# OFFICE OF DEVICE EVALUATION

# ANNUAL PERFORMANCE REPORT

## FISCAL YEAR 2009


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 09 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
Cathy Hobbs, Editor
MaryAnn Gornick, Production Specialist

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# Key Performance Indices

Here are the major submissions[1] received in ODE from FY 99 to FY 09. 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 09 (known as "the decision cohort").

## Major Submissions Received

As shown in Table 1, during FY 09, ODE received 9,655 major submissions, up from 9,601 in FY 08. This increase is primarily due to an increase in the total number of 510(k)s received.

Of the 20 original PMAs and 11 panel track supplements received in FY 09, 4 were granted expedited status. In FY 09, 11 of the 20 (55%) original PMAs were submitted as modular PMAs as compared to 13 (50%) modular PMAs submitted in FY 08.

Of the 1,394 PMA supplements (all types) received in ODE in FY 09, 247 were categorized as 180-day PMA supplements, down from 282 in FY 08. The number of fee paying 180-day supplements, remains fairly stable between FY 09 (125) compared to FY 08 (142).

A total of 275 requests were received and processed for real-time PMA supplements in FY 09. Of those submissions, 249 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a videoconference.

Of the remaining PMA supplement types, 11 were Panel-Track, 56 were Special, and 137 were 135-day Manufacturing Supplements, and for 30-day manufacturing change notices, there were 668 received.

Of the 3,597 510(k)s received in ODE FY 09, 2,795 were submitted as traditional 510(k)s, 134 were submitted as abbreviated 510(k)s and the remaining 668 were Special 510(k)s.

No 510(k)s were granted expedited status in FY 09.

A 513(g) is a request for information regarding FDA regulatory requirements applicable to a device. Ninety-eight were received in ODE in FY 09.

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

ODE received approximately the same number of original IDEs and IDE supplements in 2009 as in FY 08. In FY 09, ODE received and processed 222 original IDEs and 4,281 IDE supplements as compared to 216 original IDEs and 4,409 IDE supplements in FY 08.

In FY 09, the number of original HDEs received was 3, the same as in FY 08. The number of HDE supplements received remained the same (40) in FY 09 as in FY 08.

**Table 1. Major Submissions Received**
**FY 99 – FY 09**

| TYPE OF SUBMISSION | 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 | 2009 ODE Only |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Original PMAs | 64 | 67 | 71 | 49 | 54 | 37 | 43 | 25 | 31 | 26 | 20 |
| PMA Supplements | 557 | 546 | 641 | 645 | 666 | 565 | 712 | 1,113 | 1,087 | 1,448 | 1,394 |
| Original IDEs | 304 | 311 | 283 | 312 | 242 | 222 | 226 | 251 | 211 | 216 | 222 |
| IDE Supplements | 4,127 | 4,388 | 4,810 | 4,722 | 4,415 | 4,297 | 4,264 | 4,485 | 4,345 | 4,409 | 4,281 |
| 510(k)s | 4,458 | 4,202 | 4,248 | 4,320 | 4,247 | 3,107 | 3,130 | 3,240 | 3,192 | 3,363 | 3,597 |
| Original HDE | 12 | 11 | 5 | 5 | 10 | 9 | 4 | 4 | 6 | 3 | 3 |
| HDE Supplements | 4 | 10 | 16 | 16 | 29 | 28 | 24 | 53 | 23 | 40 | 40 |
| 513(g)s | 43 | 59 | 82 | 104 | 156 | 239 | 287 | 244 | 381 | 96 | 98 |
| **Total** | **9,569** | **9,594** | **10,156** | **10,192** | **9,819** | **8,504** | **8,690** | **9,415** | **9,276** | **9,601** | **9,655** |

## ODE Review Performance

### - Premarket Approval Applications (PMAs)

The figures below provide the ODE review performance for PMAs filed in FY 04 to FY 08. The data for FY 09 was not included because a significant number of PMA submissions received in FY 09 are still under review and a final decision has not been issued.

As shown in Figure 1, the average total FDA review time for original PMAs and panel track supplements has decreased from FY 06 to FY 08.

As shown in Figure 2, the trend of a decrease in total FDA time has been accompanied by a decrease in total elapsed time.

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

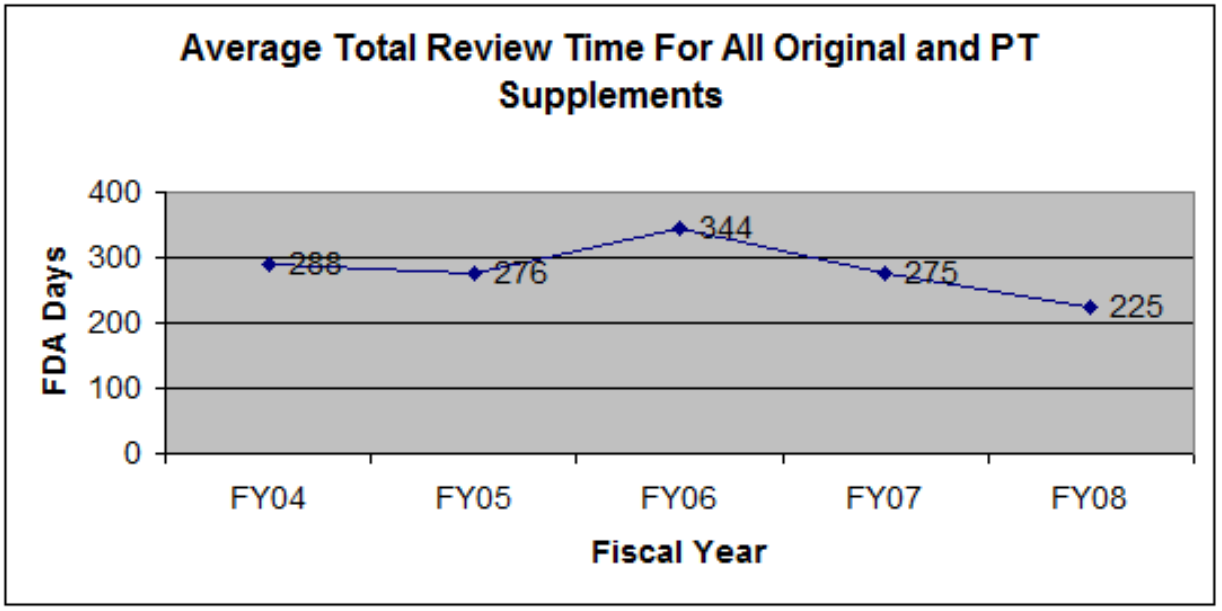
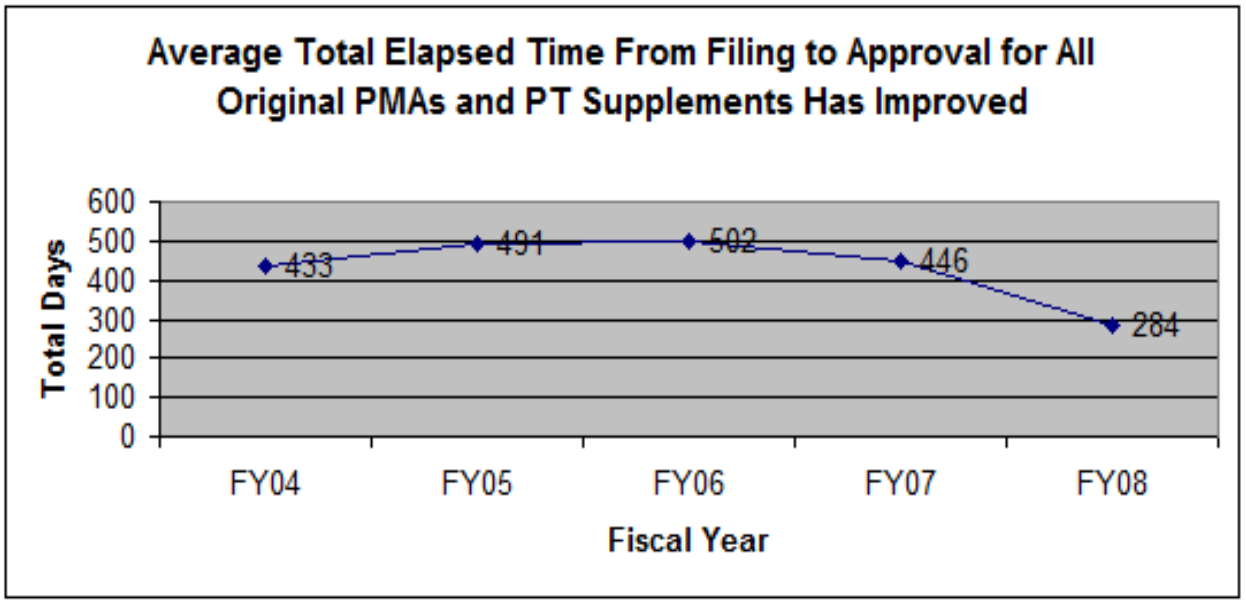
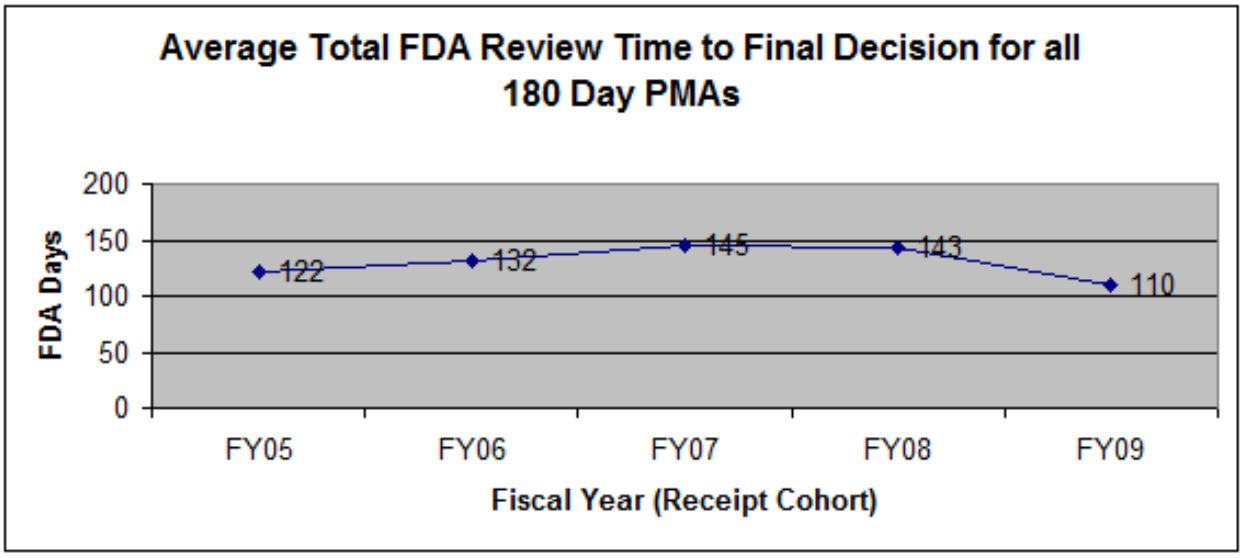



**Figure 2**: Average Total Elapsed Days from Filing to Approval (excluding withdrawals) for All Original and Panel Track PMA Supplements



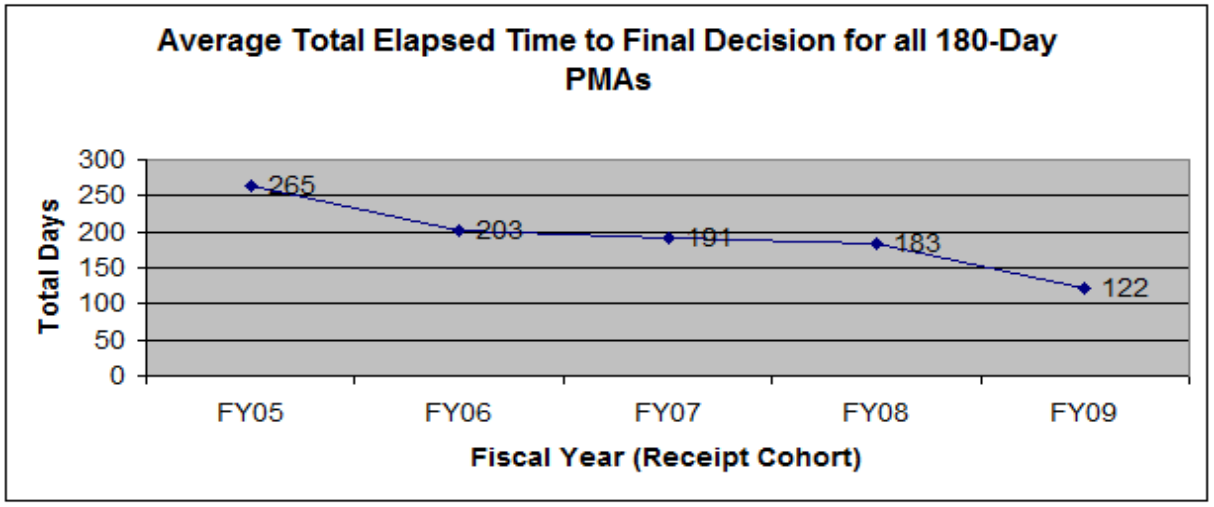
As shown in Figure 3, the average ODE review time from receipt to final decision, one that closes a file (i.e., approvals and other final decisions such as withdrawals and conversions) for 180-day PMA supplements is relatively flat. For the FY 09 receipt cohort, the average ODE review time was 110 days, down from 143 days in FY 08.

**Figure 3**: Average Total FDA Review Time to Final Decision for all 180-day PMAs



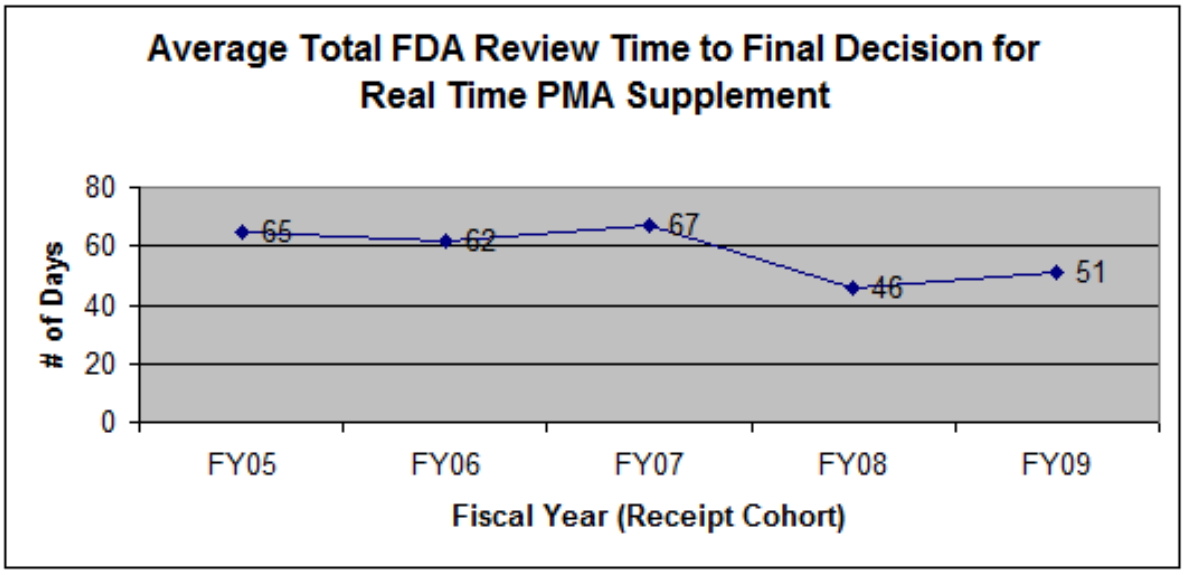

There has been an improvement in the average total elapsed time for 180-day PMA supplements since FY 08. For the FY 09 receipt cohort, the total time was 122 days, down significantly from 183 days in for the FY 08 receipt cohort (see Figure 4).

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




For the years FY 05 to FY 07, 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) then up slightly to 51 in FY 09. 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 09, 276 real-time supplements were received as compared to 217 received in FY 08, an increase of 27%.

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



### - Product Development Protocols (PDPs)

No original PDPs were approved in FY 09. Two routine PDP supplements, 4 Real-Time PDP Supplements, and 17 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 09 receipt cohort (which is still incomplete) stands at 63 days, compared to 65 days for FY 08 receipts. Average total elapsed time from receipt to final decision stands at 98 days for the FY 09 receipt cohort (still incomplete), compared to 115 days for FY 08 receipts (Figure 7).

**Figure 6:** Average FDA Time From Receipt To Final Decision

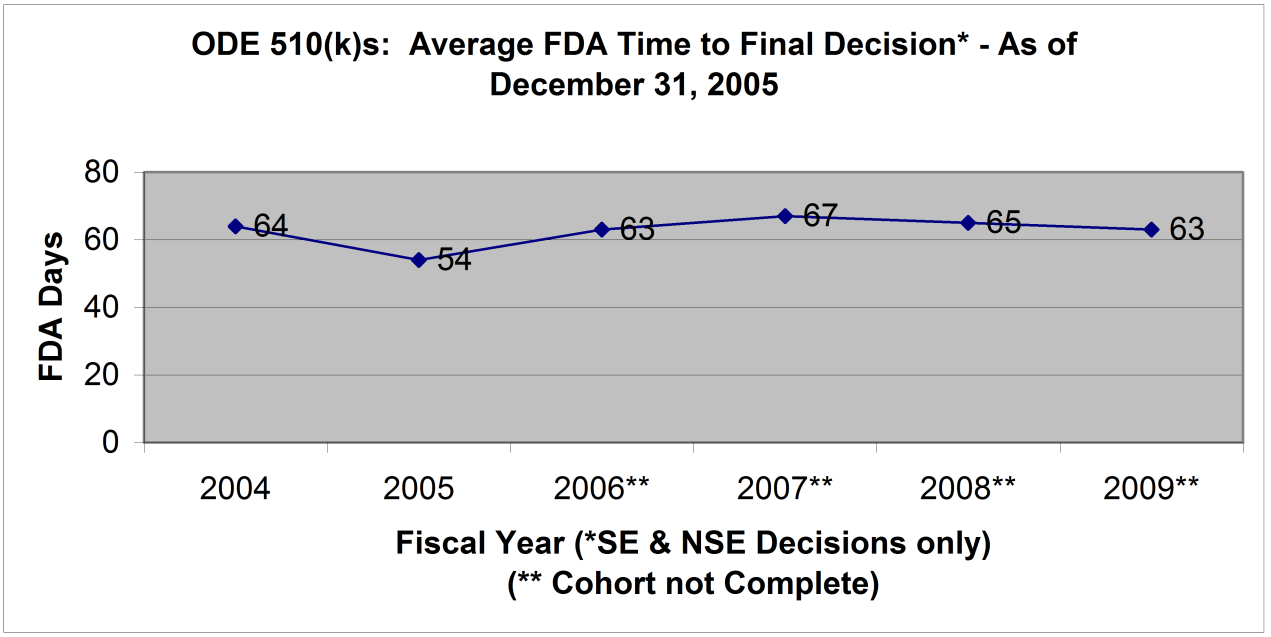
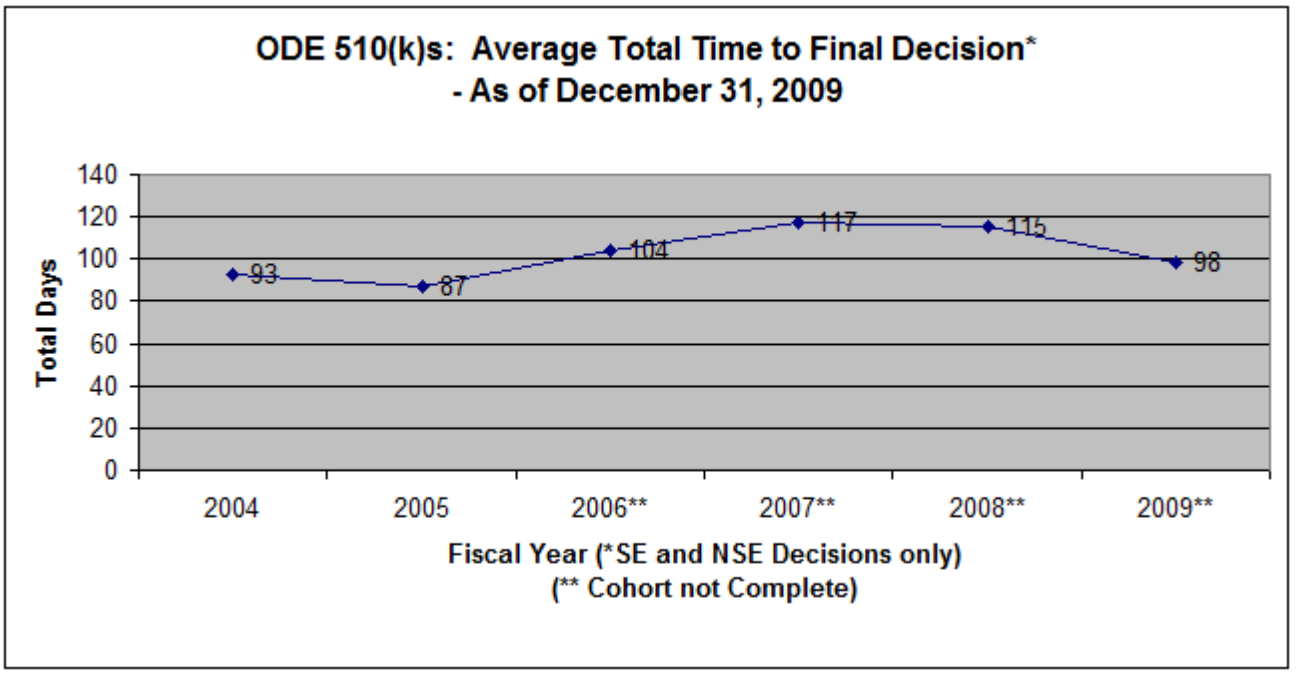


**Figure 7**: Average Total Elapsed Time From Receipt To Final Decision

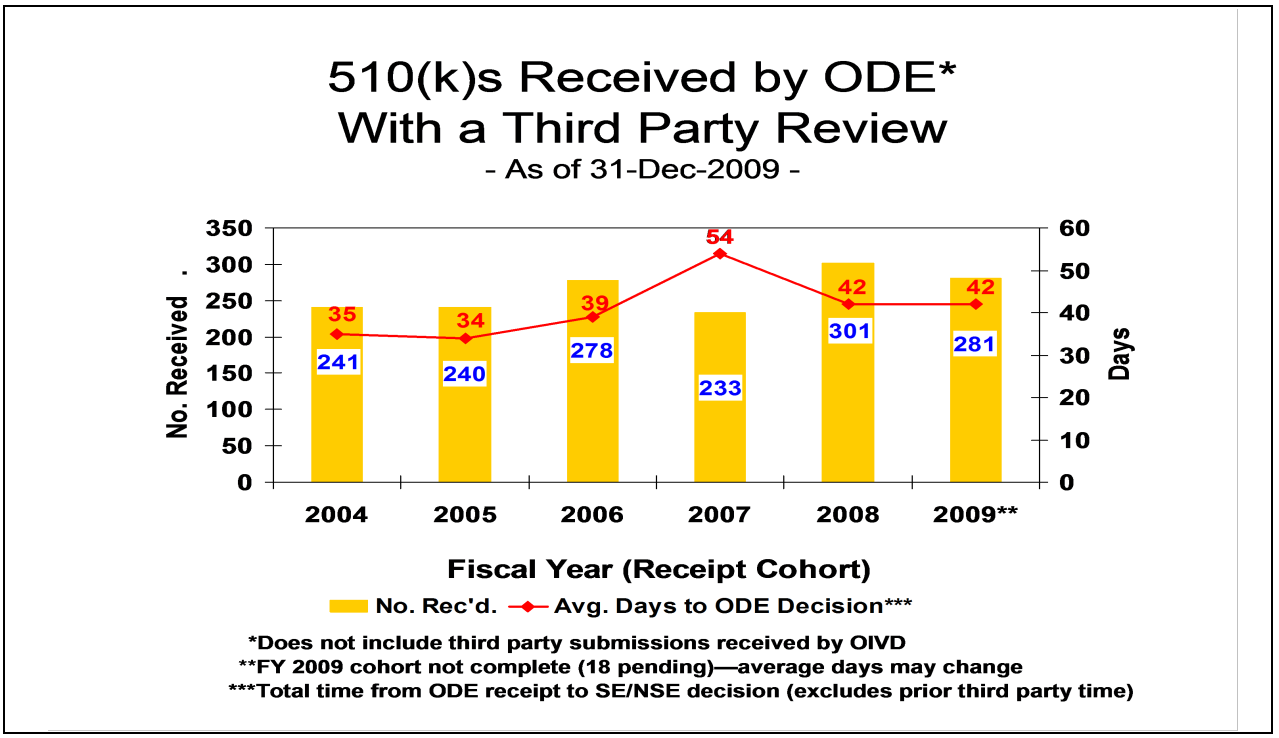



### - Third-Party Review of 510(k)s

During FY 09, ODE received 281 510(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 7% decrease from the 301 submissions received last fiscal year. ODE made final decisions on 274 "third party" 510(k)s in FY 09, a 9% decrease from the 300 final decisions in FY 08. 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 09, with 18 submissions still pending as of December 31, 2009.

Information on the 510(k) Accredited Persons Program is available on the Center's third party review web page.

**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 09. All were still under review at the end of FY 09. Two HDEs were approved in FY 09.

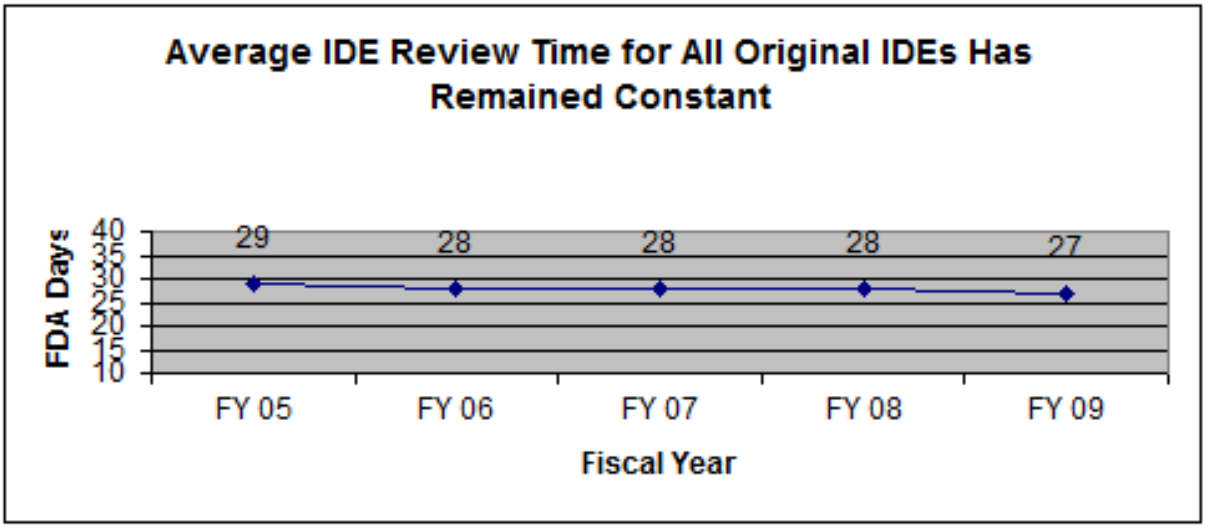
### - Investigational Device Exemptions (IDE) Applications

In FY 09, ODE received 222 original IDEs. There were 221 decisions made on original IDEs. Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 09. The average review time was 27 days.

### - Investigational Device Exemptions (IDEs)

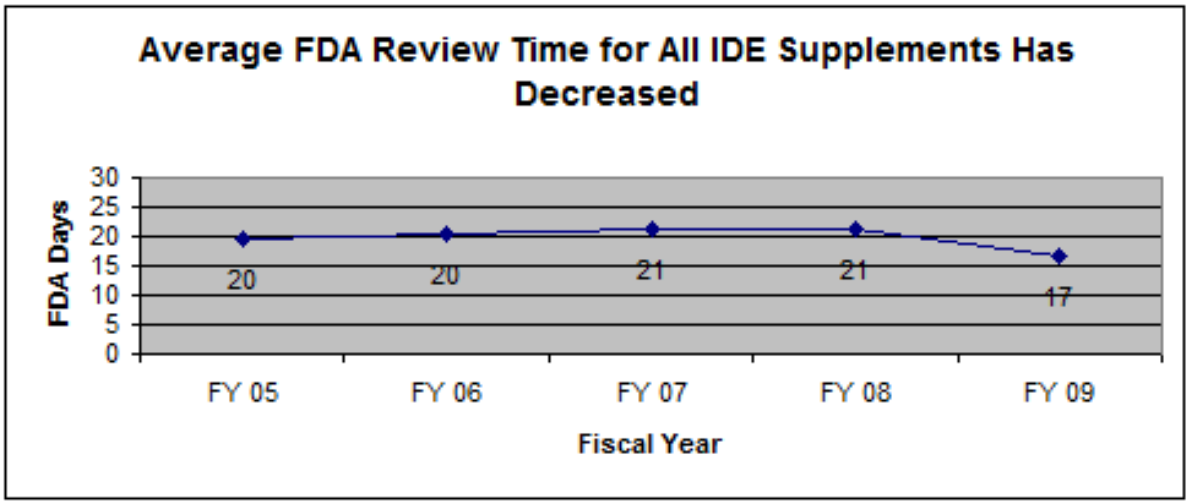
Of the original IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle was 56% in FY 09. This represents a slight decrease from the FY 08 performance level of 57%. This may represent an increasing complexity of submissions, and increasing number of combination product submissions.

**Figure 9:** Average FDA Review Time for Original IDEs




In FY 09, 99% of the IDE supplements received were reviewed within the 30-day statutory timeframe. The average review time for IDE supplements decreased to 17 days.

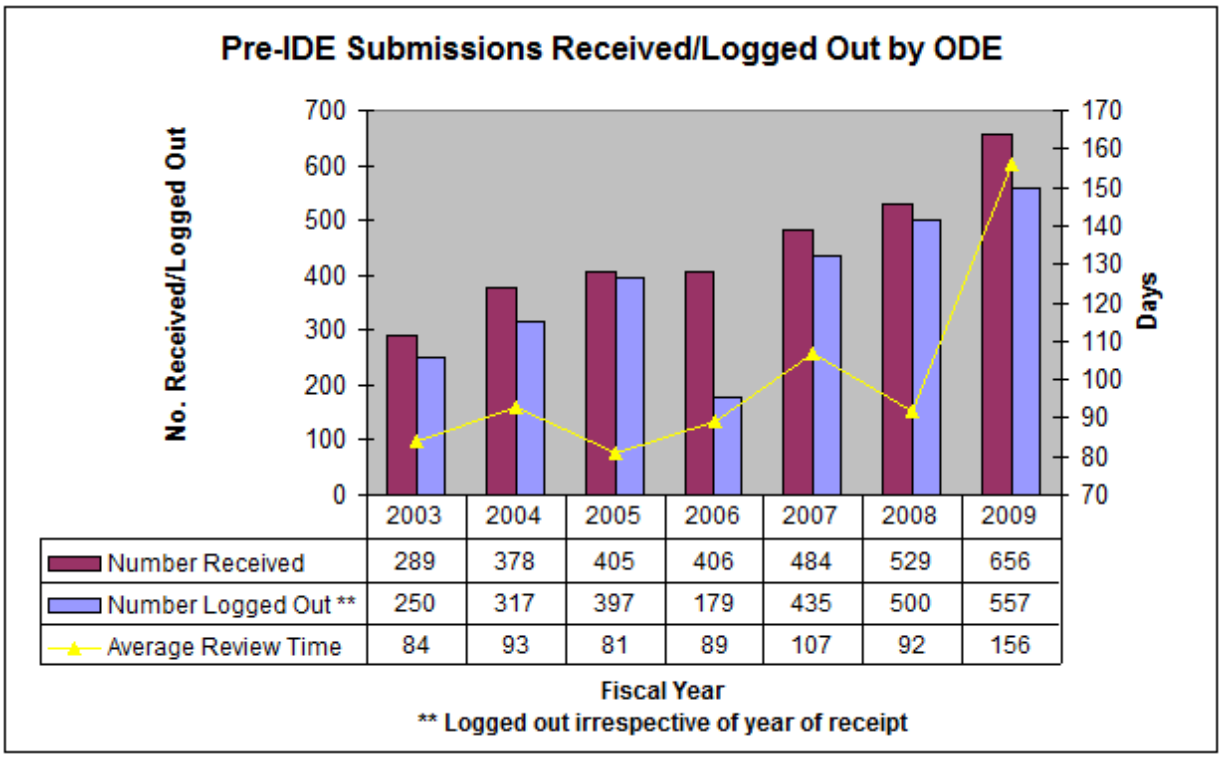
**Figure 10**: Average Total FDA Review Time for All IDE Supplements




### - Pre-IDE Submissions

During FY 09, ODE reviewed 656 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 Received/Logged Out by ODE




## Performance on MDUFMA Goals

FDA provides regular updates on MDUFMA performance and these reports are available at the following website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109210.htm. 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.

## 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 were three de novo requests approved by ODE in FY 09.

## 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 09.