTA review	7				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.OIR for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.OIR OIR – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10				
Number Accepted[#]	10				
Completed RTF	10				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.OIR OIR – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	10				
SI within 90 FDA days	9*				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%*				

* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	9				
Average number of FDA days to Substantive Interaction	89				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	89				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	112				

Table 1.5.OIR OIR - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	8				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	2				
MDUFA III Decisions within 180 FDA Days	2				
PMAs pending MDUFA III Decision	6				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6.OIR OIR – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 320 FDA Days	1				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	2				
Average FDA days to MDUFA III decision	108				
20th Percentile FDA days to MDUFA III decision	102				
40th Percentile FDA days to MDUFA III decision	106				
60th Percentile FDA days to MDUFA III decision	109				
80th Percentile FDA days to MDUFA III decision	113				
Maximum FDA days to MDUFA III decision	116				
Average Industry days to MDUFA III decision	95				
20th Percentile Industry days to MDUFA III decision	80				
40th Percentile Industry days to MDUFA III decision	90				
60th Percentile Industry days to MDUFA III decision	99				
80th Percentile Industry days to MDUFA III decision	109				
Maximum Industry days to MDUFA III decision	118				
Average Total days to MDUFA III decision	202				
20th Percentile Total days to MDUFA III decision	193				
40th Percentile Total days to MDUFA III decision	199				
60th Percentile Total days to MDUFA III decision	205				
80th Percentile Total days to MDUFA III decision	211				
Maximum Total days to MDUFA III decision	217				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	206				
20th Percentile FDA days to MDUFA III decision	206				
40th Percentile FDA days to MDUFA III decision	206				
60th Percentile FDA days to MDUFA III decision	206				
80th Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	206				
20th Percentile Total days to MDUFA III decision	206				
40th Percentile Total days to MDUFA III decision	206				
60th Percentile Total days to MDUFA III decision	206				
80th Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	8				
Number with MDUFA decision	2				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

Table 1.11.OIR OIR – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

PMA Originals and Panel Track Supplements – Division Level

Table 1.1.DAGRID DAGRID – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of submissions not accepted for filing review	100%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DAGRID for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DAGRID DAGRID – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Number Accepted[#]	1				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DAGRID DAGRID – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	2				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2				
Average number of FDA days to Substantive Interaction	85				
20th Percentile FDA days to Substantive Interaction	84				
40th Percentile FDA days to Substantive Interaction	85				
60th Percentile FDA days to Substantive Interaction	85				
80th Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	87				

Table 1.5.DAGRID DAGRID - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	2				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.DAGRID DAGRID – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DAGRID DAGRID – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DAGRID DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DCD DCD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	16				
Closed before RTA action	1				
Number with accepted RTA review	14				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DCD DCD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	19				
Number Accepted[#]	18				
Completed RTF	18				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DCD DCD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	18				
SI within 90 FDA days	15				
SI over 90 FDA days	1				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	94%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	16				
Average number of FDA days to Substantive Interaction	89				
20th Percentile FDA days to Substantive Interaction	84				
40th Percentile FDA days to Substantive Interaction	89				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	117				

Table 1.5.DCD DCD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	15				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
PMAs pending MDUFA III Decision	14				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6.DCD DCD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	3				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	180				
20th Percentile FDA days to MDUFA III decision	180				
40th Percentile FDA days to MDUFA III decision	180				
60th Percentile FDA days to MDUFA III decision	180				
80th Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	180				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	180				
20th Percentile Total days to MDUFA III decision	180				
40th Percentile Total days to MDUFA III decision	180				
60th Percentile Total days to MDUFA III decision	180				
80th Percentile Total days to MDUFA III decision	180				
Maximum Total days to MDUFA III decision	180				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	15				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DCD DCD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DNPMD DNPMD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of submissions not accepted for filing review	100%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2. DNPMD DNPMD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1				
Number Accepted[#]	0				
Completed RTF	1				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3. DNPMD DNPMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	1				
SI within 90 FDA days	0				
SI over 90 FDA days	1				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	0%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1				
Average number of FDA days to Substantive Interaction	92				
20th Percentile FDA days to Substantive Interaction	92				
40th Percentile FDA days to Substantive Interaction	92				
60th Percentile FDA days to Substantive Interaction	92				
80th Percentile FDA days to Substantive Interaction	92				
Maximum FDA days to Substantive Interaction	92				

Table 1.5. DNPMD DNPMD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6. DNPMD DNPMD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11. DNPMD DNPMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DOD DOD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	n/a				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DOD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DOD DOD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DOD DOD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	2				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2				
Average number of FDA days to Substantive Interaction	86				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	86				
60th Percentile FDA days to Substantive Interaction	86				
80th Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	86				

Table 1.5.DOD DOD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	2				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.DOD DOD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DOD DOD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DOED DOED – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5				
Closed before RTA action	0				
Number with accepted RTA review	4				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of submissions not accepted for filing review	20%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DOED for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DOED DOED – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6				
Number Accepted[#]	5				
Completed RTF	6				
Number Not Filed[@]	1				
Rate of submissions Not Filed	17%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

Table 1.3.DOED DOED – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	6				
SI within 90 FDA days	4				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	4				
Average number of FDA days to Substantive Interaction	88				
20th Percentile FDA days to Substantive Interaction	87				
40th Percentile FDA days to Substantive Interaction	88				
60th Percentile FDA days to Substantive Interaction	89				
80th Percentile FDA days to Substantive Interaction	89				
Maximum FDA days to Substantive Interaction	90				

Table 1.5.DOED DOED - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	5				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
PMAs pending MDUFA III Decision	4				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6.DOED DOED – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	177				
20th Percentile FDA days to MDUFA III decision	177				
40th Percentile FDA days to MDUFA III decision	177				
60th Percentile FDA days to MDUFA III decision	177				
80th Percentile FDA days to MDUFA III decision	177				
Maximum FDA days to MDUFA III decision	177				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	177				
20th Percentile Total days to MDUFA III decision	177				
40th Percentile Total days to MDUFA III decision	177				
60th Percentile Total days to MDUFA III decision	177				
80th Percentile Total days to MDUFA III decision	177				
Maximum Total days to MDUFA III decision	177				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	5				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DOED DOED – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DOED DOED – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DRGUD DRGUD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4				
Closed before RTA action	0				
Number with accepted RTA review	1				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	3				
Rate of submissions not accepted for filing review	75%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DRGUD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DRGUD DRGUD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4				
Number Accepted[#]	1				
Completed RTF[@]	4				
Number Not Filed	2				
Rate of submissions Not Filed	50%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

Table 1.3.DRGUD DRGUD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	3				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2				
Average number of FDA days to Substantive Interaction	89				
20th Percentile FDA days to Substantive Interaction	88				
40th Percentile FDA days to Substantive Interaction	89				
60th Percentile FDA days to Substantive Interaction	89				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

Table 1.5.DRGUD DRGUD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	3				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.DRGUD DRGUD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DRGUD DRGUD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DRGUD DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

There were no PMA Original or Panel Track Supplements received by DSD between October 1, 2012 and September 30, 2013.

Table 1.1.DCTD DCTD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Closed before RTA action	0				
Number with accepted RTA review	2				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DCTD DCTD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DCTD DCTD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	2				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2				
Average number of FDA days to Substantive Interaction	90				
20th Percentile FDA days to Substantive Interaction	90				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

Table 1.5.DCTD DCTD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	2				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.DCTD DCTD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DCTD DCTD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DCTD DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DIHD DIHD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Closed before RTA action	0				
Number with accepted RTA review	2				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DIHD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DIHD DIHD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4				
Number Accepted[#]	4				
Completed RTF	4				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DIHD DIHD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	4				
SI within 90 FDA days	4*				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%*				

* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	4				
Average number of FDA days to Substantive Interaction	95				
20th Percentile FDA days to Substantive Interaction	90				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	99				
Maximum FDA days to Substantive Interaction	112				

Table 1.5.DIHD DIHD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	2				
MDUFA III Decisions within 180 FDA Days	2				
PMAs pending MDUFA III Decision	2				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 1.6.DIHD DIHD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	2				
Average FDA days to MDUFA III decision	108				
20th Percentile FDA days to MDUFA III decision	102				
40th Percentile FDA days to MDUFA III decision	106				
60th Percentile FDA days to MDUFA III decision	109				
80th Percentile FDA days to MDUFA III decision	113				
Maximum FDA days to MDUFA III decision	116				
Average Industry days to MDUFA III decision	95				
20th Percentile Industry days to MDUFA III decision	80				
40th Percentile Industry days to MDUFA III decision	90				
60th Percentile Industry days to MDUFA III decision	99				
80th Percentile Industry days to MDUFA III decision	109				
Maximum Industry days to MDUFA III decision	118				
Average Total days to MDUFA III decision	202				
20th Percentile Total days to MDUFA III decision	193				
40th Percentile Total days to MDUFA III decision	199				
60th Percentile Total days to MDUFA III decision	205				
80th Percentile Total days to MDUFA III decision	211				
Maximum Total days to MDUFA III decision	217				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4				
Number with MDUFA decision	2				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DIHD DIHD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DMD DMD – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Closed before RTA action	0				
Number with accepted RTA review	2				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DMD DMD – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DMD DMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	2				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 1.4.DRH DMD – DMD Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2				
Average number of FDA days to Substantive Interaction	86				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	86				
60th Percentile FDA days to Substantive Interaction	86				
80th Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	86				

Table 1.5.DMD DMD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.DMD DMD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11. DMD DMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.1.DRH DRH – PMA Original and Panel Track Supplements – Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1				
Closed before RTA action	0				
Number with accepted RTA review	1				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.**

Table 1.2.DRH DRH – PMA Original and Panel Track Supplements – Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DRH DRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	2				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1				
Average number of FDA days to Substantive Interaction	65				
20th Percentile FDA days to Substantive Interaction	65				
40th Percentile FDA days to Substantive Interaction	65				
60th Percentile FDA days to Substantive Interaction	65				
80th Percentile FDA days to Substantive Interaction	65				
Maximum FDA days to Substantive Interaction	65				

Table 1.5.DRH DRH - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.DRH DRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 320 FDA Days	1				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	206				
20th Percentile FDA days to MDUFA III decision	206				
40th Percentile FDA days to MDUFA III decision	206				
60th Percentile FDA days to MDUFA III decision	206				
80th Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	O				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	206				
20th Percentile Total days to MDUFA III decision	206				
40th Percentile Total days to MDUFA III decision	206				
60th Percentile Total days to MDUFA III decision	206				
80th Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0%				
Rate of Not Approvable	0%				

Table 1.11.DRH DRH – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 1.12.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Section 2 PMA 180 Day Supplements

PMA 180 Day Supplements – Center Level

Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	181^				
SI within 90 FDA days	133				
SI over 90 FDA days	10				
SI pending within 90 FDA days	35				
SI pending over 90 FDA days	0				
Closed without SI	3^				
Current SI Performance Percent within 90 FDA days	93%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.2 CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	181^				
Non-MDUFA III Decisions	4				
MDUFA III Decisions	99				
MDUFA III Decisions within 180 FDA Days	98				
Supplements pending MDUFA III Decision	79				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	98%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.3 CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	181^				
Number with MDUFA decision	99				
Number of Not Approvable	3				
Rate of Not Approvable	3%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.4 CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

PMA 180 Day Supplements – Office Level

Table 2.1.ODE ODE – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	160^				
SI within 90 FDA days	119				
SI over 90 FDA days	10				
SI pending within 90 FDA days	28				
SI pending over 90 FDA days	0				
Closed without SI	3^				
Current SI Performance Percent within 90 FDA days	93%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.2.ODE ODE – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	160^				
Non-MDUFA III Decisions	4				
MDUFA III Decisions	88				
MDUFA III Decisions within 180 FDA Days	87				
Supplements pending MDUFA III Decision	69				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	98%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.3.ODE ODE – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	160^				
Number with MDUFA decision	88				
Number of Not Approvable	3				
Rate of Not Approvable	3%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.4.ODE ODE – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

Table 2.1.OIR OIR – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	21				
SI within 90 FDA days	14				
SI over 90 FDA days	0				
SI pending within 90 FDA days	7				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.OIR OIR – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	21				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	11				
MDUFA III Decisions within 180 FDA Days	11				
Supplements pending MDUFA III Decision	10				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.OIR OIR – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	21				
Number with MDUFA decision	11				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.OIR OIR – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

PMA 180 Day Supplements – Division Level

Table 2.1.DAGRID DAGRID – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	9				
SI within 90 FDA days	6				
SI over 90 FDA days	2				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	75%				

Table 2.2.DAGRID DAGRID – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	9				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 180 FDA Days	3				
Supplements pending MDUFA III Decision	6				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DAGRID DAGRID – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	9				
Number with MDUFA decision	3				
Number of Not Approvable	1				
Rate of Not Approvable	33%				

Table 2.4.DAGRID DAGRID – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DCD DCD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	116^				
SI within 90 FDA days	88				
SI over 90 FDA days	5				
SI pending within 90 FDA days	20				
SI pending over 90 FDA days	0				
Closed without SI	3^				
Current SI Performance Percent within 90 FDA days	95%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.2.DCD DCD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	116^				
Non-MDUFA III Decisions	3				
MDUFA III Decisions	70				
MDUFA III Decisions within 180 FDA Days	69				
Supplements pending MDUFA III Decision	43				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	99%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.3.DCD DCD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	116^				
Number with MDUFA decision	70				
Number of Not Approvable	1				
Rate of Not Approvable	1%				

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.4.DCD DCD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

Table 2.1.DNPMD DNPMD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	7				
SI within 90 FDA days	5				
SI over 90 FDA days	1				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	83%				

Table 2.2.DNPMD DNPMD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	7				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DNPMD DNPMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7				
Number with MDUFA decision	4				
Number of Not Approvable	1				
Rate of Not Approvable	25%				

Table 2.4.DNPMD DNPMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DOD DOD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	2				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DOD DOD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 2.3.DOD DOD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

Table 2.4.DOD DOD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DOED DOED – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	12				
SI within 90 FDA days	8				
SI over 90 FDA days	1				
SI pending within 90 FDA days	3				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	89%				

Table 2.2.DOED DOED – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	12				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
Supplements pending MDUFA III Decision	9				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DOED DOED – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12				
Number with MDUFA decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.DOED DOED – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DRGUD DRGUD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	10				
SI within 90 FDA days	7				
SI over 90 FDA days	0				
SI pending within 90 FDA days	3				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DRGUD DRGUD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	10				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	5				
MDUFA III Decisions within 180 FDA Days	5				
Supplements pending MDUFA III Decision	5				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DRGUD DRGUD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10				
Number with MDUFA decision	5				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.DRGUD DRGUD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DSD DSD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	4				
SI within 90 FDA days	3				
SI over 90 FDA days	1				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	75%				

Table 2.2.DSD DSD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	2				
MDUFA III Decisions within 180 FDA Days	2				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DSD DSD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4				
Number with MDUFA decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.DSD DSD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DCTD DCTD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	3				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DCTD DCTD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 2.3.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

Table 2.4.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DIHD DIHD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	6				
SI within 90 FDA days	4				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DIHD DIHD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	6				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6				
Number with MDUFA decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DMD DMD – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	7				
SI within 90 FDA days	5				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DMD DMD – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	7				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DMD DMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7				
Number with MDUFA decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.DMD DMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 2.1.DRH DRH – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	5				
SI within 90 FDA days	4				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DRH DRH – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	5				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 180 FDA Days	3				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 2.3.DRH DRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5				
Number with MDUFA decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 2.4.DRH DRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Section 3 PMA Real Time Supplements

PMA Real Time Supplements – Center Level

Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	304				
Non-MDUFA III Decisions	8				
MDUFA III Decisions	258				
MDUFA III Decisions within 90 FDA Days	257				
Supplements pending MDUFA III Decision	38				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99.6%				

Table 3.2 CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	304				
Number with MDUFA decision	258				
Number of Not Approvable	17				
Rate of Not Approvable	7%				

Table 3.3 CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	0				

PMA Real Time Supplements – Office Level

Table 3.1.ODE ODE – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	265				
Non-MDUFA III Decisions	7				
MDUFA III Decisions	220				
MDUFA III Decisions within 90 FDA Days	219				
Supplements pending MDUFA III Decision	38				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99.5%				

Table 3.2.ODE ODE – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	265				
Number with MDUFA decision	220				
Number of Not Approvable	12				
Rate of Not Approvable	6%				

Table 3.3.ODE ODE – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	0				

Table 3.1.OIR OIR – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	39				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	38				
MDUFA III Decisions within 90 FDA Days	38				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.OIR OIR – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	39				
Number with MDUFA decision	38				
Number of Not Approvable	5				
Rate of Not Approvable	13%				

Table 3.3.OIR OIR – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

PMA Real Time Supplements – Division Level

Table 3.1.DAGRID DAGRID – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	13				
MDUFA III Decisions within 90 FDA Days	13				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DAGRID DAGRID – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13				
Number with MDUFA decision	13				
Number of Not Approvable	1				
Rate of Not Approvable	8%				

Table 3.3.DAGRID DAGRID – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DCD DCD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	174				
Non-MDUFA III Decisions	5				
MDUFA III Decisions	147				
MDUFA III Decisions within 90 FDA Days	147				
Supplements pending MDUFA III Decision	22				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DCD DCD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	174				
Number with MDUFA decision	147				
Number of Not Approvable	5				
Rate of Not Approvable	3%				

Table 3.3.DCD DCD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DNPMD DNPMD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	23				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	22				
MDUFA III Decisions within 90 FDA Days	22				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DNPMD DNPMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	23				
Number with MDUFA decision	22				
Number of Not Approvable	1				
Rate of Not Approvable	5%				

Table 3.3.DNPMD DNPMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DOD DOD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	7				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 90 FDA Days	3				
Supplements pending MDUFA III Decision	4				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DOD DOD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7				
Number with MDUFA decision	3				
Number of Not Approvable	1				
Rate of Not Approvable	33%				

Table 3.3.DOD DOD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DOED DOED – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	16				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	11				
MDUFA III Decisions within 90 FDA Days	11				
Supplements pending MDUFA III Decision	5				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DOED DOED – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	16				
Number with MDUFA decision	11				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.DOED DOED – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DRGUD DRGUD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	19				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	15				
MDUFA III Decisions within 90 FDA Days	15				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DRGUD DRGUD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	19				
Number with MDUFA decision	15				
Number of Not Approvable	1				
Rate of Not Approvable	7%				

Table 3.3.DRGUD DRGUD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0%				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DSD DSD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	9				
MDUFA III Decisions within 90 FDA Days	8				
Supplements pending MDUFA III Decision	4				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	89%				

Table 3.2.DSD DSD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13				
Number with MDUFA decision	9				
Number of Not Approvable	3				
Rate of Not Approvable	33%				

Table 3.3.DSD DSD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	0				

Table 3.1.DCTD DCTD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	6				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	6				
MDUFA III Decisions within 90 FDA Days	6				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6				
Number with MDUFA decision	6				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DIHD DIHD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	20				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	19				
MDUFA III Decisions within 90 FDA Days	19				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	20				
Number with MDUFA decision	19				
Number of Not Approvable	2				
Rate of Not Approvable	10%				

Table 3.3.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DMD DMD – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	13				
MDUFA III Decisions within 90 FDA Days	13				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.DMD DMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	13				
Number with MDUFA decision	13				
Number of Not Approvable	3				
Rate of Not Approvable	23%				

Table 3.3.DMD DMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

There were no PMA 180 Day Supplements received by DRH between October 1, 2012 and September 30, 2013.

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2012 and September 30, 2013.

Section 5 PMA Annual Metrics and Goals

PMA Annual Metrics and Goals – Center Level

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

PMA Submissions Received	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Premarket Report Submissions	0				
Original PMAs (Panel) – Priority	1				
Original PMAs (No Panel) – Priority	3				
Original PMAs (Panel) – Non-Priority	1				
Original PMAs (No Panel) – Non-Priority	24				
Panel Track Supplements (Panel) – Priority	2				
Panel Track Supplements (No Panel) – Priority	0				
Panel Track Supplements (Panel) – Non-Priority	2				
Panel Track Supplements (No Panel) – Non-Priority	11				
PMA Modules	52				
180-Day Supplements	182				
Real-Time Supplements	304				

Table 5.2 CDRH – PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Percent Cohorts Closed

Performance Metric	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	51	34	42				
Number with a decision (MDUFA or Non-MDUFA)	49	32	5				
% of FY closed	96%	94%	12%				

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

Performance Metric	FY 2013 3 year cohort 395 days	FY 2014 3 year cohort 395 days	FY 2015 3 year cohort 390 days	FY 2016 3 year cohort 390 days	FY 2017 3 year cohort 385 days
Number with a MDUFA decision	86				
Number with a MDUFA decision after trimming the upper and lower 5%	78				
Three-year Rolling Average Total Time to MDUFA decision	NA				

Section 6 510(k) MDUFA III Performance

510(k) MDUFA III Performance – Center Level

Table 6.1 CDRH – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2958				
Closed before RTA action	12				
Number Accepted	1091				
RTA Review not done and > 15 days since Date Received	42				
RTA Review not done and <= 15 days since Date Received	196				
Number Not Accepted	1617				
Rate of submissions not accepted	59%				

*** RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2 CDRH – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	3230				
Deleted or withdrawn prior to SI	10				
SI within 60 FDA days	2599				
SI over 60 FDA days	159				
SI pending within 60 FDA days	456				
SI pending over 60 FDA days	2				
510(k)s NSE without SI	4				
Current SI Performance Percent within 60 FDA days	94%				

Table 6.3 CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2758				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	45				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	98				

Table 6.4 CDRH – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	3358				
Non-MDUFA III Decisions	167				
MDUFA III Decisions (SE/NSE)	1873				
MDUFA III Decisions within 90 FDA Days	1859				
510(k)s pending MDUFA III Decision	1318				
510(k) pending MDUFA III Decision over 90 FDA days	11				
Current Performance Percent within 90 FDA Days	99%				

Table 6.5 CDRH – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.58				
Number with MDUFA decision	1873				
Average FDA days to MDUFA III decision	63				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	81				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	31				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	21				
80th Percentile Industry days to MDUFA III decision	57				
Maximum Industry days to MDUFA III decision	251				
Average Total days to MDUFA III decision	94				
20th Percentile Total days to MDUFA III decision	31				
40th Percentile Total days to MDUFA III decision	70				
60th Percentile Total days to MDUFA III decision	96				
80th Percentile Total days to MDUFA III decision	136				
Maximum Total days to MDUFA III decision	334				

Table 6.6 CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3358				
Number with MDUFA decision	1873				
Number of SE decisions	1826				
Number of NSE decisions	47				
Number of Withdrawals	89				
Number deleted	62				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	3%				
Rate of Deleted	2%				

Table 6.7 CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	14				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	86				

510(k) MDUFA III Performance – Office Level

Table 6.1.ODE ODE – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2381				
Closed before RTA action	10				
Number Accepted	749				
RTA Review not done and > 15 days since Date Received	24				
RTA Review not done and <= 15 days since Date Received	149				
Number Not Accepted	1449				
Rate of submissions not accepted	65%				

*** RTA was not in place 1st quarter, thus Table 6.1.ODE for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.ODE ODE – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	2548				
Deleted or withdrawn prior to SI	9				
SI within 60 FDA days	2030				
SI over 60 FDA days	119				
SI pending within 60 FDA days	384				
SI pending over 60 FDA days	2				
510(k)s NSE without SI	4				
Current SI Performance Percent within 60 FDA days	94%				

Table 6.3.ODE ODE – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2149				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	46				
60th Percentile FDA days to Substantive Interaction	55				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	98				

Table 6.4.ODE ODE – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	2622				
Non-MDUFA III Decisions	136				
MDUFA III Decisions (SE/NSE)	1414				
MDUFA III Decisions within 90 FDA Days	1404				
510(k)s pending MDUFA III Decision	1072				
510(k) pending MDUFA III Decision over 90 FDA days	11				
Current Performance Percent within 90 FDA Days	99%				

Table 6.5.ODE ODE – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.61				
Number with MDUFA decision	1414				
Average FDA days to MDUFA III decision	65				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	59				
60th Percentile FDA days to MDUFA III decision	83				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	32				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	24				
80th Percentile Industry days to MDUFA III decision	57				
Maximum Industry days to MDUFA III decision	251				
Average Total days to MDUFA III decision	96				
20th Percentile Total days to MDUFA III decision	36				
40th Percentile Total days to MDUFA III decision	73				
60th Percentile Total days to MDUFA III decision	101				
80th Percentile Total days to MDUFA III decision	137				
Maximum Total days to MDUFA III decision	334				

Table 6.6.ODE ODE – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	2622				
Number with MDUFA decision	1414				
Number of SE decisions	1373				
Number of NSE decisions	41				
Number of Withdrawals	73				
Number deleted	49				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	3%				
Rate of Deleted	2%				

Table 6.7.ODE ODE – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	10				
Mean FDA days for submissions that missed goal	96				
Mean Industry days for submissions that missed goal	83				

Table 6.1.OIR OIR – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	577				
Closed before RTA action	2				
Number Accepted	342				
RTA Review not done and > 15 days since Date Received	18				
RTA Review not done and <= 15 days since Date Received	47				
Number Not Accepted	168				
Rate of submissions not accepted	32%				

*** RTA was not in place 1st quarter, thus Table 6.1.OIR for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

.

Table 6.2.OIR OIR – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	682				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	569				
SI over 60 FDA days	40				
SI pending within 60 FDA days	72				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	93%				

Table 6.3.OIR OIR – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	609				
Average number of FDA days to Substantive Interaction	44				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	51				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	91				

Table 6.4.OIR OIR – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	736				
Non-MDUFA III Decisions	31				
MDUFA III Decisions (SE/NSE)	459				
MDUFA III Decisions within 90 FDA Days	455				
510(k)s pending MDUFA III Decision	246				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

Table 6.5.OIR OIR – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.47				
Number with MDUFA decision	459				
Average FDA days to MDUFA III decision	57				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	45				
60th Percentile FDA days to MDUFA III decision	72				
80th Percentile FDA days to MDUFA III decision	85				
Maximum FDA days to MDUFA III decision	109				
Average Industry days to MDUFA III decision	29				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	9				
80th Percentile Industry days to MDUFA III decision	56				
Maximum Industry days to MDUFA III decision	205				
Average Total days to MDUFA III decision	86				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	53				
60th Percentile Total days to MDUFA III decision	84				
80th Percentile Total days to MDUFA III decision	131				
Maximum Total days to MDUFA III decision	294				

Table 6.6.OIR OIR – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	736				
Number with MDUFA decision	459				
Number of SE decisions	453				
Number of NSE decisions	6				
Number of Withdrawals	16				
Number deleted	13				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	2%				
Rate of Deleted	2%				

Table 6.7.OIR OIR – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	93				

510(k) MDUFA III Performance – Division Level

Table 6.1.DAGRID DAGRID – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	635				
Closed before RTA action	6				
Number Accepted	168				
RTA Review not done and > 15 days since Date Received	5				
RTA Review not done and <= 15 days since Date Received	41				
Number Not Accepted	415				
Rate of submissions not accepted	71%				

*** RTA was not in place 1st quarter, thus Table 6.1.DAGRID for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DAGRID DAGRID – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	636				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	511				
SI over 60 FDA days	17				
SI pending within 60 FDA days	106				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	2				
Current SI Performance Percent within 60 FDA days	96%				

Table 6.3.DAGRID DAGRID – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	528				
Average number of FDA days to Substantive Interaction	49				
20th Percentile FDA days to Substantive Interaction	32				
40th Percentile FDA days to Substantive Interaction	51				
60th Percentile FDA days to Substantive Interaction	58				
80th Percentile FDA days to Substantive Interaction	60				
Maximum FDA days to Substantive Interaction	90				

Table 6.4.DAGRID DAGRID – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	651				
Non-MDUFA III Decisions	41				
MDUFA III Decisions (SE/NSE)	304				
MDUFA III Decisions within 90 FDA Days	301				
510(k)s pending MDUFA III Decision	306				
510(k) pending MDUFA III Decision over 90 FDA days	4				
Current Performance Percent within 90 FDA Days	98%				

Table 6.5.DAGRID DAGRID – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.63				
Number with MDUFA decision	304				
Average FDA days to MDUFA III decision	70				
20th Percentile FDA days to MDUFA III decision	52				
40th Percentile FDA days to MDUFA III decision	74				
60th Percentile FDA days to MDUFA III decision	85				
80th Percentile FDA days to MDUFA III decision	89				
Maximum FDA days to MDUFA III decision	95				
Average Industry days to MDUFA III decision	37				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	26				
80th Percentile Industry days to MDUFA III decision	65				
Maximum Industry days to MDUFA III decision	251				
Average Total days to MDUFA III decision	107				
20th Percentile Total days to MDUFA III decision	57				
40th Percentile Total days to MDUFA III decision	85				
60th Percentile Total days to MDUFA III decision	108				
80th Percentile Total days to MDUFA III decision	145				
Maximum Total days to MDUFA III decision	334				

Table 6.6.DAGRID DAGRID – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	651				
Number with MDUFA decision	304				
Number of SE decisions	295				
Number of NSE decisions	9				
Number of Withdrawals	19				
Number deleted	18				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	3%				
Rate of Deleted	3%				

Table 6.7.DAGRID DAGRID – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3				
Mean FDA days for submissions that missed goal	93				
Mean Industry days for submissions that missed goal	99				

Table 6.1.DCD DCD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	334				
Closed before RTA action	0				
Number Accepted	143				
RTA Review not done and > 15 days since Date Received	10				
RTA Review not done and <= 15 days since Date Received	21				
Number Not Accepted	160				
Rate of submissions not accepted	51%				

*** RTA was not in place 1st quarter, thus Table 6.1.DCD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DCD DCD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	389				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	310				
SI over 60 FDA days	34				
SI pending within 60 FDA days	43				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	1				
Current SI Performance Percent within 60 FDA days	90%				

Table 6.3.DCD DCD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	344				
Average number of FDA days to Substantive Interaction	44				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	41				
60th Percentile FDA days to Substantive Interaction	50				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	98				

Table 6.4.DCD DCD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	413				
Non-MDUFA III Decisions	5				
MDUFA III Decisions (SE/NSE)	277				
MDUFA III Decisions within 90 FDA Days	273				
510(k)s pending MDUFA III Decision	131				
510(k) pending MDUFA III Decision over 90 FDA days	3				
Current Performance Percent within 90 FDA Days	98%				

Table 6.5.DCD DCD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.57				
Number with MDUFA decision	277				
Average FDA days to MDUFA III decision	59				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	50				
60th Percentile FDA days to MDUFA III decision	76				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	25				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	20				
80th Percentile Industry days to MDUFA III decision	42				
Maximum Industry days to MDUFA III decision	187				
Average Total days to MDUFA III decision	84				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	57				
60th Percentile Total days to MDUFA III decision	90				
80th Percentile Total days to MDUFA III decision	127				
Maximum Total days to MDUFA III decision	273				

Table 6.6.DCD DCD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	413				
Number with MDUFA decision	277				
Number of SE decisions	272				
Number of NSE decisions	5				
Number of Withdrawals	2				
Number deleted	3				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	0.5%				
Rate of Deleted	0.7%				

Table 6.7.DCD DCD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	58				

Table 6.1.DNPMD DNPMD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	191				
Closed before RTA action	0				
Number Accepted	36				
RTA Review not done and > 15 days since Date Received	1				
RTA Review not done and <= 15 days since Date Received	16				
Number Not Accepted	138				
Rate of submissions not accepted	79%				

*** RTA was not in place 1st quarter, thus Table 6.1.DNPMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DNPMD DNPMD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	181				
Deleted or withdrawn prior to SI	2				
SI within 60 FDA days	133				
SI over 60 FDA days	14				
SI pending within 60 FDA days	31				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	90%				

Table 6.3.DNPMD DNPMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	147				
Average number of FDA days to Substantive Interaction	49				
20th Percentile FDA days to Substantive Interaction	33				
40th Percentile FDA days to Substantive Interaction	49				
60th Percentile FDA days to Substantive Interaction	57				
80th Percentile FDA days to Substantive Interaction	60				
Maximum FDA days to Substantive Interaction	80				

Table 6.4.DNPMD DNPMD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	187				
Non-MDUFA III Decisions	13				
MDUFA III Decisions (SE/NSE)	86				
MDUFA III Decisions within 90 FDA Days	85				
510(k)s pending MDUFA III Decision	88				
510(k) pending MDUFA III Decision over 90 FDA days	2				
Current Performance Percent within 90 FDA Days	97%				

Table 6.5.DNPMD DNPMD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.79				
Number with MDUFA decision	86				
Average FDA days to MDUFA III decision	80				
20th Percentile FDA days to MDUFA III decision	67				
40th Percentile FDA days to MDUFA III decision	88				
60th Percentile FDA days to MDUFA III decision	89				
80th Percentile FDA days to MDUFA III decision	90				
Maximum FDA days to MDUFA III decision	92				
Average Industry days to MDUFA III decision	53				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	19				
60th Percentile Industry days to MDUFA III decision	44				
80th Percentile Industry days to MDUFA III decision	94				
Maximum Industry days to MDUFA III decision	180				
Average Total days to MDUFA III decision	133				
20th Percentile Total days to MDUFA III decision	87				
40th Percentile Total days to MDUFA III decision	103				
60th Percentile Total days to MDUFA III decision	131				
80th Percentile Total days to MDUFA III decision	183				
Maximum Total days to MDUFA III decision	270				

Table 6.6.DNPMD DNPMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	187				
Number with MDUFA decision	86				
Number of SE decisions	80				
Number of NSE decisions	6				
Number of Withdrawals	8				
Number deleted	2				
Rate of SE decisions	93%				
Rate of NSE decisions	7%				
Rate of Withdrawals	4%				
Rate of Deleted	1%				

Table 6.7.DNPMD DNPMD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	92				
Mean Industry days for submissions that missed goal	82				

Table 6.1.DOD DOD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	520				
Closed before RTA action	0				
Number Accepted	167				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	32				
Number Not Accepted	321				
Rate of submissions not accepted	66%				

*** RTA was not in place 1st quarter, thus Table 6.1.DOD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DOD DOD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	585				
Deleted or withdrawn prior to SI	3				
SI within 60 FDA days	485				
SI over 60 FDA days	18				
SI pending within 60 FDA days	78				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	96%				

Table 6.3.DOD DOD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	503				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	45				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	88				

Table 6.4.DOD DOD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	586				
Non-MDUFA III Decisions	25				
MDUFA III Decisions (SE/NSE)	352				
MDUFA III Decisions within 90 FDA Days	351				
510(k)s pending MDUFA III Decision	209				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99.7%				

Table 6.5.DOD DOD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.51				
Number with MDUFA decision	352				
Average FDA days to MDUFA III decision	64				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	59				
60th Percentile FDA days to MDUFA III decision	80				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	100				
Average Industry days to MDUFA III decision	23				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	14				
80th Percentile Industry days to MDUFA III decision	44				
Maximum Industry days to MDUFA III decision	180				
Average Total days to MDUFA III decision	87				
20th Percentile Total days to MDUFA III decision	34				
40th Percentile Total days to MDUFA III decision	69				
60th Percentile Total days to MDUFA III decision	92				
80th Percentile Total days to MDUFA III decision	126				
Maximum Total days to MDUFA III decision	268				

Table 6.6.DOD DOD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	586				
Number with MDUFA decision	352				
Number of SE decisions	343				
Number of NSE decisions	9				
Number of Withdrawals	17				
Number deleted	7				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	3%				
Rate of Deleted	1%				

Table 6.7.DOD DOD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	65				

Table 6.1.DOED DOED – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	117				
Closed before RTA action	0				
Number Accepted	50				
RTA Review not done and > 15 days since Date Received	5				
RTA Review not done and <= 15 days since Date Received	11				
Number Not Accepted	51				
Rate of submissions not accepted	48%				

*** RTA was not in place 1st quarter, thus Table 6.1.DOED for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DOED DOED – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	120				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	93				
SI over 60 FDA days	3				
SI pending within 60 FDA days	24				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	97%				

Table 6.3.DOED DOED – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	96				
Average number of FDA days to Substantive Interaction	47				
20th Percentile FDA days to Substantive Interaction	42				
40th Percentile FDA days to Substantive Interaction	47				
60th Percentile FDA days to Substantive Interaction	50				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	88				

Table 6.4.DOED DOED – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	127				
Non-MDUFA III Decisions	5				
MDUFA III Decisions (SE/NSE)	58				
MDUFA III Decisions within 90 FDA Days	57				
510(k)s pending MDUFA III Decision	64				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	98%				

Table 6.5.DOED DOED – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.79				
Number with MDUFA decision	58				
Average FDA days to MDUFA III decision	69				
20th Percentile FDA days to MDUFA III decision	47				
40th Percentile FDA days to MDUFA III decision	62				
60th Percentile FDA days to MDUFA III decision	87				
80th Percentile FDA days to MDUFA III decision	89				
Maximum FDA days to MDUFA III decision	91				
Average Industry days to MDUFA III decision	35				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	7				
60th Percentile Industry days to MDUFA III decision	30				
80th Percentile Industry days to MDUFA III decision	69				
Maximum Industry days to MDUFA III decision	182				
Average Total days to MDUFA III decision	104				
20th Percentile Total days to MDUFA III decision	54				
40th Percentile Total days to MDUFA III decision	89				
60th Percentile Total days to MDUFA III decision	116				
80th Percentile Total days to MDUFA III decision	138				
Maximum Total days to MDUFA III decision	272				

Table 6.6.DOED DOED – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	127				
Number with MDUFA decision	58				
Number of SE decisions	57				
Number of NSE decisions	1				
Number of Withdrawals	2				
Number deleted	2				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	2%				
Rate of Deleted	2%				

Table 6.7.DOED DOED – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	91				
Mean Industry days for submissions that missed goal	153				

Table 6.1.DRGUD DRGUD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	210				
Closed before RTA action	1				
Number Accepted	60				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	7				
Number Not Accepted	142				
Rate of submissions not accepted	70%				

*** RTA was not in place 1st quarter, thus Table 6.1.DRGUD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DRGUD DRGUD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	225				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	188				
SI over 60 FDA days	5				
SI pending within 60 FDA days	30				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	1				
Current SI Performance Percent within 60 FDA days	97%				

Table 6.3.DRGUD DRGUD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	193				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	48				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	63				

Table 6.4.DRGUD DRGUD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	238				
Non-MDUFA III Decisions	17				
MDUFA III Decisions (SE/NSE)	123				
MDUFA III Decisions within 90 FDA Days	123				
510(k)s pending MDUFA III Decision	98				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 6.5.DRGUD DRGUD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.78				
Number with MDUFA decision	123				
Average FDA days to MDUFA III decision	65				
20th Percentile FDA days to MDUFA III decision	31				
40th Percentile FDA days to MDUFA III decision	61				
60th Percentile FDA days to MDUFA III decision	83				
80th Percentile FDA days to MDUFA III decision	87				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	41				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	11				
60th Percentile Industry days to MDUFA III decision	36				
80th Percentile Industry days to MDUFA III decision	80				
Maximum Industry days to MDUFA III decision	200				
Average Total days to MDUFA III decision	106				
20th Percentile Total days to MDUFA III decision	46				
40th Percentile Total days to MDUFA III decision	84				
60th Percentile Total days to MDUFA III decision	114				
80th Percentile Total days to MDUFA III decision	156				
Maximum Total days to MDUFA III decision	290				

Table 6.6.DRGUD DRGUD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	238				
Number with MDUFA decision	123				
Number of SE decisions	115				
Number of NSE decisions	8				
Number of Withdrawals	9				
Number deleted	7				
Rate of SE decisions	93%				
Rate of NSE decisions	7%				
Rate of Withdrawals	4%				
Rate of Deleted	3%				

Table 6.7.DRGUD DRGUD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 6.1.DSD DSD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	374				
Closed before RTA action	3				
Number Accepted	125				
RTA Review not done and > 15 days since Date Received	3				
RTA Review not done and <= 15 days since Date Received	21				
Number Not Accepted	222				
Rate of submissions not accepted	63%				

*** RTA was not in place 1st quarter, thus Table 6.1.DSD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DSD DSD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	412				
Deleted or withdrawn prior to SI	2				
SI within 60 FDA days	310				
SI over 60 FDA days	28				
SI pending within 60 FDA days	72				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	92%				

Table 6.3.DSD DSD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	338				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	24				
40th Percentile FDA days to Substantive Interaction	35				
60th Percentile FDA days to Substantive Interaction	51				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	90				

Table 6.4.DSD DSD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	420				
Non-MDUFA III Decisions	30				
MDUFA III Decisions (SE/NSE)	214				
MDUFA III Decisions within 90 FDA Days	214				
510(k)s pending MDUFA III Decision	176				
510(k) pending MDUFA III Decision over 90 FDA days	2				
Current Performance Percent within 90 FDA Days	99%				

Table 6.5.DSD DSD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.60				
Number with MDUFA decision	214				
Average FDA days to MDUFA III decision	58				
20th Percentile FDA days to MDUFA III decision	27				
40th Percentile FDA days to MDUFA III decision	50				
60th Percentile FDA days to MDUFA III decision	72				
80th Percentile FDA days to MDUFA III decision	86				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	31				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	22				
80th Percentile Industry days to MDUFA III decision	51				
Maximum Industry days to MDUFA III decision	206				
Average Total days to MDUFA III decision	89				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	61				
60th Percentile Total days to MDUFA III decision	92				
80th Percentile Total days to MDUFA III decision	129				
Maximum Total days to MDUFA III decision	292				

Table 6.6.DSD DSD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	420				
Number with MDUFA decision	214				
Number of SE decisions	211				
Number of NSE decisions	3				
Number of Withdrawals	16				
Number deleted	10				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	4%				
Rate of Deleted	2%				

Table 6.7.DSD DSD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 6.1.DCTD DCTD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	188				
Closed before RTA action	1				
Number Accepted	110				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	11				
Number Not Accepted	66				
Rate of submissions not accepted	38%				

*** RTA was not in place 1st quarter, thus Table 6.1.DCTD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DCTD DCTD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	225				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	203				
SI over 60 FDA days	0				
SI pending within 60 FDA days	22				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	100%				

Table 6.3.DCTD DCTD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	203				
Average number of FDA days to Substantive Interaction	40				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	38				
60th Percentile FDA days to Substantive Interaction	45				
80th Percentile FDA days to Substantive Interaction	52				
Maximum FDA days to Substantive Interaction	60				

Table 6.4.DCTD DCTD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	225				
Non-MDUFA III Decisions	11				
MDUFA III Decisions (SE/NSE)	119				
MDUFA III Decisions within 90 FDA Days	118				
510(k)s pending MDUFA III Decision	95				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

Table 6.5.DCTD DCTD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.55				
Number with MDUFA decision	119				
Average FDA days to MDUFA III decision	57				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	41				
60th Percentile FDA days to MDUFA III decision	75				
80th Percentile FDA days to MDUFA III decision	86				
Maximum FDA days to MDUFA III decision	99				
Average Industry days to MDUFA III decision	40				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	27				
80th Percentile Industry days to MDUFA III decision	84				
Maximum Industry days to MDUFA III decision	205				
Average Total days to MDUFA III decision	97				
20th Percentile Total days to MDUFA III decision	30				
40th Percentile Total days to MDUFA III decision	42				
60th Percentile Total days to MDUFA III decision	107				
80th Percentile Total days to MDUFA III decision	166				
Maximum Total days to MDUFA III decision	294				

Table 6.6.DCTD DCTD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	225				
Number with MDUFA decision	119				
Number of SE decisions	118				
Number of NSE decisions	1				
Number of Withdrawals	7				
Number deleted	4				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	3%				
Rate of Deleted	2%				

Table 6.7.DCTD DCTD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1				
Mean FDA days for submissions that missed goal	99				
Mean Industry days for submissions that missed goal	193				

Table 6.1.DIHD DIHD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	73				
Closed before RTA action	1				
Number Accepted	46				
RTA Review not done and > 15 days since Date Received	3				
RTA Review not done and <= 15 days since Date Received	7				
Number Not Accepted	16				
Rate of submissions not accepted	25%				

*** RTA was not in place 1st quarter, thus Table 6.1.DIHD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DIHD DIHD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	77				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	71				
SI over 60 FDA days	1				
SI pending within 60 FDA days	5				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	99%				

Table 6.3.DIHD DIHD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	72				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	41				
40th Percentile FDA days to Substantive Interaction	48				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	63				

Table 6.4.DIHD DIHD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	77				
Non-MDUFA III Decisions	9				
MDUFA III Decisions (SE/NSE)	27				
MDUFA III Decisions within 90 FDA Days	27				
510(k)s pending MDUFA III Decision	41				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 6.5.DIHD DIHD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.74				
Number with MDUFA decision	27				
Average FDA days to MDUFA III decision	67				
20th Percentile FDA days to MDUFA III decision	47				
40th Percentile FDA days to MDUFA III decision	71				
60th Percentile FDA days to MDUFA III decision	82				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	77				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	27				
60th Percentile Industry days to MDUFA III decision	95				
80th Percentile Industry days to MDUFA III decision	162				
Maximum Industry days to MDUFA III decision	183				
Average Total days to MDUFA III decision	144				
20th Percentile Total days to MDUFA III decision	73				
40th Percentile Total days to MDUFA III decision	96				
60th Percentile Total days to MDUFA III decision	156				
80th Percentile Total days to MDUFA III decision	247				
Maximum Total days to MDUFA III decision	273				

Table 6.6.DIHD DIHD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	77				
Number with MDUFA decision	27				
Number of SE decisions	25				
Number of NSE decisions	2				
Number of Withdrawals	0				
Number deleted	7				
Rate of SE decisions	93%				
Rate of NSE decisions	7%				
Rate of Withdrawals	0%				
Rate of Deleted	9%				

Table 6.7.DIHD DIHD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 6.1.DMD DMD – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59				
Closed before RTA action	0				
Number Accepted	53				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	2				
Number Not Accepted	4				
Rate of submissions not accepted	7%				

*** RTA was not in place 1st quarter, thus Table 6.1.DMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DMD DMD – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	76				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	67				
SI over 60 FDA days	1				
SI pending within 60 FDA days	8				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	99%				

Table 6.3.DMD DMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	68				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	27				
40th Percentile FDA days to Substantive Interaction	38				
60th Percentile FDA days to Substantive Interaction	52				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	61				

Table 6.4.DMD DMD – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	76				
Non-MDUFA III Decisions	4				
MDUFA III Decisions (SE/NSE)	51				
MDUFA III Decisions within 90 FDA Days	51				
510(k)s pending MDUFA III Decision	21				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 6.5.DMD DMD – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.2				
Number with MDUFA decision	51				
Average FDA days to MDUFA III decision	52				
20th Percentile FDA days to MDUFA III decision	27				
40th Percentile FDA days to MDUFA III decision	34				
60th Percentile FDA days to MDUFA III decision	67				
80th Percentile FDA days to MDUFA III decision	80				
Maximum FDA days to MDUFA III decision	89				
Average Industry days to MDUFA III decision	24				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	175				
Average Total days to MDUFA III decision	76				
20th Percentile Total days to MDUFA III decision	27				
40th Percentile Total days to MDUFA III decision	34				
60th Percentile Total days to MDUFA III decision	77				
80th Percentile Total days to MDUFA III decision	84				
Maximum Total days to MDUFA III decision	256				

Table 6.6.DMD DMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	76				
Number with MDUFA decision	51				
Number of SE decisions	51				
Number of NSE decisions	0				
Number of Withdrawals	2				
Number deleted	2				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	3%				
Rate of Deleted	3%				

Table 6.7.DMD DMD – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 6.1.DRH DRH – 510(k) Acceptance Review Decision

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	257				
Closed before RTA action	0				
Number Accepted	133				
RTA Review not done and > 15 days since Date Received	15				
RTA Review not done and <= 15 days since Date Received	27				
Number Not Accepted	82				
Rate of submissions not accepted	36%				

*** RTA was not in place 1st quarter, thus Table 6.1.DRH for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.**

Table 6.2.DRH DRH – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	304				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	228				
SI over 60 FDA days	38				
SI pending within 60 FDA days	37				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	86%				

Table 6.3.DRH DRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	266				
Average number of FDA days to Substantive Interaction	47				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	44				
60th Percentile FDA days to Substantive Interaction	56				
80th Percentile FDA days to Substantive Interaction	60				
Maximum FDA days to Substantive Interaction	91				

Table 6.4.DRH DRH – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	358				
Non-MDUFA III Decisions	7				
MDUFA III Decisions (SE/NSE)	262				
MDUFA III Decisions within 90 FDA Days	259				
510(k)s pending MDUFA III Decision	89				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

Table 6.5.DRH DRH – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.46				
Number with MDUFA decision	262				
Average FDA days to MDUFA III decision	57				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	46				
60th Percentile FDA days to MDUFA III decision	71				
80th Percentile FDA days to MDUFA III decision	86				
Maximum FDA days to MDUFA III decision	109				
Average Industry days to MDUFA III decision	21				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	3				
80th Percentile Industry days to MDUFA III decision	36				
Maximum Industry days to MDUFA III decision	195				
Average Total days to MDUFA III decision	77				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	55				
60th Percentile Total days to MDUFA III decision	83				
80th Percentile Total days to MDUFA III decision	112				
Maximum Total days to MDUFA III decision	283				

Table 6.6.DRH DRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	358				
Number with MDUFA decision	262				
Number of SE decisions	259				
Number of NSE decisions	3				
Number of Withdrawals	7				
Number deleted	0				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	2%				
Rate of Deleted	0%				

Table 6.7.DRH DRH – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	59				

Section 7 510(k) Annual General Metrics

510(k) Annual General Metrics – Center Level

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3358				
Number of Traditional submissions	2580				
Number of Special submissions	551				
Number of Abbreviated submissions	99				
Average number of days to Accept / Refuse to Accept	11				
Number of Third Party submissions	128				

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

Performance Metric	FY 2013 135 days	FY 2014 135 days	FY 2015 130 days	FY 2016 130 days	FY 2017 124 days
Number Accepted	3358				
Currently Under Review	1318				
Number with Non-MDUFA Decision	167				
Number with MDUFA III Decision	1873				
Percent of cohort closed	59%				
Number with MDUFA III decision after trimming the upper and lower 2%	1798				
Average Total Time to MDUFA III decision	N/A				

Section 8 Annual Metrics for De Novo Requests

Annual Metrics for De Novo Requests – Center Level

Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of *De Novo* Requests Received	46				
Number of *De Novo* Requests with Decision	20				
Number of *De Novo* Requests with Decision Pending	26				
Average Number of Days to Decision	103				

Section 9 Pre-Submissions

Pre-Submissions – Center Level

Table 9.1 CDRH – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	1785				
Number requesting a meeting or teleconference	983				
Number with meetings or teleconferences held	614				
Average days to meeting	57				
20th Percentile days to meeting	36				
40th Percentile days to meeting	52				
60th Percentile days to meeting	64				
80th Percentile days to meeting	75				
Maximum days to meeting	183				

.

Pre-Submissions – Office Level

Table 9.1.ODE ODE – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	987				
Number requesting a meeting or teleconference	618				
Number with meetings or teleconferences held	365				
Average days to meeting	58				
20th Percentile days to meeting	36				
40th Percentile days to meeting	53				
60th Percentile days to meeting	66				
80th Percentile days to meeting	77				
Maximum days to meeting	183				

Table 9.1.OIR OIR – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	798				
Number requesting a meeting or teleconference	365				
Number with meetings or teleconferences held	249				
Average days to meeting	54				
20th Percentile days to meeting	35				
40th Percentile days to meeting	49				
60th Percentile days to meeting	62				
80th Percentile days to meeting	71				
Maximum days to meeting	138				

Pre-Submissions – Division Level

Table 9.1.DAGRID DAGRID – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	156				
Number requesting a meeting or teleconference	83				
Number with meetings or teleconferences held	47				
Average days to meeting	67				
20th Percentile days to meeting	46				
40th Percentile days to meeting	65				
60th Percentile days to meeting	75				
80th Percentile days to meeting	87				
Maximum days to meeting	121				

Table 9.1.DCD DCD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	308				
Number requesting a meeting or teleconference	218				
Number with meetings or teleconferences held	144				
Average days to meeting	51				
20th Percentile days to meeting	32				
40th Percentile days to meeting	46				
60th Percentile days to meeting	56				
80th Percentile days to meeting	71				
Maximum days to meeting	111				

Table 9.1.DNPMD DNPMD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	80				
Number requesting a meeting or teleconference	52				
Number with meetings or teleconferences held	27				
Average days to meeting	70				
20th Percentile days to meeting	48				
40th Percentile days to meeting	62				
60th Percentile days to meeting	77				
80th Percentile days to meeting	90				
Maximum days to meeting	163				

Table 9.1.DOD DOD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	98				
Number requesting a meeting or teleconference	62				
Number with meetings or teleconferences held	27				
Average days to meeting	56				
20th Percentile days to meeting	38				
40th Percentile days to meeting	52				
60th Percentile days to meeting	66				
80th Percentile days to meeting	78				
Maximum days to meeting	98				

Table 9.1.DOED DOED – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	89				
Number requesting a meeting or teleconference	49				
Number with meetings or teleconferences held	31				
Average days to meeting	66				
20th Percentile days to meeting	51				
40th Percentile days to meeting	63				
60th Percentile days to meeting	70				
80th Percentile days to meeting	85				
Maximum days to meeting	118				

Table 9.1.DRGUD DRGUD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	132				
Number requesting a meeting or teleconference	77				
Number with meetings or teleconferences held	48				
Average days to meeting	56				
20th Percentile days to meeting	43				
40th Percentile days to meeting	58				
60th Percentile days to meeting	65				
80th Percentile days to meeting	70				
Maximum days to meeting	115				

Table 9.1.DSD DSD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	124				
Number requesting a meeting or teleconference	77				
Number with meetings or teleconferences held	41				
Average days to meeting	64				
20th Percentile days to meeting	37				
40th Percentile days to meeting	60				
60th Percentile days to meeting	71				
80th Percentile days to meeting	81				
Maximum days to meeting	183				

Table 9.1.DCTD DCTD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	219				
Number requesting a meeting or teleconference	108				
Number with meetings or teleconferences held	75				
Average days to meeting	50				
20th Percentile days to meeting	33				
40th Percentile days to meeting	47				
60th Percentile days to meeting	59				
80th Percentile days to meeting	68				
Maximum days to meeting	90				

Table 9.1.DIHD DIHD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	275				
Number requesting a meeting or teleconference	151				
Number with meetings or teleconferences held	103				
Average days to meeting	61				
20th Percentile days to meeting	39				
40th Percentile days to meeting	58				
60th Percentile days to meeting	70				
80th Percentile days to meeting	83				
Maximum days to meeting	138				

Table 9.1.DMD DMD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	234				
Number requesting a meeting or teleconference	62				
Number with meetings or teleconferences held	43				
Average days to meeting	51				
20th Percentile days to meeting	41				
40th Percentile days to meeting	49				
60th Percentile days to meeting	60				
80th Percentile days to meeting	64				
Maximum days to meeting	81				

Table 9.1.DRH DRH – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	70				
Number requesting a meeting or teleconference	44				
Number with meetings or teleconferences held	28				
Average days to meeting	42				
20th Percentile days to meeting	28				
40th Percentile days to meeting	40				
60th Percentile days to meeting	50				
80th Percentile days to meeting	61				
Maximum days to meeting	71				

Section 10 CLIA Waiver Annual Metrics

Section 10 CLIA Waiver Annual Metrics

Table 10.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 95% SI within 90 FDA days	FY 2014 95% SI within 90 FDA Days	FY 2015 95% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	3				
Deleted or withdrawn prior to SI	0				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Denial without SI	1				
Current SI Performance Percent within 90 FDA days	50%				

Table 10.2.CDRH – CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1				
Average number of FDA days to Substantive Interaction	73				
20th Percentile FDA days to Substantive Interaction	n/a				
40th Percentile FDA days to Substantive Interaction	n/a				
60th Percentile FDA days to Substantive Interaction	n/a				
80th Percentile FDA days to Substantive Interaction	n/a				
Maximum FDA days to Substantive Interaction	73				

Table 10.3.CDRH – CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 95% within 180 FDA days	FY 2014 95% within 180 FDA days	FY 2015 95% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
CLIA Waiver Applications accepted	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
CLIA Waiver Applications pending MDUFA III Decision	2				
CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

Table 10.4.CDRH – CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 95% within 330 FDA days	FY 2014 95% within 330 FDA days	FY 2015 95% within 330 FDA days	FY 2016 95% within 330 FDA days	FY 2017 95% within 330 FDA days
CLIA Waiver Applications accepted	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 330 FDA Days	0				
CLIA Waiver Applications pending MDUFA III Decision	0				
CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	0				
Current Performance Percent within 330 FDA Days	0				

Table 10.5.CDRH – CLIA Waiver (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	61				
20th Percentile FDA days to MDUFA III decision	n/a				
40th Percentile FDA days to MDUFA III decision	n/a				
60th Percentile FDA days to MDUFA III decision	n/a				
80th Percentile FDA days to MDUFA III decision	n/a				
Maximum FDA days to MDUFA III decision	61				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	n/a				
40th Percentile Industry days to MDUFA III decision	n/a				
60th Percentile Industry days to MDUFA III decision	n/a				
80th Percentile Industry days to MDUFA III decision	n/a				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	61				
20th Percentile Total days to MDUFA III decision	n/a				
40th Percentile Total days to MDUFA III decision	n/a				
60th Percentile Total days to MDUFA III decision	n/a				
80th Percentile Total days to MDUFA III decision	n/a				
Maximum Total days to MDUFA III decision	61				

Table 10.6.CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision	n/a				
20th Percentile FDA days to MDUFA III decision	n/a				
40th Percentile FDA days to MDUFA III decision	n/a				
60th Percentile FDA days to MDUFA III decision	n/a				
80th Percentile FDA days to MDUFA III decision	n/a				
Maximum FDA days to MDUFA III decision	n/a				
Average Industry days to MDUFA III decision	n/a				
20th Percentile Industry days to MDUFA III decision	n/a				
40th Percentile Industry days to MDUFA III decision	n/a				
60th Percentile Industry days to MDUFA III decision	n/a				
80th Percentile Industry days to MDUFA III decision	n/a				
Maximum Industry days to MDUFA III decision	n/a				
Average Total days to MDUFA III decision	n/a				
20th Percentile Total days to MDUFA III decision	n/a				
40th Percentile Total days to MDUFA III decision	n/a				
60th Percentile Total days to MDUFA III decision	n/a				
80th Percentile Total days to MDUFA III decision	n/a				
Maximum Total days to MDUFA III decision	n/a				

Section 11 Investigational Device Exemptions (IDEs)

Investigational Device Exemption data will be reported for FY2014 –FY2017.

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 (see definition for the Received cohort above).
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 (see definition for the Received cohort above).
2	Number Accepted[#]	Number Received (line 1) that got "RTA Accepted" (RTAA), RTAX, 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).

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013

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 within 90 FDA days	Number of submissions with SI action within 90 FDA days.
3	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
4	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI.
5	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI.
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 within 90 FDA days	Number of submissions with SI within 90 FDA days (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 III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 180 FDA Days	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III 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 III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 320 FDA Days	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision over 320 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III 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 III 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 III 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 III 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 III 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 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	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

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	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	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 III 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 III 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).

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. See definition of the received cohort above.
2	SI within 90 FDA days	Number of submissions with an SI action taken within 90 FDA days.
3	SI over 90 FDA days	Number of submissions with an SI action taken in more than 90 FDA days.
4	SI pending within 90 FDA days	Submissions that are under review for not more than 90 FDA days and that do not have an SI.
5	SI pending over 90 FDA days	Submissions that are under review for more than 90 FDA days and that do not have an SI.
6	Closed without SI	Number of submissions that are closed with a MDUFA or NON-MDUFA decision but without an SI.
7	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (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 III Decisions	Supplements received (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 180 FDA Days	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	Supplements pending MDUFA III Decision	Number of supplements received (line 1) that do not have a MDUFA III decision or a final decision.
6	Supplements pending MDUFA III Decision over 180 FDA days	Number of supplements pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent within 180 FDA Days	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III 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 III 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. See the Received cohort definition above.
2	Non-MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 90 FDA Days	Submissions with MDUFA III decisions (line 3) made in less than or equal to 90 FDA days.
5	Supplements pending MDUFA III Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA III decision and are not closed with a final decision.
6	Supplements pending MDUFA III Decision over 90 FDA days	Number of supplements pending MDUFA III Decision (line 5) for more than 90 FDA Days. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III 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 (line2).

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) – Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non-Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority 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 III decision and 5% of submissions with the highest number of Total Days to MDUFA III 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 FY20111 and FY2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA III Performance

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. See definition for received cohort above. Third party reviews shall be excluded from this table.
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 got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	RTA Review not done and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN or RTAS) 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	RTA Review not done 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 "Refuse to accept" decision in the first RTA review cycle.
7	Rate of submissions not accepted	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 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goals - Definitions

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions with RTA review accepted in this fiscal year (RTAA, RTAX, RTAN, or RTAS.). Third party 510(k) submissions are excluded from SI performance report.
2	510(k) withdrawn or deleted prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made before or on the cutoff date and before any SI action: WD, DD, DE, HD, K4, NR, RC, RD .
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 under review for not more than 60 FDA days and that do not have an SI.
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 (or with an AN, DN, or ON decision where Date Received does not equal Date Final 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) 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 6.3 and Tables 6.3.x 510(k) Substantive Interaction Metrics – Time to Substantive Interaction - Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of 510(k) submissions accepted in this fiscal year that had an SI. Third party 510(k) submissions shall be excluded from this report.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days 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 Goals - Definitions

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions accepted in this fiscal year. Third party 510(k) shall also be included into this report.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not SE or NSE).
3	MDUFA III Decisions (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA III decision (SE or NSE).
4	MDUFA III Decisions within 90 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA III Decision over 90 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of submissions with MDUFA III Decisions within 90 FDA Days (line 4) divided by the total number of submissions with MDUFA III 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 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 III Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III 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 6.6 and Tables 6.6.x 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions - Definitions

#	Measure	Description
1	Number Accepted	Number of 510(k) submissions accepted in this fiscal year. See definition for Accepted cohort above.
2	Number with MDUFA decision	Number submissions accepted (line 1) that also had a MDUFA decision.
3	Number of SE decisions	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE decisions	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) and closed with Withdrawal (WD) final decision.
6	Number deleted	Number of submissions accepted (line 1) and closed with Delete (DE) final decision.
7	Rate of SE decisions	Number of SE decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of NSE decisions	Number of NSE decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number Received (line 1).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number Received (line 1).

Table 6.7 and Tables 6.7.x 510(k) Performance Metrics – Submissions Missing Performance Goals - 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. Third Party 510(k) submissions shall also be included into this report.
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).

Section 7 510(k) Annual General Metrics

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. Third party 510(k) submissions shall also be included into this count.
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. Third-party 510(k) submissions shall also be included into this report.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA III Decision	Total number of 510(k) submissions accepted (line 1) that had a MDUFA III decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) divided by the total of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA III decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA III Decision (line 4) excluding 2% of submissions with the lowest number of Total Days to MDUFA III decision and 2% of submissions with the highest number of Total Days to MDUFA III decision.
7	Average Total Time to MDUFA III decision	Average Total Time (FDA and Industry) to MDUFA decision. If the cohort is not closed (less than 99% of 510(k) submissions have a decision) “N/A” shall be displayed instead.

Section 8 Annual Metrics for De Novo Requests

Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests - Definitions

#	Measure	Description
1	Number of *De Novo* Requests Received	Total number of *de novo* requests received in this fiscal year as of the report cutoff date.
2	Number of *De Novo* Requests with Decision	Number of *de novo* requests received (line 1) which also have a final decision (AN, DN, or ON) as of the report cutoff date.
3	Number of *De Novo* Requests with Decision Pending	Number *de novo* requests received (line 1) which do not have a final decision (AN, DN, or ON) as of the report cutoff date.
4	Average Number of Days to Decision	Average total number of days to decision (days between *De Novo* Date Received and *De Novo* Decision Date) for *de novo* requests with Decision (line 2).

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Submissions Performance Metrics - Definitions

#	Measure	Description
1	Number of all qualified Pre-Submissions received	Number of all qualified Pre-Submissions received. This include those with a type="pre-sub" either with a meeting request or written feedback requested in the fiscal year.
2	Number requesting a meeting or teleconference	Number of qualified Pre-submission received (line 1) with the Sub-Type of "Pre-Sub Meeting Request".
3	Number with meetings or teleconferences held	Number requesting a meeting or teleconference (line 2) with Actual Meeting Date populated with a value prior to the cutoff date.
4	Days to meeting	Table shall show average days from Date FDA Initial Clock Start to Actual Meeting Date as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting days, Industry days, and Total days. The calculation includes meetings where the Actual Meeting Date is greater than the Date FDA Initial Clock Start and the Actual Meeting Date is prior to as of the cutoff date.

Section 10 CLIA Waiver Annual Metrics

Table 10.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Deleted or withdrawn prior to SI	Number of submissions with MDUFA Decision WTDR 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	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no 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 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1)

Table 10.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications 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 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 10.3 CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals) – Definitions

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 180 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 180 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 180 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions within 180 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

Table 10.4 CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals) – Definitions

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 330 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 330 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

Table 10.5 CLIA Waiver (without Panel Review) Time to MDUFA Decision – Definitions

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn)
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III 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 10.6 CLIA Waiver (with Panel Review) Time to MDUFA Decision - Definitions

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn)
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III 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.

Quarterly Update on
Medical Device Performance Goals
----MDUFA III CBER Performance Data ----
Action through 31 March 2013

Section 1 PMA Original and Panel Track Supplements - Center Level

Table 1.1 CBER – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1				
Closed before RTA action	0				
Number Accepted	1				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0.0%				
Completed RTF	0				
Number Not Filed	0				
Rate of submissions Not Filed	0.0%				

Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	1				
SI within 90 FDA days	0				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	1				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	0.0%				

Table 1.3 CBER – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	0				
Average number of FDA days to Substantive Interaction	0				
20th Percentile FDA days to Substantive Interaction	0				

40th Percentile FDA days to Substantive Interaction	0				
60th Percentile FDA days to Substantive Interaction	0				
80th Percentile FDA days to Substantive Interaction	0				
Maximum FDA days to Substantive Interaction	0				

Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	0.0%				

Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 50% within 320 FDA days	FY 2014 70% within 320 FDA days	FY 2015 80% within 320 FDA days	FY 2016 80% within 320 FDA days	FY 2017 90% within 320 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 320 FDA Days	0				
PMAs pending MDUFA III Decision	1				
PMAs pending MDUFA III Decision over 320 FDA days	0				
Current Performance Percent within 320 FDA Days	0.0%				

Table 1.6 CBER – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	0				

Average FDA days to MDUFA III decision	**0**				
20th Percentile FDA days to MDUFA III decision	0				
40th Percentile FDA days to MDUFA III decision	0				
60th Percentile FDA days to MDUFA III decision	0				
80th Percentile FDA days to MDUFA III decision	0				
Maximum FDA days to MDUFA III decision	0				
Average Industry days to MDUFA III decision	**0**				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	**0**				
20th Percentile Total days to MDUFA III decision	0				
40th Percentile Total days to MDUFA III decision	0				
60th Percentile Total days to MDUFA III decision	0				
80th Percentile Total days to MDUFA III decision	0				
Maximum Total days to MDUFA III decision	0				

Table 1.7 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	0				
Average FDA days to MDUFA III decision	**0**				
20th Percentile FDA days to MDUFA III decision	0				
40th Percentile FDA days to MDUFA III decision	0				
60th Percentile FDA days to MDUFA III decision	0				
80th Percentile FDA days to MDUFA III decision	0				
Maximum FDA days to MDUFA III decision	0				

Average Industry days to MDUFA III decision	**0**				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	**0**				
20th Percentile Total days to MDUFA III decision	0				
40th Percentile Total days to MDUFA III decision	0				
60th Percentile Total days to MDUFA III decision	0				
80th Percentile Total days to MDUFA III decision	0				
Maximum Total days to MDUFA III decision	0				

Table 1.8 CBER – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0.0%				
Rate of Not Approvable	0.0%				

Table 1.9 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0.0%				
Rate of Not Approvable	0.0%				

Table 1.10 CBER – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal	0				
Mean industry days for submissions that missed goal	0				

Table 1.11 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal	0				
Mean industry days for submissions that missed goal	0				

Section 2 PMA 180 Day Supplements - Center Level

Table 2.1 CBER – PMA 180 Day Supplements Substantive Interaction Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	1				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	1				
Current SI Performance Percent within 90 FDA days	100.0%				

Table 2.2 CBER – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	3				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100.0%				

Table 2.3 CBER – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3				
Number with MDUFA decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0.0%				

Table 2.4 CBER – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal	0				
Mean Industry days for submissions that missed goal	0				

Section 3 PMA Real Time Supplements - Center Level Metrics

Table 3.1 CBER – Real Time PMA Supplements MDUFA Performance Goals

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 90 FDA Days	3				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100.0%				

Table 3.2 CBER – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3				
Number with MDUFA decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	0.0%				

Table 3.3 CBER – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal	0				
Mean Industry days for submissions that missed goal	0				

Section 5 PMA Annual Metrics and Goals

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

PMA Submissions Received	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Premarket Report Submissions	0				
Original PMAs (Panel) – Priority	0				
Original PMAs (No Panel) – Priority	0				
Original PMAs (Panel) – Non-Priority	1				
Original PMAs (No Panel) – Non-Priority	0				
Panel-Tracked Supplements (Panel) – Priority	0				
Panel-Tracked Supplements (No Panel) – Priority	0				
Panel-Tracked Supplements (Panel) – Non-Priority	0				
Panel-Tracked Supplements (No Panel) – Non-Priority	0				
PMA Modules	7				
180-Day Supplements	3				
Real-Time Supplements	3				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1				
Number with a decision (MDUFA or Non-MDUFA)	0				
% of FY closed	0.0%				

Section 6 510(k) Center Level Metrics

Table 6.1 CBER – 510(k) Acceptance Review Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59				
Closed before RTA action	2				
Number Accepted	39				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	8				
Number Not Accepted	10				
Rate of submissions not accepted for review	25.6%				

Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Performance Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA days	FY 2015 85% SI within 60 FDA days	FY 2016 95% SI within 60 FDA days	FY 2017 95% SI within 60 FDA days
Eligible for SI	35				
SI within 60 FDA days	23				
SI over 60 FDA days	5				
SI pending within 60 FDA days	7				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	82.1%				

Table 6.3 CBER – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	28				
Average number of FDA days to Substantive Interaction	49				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	47				
60th Percentile FDA days to Substantive Interaction	57				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	90				

Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals

Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	39				
Non-MDUFA III Decisions	26				
MDUFA III Decisions (SE/NSE)	23				
MDUFA III Decisions within 90 FDA Days	23				
510(k)s pending MDUFA III Decision	12				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100.0%				

Table 6.5 CBER – 510(k) Time to MDUFA Decision

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.43				
Number with MDUFA III decision	23				
Average FDA days to MDUFA III decision	61				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	49				
60th Percentile FDA days to MDUFA III decision	85				
80th Percentile FDA days to MDUFA III decision	89				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	38				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	83				
Maximum Industry days to MDUFA III decision	222				
Average Total days to MDUFA III decision	98				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	49				
60th Percentile Total days to MDUFA III decision	90				

80th Percentile Total days to MDUFA III decision	142				
Maximum Total days to MDUFA III decision	307				

Table 6.6 CBER – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	39				
Number with MDUFA decision	23				
Number of SE decisions	21				
Number of NSE decisions	2				
Number of Withdrawals	6				
Number deleted	0				
Rate of SE decisions	72.4%				
Rate of NSE decisions	6.9%				
Rate of Withdrawals	20.7%				
Rate of Deleted	0.0%				

Table 6.7 CBER – 510(k) Performance Metrics – Submissions Missing Performance Goals

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0				
Mean FDA days for submissions that missed goal	0				
Mean industry days for submissions that missed goal	0				

Section 7 510(k) Annual General Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	39				
Number of Traditional submissions	30				
Number of Special submissions	8				

Number of Abbreviated submissions	1				
Average number of days to Accept / Refuse to Accept	12				
Number of Third Party submissions	0				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	39				
Currently Under Review	12				
Number with Non-MDUFA Decision	26				
Number with MDUFA III Decision	23				
Percent of cohort closed	69.2%				
Number with MDUFA III decision after trimming the upper and lower 2%	21				
Average Total Time to MDUFA III decision	98				

Section 8 De Novo Petitions

Table 8.1 CBER – Annual General Metric Report for De Novo Classification Petitions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of De Novo Petitions Received	2				
Number of De Novo Petitions with Decision	0				
Number of De Novo Petitions with Decision Pending	2				
Average Number of Days to Decision	0				

Section 9 Pre-Submissions

Section 9 Pre-Submission Center Level Metrics

Table 9.1 CBER – Pre-Submission Center Level Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	44				
Number requesting a meeting or teleconference	34				
Number with meetings or teleconferences granted	29				
Number with meeting granted and industry cancelled	9				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and pending within timeframe	10				
Number with meeting granted and pending outside timeframe	0				
Number with meetings or teleconferences held	10				
Average days to meeting	61				
20th Percentile days to meeting	55				
40th Percentile days to meeting	58				
60th Percentile days to meeting	59				
80th Percentile days to meeting	61				
Maximum days to meeting	91				

BLAs

CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard BLAs Filed	9				
Number of Standard BLA First Actions less than or equal to 10 months	3				
Number of Standard BLA Frist Actions greater than 10 months	0				
Number of Standard BLAs Pending	6				
Number of Priority BLA Filed	0				
Number of Priority BLA First Actions less than or equal to 10 months	0				
Number of Priority BLA Frist Actions greater than 10 months	0				
Number of Priority BLAs Pending	0				

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard Efficacy Supplements Filed	0				
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0				
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0				
Number of Standard Efficacy Supplements Pending	0				
Number of Priority Efficacy Supplements Filed	0				
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0				

Number of Priority Efficacy Supplements Frist Actions greater than 10 months	0				
Number of Priority Efficacy Supplements Pending	0				

BLA Prior Approval Manufacturing Supplements

CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard PAS Supplements Filed	19				
Number of Standard PAS Supplements First Actions less than or equal to 4months	12				
Number of Standard PAS Supplements First Actions greater than 4 months	0				
Number of Standard PAS Supplements Pending	7				

BLA/BLA Resubmissions

CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Class 1 Resubmissions Received	10				
Number of Class 1 Resubmission Actions less than or equal to 2 months	10				
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0				
Number of Class 1 Resbumssions Pending	0				
Number of Class 2 Resubmissions Received	0				
Number of Class 2 Resubmission Actions less than or equal to 6 months	0				
Number of Class 2 Resubmission Actions greater than 6 months	0				

Number of Class 2 Resubmissions Pending	0				

FY 2013 Medical Device User Fee Collections as of September 30, 2013 [1, 2] Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$61,643,564	$527,075	$61,116,489		
Application Fees	$38,442,963	$406,174	$38,036,789		
Total	**$100,086,527**	**$933,249**	**$99,153,277**	**$97,722,301**	**102%**

Medical Device User Fee Collection History [3] Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,276,610	$31,724,956	$34,469,732	$27,806,656
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,388,363	$55,715,554	$62,743,440	$69,662,436	$64,655,026

Notes:

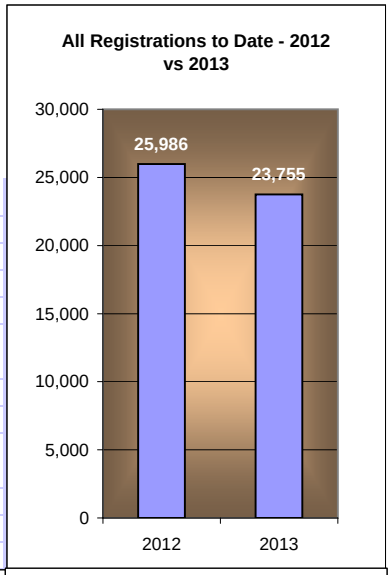
[1] Figures are based on preliminary year-end data; subject to revision.

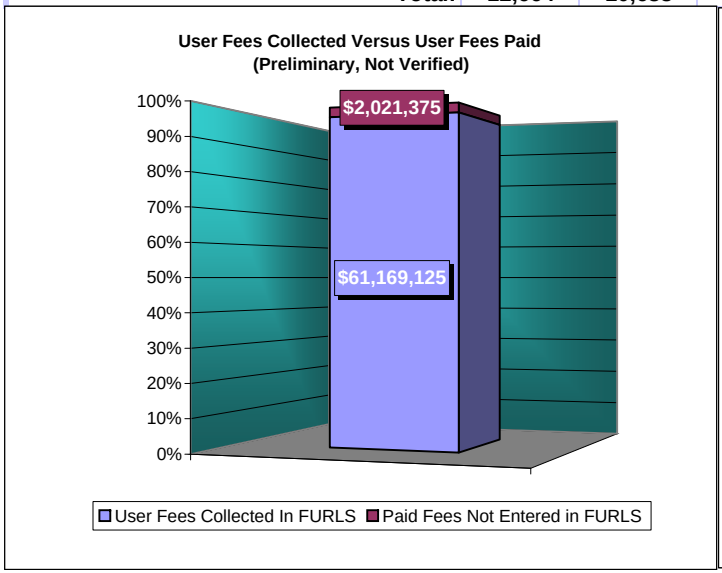
[2] Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2013.

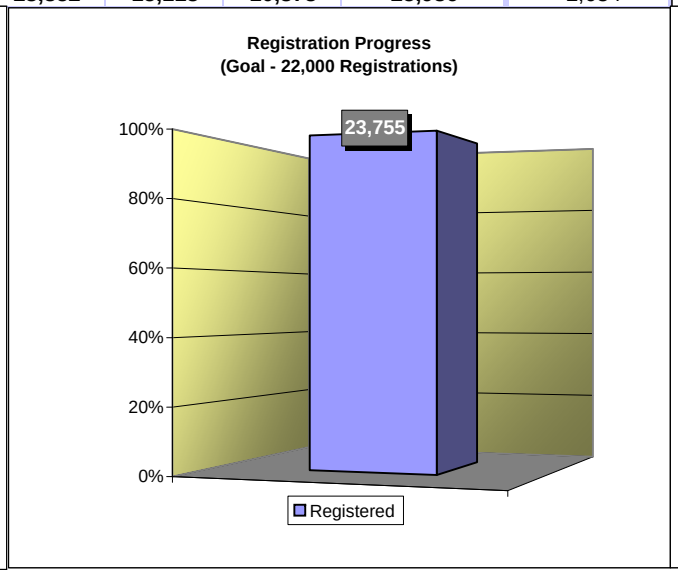
[3] Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

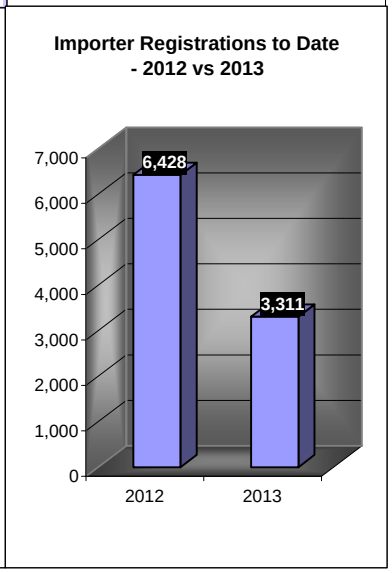
MDUFA III, Fourth Quarter Summary FY2013

Registrations by Type	FY2013 (Active at End of FY)			FY2012 Year End Totals			Difference
Est Type	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,517	8,376	13,893	5,291	7,785	13,076	817
Contract Manufacturer	786	1,014	1,800	305	726	1,031	769
Contract Sterilizer	73	107	180	21	43	64	116
Specification Developer	1,661	363	2,024	1,599	342	1,941	83
Reprocessor of Single Use Devices	21	2	23	16	1	17	6
U.S. Manufacturer of Export Only Devices	127		127	133		133	-6
Repackager/Relabeler	1,164	169	1,333	2,030	483	2,513	-1,180
Remanufacturer	28	19	47	71	105	176	-129
Foreign Exporter/Private Label Distributor	0	630	630	0	1,388	1,388	-758
Initial Importer	3,272		3,272	5,639		5,639	-2,367
Unknown	15	8	23	8		8	15
Total:	**12,664**	**10,688**	**23,352**	**15,113**	**10,873**	**25,986**	-2,634









MDUFA III Quarterly Performance Update
Independent Assessment of Medical Device Review Process

4th Quarter FY 2013 Status – November 5, 2013

Objectives

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications.

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications. Primary objectives include:

Phase 1:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket device reviews across FDA
- Development of implementation plans for selected recommendations
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results

Phase 2:

- Evaluation of the implementation of selected recommendations

Timeline

Milestone	Planned	Status
FY 2013		
Publish Federal Register notice	December 2012	Completed
Award contract	May 2013	Completed June 2013
Contract kickoff meeting between FDA and contractor	June 2013	Completed July 2013
Final workplan for Phase 1	July 2013	Completed August 2013
Report on preliminary findings and high-priority recommendations	December 2013	On target
FY 2014		
Implementation plan for high-priority recommendations	May 2014	
Final report on complete findings and recommendations	May 2014	
Implementation plan for final recommendations	November 2014	

Milestone	Planned	Status
FY 2015		
Phase 2 kickoff meeting between FDA and contractor	April 2015	
Final workplan for Phase 2	May 2015	
FY 2016		
Final evaluation report	February 1, 2016	

Progress to-date:

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1st Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013
- Finalized SOW based on feedback from Federal Register notice – March 25, 2013
- Issued request for proposal – April 19, 2013
- Awarded task order to Booz-Allen-Hamilton – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – August 2, 2013
- Focus group with Medical Device Industry Representatives – August 17, 2013

Planned Progress prior to 1st Quarter Meeting FY 2014:

- Progress reports and updates from assessment team – Ongoing
- Report on preliminary findings and high-priority recommendations – Posted to FDA website by December 11, 2013

Staff College Internal Training Summary Report

From 10/1/2012 to 9/30/2013

As of: **10/22/2013**

FY13 ***(October 1, 2012 – September 30, 2013)*** **MDUFA-Related Training Data**

FDA continues to invest in internal and external training opportunities supporting the medical device review process. CDRH's Staff College is a workforce development organization that designs and delivers internal training opportunities to meet the professional needs of FDA staff. As medical devices grow increasingly complex, training must keep pace with these advancements. Staff College is committed to leveraging internal and external resources to enhance the training provided to Center staff.

Table X provides a summary of internal training conducted between October 1, 2012 and September 30, 2013. Staff College offered 541 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and activities. Overall, 92% (1386) of the approximately 1500 Center staff participated in training and on average attended 15 (7932÷541) learning events.

Table X: FY13 CDRH Staff College Internal Training

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended Between 10/1/12– 9/30/13
Regulatory and Law (LAW)	316	2497	10741	• Reviewer Certification Program – Introduction to Medical Device Law – Basic Food and Drug Law – How to Write Deficiencies in Four-Part Harmony • Benefit-Risk Guidance – Online • Compiling the Administrative File for Premarket Submission Decisions – Online
➢ ***MDUFA III Training****	*6*	*464*	*1149*	• *Introduction to MDUFA III* • *510(k)s* • *PMAs* • *Pre-Submissions* • *CLIA Waivers* • *Electronic Workload Management*
➢ ***ELP***	*3*	*37*	*297*	
Leadership Education and Development (LED)	53	798	5719	• Adaptive Leadership • Leading in a Telework Environment • Masterful e-Meetings • CDRH Management Administrative Learning Forum's
➢ ***LEAD****	*35*	*171*	*1300*	• *Adaptive Leadership* • *Giving and Receiving Feedback* • *Leading with Influence* • *The Successful Mentor*
Professional Development (PRO)	53	886	5791	• Building High Performing Teams • Effective Communication skills for Scientific and Technical Professionals • Effective Briefing and Presentation Skills • Negotiation with Confidence • Fundamentals of Project Management • Decision Making and Critical Thinking Techniques for Results
➢ ***New Employee Orientation (NEO)****	*4*	*82*	*574*	• *New Employee Orientation: Discover the Mission, Embrace the Vision*
Science (SCI)	119	3751	10181	• CDRH Science Sharing Seminars – Topics include: • Breast Imaging Research in DIAM • Role of NVLAP Accreditation Process • Bone Seminar 2013 • UDI: A Foundation of Health Informatics Initiatives - Online • Pre-market Requirements for MRI Safety
Total:	**541**	**7932**	**32432**	

*** The MDUFA III data has been incorporated under the Law category within the subsequent data charts.**
****The ELP data has been incorporated under the Law category within the subsequent data charts.**
*****The LEAD data has been incorporated under the Leadership category within the subsequent data charts.**
******The NEO data has been incorporated under the Professional Development category within the subsequent data charts.**

Leadership Readiness Program (LRP) Graduates

LRP Program Year	# of Enrolled Participants	# of Participant Completions
2006-2007	OIVD=3 ODE =13 Total = 16	OIVD = 3 ODE = 12 Total = 15
2008-2009	OIVD=3 ODE = 10 Total = 30	OIVD = 3 ODE = 10 Total = 29
2010-2011	OIVD = 3 ODE = 9 Total = 20	OIVD = 3 ODE = 8 Total = 19
2012-2013*	OIR = 3 ODE = 6 Total = 20	OIR = 3 ODE = 6 Total = 20
Sub total	**OIR=12** **ODE =38** **Total = 86**	**OIR = 12** **ODE = 36** **Total = 83**

****The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) is now the Office of In Vitro Diagnostics and Radiological Health (OIR).**

FY13 Percentage of Center Participation by Category

October 1, 2012 – September 30, 2013

Category	Center Participation (Unique)	% of Center Participation (Unique)*
LAW	822	59%
LED	250	18%
PRO	544	39%
SCI	937	67%

FY13 Participant Attendance by Office

October 1, 2012 –September 30, 2013

Office	Total # of Participants	% of Office Participation*
OC	161	87%
OCD	70	68%
OCER	108	68%
ODE	439	100%
OIR	191	100%
OMO	51	68%
OSB	177	100%
OSEL	189	100%

***These percentages are based on the Center and Office staffing levels as of October 2012. This data was used as the baseline throughout FY13.**

Reviewer Certification Program (RCP) Training Data

September 2011 – September 2013

RCP Training Data by Office

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
RCP	41	174	13556	– Introduction to Medical Devices – How to Write Deficiencies in Four-Part Harmony – How to Write Effective Pre-market Consulting Reviews – Effective Communication Skills for Scientific and Technical Professionals – Basic Food and Drug Law – Freedom of Information (FOI) Training – The 7 Habits of Highly Effective People – 510(k) Essentials Online – MDUFA III Training – Introduction to IDE Webcast

	Cohort	# of Attendees	Total Training Hours
ODE	**Fall 2011**	11	885
	Spring 2012	19	1711
	Summer 2012	15	1360
	Fall 2012	22	2082
	Spring 2013	18	1516
	Fall 2013	21	333
Totals:	**6 Cohorts**	**109 Participants**	**7, 890 Hours**

	Cohort	# of Attendees	Total Training Hours
OIR	**Fall 2011**	5	416
	Spring 2012	18	1790
	Summer 2012	8	863
	Fall 2012	12	1207
	Spring 2013	13	1196
	Fall 2013	9	194
Totals:	**6 Cohorts**	**65 Participants**	**5,666 Hours**

Experiential Learning Program (ELP)

May 2012 – September 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
ELP	17	147	1944	Topic areas addressed during the ELP site visits include: – Orthopedic and Dental Device Coatings – Implantable Pacemakers/Defibrillators – Patient-matched Technologies – Clinical Trials – Microbiology Manufacturing – Molecular Devices – Diabetes Care Devices

FY 2012 Experiential Learning Program (ELP) by Office

Office	# of Site Visits	# of Training Days	# of Attendees	Training Conducted
ODE	9	16	63	– Coatings on Orthopedic and Dental Devices – Patient-matched Technologies – Clinical Trial Conduct - Meeting with Institutional Review Boards (IRBs)
OIR	5	10	47	– Microbiology Manufacturing – Molecular – Diabetes Care

***FY 2013 Experiential Learning Program (ELP) by Office**

Office	# of Site Visits	# of Training Days	# of Attendees	Training Conducted
ODE	2	2	25	– Bariatric Surgery – Implantation techniques for spinal devices
OIR	1	1	12	– Manufacturing and development of molecular/immunology devices – Molecular diagnostics devices and companion diagnostics devices

***Responses to the FY13 ELP Federal Register Notice and the program budget were received late in Q3. As a result, ODE and OIR requested that the FY13 ELP site visits occur between August 2013 and March 2014. Also, many of the FY13 program visits scheduled for Q1 FY14 were postponed due to the Federal government shutdown. These visits are being rescheduled with an expected completion in March 2014.**

FY13 ODE and OIR Leadership Development Training

October 1, 2012 – September 30, 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
LEAD	35	171	1300	• Adaptive Leadership • Giving and Receiving Feedback • CDRH Employee/Labor Relations for Managers • Leading at the Speed of Trust • Leading in a Telework Environment • The Foundation of Leadership – The New Supervisor • Introduction to Situational Leadership • CDRH Administrative Forums for Managers

	Office	Total # of Managers and Supervisors*	# of Training Participants (Unique)	Hours Completed	Office Participation Percentage
FY13	ODE	46	41	937	89%
	OIR	22	20	363	91%

***The total number of managers and supervisors is based on current data as of October 2012. These numbers served as the baseline throughout FY13.**