OFFICE OF DEVICE EVALUATION

ANNUAL PERFORMANCE REPORT

FISCAL YEAR 2008

Office of Device Evaluation

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

Introduction

In the past, the ODE Annual Report included information from and about the ODE Review Divisions, our initiatives, and data analysis from the ODE Program Operations Staff (POS). The FY 08 Report only includes data from POS on our premarket review program. ODE continues to work towards accomplishing the Center's Strategic Goals and new direction.

Acknowledgements

Thank you to the employees of the ODE Program Operations Staff for their invaluable assistance in preparing this report.

Barbara Zimmerman, Project Director
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Key Performance Indices

Here are the major submissions[1] received in ODE from FY 98 to FY 08. For these submissions (known as "the receipt cohort"), we provide our review performance for Premarket Approval Applications (PMAs), PMA supplements, Premarket Notifications (510(k)s), Investigational Device Exemptions (IDEs), Humanitarian Device Exemptions (HDEs), and Request for Information (513(g)s). For PMAs and 510(k)s, in addition to review performance data, we also provide our progress toward meeting MDUFMA performance goals. In the remainder of this part, we provide information on the number of major submissions processed in FY 08 (known as "the decision cohort").

Major Submissions Received

As shown in Table 1, during FY 08, ODE received 9,601 major submissions, up from 9,276 in FY 07. This increase is primarily due to an increase in the total number of PMA supplements received.

Of the 26 original PMAs and 9 panel track supplements received in FY 08, 4 were granted expedited status. In FY 08, 13 of the 26 (50%) original PMAs were submitted as modular PMAs as compared to 18 (58%) modular PMAs submitted in FY 07.

Of the 1,448 PMA supplements received in ODE in FY 08, 282 were categorized as 180-day PMA supplements, up from 234 in FY 07. The number of fee paying 180-day supplements, remains fairly stable between FY 08 (142) compared to FY 07 (130).

A total of 223 requests were received and processed for real-time PMA supplements in FY 08. Of those submissions, 207 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a videoconference.

Of the 3,363 510(k)s received in ODE FY 08, 2,572 were submitted as traditional 510(k)s, 138 were submitted as abbreviated 510(k)s and the remaining 653 were Special 510(k)s.

Three 510(k)s were granted expedited status in FY 08.

A 513(g) is a request for information regarding FDA regulatory requirements applicable to a device. Ninety-six were received in ODE in FY 08.

ODE received approximately the same number of original IDEs and IDE supplements in 2008 as in FY 07. In FY 08, ODE received and processed 216 original IDEs and 4,409 IDE supplements as compared to 211 original IDEs and 4,345 IDE supplements in FY 07.

[1] A major submission is defined as an original statutory premarket application that requires FDA's scientific review and decision.

In FY 08, the number of original HDEs received was 3, a decrease from 6 in FY 07. The number of HDE supplements received increased from 23 in FY 07 to 40 in FY 08.

Table 1. Major Submissions Received FY 98 – FY 08

TYPE OF SUBMISSION	1998 ODE& OIVD	1999 ODE& OIVD	2000 ODE& OIVD	2001 ODE& OIVD	2002 ODE& OIVD	2003 ODE& OIVD	2004 ODE Only	2005 ODE Only	2006 ODE Only	2007 ODE Only	2008 ODE Only
Original PMAs	48	64	67	71	49	54	37	43	25	31	26
PMA Supplements	517	557	546	641	645	666	565	712	1,113	1,087	1,448
Original IDEs	322	304	311	283	312	242	222	226	251	211	216
IDE Supplements	4,277	4,127	4,388	4,810	4,722	4,415	4,297	4,264	4,485	4,345	4,409
510(k)s	4,623	4,458	4,202	4,248	4,320	4,247	3,107	3,130	3,240	3,192	3,363
Original HDE	8	12	11	5	5	10	9	4	4	6	3
HDE Supplements	0	4	10	16	16	29	28	24	53	23	40
513(g)s	34	43	59	82	104	156	239	287	244	381	96
Total	**9,829**	**9,569**	**9,594**	**10,156**	**10,192**	**9,819**	**8,504**	**8,690**	**9,415**	**9,276**	**9,601**

ODE Review Performance

- Premarket Approval Applications (PMAs)

The figures below provide the ODE review performance for PMAs filed in FY 03 to FY 07. The data for FY 08 was not included because a significant number of PMA submissions received in FY 08 are still under review and a final decision has not been issued.

As shown in Figure 2, the average total elapsed time for original PMAs and panel track PMA supplements has decreased slightly from FY 03 to FY 07. The increase in FY 05 and FY 06 is likely due to a staffing shortage that occurred in 2005 due to uncertainties over the continuation of the Medical Device User Fee Program.

Figure 1: Average Total FDA Review Days from Filing to Approval (excluding withdrawals) for All Original and Panel Track PMA Supplements

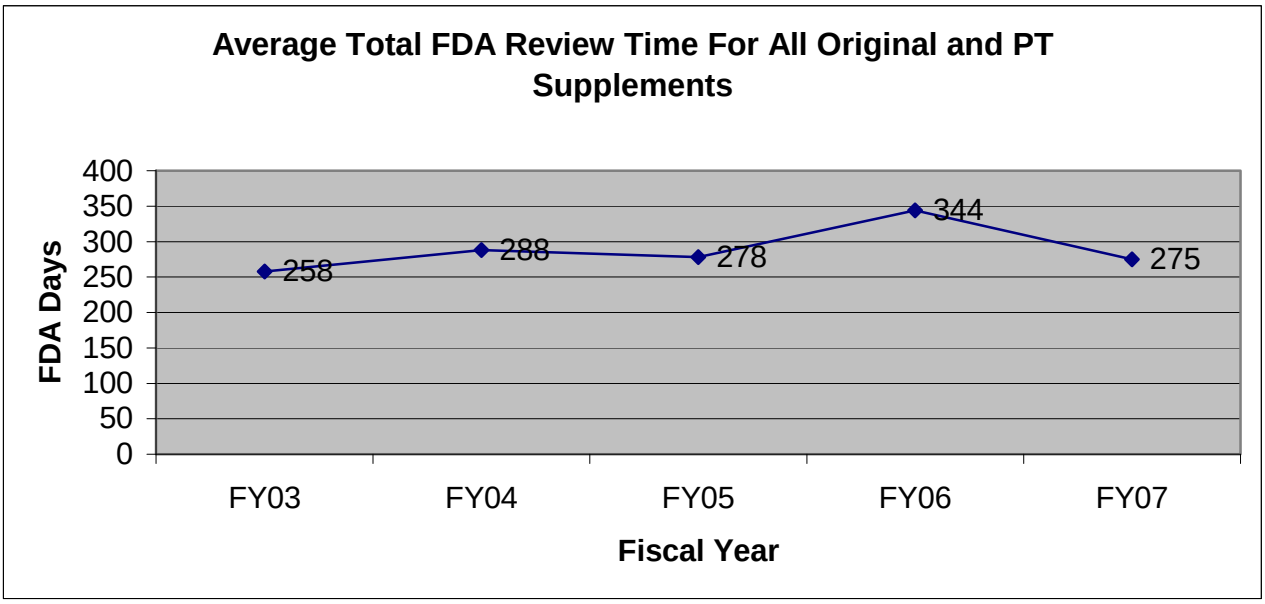


Figure 2: Average Total Elapsed Days from Filing to Approval (excluding withdrawals) for All Original and Panel Track PMA Supplements

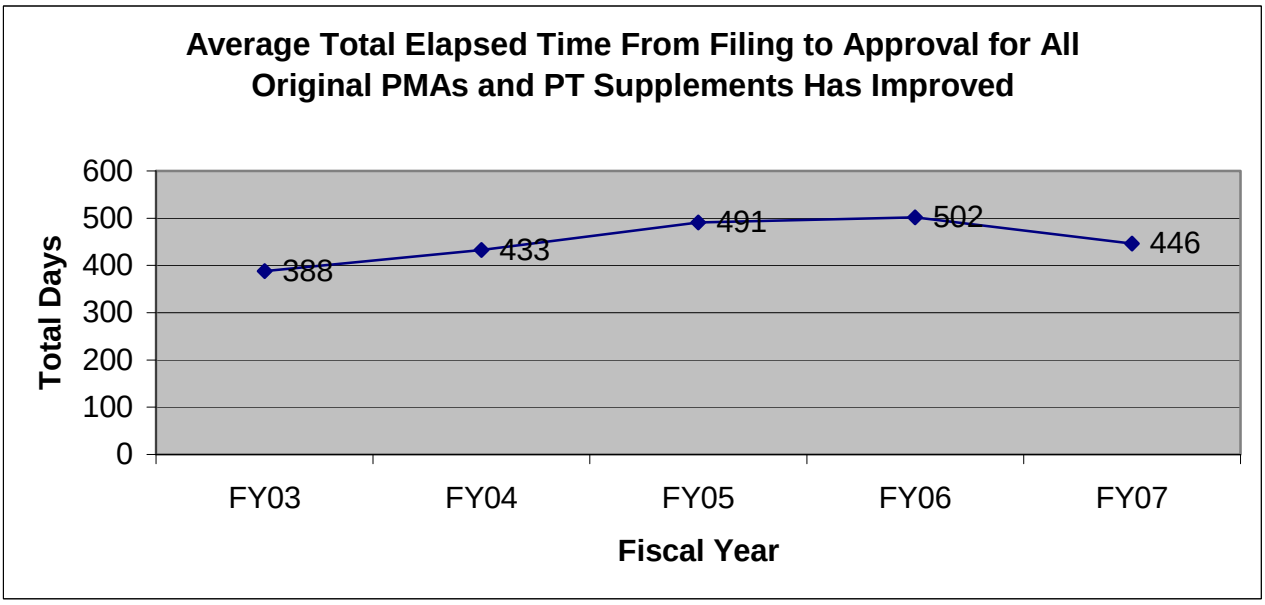
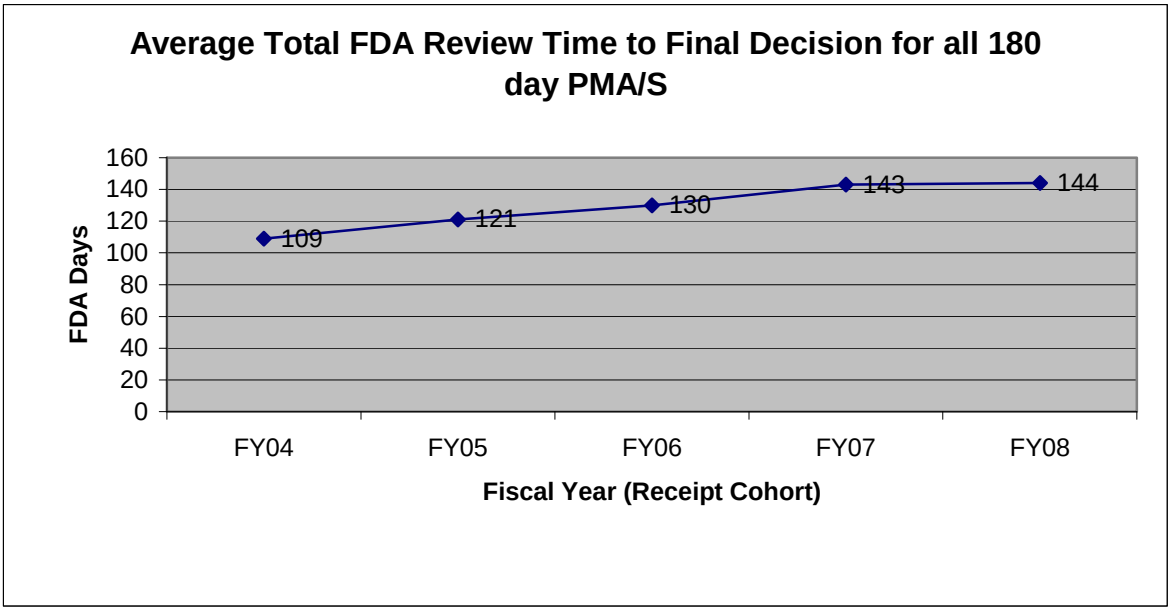


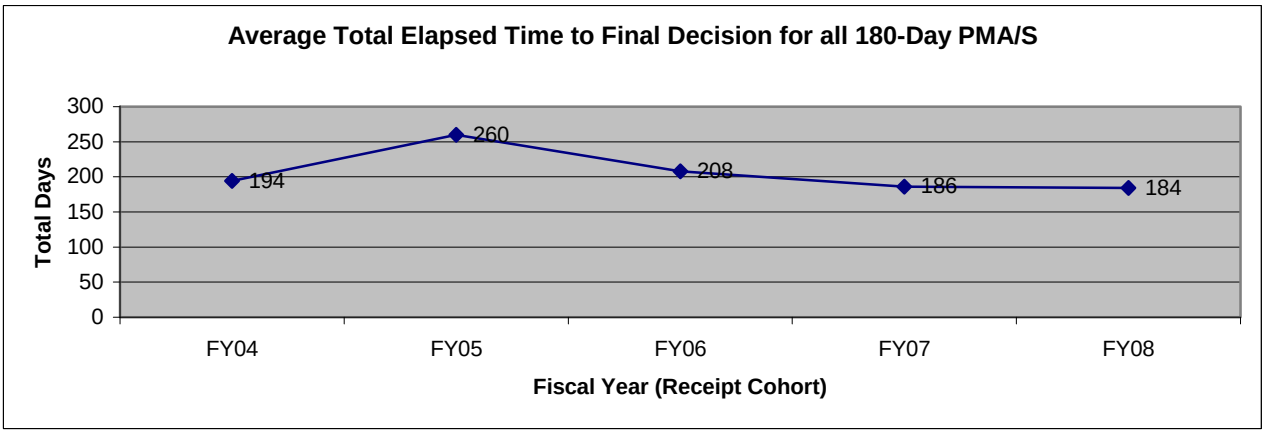
Figure 3: Average Total FDA Days from Receipt to Final Decision for all 180-day PMA Supplements –



As shown in Figure 3, the average ODE review time from receipt to final decision, one that closes a file (i.e., approvals and other final decisions such as withdrawals and conversions) for 180-day PMA supplements is relatively flat. For the FY 08 receipt cohort, the average ODE review time was 144 days, similar to 143 days in FY 07.

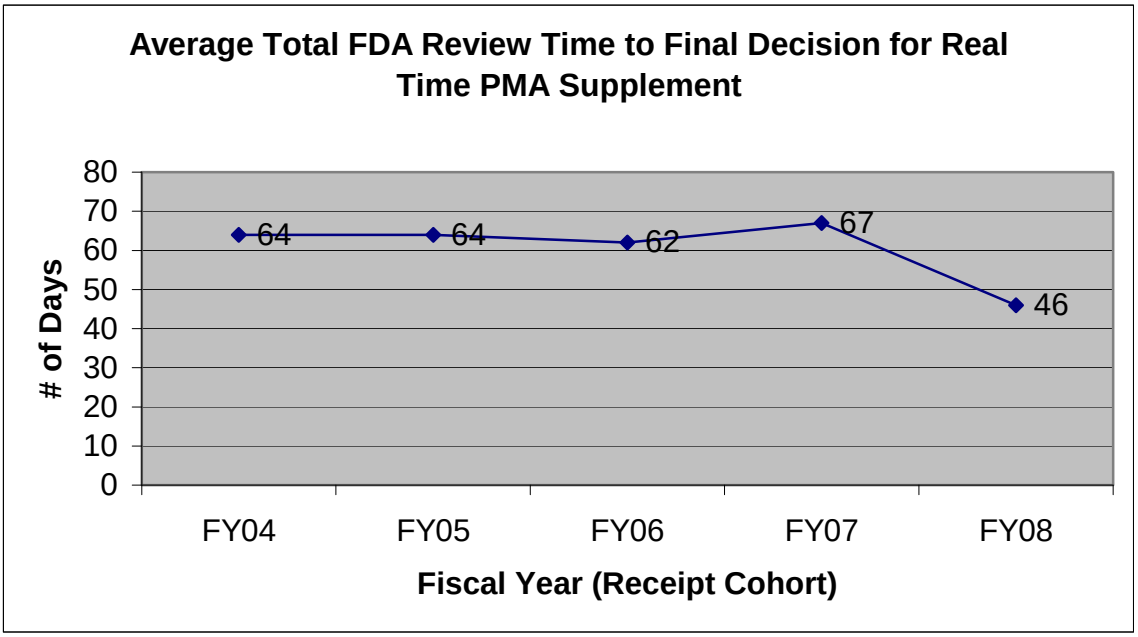
There has been a slight improvement in the average total elapsed time for 180-day PMA supplements since FY 07. For the FY 08 receipt cohort, the total time was 184 days, down from 186 days in for the FY 07 receipt cohort (see Figure 4).

Figure 4: Average Total Elapsed Days from Receipt to Final Decision for all 180-day PMA supplements.



Since FY 04, the average total FDA review time from receipt to final decisions (i.e., approvals and other final decisions such as withdrawals and conversions) for real-time supplements has remained fairly constant between 62 and 67 days. It decreased to 46 in FY 08 due to new performance goals (see Figure 5). Since the average review cycle for a real time PMA supplement is one cycle, the average FDA review time is approximately the same as the average total elapsed time. MDUFMA has resulted in a significant increase in the number of real-time supplements received by CDRH. In FY 08, 219 real-time supplements were received as compared to 255 received in FY 07, a decrease of 14%.

Figure 5: Average Total FDA Review Time for Real Time PMA Supplements



- Product Development Protocols (PDPs)

No original PDPs were approved in FY 08. One routine PDP supplement, 5 Real-Time PDP Supplements, and 20 30-day/135-day supplements were "approved." Note that a PDP that has been "declared complete" is considered to have an approved PMA.

- 510(k) Review Performance

As shown in Figure 6, the average FDA review time from receipt to final decision increased in recent years but leveled off in FY 08. Average FDA review time for the FY 08 receipt cohort (which is still incomplete) stands at 64 days, compared to 65 days for FY 07 receipts. Average total elapsed time from receipt to final decision stands at 109 days for the FY 08 receipt cohort (still incomplete), compared to 110 days for FY 07 receipts (Figure 7).

Figure 6: Average FDA Time From Receipt To Final Decision

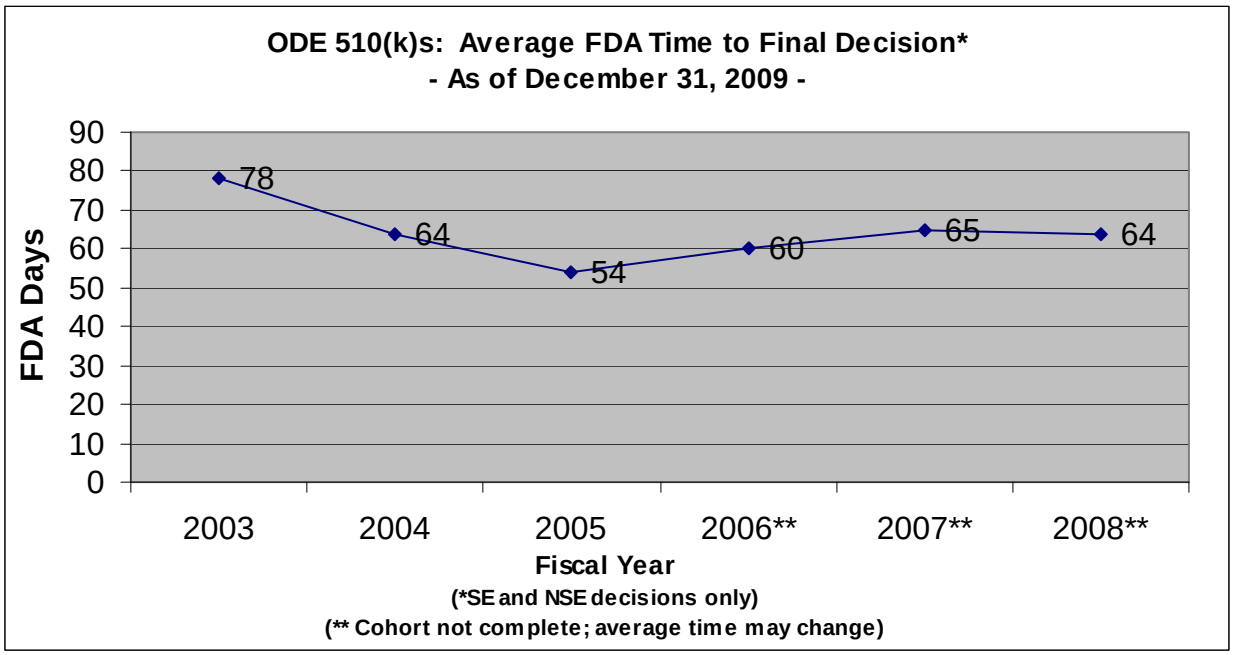
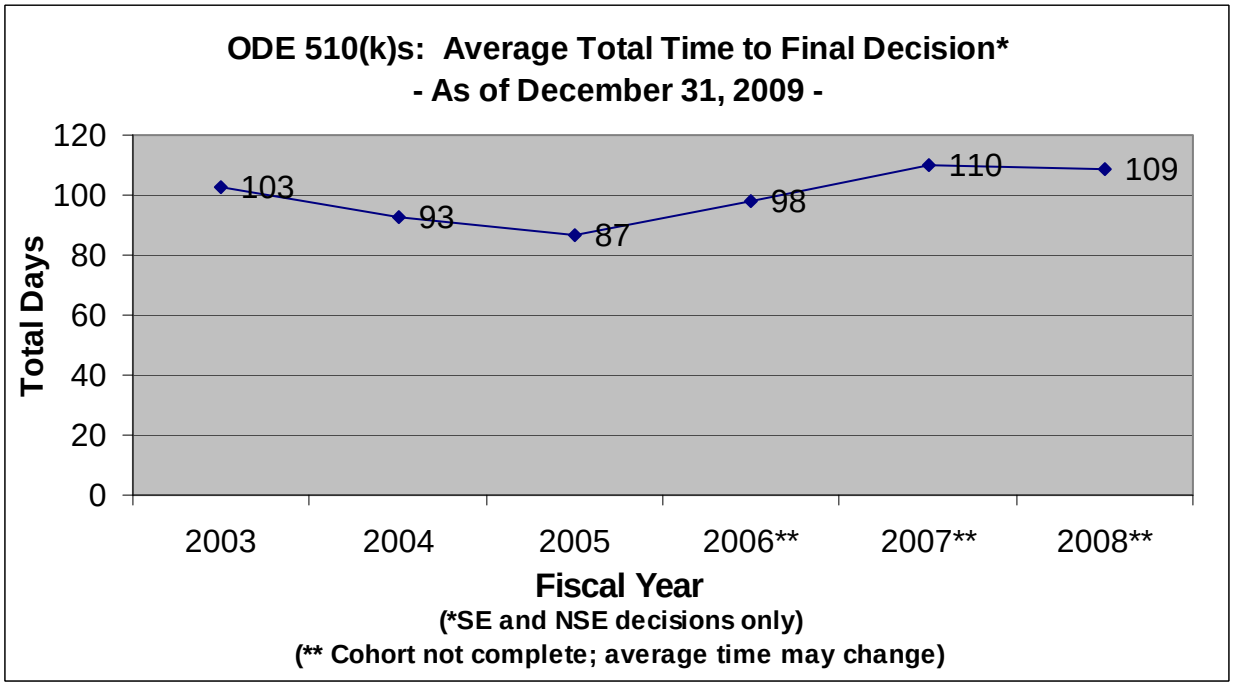


Figure 7: Average Total Elapsed Time From Receipt To Final Decision

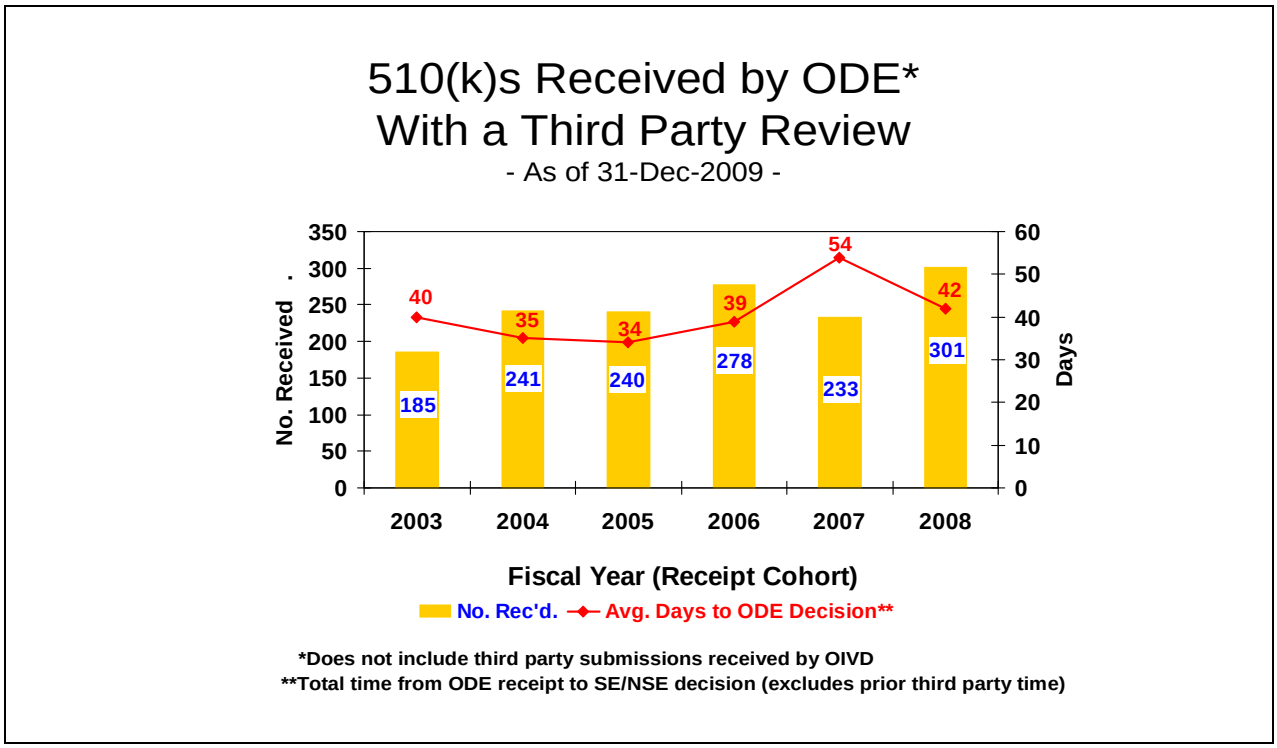


- Third-Party Review of 510(k)s

During FY 08, ODE received 301 510(k)s reviewed by third party organizations under the Accredited Persons provisions (Section 523) of the Federal Food, Drug, and Cosmetic Act. This was a 29% increase from the 233 submissions received last fiscal year. ODE made final decisions on 300 "third party" 510(k)s in FY 08, a 30% increase from the 230 final decisions in FY 07. As shown in Figure 8, the average total days from the time ODE received a 510(k) with a third party's review to the time ODE issued the final decision to the 510(k) holder was 42 days in FY 08, compared to 54 days in FY 07.

Information on the 510(k) Accredited Persons Program is available on the Center's third party review web page at http://www.fda.gov/cdrh/thirdparty/ .

Figure 8: 510(k)s Received By ODE with a Third Party Review



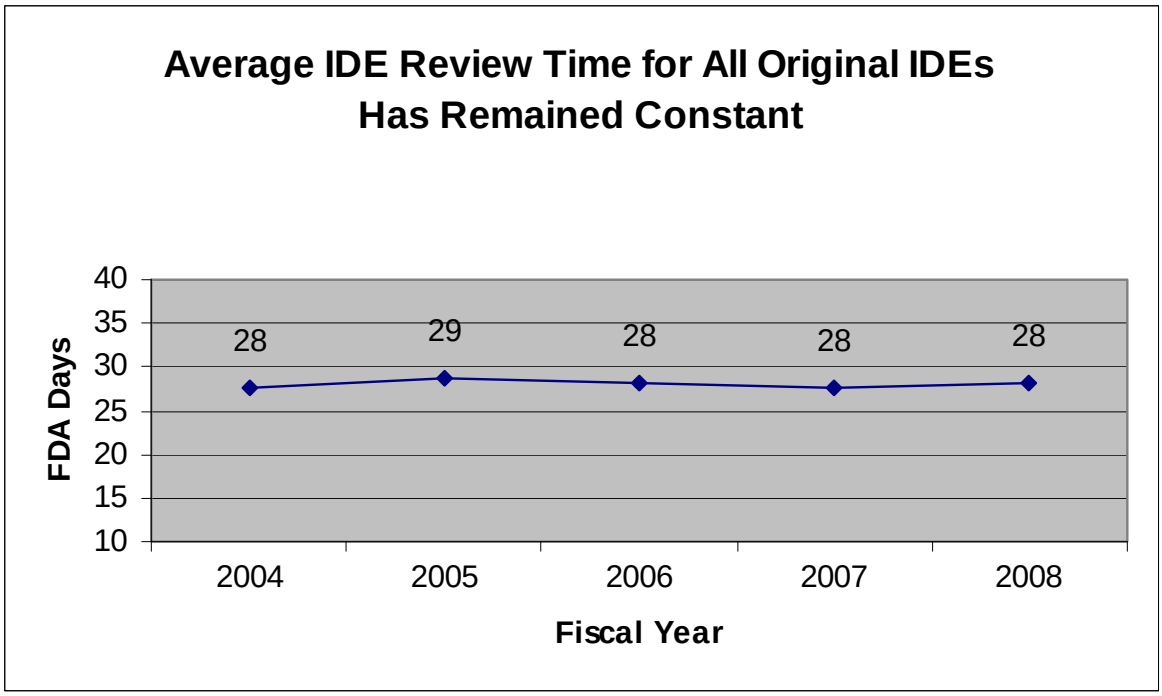
- Humanitarian Device Exemption (HDE) Applications

ODE received 3 original HDEs in FY 08. All were still under review at the end of FY 08. Two HDEs were approved in FY 08.

- Investigational Device Exemptions (IDE) Applications

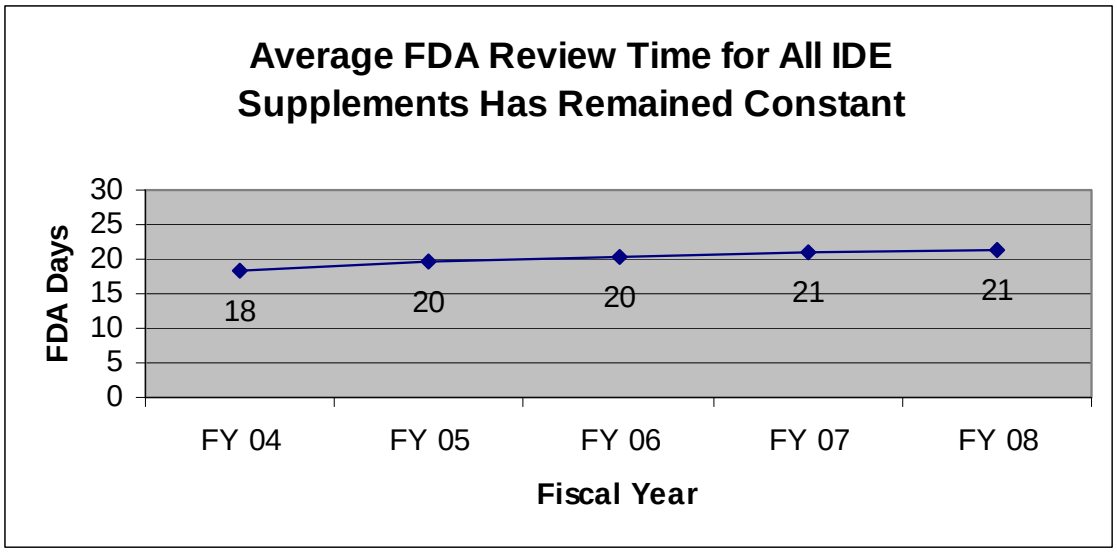
In FY 08, ODE received 216 original IDEs. There were 215 decisions made on original IDEs. Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 08. The average review time was 28 days.

Figure 9: Average FDA Review Time for Original IDEs



In FY 08, 100% of the IDE supplements received were reviewed within the 30-day statutory timeframe. The average review time for IDE supplements has remained constant at 21 days.

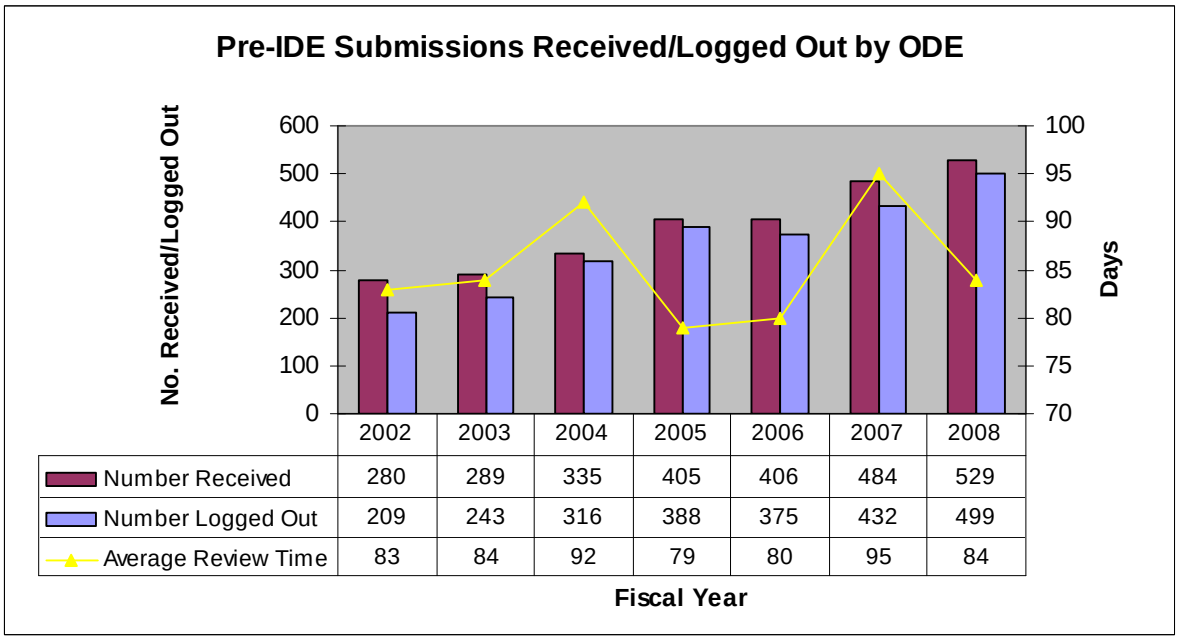
Figure 10: Average Total FDA Review Time for All IDE Supplements



- Pre-IDE Submissions

During FY 08, ODE reviewed 529 pre-IDEs. Based on these reviews, guidance for the pre-original IDE submissions were provided to the sponsors through meetings, letters, fax, or by phone. The number of pre-IDE submissions has increased steadily every year due primarily to increasing awareness of the existence and usefulness of the program, as well as increasingly complex devices and combination products.

Figure 11: Pre-IDE Submissions and Average Review Days



	2002	2003	2004	2005	2006	2007	2008
Number Received	280	289	335	405	406	484	529
Number Logged Out	209	243	316	388	375	432	499
Average Review Time	83	84	92	79	80	95	84

Performance on MDUFMA Goals

FDA provides regular updates on MDUFMA performance and these reports are available at the following website: http://www.fda.gov/cdrh/mdufma. Overall, ODE has made excellent progress in implementing MDUFMA and is achieving nearly all of the performance goals. CDRH has worked hard to communicate the new requirements and challenges of MDUFMA to its staff and stakeholders. To ensure that the implementation of the new law proceeds smoothly, CDRH has worked with its stakeholders and is confident that the implementation of MDUFMA will result in significant benefits to industry, health care professionals, and, most importantly, patients.

Major Submissions Completed (Decision Cohort)

The table below summarizes the actions that ODE completed in fiscal years 1998-2008 (i.e., the "decision cohort"). Note that decisions may be made in one fiscal year for an application that was submitted in a previous fiscal year.

Table 2. Major Submissions Completed FY 98 - FY 08

TYPE OF SUBMISSION	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE& OIVD	ODE Only	ODE Only	ODE Only	ODE Only	ODE Only
Original PMAs	40	36	42	53	41	31	29	28	27	27	16
PMA Supplements	421	440	474	442	533	494	424	354	594	578	630
Original IDEs	325	305	320	284	307	246	217	238	234	214	215
IDE Amendments	225	268	251	207	251	217	162	208	178	163	184
IDE Supplements	4,209	4,224	4,335	4,802	4,711	4,424	4,336	4,226	4,430	4,324	4,369
510(k)s	5,229	4,593	4,397	4,150	4,376	4,132	3,376	3,184	3,080	3,052	3,238
Original HDE	4	6	6	4	10	2	6	2	3	2	2
HDE Supplements	0	3	10	11	14	24	22	31	69	47	42
Total	**10,453**	**9,876**	**9,835**	**9,953**	**10,243**	**9,570**	**8,573**	**8,272**	**8,615**	**8,407**	**8,696**

- Premarket Approval Applications (PMAs)

In FY 08, ODE completed 94 PMA actions. These actions included 26 filing decisions, 26 major deficiency decisions, and 42 approval/approvable/not approvable decisions.

Of the 42 decisions made in FY 08 on original PMAs, 16 were approval orders, 10 were approvable and 16 were not approvable. Of the 16 approvals, none were for expedited PMAs.

In FY 08, ODE completed 895 PMA supplement actions. These actions included 7 panel track PMA supplement filing decisions, 57 major deficiency decisions, 106 not approvable decisions, 95 approvable decisions and 630 approval decisions.

- Premarket Notifications (510(k)s)

ODE completed 3,238 510(k) actions in FY 08. These actions included 2,702 substantially equivalent decisions, 112 not substantially equivalent decisions, and 424 other decisions such as withdrawn or deleted.

During the FY 08, 620 Special 510(k)s received final decisions (605 were found substantially equivalent, 0 were found not substantially equivalent, and the remaining 15 had other decisions).

One hundred fifty abbreviated 510(k)s received final decisions (127 substantially equivalent, 2 not substantially equivalent, and 21 other decisions) in FY 08.

ODE made final decisions on 300 “third party” 510(k)s in FY 08, a 30% increase from the 230 final decisions in FY 07.

- Investigational Device Exemptions (IDEs)

Of the original IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle was 57% in FY 08. This represents a slight decrease from the FY 07 performance level of 61%. This may represent an increasing complexity of submissions, and increasing number of combination product submissions.

The percentage of IDE supplements reviewed within the 30-day statutory timeframe was 100% in FY 08.

In FY 08, decisions as follows were made on 184 amendments: 70 approvals (37%); 48 disapprovals (25%); and 66 other administrative actions (35%).

Automatic Evaluation of Class III Designation

The Food and Drug Administration Modernization Act of 1997 (FDAMA) amended Section 513(f) (21 U.S.C. 360c(f)) to provide a new mechanism to reclassify statutorily classified class III products. This provision, which is referred to as the Evaluation of Automatic Class III Designation provision (also known as "de novo" or "risk-based" classification), is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable predicate device. The process permits the Secretary (FDA, by delegation) to reclassify certain low risk devices into class I or II on the basis of established risk-based classification criteria. There was one de novo cleared in FY 08.

515(b)

Section 515(b) of the Federal Food, Drug, and Cosmetic Act (the Act) specifies that FDA will promulgate regulations requiring that the class III devices have an approval of an application for premarket approval (PMA). Class III devices are described in section 513(a)(1)(C) of the Act.

The devices covered by 515(b) requirements fall into two categories:

- Devices in commercial distribution before May 28, 1976 (preamendment devices) that were subsequently classified by the Food and Drug Administration (FDA) as class III devices by means of classification regulations promulgated under Section 513 of the Act.

- Devices offered for commercial distribution on or after May 28, 1976, (postamendment devices) that are determined through the 510(k) process to be substantially equivalent to class III preamendment devices.

Manufacturers of class III preamendment devices (categories 1 and 2 above) are allowed to commercially market their devices without an approved PMA until FDA publishes a final rule under 515(b) to require the filing of a PMA. In addition, these manufacturers are not required to submit a PMA until 30 months after the final promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later (See 501(f)(2)(B)). FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA.

ODE did not publish any proposed or final rules under this provision in FY 08.