

Quarterly Update on  
Medical Device Performance Goals  
— CDRH Performance Data —  
Actions through December 31, 2008

**Data on FY 2003 – FY 2007 Cohorts**

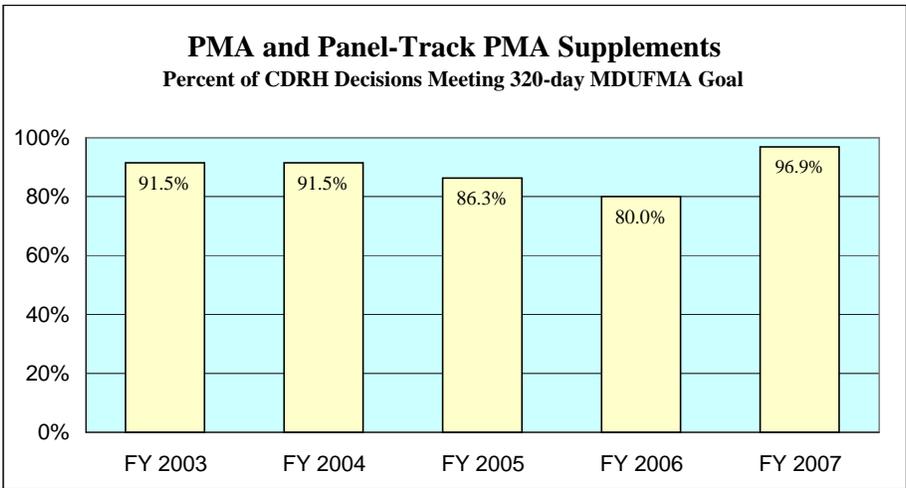
**PMAs and Panel-Track Supplements**  
CDRH Actions through December 31, 2008

**Workload (Applications Filed to Date)**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
PMAs	40	39	41	37	33
Panel-Track Supplements	7	8	11	16	4
<b>Total Workload</b>	<b>47</b>	<b>47</b>	<b>52</b>	<b>53</b>	<b>37</b>

**FDA Decisions**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
<b>FDA Decisions</b>	47	47	51	50	32
Goal – <i>Percent within 320 days</i>	—	—	—	80%	90%
Percent of decisions within 320 days	91.5%	91.5%	86.3%	80.0%	96.9%
Applications without a decision	0	0	1	3	5
Cohort status	<i>Complete</i>	<i>Complete</i>	Open	Open	Open
Goal – <i>Percent within 180 days</i>	—	—	—	—	50%
Percent of decisions within 180 days	44.7%	36.2%	31.4%	36.0%	62.5%



- Progress to date indicates CDRH will likely meet the goals for FY 2006 and FY 2007.
- The FY 2003 and FY 2004 cohorts are complete. All other cohorts remain open.

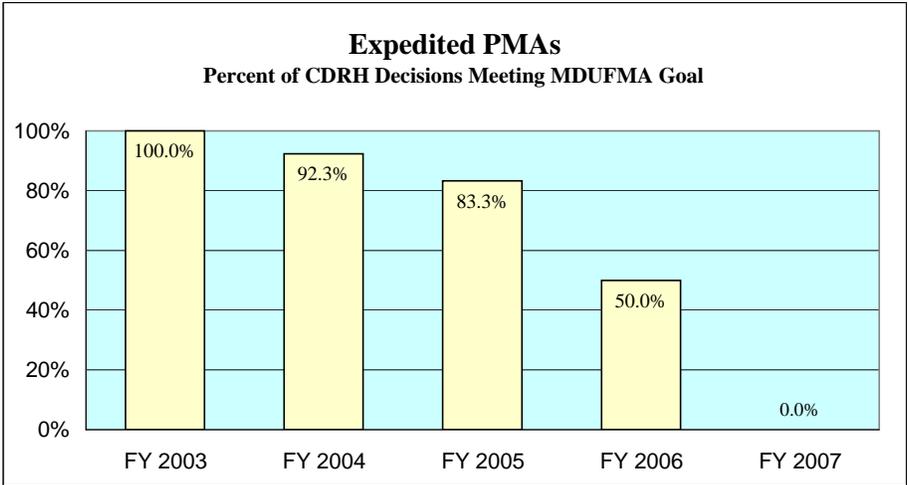
**Expedited PMAs**  
CDRH Actions through December 31, 2008

**Workload (Applications Filed to Date)**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Expedited PMAs	3	14	6	2	2

**FDA Decisions**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
<b>FDA Decisions</b>	3	13	6	2	1
Goal – <i>Percent within 300 days</i>	—	—	70%	80%	90%
Percent of decisions within 300 days	100.0%	92.3%	83.3%	50.0%	0
Applications without a decision	0	1	0	0	1
Cohort status	<i>Complete</i>	Open	<i>Complete</i>	Open	Open



- FY 2003 and FY 2005 cohorts are complete; all other cohorts remain open.
- Because of the small number of Expedited PMAs, a single action may significantly affect performance measures.

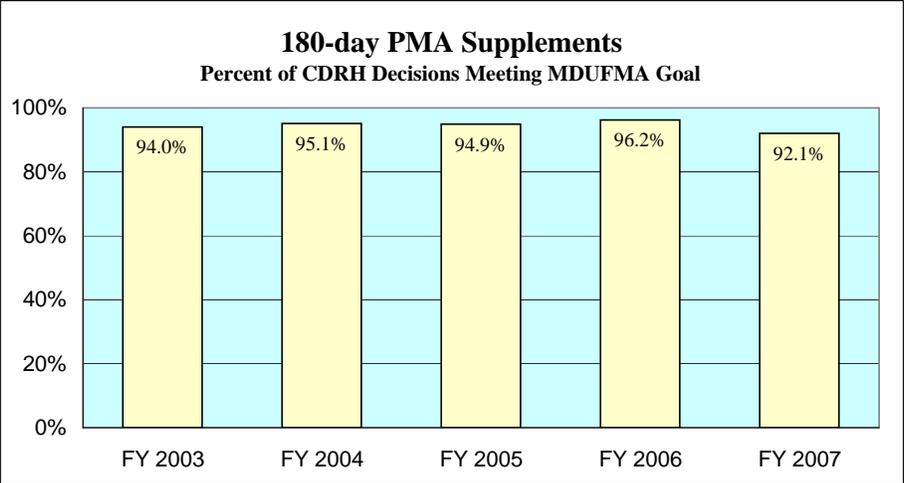
**180-day PMA Supplements**  
CDRH Actions through December 31, 2008

**Workload**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
180-day PMA Supplements	201	103	99	134	140

**FDA Decisions**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
<b>FDA Decisions</b>	201	103	99	133	139
Goal – <i>Percent within 180 days</i>	—	—	80%	80%	90%
Percent of decisions within 180 days	94.0%	95.1%	94.9%	96.2%	92.1%
Applications without a decision	0	0	0	1	1
Cohort status	<i>Complete</i>	<i>Complete</i>	<i>Complete</i>	Open	Open



- FY 2003, FY 2004, and FY 2005 cohorts are complete.

**510(k) Premarket Notifications**  
CDRH Actions through December 31, 2008

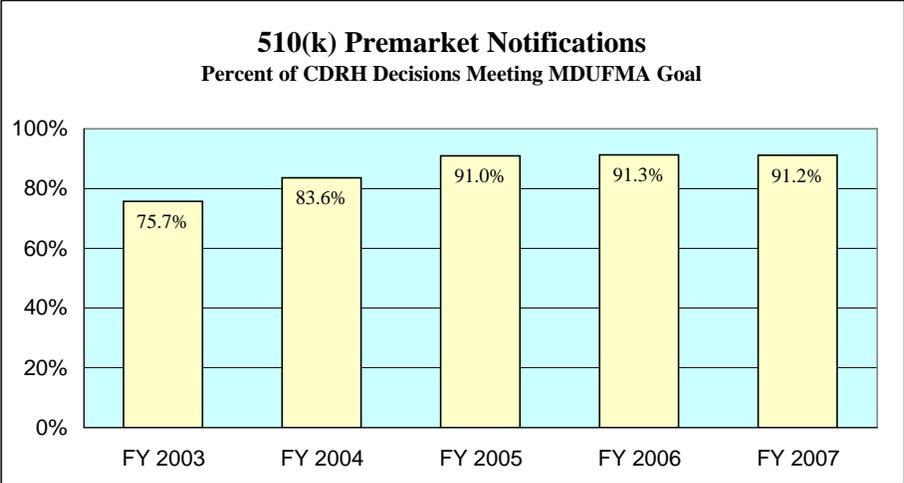
**Workload**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Received	4,225	3,632	3,650	3,853	3,656
MDUFMA Cohort <sup>1</sup>	3,741	3,309	3,344	3,446	3,168

<sup>1</sup> The MDUFMA Cohort excludes 510(k)s that were closed for any reason other than an SE or NSE decision (e.g., when FDA finds that a 510(k) was not required). The number of 510(k)s in the MDUFMA Cohort is subject to change until the cohort is complete.

**FDA Decisions (SE and NSE Determinations)**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
FDA Decisions (SE and NSE)	3,741	3,309	3,344	3,446	3,168
Goal – Percent within 90 days	—	—	75%	75%	80%
Percent of decisions within 90 days	75.7%	83.6%	91.0%	91.3%	91.2%
Remaining applications	0	0	1	4	26
Cohort status	Complete	Complete	Open	Open	Open

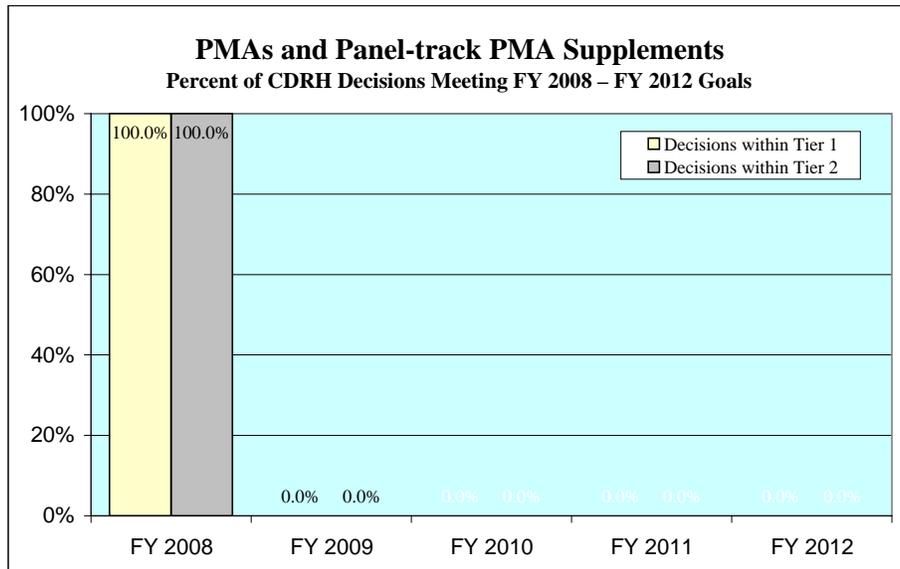


- FY 2003 and FY 2004 cohorts are closed; only one 510(k) remains open in the FY 2005 cohort, six in the FY 2006 cohort, and 68 in the FY 2007 cohort.

**Data on FY 2008 – FY 2012 Cohorts**

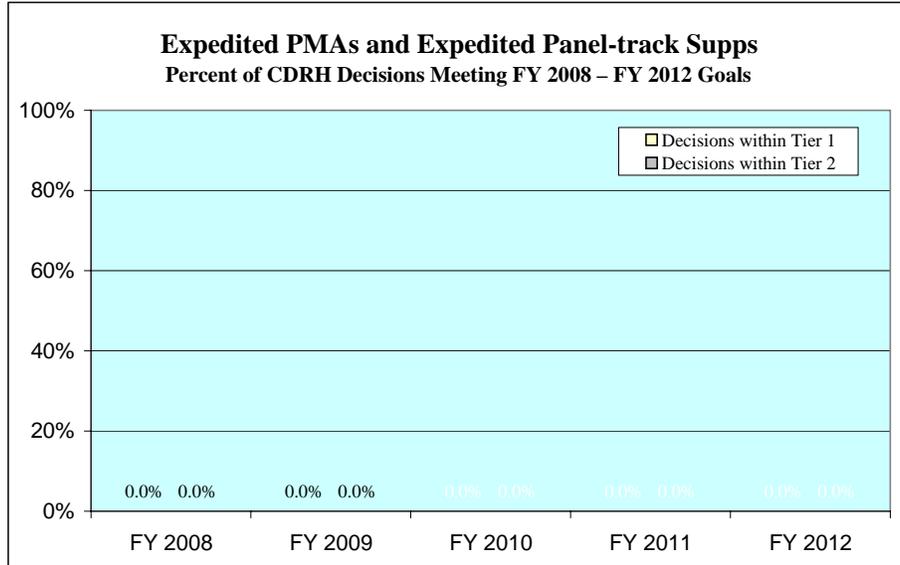
**PMAs and Panel-track Supplements**

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	4	—	—	—
Total FDA Decisions	8	0	—	—	—
Percent within Tier 1 goal (180 days)	100.0%	--	—	—	—
Tier 1 goal — <i>Percent within 180 days</i>	60%	60%	60%	60%	60%
Percent within Tier 2 goal (295 days)	100.0%	0.0%	—	—	—
Tier 2 goal — <i>Percent within 295 days</i>	90%	90%	90%	90%	90%
Cohort status	Open	Open	—	—	—



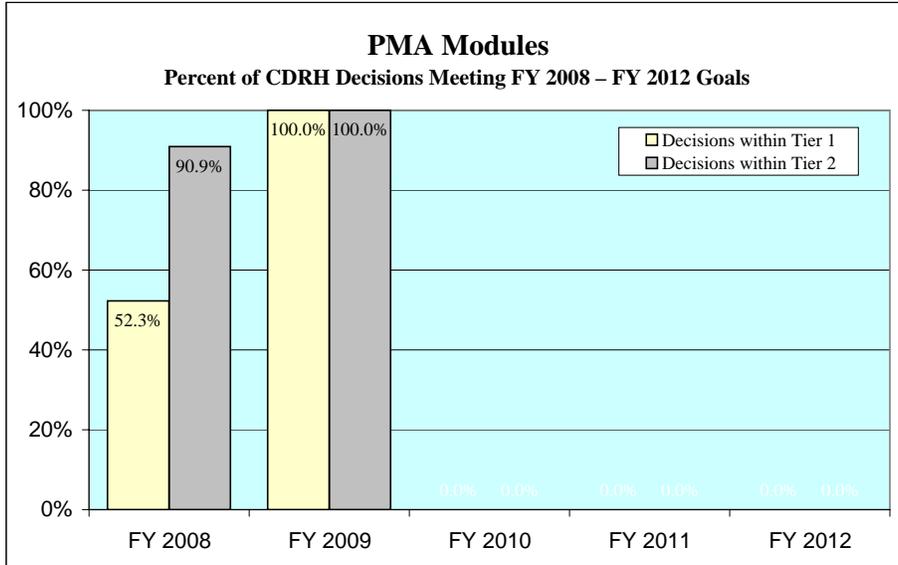
**Expedited PMAs and Expedited Panel-track Supplements**

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	0	—	—	—
Total FDA Decisions	0	0	—	—	—
Percent within Tier 1 goal (180 days)	--	--	—	—	—
Tier 1 goal — <i>Percent within 180 days</i>	50%	50%	50%	50%	50%
Percent within Tier 2 goal (280 days)	--	--	—	—	—
Tier 2 goal — <i>Percent within 280 days</i>	90%	90%	90%	90%	90%
Cohort status	Open	Open	—	—	—



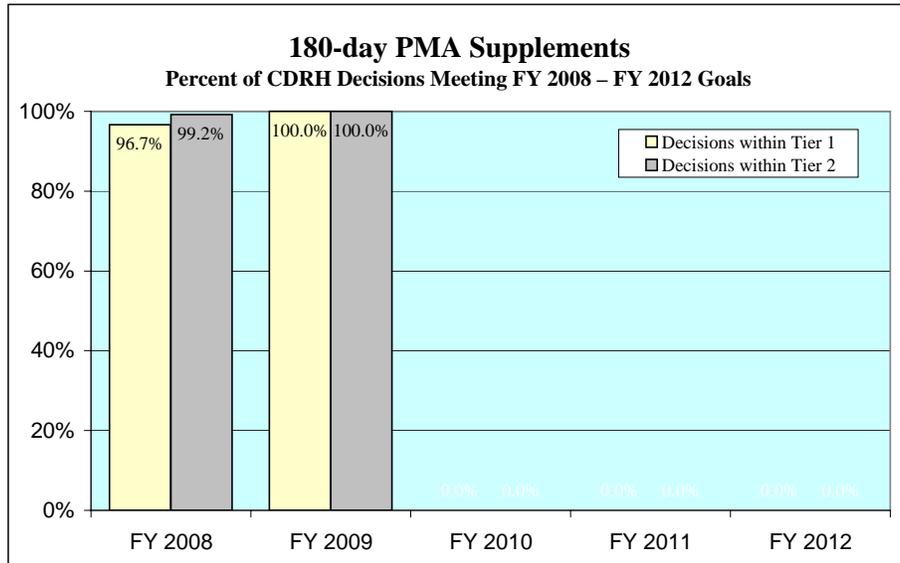
**PMA Modules**

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	43	15	—	—	—
MDUFMA Cohort	44	15	—	—	—
Total FDA Decisions	44	1	—	—	—
Percent within Tier 1 goal (90 days)	52.3%	100.0%	—	—	—
Tier 1 goal — <i>Percent within 90 days</i>	75%	75%	75%	75%	75%
Percent within Tier 2 goal (120 days)	90.9%	100.0%	—	—	—
Tier 2 goal — <i>Percent within 120 days</i>	90%	90%	90%	90%	90%
Cohort status	Open	Open	—	—	—



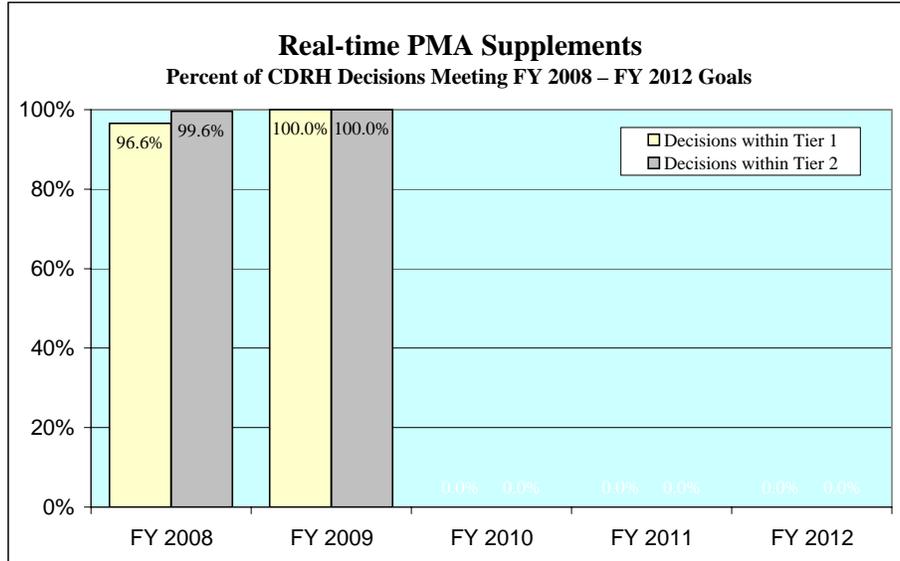
### 180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	168	33	—	—	—
Total FDA Decisions	120	3	—	—	—
Percent within Tier 1 goal (180 days)	96.7%	100.0%	—	—	—
Tier 1 goal — <i>Percent within 180 days</i>	85%	85%	85%	85%	85%
Percent within Tier 2 goal (210 days)	99.2%	100.0%	—	—	—
Tier 2 goal — <i>Percent within 210 days</i>	95%	95%	95%	95%	95%
Cohort status	Open	Open	—	—	—



**Real-time PMA Supplements**

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	248	80	—	—	—
Total FDA Decisions	235	44	—	—	—
Percent within Tier 1 goal (60 days)	96.6%	100.0%	—	—	—
Tier 1 goal — <i>Percent within 60 days</i>	80%	80%	80%	80%	80%
Percent within Tier 2 goal (90 days)	99.6%	100.0%	—	—	—
Tier 2 goal — <i>Percent within 90 days</i>	90%	90%	90%	90%	90%
Cohort status	Open	Open	—	—	—



**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)	3,851	995	—	—	—
MDUFMA Cohort	2,820	159	—	—	—
Total FDA Decisions	2,830	0	—	—	—
Percent within Tier 1 goal (90 days)	96.4%	--	—	—	—
Tier 1 goal — <i>Percent within 90 days</i>	90%	90%	90%	90%	90%
Percent within Tier 2 goal (150 days)	99.6%	--	—	—	—
Tier 2 goal — <i>Percent within 150 days</i>	98%	98%	98%	98%	98%
Cohort status	Open	Open	—	—	—

