

**Agenda for Quarterly Meeting on MDUFA II (2008-2012) Performance**  
**April 23, 2012**  
**1:30 P.M.**

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**Welcome.** *Barbara Zimmerman, CDRH-ODE.*

**FDA MDUFMA / MDUFA Performance — Actions through March 31, 2013**

- Reports on all decision goals for the FY 2008 - FY 2012 cohorts.
  - CBER: *Sheryl Kochman, CBER.*
  - CDRH: *Barbara Zimmerman, CDRH.*

**CLIA Waiver Review Times**

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

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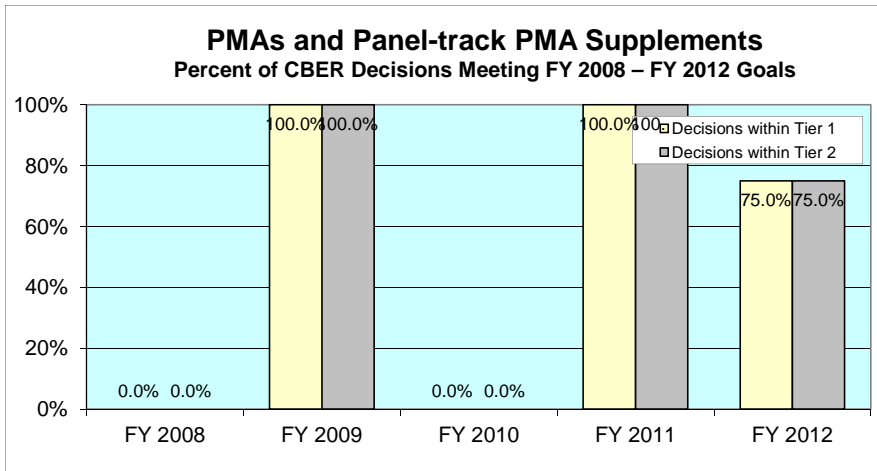
Quarterly Update on  
Medical Device Performance Goals  
— CBER Performance Data —  
Actions through 31 March 2013

## Data on FY 2008 – FY 2012 Cohorts

Actions through 31 March 2013

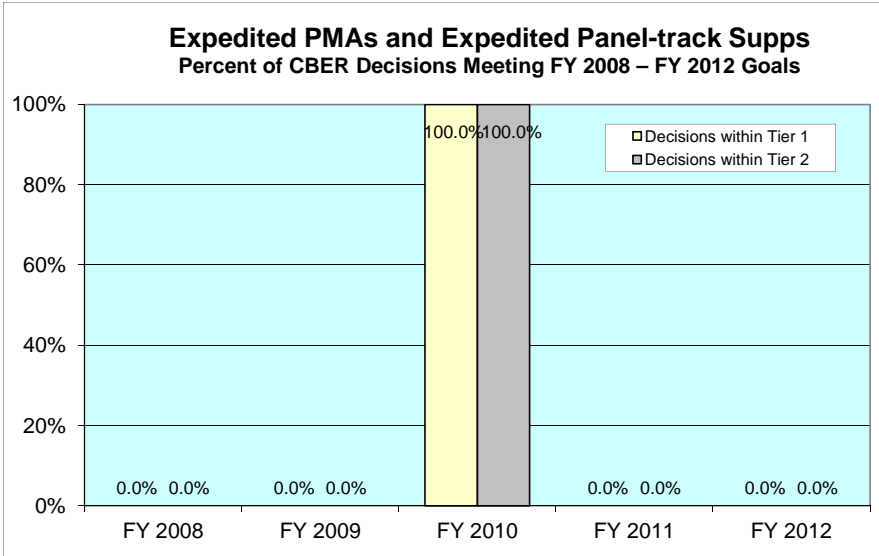
### PMA and Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	2	0	1	4
Total FDA Decisions	0	2	0	1	3
Percent within Tier 1 goal (180 days)	--	100.0%	--	100.0%	75.0%
Tier 1 goal — <i>Percent within 180 days</i>	60%	60%	60%	60%	60%
Percent within Tier 2 goal (295 days)	--	100.0%	--	100.0%	75.0%
Tier 2 goal — <i>Percent within 295 days</i>	90%	90%	90%	90%	90%
Cohort status	Complete	Complete	Complete	Complete	Open



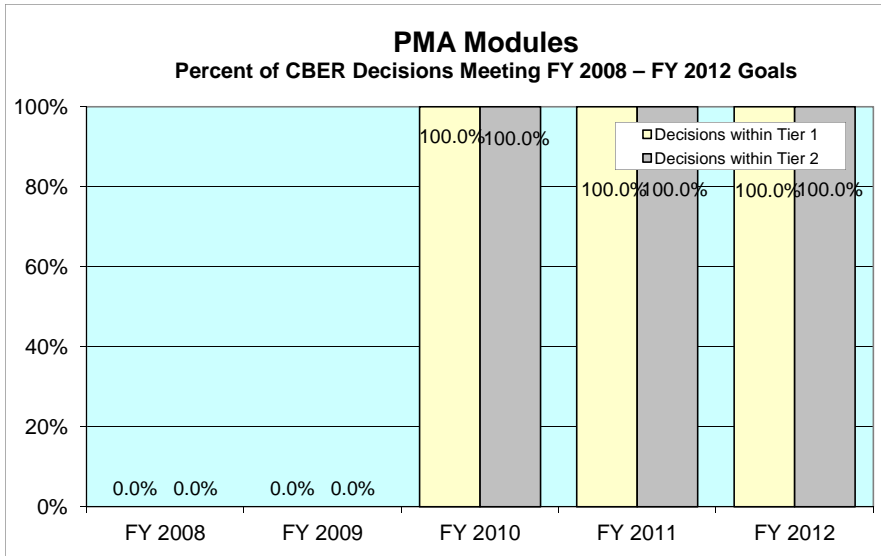
**Expedited PMAs and Expedited Panel-track Supplements**

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	0
Total FDA Decisions	0	0	1	0	0
Percent within Tier 1 goal (180 days)	--	--	100.0%	--	--
Tier 1 goal — <i>Percent within 180 days</i>	50%	50%	50%	50%	50%
Percent within Tier 2 goal (280 days)	--	--	100.0%	--	--
Tier 2 goal — <i>Percent within 280 days</i>	90%	90%	90%	90%	90%
Cohort status	Complete	Complete	Complete	Complete	Complete



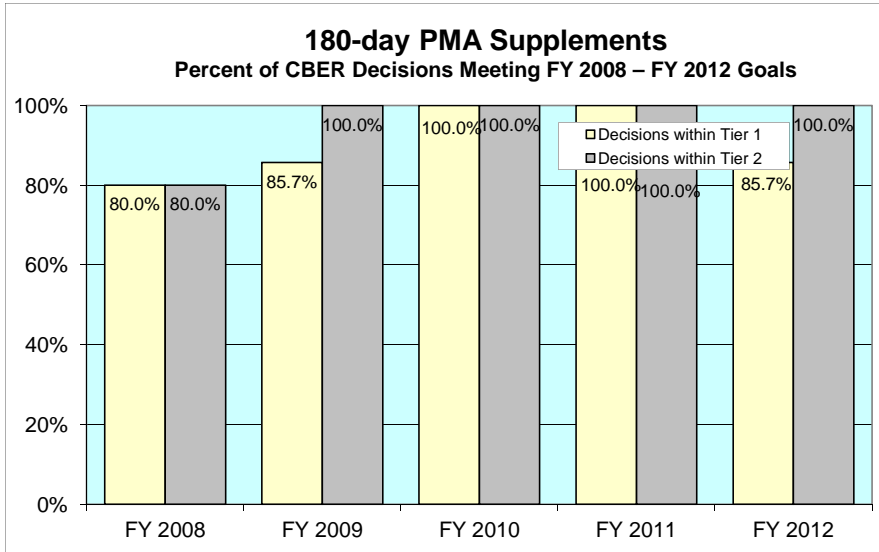
**PMA Modules**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
Workload (Filed to Date)	0	0	1	5	4
MDUFMA Cohort	0	0	1	5	4
Total FDA Decisions	0	0	1	5	3
Percent within Tier 1 goal (90 days)	--	--	100.0%	100.0%	100.0%
Tier 1 goal — <i>Percent within 90 days</i>	75%	75%	75%	75%	75%
Percent within Tier 2 goal (120 days)	--	--	100.0%	100.0%	100.0%
Tier 2 goal — <i>Percent within 120 days</i>	90%	90%	90%	90%	90%
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Open</i>



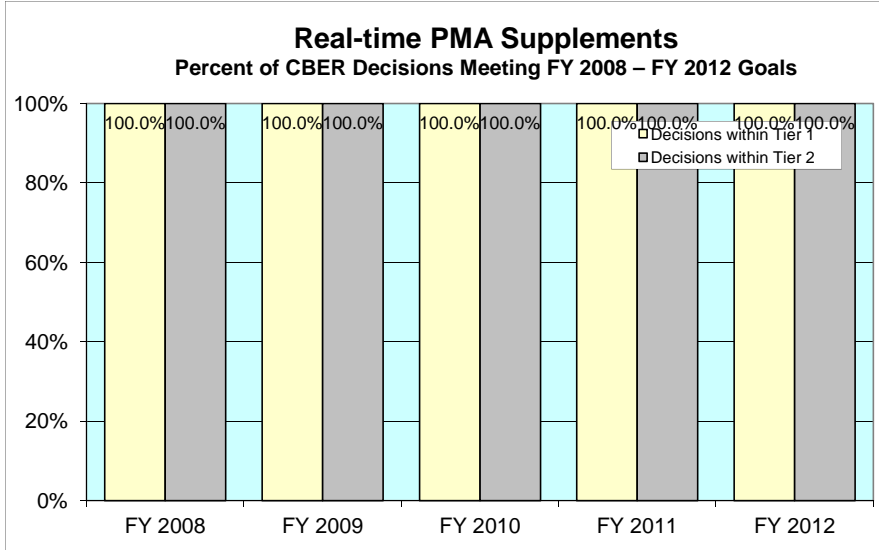
## 180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	9	7
Total FDA Decisions	5	7	7	9	7
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	100.0%	85.7%
Tier 1 goal — <i>Percent within 180 days</i>	85%	85%	85%	85%	85%
Percent within Tier 2 goal (210 days)	80.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — <i>Percent within 210 days</i>	95%	95%	95%	95%	95%
Cohort status	Complete	Complete	Complete	Complete	Open



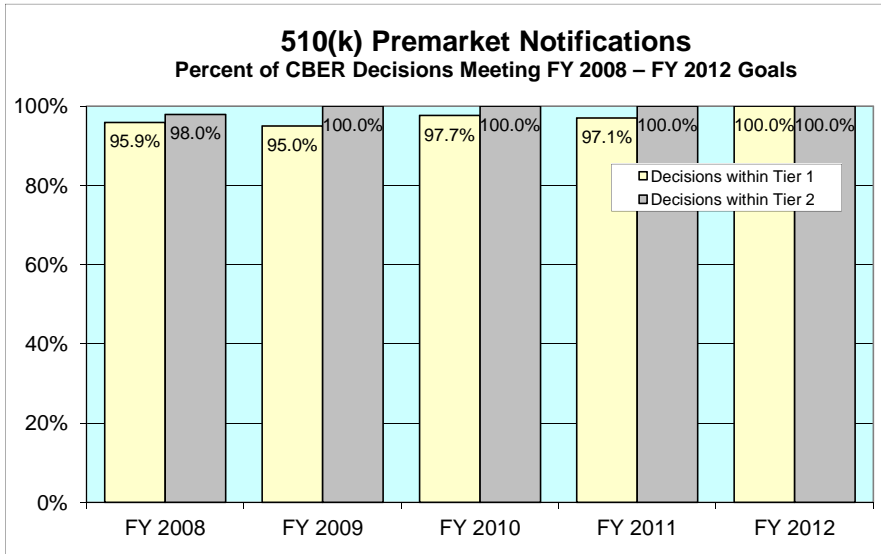
## Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	2	4	2	1	4
Total FDA Decisions	2	4	2	1	4
Percent within Tier 1 goal (60 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 1 goal — <i>Percent within 60 days</i>	80%	80%	80%	80%	80%
Percent within Tier 2 goal (90 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — <i>Percent within 90 days</i>	90%	90%	90%	90%	90%
Cohort status	Complete	Complete	Complete	Complete	Complete



**510(k)s**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
Workload (Received to Date)	53	50	55	44	54
MDUFMA Cohort	49	40	43	34	49
Total FDA Decisions	49	40	43	34	42
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	97.1%	100.0%
Tier 1 goal — <i>Percent within 90 days</i>	90%	90%	90%	90%	90%
Percent within Tier 2 goal (150 days)	98.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — <i>Percent within 150 days</i>	98%	98%	98%	98%	98%
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	<i>Open</i>



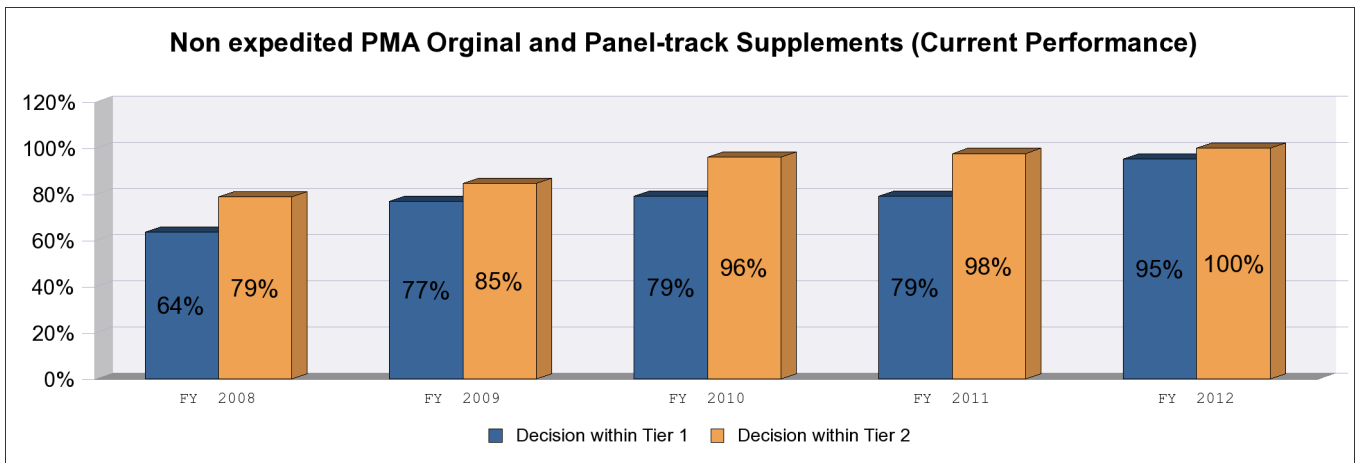




**Quarterly Update on  
Medical Device Performance Goals  
---- CDRH Performance Data ----  
Action through 31 March 2013**

**MDUFA II Quarterly (Non expedited PMA Original and Panel-track Supplements)**  
**For Submissions Filed Between Year 2008 to 2012 as of 3/31/2013 11:59:00 PM**

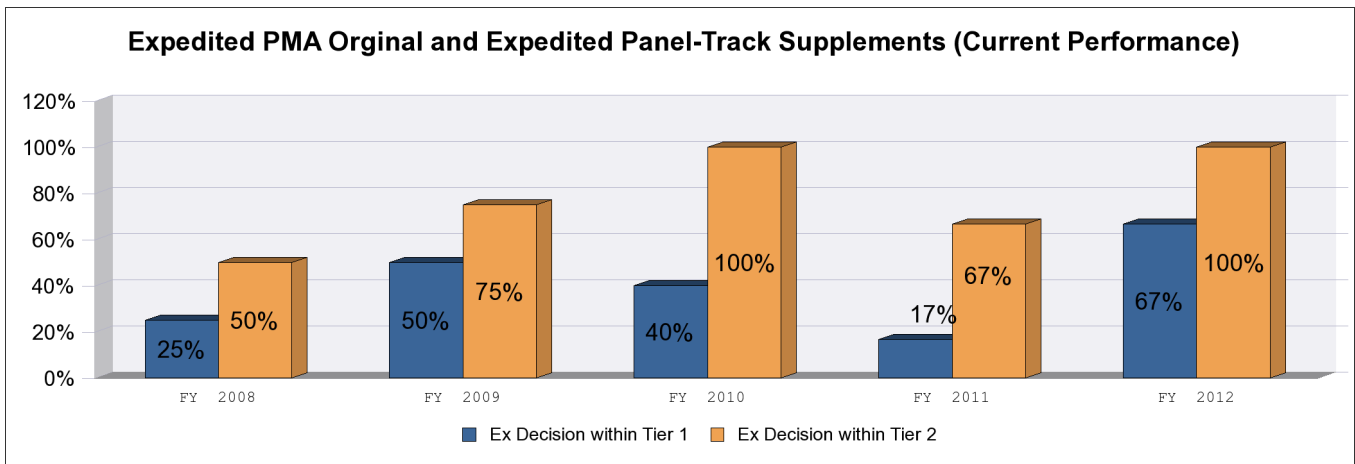
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	39	53	44	31
Total FDA Decision	33	39	53	43	21
Tier 1 goal -- Percent within 180 Days	60%	60%	60%	60%	60%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	64%	77%	79%	77%	87%
Pending Performance-Worst Case	64%	77%	79%	77%	65%
Tier 2 goal -- Percent within 295 days	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	no	no	yes	yes	unknown
Pending Performance-Best Case	79%	85%	96%	98%	100%
Pending Performance-Worst Case	79%	85%	96%	95%	68%
Cohort status	Complete	Complete	Complete	Open	Open



## MDUFA II Quarterly (Expedited PMA Original and Expedited Panel-Track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2013 11:59:00 PM

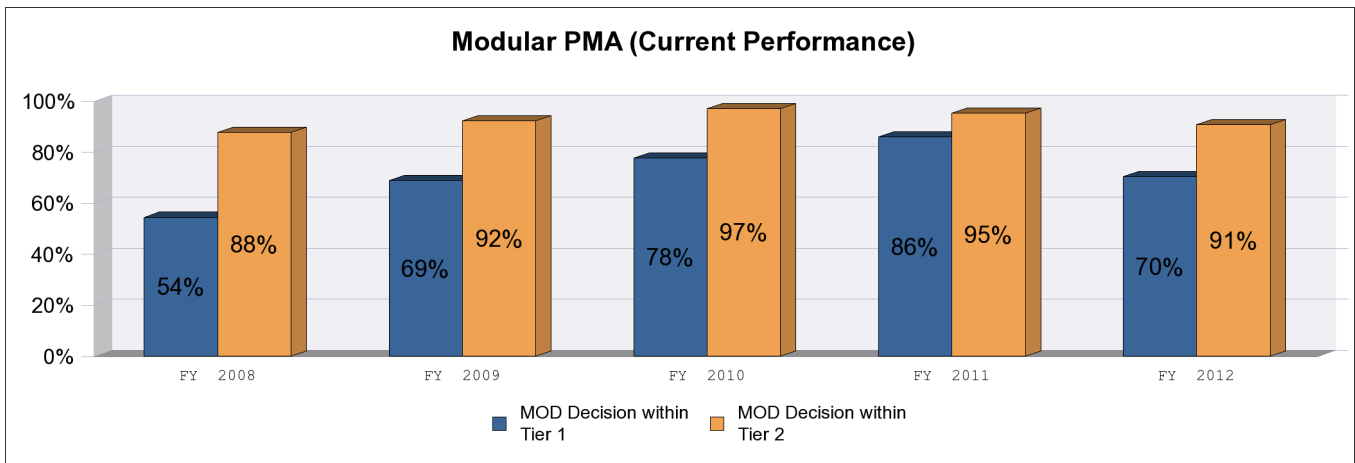
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	4	6	7	3
Total FDA Decision	4	4	5	6	3
<i>Tier 1 goal -- Percent within 180 Days</i>	50%	50%	50%	50%	50%
Goal met(yes/no/unknown)	no	yes	no	no	yes
Pending Performance-Best Case	25%	50%	33%	14%	67%
Pending Performance-Worst Case	25%	50%	33%	14%	67%
<i>Tier 2 goal -- Percent within 280 days</i>	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	no	no	no	no	yes
Pending Performance-Best Case	50%	75%	83%	57%	100%
Pending Performance-Worst Case	50%	75%	83%	57%	100%
Cohort status	Complete	Complete	Open	Open	Complete



## MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2012 as of 3/31/2013 11:59:00 PM

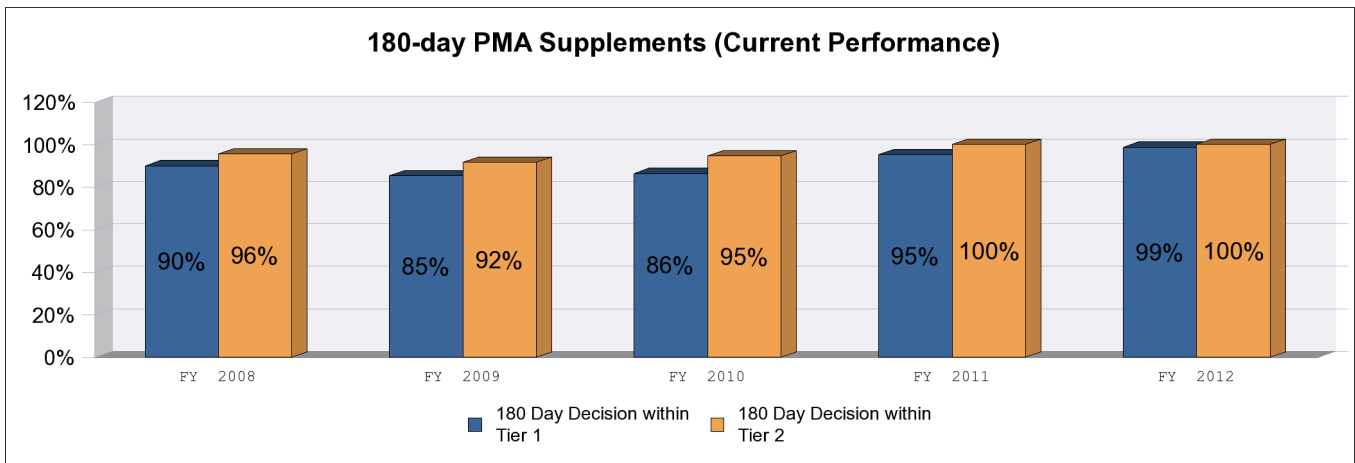
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Cycle Started)	57	90	104	85	64
Total FDA Decision	57	90	103	85	64
<i>Tier 1 goal -- Percent within 90 Days</i>	75%	75%	75%	75%	75%
Goal met(yes/no/unknown)	no	no	yes	yes	no
Pending Performance-Best Case	54%	69%	78%	86%	70%
Pending Performance-Worst Case	54%	69%	78%	86%	70%
<i>Tier 2 goal -- Percent within 120 days</i>	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	no	yes	yes	yes	yes
Pending Performance-Best Case	88%	92%	97%	95%	91%
Pending Performance-Worst Case	88%	92%	97%	95%	91%
Cohort status	Complete	Complete	Complete	Complete	Complete



## MDUFA II Quarterly (180-day PMA Supplements)

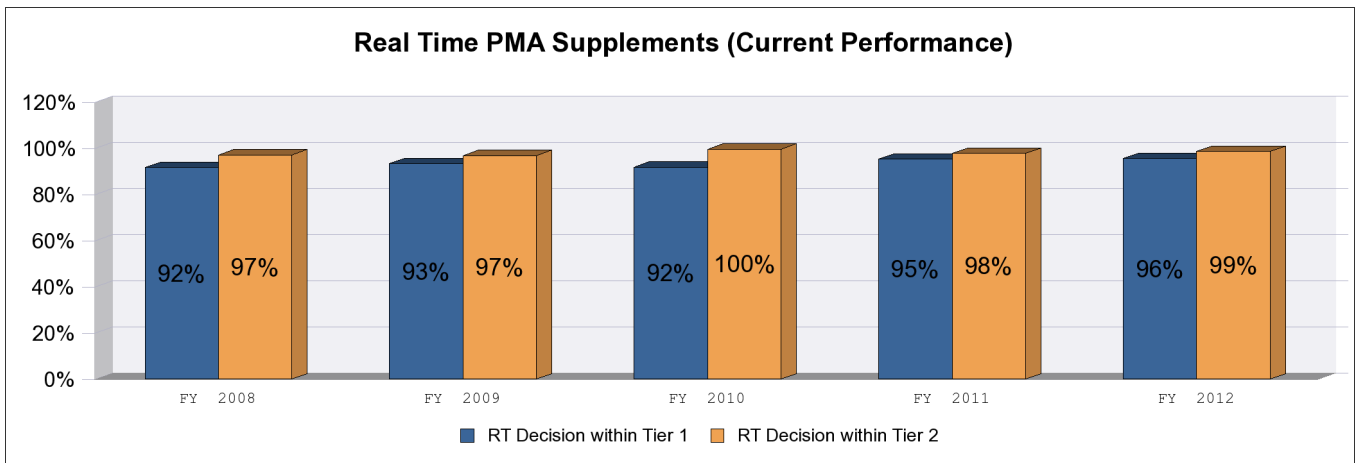
For Submissions Filed Between Year 2008 to 2012 as of 3/31/2013 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	170	164	157	145	210
Total FDA Decision	160	157	132	129	158
<i>Tier 1 goal -- Percent within 180 Days</i>	85%	85%	85%	85%	85%
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	90%	85%	86%	95%	98%
Pending Performance-Worst Case	90%	85%	86%	95%	80%
<i>Tier 2 goal -- Percent within 210 days</i>	95%	95%	95%	95%	95%
Goal met(yes/no/unknown)	yes	no	yes	yes	unknown
Pending Performance-Best Case	96%	92%	95%	100%	99%
Pending Performance-Worst Case	96%	92%	95%	100%	81%
Cohort status	Complete	Complete	Complete	Complete	Open



**MDUFA II Quarterly (Real Time PMA Supplements)**  
**For Submissions Filed Between Year 2008 to 2012 as of 3/31/2013 11:59:00 PM**

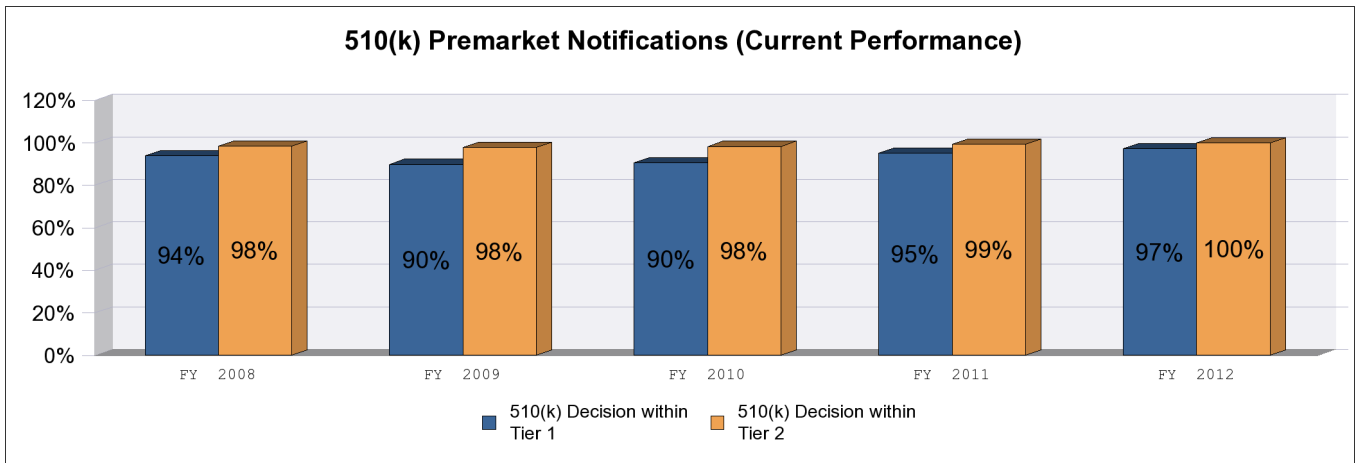
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	249	296	269	245	304
Total FDA Decision	241	281	257	235	293
Tier 1 goal -- Percent within 60 Days	80%	80%	80%	80%	80%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	92%	93%	92%	95%	96%
Pending Performance-Worst Case	92%	93%	92%	95%	96%
Tier 2 goal -- Percent within 90 days	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	97%	97%	100%	98%	99%
Pending Performance-Worst Case	97%	97%	100%	98%	99%
Cohort status	Complete	Complete	Complete	Complete	Complete



## MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2012 as of 3/31/2013 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	3,848	4,103	3,880	3,833	3,991
MDUFA Cohort	3,260	3,402	3,145	3,201	3,492
Total FDA Decision	3,259	3,398	3,144	3,193	3,019
<i>Tier 1 goal -- Percent within 90 Days</i>	90%	90%	90%	90%	90%
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	94%	90%	90%	95%	97%
Pending Performance-Worst Case	94%	90%	90%	95%	84%
<i>Tier 2 goal -- Percent within 150 Days</i>	98%	98%	98%	98%	98%
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	98%	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	98%	99%	86%
Cohort status	Open	Open	Open	Open	Open







**CLIA Waiver by Application**

<b>MDUFA II Cohort Summary as of 4/02/2013</b>					
	FY08	FY09	FY10	FY11	FY12
Received	12	7	5	6	6
Approved	5	3	2	3	2
Denied	6	3	3	0	4
No Response Necessary	0	0	0	1	0
On Hold	1	1	0	2	0

Fiscal Year	Recommendation	Total FDA Days	Total Mfr Days	Total days
2008	Approved	398	0	398
		61	0	61
		248	38	286
		248	38	286
		398	0	398
	Denied	287	0	287
		199	0	199
		189	0	189
		320	424	744
		129	0	129
		102	0	102
	Telephone Hold	136	1764	1900
	2009	Approved	233	0
204			64	268
304			908	1212
Denied		740	0	740
		285	0	285
		644	7	651
Telephone Hold	33	1489	1522	
2010	Approved	77	0	77
		105	106	211
	Denied	172	0	172
		266	0	266
		248	0	248
2011	Approved	27	0	27
		229	97	326
		165	87	252
	No Response Necessary	788	0	788
	Request For Additional Information	95	465	560
		95	465	560
2012	Approved	79	0	79
		24	0	24
	Denied	153	0	153
		64	56	120
		235	0	235
		165	0	165