Agenda for 2nd Quarter Meeting on MDUFA III (FY 2013-2017) Performance

April 23, 2013
1:30 P.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 12 medical device guidance documents during the 2nd quarter. *Barbara Zimmerman, CDRH-ODE*; *Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIR, Philip Desjardins, CDRH-OCD.*

FDA MDUFA Performance — Actions through March 31, 2013

- Report on decisions goals for 2nd quarter of FY 2013.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

Qualitative Update on Finances – 2nd Quarter of FY 2013

- User fee receipts through the 2nd 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- Don Lipkey and Amber Sligar, FDA-OC.

CDRH Staff Training Update

- Report on CDRH staff training. *Laura Stewart and Jackie Woodard*, CDRH-OCE

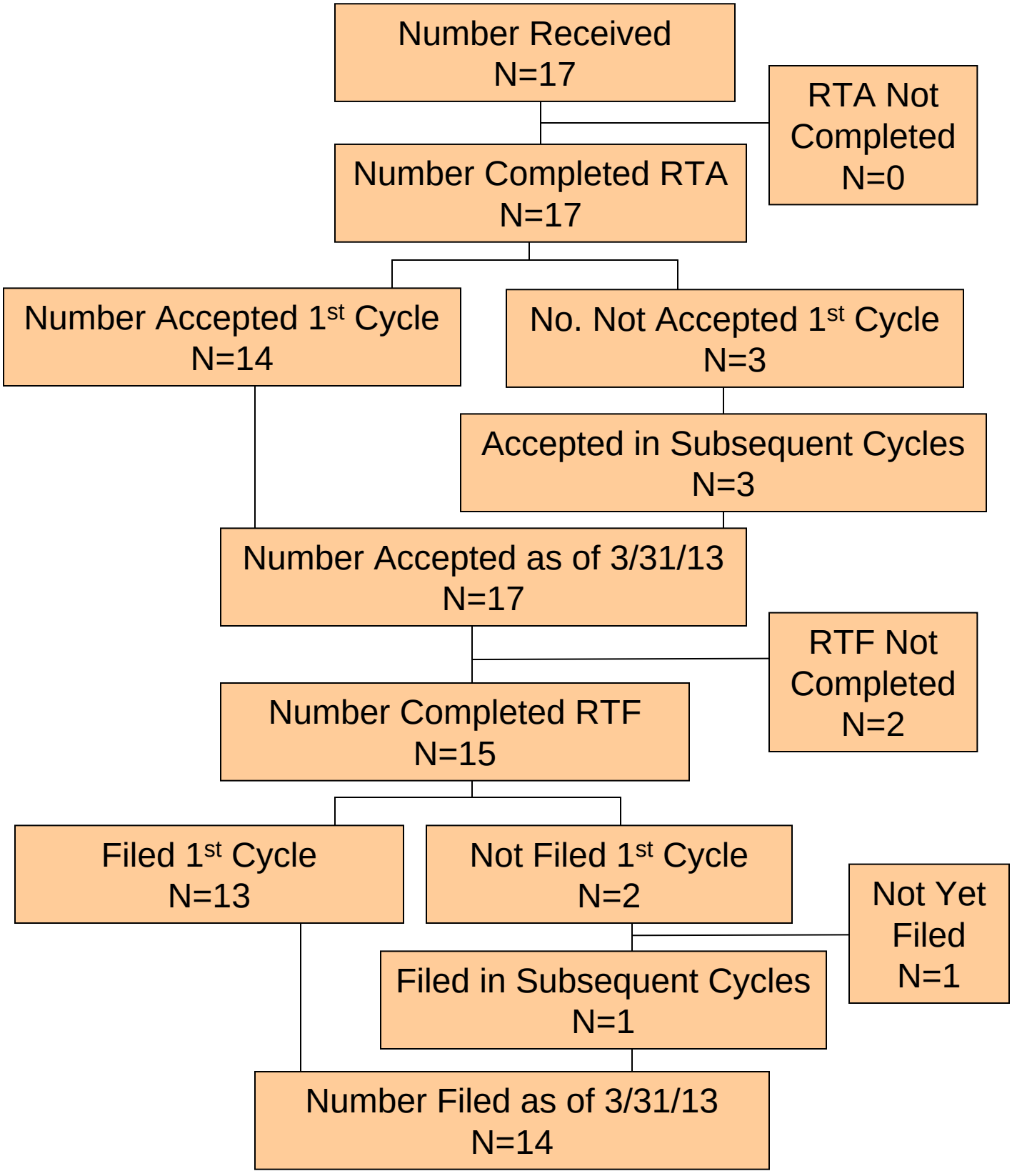
Set date for next meeting, following close of Q3. Target Date: 7/30/ 2013 at 10:00 am.

Medical Device Related Guidance Documents

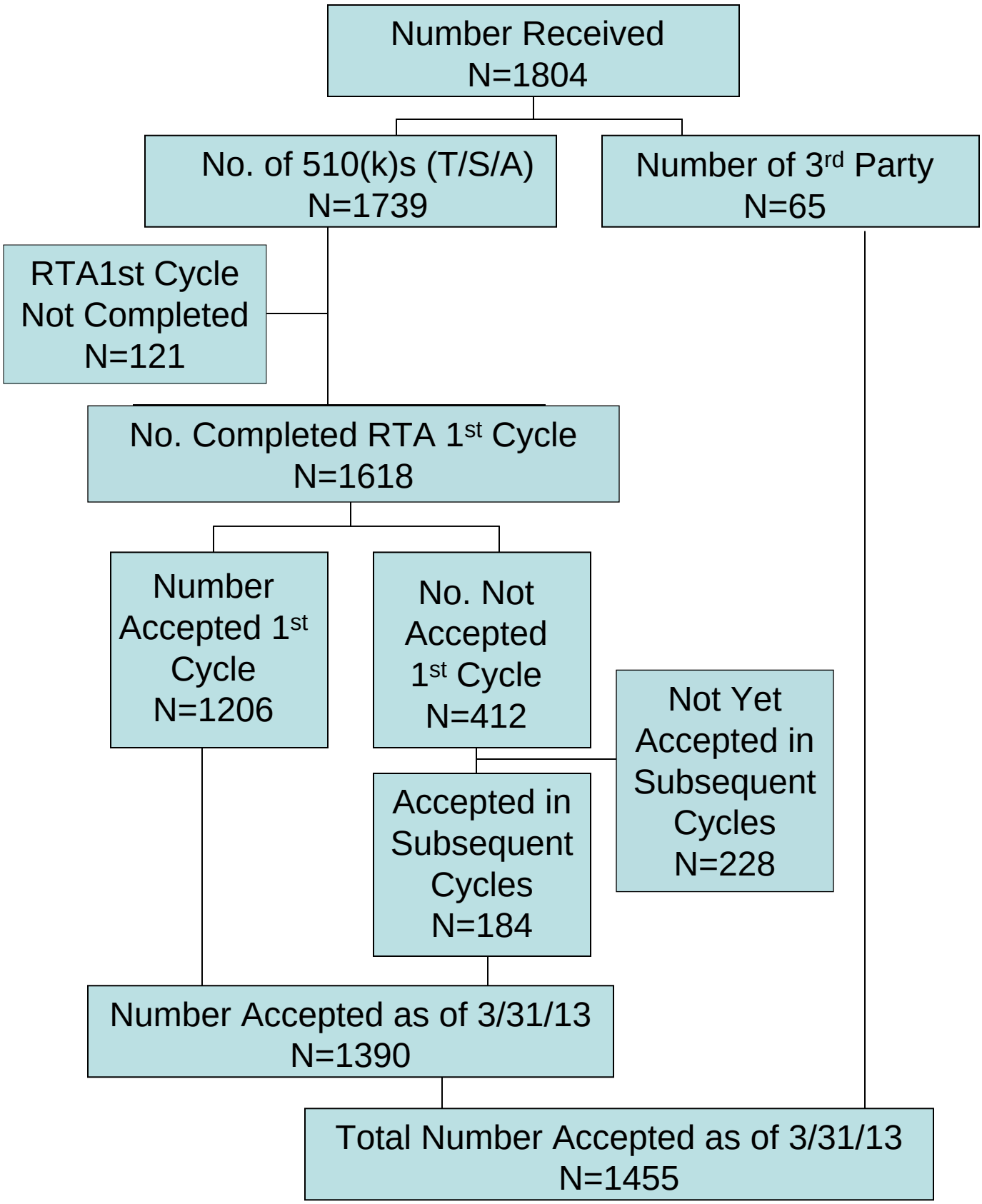
(January 1, 2013 thru March 31, 2013)

1. Guidance for Industry and FDA Staff - HUD Designations (PDF - 92KB) (CDRH/CBER/OOPD, issued 1/24/2013)
2. Draft Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate (ODE, issued 2/7/2013
3. Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation - Guidance for Industry and Food and Drug Administration Staff (ODE, issued 2/15/2013)
4. Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I - Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers (ODE/OIR, issued 2/15/2013)
5. Draft Guidance for Industry and Food and Drug Administration Staff - Providing Information about Pediatric Uses of Medical Devices Under Section 515A of the Federal Food,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 (CDRH/CBER, issued 2/19/2013)
6. Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements - Draft Guidance for Industry and Food and Drug Administration Staff (OC, issued 2/22/2013)
7. Financial Disclosure by Clinical Investigators- Guidance for Clinical Investigators , Industry, and FDA Staff (PDF - 165KB) (FDA, issued February 2013)
8. Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (ODE, issued 3/4/2013)
9. Types of Communication During the Review of Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff (CDRH/CBER, issued 3/5/2013)
10. Guidance for Industry and FDA Staff - Investigational Device Exemption (IDE) Guidance for Retinal Prostheses (ODE/OSEL, issued 3/6/2013)
11. 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 (CDRH/CDER/CBER/CVM, issued 3/11/2013)
12. 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 (OIR, issued 3/28/2013)

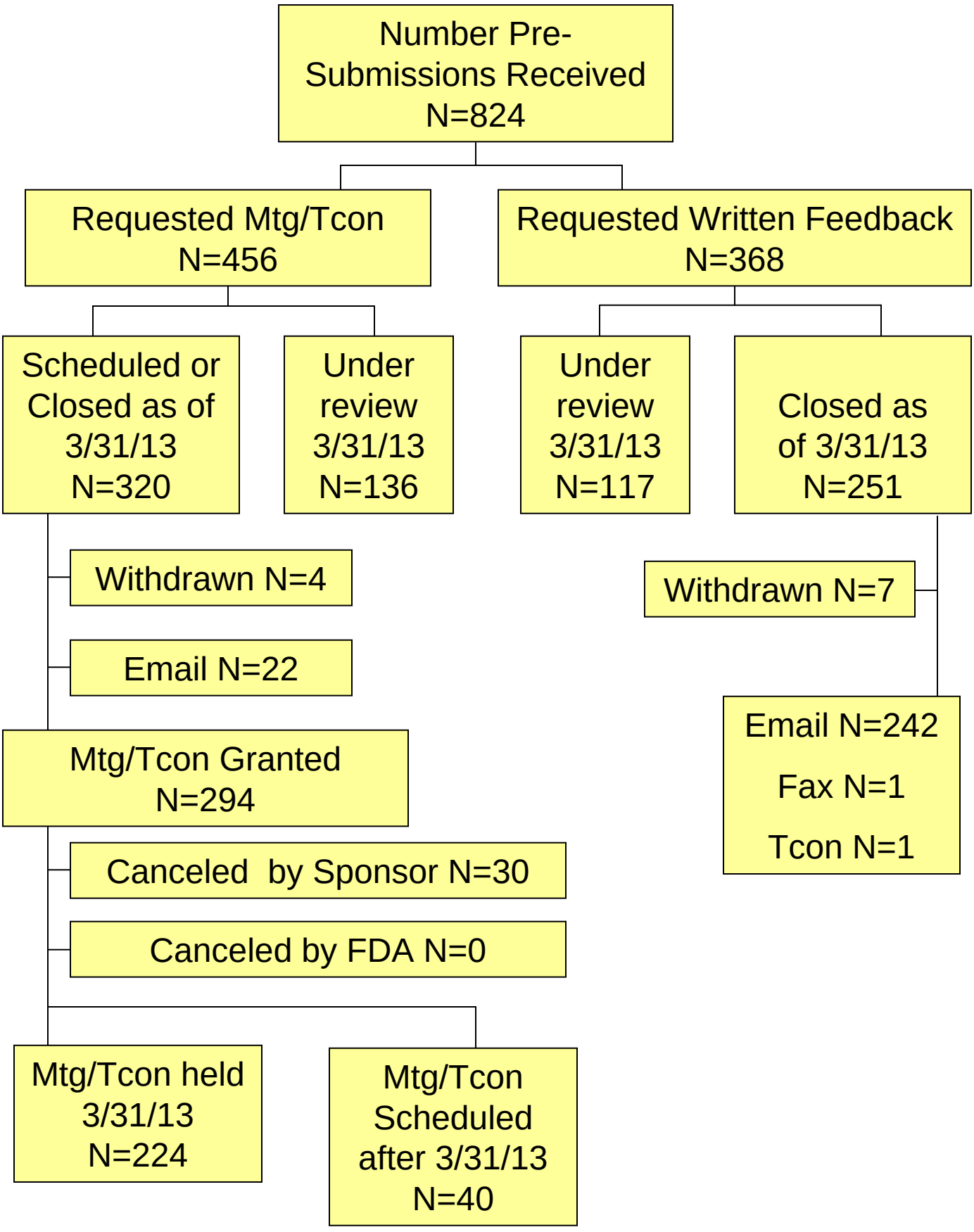
CDRH PMA Original and Panel Track Supplements (10/1/12 – 3/31/13)



CDRH 510(k)s (10/1/12 – 3/31/13)



Pre Submissions (10/1/12 – 3/31/13)



Quarterly Update on
Medical Device Performance Goals
MDUFA III Performance Data

October 1, 2012 – March 31, 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

Updated: 4/17/2013

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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	7				
Closed before RTA action	0				
Number Accepted	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	3				
Rate of submissions not accepted for filing review	43%				

*** 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	17				
Number Accepted[#]	17				
Completed RTF	15				
Number Not Filed[@]	2				
Rate of submissions Not Filed	13%				

[#] 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 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	14				
SI within 90 FDA days	8				
SI over 90 FDA days	1				
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	89%				

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

	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	87				
60th Percentile FDA days to Substantive Interaction	89				
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

	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	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	13				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6 CDRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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 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	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 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	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 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	13				
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 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	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 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	5				
Closed before RTA action	0				
Number Accepted	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	3				
Rate of submissions not accepted for filing review	60%				

*** 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	12				
Number Accepted[#]	12				
Completed RTF	10				
Number Not Filed[@]	2				
Rate of submissions Not Filed	20%				

[#] 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.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	9				
SI within 90 FDA days	5				
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	83%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	6				
Average number of FDA days to Substantive Interaction	93				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	87				
60th Percentile FDA days to Substantive Interaction	89				
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

	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	9				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	9				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.ODE ODE – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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.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	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.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	9				
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.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	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.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	2				
Closed before RTA action	0				
Number Accepted	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.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	5				
Number Accepted[#]	5				
Completed RTF	5				
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	5				
SI within 90 FDA days	3				
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.OIR OIR – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	3				
Average number of FDA days to Substantive Interaction	81				
20th Percentile FDA days to Substantive Interaction	75				
40th Percentile FDA days to Substantive Interaction	84				
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.OIR OIR - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision 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	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	4				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 1.6.OIR OIR – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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.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	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.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	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.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	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 1.10.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	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.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	0				
Closed before RTA action	0				
Number Accepted	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.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	1				
Number Accepted[#]	1				
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.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	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	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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1				
Average number of FDA days to Substantive Interaction	87				
20th Percentile FDA days to Substantive Interaction	87				
40th Percentile FDA days to Substantive Interaction	87				
60th Percentile FDA days to Substantive Interaction	87				
80th Percentile FDA days to Substantive Interaction	87				
Maximum FDA days to Substantive Interaction	87				

Table 1.5.DAGRID DAGRID - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision 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.DAGRID DAGRID – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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	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.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	2				
Closed before RTA action	0				
Number Accepted	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.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	5				
Number Accepted[#]	5				
Completed RTF	3				
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	3				
SI within 90 FDA days	2				
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	67%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	3				
Average number of FDA days to Substantive Interaction	99				
20th Percentile FDA days to Substantive Interaction	89				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	95				
80th Percentile FDA days to Substantive Interaction	106				
Maximum FDA days to Substantive Interaction	117				

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

There were no PMA Original or Panel Track Supplements received by DNPMD between October 1, 2012 and March 31, 2013.

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 Accepted	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

	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

	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

	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	1				
Closed before RTA action	0				
Number Accepted	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.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	2				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed[@]	1				
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.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	2				
SI within 90 FDA days	0				
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	n/a				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	0				
Average number of FDA days to Substantive Interaction					
20th Percentile FDA days to Substantive Interaction					
40th Percentile FDA days to Substantive Interaction					
60th Percentile FDA days to Substantive Interaction					
80th Percentile FDA days to Substantive Interaction					
Maximum FDA days to Substantive Interaction					

Table 1.5.DOED DOED - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision 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.DOED DOED – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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.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	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.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	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.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	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.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	2				
Closed before RTA action	0				
Number Accepted	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	2				
Rate of submissions not accepted for filing review	100%				

*** 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	2				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	1				
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.

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	1				
SI within 90 FDA days	0				
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	n/a				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	0				
Average number of FDA days to Substantive Interaction					
20th Percentile FDA days to Substantive Interaction					
40th Percentile FDA days to Substantive Interaction					
60th Percentile FDA days to Substantive Interaction					
80th Percentile FDA days to Substantive Interaction					
Maximum FDA days to Substantive Interaction					

Table 1.5.DRGUD DRGUD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision 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.DRGUD DRGUD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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	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.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 March 31, 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	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%				

*** 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	1				
Number Accepted[#]	1				
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.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	1				
SI within 90 FDA days	0				
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	n/a				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	0				
Average number of FDA days to Substantive Interaction					
20th Percentile FDA days to Substantive Interaction					
40th Percentile FDA days to Substantive Interaction					
60th Percentile FDA days to Substantive Interaction					
80th Percentile FDA days to Substantive Interaction					
Maximum FDA days to Substantive Interaction					

Table 1.5.DCTD DCTD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision 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.DCTD DCTD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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	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.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	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%				

*** 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	3				
Number Accepted[#]	3				
Completed RTF	3				
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	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.DIHD DIHD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

	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	89				
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	90				

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

There were no PMA Original or Panel Track Supplements received by DMD between October 1, 2012 and March 31, 2013.

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	0				
Closed before RTA action	0				
Number Accepted	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.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	1				
Number Accepted[#]	1				
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.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	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	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

	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

	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	n/a				

Table 1.6.DRH DRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision 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.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	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.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	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 1.10.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	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

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	106				
SI within 90 FDA days	65				
SI over 90 FDA days	4				
SI pending within 90 FDA days	35				
SI pending over 90 FDA days	1				
Closed without SI	1				
Current SI Performance Percent within 90 FDA days	93%				

Table 2.2 CDRH – PMA 180 Day Supplements MDUFA Decision 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	106				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	13				
MDUFA III Decisions within 180 FDA Days	13				
Supplements pending MDUFA III Decision	92				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	106				
Number with MDUFA decision	13				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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	93				
SI within 90 FDA days	60				
SI over 90 FDA days	4				
SI pending within 90 FDA days	27				
SI pending over 90 FDA days	1				
Closed without SI	1				
Current SI Performance Percent within 90 FDA days	92%				

Table 2.2.ODE ODE – PMA 180 Day Supplements MDUFA Decision 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	93				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	12				
MDUFA III Decisions within 180 FDA Days	12				
Supplements pending MDUFA III Decision	80				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	93				
Number with MDUFA decision	12				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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	13				
SI within 90 FDA days	5				
SI over 90 FDA days	0				
SI pending within 90 FDA days	8				
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

	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	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	12				
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	13				
Number with MDUFA decision	1				
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	6				
SI within 90 FDA days	3				
SI over 90 FDA days	1				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	1				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	60%				

Table 2.2.DAGRID DAGRID – PMA 180 Day Supplements MDUFA Decision 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	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	6				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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	6				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	67				
SI within 90 FDA days	46				
SI over 90 FDA days	2				
SI pending within 90 FDA days	18				
SI pending over 90 FDA days	0				
Closed without SI	1				
Current SI Performance Percent within 90 FDA days	96%				

Table 2.2.DCD DCD – PMA 180 Day Supplements MDUFA Decision 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	67				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	10				
MDUFA III Decisions within 180 FDA Days	10				
Supplements pending MDUFA III Decision	56				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	67				
Number with MDUFA decision	10				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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	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.DNPMD DNPMD – PMA 180 Day Supplements MDUFA Decision 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.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	3				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	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	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 2.2.DOD DOD – PMA 180 Day Supplements MDUFA Decision 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	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	1				
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	1				
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	8				
SI within 90 FDA days	6				
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.DOED DOED – PMA 180 Day Supplements MDUFA Decision 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	8				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	7				
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	8				
Number with MDUFA decision	1				
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	5				
SI within 90 FDA days	2				
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

	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	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	4				
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	5				
Number with MDUFA decision	1				
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	3				
SI within 90 FDA days	1				
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	50%				

Table 2.2.DSD DSD – PMA 180 Day Supplements MDUFA Decision 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.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	3				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	1				
SI within 90 FDA days	0				
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	n/a				

Table 2.2.DCTD DCTD – PMA 180 Day Supplements MDUFA Decision 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	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	1				
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	1				
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	4				
SI within 90 FDA days	3				
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.DIHD DIHD – PMA 180 Day Supplements MDUFA Decision 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	1				
MDUFA III Decisions within 180 FDA Days	1				
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.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	4				
Number with MDUFA decision	1				
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	4				
SI within 90 FDA days	1				
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.DMD DMD – PMA 180 Day Supplements MDUFA Decision 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	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	4				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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	4				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	4				
SI within 90 FDA days	1				
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.DRH DRH – PMA 180 Day Supplements MDUFA Decision 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	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	4				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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	4				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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

	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	141				
Non-MDUFA III Decisions	3				
MDUFA III Decisions	86				
MDUFA III Decisions within 90 FDA Days	86				
Supplements pending MDUFA III Decision	52				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	141				
Number with MDUFA decision	86				
Number of Not Approvable	3				
Rate of Not Approvable	3.5%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

PMA Real Time Supplements – Office Level

Table 3.1.ODE ODE – Real Time PMA Supplements MDUFA 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	116				
Non-MDUFA III Decisions	3				
MDUFA III Decisions	66				
MDUFA III Decisions within 90 FDA Days	66				
Supplements pending MDUFA III Decision	47				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	116				
Number with MDUFA decision	66				
Number of Not Approvable	3				
Rate of Not Approvable	4.5%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.OIR OIR – Real Time PMA Supplements MDUFA 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	25				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	20				
MDUFA III Decisions within 90 FDA Days	20				
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.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	25				
Number with MDUFA decision	20				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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

	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	9				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 90 FDA Days	4				
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.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	9				
Number with MDUFA decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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

	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	65				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	40				
MDUFA III Decisions within 90 FDA Days	40				
Supplements pending MDUFA III Decision	24				
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	65				
Number with MDUFA decision	40				
Number of Not Approvable	1				
Rate of Not Approvable	2.5%				

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

	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	5				
MDUFA III Decisions within 90 FDA Days	5				
Supplements pending MDUFA III Decision	11				
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	16				
Number with MDUFA decision	5				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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					

There were no PMA Real Time Supplements received by DOD between October 1, 2012 and March 31, 2013.

Table 3.1.DOED DOED – Real Time PMA Supplements MDUFA 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	4				
MDUFA III Decisions within 90 FDA Days	4				
Supplements pending MDUFA III Decision	3				
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	7				
Number with MDUFA decision	4				
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

	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	11				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	6				
MDUFA III Decisions within 90 FDA Days	6				
Supplements pending MDUFA III Decision	3				
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	11				
Number with MDUFA decision	6				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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

	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	8				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	7				
MDUFA III Decisions within 90 FDA Days	7				
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.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	8				
Number with MDUFA decision	7				
Number of Not Approvable	2				
Rate of Not Approvable	29%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

Table 3.1.DCTD DCTD – Real Time PMA Supplements MDUFA 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	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 90 FDA Days	4				
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	4				
Number with MDUFA decision	4				
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

	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	12				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	8				
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	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	12				
Number with MDUFA decision	8				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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

	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	9				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	8				
MDUFA III Decisions within 90 FDA Days	8				
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.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	9				
Number with MDUFA decision	8				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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 March 31, 2013.

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2012 and March 31, 2013.

Section 5 PMA Annual Metrics and Goals

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

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	812				
Closed before RTA action	6				
Number Accepted	271				
RTA Review not done and > 15 days since Date Received	16				
RTA Review not done and <= 15 days since Date Received	109				
Number Not Accepted	410				
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	1390				
Deleted or withdrawn prior to SI	8				
SI within 60 FDA days	1008				
SI over 60 FDA days	91				
SI pending within 60 FDA days	281				
SI pending over 60 FDA days	2				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	92%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1099				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	44				
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

	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	1455				
Non-MDUFA III Decisions	29				
MDUFA III Decisions (SE/NSE)	559				
MDUFA III Decisions within 90 FDA Days	557				
510(k)s pending MDUFA III Decision	867				
510(k) pending MDUFA III Decision over 90 FDA days	2				
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	1.44				
Number with MDUFA decision	559				
Average FDA days to MDUFA III decision	58				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	49				
60th Percentile FDA days to MDUFA III decision	71				
80th Percentile FDA days to MDUFA III decision	87				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	13				
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	5				
80th Percentile Industry days to MDUFA III decision	30				
Maximum Industry days to MDUFA III decision	118				
Average Total days to MDUFA III decision	71				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	56				
60th Percentile Total days to MDUFA III decision	85				
80th Percentile Total days to MDUFA III decision	108				
Maximum Total days to MDUFA III decision	174				

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	1455				
Number with MDUFA decision	559				
Number of SE decisions	550				
Number of NSE decisions	9				
Number of Withdrawals	23				
Number deleted	0				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	2%				
Rate of Deleted	0%				

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	2				
Mean FDA days for submissions that missed goal	102				
Mean Industry days for submissions that missed goal	13				

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	658				
Closed before RTA action	5				
Number Accepted	184				
RTA Review not done and > 15 days since Date Received	7				
RTA Review not done and <= 15 days since Date Received	86				
Number Not Accepted	376				
Rate of submissions not accepted	66%				

*** 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	1073				
Deleted or withdrawn prior to SI	7				
SI within 60 FDA days	768				
SI over 60 FDA days	68				
SI pending within 60 FDA days	229				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	92%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	836				
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	56				
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

	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	1113				
Non-MDUFA III Decisions	20				
MDUFA III Decisions (SE/NSE)	414				
MDUFA III Decisions within 90 FDA Days	413				
510(k)s pending MDUFA III Decision	679				
510(k) pending MDUFA III Decision over 90 FDA days	2				
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	1.52				
Number with MDUFA decision	414				
Average FDA days to MDUFA III decision	60				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	56				
60th Percentile FDA days to MDUFA III decision	75				
80th Percentile FDA days to MDUFA III decision	87				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	16				
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	12				
80th Percentile Industry days to MDUFA III decision	34				
Maximum Industry days to MDUFA III decision	118				
Average Total days to MDUFA III decision	76				
20th Percentile Total days to MDUFA III decision	30				
40th Percentile Total days to MDUFA III decision	63				
60th Percentile Total days to MDUFA III decision	89				
80th Percentile Total days to MDUFA III decision	114				
Maximum Total days to MDUFA III decision	174				

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	1113				
Number with MDUFA decision	414				
Number of SE decisions	406				
Number of NSE decisions	8				
Number of Withdrawals	16				
Number deleted	0				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	1%				
Rate of Deleted	0%				

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	1				
Mean FDA days for submissions that missed goal	113				
Mean Industry days for submissions that missed goal	26				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	154				
Closed before RTA action	1				
Number Accepted	87				
RTA Review not done and > 15 days since Date Received	9				
RTA Review not done and <= 15 days since Date Received	23				
Number Not Accepted	34				
Rate of submissions not accepted	26%				

*** 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.**

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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	317				
Deleted or withdrawn prior to SI	8				
SI within 60 FDA days	240				
SI over 60 FDA days	23				
SI pending within 60 FDA days	52				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	91%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	263				
Average number of FDA days to Substantive Interaction	45				
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	58				
Maximum FDA days to Substantive Interaction	91				

Table 6.4.OIR OIR – 510(k) MDUFA Decision 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	342				
Non-MDUFA III Decisions	9				
MDUFA III Decisions (SE/NSE)	145				
MDUFA III Decisions within 90 FDA Days	144				
510(k)s pending MDUFA III Decision	188				
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	1.23				
Number with MDUFA decision	145				
Average FDA days to MDUFA III decision	50				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	36				
60th Percentile FDA days to MDUFA III decision	55				
80th Percentile FDA days to MDUFA III decision	78				
Maximum FDA days to MDUFA III decision	91				
Average Industry days to MDUFA III decision	6				
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	6				
Maximum Industry days to MDUFA III decision	86				
Average Total days to MDUFA III decision	56				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	37				
60th Percentile Total days to MDUFA III decision	59				
80th Percentile Total days to MDUFA III decision	87				
Maximum Total days to MDUFA III decision	160				

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	342				
Number with MDUFA decision	145				
Number of SE decisions	144				
Number of NSE decisions	1				
Number of Withdrawals	7				
Number deleted	0				
Rate of SE decisions	99%				
Rate of NSE decisions	0.7%				
Rate of Withdrawals	2%				
Rate of Deleted	0%				

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	1				
Mean FDA days for submissions that missed goal	91				
Mean Industry days for submissions that missed goal	0				

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	181				
Closed before RTA action	3				
Number Accepted	50				
RTA Review not done and > 15 days since Date Received	1				
RTA Review not done and <= 15 days since Date Received	29				
Number Not Accepted	98				
Rate of submissions not accepted	66%				

*** 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	261				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	200				
SI over 60 FDA days	14				
SI pending within 60 FDA days	47				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	94%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	214				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	49				
60th Percentile FDA days to Substantive Interaction	57				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	86				

Table 6.4.DAGRID DAGRID – 510(k) MDUFA Decision 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	271				
Non-MDUFA III Decisions	3				
MDUFA III Decisions (SE/NSE)	97				
MDUFA III Decisions within 90 FDA Days	97				
510(k)s pending MDUFA III Decision	171				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.49				
Number with MDUFA decision	97				
Average FDA days to MDUFA III decision	63				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	59				
60th Percentile FDA days to MDUFA III decision	79				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	14				
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	32				
Maximum Industry days to MDUFA III decision	91				
Average Total days to MDUFA III decision	78				
20th Percentile Total days to MDUFA III decision	32				
40th Percentile Total days to MDUFA III decision	68				
60th Percentile Total days to MDUFA III decision	87				
80th Percentile Total days to MDUFA III decision	115				
Maximum Total days to MDUFA III decision	174				

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	271				
Number with MDUFA decision	97				
Number of SE decisions	95				
Number of NSE decisions	2				
Number of Withdrawals	1				
Number deleted	0				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	0.4%				
Rate of Deleted	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	94				
Closed before RTA action	0				
Number Accepted	46				
RTA Review not done and > 15 days since Date Received	3				
RTA Review not done and <= 15 days since Date Received	9				
Number Not Accepted	36				
Rate of submissions not accepted	42%				

*** 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	170				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	112				
SI over 60 FDA days	17				
SI pending within 60 FDA days	40				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	86%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	129				
Average number of FDA days to Substantive Interaction	45				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	35				
60th Percentile FDA days to Substantive Interaction	49				
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

	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	180				
Non-MDUFA III Decisions	0				
MDUFA III Decisions (SE/NSE)	82				
MDUFA III Decisions within 90 FDA Days	81				
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	99%				

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	1.44				
Number with MDUFA decision	82				
Average FDA days to MDUFA III decision	56				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	47				
60th Percentile FDA days to MDUFA III decision	61				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	14				
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	10				
80th Percentile Industry days to MDUFA III decision	34				
Maximum Industry days to MDUFA III decision	71				
Average Total days to MDUFA III decision	70				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	48				
60th Percentile Total days to MDUFA III decision	84				
80th Percentile Total days to MDUFA III decision	109				
Maximum Total days to MDUFA III decision	161				

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	180				
Number with MDUFA decision	82				
Number of SE decisions	82				
Number of NSE decisions	0				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	0%				
Rate of Deleted	0%				

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	1				
Mean FDA days for submissions that missed goal	113				
Mean Industry days for submissions that missed goal	26				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	49				
Closed before RTA action	0				
Number Accepted	5				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	10				
Number Not Accepted	34				
Rate of submissions not accepted	87%				

*** 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	70				
Deleted or withdrawn prior to SI	2				
SI within 60 FDA days	56				
SI over 60 FDA days	3				
SI pending within 60 FDA days	9				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	95%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	59				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	44				
60th Percentile FDA days to Substantive Interaction	56				
80th Percentile FDA days to Substantive Interaction	69				
Maximum FDA days to Substantive Interaction	77				

Table 6.4.DNPMD DNPMD – 510(k) MDUFA Decision 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	74				
Non-MDUFA III Decisions	3				
MDUFA III Decisions (SE/NSE)	16				
MDUFA III Decisions within 90 FDA Days	16				
510(k)s pending MDUFA III Decision	55				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.56				
Number with MDUFA decision	16				
Average FDA days to MDUFA III decision	72				
20th Percentile FDA days to MDUFA III decision	54				
40th Percentile FDA days to MDUFA III decision	71				
60th Percentile FDA days to MDUFA III decision	87				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	17				
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	15				
80th Percentile Industry days to MDUFA III decision	30				
Maximum Industry days to MDUFA III decision	67				
Average Total days to MDUFA III decision	89				
20th Percentile Total days to MDUFA III decision	57				
40th Percentile Total days to MDUFA III decision	71				
60th Percentile Total days to MDUFA III decision	99				
80th Percentile Total days to MDUFA III decision	118				
Maximum Total days to MDUFA III decision	156				

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	74				
Number with MDUFA decision	16				
Number of SE decisions	16				
Number of NSE decisions	0				
Number of Withdrawals	3				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	4%				
Rate of Deleted	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	143				
Closed before RTA action	0				
Number Accepted	33				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	15				
Number Not Accepted	95				
Rate of submissions not accepted	74%				

*** 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	239				
Deleted or withdrawn prior to SI	3				
SI within 60 FDA days	166				
SI over 60 FDA days	12				
SI pending within 60 FDA days	58				
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.DOD DOD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	178				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	48				
60th Percentile FDA days to Substantive Interaction	57				
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

	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	240				
Non-MDUFA III Decisions	4				
MDUFA III Decisions (SE/NSE)	99				
MDUFA III Decisions within 90 FDA Days	99				
510(k)s pending MDUFA III Decision	137				
510(k) pending MDUFA III Decision over 90 FDA days	1				
Current Performance Percent within 90 FDA Days	99%				

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	1.48				
Number with MDUFA decision	99				
Average FDA days to MDUFA III decision	66				
20th Percentile FDA days to MDUFA III decision	44				
40th Percentile FDA days to MDUFA III decision	64				
60th Percentile FDA days to MDUFA III decision	80				
80th Percentile FDA days to MDUFA III decision	87				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	15				
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	10				
80th Percentile Industry days to MDUFA III decision	38				
Maximum Industry days to MDUFA III decision	93				
Average Total days to MDUFA III decision	81				
20th Percentile Total days to MDUFA III decision	50				
40th Percentile Total days to MDUFA III decision	74				
60th Percentile Total days to MDUFA III decision	9				
80th Percentile Total days to MDUFA III decision	113				
Maximum Total days to MDUFA III decision	168				

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	240				
Number with MDUFA decision	99				
Number of SE decisions	95				
Number of NSE decisions	4				
Number of Withdrawals	4				
Number deleted	0				
Rate of SE decisions	96%				
Rate of NSE decisions	4%				
Rate of Withdrawals	2%				
Rate of Deleted	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34				
Closed before RTA action	0				
Number Accepted	12				
RTA Review not done and > 15 days since Date Received	1				
RTA Review not done and <= 15 days since Date Received	6				
Number Not Accepted	15				
Rate of submissions not accepted	54%				

*** 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	46				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	26				
SI over 60 FDA days	3				
SI pending within 60 FDA days	17				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	90%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	29				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	43				
40th Percentile FDA days to Substantive Interaction	46				
60th Percentile FDA days to Substantive Interaction	51				
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

	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	49				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	12				
MDUFA III Decisions within 90 FDA Days	12				
510(k)s pending MDUFA III Decision	36				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	2.0				
Number with MDUFA decision	12				
Average FDA days to MDUFA III decision	69				
20th Percentile FDA days to MDUFA III decision	53				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	82				
80th Percentile FDA days to MDUFA III decision	90				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	34				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	9				
60th Percentile Industry days to MDUFA III decision	43				
80th Percentile Industry days to MDUFA III decision	71				
Maximum Industry days to MDUFA III decision	83				
Average Total days to MDUFA III decision	103				
20th Percentile Total days to MDUFA III decision	68				
40th Percentile Total days to MDUFA III decision	95				
60th Percentile Total days to MDUFA III decision	119				
80th Percentile Total days to MDUFA III decision	125				
Maximum Total days to MDUFA III decision	158				

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	49				
Number with MDUFA decision	12				
Number of SE decisions	12				
Number of NSE decisions	0				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	0%				
Rate of Deleted	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	53				
Closed before RTA action	0				
Number Accepted	8				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	6				
Number Not Accepted	39				
Rate of submissions not accepted	83%				

*** 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	99				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	71				
SI over 60 FDA days	4				
SI pending within 60 FDA days	23				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	95%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	75				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	47				
60th Percentile FDA days to Substantive Interaction	51				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	66				

Table 6.4.DRGUD DRGUD – 510(k) MDUFA Decision 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	105				
Non-MDUFA III Decisions	2				
MDUFA III Decisions (SE/NSE)	32				
MDUFA III Decisions within 90 FDA Days	32				
510(k)s pending MDUFA III Decision	71				
510(k) pending MDUFA III Decision over 90 FDA days	1				
Current Performance Percent within 90 FDA Days	97%				

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	32				
Average FDA days to MDUFA III decision	61				
20th Percentile FDA days to MDUFA III decision	33				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	76				
80th Percentile FDA days to MDUFA III decision	86				
Maximum FDA days to MDUFA III decision	89				
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	13				
60th Percentile Industry days to MDUFA III decision	27				
80th Percentile Industry days to MDUFA III decision	40				
Maximum Industry days to MDUFA III decision	118				
Average Total days to MDUFA III decision	87				
20th Percentile Total days to MDUFA III decision	50				
40th Percentile Total days to MDUFA III decision	79				
60th Percentile Total days to MDUFA III decision	102				
80th Percentile Total days to MDUFA III decision	120				
Maximum Total days to MDUFA III decision	164				

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	105				
Number with MDUFA decision	32				
Number of SE decisions	31				
Number of NSE decisions	1				
Number of Withdrawals	2				
Number deleted	0				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	2%				
Rate of Deleted	0%				

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	104				
Closed before RTA action	2				
Number Accepted	30				
RTA Review not done and > 15 days since Date Received	2				
RTA Review not done and <= 15 days since Date Received	11				
Number Not Accepted	59				
Rate of submissions not accepted	65%				

*** 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	188				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	137				
SI over 60 FDA days	15				
SI pending within 60 FDA days	35				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	90%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	152				
Average number of FDA days to Substantive Interaction	41				
20th Percentile FDA days to Substantive Interaction	22				
40th Percentile FDA days to Substantive Interaction	31				
60th Percentile FDA days to Substantive Interaction	52				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	90				

Table 6.4.DSD DSD – 510(k) MDUFA Decision 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	194				
Non-MDUFA III Decisions	7				
MDUFA III Decisions (SE/NSE)	76				
MDUFA III Decisions within 90 FDA Days	76				
510(k)s pending MDUFA III Decision	111				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.49				
Number with MDUFA decision	76				
Average FDA days to MDUFA III decision	51				
20th Percentile FDA days to MDUFA III decision	22				
40th Percentile FDA days to MDUFA III decision	39				
60th Percentile FDA days to MDUFA III decision	61				
80th Percentile FDA days to MDUFA III decision	83				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	13				
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	7				
80th Percentile Industry days to MDUFA III decision	27				
Maximum Industry days to MDUFA III decision	79				
Average Total days to MDUFA III decision	64				
20th Percentile Total days to MDUFA III decision	24				
40th Percentile Total days to MDUFA III decision	43				
60th Percentile Total days to MDUFA III decision	83				
80th Percentile Total days to MDUFA III decision	98				
Maximum Total days to MDUFA III decision	144				

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	194				
Number with MDUFA decision	76				
Number of SE decisions	75				
Number of NSE decisions	1				
Number of Withdrawals	6				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	1%				
Rate of Withdrawals	3%				
Rate of Deleted	0%				

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	57				
Closed before RTA action	0				
Number Accepted	39				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	10				
Number Not Accepted	8				
Rate of submissions not accepted	17%				

*** 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	108				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	92				
SI over 60 FDA days	0				
SI pending within 60 FDA days	16				
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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	92				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	46				
80th Percentile FDA days to Substantive Interaction	55				
Maximum FDA days to Substantive Interaction	59				

Table 6.4.DCTD DCTD – 510(k) MDUFA Decision 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	108				
Non-MDUFA III Decisions	3				
MDUFA III Decisions (SE/NSE)	31				
MDUFA III Decisions within 90 FDA Days	31				
510(k)s pending MDUFA III Decision	74				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.23				
Number with MDUFA decision	31				
Average FDA days to MDUFA III decision	47				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	35				
60th Percentile FDA days to MDUFA III decision	45				
80th Percentile FDA days to MDUFA III decision	75				
Maximum FDA days to MDUFA III decision	89				
Average Industry days to MDUFA III decision	6				
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	10				
Maximum Industry days to MDUFA III decision	58				
Average Total days to MDUFA III decision	53				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	35				
60th Percentile Total days to MDUFA III decision	48				
80th Percentile Total days to MDUFA III decision	81				
Maximum Total days to MDUFA III decision	142				

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	108				
Number with MDUFA decision	31				
Number of SE decisions	31				
Number of NSE decisions	0				
Number of Withdrawals	3				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	3%				
Rate of Deleted	0%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	23				
Closed before RTA action	1				
Number Accepted	11				
RTA Review not done and > 15 days since Date Received	2				
RTA Review not done and <= 15 days since Date Received	4				
Number Not Accepted	5				
Rate of submissions not accepted	28%				

*** 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	33				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	25				
SI over 60 FDA days	1				
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	96%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	26				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	45				
40th Percentile FDA days to Substantive Interaction	51				
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

	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	33				
Non-MDUFA III Decisions	2				
MDUFA III Decisions (SE/NSE)	2				
MDUFA III Decisions within 90 FDA Days	2				
510(k)s pending MDUFA III Decision	29				
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	1.00				
Number with MDUFA decision	2				
Average FDA days to MDUFA III decision	57				
20th Percentile FDA days to MDUFA III decision	38				
40th Percentile FDA days to MDUFA III decision	51				
60th Percentile FDA days to MDUFA III decision	63				
80th Percentile FDA days to MDUFA III decision	76				
Maximum FDA days to MDUFA III decision	89				
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	57				
20th Percentile Total days to MDUFA III decision	38				
40th Percentile Total days to MDUFA III decision	51				
60th Percentile Total days to MDUFA III decision	63				
80th Percentile Total days to MDUFA III decision	76				
Maximum Total days to MDUFA III decision	89				

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	33				
Number with MDUFA decision	2				
Number of SE decisions	1				
Number of NSE decisions	1				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	50%				
Rate of NSE decisions	50%				
Rate of Withdrawals	0%				
Rate of Deleted	0%				

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	7				
Closed before RTA action	0				
Number Accepted	6				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	1				
Number Not Accepted	0				
Rate of submissions not accepted	0%				

*** 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	28				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	24				
SI over 60 FDA days	0				
SI pending within 60 FDA days	4				
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.DMD DMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	24				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	39				
60th Percentile FDA days to Substantive Interaction	52				
80th Percentile FDA days to Substantive Interaction	55				
Maximum FDA days to Substantive Interaction	60				

Table 6.4.DMD DMD – 510(k) MDUFA Decision 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	28				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	12				
MDUFA III Decisions within 90 FDA Days	12				
510(k)s pending MDUFA III Decision	15				
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	1.00				
Number with MDUFA decision	12				
Average FDA days to MDUFA III decision	56				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	44				
60th Percentile FDA days to MDUFA III decision	72				
80th Percentile FDA days to MDUFA III decision	79				
Maximum FDA days to MDUFA III decision	89				
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	56				
20th Percentile Total days to MDUFA III decision	30				
40th Percentile Total days to MDUFA III decision	44				
60th Percentile Total days to MDUFA III decision	72				
80th Percentile Total days to MDUFA III decision	79				
Maximum Total days to MDUFA III decision	89				

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	28				
Number with MDUFA decision	12				
Number of SE decisions	12				
Number of NSE decisions	0				
Number of Withdrawals	1				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	4%				
Rate of Deleted	0%				

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	67				
Closed before RTA action	0				
Number Accepted	31				
RTA Review not done and > 15 days since Date Received	7				
RTA Review not done and <= 15 days since Date Received	8				
Number Not Accepted	21				
Rate of submissions not accepted	26%				

*** 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	148				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	99				
SI over 60 FDA days	22				
SI pending within 60 FDA days	25				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	81%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	121				
Average number of FDA days to Substantive Interaction	47				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	55				
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

	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	173				
Non-MDUFA III Decisions	3				
MDUFA III Decisions (SE/NSE)	100				
MDUFA III Decisions within 90 FDA Days	99				
510(k)s pending MDUFA III Decision	70				
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	1.26				
Number with MDUFA decision	100				
Average FDA days to MDUFA III decision	50				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	37				
60th Percentile FDA days to MDUFA III decision	56				
80th Percentile FDA days to MDUFA III decision	78				
Maximum FDA days to MDUFA III decision	91				
Average Industry days to MDUFA III decision	7				
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	12				
Maximum Industry days to MDUFA III decision	86				
Average Total days to MDUFA III decision	57				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	37				
60th Percentile Total days to MDUFA III decision	59				
80th Percentile Total days to MDUFA III decision	87				
Maximum Total days to MDUFA III decision	160				

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	173				
Number with MDUFA decision	100				
Number of SE decisions	100				
Number of NSE decisions	0				
Number of Withdrawals	3				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
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	1				
Mean FDA days for submissions that missed goal	91				
Mean Industry days for submissions that missed goal	0				

Section 7 510(k) Annual General Metrics

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

Section 8 Annual Metrics for De Novo Petitions

De Novo Petition Metrics will be reported in the Annual Report.

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	824				
Number requesting a meeting or teleconference	456				
Number with meetings or teleconferences granted	294				
Number with meeting granted and industry cancelled	30				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	40				
Number with meetings or teleconferences held	224				
Average days to meeting	58				
20th Percentile days to meeting	36				
40th Percentile days to meeting	54				
60th Percentile days to meeting	67				
80th Percentile days to meeting	80				
Maximum days to meeting	138				

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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	435				
Number requesting a meeting or teleconference	280				
Number with meetings or teleconferences granted	164				
Number with meeting granted and industry cancelled	16				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	19				
Number with meetings or teleconferences held	129				
Average days to meeting	61				
20th Percentile days to meeting	39				
40th Percentile days to meeting	56				
60th Percentile days to meeting	68				
80th Percentile days to meeting	82				
Maximum days to meeting	121				

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	389				
Number requesting a meeting or teleconference	176				
Number with meetings or teleconferences granted	130				
Number with meeting granted and industry cancelled	14				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	21				
Number with meetings or teleconferences held	95				
Average days to meeting	55				
20th Percentile days to meeting	34				
40th Percentile days to meeting	50				
60th Percentile days to meeting	64				
80th Percentile days to meeting	80				
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	64				
Number requesting a meeting or teleconference	36				
Number with meetings or teleconferences granted	17				
Number with meeting granted and industry cancelled	0				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	2				
Number with meetings or teleconferences held	15				
Average days to meeting	82				
20th Percentile days to meeting	67				
40th Percentile days to meeting	78				
60th Percentile days to meeting	83				
80th Percentile days to meeting	100				
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	137				
Number requesting a meeting or teleconference	100				
Number with meetings or teleconferences granted	70				
Number with meeting granted and industry cancelled	7				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	10				
Number with meetings or teleconferences held	53				
Average days to meeting	54				
20th Percentile days to meeting	35				
40th Percentile days to meeting	48				
60th Percentile days to meeting	60				
80th Percentile days to meeting	74				
Maximum days to meeting	104				

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	37				
Number requesting a meeting or teleconference	24				
Number with meetings or teleconferences granted	8				
Number with meeting granted and industry cancelled	1				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	0				
Number with meetings or teleconferences held	7				
Average days to meeting	78				
20th Percentile days to meeting	69				
40th Percentile days to meeting	89				
60th Percentile days to meeting	91				
80th Percentile days to meeting	93				
Maximum days to meeting	97				

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	39				
Number requesting a meeting or teleconference	26				
Number with meetings or teleconferences granted	11				
Number with meeting granted and industry cancelled	2				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	1				
Number with meetings or teleconferences held	8				
Average days to meeting	59				
20th Percentile days to meeting	49				
40th Percentile days to meeting	59				
60th Percentile days to meeting	64				
80th Percentile days to meeting	73				
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	41				
Number requesting a meeting or teleconference	24				
Number with meetings or teleconferences granted	19				
Number with meeting granted and industry cancelled	2				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	5				
Number with meetings or teleconferences held	12				
Average days to meeting	65				
20th Percentile days to meeting	44				
40th Percentile days to meeting	66				
60th Percentile days to meeting	71				
80th Percentile days to meeting	83				
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	61				
Number requesting a meeting or teleconference	36				
Number with meetings or teleconferences granted	23				
Number with meeting granted and industry cancelled	1				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	1				
Number with meetings or teleconferences held	21				
Average days to meeting	57				
20th Percentile days to meeting	37				
40th Percentile days to meeting	52				
60th Percentile days to meeting	66				
80th Percentile days to meeting	72				
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	56				
Number requesting a meeting or teleconference	34				
Number with meetings or teleconferences granted	16				
Number with meeting granted and industry cancelled	3				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	0				
Number with meetings or teleconferences held	13				
Average days to meeting	56				
20th Percentile days to meeting	31				
40th Percentile days to meeting	49				
60th Percentile days to meeting	64				
80th Percentile days to meeting	77				
Maximum days to meeting	104				

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	106				
Number requesting a meeting or teleconference	50				
Number with meetings or teleconferences granted	39				
Number with meeting granted and industry cancelled	3				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	7				
Number with meetings or teleconferences held	29				
Average days to meeting	49				
20th Percentile days to meeting	30				
40th Percentile days to meeting	45				
60th Percentile days to meeting	59				
80th Percentile days to meeting	68				
Maximum days to meeting	89				

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	139				
Number requesting a meeting or teleconference	78				
Number with meetings or teleconferences granted	56				
Number with meeting granted and industry cancelled	8				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	9				
Number with meetings or teleconferences held	39				
Average days to meeting	66				
20th Percentile days to meeting	43				
40th Percentile days to meeting	61				
60th Percentile days to meeting	83				
80th Percentile days to meeting	84				
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	118				
Number requesting a meeting or teleconference	34				
Number with meetings or teleconferences granted	24				
Number with meeting granted and industry cancelled	2				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	5				
Number with meetings or teleconferences held	17				
Average days to meeting	49				
20th Percentile days to meeting	35				
40th Percentile days to meeting	45				
60th Percentile days to meeting	60				
80th Percentile days to meeting	68				
Maximum days to meeting	74				

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	26				
Number requesting a meeting or teleconference	14				
Number with meetings or teleconferences granted	11				
Number with meeting granted and industry cancelled	1				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and scheduled outside the reporting timeframe	0				
Number with meetings or teleconferences held	10				
Average days to meeting	38				
20th Percentile days to meeting	6				
40th Percentile days to meeting	36				
60th Percentile days to meeting	47				
80th Percentile days to meeting	64				
Maximum days to meeting	67				

Section 10

Section 10 CLIA Waiver Annual Metrics

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

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 Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) 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) 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 8) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 9) divided by Number with completed RTF (line 8).

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.
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 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) decision in the first RTA review cycle automatically recorded by CTS at the end of day 14 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 (see the definition for Accepted cohort above), excluding submissions with the following NON-MDUFA decisions made before or on the cutoff date: WD, DD, DE, HD, K4, NR, RC, RD. 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 accepted, but were withdrawn or deleted prior to 60 days
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 AN, DN, ON decisions 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).
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 have more than 90 FDA days to MDUFA III decision. 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 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 granted	Number requesting a meeting or teleconference (line 2) with Meeting Scheduled Date populated with a value.
4	Number with meeting granted and industry cancelled	Number with meetings or teleconferences granted (line 3) and cancelled by industry (final decision code is CNLR – Cancelled by Requestor).
5	Number with meeting granted and FDA cancelled	Number with meetings or teleconferences granted (line 3) and cancelled by FDA (final decision code is CNLF – Cancelled by FDA).
6	Number with meeting granted and scheduled outside the reporting timeframe	Number with meetings or teleconferences granted (line 3) that are not cancelled or held by the report cutoff date.
7	Number with meetings or teleconferences held	Number with meetings or teleconferences granted (line 3) that were held (Date Meeting Held is populated with a value).
	Days to meeting	Table shall show average days from Date Received to Date Meeting Planned as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting 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	0				
Closed before RTA action	0				
Number Accepted	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	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 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	0				
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	0				
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	0				
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 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	1				
SI within 90 FDA days	0				
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	0.0%				

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	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	0.0%				

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	1				
Number with MDUFA decision	0				
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	2				
MDUFA III Decisions within 90 FDA Days	2				
Supplements pending MDUFA III Decision	1				
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	2				
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	0				
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	0				
180-Day Supplements	1				
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	0				
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	33				
Closed before RTA action	0				
Number Accepted	23				
Number without a RTA Review and > 15 Days since Date Received	3				
Number without a RTA Review and <= 15 Days since Date Received	2				
Number Not Accepted	5				
Rate of submissions not accepted for filing review	17.9%				

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	21				
SI within 60 FDA days	16				
SI over 60 FDA days	5				
SI pending within 60 FDA days	0				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	76.0%				

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	21				
Average number of FDA days to Substantive Interaction	51				
20th Percentile FDA days to Substantive Interaction	27				
40th Percentile FDA days to Substantive Interaction	35				
60th Percentile FDA days to Substantive Interaction	58				
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	23				
Non-MDUFA III Decisions	13				
MDUFA III Decisions (SE/NSE)	8				
MDUFA III Decisions within 90 FDA Days	8				
510(k)s pending MDUFA III Decision	15				
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	1.00				
Number with MDUFA III decision	8				
Average FDA days to MDUFA III decision	53				
20th Percentile FDA days to MDUFA III decision	25				
40th Percentile FDA days to MDUFA III decision	27				
60th Percentile FDA days to MDUFA III decision	29				
80th Percentile FDA days to MDUFA III decision	89				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	19				
20th Percentile Industry days to MDUFA III decision	19				
40th Percentile Industry days to MDUFA III decision	19				
60th Percentile Industry days to MDUFA III decision	19				
80th Percentile Industry days to MDUFA III decision	19				
Maximum Industry days to MDUFA III decision	19				
Average Total days to MDUFA III decision	55				
20th Percentile Total days to MDUFA III decision	25				
40th Percentile Total days to MDUFA III decision	27				
60th Percentile Total days to MDUFA III decision	29				

80th Percentile Total days to MDUFA III decision	89				
Maximum Total days to MDUFA III decision	108				

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	23				
Number with MDUFA decision	8				
Number of SE decisions	8				
Number of NSE decisions	0				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	100.0%				
Rate of NSE decisions	0.0%				
Rate of Withdrawals	0.0%				
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	23				
Number of Traditional submissions	18				
Number of Special submissions	4				

Number of Abbreviated submissions	1				
Average number of days to Accept / Refuse to Accept	11				
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	23				
Currently Under Review	15				
Number with Non-MDUFA Decision	13				
Number with MDUFA III Decision	8				
Percent of cohort closed	35.0%				
Number with MDUFA III decision after trimming the upper and lower 2%	6				
Average Total Time to MDUFA III decision	55				

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	24				
Number requesting a meeting or teleconference	22				
Number with meetings or teleconferences granted	18				
Number with meeting granted and industry cancelled	7				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and pending within timeframe	6				
Number with meeting granted and pending outside timeframe	1				
Number with meetings or teleconferences held	4				
Average days to meeting	64				
20th Percentile days to meeting	55				
40th Percentile days to meeting	55				
60th Percentile days to meeting	57				
80th Percentile days to meeting	59				
Maximum days to meeting	84				

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	14				
Number of Standard BLA First Actions less than or equal to 10 months	0				
Number of Standard BLA Frist Actions greater than 10 months	0				
Number of Standard BLAs Pending	14				
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	8				
Number of Standard PAS Supplements First Actions less than or equal to 4months	6				
Number of Standard PAS Supplements First Actions greater than 4 months	0				
Number of Standard PAS Supplements Pending	2				

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	0				
Number of Class 1 Resubmission Actions less than or equal to 2 months	0				
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 March 31, 2013 [1] Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$52,233,230	$87,731	$52,145,499		
Application Fees	$18,883,972	$151,350	$18,732,622		
Total	**$71,117,202**	**$239,081**	**$70,878,121**	**$97,722,301**	**73%**

Medical Device User Fee Collection History [2] Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,280,073	$31,680,296	$34,470,161	$27,808,956
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,621,768	$55,817,986	$62,836,164	$69,593,344	$65,572,403

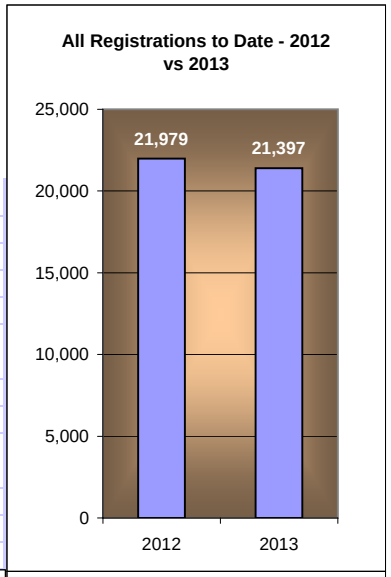
Notes:

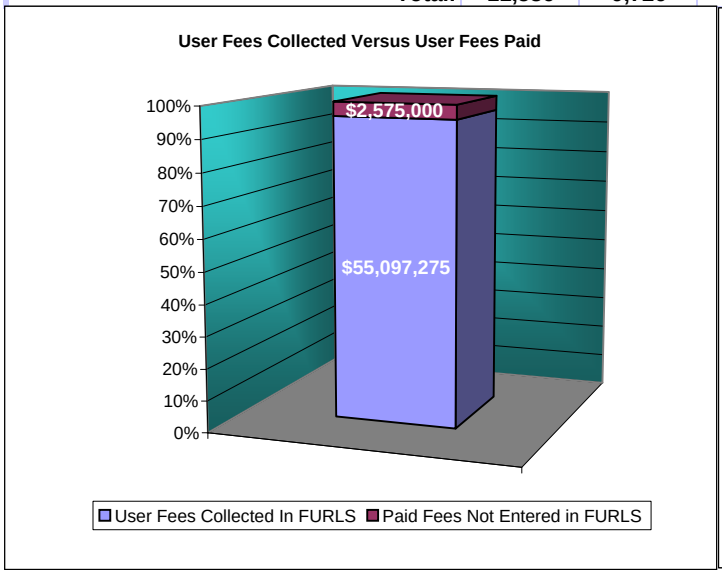
/1 Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2013.

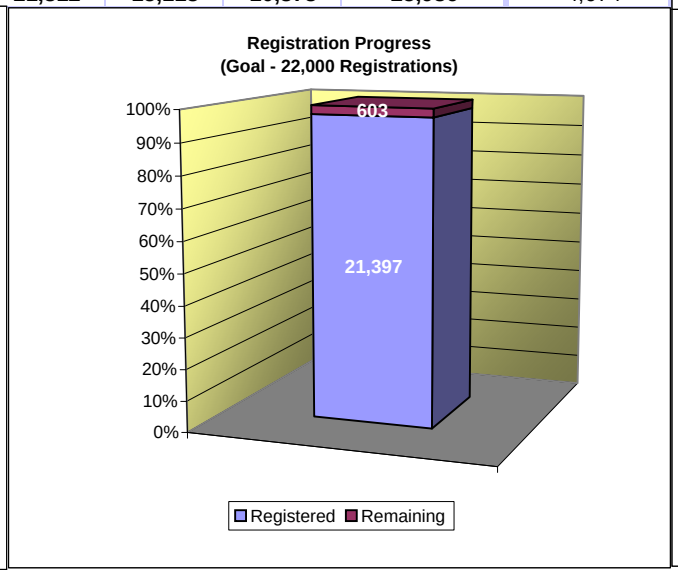
/2 Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

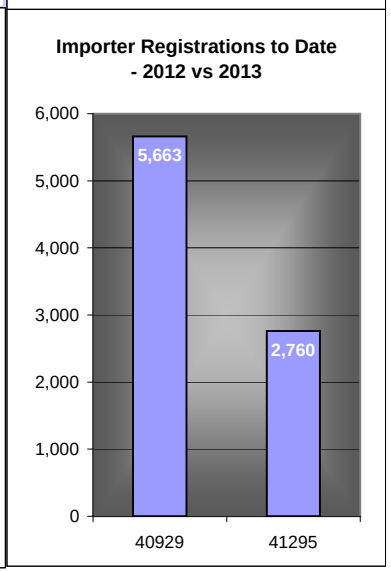
MDUFA III, Second Quarter Summary FY2013

Registrations by Type	FY13 to Date			FY2012 Year End Totals			Difference Thru 4/8/13
Est Type	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,282	7,649	12,931	5,291	7,785	13,076	-145
Contract Manufacturer	689	916	1,605	305	726	1,031	574
Contract Sterilizer	73	96	169	21	43	64	105
Specification Developer	1,526	337	1,863	1,599	342	1,941	-78
Reprocessor of Single Use Devices	19	2	21	16	1	17	4
U.S. Manufacturer of Export Only Devices	131		131	133		133	-2
Repackager/Relabeler	1,092	146	1,238	2,030	483	2,513	-1,275
Remanufacturer	29	20	49	71	105	176	-127
Foreign Exporter/Private Label Distributor	0	560	560	0	1,388	1,388	-828
Initial Importer	2,745		2,745	5,639		5,639	-2,894
Unknown			0	8		8	-8
Total:	**11,586**	**9,726**	**21,312**	**15,113**	**10,873**	**25,986**	-4,674









MDUFA III Quarterly Performance Update
Independent Assessment of Medical Device Review Process

2nd Quarter FY 2013 Status – April 23, 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	In progress. (Target date modified)
Contract kickoff meeting between FDA and contractor	June 2013	(Target date modified)
Final workplan for Phase 1	July 2013	(Target date modified)
Report on preliminary findings and high-priority recommendations	November 2013	(Target date modified)
FY 2014		
Implementation plan for high-priority recommendations	May 2014	(Target date modified)
Final report on complete findings and recommendations	May 2014	(Target date modified)
Implementation plan for final recommendations	November 2014	(Target date modified)

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:

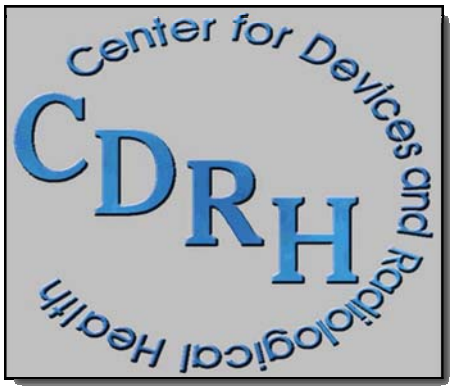
- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1st Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 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

Planned Progress prior to 3rd Quarter Meeting FY 2013:

- Contract award – May 2013
- Kickoff meeting – June 2013
- Final Workplan - July 2013

Staff College Internal Training Summary Report

From 10/1/2012 to 3/31/2013



As of: **4/2/2013**

Q1 + Q2 FY13 *(October 1, 2012 – March 31, 2013)* MDUFA-Related Training

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 device reviews 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 March 31, 2013. Staff College offered 292 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, 77% (1082) of the approximately 1400 Center staff participated in training and on average attended 13 (3736÷292) learning events.

Table X: MDUFA Q1 + Q2 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– 3/31/13
Regulatory and Law (LAW)	195	1912	7583	• Reviewer Certification Program – Introduction to Medical Device Law – Basic Food and Drug Law – How to Write Effective Premarket Consulting Reviews – How to Write Deficiencies in Four-Part Harmony • Master Technical Writing: A Plain Writing Workshop • Compiling the Administrative File for Premarket Submission Decisions – Online • Freedom of Information: What You Need to Know
➢ ***MDUFA III Training****	*6*	*431*	*1068*	• *Introduction to MDUFA III* • *510(k)s* • *PMAs* • *Pre-Submissions* • *CLIA Waivers* • *Electronic Workload Management*
Leadership Education and Development (LED)	29	415	2540	• Adaptive Leadership • CDRH Employee and Labor Relations for Managers • Leading in a Telework Environment • Masterful e-Meetings • 10 Steps to Leadership Excellence • Managing Risk and Seeing Opportunity • Introduction to Situational Leadership • The Foundation of Leadership – The New Supervisor
Professional Development (PRO)	26	404	3051	• Building High Performing Teams • Effective Communication skills for Scientific and Technical Professionals • Managing Projects and Priorities • Effective Briefing and Presentation Skills • Negotiation with Confidence • The 7 Habits of Highly Effective People • Decision Making and Critical Thinking Techniques for Results
➢ ***New Employee Orientation (NEO)***	*2*	*43*	*301*	• *New Employee Orientation: Discover the Mission, Embrace the Vision*
Science (SCI)	42	1005	3248	• CDRH Science Sharing Seminars – Topics include: – Medical Devices Incorporating Immobilized Nanomaterials: A Biological Response – Ethylene Oxide Residuals • Introduction to Public Health • Basics of Human Factors Engineering and Device Design • Current 510(k) Sterility Review Practices – Part 1: Sterility in Devices – Part 2: Labeling Recommendations • UDI: A Foundation of Health Informatics Initiatives - Online • Safety Case Assurance for Reviewers
Total:	**292**	**3736**	**16422**	

*** The MDUFA III data has been incorporated under the Law 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 ROI Update 2013

(Includes iterations for Program Years 2006-2007, 2008-2009, 2010-2011 and 2012-2013)

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	OIVD = 3 ODE = 5 Total = 20**	*Program will be completed in June 2013*
Sub total	**OIVD=12** **ODE =37** **Total = 86****	**OIVD = 9** **ODE = 30** **Total = 63****

*This total represents LRP participants from ODE and OIVD. The 2006-2007 LRP consisted of participants from ODE and OIVD only.

**This total represents LRP participants from all CDRH Offices

Q1 + Q2 FY13 Percentage of Center Participation by Category

October 1, 2012 – March 31, 2013

Category	Center Participation (Unique)	% of Center Participation (Unique)*
LAW	704	50%
LED	164	12%
PRO	265	19%
SCI	516	37%

Q1 + Q2 FY13 Participant Attendance by Office

October 1, 2012 – March 31, 2013

Office	Total # of Participants	% of Office Participation
OC	129	70%
OCD	52	50%
OCER	92	58%
ODE	352	89%
OIR	143	75%
OMO	23	31%
OSB	144	85%
OSEL	133	78%

MDUFA III Training Data

September 2012 – March 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
MDUFA III	16	5334	13347	– Introduction to MDUFA III – 510(k)s – PMAs – Pre-Submissions – CLIA Waivers – Electronic Workload Management

MDUFA Total Training Attendance

Number of participants who took at least one MDUFA class

Office	# of Completions	Completion Percentage
ODE	390 out of 394 who were required	99%
OIR	181 out of 182 who were required	99%

Office	Student Completions	# of Completions
ODE	Completed All	341
	Completed Some	46
	Completed None	4
	Total:	**394**
OIR	Completed All	178
	Completed Some	3
	Completed None	1
	Total:	**182**

ODE and OIR Reviewer Certification Program (RCP) Training Data

September 2011 – March 2013

RCP Training Data by Office

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
RCP	40	141	12,534	– 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	1234
Totals:	**5 Cohorts**	**85 Participants**	**7,272 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	995
Totals:	**5 Cohorts**	**56 Participants**	**5,271 Hours**

FY12 Experiential Learning Program (ELP)

May 2012 – September 2012

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
ELP	14	110	1648	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 – Manufacturing of Implantable Pacemakers/Defibrillators – Patient-matched Technologies – Clinical Trial Conduct - Meeting with Institutional Review Boards (IRBs)
OIR	5	10	47	– Microbiology Manufacturing – Molecular – Diabetes Care

***No additional data for FY13 Q1 or Q2, program will recommence in Q3.**

Q1 + Q2 FY13 ODE and OIR Leadership Development Training

October 1, 2012 – March 31, 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
LEAD	17	25	268	• 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

Office	Total # of Managers/Supervisors	Number of Participants	Number of Hours Completed	Participation Percentage
ODE	46	16	161	35%
OIR	22	9	107	41%