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

February 12, 2013
10:00 A.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 10 medical device guidance documents during the 1st quarter. *Barbara Zimmerman, CDRH-ODE*; *Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIR, Philip Desjardins, CDRH-OCD.*

FDA MDUFA Performance — Actions through December 30, 2012

- Report on decisions goals for 1st quarter of FY 2013.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

CLIA Waiver

- Report on qualitative goals and number of pending waiver requests. *Elizabeth Hillebrenner,* CDRH-OIR.

Qualitative Update on Finances – 1st Quarter of FY 2013

- User fee receipts through the 1st quarter of FY 2013. *Lisa Berry,* 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

Discussion

- Outreach recommendation discussion.
- Notice to Industry (NTI) feedback discussion.
- Low-risk exemptions

Set date for next meeting, following close of Q2. Target Date: 4/24/ 2013 at 10:00 am.

Medical Device Guidance Documents
Issued through 1st Quarter FY 2013
Through December 31, 2012

A comprehensive list of guidances can be found at the following:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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First Quarter (September 2012- December 2012)- 10 Guidance's Issued

Guidance for Industry and Food and Drug Administration Staff - Refuse to Accept Policy for 510(k)s	CDRH CBER	12/31/2012
Guidance for Industry and Food and Drug Administration Staff - Acceptance and Filing Review for Premarket Approval Applications (PMAs)	CDRH CBER	12/31/2012
Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions	CDRH CBER	12/31/2012
Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use	CDRH CBER	12/12/2012
IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed	CBER CDER CDRH	11/20/2012
Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems	CDRH	11/9/2012
Draft Guidance for Industry and Food and Drug Administration Staff - Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices	OIVD/DMD	11/9/2012
Draft Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions	CDRH CBER	10/17/2012
Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals	CBER CDRH	10/15/2012
Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals	CBER CDRH	10/15/2012

MDUFA III Quarterly Meeting
Guidance Development

In fulfillment of the Center's responsibilities with regard to Section I.D. *Guidance Document Development* of the MDUFA III Commitment letter, CDRH issued the "CDRH Fiscal Year 2013 (FY 2013) Proposed Guidance Development" web page on November 27, 2012. The web page is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm. The web page and associated lists include guidance documents that CDRH intends to publish in FY2013. CDRH provided two lists: (1) a list of guidance documents that the Agency fully intends to publish (the "A-list"); and (2) a list of guidance documents that the Agency intends to publish as resources permit (the "B-list"). Although resource constraints and new issues that emerge over the course of the year may preclude CDRH from issuing every guidance document on the lists and may require that CDRH issue guidance documents not on the lists, the lists are intended to provide helpful information about CDRH's current priorities for the upcoming fiscal year. CDRH plans to update this webpage on an annual basis.

The FY2013 Web list replaces the previous CDRH guidance topic list by providing a more accurate snap shot of what will actually issue in the coming fiscal year. As with previous iterations of the CDRH guidance topic list, CDRH invites interested persons to submit comments on any or all of the guidance documents on the list. As of December 31, 2013 no comments received on the FY2013 lists. In FY2008 – FY2012 CDRH received approximately 20 comments including two comments in FY 2012.

The FY2013 Proposed Guidance Development docket is reviewed by the CDRH Associate Director for Policy on a quarterly basis. All comments are reviewed and shared with appropriate Center and Office policy makers. In most instances document specific comments are forwarded to the appropriate CDRH staff for further consideration.

In addition to the information contained in the FY2013 Proposed Guidance Development web page, CDRH plans to review all previously published device guidance to identify documents that are in need of updating or deletion because they no longer represent the Agency's interpretation of, or policy on a regulatory issue. This systematic review may result in the identification of existing guidance documents that the Center publicly identifies as needing update. Updating these documents will occur as resources and competing priorities allow.

Quarterly Update on
Medical Device Performance Goals
MDUFA III Performance Data

October 1 – December 31, 2012

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: 2/3/2013

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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 and Filing Review Decision *

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10				
Closed before RTA action	n/a				
Number Accepted	n/a				
Number without a RTA Review and > 15 Days since Date Received	n/a				
Number without a RTA Review and <= 15 Days since Date Received	n/a				
Number Not Accepted for Filing Review	n/a				
Rate of submissions not accepted for filing review	n/a				
Completed RTF	4				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2 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	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 1.3 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	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 1.4 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	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 1.5 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 1.6 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 1.7 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 1.8 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	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 1.9 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 1.10 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 1.11 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 and Filing Review Decision *

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7				
Closed before RTA action	n/a				
Number Accepted	n/a				
Number without a RTA Review and > 15 Days since Date Received	n/a				
Number without a RTA Review and <= 15 Days since Date Received	n/a				
Number Not Accepted for Filing Review	n/a				
Rate of submissions not accepted for filing review	n/a				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	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 1.3.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	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 1.4.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	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 1.5.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 1.6.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 1.7.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 1.8.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	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 1.9.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 1.10.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 1.11.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 and Filing Review Decision *

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3				
Closed before RTA action	n/a				
Number Accepted	n/a				
Number without a RTA Review and > 15 Days since Date Received	n/a				
Number without a RTA Review and <= 15 Days since Date Received	n/a				
Number Not Accepted for Filing Review	n/a				
Rate of submissions not accepted for filing review	n/a				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	2				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 1.3.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	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 1.4.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	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 1.5.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 1.6.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 1.7.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 1.8.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	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 1.9.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 1.10.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 1.11.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 and Filing Review Decision *

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

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	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 1.3.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	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 1.4.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 1.5.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 1.6.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 1.7.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 1.8.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 1.9.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 1.10.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 1.11.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 and Filing Review Decision *

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

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	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 1.3.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	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 1.4.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	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 1.5.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 1.6.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 1.7.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 1.8.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	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 1.9.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 1.10.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 1.11.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 December 31, 2012.

Table 1.1.DOD DOD – 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	2				
Closed before RTA action	n/a				
Number Accepted	n/a				
Number without a RTA Review and > 15 Days since Date Received	n/a				
Number without a RTA Review and <= 15 Days since Date Received	n/a				
Number Not Accepted for Filing Review	n/a				
Rate of submissions not accepted for filing review	n/a				
Completed RTF	0				
Number Not Filed	0				
Rate of submissions Not Filed	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	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	n/a				

Table 1.3.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	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 1.4.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	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 1.5.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 1.6.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 1.7.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 1.8.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	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 1.9.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 1.10.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 1.11.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 and Filing Review Decision *

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

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	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	n/a				

Table 1.3.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 1.4.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	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 1.5.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 1.6.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 1.7.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 1.8.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	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 1.9.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 1.10.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 1.11.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					

There were no PMA Original or Panel Track Supplements received by DRGUD between October 1, 2012 and December 31, 2012.

There were no PMA Original or Panel Track Supplements received by DSD between October 1, 2012 and December 31, 2012.

There were no PMA Original or Panel Track Supplements received by DCTD between October 1, 2012 and December 31, 2012.

Table 1.1.DIHD DIHD – 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	2				
Closed before RTA action	n/a				
Number Accepted	n/a				
Number without a RTA Review and > 15 Days since Date Received	n/a				
Number without a RTA Review and <= 15 Days since Date Received	n/a				
Number Not Accepted for Filing Review	n/a				
Rate of submissions not accepted for filing review	n/a				
Completed RTF	1				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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	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 1.3.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	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 1.4.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	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 1.5.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 1.6.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 1.7.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 1.8.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	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 1.9.DIHD DIHD – 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 1.10.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 1.11.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 December 31, 2012

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

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

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

Table 1.2.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 1.3.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 1.4.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 1.5.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 1.6.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 1.7.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 1.8.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 1.9.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 1.10.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 1.11.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	69				
SI within 90 FDA days	5				
SI over 90 FDA days	0				
SI pending within 90 FDA days	64				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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	69				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
Supplements pending MDUFA III Decision	65				
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	69				
Number with MDUFA decision	4				
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	64				
SI within 90 FDA days	4				
SI over 90 FDA days	0				
SI pending within 90 FDA days	60				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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	64				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	4				
MDUFA III Decisions within 180 FDA Days	4				
Supplements pending MDUFA III Decision	60				
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	64				
Number with MDUFA decision	4				
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	5				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	4				
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	5				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	5				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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	5				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	5				
SI within 90 FDA days	0				
SI over 90 FDA days	0				
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	n/a				

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	5				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	5				
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	5				
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	47				
SI within 90 FDA days	3				
SI over 90 FDA days	0				
SI pending within 90 FDA days	44				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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	47				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 180 FDA Days	3				
Supplements pending MDUFA III Decision	44				
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	47				
Number with MDUFA decision	3				
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	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.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	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.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	1				
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	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.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	6				
SI within 90 FDA days	0				
SI over 90 FDA days	0				
SI pending within 90 FDA days	6				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	n/a				

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

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	2				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 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	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	2				
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	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 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	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

Table 2.3.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	2				
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					

There were no PMA 180 Day Supplements received by DCTD between October 1, 2012 and December 31, 2012.

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	3				
SI within 90 FDA days	0				
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	n/a				

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	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.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	3				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	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.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	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.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	1				
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	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.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	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.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	1				
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	73				
Non-MDUFA III Decisions	3				
MDUFA III Decisions	26				
MDUFA III Decisions within 90 FDA Days	26				
Supplements pending MDUFA III Decision	44				
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	73				
Number with MDUFA decision	26				
Number of Not Approvable	1				
Rate of Not Approvable	4%				

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	60				
Non-MDUFA III Decisions	3				
MDUFA III Decisions	26				
MDUFA III Decisions within 90 FDA Days	26				
Supplements pending MDUFA III Decision	31				
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	60				
Number with MDUFA decision	26				
Number of Not Approvable	1				
Rate of Not Approvable	4%				

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	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	13				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	n/a				

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	13				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	5				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 90 FDA Days	1				
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.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	5				
Number with MDUFA decision	1				
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	32				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	20				
MDUFA III Decisions within 90 FDA Days	20				
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.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	32				
Number with MDUFA decision	20				
Number of Not Approvable	1				
Rate of Not Approvable	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	5				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 90 FDA Days	3				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

Table 3.2.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	5				
Number with MDUFA decision	3				
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 December 31, 2012.

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	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 90 FDA Days	1				
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	4				
Number with MDUFA decision	1				
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	7				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	5				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	n/a				

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	7				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	7				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 90 FDA Days	1				
Supplements pending MDUFA III Decision	6				
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	7				
Number with MDUFA decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	n/a				

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	3				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	n/a				

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	2				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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	8				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	8				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	n/a				

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	8				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	n/a				

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 December 31, 2012.

Section 4 Pre-Market Report Submissions

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

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	927				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	774				
Deleted or withdrawn prior to SI	4				
SI within 60 FDA days	360				
SI over 60 FDA days	12				
SI pending within 60 FDA days	389				
SI pending over 60 FDA days	9				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	94%				

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	372				
Average number of FDA days to Substantive Interaction	40				
20th Percentile FDA days to Substantive Interaction	24				
40th Percentile FDA days to Substantive Interaction	33				
60th Percentile FDA days to Substantive Interaction	46				
80th Percentile FDA days to Substantive Interaction	56				
Maximum FDA days to Substantive Interaction	80				

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	811				
Non-MDUFA III Decisions	8				
MDUFA III Decisions (SE/NSE)	102				
MDUFA III Decisions within 90 FDA Days	102				
510(k)s pending MDUFA III Decision	701				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.12				
Number with MDUFA decision	102				
Average FDA days to MDUFA III decision	36				
20th Percentile FDA days to MDUFA III decision	22				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	36				
80th Percentile FDA days to MDUFA III decision	56				
Maximum FDA days to MDUFA III decision	80				
Average Industry days to MDUFA III decision	1				
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	6				
80th Percentile Industry days to MDUFA III decision	8				
Maximum Industry days to MDUFA III decision	25				
Average Total days to MDUFA III decision	37				
20th Percentile Total days to MDUFA III decision	22				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	38				
80th Percentile Total days to MDUFA III decision	57				
Maximum Total days to MDUFA III decision	80				

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	811				
Number with MDUFA decision	102				
Number of SE decisions	102				
Number of NSE decisions	0				
Number of Withdrawals	6				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	0.7%				
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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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	721				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	608				
Deleted or withdrawn prior to SI	4				
SI within 60 FDA days	276				
SI over 60 FDA days	11				
SI pending within 60 FDA days	308				
SI pending over 60 FDA days	9				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	93%				

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	287				
Average number of FDA days to Substantive Interaction	40				
20th Percentile FDA days to Substantive Interaction	23				
40th Percentile FDA days to Substantive Interaction	32				
60th Percentile FDA days to Substantive Interaction	46				
80th Percentile FDA days to Substantive Interaction	56				
Maximum FDA days to Substantive Interaction	80				

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	632				
Non-MDUFA III Decisions	6				
MDUFA III Decisions (SE/NSE)	66				
MDUFA III Decisions within 90 FDA Days	66				
510(k)s pending MDUFA III Decision	560				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.17				
Number with MDUFA decision	66				
Average FDA days to MDUFA III decision	37				
20th Percentile FDA days to MDUFA III decision	22				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	40				
80th Percentile FDA days to MDUFA III decision	57				
Maximum FDA days to MDUFA III decision	80				
Average Industry days to MDUFA III decision	1				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	3				
60th Percentile Industry days to MDUFA III decision	6				
80th Percentile Industry days to MDUFA III decision	8				
Maximum Industry days to MDUFA III decision	10				
Average Total days to MDUFA III decision	38				
20th Percentile Total days to MDUFA III decision	22				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	43				
80th Percentile Total days to MDUFA III decision	59				
Maximum Total days to MDUFA III decision	80				

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	632				
Number with MDUFA decision	66				
Number of SE decisions	66				
Number of NSE decisions	0				
Number of Withdrawals	5				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	0.8%				
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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	206				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	166				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	84				
SI over 60 FDA days	1				
SI pending within 60 FDA days	81				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	99%				

Table 6.3.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	85				
Average number of FDA days to Substantive Interaction	40				
20th Percentile FDA days to Substantive Interaction	26				
40th Percentile FDA days to Substantive Interaction	35				
60th Percentile FDA days to Substantive Interaction	45				
80th Percentile FDA days to Substantive Interaction	55				
Maximum FDA days to Substantive Interaction	63				

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	179				
Non-MDUFA III Decisions	2				
MDUFA III Decisions (SE/NSE)	36				
MDUFA III Decisions within 90 FDA Days	36				
510(k)s pending MDUFA III Decision	141				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.03				
Number with MDUFA decision	36				
Average FDA days to MDUFA III decision	34				
20th Percentile FDA days to MDUFA III decision	23				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	35				
80th Percentile FDA days to MDUFA III decision	50				
Maximum FDA days to MDUFA III decision	71				
Average Industry days to MDUFA III decision	0.7				
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	10				
Maximum Industry days to MDUFA III decision	25				
Average Total days to MDUFA III decision	35				
20th Percentile Total days to MDUFA III decision	23				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	35				
80th Percentile Total days to MDUFA III decision	50				
Maximum Total days to MDUFA III decision	78				

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	179				
Number with MDUFA decision	36				
Number of SE decisions	36				
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	0.6%				
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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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	186				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	163				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	66				
SI over 60 FDA days	1				
SI pending within 60 FDA days	95				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	97%				

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	67				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	49				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	65				

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	169				
Non-MDUFA III Decisions	0				
MDUFA III Decisions (SE/NSE)	16				
MDUFA III Decisions within 90 FDA Days	16				
510(k)s pending MDUFA III Decision	153				
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	1.13				
Number with MDUFA decision	16				
Average FDA days to MDUFA III decision	38				
20th Percentile FDA days to MDUFA III decision	16				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	49				
80th Percentile FDA days to MDUFA III decision	56				
Maximum FDA days to MDUFA III decision	65				
Average Industry days to MDUFA III decision	1				
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	10				
Average Total days to MDUFA III decision	39				
20th Percentile Total days to MDUFA III decision	16				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	49				
80th Percentile Total days to MDUFA III decision	57				
Maximum Total days to MDUFA III decision	70				

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	169				
Number with MDUFA decision	16				
Number of SE decisions	16				
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.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	105				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	91				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	42				
SI over 60 FDA days	1				
SI pending within 60 FDA days	43				
SI pending over 60 FDA days	5				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	88%				

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	43				
Average number of FDA days to Substantive Interaction	36				
20th Percentile FDA days to Substantive Interaction	27				
40th Percentile FDA days to Substantive Interaction	29				
60th Percentile FDA days to Substantive Interaction	36				
80th Percentile FDA days to Substantive Interaction	48				
Maximum FDA days to Substantive Interaction	63				

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	98				
Non-MDUFA III Decisions	0				
MDUFA III Decisions (SE/NSE)	12				
MDUFA III Decisions within 90 FDA Days	12				
510(k)s pending MDUFA III Decision	86				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.08				
Number with MDUFA decision	12				
Average FDA days to MDUFA III decision	30				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	28				
60th Percentile FDA days to MDUFA III decision	30				
80th Percentile FDA days to MDUFA III decision	31				
Maximum FDA days to MDUFA III decision	41				
Average Industry days to MDUFA III decision	0.4				
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	5				
Average Total days to MDUFA III decision	30				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	28				
60th Percentile Total days to MDUFA III decision	30				
80th Percentile Total days to MDUFA III decision	35				
Maximum Total days to MDUFA III decision	41				

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	98				
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.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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	44				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	20				
SI over 60 FDA days	0				
SI pending within 60 FDA days	22				
SI pending over 60 FDA days	1				
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	20				
Average number of FDA days to Substantive Interaction	34				
20th Percentile FDA days to Substantive Interaction	16				
40th Percentile FDA days to Substantive Interaction	25				
60th Percentile FDA days to Substantive Interaction	34				
80th Percentile FDA days to Substantive Interaction	54				
Maximum FDA days to Substantive Interaction	60				

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	47				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	3				
MDUFA III Decisions within 90 FDA Days	3				
510(k)s pending MDUFA III Decision	43				
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	1.00				
Number with MDUFA decision	3				
Average FDA days to MDUFA III decision	40				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	36				
80th Percentile FDA days to MDUFA III decision	49				
Maximum FDA days to MDUFA III decision	63				
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	40				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	36				
80th Percentile Total days to MDUFA III decision	49				
Maximum Total days to MDUFA III decision	63				

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	47				
Number with MDUFA decision	3				
Number of SE decisions	3				
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	2%				
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	147				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	118				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	49				
SI over 60 FDA days	2				
SI pending within 60 FDA days	65				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	94%				

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	51				
Average number of FDA days to Substantive Interaction	44				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	41				
60th Percentile FDA days to Substantive Interaction	49				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	80				

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	119				
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	106				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.08				
Number with MDUFA decision	12				
Average FDA days to MDUFA III decision	42				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	43				
80th Percentile FDA days to MDUFA III decision	61				
Maximum FDA days to MDUFA III decision	80				
Average Industry days to MDUFA III decision	0.8				
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	10				
Average Total days to MDUFA III decision	42				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	43				
80th Percentile Total days to MDUFA III decision	61				
Maximum Total days to MDUFA III decision	80				

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	119				
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	0.8%				
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	23				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	21				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	6				
SI over 60 FDA days	2				
SI pending within 60 FDA days	13				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	75%				

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	8				
Average number of FDA days to Substantive Interaction	44				
20th Percentile FDA days to Substantive Interaction	33				
40th Percentile FDA days to Substantive Interaction	43				
60th Percentile FDA days to Substantive Interaction	46				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	70				

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	23				
Non-MDUFA III Decisions	0				
MDUFA III Decisions (SE/NSE)	1				
MDUFA III Decisions within 90 FDA Days	1				
510(k)s pending MDUFA III Decision	22				
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	1				
Average FDA days to MDUFA III decision	57				
20th Percentile FDA days to MDUFA III decision	57				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	57				
80th Percentile FDA days to MDUFA III decision	57				
Maximum FDA days to MDUFA III decision	57				
Average Industry days to MDUFA III decision	6				
20th Percentile Industry days to MDUFA III decision	6				
40th Percentile Industry days to MDUFA III decision	6				
60th Percentile Industry days to MDUFA III decision	6				
80th Percentile Industry days to MDUFA III decision	6				
Maximum Industry days to MDUFA III decision	6				
Average Total days to MDUFA III decision	63				
20th Percentile Total days to MDUFA III decision	63				
40th Percentile Total days to MDUFA III decision	63				
60th Percentile Total days to MDUFA III decision	63				
80th Percentile Total days to MDUFA III decision	63				
Maximum Total days to MDUFA III decision	63				

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	23				
Number with MDUFA decision	1				
Number of SE decisions	1				
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	73				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	62				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	37				
SI over 60 FDA days	0				
SI pending within 60 FDA days	24				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	100%				

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	37				
Average number of FDA days to Substantive Interaction	41				
20th Percentile FDA days to Substantive Interaction	27				
40th Percentile FDA days to Substantive Interaction	44				
60th Percentile FDA days to Substantive Interaction	49				
80th Percentile FDA days to Substantive Interaction	52				
Maximum FDA days to Substantive Interaction	59				

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	64				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	4				
MDUFA III Decisions within 90 FDA Days	4				
510(k)s pending MDUFA III Decision	59				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.25				
Number with MDUFA decision	4				
Average FDA days to MDUFA III decision	33				
20th Percentile FDA days to MDUFA III decision	22				
40th Percentile FDA days to MDUFA III decision	27				
60th Percentile FDA days to MDUFA III decision	36				
80th Percentile FDA days to MDUFA III decision	43				
Maximum FDA days to MDUFA III decision	49				
Average Industry days to MDUFA III decision	2				
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	3				
Maximum Industry days to MDUFA III decision	8				
Average Total days to MDUFA III decision	35				
20th Percentile Total days to MDUFA III decision	22				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	42				
80th Percentile Total days to MDUFA III decision	48				
Maximum Total days to MDUFA III decision	49				

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	64				
Number with MDUFA decision	4				
Number of SE decisions	4				
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	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	128				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	109				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	56				
SI over 60 FDA days	5				
SI pending within 60 FDA days	46				
SI pending over 60 FDA days	1				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	90%				

Table 6.3.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	61				
Average number of FDA days to Substantive Interaction	36				
20th Percentile FDA days to Substantive Interaction	19				
40th Percentile FDA days to Substantive Interaction	26				
60th Percentile FDA days to Substantive Interaction	44				
80th Percentile FDA days to Substantive Interaction	56				
Maximum FDA days to Substantive Interaction	74				

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	112				
Non-MDUFA III Decisions	3				
MDUFA III Decisions (SE/NSE)	18				
MDUFA III Decisions within 90 FDA Days	18				
510(k)s pending MDUFA III Decision	91				
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	1.28				
Number with MDUFA decision	18				
Average FDA days to MDUFA III decision	35				
20th Percentile FDA days to MDUFA III decision	19				
40th Percentile FDA days to MDUFA III decision	24				
60th Percentile FDA days to MDUFA III decision	35				
80th Percentile FDA days to MDUFA III decision	59				
Maximum FDA days to MDUFA III decision	72				
Average Industry days to MDUFA III decision	2				
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	4				
Maximum Industry days to MDUFA III decision	9				
Average Total days to MDUFA III decision	37				
20th Percentile Total days to MDUFA III decision	19				
40th Percentile Total days to MDUFA III decision	24				
60th Percentile Total days to MDUFA III decision	42				
80th Percentile Total days to MDUFA III decision	59				
Maximum Total days to MDUFA III decision	73				

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	112				
Number with MDUFA decision	18				
Number of SE decisions	18				
Number of NSE decisions	0				
Number of Withdrawals	2				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	2%				
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	64				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	47				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	25				
SI over 60 FDA days	0				
SI pending within 60 FDA days	22				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	100%				

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

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	25				
Average number of FDA days to Substantive Interaction	37				
20th Percentile FDA days to Substantive Interaction	25				
40th Percentile FDA days to Substantive Interaction	29				
60th Percentile FDA days to Substantive Interaction	43				
80th Percentile FDA days to Substantive Interaction	50				
Maximum FDA days to Substantive Interaction	58				

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	47				
Non-MDUFA III Decisions	0				
MDUFA III Decisions (SE/NSE)	5				
MDUFA III Decisions within 90 FDA Days	5				
510(k)s pending MDUFA III Decision	42				
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	1.00				
Number with MDUFA decision	5				
Average FDA days to MDUFA III decision	29				
20th Percentile FDA days to MDUFA III decision	26				
40th Percentile FDA days to MDUFA III decision	27				
60th Percentile FDA days to MDUFA III decision	28				
80th Percentile FDA days to MDUFA III decision	30				
Maximum FDA days to MDUFA III decision	35				
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	29				
20th Percentile Total days to MDUFA III decision	26				
40th Percentile Total days to MDUFA III decision	27				
60th Percentile Total days to MDUFA III decision	28				
80th Percentile Total days to MDUFA III decision	30				
Maximum Total days to MDUFA III decision	35				

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	47				
Number with MDUFA decision	5				
Number of SE decisions	5				
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.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	20				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	16				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	5				
SI over 60 FDA days	1				
SI pending within 60 FDA days	10				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	83%				

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	6				
Average number of FDA days to Substantive Interaction	45				
20th Percentile FDA days to Substantive Interaction	45				
40th Percentile FDA days to Substantive Interaction	47				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	57				
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	16				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	0				
MDUFA III Decisions within 90 FDA Days	0				
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	n/a				

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					
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 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	16				
Number with MDUFA decision	0				
Number of SE decisions	0				
Number of NSE decisions	0				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	n/a				
Rate of NSE decisions	n/a				
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	22				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	18				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	11				
SI over 60 FDA days	0				
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	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	11				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	38				
60th Percentile FDA days to Substantive Interaction	49				
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	18				
Non-MDUFA III Decisions	0				
MDUFA III Decisions (SE/NSE)	5				
MDUFA III Decisions within 90 FDA Days	5				
510(k)s pending MDUFA III Decision	13				
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	5				
Average FDA days to MDUFA III decision	44				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	34				
60th Percentile FDA days to MDUFA III decision	44				
80th Percentile FDA days to MDUFA III decision	58				
Maximum FDA days to MDUFA III decision	71				
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	44				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	34				
60th Percentile Total days to MDUFA III decision	44				
80th Percentile Total days to MDUFA III decision	58				
Maximum Total days to MDUFA III decision	71				

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	18				
Number with MDUFA decision	5				
Number of SE decisions	5				
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.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	100				
Closed before RTA action	n/a				
Number Accepted	n/a				
RTA Review not done and > 15 days since Date Received	n/a				
RTA Review not done and <= 15 days since Date Received	n/a				
Number Not Accepted	n/a				
Rate of submissions not accepted	n/a				

*Note: RTA was not in place 1st quarter, and thus all submissions were accepted.

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	85				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	43				
SI over 60 FDA days	0				
SI pending within 60 FDA days	42				
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.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	43				
Average number of FDA days to Substantive Interaction	40				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	35				
60th Percentile FDA days to Substantive Interaction	45				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	60				

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	98				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	26				
MDUFA III Decisions within 90 FDA Days	26				
510(k)s pending MDUFA III Decision	71				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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	1.04				
Number with MDUFA decision	26				
Average FDA days to MDUFA III decision	33				
20th Percentile FDA days to MDUFA III decision	23				
40th Percentile FDA days to MDUFA III decision	28				
60th Percentile FDA days to MDUFA III decision	30				
80th Percentile FDA days to MDUFA III decision	49				
Maximum FDA days to MDUFA III decision	59				
Average Industry days to MDUFA III decision	1				
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	25				
Average Total days to MDUFA III decision	34				
20th Percentile Total days to MDUFA III decision	23				
40th Percentile Total days to MDUFA III decision	28				
60th Percentile Total days to MDUFA III decision	30				
80th Percentile Total days to MDUFA III decision	49				
Maximum Total days to MDUFA III decision	78				

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	98				
Number with MDUFA decision	26				
Number of SE decisions	26				
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	1%				
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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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 [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	454				
Number requesting a meeting or teleconference	222				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	59				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Pre-Submissions – Office Level

Table 9.1.ODE ODE – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	239				
Number requesting a meeting or teleconference	129				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	62				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.OIR OIR – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	215				
Number requesting a meeting or teleconference	93				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	54				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Pre-Submissions – Division Level

Table 9.1.DAGRID DAGRID – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	35				
Number requesting a meeting or teleconference	16				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	80				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DCD DCD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	67				
Number requesting a meeting or teleconference	39				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	55				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DNPMD DNPMD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	20				
Number requesting a meeting or teleconference	10				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	76				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DOD DOD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	16				
Number requesting a meeting or teleconference	9				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	78				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DOED DOED – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	28				
Number requesting a meeting or teleconference	17				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	62				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DRGUD DRGUD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	39				
Number requesting a meeting or teleconference	18				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	56				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DSD DSD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	34				
Number requesting a meeting or teleconference	20				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	62				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DCTD DCTD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	59				
Number requesting a meeting or teleconference	30				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	50				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DIHD DIHD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	78				
Number requesting a meeting or teleconference	37				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	70				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DMD DMD – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	64				
Number requesting a meeting or teleconference	17				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	43				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Table 9.1.DRH DRH – Pre-Submissions Performance Metrics [#]

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	14				
Number requesting a meeting or teleconference	9				
Number with meetings or teleconferences granted					
Number with meeting granted and industry cancelled					
Number with meeting granted and FDA cancelled					
Number with meeting granted and scheduled outside the reporting timeframe					
Number with meetings or teleconferences held					
Average days to meeting	42				
20th Percentile days to meeting					
40th Percentile days to meeting					
60th Percentile days to meeting					
80th Percentile days to meeting					
Maximum days to meeting					

[#]Additional information on Pre-Submissions will be included in the 2nd Quarterly Report.

Section 10 CLIA Waivers

There were no CLIA Waivers received by FDA between October 1, 2012 and December 31, 2012.

Section 11 CLIA Waiver Annual Metrics

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

Section 12 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 and 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	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).
8	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
9	Number Not Filed	Number of submissions with completed RTF (line 8) that got the NOFI decision in the first RTF review.
10	Rate of submissions Not Filed	Number Not Filed (line 9) divided by Number with completed RTF (line 8).

Table 1.2 and Tables 1.2.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 and line 6).

Table 1.3 and Tables 1.3.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 1.4 and Tables 1.4.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 1.5 and Tables 1.5.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 1.6 and Tables 1.6.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 1.7 and Tables 1.7.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 1.8 and Tables 1.8.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 1.9 and Tables 1.9.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 1.10 and Tables 1.10.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 1.11 and Tables 1.11.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 and line 6).

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, Industry days, and Total days.

Quarterly Update on
Medical Device Performance Goals
----MDUFA III CBER Performance Data ----
Action through 31 December 2012

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	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	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	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 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	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	0				
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	0				
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	2				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	0.0%				

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	2				
Number with MDUFA decision	0				
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	0				
Real-Time Supplements	2				

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	21				
Closed before RTA action	0				
Number Accepted	20				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted	1				
Rate of submissions not accepted for filing review	4.8%				

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	20				
SI within 60 FDA days	9				
SI over 60 FDA days	1				
SI pending within 60 FDA days	10				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	90.0%				

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	10				
Average number of FDA days to Substantive Interaction	42				
20th Percentile FDA days to Substantive Interaction	26				
40th Percentile FDA days to Substantive Interaction	35				
60th Percentile FDA days to Substantive Interaction	49				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	65				

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	20				
Non-MDUFA III Decisions	6				
MDUFA III Decisions (SE/NSE)	4				
MDUFA III Decisions within 90 FDA Days	4				
510(k)s pending MDUFA III Decision	16				
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	4				
Average FDA days to MDUFA III decision	32				
20th Percentile FDA days to MDUFA III decision	25				
40th Percentile FDA days to MDUFA III decision	26				
60th Percentile FDA days to MDUFA III decision	29				
80th Percentile FDA days to MDUFA III decision	49				
Maximum FDA days to MDUFA III decision	49				
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	32				
20th Percentile Total days to MDUFA III decision	25				
40th Percentile Total days to MDUFA III decision	26				
60th Percentile Total days to MDUFA III decision	29				

80th Percentile Total days to MDUFA III decision	49				
Maximum Total days to MDUFA III decision	49				

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	20				
Number with MDUFA decision	4				
Number of SE decisions	4				
Number of NSE decisions	0				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	20.0%				
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 CDRH – 510(k) Annual General Metrics – 510(k)s Received by Type

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	20				
Number of Traditional submissions	14				
Number of Special submissions	5				

Number of Abbreviated submissions	1				
Average number of days to Accept / Refuse to Accept	11				
Number of Third Party submissions	0				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	20				
Currently Under Review	16				
Number with Non-MDUFA Decision	6				
Number with MDUFA III Decision	4				
Percent of cohort closed	20.0%				
Number with MDUFA III decision after trimming the upper and lower 2%	2				
Average Total Time to MDUFA III decision	32				

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	1				
Number of De Novo Petitions with Decision	0				
Number of De Novo Petitions with Decision Pending	1				
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	5				
Number requesting a meeting or teleconference	5				
Number with meetings or teleconferences granted	4				
Number with meeting granted and industry cancelled	0				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and pending within timeframe	4				
Number with meeting granted and pending outside timeframe	1				
Number with meetings or teleconferences held	0				
Average days to meeting	0				
20th Percentile days to meeting	0				
40th Percentile days to meeting	0				
60th Percentile days to meeting	0				
80th Percentile days to meeting	0				
Maximum days to meeting	0				

CLIA Waiver Status:

No CLIA Waiver by Application submissions have been received since October 1, 2012.

FY 2013 Medical Device User Fee Collections as of December 31, 2012 /1 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$36,923,794	$20,054	$36,903,740		
Application Fees	$7,872,452	$22,650	$7,849,802		
Total	**$44,796,246**	**$42,704**	**$44,753,542**	**$97,722,301**	**46%**

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	$47,621,685	$55,816,125	$62,788,025	$69,525,693	$65,366,736

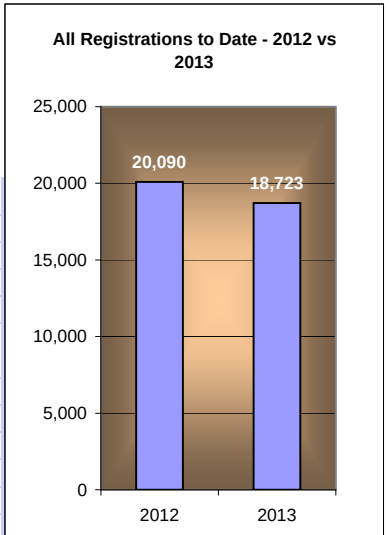
Notes:

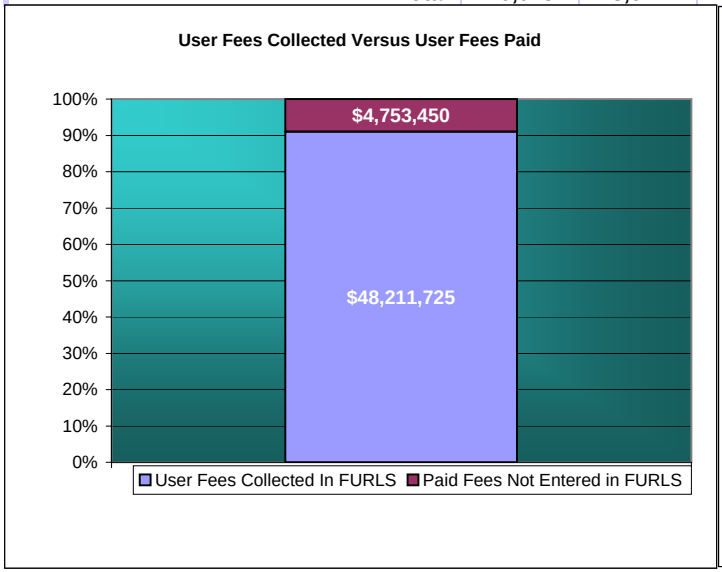
/1 Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2013.

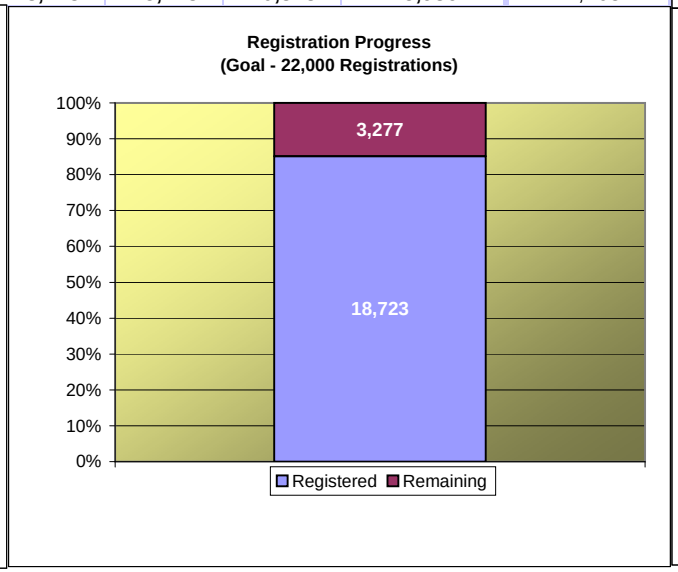
/2 Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

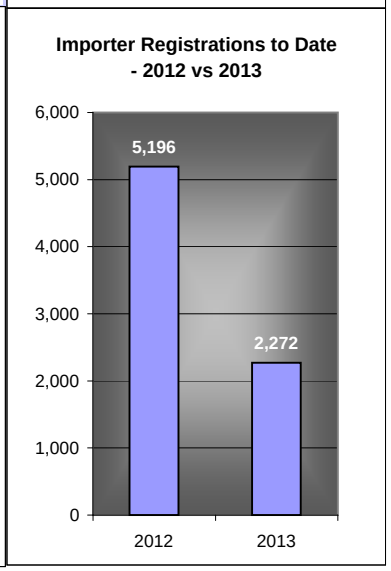
MDUFA III, FY2013, End of Cycle Registration Data

Registrations by Type	FY13 to Date			FY2012 Year End Totals			Difference Thru 1/31/13
Est Type	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	4,777	6,848	11,625	5,291	7,785	13,076	-1,451
Contract Manufacturer	572	779	1,351	305	726	1,031	320
Contract Sterilizer	72	78	150	21	43	64	86
Specification Developer	1,325	291	1,616	1,599	342	1,941	-325
Reprocessor of Single Use Devices	14	1	15	16	1	17	-2
U.S. Manufacturer of Export Only Devices	117		117	133		133	-16
Repackager/Relabeler	899	115	1,014	2,030	483	2,513	-1,499
Remanufacturer	24	19	43	71	105	176	-133
Foreign Exporter	0	483	483	0	1,388	1,388	-905
Initial Importer	2,275		2,275	5,639		5,639	-3,364
Unknown			34	8		8	26
Total:	**10,075**	**8,614**	**18,723**	**15,113**	**10,873**	**25,986**	-7,263









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

1st Quarter FY 2013 Status – February 12, 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	April 2013	In progress; delayed
Contract kickoff meeting between FDA and contractor	May 2013	Revised
Final workplan for Phase 1	June 2013	Revised
Report on preliminary findings and high-priority recommendations	September 30, 2013	
FY 2014		
Implementation plan for high-priority recommendations	March 31, 2014	
Final report on complete findings and recommendations	March 31, 2014	
Implementation plan for final recommendations	September 30, 2014	

Milestone	Planned	Status
FY 2015		
Phase 2 kickoff meeting between FDA and contractor	April 2015	
Final workplan for Phase 2	May 2015	
FY 2016		
Final evaluation report	February 1, 2016	

Progress to-date:

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1st Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013

FY 2012 Experiential Learning Program (ELP)

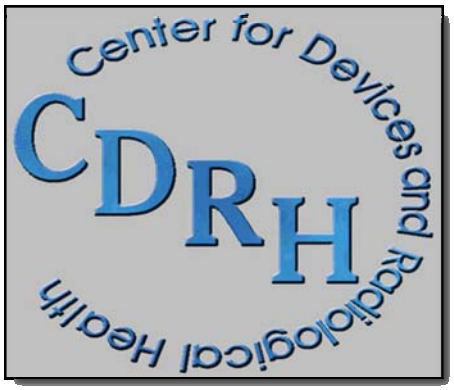
Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
ELP	14	110	1648	Topic areas addressed during the ELP site visits include: – Orthopedic and Dental Device Coatings – Implantable Pacemakers/Defibrillators – Patient-matched Technologies – Clinical Trials – Microbiology Manufacturing – Molecular Devices – Diabetes Care Devices

FY 2012 Experiential Learning Program (ELP) by Office

	Sites	Dates	# of Attendees
ODE	ELP: APS Materials, Inc.	05/16/2012	**7**
	ELP: APS Materials, Inc.	06/11/2012	**9**
	ELP: Boston Scientific	7/17/2012 - 7/182012	**6**
	ELP: Boston Scientific	8/21/2012 - 8/22/2012	**6**
	ELP: Duke University IRB	8/15/2012 - 8/16/2012	**7**
	ELP: Duke University IRB	8/22/2012 - 8/23/2012	**6**
	ELP: Duke University IRB	9/5/2012 - 9/6/2012	**8**
	ELP: Duke University IRB	9/12/2012 - 9/13/2012	**8**
	ELP: Wright Medical Technology, Inc.	6/5/2012 - 6/6/2012	**6**
OIR	ELP: Becton Dickinson & Co.	6/26/2012 - 6/28/2012	**10**
	ELP: Qiagen	07/23/2012	**8**
	ELP: Qiagen	09/27/2012	**7**
	ELP: Roche Diagnostic	7/31/2012 - 8/2/2012	**7**
	ELP: Roche Molecular	6/4/2012 - 6/5/2012	**15**
Totals:	**14 Site Visits**	**26 Training Days**	**110 Attendees**

Staff College Internal Training Summary Report

From 10/01/2012 to 12/31/2012



As of: **1/17/2012**

1st Qtr FY13 *(October 1, 2012 – December 31, 2012)* 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 December 31, 2012. Staff College offered 151 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, 68% (947) of the approximately 1400 Center staff participated in training and on average attended 6 (947÷151) learning events.

Table X: MDUFA 1st Qtr 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 – 12/31/12
Regulatory and Law (LAW)	93	1353	5469	• 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 • Medical Device Mobile Apps Webcast: What Needs FDA Approval • Compiling the Administrative File for Premarket Submission Decisions – Online
➢ ***MDUFA III Training****	*6*	*377*	*936*	• *Introduction to MDUFA III* • *510(k)s* • *PMAs* • *Pre-Submissions* • *CLIA Waivers* • *Electronic Workload Management*
Leadership Education and Development (LED)	22	298	1965	• 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
Professional Development (PRO)	20	272	2126	• 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
➢ ***New Employee Orientation (NEO)***	*1*	*19*	*133*	• *New Employee Orientation: Discover the Mission, Embrace the Vision*
Science (SCI)	16	500	1711	• CDRH Science Sharing Seminars – Topics include: – Long-Term Safety and Reliability of Neural Recording Electrodes for Neuroprosthetics – Medical Devices Incorporating Immobilized Nanomaterials: A Biological Response • Introduction to Public Health • Basics of Human Factors Engineering and Device Design • Adaptive Trial Initiative • Current 510(k) Sterility Review Practices – Part 1: Sterility in Devices – Part 2: Labeling Recommendations • UDI: A Foundation of Health Informatics Initiatives - Online
Total:	**151**	**2423**	**11271**	

*** 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 2012

(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

Total Percentage of Unique Center Participation by Category

October 1, 2012 – December 31, 2012

Category	Center Participation (Unique)	% of Center Participation (Unique)*
LAW	659	47%
LED	154	11%
PRO	191	14%
SCI	311	22%

CDRH Q1 Participant Attendance by Office

October 1, 2012 – December 31, 2012

Office	Total # of Participants	% of Office Participation
OC	122	66%
OCD	40	42%
OCER	81	51%
ODE	299	76%
OIR	130	68%
OMO	20	27%
OSB	137	81%
OSEL	107	63%

MDUFA III Training Data

September 2012 – January 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
MDUFA III	16	5280	13215	– 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 – January 2013

RCP Training Data by Office

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
RCP	40	140	10,858	– 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	1342
	Fall 2012	22	2008
	Spring 2013	17	290
Totals:	**5 Cohorts**	**84 Participants**	**6,236 Hours**

	Cohort	# of Attendees	Total Training Hours
OIR	**Fall 2011**	5	416
	Spring 2012	18	1785
	Summer 2012	8	863
	Fall 2012	12	1207
	Spring 2013	13	351
Totals:	**5 Cohorts**	**56 Participants**	**4,622 Hours**

FY 2012 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

Q1 FY13 ODE and OIR Leadership Development Training

October 1, 2012 – December 31, 2012

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
LEAD	13	30	314	• Adaptive Leadership • Giving and Receiving Feedback • CDRH Employee/Labor Relations for Managers • Leading at the Speed of Trust • Leading in a Telework Environment

Office	Total # of Managers/Supervisors	Number of Participants	Number of Hours Completed	Participation Percentage
ODE	46	18	191	39%
OIR	22	8	95	36%