United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Commerce, House of Representatives

October 1995

# MEDICAL DEVICES

# FDA Review Time

GAO/PEMD-96-2

GAO

**United States**
**General Accounting Office**
**Washington, D.C. 20548**

**Program Evaluation and**
**Methodology Division**

B-261822

October 30, 1995

The Honorable Joe Barton
Chairman, Subcommittee on Oversight
and Investigations
Committee on Commerce
House of Representatives

Dear Mr. Chairman:

As you know, the Food and Drug Administration (FDA) regulates the manufacture and marketing of medical devices in this country. Some criticism has been expressed that FDA's review of medical devices is excessively lengthy and can impose inordinate delays upon the introduction of new devices into the market. At your request, we examined FDA's review time and how it has changed from fiscal year 1989 to May 18, 1995. We analyzed data provided by FDA on applications to market new devices or to begin clinical research on unapproved devices. We briefed your staff on the findings of our preliminary analysis in June 1995, and we have since requested and received comments on these findings from FDA.

# Background

## Types of FDA Reviews

Medical devices can range in complexity from a simple tongue depressor to a sophisticated CT (computed tomography) x-ray system. Most of the devices reach the market through FDA's premarket notification (or 510(k)) review process.[1] Under its 510(k) authority, FDA may determine that a device is substantially equivalent to a device already on the market and therefore not likely to pose a significant increase in risk to public safety. When evaluating 510(k) applications, FDA makes a determination regarding whether the new device is as safe and effective as a legally marketed predicate device. Performance data (bench, animal, or clinical) are required in most 510(k) applications, but clinical data are needed in less than 10 percent of applications.[2]

[1]Premarket notification is commonly called 510(k) in reference to section 510(k) of the Federal Food, Drug, and Cosmetic Act.

[2]510(k) applications must contain a description of the device, description of the predicate device with which it is substantially equivalent, proposed labeling, intended use, and directions for use.

An alternative mode of entry into the market is through the premarket approval (PMA) process. PMA review is more stringent and typically longer than 510(k) review. For PMAs, FDA determines the safety and effectiveness of the device based on information provided by the applicant. Nonclinical data are included as appropriate.[3] However the answers to the fundamental questions of safety and effectiveness are determined from data derived from clinical trials.[4]

FDA also regulates research conducted to determine the safety and effectiveness of unapproved devices. FDA approval is required only for "significant risk" devices.[5] Applicants submit applications for such devices to obtain an investigational device exemption (IDE) from regulatory requirements and approval to conduct clinical research. For an IDE, unlike PMAs and 510(k)s, it is the proposed clinical study that is being assessed—not just the device.

## Modification of Cleared or Approved Applications for Devices

Modifications of medical devices, including any expansion of their labeled uses, are also subject to FDA regulation. Applications to modify a device that entered the market through a PMA are generally linked to the original PMA application and are called PMA supplements. In contrast, modifications to a 510(k) device are submitted as new 510(k) applications. References may be made to previous 510(k) applications.

## Measuring the Length of FDA Reviews

FDA uses several measures of duration to report the amount of time spent reviewing applications. In this letter, we use only three of those measures. The first is simply the time that elapses between FDA's receipt of an application and its final decision on it (total elapsed time). The second measure is the time that FDA has the application under its review process (FDA time). This includes both the time the application is under active review and the time it is in the FDA review queue. The amount of time FDA's

[3]Nonclinical data may include microbiological, toxicological, immunological, biocompatibility, shelf life, animal, engineering (stress, wear, fatigue) data.

[4]For PMAs, information on the device and its components, the manufacturing process, labeling that includes its intended use and directions for use as well as clinical and nonclinical studies are included in the submission.

[5]A "significant risk" device is one that is intended as an implant, used in supporting or sustaining human life, of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health, and presents a potential for serious risks to the health, safety, or welfare of a subject (21 C.F.R. 812.3(m)). For a nonsignificant risk device only Institutional Review Board approval is required.

review process has been suspended, waiting for additional information from the applicant, is our third measure (non-FDA time).

Our measures of review time are not intended to be used to assess the agency's compliance with time limits for review established under the Federal Food, Drug, and Cosmetic Act (the act).[6] The time limits for PMA, 510(k), and IDE applications are 180, 90, and 30 days, respectively. FDA regulations allow for both the suspension and resetting of the FDA review clock under certain circumstances.[7]

How review time is calculated differs for 510(k)s and PMAs. If a PMA application is incomplete, depending on the extent of the deficiencies, FDA may place the application on hold and request further information. When the application is placed on hold, the FDA review clock is stopped until the agency receives the additional information. With minor deficiencies, the FDA review clock resumes running upon receipt of the information. With major deficiencies, FDA resets the FDA clock to zero upon receipt of the information. In this situation, all previously accrued FDA time is disregarded. (The resetting of the FDA clock can also be triggered by the applicant's submission of unsolicited supplementary information.) The amount of time that accrues while the agency is waiting for the additional information constitutes non-FDA time. For 510(k)s, the FDA clock is reset upon receipt of a response to either major or minor deficiencies.

For this report, we define FDA time as the total amount of time that the application is under FDA's review process. That is, our measure of FDA time does not include the time that elapses during any suspension, but does include time that elapsed before the resetting of the FDA clock. The total amount of time that accrues while the agency is waiting for additional information constitutes non-FDA time. (The sum of FDA and non-FDA time is our first measure of duration—total elapsed time.)

## Classes and Tiers of Medical Devices

The act establishes three classes of medical devices, each with an increasing level of regulation to ensure safety and effectiveness. The least regulated, class I devices, are subject to compliance with general controls. Approximately 40 percent of the different types of medical devices fall into

[6]FDA, as indicated by its own reports, has sometimes failed to meet these time limits. For example, in 1994, only 45 percent of its 510(k) reviews were completed within 90 days.

[7]See 21 C.F.R. 814.37 and 814.40 for PMAs and 21 C.F.R. 807.87(k) for 510(k)s. The review of IDE applications is not subject to the resetting of the FDA review clock; investigations for which IDE applications are submitted may begin within 30 days of application receipt if FDA fails to act (see 21 C.F.R. 812.30).

class I. At the other extreme is premarket approval for class III devices, which constitute about 12 percent of the different types of medical devices. Of the remainder, a little over 40 percent are class II devices, and about 3 percent are as yet unclassified.[8]

In May 1994, FDA implemented a three-tier system to manage its review workload. Classified medical devices are assigned to one of three tiers according to an assessment of the risk posed by the device and its complexity. Tier 3 devices are considered the riskiest and require intensive review of the science (including clinical data) and labeling. Review of the least risky devices, tier 1, entails a "focused labeling review" of the intended use. In addition to the three tiers is a group of class I devices that pose little or no risk and were exempted from the premarket notification (510(k)) requirements of the act.[9]

Under the class and tier systems, approximately 20 percent of the different types of medical devices are exempted from premarket notification.[10] A little over half of all the different types of medical devices are classified as tier 2 devices. Tiers 1 and 3 constitute 14 and 12 percent of the different types of medical devices, respectively.[11]

## Results in Brief

Review times and trends for medical device applications varied widely over the period beginning October 1, 1988, through May 18, 1995. For 510(k) applications submitted in a given fiscal year, the review time remained stable over the 3 years from 1989 to 1991, then rose sharply in 1992 and 1993 before dropping in 1994. For 1994, the median was 152 days. The mean time to a decision was higher, at 166 days, and this mean will

[8]General controls for class I devices include registering device manufacturing facilities, providing FDA with regularly updated lists of marketed devices, complying with good manufacturing practices (as established by FDA), and maintaining records and filing reports of device-related injuries and malfunctions. The Safe Medical Devices Act of 1990 revised the requirements for class II devices, subjecting them to both general and special controls. Special controls include performance standards, postmarket surveillance, patient registries, and other controls as deemed necessary. Class III devices require clinical data to demonstrate safety and effectiveness.

[9]These exempted devices remain subject to other requirements of the act. (See footnote 8.)

[10]Our 20-percent figure was determined by obtaining a frequency distribution by tiers of the information FDA provided.

[11]Medical devices have both a class and a tier designation associated with them. Although tiers were not implemented until 1994, for this report, we have applied the tier classification retrospectively to our data to examine review time.

continue to grow as the remaining open cases (13 percent) are completed.[12]

The review time trend for original PMAs was less clear, in part because a large proportion of the applications have yet to be completed. Open cases ranged from 4 percent of 1989 to 81 percent of 1994 applications. More than 40 percent of the 1992 and 1993 applications were still open. The median for 1994 was undetermined as less than 50 percent of the applications were completed. For 1993, the median review time was 804 days.

The review time for PMA supplements, however, fluctuated slightly in the first 3 years, before peaking in 1992 and declining thereafter. The median for 1994 was 193 days as opposed to a mean of 162 days. Again, the mean will increase when the remaining open cases (21 percent) are closed.

Not all the time that elapsed between an application's submission and its final determination was spent under FDA's review process. In many instances, FDA had to wait for additional information. This non-FDA time comprised about one-fifth of total elapsed review time for 510(k)s. It constituted about one-fourth of total elapsed review time for original PMAs and one-third for PMA supplements.

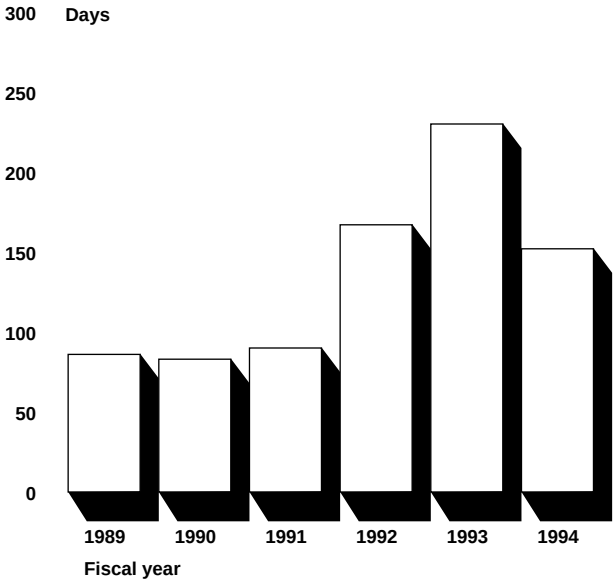
# Principal Findings

## Premarket Notifications (510(k)s)

From 1989 through 1991, the median time between the submission of a 510(k) application and FDA's decision (total elapsed time) was relatively stable at about 80 to 90 days. The next 2 years showed a sharp increase that peaked at 230 days in 1993. Although the median review time showed a decline in 1994 (152 days), it remained higher than that of the initial 3 years. (See figure 1.)

[12]We report our findings here in terms of two measures: median review time (that is, how long the case representing the midpoint in review time took to complete review), and mean review time (the average time to complete review). The median includes all cases (so long as at least one-half of cases submitted in a given year were completed). By necessity, the mean includes only those cases that have been completed. Both measures are reported by year of submission, not year of decision. For greater detail on the two measures and the implications of their use, see pp. 12-14.

**Figure 1: Median Review Time for 510(k)s by Fiscal Year[a]**




[a]The median includes open cases.

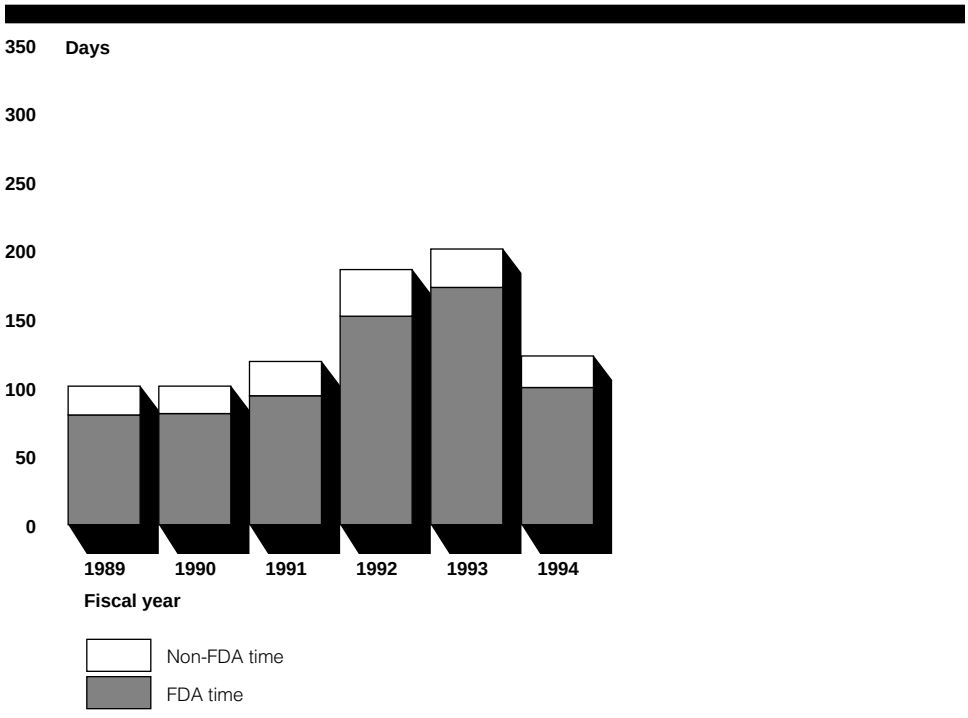
Similarly, the mean also indicated a peak in review time in 1993 and a subsequent decline. The mean review time increased from 124 days in 1989 to 269 days in 1993. In 1994, the mean dropped to 166 days; however, this mean will increase as the 13 percent of the applications that remained open are closed. (See table II.1.)

Of all the applications submitted to FDA to market new devices during the period under review, a little over 90 percent were for 510(k)s. Between 1989 and 1994, the number of 510(k) applications remained relatively stable, ranging from a high of 7,023 in 1989 to a low of 5,774 in 1991. In 1994, 6,446 applications were submitted.

Of the 40,950 510(k) applications submitted during the period under review, approximately 73 percent were determined to be substantially equivalent. (That is, the device is equivalent to a predicate device already on the market and thus is cleared for marketing.) Only 2 percent were found to be nonequivalent, and 6 percent remained open. Other decisions—including applications for which a 510(k) was not required and those that were withdrawn by the applicant—account for the rest. (See appendix I for details on other FDA decision categories.)

For applications determined to be substantially equivalent, non-FDA time—the amount of time FDA placed the application on hold while waiting for additional information—comprised almost 20 percent of the total elapsed time. (See table II.7.) Figure 2 displays FDA and non-FDA time to determine equivalency for 510(k) applications.

**Figure 2: Mean Time to Determine Equivalency for 510(k)s by FDA and Non-FDA Time[a]**

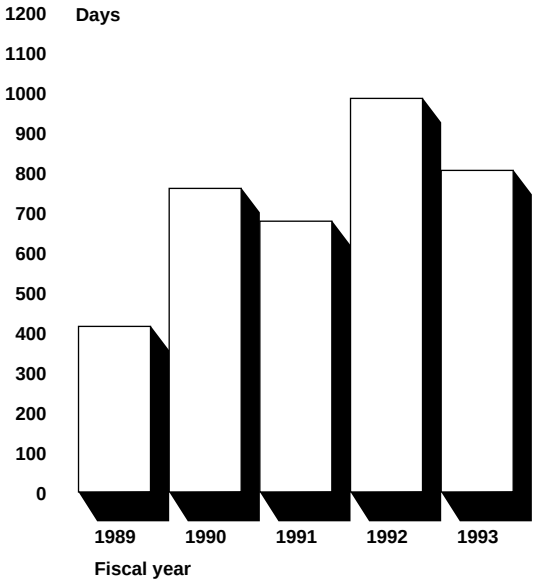



[a]Open cases are not included. The means shown will increase when open cases are completed.

## Premarket Approvals (PMAs)

The trends in review time differed for original PMAs and PMA supplements. There was no clear trend in review times for original PMA applications using either medians or means since a large proportion of the applications had yet to be completed. The median time between the submission of an application and FDA's decision (total elapsed time) fluctuated from a low of 414 days in 1989 to a high of 984 days in 1992. Less than 50 percent of the applications submitted in 1994 were completed; thus, the median review time was undetermined. (See figure 3.)

**Figure 3: Median Review Time for Original PMAs by Fiscal Year[a]**

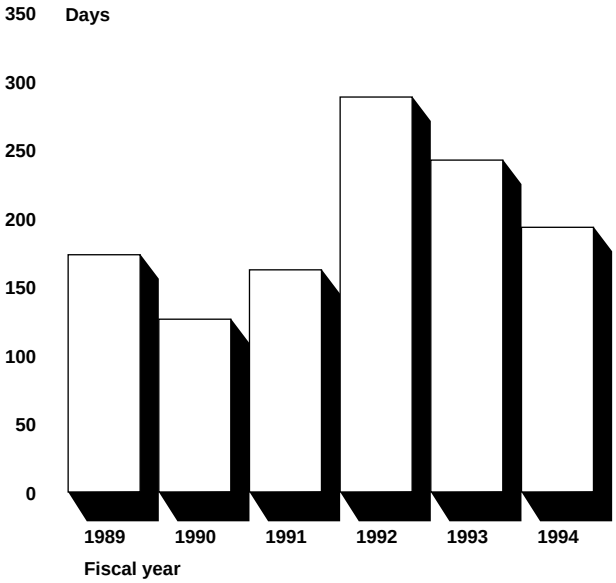



[a]The median includes open cases. Data for 1994 are omitted because less than 50 percent of the applications submitted had been completed.

Except for 1989, the means were lower than the medians because of the large number of open cases. The percent of applications that remained open increased from 4 percent in 1989 to 81 percent in 1994. The means, then, represent the time to a decision for applications that were less time-consuming. When the open cases are completed, lengthy review times will cause an increase in the means. (See table III.1.)

For PMA supplements, the median time ranged from 126 days to 173 days in the first 3 years, then jumped to 288 days in 1992. In 1993 and 1994, the median declined to 242 and 193 days, respectively. (See figure 4.)

**Figure 4: Median Review Time for PMA Supplements by Fiscal Year[a]**




[a]The median includes open cases.

This trend was reflected in the mean review time that peaked at 336 days in 1992. Although the mean dropped to 162 days in 1994, this is expected to increase because 21 percent of the applications had not been completed at the time of our study. (See table III.7.)

Applications for original PMAs made up less than 1 percent of all applications submitted to FDA to market new devices in the period we reviewed. PMA supplements comprised about 8 percent of the applications.

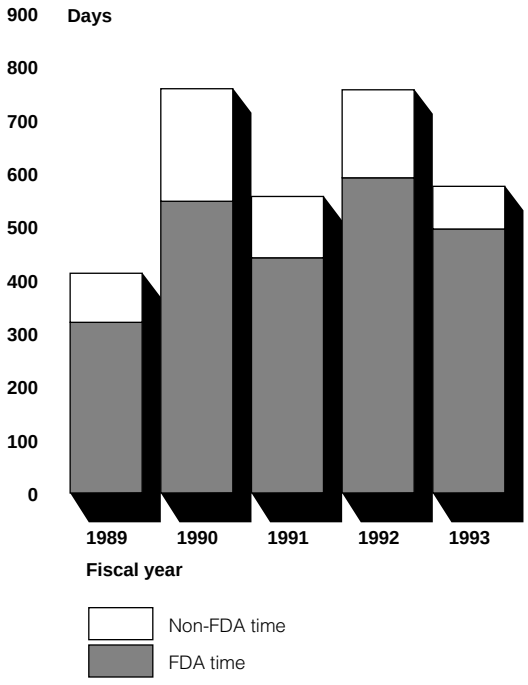
The number of applications submitted for PMA review declined each year. In 1989, applications for original PMAs numbered 84. By 1994, they were down to 43. Similarly, PMA supplements decreased from 804 in 1989 to 372 in 1994. (See tables III.1 and III.7.)

Of the 401 applications submitted for original PMAs, 33 percent were approved, 26 were withdrawn, and nearly a third remained open. The remainder (about 9 percent) fell into a miscellaneous category. (See appendix I.) A much higher percentage of the 3,640 PMA supplements (78 percent) were approved in this same period, and fewer PMA supplements were withdrawn (12 percent). About 9 percent of the

applications remained open, and 2 percent fell into the miscellaneous category.

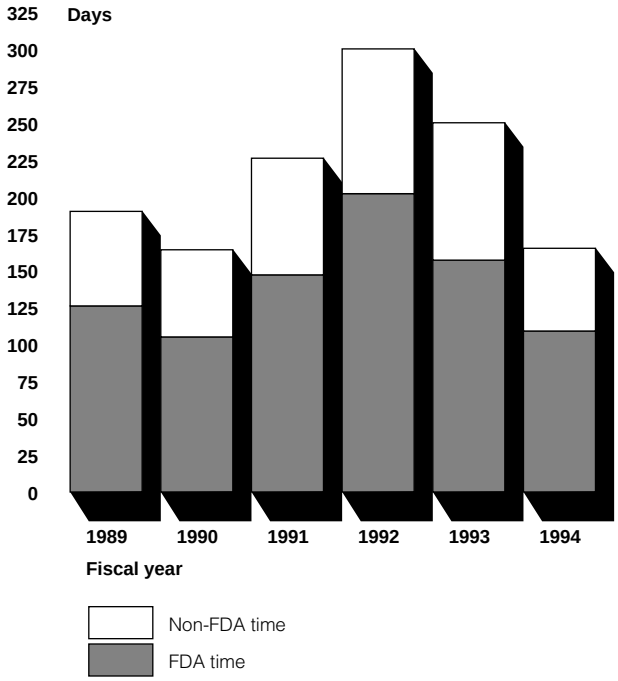
For PMA reviews that resulted in approval, non-FDA time constituted approximately one-fourth of the total elapsed time for original PMAs and about one-third for PMA supplements. The mean FDA time for original PMAs ranged from 155 days in 1994 to 591 days in 1992. Non-FDA times for those years were 34 days in 1994 and 165 days in 1992. For PMA supplements, FDA review times were lower, ranging from a low of 105 days (1990) to a high of 202 days (1992). Non-FDA time for those years were 59 days (1990) and 98 days (1992), respectively. (See table III.13.) Figures 5 and 6 display the proportion of FDA and non-FDA time for the subset of PMAs that were approved.

**Figure 5: Mean Time to an Approval for Original PMAs by FDA and Non-FDA Time[a]**




[a]Data for 1994 are omitted because less than 50 percent of the applications submitted had been completed. Open cases are not included. The mean times shown will increase when open cases are closed.

**Figure 6: Mean Time to an Approval for PMA Supplements by FDA and Non-FDA Time[a]**




[a]Open cases are not included. The mean times shown will increase when open cases are closed.

## Investigational Device Exemptions (IDEs)

For IDEs, the mean review time between submission and FDA action was 30 days, and it has not changed substantially over time. Unlike 510(k)s and PMAs, IDEs are "deemed approved" if FDA does not act within 30 days. Of the 1,478 original IDE submissions from fiscal year 1989 to 1995, 33 percent were initially approved (488) and 62 percent were denied or withdrawn (909). The number of IDE submissions each year ranged from a high of 264 in 1990 to a low of 171 in 1994. (See table IV.1.)

# Objectives, Scope, and Methodology

Our objective was to address the following general question: How has the time that 510(k), PMA, and IDE applications spend under FDA review changed between fiscal year 1989 and the present? To answer that question, we also looked at a subset of applications that were approved, distinguishing the portion of time spent in FDA's review process (FDA time) from that spent waiting for additional information (non-FDA time). For applications that were approved, we present the average number of

amendments that were subsequently added to the initial application as well as the average number of times FDA requested additional information from the applicant. (Both of these activities affect FDA's review time.)

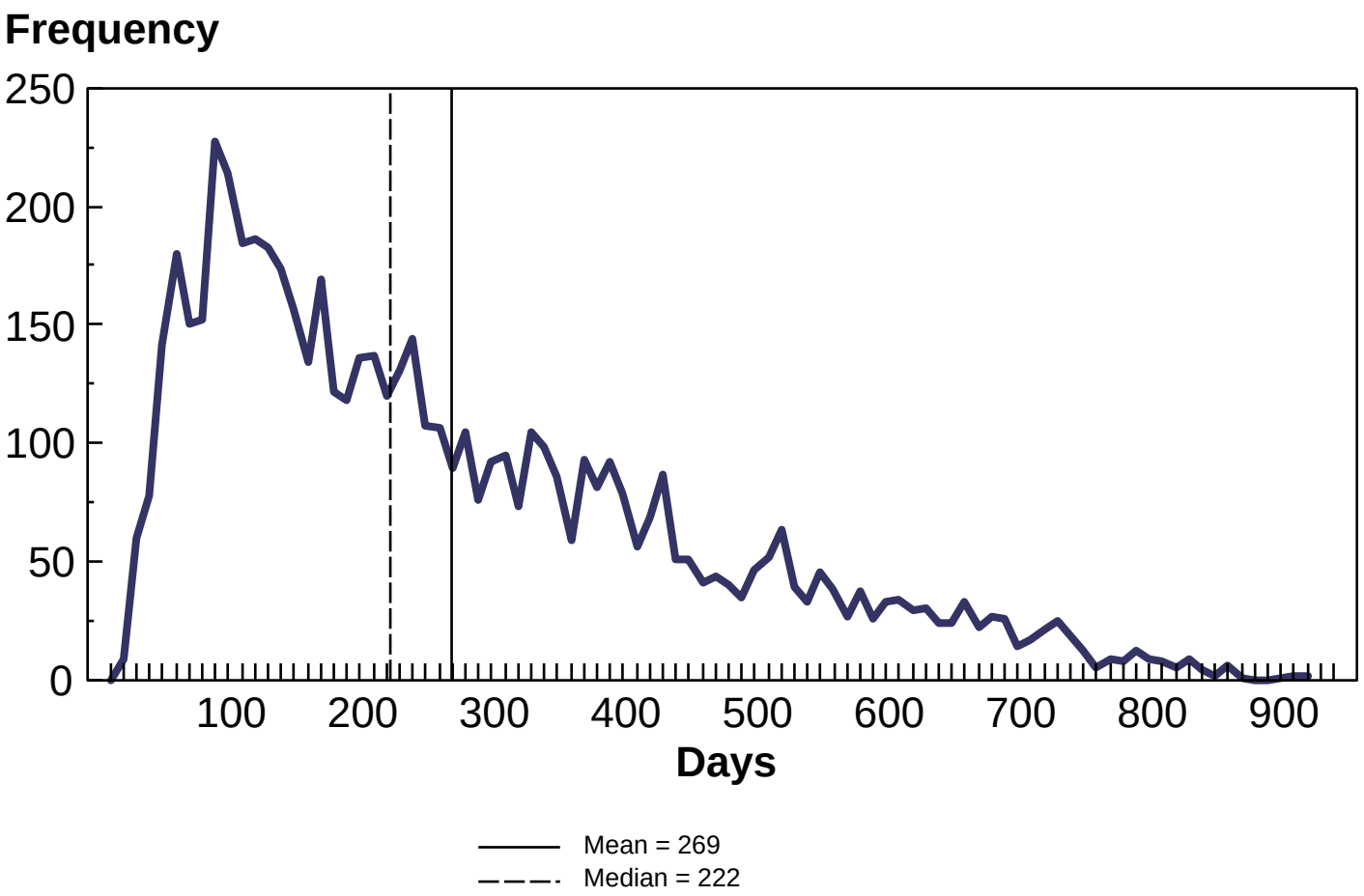
We used both the median and mean to characterize review time. We use the median for two reasons. First, a large proportion of the applications have yet to be completed. Since the median is the midpoint when all review times are arranged in consecutive order, its value can be determined even when some applications requiring lengthy review remain open. In contrast, the mean can only be determined from completed applications. (In this case, applications that have been completed by May 18, 1995.) In addition, the mean will increase as applications with lengthy reviews are completed.

To illustrate, for applications submitted in 1993, the mean time to a decision was 269 days for 510(k) applications that have been closed. However, 3 percent of the applications have yet to be decided. If these lengthy reviews were arbitrarily closed at May 18, 1995 (the cutoff date for our data collection), the mean would increase to 285 days. In contrast, the median review time (230 days) would remain the same regardless of when these open applications were completed.

The second reason for using the median is that the distributions of review time for 510(k), original PMA, and PMA supplement applications are not symmetric, that is, having about the same number of applications requiring short reviews as lengthy reviews. The median is less sensitive to extreme values than the mean. As a result, the review time of a single application requiring an extremely lengthy review would have considerably more effect on the mean than the median. Figure 7 shows the distribution for 510(k)s submitted in 1993, the most recent year in which at least 95 percent of all 510(k) applications had been completed. The distribution is skewed with a mean review time of 269 days and a median review time of 222 days for all completed applications.[13]

[13]See appendix III for the distribution of review time for original PMAs and PMA supplements.

**Figure 7: Time to a Decision for 510(k)s Submitted in Fiscal Year 1993[a]**




[a]The number of cases in this frequency distribution is 6,101. (The one application with over 1,500 days was dropped from this figure.) As of May 18, 1995, 3 percent of applications submitted had not been completed and were not included. When these applications are closed, the mean will increase.

To provide additional information, we report on the mean review times as well as the median. The discrepancy between the two measures gives some indication of the distribution of review time. When the mean is larger than the median, as in the case of the 510(k)s above, it indicates that a group of applications required lengthy reviews.[14] Another reason we report

[14]For original PMAs, the mean is smaller than the median. The smaller mean results from the large number of open cases. Applications requiring lengthy reviews have yet to be completed. As these reviews are completed, the mean will increase.

the means is that, until recently, FDA reported review time in terms of means.

In appendix I, we provide the categories we used to designate the different FDA decisions and how our categories correspond to those used by FDA. Detailed responses to our study objective are found in tabular form in appendixes II, III, and IV for 510(k)s, PMAs, and IDEs, respectively.

We report our findings according to the fiscal year in which the applications were submitted to FDA. By contrast, FDA commonly reports review time according to the fiscal year in which the review was completed.[15] Although both approaches measure review time, their resultant statistics can vary substantially. For example, several complex applications involving lengthy 2-year reviews submitted in 1989 would increase the average review time for fiscal year 1989 in our statistics and for fiscal year 1991 in FDA's statistics. Consequently, the trend for review time based on date-of-submission cohorts can differ from the trend based on date-of-decision cohorts. (See appendix V for a comparison of mean review time based on the two methods.)

The two methods provide different information and are useful for different purposes. Using the date-of-decision cohort is useful when examining productivity and the management of resources. This method takes into consideration the actual number of applications reviewed in a given year including all backlogs from previous years. Alternatively, using the date-of-submission cohort is useful when examining the impact of a change in FDA review policy, which quite often only affects those applications submitted after its implementation.[16] To minimize the effect of different policies on review time within a cohort, we used the date-of-submission method.

We conducted our work in accordance with generally accepted government auditing standards between May and June 1995.

## Agency Comments

Officials from FDA reviewed a draft of this report and provided written comments, which are reproduced in appendix VI. Their technical

[15]Using date-of-decision cohorts obviates the problem of open cases. Both means and medians can be easily determined.

[16]FDA has indicated that it plans to include statistics on review time based on the year of submission in its reports.

comments, which have been incorporated into the text where appropriate, have not been reprinted in the appendix.

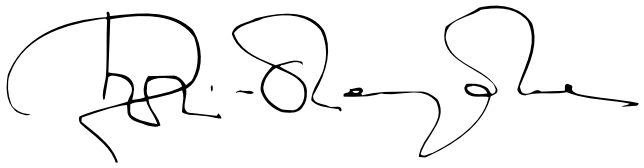
FDA believed that the report misrepresented the current state of the program as the draft did not acknowledge recent changes in the review process. FDA officials suggested a number of explanations for the apparent trends in the data we reported (see appendix VI). Although recent initiatives to improve the review process provide a context in which to explain the data, they were outside the scope of our work. We were not able to verify the effect these changes have actually had on review time. To the extent that these changes did affect review time, they are reflected in the review times as presented and are likely to be reflected in future review times.

The agency also believed that the draft did not reflect the recent improvements in review time. We provided additional measures of review time in order to present the review times for the more recent years. We have also included more information on the difference between the date-of-submission and date-of-decision cohorts, and we have expanded our methodological discussion in response to points FDA made on the clarity of our presentation. (Additional responses to the agency comments are included in appendix VI.)

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its date of issue. We will then send copies to other interested congressional committees, the Secretary of the Department of Health and Human Services, and the Commissioner of Food and Drugs. Copies will also be made available to others upon request.

If you or your staff have any questions about this report, please call me at (202) 512-3092. The major contributors to this report are listed in appendix VII.

Sincerely yours,



Kwai-Cheung Chan
Director of Program Evaluation
in Physical Systems Areas

# Contents

## Abbreviations

| | |
|---|---|
| CT | Computed tomography |
| DCLD | Division of Clinical Laboratory Devices |
| DCRND | Division of Cardiovascular, Respiratory and Neurological Devices |
| DGRD | Division of General and Restorative Devices |
| DOD | Division of Ophthalmic Devices |
| DRAER | Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices |
| FDA | Food and Drug Administration |
| IDE | Investigational device exemption |
| PMA | Premarket approval |

# FDA Decision Codes and GAO's Categories

FDA uses different categories to specify the type of decision for 510(k)s, PMAs, and IDEs. For our analysis, we collapsed the multiple decision codes into several categories. The correspondence between our categories and FDA's are in table I.1.

**Table I.1: Correspondence Between GAO Categories and FDA Decision Codes**

| Type of application | GAO category | FDA decision code |
|---|---|---|
| Premarket notification | Equivalent | Equivalent |
| | Nonequivalent | Nonequivalent |
| | Other | Additional information requested; applicant cannot respond within 30 days |
| | | Forwarded to drugs/biologics |
| | | Deleted/duplicate |
| | | Deleted |
| | | Drug (CDER) review required |
| | | Exempted by regulation |
| | | General purpose article |
| | | Closeout letter issued |
| | | Not actively regulated |
| | | Not a device |
| | | Not a finished product |
| | | Not a required submission |
| | | Preamendment exempt |
| | | Refuse to accept |
| | | Reconditioner/remanufacturer |
| | | Transitional device |
| | | Withdrawn by applicant |
| Premarket approval | Approved | Approved |
| | Denied | Denied |
| | Withdrawn | Withdrawn |
| | Other | Abandoned |
| | | Converted |
| | | Reclassified |
| | | Other |

(continued)

| Type of application | GAO category | FDA decision code |
|---|---|---|
| Investigational device exemption | Approved | Approved |
| | | Approved with conditions |
| | | Deemed approved and request information |
| | Denied | Disapproved |
| | | Refuse to accept |
| | Withdrawn | Deemed approved/immediate withdraw |
| | | Immediate withdrawal by FDA |
| | | Withdrawn by sponsor |
| | Other | Acknowledge incoming |
| | | Study exempt from part 812 |
| | | Inadequate incoming |
| | | Incomplete |
| | | Product jurisdiction pending |
| | | Product jurisdiction transferred |
| | | No response necessary |
| | | Nonsignificant risk device study |
| | | Other |
| | | Request for progress report |
| | | Investigation terminated/ inadequate/no final report |
| | | Telephone response |
| | | Voluntary termination requested |

# Premarket Notification (510(k)) Tables II.1 - II.12

## Review Time for Premarket Notification

The following tables present the data for premarket notifications, or 510(k)s, for fiscal years 1989 through May 18, 1995. The first set of tables (tables II.1 through II.6) presents the time to a decision—from the date the application is submitted to the date a decision is rendered.

We first present a summary table on the time to a decision by fiscal year (table II.1). The grand total for the number of applications includes open cases—that is, applications for which there had not been any decision made as of May 18, 1995. As the distribution for time to a decision is not symmetric (see figure 1 in the letter), we present the means and percentiles to characterize the distribution. (The means and percentiles do not include open cases.)

The second table is a summary of the time to a decision by class, tier, medical specialty of the device, and reviewing division (table II.2). The next four tables (II.3 through II.6) provide the details for these summary tables. The totals in these tables include only applications for which a decision has been rendered.

The class, tier, and medical specialty of some of the devices have yet to be determined and are designated with N/A. Medical specialties other than general hospital or general and plastic surgery include anesthesiology; cardiovascular; clinical chemistry; dental; ear, nose, and throat; gastroenterology/urology; hematology; immunology; microbiology; neurology; obstetrics/gynecology; ophthalmic; orthopedic; pathology; physical medicine; radiology; and clinical toxicology.

The five reviewing divisions in FDA's Center for Devices and Radiological Health are Division of Clinical Laboratory Devices (DCLD); Division of Cardiovascular, Respiratory and Neurological Devices (DCRND); Division of General and Restorative Devices (DGRD); Division of Ophthalmic Devices (DOD); and Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices (DRAER).

The second set of tables (tables II.7 through II.12) presents the mean time to determine equivalency. We provide the means for total FDA time, non-FDA time, and total elapsed time. FDA time is the total amount of time the application was under FDA review including queue time—the time to equivalency without resetting the FDA review clock. The total elapsed time, the duration between the submission of the application and FDA's decision, equals the sum of the FDA and non-FDA time.

We deleted cases that had missing values or apparent data entry errors for the values relevant to calculating FDA and non-FDA time. Therefore, the total number of applications determined to be equivalent in this group of tables differs from that in the first set. Again, we have two summary tables, followed by four tables providing time to determine equivalency by class, tier, medical specialty, and reviewing division (tables II.7 through II.12).

**Table II.1: Average Days to Decision on 510(k)s and Number of Open Cases by Fiscal Year (October 1, 1988 - May 18, 1995)**

| Fiscal year | Equivalent N | Equivalent Days | Nonequivalent N | Nonequivalent Days | Other N | Other Days | Percentile 5 | Percentile 50 | Percentile 95 | Mean | Open N | Open Days | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | 5258 | 98 | 108 | 167 | 1655 | 205 | 19 | 86 | 336 | 124 | 2 | 2188 | 7023 |
| **1990** | 4633 | 100 | 142 | 162 | 1060 | 207 | 15 | 83 | 347 | 121 | 0 | 0 | 5835 |
| **1991** | 4513 | 124 | 140 | 225 | 1110 | 263 | 18 | 90 | 466 | 153 | 11 | 1458 | 5774 |
| **1992** | 4888 | 204 | 203 | 260 | 1388 | 387 | 32 | 164 | 685 | 245 | 54 | 1086 | 6533 |
| **1993** | 4654 | 233 | 108 | 296 | 1340 | 391 | 52 | 222 | 651 | 269 | 204 | 749 | 6306 |
| **1994** | 4342 | 141 | 86 | 182 | 1207 | 254 | 26 | 126 | 427 | 166 | 811 | 363 | 6446 |
| **1995** | 1429 | 70 | 16 | 73 | 260 | 49 | 14 | 58 | 153 | 67 | 1328 | 122 | 3033 |
| **Total** | **29717** | **146** | **803** | **217** | **8020** | **278** | **21** | **111** | **518** | **175** | **2410** | **285** | **40950** |

Table II.2: Summary of Average Days to Decision on 501(k)s and Number of Open Cases (October 1, 1988 - May 18, 1995)

| | Equivalent | | | Nonequivalent | | | Other | | | Percentile | | | | Open | | Grand |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Class | N | Percent | Days | N | Percent | Days | N | Percent | Days | 5 | 50 | 95 | Mean | N | Percent | total |
| I | 7819 | 96.0 | 112 | 9 | 0.1 | 181 | 315 | 3.9 | 93 | 18 | 81 | 324 | 111 | 2 | 0 | 8145 |
| II | 20196 | 99.6 | 153 | 36 | 0.2 | 170 | 35 | 0.2 | 413 | 23 | 102 | 440 | 154 | 4 | 0 | 20271 |
| III | 1113 | 97.5 | 215 | 24 | 2.1 | 245 | 3 | 0.3 | 306 | 37 | 156 | 638 | 216 | 1 | 1 | 1141 |
| N/A | 589 | 5.2 | 207 | 734 | 6.4 | 218 | 7667 | 67.3 | 285 | 20 | 245 | 664 | 275 | 2403 | 21.1 | 11393 |
| **Tier** | | | | | | | | | | | | | | | | |
| 1 | 5604 | 98.1 | 120 | 7 | 0.1 | 231 | 101 | 1.8 | 114 | 17 | 86 | 349 | 120 | 2 | 0 | 5714 |
| 2 | 21510 | 99.6 | 149 | 36 | 0.2 | 159 | 49 | 0.2 | 278 | 23 | 98 | 434 | 149 | 4 | 0 | 21599 |
| 3 | 1448 | 97.4 | 210 | 26 | 1.7 | 249 | 11 | 0.7 | 218 | 38 | 155 | 579 | 211 | 1 | 1 | 1486 |
| Exempt | 882 | 82.0 | 115 | 1 | 0.1 | 54 | 192 | 17.9 | 92 | 18 | 79 | 324 | 111 | 0 | 0 | 1075 |
| N/A | 273 | 2.5 | 189 | 733 | 6.6 | 218 | 7667 | 69.2 | 285 | 20 | 249 | 667 | 276 | 2403 | 21.7 | 11076 |
| **Medical specialty** | | | | | | | | | | | | | | | | |
| General hospital | 3294 | 99.0 | 152 | 3 | 0.1 | 553 | 31 | 0.9 | 166 | 22 | 109 | 430 | 152 | 0 | 0 | 3328 |
| General/plastic surgery | 3899 | 98.1 | 134 | 6 | 0.2 | 225 | 70 | 1.8 | 105 | 19 | 90 | 372 | 134 | 0 | 0 | 3975 |
| Other | 22513 | 98.6 | 147 | 62 | 0.3 | 178 | 254 | 1.1 | 130 | 22 | 94 | 434 | 147 | 7 | 0 | 22836 |
| N/A | 11 | 0.1 | 203 | 732 | 6.8 | 219 | 7665 | 70.9 | 285 | 20 | 255 | 669 | 279 | 2403 | 22.2 | 10811 |
| **Division** | | | | | | | | | | | | | | | | |
| DCLD | 5437 | 80.0 | 108 | 71 | 1.0 | 205 | 916 | 13.5 | 217 | 21 | 81 | 405 | 125 | 376 | 5.5 | 6800 |
| DCRND | 4892 | 70.1 | 167 | 182 | 2.6 | 213 | 1380 | 19.8 | 328 | 30 | 156 | 520 | 203 | 527 | 7.5 | 6981 |
| DGRD | 12419 | 69.8 | 150 | 406 | 2.3 | 209 | 4007 | 22.5 | 270 | 20 | 117 | 523 | 180 | 962 | 5.4 | 17794 |
| DOD | 1300 | 70.8 | 115 | 8 | 0.4 | 291 | 462 | 25.2 | 207 | 21 | 88 | 435 | 140 | 65 | 3.5 | 1835 |
| DRAER | 5667 | 75.5 | 161 | 128 | 1.7 | 238 | 1240 | 16.5 | 323 | 23 | 117 | 599 | 191 | 471 | 6.3 | 7506 |
| N/A | 2 | 5.9 | 233 | 8 | 23.5 | 300 | 15 | 44.1 | 389 | 7 | 288 | 1361 | 269 | 9 | 3.3 | 34 |
| **Total** | **29717** | **72.2** | **146** | **803** | **2.0** | **217** | **8020** | **19.6** | **278** | **21** | **111** | **518** | **175** | **2410** | **5.9** | **40950** |

Table II.3: Average Days to Decision and Number of Open Cases for 510(k)s by Class of Medical Device (October 1, 1988 - May 18, 1995)

| Fiscal year | Class | Equivalent N | Equivalent Days | Nonequivalent N | Nonequivalent Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | I | 2003 | 87 | 1 | 54 | 28 | 63 | 2032 | 87 | 0 |
| | II | 2956 | 103 | 5 | 196 | 5 | 245 | 2966 | 103 | 0 |
| | III | 239 | 127 | 6 | 145 | 0 | 0 | 245 | 127 | 0 |
| | N/A | 60 | 104 | 96 | 168 | 1622 | 207 | 1778 | 201 | 2 |
| | **Total** | **5258** | **98** | **108** | **167** | **1655** | **205** | **7021** | **124** | **2** |
| 1990 | I | 1087 | 79 | 2 | 50 | 4 | 80 | 1093 | 79 | 0 |
| | II | 3236 | 103 | 6 | 245 | 3 | 147 | 3245 | 103 | 0 |
| | III | 241 | 155 | 11 | 294 | 2 | 287 | 254 | 162 | 0 |
| | N/A | 69 | 124 | 123 | 148 | 1051 | 208 | 1243 | 197 | 0 |
| | **Total** | **4633** | **100** | **142** | **162** | **1060** | **207** | **5835** | **121** | **0** |
| 1991 | I | 928 | 84 | 2 | 158 | 10 | 49 | 940 | 84 | 0 |
| | II | 3299 | 128 | 4 | 196 | 6 | 832 | 3309 | 129 | 0 |
| | III | 199 | 220 | 3 | 393 | 0 | 0 | 202 | 222 | 0 |
| | N/A | 87 | 172 | 131 | 223 | 1094 | 262 | 1312 | 252 | 11 |
| | **Total** | **4513** | **124** | **140** | **225** | **1110** | **263** | **5763** | **153** | **11** |
| 1992 | I | 1106 | 157 | 2 | 231 | 66 | 120 | 1174 | 155 | 0 |
| | II | 3496 | 211 | 12 | 117 | 10 | 363 | 3518 | 211 | 0 |
| | III | 183 | 292 | 0 | 0 | 0 | 0 | 183 | 292 | 0 |
| | N/A | 103 | 296 | 189 | 269 | 1312 | 401 | 1604 | 378 | 54 |
| | **Total** | **4888** | **204** | **203** | **260** | **1388** | **387** | **6479** | **245** | **54** |
| 1993 | I | 1112 | 186 | 0 | 0 | 76 | 138 | 1188 | 183 | 0 |
| | II | 3253 | 241 | 2 | 129 | 8 | 423 | 3263 | 241 | 0 |
| | III | 147 | 360 | 2 | 164 | 1 | 344 | 150 | 357 | 0 |
| | N/A | 142 | 302 | 104 | 302 | 1255 | 406 | 1501 | 389 | 204 |
| | **Total** | **4654** | **233** | **108** | **296** | **1340** | **391** | **6102** | **269** | **204** |
| 1994 | I | 1225 | 110 | 2 | 349 | 45 | 106 | 1272 | 110 | 1 |
| | II | 2952 | 150 | 6 | 189 | 3 | 264 | 2961 | 150 | 1 |
| | III | 77 | 238 | 2 | 141 | 0 | 0 | 79 | 235 | 1 |
| | N/A | 88 | 176 | 76 | 178 | 1159 | 260 | 1323 | 250 | 808 |
| | **Total** | **4342** | **141** | **86** | **182** | **1207** | **254** | **5635** | **166** | **811** |
| 1995 | I | 358 | 67 | 0 | 0 | 86 | 40 | 444 | 62 | 1 |
| | II | 1004 | 70 | 1 | 90 | 0 | 0 | 1005 | 70 | 3 |
| | III | 27 | 111 | 0 | 0 | 0 | 0 | 27 | 111 | 0 |
| | N/A | 40 | 82 | 15 | 72 | 174 | 54 | 229 | 60 | 1324 |
| | **Total** | **1429** | **70** | **16** | **73** | **260** | **49** | **1705** | **67** | **1328** |
| **Total** | | **29717** | **146** | **803** | **217** | **8020** | **278** | **38540** | **175** | **2410** |

**Table II.4: Average Days to Decision and Number of Open Cases for 510(k)s by Tier of Medical Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Tier | Equivalent N | Equivalent Days | Nonequivalent N | Nonequivalent Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | 1 | 1619 | 90 | 0 | 0 | 17 | 72 | 1636 | 90 | 0 |
| | 2 | 3162 | 102 | 5 | 196 | 9 | 166 | 3176 | 102 | 0 |
| | 3 | 239 | 122 | 7 | 147 | 0 | 0 | 246 | 123 | 0 |
| | Exempt | 195 | 66 | 1 | 54 | 8 | 44 | 204 | 65 | 0 |
| | N/A | 43 | 92 | 95 | 168 | 1621 | 207 | 1759 | 202 | 2 |
| | **Total** | **5258** | **98** | **108** | **167** | **1655** | **205** | **7021** | **124** | **2** |
| **1990** | 1 | 715 | 79 | 1 | 66 | 2 | 38 | 718 | 79 | 0 |
| | 2 | 3528 | 101 | 7 | 215 | 1 | 266 | 3536 | 101 | 0 |
| | 3 | 246 | 163 | 11 | 294 | 4 | 187 | 261 | 169 | 0 |
| | Exempt | 106 | 84 | 0 | 0 | 2 | 123 | 108 | 85 | 0 |
| | N/A | 38 | 93 | 123 | 148 | 1051 | 208 | 1212 | 198 | 0 |
| | **Total** | **4633** | **100** | **142** | **162** | **1060** | **207** | **5835** | **121** | **0** |
| **1991** | 1 | 614 | 110 | 2 | 304 | 6 | 288 | 622 | 113 | 0 |
| | 2 | 3513 | 121 | 4 | 123 | 5 | 708 | 3522 | 122 | 0 |
| | 3 | 248 | 202 | 3 | 393 | 1 | 60 | 252 | 204 | 0 |
| | Exempt | 105 | 95 | 0 | 0 | 4 | 40 | 109 | 93 | 0 |
| | N/A | 33 | 174 | 131 | 223 | 1094 | 262 | 1258 | 253 | 11 |
| | **Total** | **4513** | **124** | **140** | **225** | **1110** | **263** | **5763** | **153** | **11** |
| **1992** | 1 | 733 | 190 | 1 | 98 | 10 | 110 | 744 | 189 | 0 |
| | 2 | 3748 | 202 | 12 | 117 | 10 | 385 | 3770 | 202 | 0 |
| | 3 | 234 | 279 | 1 | 363 | 1 | 748 | 236 | 282 | 0 |
| | Exempt | 132 | 162 | 0 | 0 | 56 | 118 | 188 | 149 | 0 |
| | N/A | 41 | 339 | 189 | 269 | 1311 | 400 | 1541 | 370 | 54 |
| | **Total** | **4888** | **204** | **203** | **260** | **1388** | **387** | **6479** | **245** | **54** |
| **1993** | 1 | 793 | 200 | 0 | 0 | 26 | 195 | 819 | 199 | 0 |
| | 2 | 3404 | 235 | 2 | 129 | 12 | 250 | 3418 | 235 | 0 |
| | 3 | 245 | 329 | 2 | 190 | 5 | 168 | 252 | 325 | 0 |
| | Exempt | 155 | 191 | 0 | 0 | 42 | 126 | 197 | 177 | 0 |
| | N/A | 57 | 286 | 104 | 302 | 1255 | 406 | 1416 | 344 | 204 |
| | **Total** | **4654** | **233** | **108** | **296** | **1340** | **391** | **6102** | **269** | **204** |
| **1994** | 1 | 848 | 104 | 3 | 282 | 8 | 138 | 859 | 105 | 1 |
| | 2 | 3115 | 150 | 5 | 197 | 6 | 211 | 3126 | 150 | 1 |
| | 3 | 187 | 182 | 2 | 141 | 0 | 0 | 189 | 180 | 1 |
| | Exempt | 158 | 103 | 0 | 0 | 34 | 94 | 192 | 102 | 0 |
| | N/A | 34 | 177 | 76 | 178 | 1159 | 260 | 1269 | 154 | 808 |
| | **Total** | **4342** | **141** | **86** | **182** | **1207** | **254** | **5635** | **166** | **811** |
| **1995** | 1 | 282 | 60 | 0 | 0 | 32 | 37 | 314 | 57 | 1 |
| | 2 | 1040 | 72 | 1 | 90 | 6 | 35 | 1050 | 72 | 3 |
| | 3 | 49 | 92 | 0 | 0 | 0 | 0 | 49 | 92 | 0 |
| | Exempt | 31 | 69 | 0 | 0 | 46 | 41 | 77 | 52 | 0 |
| | N/A | 27 | 82 | 15 | 72 | 176 | 54 | 218 | 8 | 1324 |
| | **Total** | **1429** | **70** | **16** | **73** | **260** | **49** | **1705** | **67** | **1328** |
| **Total** | | **29717** | **146** | **803** | **217** | **8020** | **278** | **38540** | **175** | **2410** |

**Table II.5: Average Days to Decision and Number of Open Cases for 510(k)s by Medical Specialty of Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Medical specialty | Equivalent N | Equivalent Days | Nonequivalent N | Nonequivalent Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | General hospital | 1219 | 105 | 95 | 168 | 1 | 78 | 1220 | 105 | 0 |
| | General/plastic surgery | 496 | 71 | 0 | 0 | 13 | 40 | 509 | 70 | 0 |
| | Other | 3539 | 99 | 13 | 159 | 20 | 124 | 3572 | 99 | 0 |
| | N/A | 4 | 106 | 95 | 168 | 1621 | 207 | 1720 | 204 | 2 |
| | **Total** | **5258** | **98** | **108** | **167** | **1655** | **205** | **7021** | **124** | **2** |
| **1990** | General hospital | 410 | 97 | 2 | 665 | 0 | 0 | 412 | 99 | 0 |
| | General/plastic surgery | 453 | 83 | 2 | 496 | 5 | 141 | 460 | 86 | 0 |
| | Other | 3767 | 103 | 15 | 165 | 4 | 158 | 3786 | 103 | 0 |
| | N/A | 3 | 110 | 123 | 148 | 1051 | 208 | 1177 | 201 | 0 |
| | **Total** | **4633** | **100** | **142** | **162** | **1060** | **207** | **5835** | **121** | **0** |
| **1991** | General hospital | 400 | 136 | 0 | 0 | 1 | 76 | 401 | 136 | 0 |
| | General/plastic surgery | 570 | 111 | 0 | 0 | 6 | 58 | 576 | 110 | 0 |
| | Other | 3541 | 124 | 9 | 253 | 9 | 562 | 3559 | 126 | 0 |
| | N/A | 2 | 490 | 131 | 223 | 1094 | 262 | 1227 | 256 | 11 |
| | **Total** | **4513** | **124** | **140** | **225** | **1110** | **263** | **5763** | **153** | **11** |
| **1992** | General hospital | 369 | 277 | 0 | 0 | 8 | 319 | 377 | 278 | 0 |
| | General/plastic surgery | 662 | 200 | 3 | 77 | 7 | 162 | 672 | 199 | 0 |
| | Other | 3857 | 197 | 11 | 149 | 62 | 139 | 3930 | 196 | 0 |
| | N/A | 0 | 0 | 189 | 269 | 1311 | 400 | 1500 | 371 | 54 |
| | **Total** | **4888** | **204** | **203** | **260** | **1388** | **387** | **6479** | **245** | **54** |
| **1993** | General hospital | 389 | 284 | 0 | 0 | 12 | 137 | 401 | 280 | 0 |
| | General/plastic surgery | 752 | 221 | 1 | 126 | 21 | 165 | 774 | 219 | 0 |
| | Other | 3512 | 230 | 4 | 175 | 52 | 175 | 3568 | 229 | 0 |
| | N/A | 1 | 302 | 103 | 303 | 1255 | 406 | 1359 | 346 | 204 |
| | **Total** | **4654** | **233** | **108** | **296** | **1340** | **391** | **6102** | **269** | **204** |
| **1994** | General hospital | 398 | 146 | 1 | 329 | 2 | 259 | 401 | 147 | 0 |
| | General/plastic surgery | 692 | 103 | 0 | 0 | 5 | 130 | 697 | 104 | 0 |
| | Other | 3251 | 148 | 9 | 198 | 41 | 107 | 3301 | 148 | 3 |
| | N/A | 1 | 203 | 76 | 178 | 1159 | 260 | 1236 | 154 | 808 |
| | **Total** | **4342** | **141** | **86** | **182** | **1207** | **254** | **5635** | **166** | **811** |
| **1995** | General hospital | 109 | 78 | 0 | 0 | 7 | 39 | 116 | 76 | 0 |
| | General/plastic surgery | 274 | 62 | 0 | 0 | 13 | 40 | 287 | 61 | 0 |
| | Other | 1046 | 72 | 1 | 90 | 66 | 40 | 1113 | 70 | 4 |
| | N/A | 0 | 0 | 15 | 72 | 174 | 54 | 189 | 7 | 1324 |
| | **Total** | **1429** | **70** | **16** | **73** | **260** | **49** | **1705** | **67** | **1328** |
| **Total** | | **29717** | **146** | **803** | **217** | **8020** | **278** | **38540** | **175** | **2410** |

Table II.6: Average Days to Decision and Number of Open Cases for 510(k)s by Reviewing Division (October 1, 1988 - May 18, 1995)

| Fiscal year | Division | Equivalent N | Equivalent Days | Nonequivalent N | Nonequivalent Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | DCLD | 1011 | 76 | 8 | 133 | 168 | 142 | 1187 | 85 | 0 |
| | DCRND | 853 | 119 | 18 | 140 | 174 | 247 | 1045 | 141 | 0 |
| | DGRD | 2494 | 97 | 59 | 187 | 1102 | 214 | 3655 | 133 | 0 |
| | DOD | 106 | 85 | 0 | 0 | 36 | 120 | 142 | 94 | 0 |
| | DRAER | 793 | 108 | 23 | 147 | 170 | 182 | 986 | 121 | 2 |
| | N/A | 1 | 511 | 0 | 0 | 5 | 175 | 6 | 231 | 0 |
| | **Total** | **5258** | **98** | **108** | **167** | **1655** | **205** | **7021** | **124** | **2** |
| 1990 | DCLD | 903 | 72 | 10 | 227 | 122 | 151 | 1035 | 82 | 0 |
| | DCRND | 908 | 129 | 32 | 145 | 189 | 274 | 1129 | 154 | 0 |
| | DGRD | 1649 | 96 | 81 | 162 | 525 | 179 | 2255 | 117 | 0 |
| | DOD | 173 | 81 | 0 | 0 | 31 | 115 | 204 | 86 | 0 |
| | DRAER | 1000 | 111 | 18 | 128 | 192 | 265 | 1210 | 135 | 0 |
| | N/A | 0 | 0 | 1 | 672 | 1 | 1010 | 2 | 841 | 0 |
| | **Total** | **4633** | **100** | **142** | **162** | **1060** | **207** | **5835** | **121** | **0** |
| 1991 | DCLD | 836 | 85 | 12 | 181 | 130 | 202 | 978 | 101 | 2 |
| | DCRND | 881 | 159 | 26 | 259 | 223 | 336 | 1130 | 196 | 3 |
| | DGRD | 1761 | 121 | 64 | 172 | 526 | 225 | 2351 | 146 | 2 |
| | DOD | 127 | 102 | 3 | 342 | 40 | 178 | 170 | 124 | 0 |
| | DRAER | 907 | 134 | 28 | 298 | 190 | 342 | 1125 | 173 | 1 |
| | N/A | 1 | 3 | 7 | 308 | 1 | 86 | 9 | 187 | 3 |
| | **Total** | **4513** | **124** | **140** | **225** | **1110** | **263** | **5763** | **153** | **11** |
| 1992 | DCLD | 969 | 119 | 25 | 223 | 145 | 278 | 1139 | 142 | 2 |
| | DCRND | 812 | 237 | 53 | 250 | 244 | 387 | 1109 | 268 | 10 |
| | DGRD | 1953 | 220 | 94 | 272 | 677 | 391 | 2724 | 262 | 18 |
| | DOD | 167 | 154 | 2 | 201 | 70 | 289 | 239 | 194 | 0 |
| | DRAER | 987 | 236 | 29 | 274 | 244 | 480 | 1260 | 279 | 19 |
| | N/A | 0 | 0 | 0 | 0 | 8 | 92 | 8 | 57 | 5 |
| | **Total** | **4888** | **204** | **203** | **260** | **1388** | **387** | **6479** | **245** | **54** |
| 1993 | DCLD | 788 | 165 | 6 | 239 | 167 | 319 | 961 | 188 | 21 |
| | DCRND | 687 | 219 | 35 | 242 | 267 | 412 | 989 | 261 | 41 |
| | DGRD | 2077 | 260 | 45 | 315 | 583 | 412 | 2705 | 283 | 96 |
| | DOD | 216 | 211 | 2 | 404 | 93 | 348 | 311 | 251 | 3 |
| | DRAER | 886 | 249 | 20 | 355 | 230 | 384 | 1136 | 268 | 42 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | **Total** | **4654** | **233** | **108** | **296** | **1340** | **391** | **6102** | **269** | **204** |
| 1994 | DCLD | 724 | 160 | 8 | 220 | 149 | 231 | 881 | 146 | 158 |
| | DCRND | 590 | 176 | 18 | 179 | 260 | 294 | 868 | 174 | 185 |
| | DGRD | 1863 | 128 | 52 | 181 | 481 | 256 | 2396 | 138 | 289 |
| | DOD | 377 | 92 | 0 | 0 | 131 | 198 | 508 | 117 | 11 |
| | DRAER | 788 | 151 | 8 | 158 | 186 | 251 | 982 | 145 | 168 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **4342** | **141** | **86** | **182** | **1207** | **254** | **5635** | **166** | **811** |
| 1995 | DCLD | 206 | 79 | 2 | 133 | 35 | 56 | 243 | 43 | 193 |
| | DCRND | 161 | 70 | 0 | 0 | 23 | 74 | 184 | 27 | 288 |
| | DGRD | 622 | 70 | 11 | 56 | 113 | 45 | 746 | 38 | 557 |
| | DOD | 134 | 57 | 1 | 90 | 61 | 37 | 196 | 40 | 51 |
| | DRAER | 306 | 71 | 2 | 96 | 28 | 62 | 336 | 41 | 239 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **1429** | **70** | **16** | **73** | **260** | **49** | **1705** | **69** | **1328** |
| **Total** | | **29717** | **146** | **803** | **217** | **8020** | **278** | **38540** | **175** | **2410** |

**Table II.7: Average Days to Equivalency for 510(k)s by Fiscal Year (October 1, 1988 - May 18, 1995)**

| Fiscal year | N | Total FDA time | Non-FDA time | Time lapse | Percentiles for time lapse 5 | 50 | 95 |
|---|---|---|---|---|---|---|---|
| 1989 | 5149 | 80 | 21 | 101 | 18 | 77 | 252 |
| 1990 | 4518 | 81 | 20 | 102 | 16 | 78 | 274 |
| 1991 | 4275 | 94 | 25 | 119 | 19 | 86 | 322 |
| 1992 | 4368 | 152 | 34 | 185 | 33 | 132 | 505 |
| 1993 | 3123 | 173 | 28 | 201 | 49 | 161 | 486 |
| 1994 | 2650 | 100 | 23 | 122 | 24 | 92 | 318 |
| 1995 | 834 | 60 | 7 | 66 | 14 | 57 | 148 |
| **Total** | **24917** | **108** | **25** | **133** | **21** | **90** | **378** |

**Table II.8: Average Days to Equivalency for 510(k)s by Class, Tier, Medical Specialty, and Division (October 1, 1988 - May 18, 1995)**

| Class | N | Total FDA time | Non-FDA time | Time lapse |
|---|---|---|---|---|
| I | 6839 | 85 | 19 | 104 |
| II | 16726 | 115 | 25 | 140 |
| III | 917 | 144 | 46 | 189 |
| N/A | 435 | 144 | 33 | 177 |
| **Tier** | | | | |
| 1 | 5001 | 90 | 22 | 111 |
| 2 | 17774 | 111 | 25 | 136 |
| 3 | 1134 | 150 | 40 | 191 |
| Exempt | 797 | 94 | 12 | 106 |
| N/A | 211 | 117 | 34 | 151 |
| **Medical specialty** | | | | |
| General hospital | 2773 | 108 | 31 | 139 |
| General/plastic surgery | 3093 | 109 | 17 | 125 |
| Other | 19044 | 108 | 25 | 133 |
| N/A | 7 | 66 | 12 | 77 |
| **Division** | | | | |
| DCLD | 4415 | 78 | 18 | 96 |
| DCRND | 4222 | 122 | 36 | 158 |
| DGRD | 10307 | 113 | 24 | 137 |
| DOD | 1134 | 92 | 13 | 105 |
| DRAER | 4837 | 117 | 24 | 141 |
| N/A | 2 | 203 | 54 | 257 |
| **Total** | **24917** | **108** | **25** | **133** |

**Table II.9: Average Days to Equivalency for 510(k)s by Class of Medical Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Class | N | Total FDA time | Non-FDA time | Time lapse |
|---|---|---|---|---|---|
| **1989** | I | 1966 | 66 | 23 | 88 |
| | II | 2894 | 88 | 19 | 106 |
| | III | 230 | 104 | 31 | 135 |
| | N/A | 59 | 84 | 16 | 101 |
| | **Total** | **5149** | **80** | **21** | **101** |
| **1990** | I | 1073 | 64 | 16 | 80 |
| | II | 3153 | 84 | 21 | 105 |
| | III | 227 | 115 | 36 | 151 |
| | N/A | 65 | 94 | 24 | 117 |
| | **Total** | **4518** | **81** | **20** | **102** |
| **1991** | I | 898 | 68 | 15 | 84 |
| | II | 3115 | 97 | 27 | 123 |
| | III | 181 | 153 | 47 | 201 |
| | N/A | 81 | 115 | 44 | 159 |
| | **Total** | **4275** | **94** | **25** | **119** |
| **1992** | I | 1017 | 126 | 23 | 150 |
| | II | 3109 | 156 | 35 | 191 |
| | III | 156 | 186 | 68 | 254 |
| | N/A | 86 | 226 | 49 | 275 |
| | **Total** | **4368** | **152** | **34** | **185** |
| **1993** | I | 800 | 145 | 18 | 162 |
| | II | 2170 | 179 | 31 | 210 |
| | III | 80 | 237 | 62 | 299 |
| | N/A | 73 | 215 | 30 | 245 |
| | **Total** | **3123** | **173** | **28** | **201** |
| **1994** | I | 870 | 78 | 16 | 94 |
| | II | 1699 | 109 | 25 | 134 |
| | III | 31 | 155 | 71 | 226 |
| | N/A | 50 | 114 | 32 | 146 |
| | **Total** | **2650** | **100** | **23** | **122** |
| **1995** | I | 215 | 51 | 10 | 61 |
| | II | 586 | 62 | 5 | 67 |
| | III | 12 | 100 | 13 | 113 |
| | N/A | 21 | 69 | 6 | 75 |
| | **Total** | **834** | **60** | **7** | **66** |
| **Total** | | **24917** | **108** | **25** | **133** |

**Table II.10: Average Days to Equivalency for 510(k)s by Tier of Medical Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Tier | N | Total FDA time | Non-FDA time | Time lapse |
|---|---|---|---|---|---|
| **1989** | 1 | 1589 | 67 | 25 | 91 |
| | 2 | 3096 | 86 | 19 | 105 |
| | 3 | 230 | 109 | 27 | 137 |
| | Exempt | 194 | 57 | 9 | 66 |
| | N/A | 40 | 71 | 17 | 87 |
| | **Total** | **5149** | **80** | **21** | **101** |
| **1990** | 1 | 705 | 67 | 17 | 84 |
| | 2 | 3447 | 82 | 20 | 102 |
| | 3 | 227 | 118 | 41 | 159 |
| | Exempt | 105 | 75 | 8 | 84 |
| | N/A | 34 | 72 | 18 | 89 |
| | **Total** | **4518** | **81** | **20** | **102** |
| **1991** | 1 | 584 | 82 | 24 | 106 |
| | 2 | 3335 | 93 | 25 | 117 |
| | 3 | 223 | 138 | 42 | 181 |
| | Exempt | 102 | 83 | 12 | 94 |
| | N/A | 31 | 112 | 42 | 154 |
| | **Total** | **4275** | **94** | **25** | **119** |
| **1992** | 1 | 679 | 149 | 28 | 177 |
| | 2 | 3329 | 150 | 34 | 184 |
| | 3 | 207 | 200 | 53 | 253 |
| | Exempt | 122 | 126 | 17 | 143 |
| | N/A | 31 | 176 | 62 | 238 |
| | **Total** | **4368** | **152** | **34** | **185** |
| **1993** | 1 | 586 | 151 | 18 | 169 |
| | 2 | 2242 | 174 | 31 | 205 |
| | 3 | 139 | 238 | 45 | 283 |
| | Exempt | 121 | 166 | 13 | 179 |
| | N/A | 35 | 195 | 41 | 236 |
| | **Total** | **3123** | **173** | **28** | **201** |
| **1994** | 1 | 658 | 71 | 20 | 91 |
| | 2 | 1752 | 110 | 23 | 133 |
| | 3 | 85 | 131 | 41 | 172 |
| | Exempt | 131 | 81 | 14 | 95 |
| | N/A | 24 | 106 | 53 | 159 |
| | **Total** | **2650** | **100** | **23** | **122** |
| **1995** | 1 | 200 | 52 | 4 | 56 |
| | 2 | 573 | 61 | 7 | 69 |
| | 3 | 23 | 85 | 10 | 94 |
| | Exempt | 22 | 55 | 5 | 60 |
| | N/A | 16 | 64 | 5 | 70 |
| | **Total** | **834** | **60** | **7** | **66** |
| **Total** | | **24917** | **108** | **25** | **133** |

**Table II.11: Average Days to Equivalency for 510(k)s by Medical Specialty of Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Medical specialty | N | Total FDA time | Non-FDA time | Time lapse |
|---|---|---|---|---|---|
| **1989** | General hospital | 1198 | 79 | 30 | 109 |
| | General/plastic surgery | 489 | 55 | 19 | 74 |
| | Other | 3459 | 84 | 18 | 102 |
| | N/A | 3 | 38 | 0 | 38 |
| | **Total** | **5149** | **80** | **21** | **101** |
| **1990** | General hospital | 402 | 79 | 25 | 104 |
| | General/plastic surgery | 441 | 75 | 14 | 88 |
| | Other | 3672 | 82 | 21 | 103 |
| | N/A | 3 | 90 | 20 | 110 |
| | **Total** | **4518** | **81** | **20** | **102** |
| **1991** | General hospital | 379 | 90 | 37 | 127 |
| | General/plastic surgery | 534 | 89 | 16 | 106 |
| | Other | 3361 | 95 | 25 | 120 |
| | N/A | 1 | 75 | 22 | 97 |
| | **Total** | **4275** | **94** | **25** | **119** |
| **1992** | General hospital | 324 | 211 | 40 | 251 |
| | General/plastic surgery | 583 | 165 | 25 | 189 |
| | Other | 3461 | 144 | 35 | 179 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **4368** | **152** | **34** | **185** |
| **1993** | General hospital | 213 | 217 | 26 | 243 |
| | General/plastic surgery | 495 | 184 | 17 | 201 |
| | Other | 2415 | 166 | 31 | 197 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **3123** | **173** | **28** | **201** |
| **1994** | General hospital | 206 | 102 | 34 | 136 |
| | General/plastic surgery | 403 | 82 | 11 | 93 |
| | Other | 2041 | 103 | 24 | 127 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **2650** | **100** | **23** | **122** |
| **1995** | General hospital | 51 | 72 | 5 | 77 |
| | General/plastic surgery | 148 | 55 | 3 | 58 |
| | Other | 635 | 60 | 8 | 67 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **834** | **60** | **7** | **66** |
| **Total** | | **24917** | **108** | **25** | **133** |

Table II.12: Average Days to Equivalency for 510(k)s by Reviewing Division (October 1, 1988 - May 18, 1995)

| Fiscal year | Division | N | Total FDA time | Non-FDA time | Time lapse |
|---|---|---|---|---|---|
| 1989 | DCLD | 994 | 68 | 11 | 79 |
| | DCRND | 818 | 103 | 24 | 127 |
| | DGRD | 2451 | 75 | 24 | 100 |
| | DOD | 105 | 72 | 10 | 82 |
| | DRAER | 780 | 87 | 20 | 107 |
| | N/A | 1 | 403 | 108 | 511 |
| | **Total** | **5149** | **80** | **21** | **101** |
| 1990 | DCLD | 888 | 60 | 16 | 76 |
| | DCRND | 866 | 100 | 27 | 127 |
| | DGRD | 1611 | 79 | 19 | 98 |
| | DOD | 170 | 67 | 13 | 80 |
| | DRAER | 983 | 90 | 23 | 113 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **4518** | **81** | **20** | **102** |
| 1991 | DCLD | 799 | 64 | 20 | 84 |
| | DCRND | 825 | 118 | 35 | 153 |
| | DGRD | 1663 | 90 | 24 | 114 |
| | DOD | 120 | 91 | 11 | 102 |
| | DRAER | 867 | 104 | 27 | 131 |
| | N/A | 1 | 3 | 0 | 3 |
| | **Total** | **4275** | **94** | **25** | **119** |
| 1992 | DCLD | 884 | 88 | 23 | 111 |
| | DCRND | 730 | 168 | 61 | 228 |
| | DGRD | 1741 | 172 | 32 | 204 |
| | DOD | 160 | 136 | 13 | 148 |
| | DRAER | 853 | 165 | 30 | 195 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **4368** | **152** | **34** | **185** |
| 1993 | DCLD | 508 | 115 | 19 | 134 |
| | DCRND | 499 | 149 | 47 | 196 |
| | DGRD | 1352 | 205 | 26 | 231 |
| | DOD | 156 | 161 | 19 | 180 |
| | DRAER | 608 | 171 | 29 | 200 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **3123** | **173** | **28** | **201** |
| 1994 | DCLD | 269 | 118 | 28 | 146 |
| | DCRND | 382 | 113 | 34 | 146 |
| | DGRD | 1141 | 94 | 21 | 115 |
| | DOD | 318 | 69 | 17 | 86 |
| | DRAER | 540 | 110 | 21 | 131 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **2650** | **100** | **23** | **122** |
| 1995 | DCLD | 73 | 62 | 9 | 71 |
| | DCRND | 102 | 58 | 8 | 65 |
| | DGRD | 348 | 59 | 7 | 66 |
| | DOD | 105 | 53 | 3 | 56 |
| | DRAER | 206 | 64 | 6 | 70 |
| | N/A | 0 | 0 | 0 | 0 |
| | **Total** | **834** | **60** | **7** | **66** |
| **Total** | | **24917** | **108** | **25** | **133** |

# Premarket Approval Tables III.1 - III.18

## Review Time for Premarket Approval

In reviewing a PMA application, FDA conducts an initial review to determine whether the application contains sufficient information to make a determination on its safety and effectiveness. A filing decision is made—filed, filed with deficiencies specified, or not filed—based on the adequacy of the information submitted. The manufacturer is notified of the status of the application at this time, especially since deficiencies need to be addressed.

As part of the substantive review, a small proportion of PMA applications are also reviewed by an advisory panel.[1] These panels include clinical scientists in specific medical specialties and representatives from both industry and consumer groups. The advisory panels review the applications and provide recommendations to the agency to either approve, deny, or conditionally approve them. FDA then makes a final determination on the application.

To examine in greater detail those cases where the intermediate milestones were applicable, we calculated the average duration between the various dates—submission, filing, panel decision, and final decision. The number of applications differs for each of the milestones as not all have filing or panel dates. (See figure III.1.)

[1]Of the 401 original PMAs, 87 (22 percent) were reviewed by panels. Of the 3,640 PMA supplements, only 9 (0.2 percent) received panel review.

Figure III.1: Average Days to Decision on Premarket Approvals by Milestone by Year, October 1, 1988 - May 18, 1995

**Original PMAs**

| Fiscal year | Submission to filing N | Submission to filing Days | Filing to panel N | Filing to panel Days | Panel to decision N | Panel to decision Days | Submission to panel N | Submission to panel Days | Submission to decision N | Submission to decision Days | Total applications |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | 61 | 117 | 32 | 161 | 30 | 344 | 32 | 309 | 81 | 513 | 84 |
| 1990 | 61 | 194 | 33 | 201 | 28 | 615 | 33 | 397 | 67 | 744 | 77 |
| 1991 | 48 | 106 | 10 | 208 | 10 | 435 | 10 | 343 | 60 | 580 | 72 |
| 1992 | 49 | 203 | 10 | 432 | 8 | 260 | 10 | 587 | 37 | 674 | 66 |
| 1993 | 29 | 179 | 1 | 295 | 1 | 216 | 1 | 357 | 21 | 462 | 40 |
| 1994 | 31 | 99 | 1 | 301 | 0 | 0 | 1 | 373 | 8 | 222 | 43 |
| 1995 | 10 | 46 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 23 | 19 |
| **Total** | **289** | **148** | **87** | **216** | **77** | **444** | **87** | **379** | **275** | **591** | **401** |

**PMA supplements**

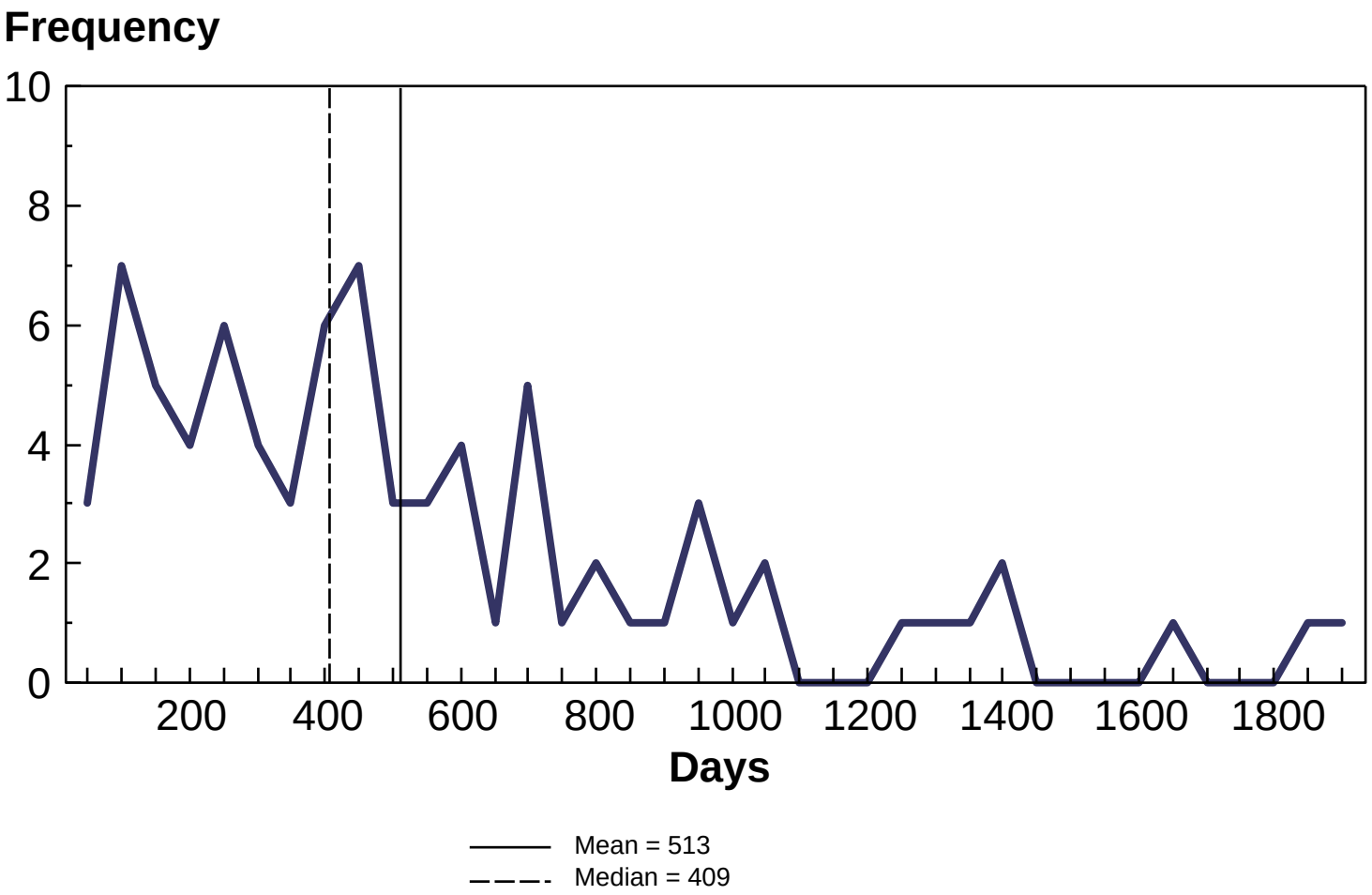
| Fiscal year | Submission to filing N | Submission to filing Days | Filing to panel N | Filing to panel Days | Panel to decision N | Panel to decision Days | Submission to panel N | Submission to panel Days | Submission to decision N | Submission to decision Days | Total applications |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | 15 | 152 | 5 | 113 | 5 | 194 | 5 | 227 | 803 | 219 | 804 |
| 1990 | 6 | 143 | 3 | 161 | 3 | 536 | 3 | 403 | 650 | 193 | 660 |
| 1991 | 6 | 128 | 0 | 0 | 0 | 0 | 0 | 0 | 577 | 261 | 595 |
| 1992 | 6 | 185 | 1 | 516 | 1 | 206 | 1 | 581 | 572 | 336 | 605 |
| 1993 | 1 | 688 | 0 | 0 | 0 | 0 | 0 | 0 | 351 | 266 | 394 |
| 1994 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 295 | 162 | 372 |
| 1995 | 1 | 36 | 0 | 0 | 0 | 0 | 0 | 0 | 84 | 79 | 210 |
| **Total** | **35** | **164** | **9** | **174** | **9** | **309** | **9** | **325** | **3332** | **238** | **3640** |

The following tables present information on review time for PMA applications for fiscal years 1989 through 1995. Original PMA applications are distinguished from PMA supplements. Some observations were deleted from our data because of apparent data entry errors. The first set of tables (tables III.1 through III.6) presents the time to a decision for original PMAs—from the date the application is submitted to the date a decision is rendered. The second set of tables (tables III.7 through III.12) provides similar information, in the same format, for PMA supplements.

We first present a summary table on the time to a decision by fiscal year (tables III.1 and III.7). Again, the grand total for the number of applications includes the number of open cases—that is, applications for which there had not been any decision made as of May 18, 1995. As with 510(k)s, the distributions of time to a decision for original PMAs and PMA supplements are not symmetric. Thus we report means and percentiles to characterize these distributions. (These means and percentiles do not include open cases.)

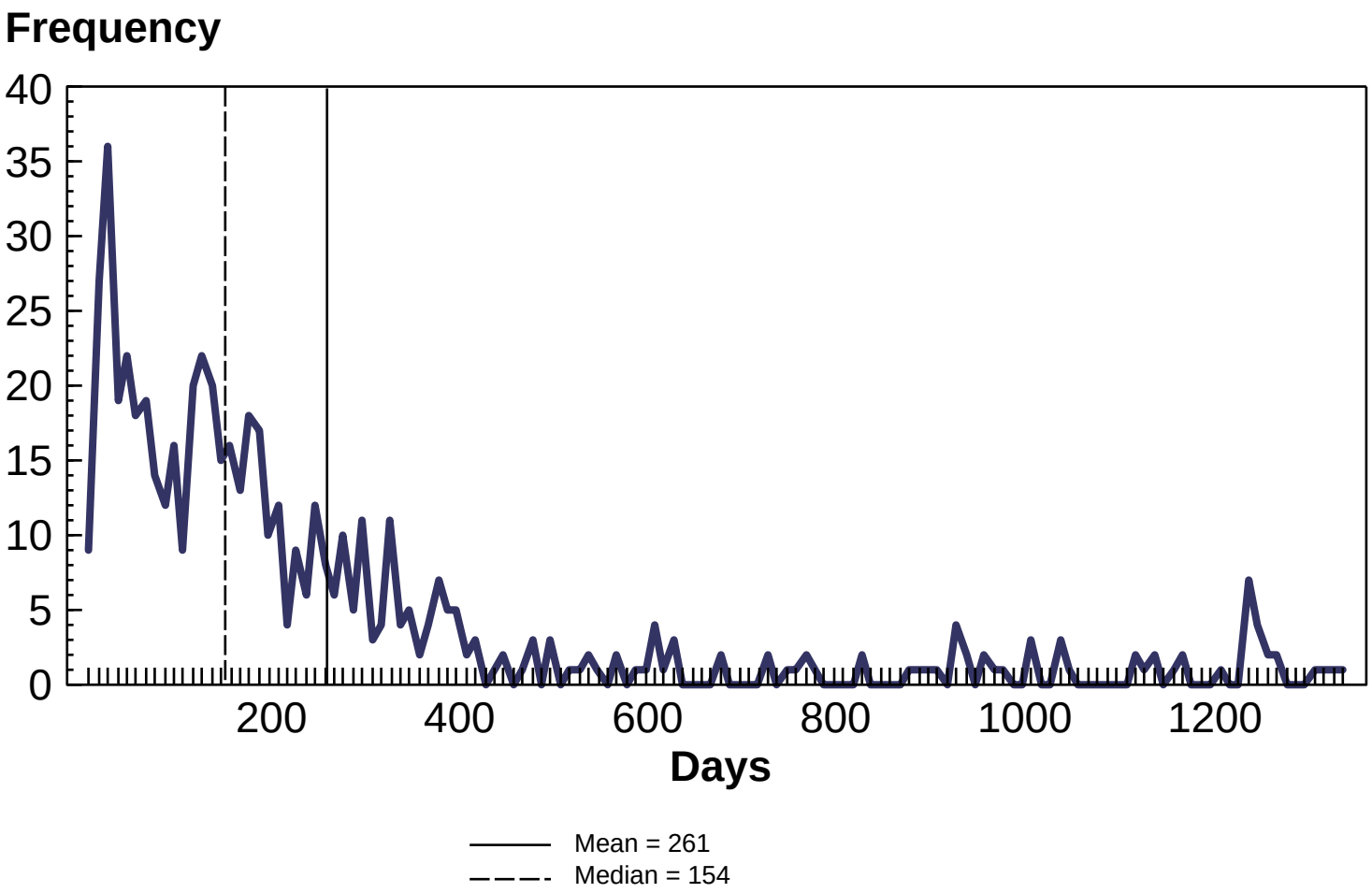
Figure III.2 presents the distribution for original PMAs submitted in 1989, the most recent year for which at least 95 percent of the applications had been completed. Figure III.3 presents the distribution for PMA supplements submitted in 1991, the most recent year with at least a 95-percent completion date.

**Figure III.2: Time to a Decision for Original PMAs Submitted in Fiscal Year 1989[a]**




[a]The number of cases in this frequency distribution is 81. As of May 18, 1995, about 4 percent of the applications submitted had not been completed and were not included.

**Figure III.3: Time to a Decision for PMA Supplements Submitted in Fiscal Year 1991[a]**




[a]The number of cases in this frequency distribution is 577. As of May 18, 1995, 3 percent of the applications submitted had not been completed and were not included.

The second table is a summary of the time to a decision by class, tier, relevant medical specialty of the device, and reviewing division (tables III.2 and III.8). The two summary tables are followed by four tables (tables III.3 through III.6 and III.9 through III.12) presenting the details by class, tier, medical specialty, and reviewing division. The totals in these tables include only applications for which a decision has been rendered.

The class, tier, and medical specialty of some of the devices have yet to be determined and are designated with N/A. Medical specialities other than cardiovascular or ophthalmic include anesthesiology; clinical chemistry; dental; ear, nose, and throat; gastroenterology/urology; general and plastic surgery; general hospital; hematology; immunology; microbiology; neurology; obstetrics/gynecology; orthopedic; pathology; physical medicine; radiology; and clinical toxicology.

The third set of tables provides information on the time to an approval, for both original PMAs and PMA supplements (tables III.13 through III.18). Four different measures of duration are provided—total FDA time, non-FDA time, total elapsed time, and FDA review time. Total FDA time is the amount of time the application is under FDA's review process. Non-FDA time is the time the FDA clock is suspended waiting for additional information from the applicant. The total elapsed time, the duration from the date the application is submitted to the date of FDA's decision, equals the sum of total FDA and non-FDA time. FDA review time is FDA time for the last cycle—excluding any time accrued before the latest resetting of the FDA clock.

Again, we first provide a summary table for time to an approval by fiscal year (table III.13). In this table, we also provide the number of amendments or the number of times additional information was added to the initial submission. Not all amendments were for information requested by FDA as can be seen from the number of requests for information.

Table III.13 is followed by a summary by class, tier, medical specialty, and reviewing division (table III.14). Tables III.15 though III.18 provide the details for these two summary tables.

**Table III.1: Average Days to Decision on Original PMAs by Fiscal Year and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Approved | | Withdrawn | | Other | | Percentile | | | Mean | Open | | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | Days | N | Days | N | Days | 5 | 50 | 95 | | N | Days | |
| **1989** | 45 | 412 | 27 | 747 | 9 | 320 | 57 | 409 | 1373 | 513 | 3 | 2140 | 84 |
| **1990** | 36 | 758 | 22 | 740 | 9 | 698 | 29 | 700 | 1697 | 744 | 10 | 1813 | 77 |
| **1991** | 21 | 556 | 27 | 528 | 12 | 741 | 51 | 559 | 1422 | 580 | 12 | 1427 | 72 |
| **1992** | 21 | 756 | 11 | 583 | 5 | 529 | 106 | 734 | 1127 | 674 | 29 | 1150 | 66 |
| **1993** | 7 | 575 | 12 | 406 | 2 | 402 | 210 | 447 | 792 | 462 | 19 | 705 | 40 |
| **1994** | 3 | 189 | 5 | 241 | 0 | 0 | 133 | 234 | 294 | 222 | 35 | 396 | 43 |
| **1995** | 0 | 0 | 1 | 23 | 0 | 0 | 23 | 23 | 23 | 23 | 18 | 120 | 19 |
| **Total** | **133** | **586** | **105** | **602** | **37** | **581** | **42** | **513** | **1455** | **591** | **126** | **829** | **401** |

**Table III.2: Summary of Average Days to Decision on Original PMAs and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| | Approved | | | Withdrawn | | | Other | | | Percentile | | | | Open | | Grand |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | Percent | Days | N | Percent | Days | N | Percent | Days | 5 | 50 | 95 | Mean | N | Percent | total |
| **Class** | | | | | | | | | | | | | | | | |
| I | 3 | 42.9 | 636 | 1 | 14.3 | 747 | 1 | 14.3 | 683 | 277 | 683 | 1206 | 668 | 2 | 28.6 | 7 |
| II | 25 | 52.1 | 364 | 10 | 20.8 | 735 | 11 | 22.9 | 851 | 71 | 465 | 1343 | 561 | 2 | 4.2 | 48 |
| III | 99 | 43.8 | 630 | 48 | 21.2 | 785 | 14 | 6.2 | 686 | 116 | 597 | 1503 | 681 | 65 | 28.8 | 226 |
| N/A | 6 | 5.0 | 766 | 46 | 38.3 | 379 | 11 | 9.2 | 168 | 0 | 327 | 841 | 379 | 57 | 47.5 | 120 |
| **Tier** | | | | | | | | | | | | | | | | |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 62 | 59.0 | 454 | 18 | 17.1 | 720 | 12 | 11.4 | 791 | 60 | 431 | 1455 | 550 | 13 | 12.4 | 105 |
| 3 | 62 | 35.4 | 707 | 43 | 24.6 | 774 | 13 | 7.4 | 728 | 168 | 653 | 1603 | 734 | 57 | 32.6 | 175 |
| Exempt | 1 | 20.0 | 1206 | 1 | 20.0 | 747 | 1 | 20.0 | 683 | 683 | 747 | 1206 | 879 | 2 | 40.0 | 5 |
| N/A | 8 | 6.9 | 589 | 43 | 37.1 | 377 | 11 | 9.5 | 168 | 0 | 342 | 815 | 368 | 54 | 46.6 | 116 |
| **Medical specialty** | | | | | | | | | | | | | | | | |
| Cardiovascular | 34 | 54.0 | 712 | 8 | 12.7 | 983 | 5 | 7.9 | 444 | 225 | 738 | 1373 | 729 | 16 | 25.4 | 63 |
| Ophthalmic | 55 | 57.3 | 456 | 13 | 13.5 | 673 | 9 | 9.4 | 903 | 60 | 360 | 1521 | 545 | 19 | 19.8 | 96 |
| Other | 39 | 30.2 | 650 | 41 | 31.8 | 741 | 12 | 9.3 | 775 | 168 | 631 | 1702 | 707 | 37 | 28.7 | 129 |
| N/A | 5 | 4.4 | 669 | 43 | 38.1 | 377 | 11 | 9.7 | 168 | 0 | 327 | 837 | 363 | 54 | 47.8 | 113 |
| **Division** | | | | | | | | | | | | | | | | |
| DCLD | 15 | 25.0 | 515 | 17 | 28.3 | 563 | 2 | 3.3 | 322 | 133 | 493 | 1313 | 528 | 26 | 43.3 | 60 |
| DCRND | 36 | 40.9 | 713 | 19 | 21.6 | 680 | 8 | 9.1 | 453 | 82 | 636 | 1239 | 670 | 25 | 28.4 | 88 |
| DGRD | 12 | 15.0 | 721 | 26 | 32.5 | 561 | 9 | 11.3 | 671 | 42 | 630 | 1707 | 623 | 33 | 41.3 | 80 |
| DOD | 58 | 46.0 | 461 | 27 | 21.4 | 506 | 16 | 12.7 | 515 | 9 | 357 | 1372 | 482 | 25 | 19.8 | 126 |
| DRAER | 12 | 25.5 | 763 | 16 | 34.0 | 780 | 2 | 4.3 | 1473 | 102 | 779 | 1702 | 819 | 17 | 36.2 | 47 |
| **Total** | **133** | **33.2** | **586** | **105** | **26.2** | **602** | **37** | **9.2** | **581** | **42** | **513** | **1455** | **591** | **126** | **31.4** | **401** |

**Table III.3: Average Days to Decision on Original PMAs by Class of Medical Device and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Class | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 14 | 269 | 4 | 870 | 3 | 661 | 21 | 440 | 0 |
| | III | 31 | 476 | 11 | 1016 | 1 | 1 | 43 | 603 | 3 |
| | N/A | 0 | 0 | 12 | 459 | 5 | 179 | 17 | 377 | 0 |
| | **Total** | **45** | **412** | **27** | **747** | **9** | **320** | **81** | **513** | **3** |
| 1990 | I | 1 | 277 | 0 | 0 | 0 | 0 | 1 | 277 | 0 |
| | II | 4 | 532 | 2 | 818 | 4 | 1310 | 10 | 900 | 0 |
| | III | 30 | 787 | 9 | 1125 | 1 | 956 | 40 | 868 | 10 |
| | N/A | 1 | 1252 | 11 | 411 | 4 | 21 | 16 | 366 | 0 |
| | **Total** | **36** | **758** | **22** | **740** | **9** | **698** | **67** | **744** | **10** |
| 1991 | I | 0 | 0 | 0 | 0 | 1 | 683 | 1 | 683 | 1 |
| | II | 2 | 357 | 1 | 926 | 2 | 844 | 5 | 665 | 1 |
| | III | 19 | 577 | 20 | 611 | 9 | 724 | 48 | 619 | 9 |
| | N/A | 0 | 0 | 6 | 185 | 0 | 0 | 6 | 185 | 1 |
| | **Total** | **21** | **556** | **27** | **528** | **12** | **741** | **60** | **580** | **12** |
| 1992 | I | 1 | 1206 | 1 | 747 | 0 | 0 | 2 | 977 | 1 |
| | II | 4 | 589 | 2 | 419 | 1 | 0 | 7 | 456 | 0 |
| | III | 15 | 765 | 7 | 563 | 2 | 885 | 24 | 716 | 24 |
| | N/A | 1 | 837 | 1 | 888 | 2 | 437 | 4 | 650 | 4 |
| | **Total** | **21** | **756** | **11** | **583** | **5** | **529** | **37** | **674** | **29** |
| 1993 | I | 1 | 426 | 0 | 0 | 0 | 0 | 1 | 426 | 0 |
| | II | 0 | 0 | 1 | 468 | 1 | 447 | 2 | 458 | 1 |
| | III | 2 | 545 | 1 | 210 | 1 | 357 | 4 | 414 | 7 |
| | N/A | 4 | 627 | 10 | 419 | 0 | 0 | 14 | 479 | 11 |
| | **Total** | **7** | **575** | **12** | **406** | **2** | **402** | **21** | **462** | **19** |
| 1994 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 1 | 147 | 0 | 0 | 0 | 0 | 1 | 147 | 0 |
| | III | 2 | 211 | 0 | 0 | 0 | 0 | 2 | 211 | 7 |
| | N/A | 0 | 0 | 5 | 241 | 0 | 0 | 5 | 241 | 28 |
| | **Total** | **3** | **189** | **5** | **241** | **0** | **0** | **8** | **222** | **35** |
| 1995 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | III | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| | N/A | 0 | 0 | 1 | 23 | 0 | 0 | 1 | 23 | 13 |
| | **Total** | **0** | **0** | **1** | **23** | 0 | **0** | **1** | **23** | **18** |
| **Total** | | **133** | **586** | **105** | **602** | **37** | **581** | **275** | **591** | **126** |

**Table III.4: Average Days to Decision on Original PMAs by Tier of Medical Device and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Tier | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 27 | 325 | 5 | 849 | 0 | 0 | 32 | 407 | 0 |
| | 3 | 17 | 534 | 11 | 973 | 4 | 496 | 32 | 680 | 3 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 1 | 664 | 11 | 474 | 5 | 179 | 17 | 399 | 0 |
| | **Total** | **45** | **412** | **27** | **747** | **9** | **320** | **81** | **512** | **3** |
| **1990** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 15 | 586 | 3 | 731 | 4 | 1310 | 22 | 738 | 1 |
| | 3 | 19 | 936 | 8 | 1196 | 1 | 956 | 28 | 1011 | 9 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 2 | 353 | 11 | 411 | 4 | 21 | 17 | 313 | 0 |
| | **Total** | **36** | **758** | **22** | **740** | **9** | **698** | **67** | **744** | **10** |
| **1991** | | | | | | | | | | |
| | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 9 | 401 | 4 | 930 | 4 | 579 | 17 | 567 | 2 |
| | 3 | 12 | 673 | 18 | 526 | 7 | 841 | 37 | 633 | 8 |
| | Exempt | 0 | 0 | 0 | 0 | 1 | 683 | 1 | 683 | 1 |
| | N/A | 0 | 0 | 5 | 213 | 0 | 0 | 5 | 213 | 1 |
| | **Total** | **21** | **556** | **27** | **528** | **12** | **741** | **60** | **580** | **12** |
| **1992** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 9 | 712 | 5 | 467 | 2 | 564 | 16 | 617 | 4 |
| | 3 | 10 | 742 | 5 | 666 | 1 | 643 | 16 | 712 | 22 |
| | Exempt | 1 | 1206 | 1 | 747 | 0 | 0 | 2 | 977 | 1 |
| | N/A | 1 | 837 | 0 | 0 | 2 | 437 | 3 | 570 | 2 |
| | **Total** | **21** | **756** | **11** | **583** | **5** | **529** | **37** | **674** | **29** |
| **1993** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 1 | 426 | 1 | 468 | 2 | 402 | 4 | 425 | 1 |
| | 3 | 2 | 545 | 1 | 210 | 0 | 0 | 3 | 433 | 8 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 4 | 627 | 10 | 419 | 0 | 0 | 14 | 479 | 10 |
| | **Total** | **7** | **575** | **12** | **406** | **2** | **402** | **21** | **462** | **19** |
| **1994** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 1 | 147 | 0 | 0 | 0 | 0 | 1 | 147 | 2 |
| | 3 | 2 | 211 | 0 | 0 | 0 | 0 | 2 | 211 | 5 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 0 | 0 | 5 | 241 | 0 | 0 | 5 | 241 | 28 |
| | **Total** | **3** | **189** | **5** | **241** | **0** | **0** | **8** | **222** | **35** |
| **1995** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 23 | 0 |
| | N/A | 0 | 0 | 1 | 23 | 0 | 0 | 0 | 0 | 13 |
| | **Total** | **0** | **0** | **1** | **23** | **0** | **0** | **1** | **23** | **18** |
| **Total** | | **133** | **586** | **105** | **602** | **37** | **581** | **275** | **591** | **126** |

**Table III.5: Average Days to Decision on Original PMAs by Medical Specialty of Device and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Medical specialty | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | Cardiovascular | 9 | 546 | 2 | 1374 | 1 | 1 | 12 | 638 | 1 |
| | Ophthalmic | 25 | 306 | 3 | 538 | 0 | 0 | 28 | 331 | 0 |
| | Other | 11 | 543 | 11 | 962 | 3 | 661 | 25 | 742 | 2 |
| | N/A | 0 | 0 | 11 | 474 | 5 | 179 | 16 | 382 | 0 |
| | **Total** | **45** | **412** | **27** | **747** | **9** | **320** | **81** | **513** | **3** |
| **1990** | Cardiovascular | 7 | 942 | 1 | 993 | 1 | 956 | 9 | 949 | 2 |
| | Ophthalmic | 11 | 607 | 3 | 880 | 3 | 1447 | 17 | 803 | 3 |
| | Other | 18 | 779 | 7 | 1161 | 1 | 900 | 26 | 886 | 5 |
| | N/A | 0 | 0 | 11 | 411 | 4 | 21 | 15 | 307 | 0 |
| | **Total** | **36** | **758** | **22** | **740** | **9** | **698** | **67** | **744** | **10** |
| **1991** | Cardiovascular | 8 | 759 | 4 | 826 | 3 | 421 | 15 | 709 | 0 |
| | Ophthalmic | 9 | 401 | 3 | 931 | 3 | 618 | 15 | 550 | 3 |
| | Other | 4 | 499 | 15 | 473 | 6 | 962 | 25 | 594 | 8 |
| | N/A | 0 | 0 | 5 | 213 | 0 | 0 | 5 | 213 | 1 |
| | **Total** | **21** | **556** | **27** | **528** | **12** | **741** | **60** | **580** | **12** |
| **1992** | Cardiovascular | 7 | 757 | 1 | 819 | 0 | 0 | 8 | 765 | 5 |
| | Ophthalmic | 9 | 777 | 4 | 426 | 1 | 1127 | 14 | 702 | 7 |
| | Other | 4 | 684 | 6 | 648 | 2 | 322 | 12 | 606 | 15 |
| | N/A | 1 | 837 | 0 | 0 | 2 | 437 | 3 | 570 | 2 |
| | **Total** | **21** | **756** | **11** | **583** | **5** | **529** | **37** | **674** | **29** |
| **1993** | Cardiovascular | 2 | 545 | 0 | 0 | 0 | 0 | 2 | 545 | 4 |
| | Ophthalmic | 0 | 0 | 0 | 0 | 2 | 402 | 2 | 402 | 1 |
| | Other | 1 | 426 | 2 | 339 | 0 | 0 | 3 | 368 | 4 |
| | N/A | 4 | 627 | 10 | 419 | 0 | 0 | 14 | 479 | 10 |
| | **Total** | **7** | **575** | **12** | **406** | **2** | **402** | **21** | **462** | **19** |
| **1994** | Cardiovascular | 1 | 225 | 0 | 0 | 0 | 0 | 1 | 225 | 3 |
| | Ophthalmic | 1 | 147 | 0 | 0 | 0 | 0 | 1 | 147 | 2 |
| | Other | 1 | 196 | 0 | 0 | 0 | 0 | 1 | 196 | 2 |
| | N/A | 0 | 0 | 5 | 241 | 0 | 0 | 5 | 241 | 28 |
| | **Total** | **3** | **189** | **5** | **241** | **0** | **0** | **8** | **222** | **35** |
| **1995** | Cardiovascular | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | Ophthalmic | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| | Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | N/A | 0 | 0 | 1 | 23 | 0 | 0 | 1 | 23 | 13 |
| | **Total** | **0** | **0** | **1** | **23** | **0** | **0** | **1** | **23** | **18** |
| **Total** | | **133** | **586** | **105** | **602** | **37** | **581** | **275** | **591** | **126** |

**Table III.6: Average Days to Decision on Original PMAs by Reviewing Division and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Division | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | DCLD | 3 | 411 | 2 | 1087 | 0 | 0 | 5 | 682 | 1 |
| | DCRND | 10 | 583 | 9 | 722 | 1 | 1 | 20 | 617 | 1 |
| | DGRD | 3 | 551 | 3 | 858 | 4 | 691 | 10 | 699 | 1 |
| | DOD | 25 | 306 | 4 | 450 | 4 | 29 | 33 | 290 | 0 |
| | DRAER | 4 | 541 | 9 | 790 | 0 | 0 | 13 | 714 | 0 |
| | **Total** | **45** | **412** | **27** | **747** | **9** | **320** | **81** | **513** | **3** |
| **1990** | DCLD | 5 | 495 | 3 | 882 | 0 | 0 | 8 | 640 | 2 |
| | DCRND | 8 | 892 | 1 | 993 | 2 | 519 | 11 | 833 | 2 |
| | DGRD | 7 | 797 | 7 | 933 | 1 | 900 | 15 | 867 | 2 |
| | DOD | 11 | 607 | 8 | 522 | 6 | 724 | 25 | 608 | 3 |
| | DRAER | 5 | 1084 | 3 | 645 | 0 | 0 | 8 | 919 | 1 |
| | **Total** | **36** | **758** | **22** | **740** | **9** | **698** | **67** | **744** | **10** |
| **1991** | DCLD | 3 | 470 | 4 | 363 | 0 | 0 | 7 | 409 | 0 |
| | DCRND | 8 | 759 | 5 | 696 | 5 | 516 | 18 | 674 | 1 |
| | DGRD | 1 | 585 | 10 | 371 | 2 | 753 | 13 | 446 | 6 |
| | DOD | 9 | 401 | 5 | 615 | 3 | 618 | 17 | 502 | 3 |
| | DRAER | 0 | 0 | 3 | 848 | 2 | 1473 | 5 | 1098 | 2 |
| | **Total** | **21** | **556** | **27** | **528** | **12** | **741** | **60** | **580** | **12** |
| **1992** | DCLD | 3 | 727 | 3 | 619 | 2 | 322 | 8 | 585 | 4 |
| | DCRND | 7 | 757 | 2 | 666 | 0 | 0 | 9 | 737 | 7 |
| | DGRD | 1 | 837 | 1 | 632 | 2 | 437 | 4 | 586 | 3 |
| | DOD | 9 | 777 | 4 | 426 | 1 | 1127 | 14 | 702 | 8 |
| | DRAER | 1 | 556 | 1 | 888 | 0 | 0 | 2 | 722 | 7 |
| | **Total** | **21** | **756** | **11** | **583** | **5** | **529** | **37** | **674** | **29** |
| **1993** | DCLD | 1 | 426 | 3 | 356 | 0 | 0 | 4 | 373 | 4 |
| | DCRND | 2 | 545 | 2 | 308 | 0 | 0 | 4 | 426 | 6 |
| | DGRD | 0 | 0 | 3 | 288 | 0 | 0 | 3 | 288 | 6 |
| | DOD | 3 | 564 | 4 | 581 | 2 | 402 | 9 | 536 | 1 |
| | DRAER | 1 | 815 | 0 | 0 | 0 | 0 | 1 | 815 | 2 |
| | **Total** | **7** | **575** | **12** | **406** | **2** | **402** | **21** | **462** | **19** |
| **1994** | DCLD | 0 | 0 | 2 | 188 | 0 | 0 | 2 | 188 | 10 |
| | DCRND | 1 | 225 | 0 | 0 | 0 | 0 | 1 | 225 | 7 |
| | DGRD | 0 | 0 | 1 | 256 | 0 | 0 | 1 | 256 | 9 |
| | DOD | 1 | 147 | 2 | 287 | 0 | 0 | 3 | 240 | 5 |
| | DRAER | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 196 | 4 |
| | **Total** | **3** | **189** | **5** | **241** | **0** | **0** | **8** | **222** | **35** |
| **1995** | DCLD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| | DCRND | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | DGRD | 0 | 0 | 1 | 23 | 0 | 0 | 1 | 23 | 6 |
| | DOD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| | DRAER | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | **Total** | **0** | **0** | **1** | **23** | **0** | **0** | **1** | **23** | **18** |
| **Total** | | **133** | **586** | **105** | **602** | **37** | **581** | **275** | **591** | **126** |

**Table III.7: Average Days to Decision on PMA Supplements by Fiscal Year and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Percentile 5 | Percentile 50 | Percentile 95 | Mean | Open N | Open Days | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | 640 | 190 | 137 | 363 | 26 | 167 | 22 | 172 | 576 | 219 | 1 | 2057 | 804 |
| **1990** | 557 | 164 | 70 | 442 | 23 | 142 | 18 | 125 | 597 | 193 | 10 | 1870 | 660 |
| **1991** | 493 | 226 | 72 | 462 | 12 | 479 | 18 | 154 | 1042 | 261 | 18 | 1476 | 595 |
| **1992** | 474 | 300 | 84 | 478 | 13 | 747 | 24 | 251 | 924 | 336 | 34 | 1119 | 605 |
| **1993** | 311 | 250 | 30 | 403 | 10 | 372 | 22 | 217 | 674 | 266 | 43 | 747 | 394 |
| **1994** | 269 | 165 | 22 | 141 | 4 | 75 | 21 | 144 | 378 | 162 | 77 | 394 | 372 |
| **1995** | 78 | 80 | 5 | 74 | 1 | 39 | 21 | 75 | 182 | 79 | 126 | 120 | 210 |
| **Total** | **2822** | **211** | **420** | **404** | **89** | **305** | **21** | **167** | **749** | **238** | **309** | **527** | **3640** |

**Table III.8: Summary of Average Days to Decision on PMA Supplements and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| | Approved | | | Withdrawn | | | Other | | | Percentile | | | | Open | | Grand |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Class | N | Percent | Days | N | Percent | Days | N | Percent | Days | 5 | 50 | 95 | Mean | N | Percent | total |
| I | 2 | 25.0 | 98 | 2 | 25.0 | 740 | 1 | 12.5 | 0 | 0 | 114 | 1329 | 335 | 3 | 37.5 | 8 |
| II | 588 | 83.3 | 159 | 66 | 9.3 | 390 | 22 | 3.1 | 479 | 16 | 105 | 699 | 192 | 30 | 4.2 | 706 |
| III | 2223 | 76.4 | 224 | 350 | 12.0 | 405 | 65 | 2.2 | 244 | 23 | 176 | 758 | 249 | 272 | 9.3 | 2910 |
| N/A | 9 | 56.3 | 276 | 2 | 12.5 | 353 | 1 | 6.3 | 746 | 22 | 193 | 777 | 328 | 4 | 25.0 | 16 |
| **Tier** | | | | | | | | | | | | | | | | |
| 1 | 2 | 33.3 | 98 | 2 | 33.3 | 740 | 1 | 16.7 | 0 | 0 | 114 | 1329 | 335 | 1 | 16.7 | 6 |
| 2 | 1317 | 76.5 | 229 | 265 | 15.4 | 369 | 38 | 2.2 | 359 | 21 | 171 | 840 | 255 | 101 | 5.9 | 1721 |
| 3 | 1487 | 78.7 | 195 | 151 | 8.0 | 464 | 49 | 2.6 | 261 | 21 | 161 | 647 | 221 | 202 | 10.7 | 1889 |
| Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| N/A | 16 | 66.7 | 241 | 2 | 8.3 | 206 | 1 | 4.2 | 746 | 30 | 212 | 777 | 264 | 5 | 20.8 | 24 |
| **Medical specialty** | | | | | | | | | | | | | | | | |
| Cardiovascular | 985 | 81.2 | 183 | 83 | 6.8 | 476 | 22 | 1.8 | 63 | 20 | 159 | 576 | 203 | 123 | 10.1 | 1213 |
| Ophthalmic | 1239 | 77.3 | 229 | 251 | 15.7 | 346 | 36 | 2.2 | 354 | 20 | 173 | 767 | 251 | 77 | 4.8 | 1603 |
| Other | 592 | 72.8 | 218 | 86 | 10.6 | 503 | 30 | 3.7 | 409 | 25 | 165 | 924 | 261 | 105 | 12.9 | 813 |
| N/A | 6 | 54.5 | 371 | 0 | 0 | 0 | 1 | 9.1 | 746 | 30 | 468 | 777 | 425 | 4 | 36.4 | 11 |
| **Division** | | | | | | | | | | | | | | | | |
| DCLD | 131 | 74.9 | 201 | 21 | 12.0 | 430 | 3 | 1.7 | 176 | 28 | 140 | 829 | 232 | 20 | 11.4 | 175 |
| DCRND | 1025 | 80.7 | 186 | 86 | 6.8 | 478 | 22 | 1.7 | 63 | 20 | 160 | 585 | 205 | 137 | 10.8 | 1270 |
| DGRD | 253 | 72.7 | 222 | 36 | 10.3 | 520 | 20 | 5.7 | 367 | 25 | 174 | 1015 | 266 | 39 | 11.2 | 348 |
| DOD | 1244 | 77.3 | 228 | 252 | 15.7 | 345 | 36 | 2.2 | 354 | 20 | 173 | 767 | 251 | 78 | 4.8 | 1610 |
| DRAER | 169 | 71.3 | 226 | 25 | 10.5 | 552 | 8 | 3.4 | 643 | 19 | 165 | 961 | 283 | 35 | 14.8 | 237 |
| **Total** | **2822** | **77.5** | **211** | **420** | **11.5** | **404** | **89** | **2.4** | **305** | **21** | **167** | **749** | **238** | **309** | **8.5** | **3640** |

**Table III.9: Average Days to Decision on PMA Supplements by Class of Medical Device and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Class | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 154 | 170 | 10 | 394 | 8 | 409 | 172 | 194 | 0 |
| | III | 485 | 195 | 127 | 361 | 18 | 60 | 630 | 225 | 1 |
| | N/A | 1 | 569 | 0 | 0 | 0 | 0 | 1 | 569 | 0 |
| | **Total** | **640** | **190** | **137** | **363** | **26** | **167** | **803** | **219** | **1** |
| 1990 | I | 1 | 114 | 2 | 740 | 1 | 0 | 4 | 398 | 0 |
| | II | 116 | 127 | 8 | 294 | 8 | 187 | 132 | 141 | 1 |
| | III | 439 | 174 | 58 | 455 | 14 | 127 | 511 | 205 | 9 |
| | N/A | 1 | 131 | 2 | 353 | 0 | 0 | 3 | 279 | 0 |
| | **Total** | **557** | **164** | **70** | **442** | **23** | **142** | **650** | **193** | **10** |
| 1991 | I | 1 | 81 | 0 | 0 | 0 | 0 | 1 | 81 | 0 |
| | II | 112 | 154 | 15 | 391 | 4 | 937 | 131 | 205 | 1 |
| | III | 379 | 247 | 57 | 481 | 7 | 180 | 443 | 276 | 17 |
| | N/A | 1 | 777 | 0 | 0 | 1 | 746 | 2 | 762 | 0 |
| | **Total** | **493** | **226** | **72** | **462** | **12** | **479** | **577** | **261** | **18** |
| 1992 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 85 | 206 | 18 | 482 | 1 | 1161 | 104 | 263 | 2 |
| | III | 388 | 320 | 66 | 477 | 12 | 713 | 466 | 352 | 32 |
| | N/A | 1 | 468 | 0 | 0 | 0 | 0 | 1 | 468 | 0 |
| | **Total** | **474** | **300** | **84** | **478** | **13** | **747** | **571** | **336** | **34** |
| 1993 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | II | 71 | 162 | 10 | 476 | 1 | 877 | 82 | 209 | 3 |
| | III | 240 | 276 | 20 | 366 | 9 | 316 | 269 | 284 | 37 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | **Total** | **311** | **250** | **30** | **403** | **10** | **372** | **351** | **266** | **43** |
| 1994 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | II | 44 | 133 | 5 | 32 | 0 | 0 | 49 | 122 | 9 |
| | III | 222 | 172 | 17 | 173 | 4 | 75 | 243 | 171 | 66 |
| | N/A | 3 | 138 | 0 | 0 | 0 | 0 | 3 | 138 | 1 |
| | **Total** | **269** | **165** | **22** | **141** | **4** | **75** | **295** | **162** | **77** |
| 1995 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 6 | 57 | 0 | 0 | 0 | 0 | 6 | 57 | 14 |
| | III | 70 | 82 | 5 | 74 | 1 | 39 | 76 | 81 | 110 |
| | N/A | 2 | 64 | 0 | 0 | 0 | 0 | 2 | 64 | 2 |
| | **Total** | **78** | **80** | **5** | **74** | **1** | **39** | **84** | **79** | **126** |
| **Total** | | **2822** | **211** | **420** | **404** | **89** | **305** | **3331** | **238** | **309** |

**Table III.10: Average Days to Decision on PMA Supplements by Tier of Medical Device and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Tier | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 399 | 214 | 105 | 340 | 12 | 50 | 516 | 235 | 0 |
| | 3 | 238 | 149 | 32 | 440 | 14 | 268 | 284 | 188 | 1 |
| | N/A | 3 | 243 | 0 | 0 | 0 | 0 | 3 | 243 | 0 |
| | **Total** | **640** | **190** | **137** | **363** | **26** | **167** | **803** | **219** | **1** |
| **1990** | 1 | 1 | 114 | 2 | 740 | 1 | 0 | 4 | 398 | 0 |
| | 2 | 283 | 166 | 38 | 337 | 6 | 0 | 327 | 183 | 4 |
| | 3 | 268 | 163 | 29 | 570 | 16 | 205 | 313 | 202 | 6 |
| | N/A | 5 | 163 | 1 | 93 | 0 | 0 | 6 | 151 | 0 |
| | **Total** | **557** | **164** | **70** | **442** | **23** | **142** | **650** | **193** | **10** |
| **1991** | | | | | | | | | | |
| | 1 | 1 | 81 | 0 | 0 | 0 | 0 | 1 | 81 | 0 |
| | 2 | 227 | 263 | 47 | 405 | 8 | 580 | 282 | 296 | 6 |
| | 3 | 263 | 194 | 25 | 570 | 3 | 123 | 291 | 225 | 12 |
| | N/A | 2 | 412 | 0 | 0 | 1 | 746 | 3 | 523 | 0 |
| | **Total** | **493** | **226** | **72** | **462** | **12** | **479** | **577** | **261** | **18** |
| **1992** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 196 | 345 | 46 | 487 | 7 | 749 | 249 | 383 | 7 |
| | 3 | 276 | 267 | 37 | 471 | 6 | 744 | 319 | 299 | 27 |
| | N/A | 2 | 409 | 1 | 318 | 0 | 0 | 3 | 379 | 0 |
| | **Total** | **474** | **300** | **84** | **478** | **13** | **747** | **571** | **336** | **34** |
| **1993** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 2 | 117 | 257 | 17 | 424 | 5 | 631 | 139 | 291 | 20 |
| | 3 | 194 | 245 | 13 | 374 | 5 | 114 | 212 | 250 | 21 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | **Total** | **311** | **250** | **30** | **403** | **10** | **372** | **351** | **266** | **43** |
| **1994** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 75 | 137 | 11 | 49 | 0 | 0 | 86 | 126 | 23 |
| | 3 | 190 | 177 | 11 | 233 | 4 | 75 | 205 | 178 | 52 |
| | N/A | 4 | 166 | 0 | 0 | 0 | 0 | 4 | 166 | 2 |
| | **Total** | **269** | **165** | **22** | **141** | **4** | **75** | **295** | **162** | **77** |
| **1995** | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 20 | 56 | 1 | 49 | 0 | 0 | 21 | 56 | 41 |
| | 3 | 58 | 88 | 4 | 81 | 1 | 39 | 63 | 87 | 83 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | **Total** | **78** | **80** | **5** | **74** | **1** | **39** | **84** | **79** | **126** |
| **Total** | | **2822** | **211** | **420** | **404** | **89** | **305** | **3331** | **238** | **309** |

**Table III.11: Average Days to Decision on PMA Supplements by Medical Specialty of Device and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Medical specialty | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | Cardiovascular | 135 | 137 | 14 | 403 | 6 | 62 | 155 | 158 | 0 |
| | Ophthalmic | 392 | 214 | 106 | 343 | 12 | 50 | 510 | 237 | 0 |
| | Other | 112 | 165 | 17 | 460 | 8 | 423 | 137 | 216 | 1 |
| | N/A | 1 | 569 | 0 | 0 | 0 | 0 | 1 | 569 | 0 |
| | **Total** | **640** | **190** | **137** | **363** | **26** | **167** | **803** | **219** | **1** |
| **1990** | Cardiovascular | 180 | 149 | 14 | 573 | 7 | 1 | 201 | 173 | 0 |
| | Ophthalmic | 273 | 173 | 37 | 310 | 6 | 0 | 316 | 185 | 4 |
| | Other | 103 | 170 | 19 | 601 | 10 | 327 | 132 | 244 | 6 |
| | N/A | 1 | 131 | 0 | 0 | 0 | 0 | 1 | 131 | 0 |
| | **Total** | **557** | **164** | **70** | **442** | **23** | **142** | **650** | **193** | **10** |
| **1991** | Cardiovascular | 177 | 168 | 7 | 714 | 1 | 197 | 185 | 189 | 7 |
| | Ophthalmic | 211 | 258 | 46 | 356 | 7 | 662 | 264 | 286 | 4 |
| | Other | 104 | 256 | 19 | 626 | 3 | 58 | 126 | 307 | 7 |
| | N/A | 1 | 777 | 0 | 0 | 1 | 746 | 2 | 762 | 0 |
| | **Total** | **493** | **226** | **72** | **462** | **12** | **479** | **577** | **261** | **18** |
| **1992** | Cardiovascular | 171 | 255 | 29 | 528 | 1 | 197 | 201 | 294 | 19 |
| | Ophthalmic | 180 | 352 | 37 | 478 | 7 | 749 | 224 | 385 | 6 |
| | Other | 122 | 284 | 18 | 396 | 5 | 854 | 145 | 318 | 9 |
| | N/A | 1 | 468 | 0 | 0 | 0 | 0 | 1 | 468 | 0 |
| | **Total** | **474** | **300** | **84** | **478** | **13** | **747** | **571** | **336** | **34** |
| **1993** | Cardiovascular | 139 | 235 | 7 | 451 | 4 | 140 | 150 | 242 | 13 |
| | Ophthalmic | 95 | 262 | 14 | 318 | 4 | 570 | 113 | 279 | 16 |
| | Other | 77 | 263 | 9 | 496 | 2 | 442 | 88 | 291 | 13 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | **Total** | **311** | **250** | **30** | **403** | **10** | **372** | **351** | **266** | **43** |
| **1994** | Cardiovascular | 140 | 186 | 9 | 235 | 2 | 3 | 151 | 186 | 27 |
| | Ophthalmic | 68 | 117 | 10 | 53 | 0 | 0 | 78 | 109 | 13 |
| | Other | 59 | 173 | 3 | 153 | 2 | 148 | 64 | 171 | 36 |
| | N/A | 2 | 141 | 0 | 0 | 0 | 0 | 2 | 141 | 1 |
| | **Total** | **269** | **165** | **22** | **141** | **4** | **75** | **295** | **162** | **77** |
| **1995** | Cardiovascular | 43 | 77 | 3 | 89 | 1 | 39 | 47 | 77 | 57 |
| | Ophthalmic | 20 | 74 | 1 | 49 | 0 | 0 | 21 | 73 | 34 |
| | Other | 15 | 95 | 1 | 57 | 0 | 0 | 16 | 93 | 33 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | **Total** | **78** | **80** | **5** | **74** | **1** | **39** | **84** | **79** | **126** |
| **Total** | | **2822** | **211** | **420** | **404** | **89** | **305** | **3331** | **238** | **309** |

**Table III.12: Average Days to Decision on PMA Supplements by Reviewing Division and Number of Open Cases (October 1, 1988 - May 18, 1995)**

| Fiscal year | Division | Approved N | Approved Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days | Open N |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | DCLD | 29 | 112 | 1 | 106 | 0 | 0 | 30 | 112 | 0 |
| | DCRND | 142 | 137 | 15 | 392 | 6 | 62 | 163 | 157 | 0 |
| | DGRD | 57 | 189 | 6 | 421 | 6 | 540 | 69 | 240 | 0 |
| | DOD | 394 | 214 | 106 | 343 | 12 | 50 | 512 | 237 | 0 |
| | DRAER | 18 | 192 | 9 | 549 | 2 | 71 | 29 | 295 | 1 |
| | **Total** | **640** | **190** | **137** | **363** | **26** | **167** | **803** | **219** | **1** |
| 1990 | DCLD | 21 | 110 | 4 | 370 | 0 | 0 | 25 | 152 | 1 |
| | DCRND | 186 | 149 | 14 | 573 | 7 | 1 | 207 | 172 | 1 |
| | DGRD | 48 | 168 | 8 | 798 | 8 | 187 | 64 | 249 | 1 |
| | DOD | 274 | 173 | 38 | 304 | 6 | 0 | 318 | 185 | 4 |
| | DRAER | 28 | 216 | 6 | 577 | 2 | 887 | 36 | 313 | 3 |
| | **Total** | **557** | **164** | **70** | **442** | **23** | **142** | **650** | **193** | **10** |
| 1991 | DCLD | 30 | 247 | 3 | 740 | 1 | 11 | 34 | 283 | 1 |
| | DCRND | 185 | 178 | 7 | 714 | 1 | 197 | 193 | 198 | 8 |
| | DGRD | 34 | 257 | 12 | 583 | 2 | 373 | 48 | 343 | 5 |
| | DOD | 211 | 258 | 46 | 356 | 7 | 662 | 264 | 286 | 4 |
| | DRAER | 33 | 247 | 4 | 668 | 1 | 162 | 38 | 289 | 0 |
| | **Total** | **493** | **226** | **72** | **462** | **12** | **479** | **577** | **261** | **18** |
| 1992 | DCLD | 22 | 290 | 8 | 219 | 1 | 223 | 31 | 270 | 2 |
| | DCRND | 177 | 259 | 30 | 550 | 1 | 197 | 208 | 300 | 22 |
| | DGRD | 43 | 334 | 5 | 338 | 1 | 979 | 49 | 347 | 3 |
| | DOD | 180 | 352 | 37 | 478 | 7 | 749 | 224 | 385 | 6 |
| | DRAER | 52 | 236 | 4 | 629 | 3 | 1023 | 59 | 303 | 1 |
| | **Total** | **474** | **300** | **84** | **478** | **13** | **747** | **571** | **336** | **34** |
| 1993 | DCLD | 15 | 284 | 5 | 693 | 0 | 0 | 20 | 387 | 2 |
| | DCRND | 145 | 233 | 7 | 451 | 4 | 140 | 156 | 241 | 15 |
| | DGRD | 35 | 247 | 2 | 395 | 2 | 442 | 39 | 264 | 3 |
| | DOD | 95 | 262 | 14 | 318 | 4 | 570 | 113 | 279 | 16 |
| | DRAER | 21 | 291 | 2 | 108 | 0 | 0 | 23 | 275 | 7 |
| | **Total** | **311** | **250** | **30** | **403** | **10** | **372** | **351** | **266** | **43** |
| 1994 | DCLD | 10 | 223 | 0 | 0 | 1 | 295 | 11 | 229 | 7 |
| | DCRND | 146 | 186 | 10 | 231 | 2 | 3 | 158 | 187 | 31 |
| | DGRD | 29 | 169 | 2 | 131 | 1 | 0 | 32 | 161 | 15 |
| | DOD | 70 | 118 | 10 | 53 | 0 | 0 | 80 | 110 | 13 |
| | DRAER | 14 | 137 | 0 | 0 | 0 | 0 | 14 | 137 | 11 |
| | **Total** | **269** | **165** | **22** | **141** | **4** | **75** | **295** | **162** | **77** |
| 1995 | DCLD | 4 | 124 | 0 | 0 | 0 | 0 | 4 | 124 | 7 |
| | DCRND | 44 | 77 | 3 | 89 | 1 | 39 | 48 | 77 | 60 |
| | DGRD | 7 | 92 | 1 | 57 | 0 | 0 | 8 | 88 | 12 |
| | DOD | 20 | 74 | 1 | 49 | 0 | 0 | 21 | 73 | 35 |
| | DRAER | 3 | 66 | 0 | 0 | 0 | 0 | 3 | 68 | 12 |
| | **Total** | **78** | **80** | **5** | **74** | **1** | **39** | **84** | **79** | **126** |
| **Total** | | **2822** | **211** | **420** | **404** | **89** | **305** | **3331** | **238** | **309** |

Table III.13: Average Days to Approval for PMAs by Fiscal Year (October 1, 1988 - May 18, 1995)

Original PMAs

| Fiscal year | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | Percentiles for time lapse 5 | 50 | 95 | Number of amendments | Requests for information |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | 45 | 230 | 320 | 92 | 412 | 71 | 351 | 954 | 8 | 3 |
| 1990 | 36 | 327 | 547 | 211 | 758 | 168 | 530 | 1702 | 12 | 4 |
| 1991 | 21 | 264 | 441 | 115 | 556 | 60 | 585 | 1023 | 8 | 3 |
| 1992 | 21 | 346 | 591 | 165 | 756 | 495 | 780 | 1060 | 12 | 4 |
| 1993 | 7 | 264 | 495 | 80 | 575 | 327 | 557 | 815 | 9 | 3 |
| 1994 | 3 | 138 | 155 | 34 | 189 | 147 | 196 | 225 | 1 | 2 |
| 1995 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total** | **133** | **280** | **449** | **137** | **586** | **72** | **501** | **1421** | **10** | **3** |

PMA supplements

| Fiscal year | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | Percentiles for time lapse 5 | 50 | 95 | Number of amendments | Requests for information |
|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | 640 | 113 | 126 | 64 | 190 | 24 | 160 | 484 | 1 | 1 |
| 1990 | 557 | 85 | 105 | 59 | 164 | 20 | 115 | 448 | 1 | 1 |
| 1991 | 493 | 117 | 147 | 79 | 226 | 18 | 139 | 965 | 1 | 1 |
| 1992 | 474 | 164 | 202 | 98 | 300 | 23 | 204 | 878 | 1 | 2 |
| 1993 | 311 | 135 | 157 | 93 | 250 | 22 | 204 | 618 | 1 | 1 |
| 1994 | 269 | 96 | 109 | 56 | 165 | 22 | 153 | 378 | 1 | 1 |
| 1995 | 78 | 29 | 29 | 51 | 80 | 21 | 78 | 192 | 0 | 1 |
| **Total** | **2822** | **115** | **137** | **74** | **211** | **22** | **151** | **639** | **1** | **1** |

**Table III.14: Average Days to Approval for PMAs by Class, Tier, Medical Specialty, and Reviewing Division (October 1, 1988 - May 18, 1995)**

| | Original PMAs | | | | | PMA supplements | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Class | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | N | FDA review time | Total FDA time | Non-FDA time | Time lapse |
| I | 3 | 267 | 353 | 283 | 636 | 2 | 57 | 57 | 41 | 98 |
| II | 25 | 210 | 303 | 61 | 364 | 588 | 92 | 105 | 54 | 159 |
| III | 99 | 299 | 478 | 152 | 630 | 2223 | 121 | 146 | 79 | 225 |
| N/A | 6 | 255 | 625 | 141 | 766 | 9 | 120 | 188 | 88 | 276 |
| **Tier** | | | | | | | | | | |
| 1 | 0 | 0 | 0 | 0 | 0 | 2 | 57 | 57 | 41 | 98 |
| 2 | 62 | 269 | 365 | 89 | 454 | 1317 | 139 | 158 | 71 | 229 |
| 3 | 62 | 294 | 531 | 176 | 707 | 1487 | 94 | 118 | 77 | 195 |
| Exempt | 1 | 301 | 380 | 826 | 1206 | 0 | 0 | 0 | 0 | 0 |
| N/A | 8 | 246 | 464 | 125 | 589 | 16 | 145 | 180 | 61 | 241 |
| **Medical specialty** | | | | | | | | | | |
| Cardiovascular | 34 | 233 | 542 | 170 | 712 | 985 | 85 | 111 | 72 | 183 |
| Ophthalmic | 55 | 280 | 359 | 97 | 456 | 1239 | 138 | 158 | 71 | 229 |
| Other | 39 | 323 | 482 | 168 | 650 | 592 | 115 | 137 | 81 | 218 |
| N/A | 5 | 262 | 560 | 109 | 669 | 6 | 156 | 244 | 127 | 371 |
| **Division** | | | | | | | | | | |
| DCLD | 15 | 353 | 433 | 82 | 515 | 131 | 136 | 147 | 54 | 201 |
| DCRND | 36 | 229 | 540 | 173 | 713 | 1025 | 86 | 113 | 73 | 186 |
| DGRD | 12 | 312 | 496 | 225 | 721 | 253 | 116 | 125 | 97 | 222 |
| DOD | 58 | 282 | 366 | 95 | 461 | 1244 | 138 | 157 | 71 | 228 |
| DRAER | 12 | 297 | 548 | 215 | 763 | 169 | 102 | 148 | 78 | 226 |
| **Total** | **133** | **280** | **449** | **137** | **586** | **2822** | **115** | **137** | **74** | **211** |

**Table III.15: Average Days to Approval for PMAs by Fiscal Year and Class of Medical Device (October 1, 1988 - May 18, 1995)**

| | | Original PMAs | | | | | PMA supplements | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fiscal year | Class | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | N | FDA review time | Total FDA time | Non-FDA time | Time lapse |
| 1989 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 14 | 161 | 208 | 61 | 269 | 154 | 100 | 112 | 58 | 170 |
| | III | 31 | 262 | 370 | 106 | 476 | 485 | 116 | 129 | 66 | 195 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 1 | 335 | 335 | 234 | 569 |
| | **Total** | **45** | **230** | **320** | **92** | **412** | **640** | **113** | **126** | **64** | **190** |
| 1990 | I | 1 | 74 | 254 | 23 | 277 | 1 | 114 | 114 | 0 | 114 |
| | II | 4 | 211 | 450 | 82 | 532 | 116 | 70 | 78 | 49 | 127 |
| | III | 30 | 354 | 556 | 231 | 787 | 439 | 89 | 112 | 62 | 174 |
| | N/A | 1 | 224 | 953 | 299 | 1252 | 1 | 0 | 0 | 131 | 131 |
| | **Total** | **36** | **327** | **547** | **211** | **758** | **557** | **85** | **105** | **59** | **164** |
| 1991 | I | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 81 | 81 |
| | II | 2 | 143 | 267 | 90 | 357 | 112 | 90 | 110 | 44 | 154 |
| | III | 19 | 277 | 460 | 117 | 577 | 379 | 125 | 158 | 89 | 247 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 1 | 230 | 500 | 277 | 777 |
| | **Total** | **21** | **264** | **441** | **115** | **556** | **493** | **117** | **147** | **79** | **226** |
| 1992 | I | 1 | 301 | 380 | 826 | 1206 | 0 | 0 | 0 | 0 | 0 |
| | II | 4 | 458 | 558 | 31 | 589 | 85 | 132 | 157 | 49 | 206 |
| | III | 15 | 328 | 601 | 164 | 765 | 388 | 171 | 211 | 109 | 320 |
| | N/A | 1 | 214 | 778 | 59 | 837 | 1 | 118 | 379 | 89 | 468 |
| | **Total** | **21** | **346** | **591** | **165** | **756** | **474** | **164** | **202** | **98** | **300** |
| 1993 | I | 1 | 426 | 426 | 0 | 426 | 0 | 0 | 0 | 0 | 0 |
| | II | 0 | 0 | 0 | 0 | 0 | 71 | 87 | 92 | 70 | 162 |
| | III | 2 | 164 | 506 | 39 | 545 | 240 | 149 | 175 | 100 | 276 |
| | N/A | 4 | 274 | 505 | 122 | 627 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **7** | **264** | **495** | **80** | **575** | **311** | **135** | **157** | **93** | **250** |
| 1994 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 1 | 49 | 101 | 46 | 147 | 44 | 63 | 64 | 69 | 133 |
| | III | 2 | 182 | 182 | 29 | 211 | 222 | 102 | 119 | 53 | 172 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 3 | 98 | 124 | 14 | 138 |
| | **Total** | **3** | **138** | **155** | **34** | **189** | **269** | **96** | **109** | **56** | **165** |
| 1995 | I | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | II | 0 | 0 | 0 | 0 | 0 | 6 | 52 | 52 | 6 | 58 |
| | III | 0 | 0 | 0 | 0 | 0 | 70 | 26 | 25 | 57 | 82 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 2 | 53 | 53 | 11 | 64 |
| | **Total** | **0** | **0** | **0** | **0** | **0** | **78** | **29** | **29** | **51** | **80** |
| **Total** | | **133** | **280** | **449** | **137** | **586** | **2822** | **115** | **137** | **74** | **211** |

Table III.16: Average Days to Approval for PMAs by Fiscal Year and Tier of Medical Device (October 1, 1988 - May 18, 1995)

| | | Original PMAs | | | | | PMA supplements | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fiscal year | Tier | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | N | FDA review time | Total FDA time | Non-FDA time | Time lapse |
| 1989 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 27 | 196 | 265 | 60 | 325 | 399 | 138 | 149 | 65 | 214 |
| | 3 | 17 | 279 | 404 | 130 | 534 | 238 | 70 | 87 | 62 | 149 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 1 | 335 | 376 | 288 | 664 | 3 | 127 | 134 | 109 | 243 |
| | **Total** | **45** | **230** | **320** | **92** | **412** | **640** | **113** | **126** | **64** | **190** |
| 1990 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 114 | 114 | 0 | 114 |
| | 2 | 15 | 317 | 461 | 125 | 586 | 283 | 101 | 116 | 50 | 166 |
| | 3 | 19 | 351 | 644 | 292 | 936 | 268 | 68 | 94 | 69 | 163 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 2 | 163 | 268 | 85 | 353 | 5 | 113 | 113 | 50 | 163 |
| | **Total** | **36** | **327** | **547** | **211** | **758** | **557** | **85** | **105** | **59** | **164** |
| 1991 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 81 | 81 |
| | 2 | 9 | 273 | 318 | 83 | 401 | 227 | 142 | 182 | 82 | 264 |
| | 3 | 12 | 257 | 535 | 138 | 673 | 263 | 95 | 117 | 77 | 194 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 2 | 139 | 273 | 139 | 412 |
| | **Total** | **21** | **264** | **441** | **115** | **556** | **493** | **117** | **147** | **79** | **226** |
| 1992 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 9 | 413 | 577 | 135 | 712 | 196 | 226 | 260 | 85 | 345 |
| | 3 | 10 | 304 | 605 | 137 | 742 | 276 | 119 | 159 | 108 | 267 |
| | Exempt | 1 | 301 | 380 | 826 | 1206 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 1 | 214 | 778 | 59 | 837 | 2 | 234 | 364 | 45 | 409 |
| | **Total** | **21** | **346** | **591** | **165** | **756** | **474** | **164** | **202** | **98** | **300** |
| 1993 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 1 | 426 | 426 | 0 | 426 | 117 | 138 | 145 | 112 | 257 |
| | 3 | 2 | 164 | 506 | 39 | 545 | 194 | 134 | 163 | 82 | 245 |
| | Exempt | 4 | 274 | 505 | 122 | 627 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **7** | **264** | **495** | **80** | **575** | **311** | **135** | **157** | **93** | **250** |
| 1994 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 1 | 49 | 101 | 46 | 147 | 75 | 83 | 83 | 54 | 137 |
| | 3 | 2 | 182 | 182 | 29 | 211 | 190 | 100 | 120 | 57 | 177 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 4 | 158 | 158 | 8 | 166 |
| | **Total** | **3** | **138** | **155** | **34** | **189** | **269** | **96** | **109** | **56** | **165** |
| 1995 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 0 | 0 | 0 | 0 | 0 | 20 | 36 | 37 | 20 | 57 |
| | 3 | 0 | 0 | 0 | 0 | 0 | 58 | 26 | 26 | 62 | 88 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **0** | **0** | **0** | **0** | **0** | **78** | **29** | **29** | **51** | **80** |
| **Total** | | **133** | **280** | **449** | **137** | **586** | **2822** | **115** | **137** | **74** | **211** |

**Table III.17: Average Days to Approval for PMAs by Fiscal Year and Medical Specialty of Device (October 1, 1988 - May 18, 1995)**

| | | Original PMAs | | | | | PMA supplements | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fiscal year | Medical specialty | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | N | FDA review time | Total FDA time | Non-FDA time | Time lapse |
| 1989 | Cardiovascular | 9 | 226 | 409 | 137 | 546 | 135 | 54 | 74 | 64 | 138 |
| | Opthalmic | 25 | 214 | 266 | 40 | 306 | 392 | 137 | 149 | 65 | 214 |
| | Other | 11 | 270 | 371 | 172 | 543 | 112 | 95 | 106 | 59 | 165 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 1 | 335 | 335 | 234 | 569 |
| | **Total** | **45** | **230** | **320** | **92** | **412** | **640** | **113** | **126** | **64** | **190** |
| 1990 | Cardiovascular | 7 | 238 | 632 | 310 | 942 | 180 | 65 | 90 | 59 | 149 |
| | Opthalmic | 11 | 374 | 468 | 139 | 607 | 273 | 105 | 122 | 51 | 173 |
| | Other | 18 | 333 | 563 | 216 | 779 | 103 | 68 | 90 | 80 | 170 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 131 | 131 |
| | **Total** | **36** | **327** | **547** | **211** | **758** | **557** | **85** | **105** | **59** | **164** |
| 1991 | Cardiovascular | 8 | 218 | 603 | 156 | 759 | 177 | 84 | 101 | 67 | 168 |
| | Opthalmic | 9 | 273 | 318 | 83 | 401 | 211 | 137 | 176 | 82 | 258 |
| | Other | 4 | 337 | 397 | 102 | 499 | 104 | 131 | 161 | 95 | 256 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 1 | 230 | 500 | 277 | 777 |
| | **Total** | **21** | **264** | **441** | **115** | **556** | **493** | **117** | **147** | **79** | **226** |
| 1992 | Cardiovascular | 7 | 283 | 614 | 143 | 757 | 171 | 110 | 156 | 99 | 255 |
| | Opthalmic | 9 | 378 | 550 | 227 | 777 | 180 | 222 | 255 | 97 | 352 |
| | Other | 4 | 418 | 592 | 92 | 684 | 122 | 152 | 185 | 99 | 284 |
| | N/A | 1 | 214 | 778 | 59 | 837 | 1 | 118 | 379 | 89 | 468 |
| | **Total** | **21** | **346** | **591** | **165** | **756** | **474** | **164** | **202** | **98** | **300** |
| 1993 | Cardiovascular | 2 | 164 | 506 | 39 | 545 | 139 | 122 | 153 | 82 | 235 |
| | Opthalmic | 0 | 0 | 0 | 0 | 0 | 95 | 147 | 156 | 106 | 262 |
| | Other | 1 | 426 | 426 | 0 | 426 | 77 | 143 | 166 | 97 | 263 |
| | N/A | 4 | 274 | 505 | 122 | 627 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **7** | **264** | **495** | **80** | **575** | **311** | **135** | **157** | **93** | **250** |
| 1994 | Cardiovascular | 1 | 168 | 168 | 57 | 225 | 140 | 96 | 120 | 66 | 186 |
| | Opthalmic | 1 | 49 | 101 | 46 | 147 | 68 | 80 | 79 | 38 | 117 |
| | Other | 1 | 196 | 196 | 0 | 196 | 59 | 114 | 120 | 53 | 173 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 2 | 126 | 126 | 15 | 141 |
| | **Total** | **3** | **138** | **155** | **34** | **189** | **269** | **96** | **109** | **56** | **165** |
| 1995 | Cardiovascular | 0 | 0 | 0 | 0 | 0 | 43 | 16 | 17 | 61 | 78 |
| | Opthalmic | 0 | 0 | 0 | 0 | 0 | 20 | 38 | 38 | 36 | 74 |
| | Other | 0 | 0 | 0 | 0 | 0 | 15 | 51 | 51 | 44 | 95 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **0** | **0** | **0** | **0** | **0** | **78** | **29** | **29** | **51** | **80** |
| **Total** | | **133** | **280** | **449** | **137** | **586** | **2822** | **115** | **137** | **74** | **211** |

Table III.18: Average Days to Approval for PMAs by Fiscal Year and Reviewing Division (October 1, 1988 - May 18, 1995)

| | | Original PMAs | | | | | PMA supplements | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fiscal year | Division | N | FDA review time | Total FDA time | Non-FDA time | Time lapse | N | FDA review time | Total FDA time | Non-FDA time | Time lapse |
| 1989 | DCLD | 3 | 275 | 334 | 77 | 411 | 29 | 77 | 81 | 31 | 112 |
| | DCRND | 10 | 220 | 427 | 156 | 583 | 142 | 55 | 74 | 64 | 138 |
| | DGRD | 3 | 247 | 312 | 239 | 551 | 57 | 108 | 119 | 70 | 189 |
| | DOD | 25 | 214 | 266 | 40 | 306 | 394 | 138 | 148 | 66 | 214 |
| | DRAER | 4 | 311 | 396 | 145 | 541 | 18 | 94 | 118 | 74 | 192 |
| | **Total** | **45** | **230** | **320** | **92** | **412** | **640** | **113** | **126** | **64** | **190** |
| 1990 | DCLD | 5 | 325 | 380 | 115 | 495 | 21 | 59 | 72 | 38 | 110 |
| | DCRND | 8 | 229 | 608 | 284 | 892 | 186 | 65 | 90 | 59 | 149 |
| | DGRD | 7 | 336 | 544 | 253 | 797 | 48 | 66 | 73 | 95 | 168 |
| | DOD | 11 | 374 | 468 | 139 | 607 | 274 | 104 | 121 | 52 | 173 |
| | DRAER | 5 | 368 | 794 | 290 | 1084 | 28 | 80 | 127 | 89 | 216 |
| | **Total** | **36** | **327** | **547** | **211** | **758** | **557** | **85** | **105** | **59** | **164** |
| 1991 | DCLD | 3 | 306 | 385 | 85 | 470 | 30 | 129 | 150 | 97 | 247 |
| | DCRND | 8 | 218 | 603 | 156 | 759 | 185 | 86 | 106 | 72 | 178 |
| | DGRD | 1 | 432 | 432 | 153 | 585 | 34 | 152 | 154 | 103 | 257 |
| | DOD | 9 | 273 | 318 | 83 | 401 | 211 | 137 | 176 | 82 | 258 |
| | DRAER | 0 | 0 | 0 | 0 | 0 | 33 | 118 | 178 | 69 | 247 |
| | **Total** | **21** | **264** | **441** | **115** | **556** | **493** | **117** | **147** | **79** | **226** |
| 1992 | DCLD | 3 | 503 | 686 | 41 | 727 | 22 | 236 | 245 | 45 | 290 |
| | DCRND | 7 | 283 | 614 | 143 | 757 | 177 | 113 | 162 | 97 | 259 |
| | DGRD | 1 | 214 | 778 | 59 | 837 | 43 | 178 | 202 | 132 | 334 |
| | DOD | 9 | 378 | 550 | 227 | 777 | 180 | 222 | 255 | 97 | 352 |
| | DRAER | 1 | 162 | 311 | 245 | 556 | 52 | 88 | 136 | 100 | 236 |
| | **Total** | **21** | **346** | **591** | **165** | **756** | **474** | **164** | **202** | **98** | **300** |
| 1993 | DCLD | 1 | 426 | 426 | 0 | 426 | 15 | 196 | 207 | 77 | 284 |
| | DCRND | 2 | 164 | 506 | 39 | 545 | 145 | 120 | 150 | 83 | 233 |
| | DGRD | 0 | 0 | 0 | 0 | 0 | 35 | 129 | 129 | 118 | 247 |
| | DOD | 3 | 324 | 506 | 58 | 564 | 95 | 147 | 156 | 106 | 262 |
| | DRAER | 1 | 122 | 504 | 311 | 815 | 21 | 152 | 218 | 73 | 291 |
| | **Total** | **7** | **264** | **495** | **80** | **575** | **311** | **135** | **157** | **93** | **250** |
| 1994 | DCLD | 0 | 0 | 0 | 0 | 0 | 10 | 185 | 185 | 38 | 223 |
| | DCRND | 1 | 168 | 168 | 57 | 225 | 146 | 96 | 121 | 65 | 186 |
| | DGRD | 0 | 0 | 0 | 0 | 0 | 29 | 96 | 96 | 73 | 169 |
| | DOD | 1 | 49 | 101 | 46 | 147 | 70 | 81 | 81 | 37 | 118 |
| | DRAER | 1 | 196 | 196 | 0 | 196 | 14 | 105 | 111 | 26 | 137 |
| | **Total** | **3** | **138** | **155** | **34** | **189** | **269** | **96** | **109** | **56** | **165** |
| 1995 | DCLD | 0 | 0 | 0 | 0 | 0 | 4 | 124 | 124 | 0 | 124 |
| | DCRND | 0 | 0 | 0 | 0 | 0 | 44 | 17 | 18 | 60 | 78 |
| | DGRD | 0 | 0 | 0 | 0 | 0 | 7 | 4 | 4 | 88 | 92 |
| | DOD | 0 | 0 | 0 | 0 | 0 | 20 | 38 | 38 | 36 | 74 |
| | DRAER | 0 | 0 | 0 | 0 | 0 | 3 | 61 | 61 | 7 | 68 |
| | **Total** | **0** | **0** | **0** | **0** | **0** | **78** | **29** | 29 | **51** | **80** |
| Total | | **133** | **280** | **449** | **137** | **586** | **2822** | **115** | **137** | **74** | **211** |

# Investigational Device Exemption Tables IV.1 - IV.6

## Review Time for Investigational Device Exemptions

The following tables present the average days to a decision for investigational device exemptions. The first table presents the averages for the years from October 1, 1988, through May 18, 1995. This is followed by summaries by class, tier, medical specialty, and then reviewing division. The next four tables (tables IV.3 through IV.6) provide the details for these summary tables.

**Table IV.1: Average Days to Decision on Investigational Device Exemptions by Fiscal Year (October 1, 1988 - May 18, 1995)**

| Fiscal year | Approved | | Denied | | Withdrawn | | Other | | Total | Percentile | | | Mean |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | Days | N | Days | N | Days | N | Days | N | 5 | 50 | 95 | |
| **1989** | 89 | 31 | 142 | 30 | 6 | 25 | 7 | 45 | 244 | 21 | 29 | 47 | 31 |
| **1990** | 95 | 29 | 150 | 29 | 2 | 29 | 17 | 49 | 264 | 24 | 30 | 30 | 30 |
| **1991** | 71 | 28 | 133 | 29 | 0 | 0 | 17 | 64 | 221 | 23 | 30 | 30 | 32 |
| **1992** | 74 | 29 | 136 | 29 | 4 | 29 | 14 | 26 | 228 | 21 | 29 | 30 | 29 |
| **1993** | 58 | 29 | 161 | 27 | 4 | 50 | 18 | 22 | 241 | 9 | 29 | 30 | 27 |
| **1994** | 42 | 28 | 120 | 29 | 5 | 27 | 4 | 13 | 171 | 21 | 29 | 30 | 28 |
| **1995** | 59 | 30 | 44 | 30 | 2 | 26 | 4 | 18 | 109 | 22 | 30 | 40 | 30 |
| **Total** | **488** | **29** | **886** | **29** | **23** | **31** | **81** | **38** | **1478** | **21** | **30** | **31** | **30** |

Table IV.2: Summary of Average Days to Decision on Investigational Device Exemptions (October 1, 1988 - May 18, 1995)

| | Approved | | | Denied | | | Withdrawn | | | Other | | | Total | Percentile | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Class | N | Percent | Days | N | Percent | Days | N | Percent | Days | N | Percent | Days | N | 5 | 50 | 95 | Mean |
| I | 7 | 41.2 | 28 | 7 | 41.2 | 30 | 1 | 5.9 | 28 | 2 | 11.8 | 75 | 17 | 21 | 29 | 120 | 34 |
| II | 89 | 33.5 | 29 | 158 | 59.4 | 30 | 4 | 1.5 | 27 | 15 | 5.6 | 49 | 266 | 25 | 30 | 40 | 31 |
| III | 339 | 35.6 | 29 | 569 | 59.7 | 29 | 8 | 0.8 | 30 | 37 | 3.9 | 31 | 953 | 20 | 30 | 30 | 29 |
| N/A | 53 | 21.9 | 29 | 152 | 62.8 | 29 | 10 | 4.1 | 33 | 27 | 11.2 | 40 | 242 | 20 | 29 | 40 | 30 |
| **Tier** | | | | | | | | | | | | | | | | | |
| 1 | 4 | 30.8 | 29 | 7 | 53.8 | 29 | 1 | 7.7 | 28 | 1 | 7.7 | 120 | 13 | 27 | 29 | 120 | 36 |
| 2 | 208 | 44.3 | 29 | 230 | 49.0 | 29 | 5 | 1.1 | 27 | 26 | 5.5 | 38 | 469 | 20 | 30 | 32 | 29 |
| 3 | 231 | 29.0 | 30 | 531 | 66.6 | 29 | 7 | 0.9 | 36 | 28 | 3.5 | 33 | 797 | 23 | 30 | 30 | 29 |
| Exempt | 0 | 0 | 0 | 1 | 50.0 | 30 | 0 | 0 | 0 | 1 | 50.0 | 29 | 2 | 29 | 30 | 30 | 30 |
| N/A | 45 | 22.8 | 29 | 117 | 59.4 | 29 | 10 | 5.1 | 29 | 25 | 12.7 | 41 | 197 | 14 | 29 | 41 | 30 |
| **Medical specialty** | | | | | | | | | | | | | | | | | |
| Cardiovascular | 107 | 27.6 | 29 | 270 | 69.6 | 30 | 2 | 0.5 | 22 | 9 | 2.3 | 34 | 388 | 25 | 30 | 30 | 29 |
| Ophthalmic | 136 | 50.7 | 28 | 114 | 42.5 | 26 | 3 | 1.1 | 29 | 15 | 5.6 | 23 | 268 | 9 | 29 | 30 | 27 |
| Other | 209 | 32.2 | 30 | 400 | 61.5 | 29 | 9 | 1.4 | 35 | 32 | 4.9 | 45 | 650 | 24 | 30 | 33 | 30 |
| N/A | 36 | 20.9 | 29 | 102 | 59.3 | 29 | 9 | 5.2 | 29 | 25 | 14.5 | 41 | 172 | 14 | 29 | 44 | 31 |
| **Division** | | | | | | | | | | | | | | | | | |
| DCLD | 3 | 25.0 | 29 | 2 | 16.7 | 28 | 1 | 8.3 | 29 | 6 | 50.0 | 48 | 12 | 9 | 29 | 98 | 38 |
| DCRND | 169 | 29.5 | 29 | 373 | 65.1 | 29 | 5 | 0.9 | 31 | 26 | 4.5 | 44 | 573 | 24 | 30 | 31 | 30 |
| DGRD | 79 | 24.5 | 31 | 219 | 67.8 | 29 | 10 | 3.1 | 27 | 15 | 4.6 | 35 | 323 | 22 | 30 | 32 | 30 |
| DOD | 141 | 50.4 | 28 | 121 | 43.2 | 26 | 2 | 0.7 | 29 | 16 | 5.7 | 23 | 280 | 10 | 29 | 30 | 27 |
| DRAER | 96 | 33.1 | 29 | 171 | 59.0 | 29 | 5 | 1.7 | 38 | 18 | 6.2 | 44 | 290 | 24 | 30 | 33 | 30 |
| **Total** | **488** | **33.0** | **29** | **886** | **59.9** | **29** | **23** | **1.6** | **31** | **81** | **5.5** | **38** | **1478** | **21** | **30** | **31** | **30** |

**Table IV.3: Average Days to Decision on Investigational Device Exemptions by Class of Medical Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Class | Approved N | Approved Days | Denied N | Denied Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | I | 0 | 0 | 1 | 30 | 0 | 0 | 0 | 0 | 1 | 30 |
| | II | 14 | 29 | 24 | 31 | 4 | 27 | 2 | 105 | 44 | 33 |
| | III | 67 | 31 | 99 | 30 | 1 | 15 | 3 | 22 | 170 | 30 |
| | N/A | 8 | 29 | 18 | 29 | 1 | 30 | 2 | 21 | 29 | 28 |
| | **Total** | **89** | **31** | **142** | **30** | **6** | **25** | **7** | **45** | **244** | **31** |
| 1990 | I | 3 | 29 | 0 | 0 | 1 | 28 | 0 | 0 | 4 | 29 |
| | II | 17 | 30 | 35 | 29 | 0 | 0 | 4 | 68 | 56 | 32 |
| | III | 66 | 28 | 100 | 29 | 1 | 30 | 9 | 32 | 176 | 29 |
| | N/A | 9 | 28 | 15 | 28 | 0 | 0 | 4 | 70 | 28 | 34 |
| | **Total** | **95** | **29** | **150** | **29** | **2** | **29** | **17** | **49** | **264** | **30** |
| 1991 | I | 0 | 0 | 1 | 30 | 0 | 0 | 1 | 120 | 2 | 75 |
| | II | 18 | 28 | 32 | 29 | 0 | 0 | 4 | 30 | 54 | 29 |
| | III | 43 | 27 | 81 | 29 | 0 | 0 | 5 | 69 | 129 | 30 |
| | N/A | 10 | 29 | 19 | 30 | 0 | 0 | 7 | 71 | 36 | 37 |
| | **Total** | **71** | **28** | **133** | **29** | **0** | **0** | **17** | **64** | **221** | **32** |
| 1992 | I | 2 | 25 | 3 | 30 | 0 | 0 | 1 | 29 | 6 | 28 |
| | II | 8 | 30 | 18 | 29 | 0 | 0 | 0 | 0 | 26 | 29 |
| | III | 53 | 29 | 76 | 29 | 1 | 15 | 7 | 23 | 137 | 29 |
| | N/A | 11 | 28 | 39 | 29 | 3 | 33 | 6 | 29 | 59 | 29 |
| | **Total** | **74** | **29** | **136** | **29** | **4** | **29** | **14** | **26** | **228** | **29** |
| 1993 | I | 0 | 0 | 1 | 29 | 0 | 0 | 0 | 0 | 1 | 29 |
| | II | 5 | 30 | 20 | 30 | 0 | 0 | 4 | 28 | 29 | 30 |
| | III | 45 | 29 | 109 | 26 | 2 | 43 | 10 | 20 | 166 | 27 |
| | N/A | 8 | 29 | 31 | 29 | 2 | 56 | 4 | 20 | 45 | 29 |
| | **Total** | **58** | **29** | **161** | **27** | **4** | **50** | **18** | **22** | **241** | **27** |
| 1994 | I | 1 | 30 | 1 | 29 | 0 | 0 | 0 | 0 | 2 | 30 |
| | II | 8 | 28 | 22 | 31 | 0 | 0 | 1 | 28 | 31 | 30 |
| | III | 31 | 28 | 79 | 29 | 2 | 34 | 1 | 11 | 113 | 29 |
| | N/A | 2 | 30 | 18 | 28 | 3 | 22 | 2 | 6 | 25 | 25 |
| | **Total** | **42** | **28** | **120** | **29** | **5** | **27** | **4** | **13** | **171** | **28** |
| 1995 | I | 1 | 28 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 28 |
| | II | 19 | 30 | 7 | 31 | 0 | 0 | 0 | 0 | 26 | 30 |
| | III | 34 | 29 | 25 | 30 | 1 | 29 | 2 | 30 | 62 | 30 |
| | N/A | 5 | 34 | 12 | 29 | 1 | 22 | 2 | 6 | 20 | 28 |
| | **Total** | **59** | **30** | **44** | **30** | **2** | **26** | **4** | **18** | **109** | **30** |
| **Total** | | **488** | **29** | **866** | **29** | **23** | **31** | **81** | **38** | **1478** | **30** |

**Table IV.4: Average Days to Decision on Investigational Device Exemptions by Tier of Medical Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Tier | Approved N | Approved Days | Denied N | Denied Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | 1 | 0 | 0 | 1 | 29 | 0 | 0 | 0 | 0 | 1 | 29 |
| | 2 | 32 | 28 | 40 | 30 | 4 | 27 | 2 | 105 | 78 | 31 |
| | 3 | 51 | 33 | 93 | 30 | 1 | 15 | 3 | 22 | 148 | 31 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 6 | 29 | 8 | 29 | 1 | 30 | 2 | 21 | 17 | 28 |
| | **Total** | **89** | **31** | **142** | **30** | **6** | **25** | **7** | **45** | **244** | **31** |
| **1990** | 1 | 3 | 29 | 3 | 28 | 1 | 28 | 0 | 0 | 7 | 28 |
| | 2 | 42 | 29 | 48 | 29 | 0 | 0 | 6 | 55 | 96 | 31 |
| | 3 | 46 | 28 | 91 | 29 | 1 | 30 | 8 | 33 | 146 | 29 |
| | Exempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | N/A | 4 | 28 | 8 | 29 | 0 | 0 | 3 | 83 | 15 | 39 |
| | **Total** | **95** | **29** | **150** | **29** | **2** | **29** | **17** | **49** | **264** | **30** |
| **1991** | 1 | 32 | 27 | 1 | 30 | 0 | 0 | 1 | 120 | 34 | 30 |
| | 2 | 33 | 29 | 41 | 29 | 0 | 0 | 5 | 31 | 79 | 29 |
| | 3 | 0 | 0 | 74 | 29 | 0 | 0 | 5 | 68 | 79 | 32 |
| | Exempt | 6 | 29 | 1 | 30 | 0 | 0 | 0 | 0 | 7 | 29 |
| | N/A | 0 | 0 | 16 | 30 | 0 | 0 | 6 | 78 | 22 | 43 |
| | **Total** | **71** | **28** | **133** | **29** | **0** | **0** | **17** | **64** | **221** | **32** |
| **1992** | 1 | 1 | 28 | 2 | 30 | 0 | 0 | 1 | 27 | 4 | 29 |
| | 2 | 34 | 30 | 29 | 29 | 2 | 43 | 6 | 22 | 71 | 29 |
| | 3 | 29 | 28 | 72 | 29 | 0 | 0 | 1 | 29 | 102 | 29 |
| | Exempt | 0 | 0 | 0 | 0 | 2 | 15 | 6 | 29 | 8 | 25 |
| | N/A | 10 | 28 | 33 | 29 | 0 | 0 | 0 | 0 | 43 | 28 |
| | **Total** | **74** | **29** | **136** | **29** | **4** | **29** | **14** | **26** | **228** | **29** |
| **1993** | 1 | 38 | 29 | 37 | 27 | 1 | 30 | 11 | 23 | 87 | 27 |
| | 2 | 12 | 29 | 100 | 26 | 1 | 56 | 3 | 21 | 116 | 27 |
| | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Exempt | 8 | 29 | 24 | 28 | 2 | 56 | 4 | 20 | 38 | 29 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **58** | **29** | **161** | **27** | **4** | **50** | **18** | **22** | **241** | **27** |
| **1994** | 1 | 11 | 28 | 27 | 29 | 0 | 0 | 1 | 28 | 39 | 29 |
| | 2 | 27 | 28 | 77 | 29 | 1 | 38 | 1 | 11 | 106 | 29 |
| | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Exempt | 4 | 29 | 16 | 27 | 4 | 24 | 2 | 6 | 26 | 26 |
| | N/A | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | **Total** | **42** | **28** | **120** | **29** | **5** | **27** | **4** | **13** | **171** | **28** |
| **1995** | 1 | 19 | 31 | 8 | 29 | 0 | 0 | 0 | 0 | 27 | 30 |
| | 2 | 33 | 30 | 24 | 31 | 0 | 0 | 2 | 30 | 60 | 30 |
| | 3 | 0 | 0 | 0 | 0 | 1 | 29 | 0 | 0 | 0 | 0 |
| | Exempt | 7 | 30 | 12 | 30 | 0 | 0 | 2 | 6 | 22 | 26 |
| | N/A | 0 | 0 | 0 | 0 | 1 | 22 | 0 | 0 | 2 | 11 |
| | **Total** | **59** | **30** | **44** | **30** | **2** | **26** | **4** | **18** | **109** | **30** |
| **Total** | | **488** | **29** | **886** | **29** | **23** | **31** | **81** | **38** | **1478** | **30** |

**Table IV.5: Average Days to Decision on Investigational Device Exemptions by Medical Specialty of Device (October 1, 1988 - May 18, 1995)**

| Fiscal year | Medical specialty | Approved N | Approved Days | Denied N | Denied Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1989** | Cardiovascular | 29 | 29 | 55 | 30 | 0 | 0 | 0 | 0 | 84 | 30 |
| | Ophthalmic | 17 | 27 | 14 | 31 | 1 | 27 | 1 | 18 | 33 | 28 |
| | Other | 37 | 34 | 67 | 30 | 4 | 24 | 4 | 65 | 112 | 32 |
| | N/A | 6 | 29 | 6 | 28 | 1 | 30 | 2 | 21 | 15 | 28 |
| | **Total** | **89** | **31** | **142** | **30** | **6** | **25** | **7** | **45** | **244** | **31** |
| **1990** | Cardiovascular | 21 | 28 | 38 | 29 | 0 | 0 | 4 | 35 | 63 | 29 |
| | Ophthalmic | 27 | 29 | 25 | 29 | 1 | 30 | 2 | 29 | 55 | 29 |
| | Other | 43 | 29 | 81 | 29 | 1 | 28 | 8 | 50 | 133 | 30 |
| | N/A | 4 | 28 | 6 | 29 | 0 | 0 | 3 | 83 | 13 | 41 |
| | **Total** | **95** | **29** | **150** | **29** | **2** | **29** | **17** | **49** | **264** | **30** |
| **1991** | Cardiovascular | 13 | 29 | 35 | 29 | 0 | 0 | 2 | 48 | 50 | 30 |
| | Ophthalmic | 17 | 25 | 16 | 29 | 0 | 0 | 1 | 36 | 34 | 28 |
| | Other | 36 | 29 | 68 | 29 | 0 | 0 | 8 | 60 | 112 | 31 |
| | N/A | 5 | 29 | 14 | 30 | 0 | 0 | 6 | 78 | 25 | 41 |
| | **Total** | **71** | **28** | **133** | **29** | **0** | **0** | **17** | **64** | **221** | **32** |
| **1992** | Cardiovascular | 8 | 28 | 34 | 29 | 1 | 15 | 2 | 22 | 45 | 29 |
| | Ophthalmic | 32 | 30 | 14 | 30 | 0 | 0 | 2 | 28 | 48 | 30 |
| | Other | 25 | 28 | 55 | 29 | 1 | 70 | 4 | 23 | 85 | 29 |
| | N/A | 9 | 28 | 33 | 29 | 2 | 15 | 6 | 29 | 50 | 28 |
| | **Total** | **74** | **29** | **136** | **29** | **4** | **29** | **14** | **26** | **228** | **29** |
| **1993** | Cardiovascular | 4 | 30 | 45 | 29 | 0 | 0 | 1 | 29 | 50 | 29 |
| | Ophthalmic | 36 | 29 | 33 | 18 | 1 | 30 | 9 | 19 | 79 | 23 |
| | Other | 10 | 29 | 61 | 29 | 1 | 56 | 4 | 28 | 76 | 29 |
| | N/A | 8 | 29 | 22 | 29 | 2 | 56 | 4 | 20 | 36 | 29 |
| | **Total** | **58** | **29** | **161** | **27** | **4** | **50** | **18** | **22** | **241** | **27** |
| **1994** | Cardiovascular | 17 | 28 | 45 | 30 | 0 | 0 | 0 | 0 | 62 | 29 |
| | Ophthalmic | 4 | 30 | 11 | 27 | 0 | 0 | 0 | 0 | 15 | 28 |
| | Other | 19 | 28 | 52 | 29 | 2 | 34 | 2 | 20 | 75 | 29 |
| | N/A | 2 | 30 | 12 | 27 | 3 | 22 | 2 | 6 | 19 | 24 |
| | **Total** | **42** | **28** | **120** | **29** | **5** | **27** | **4** | **13** | **171** | **28** |
| **1995** | Cardiovascular | 15 | 29 | 18 | 31 | 1 | 29 | 0 | 0 | 34 | 30 |
| | Ophthalmic | 3 | 29 | 1 | 14 | 0 | 0 | 0 | 0 | 4 | 25 |
| | Other | 39 | 30 | 16 | 31 | 0 | 0 | 2 | 30 | 57 | 30 |
| | N/A | 2 | 29 | 9 | 30 | 1 | 22 | 2 | 6 | 14 | 26 |
| | **Total** | **59** | **30** | **44** | **30** | **2** | **26** | **4** | **18** | **109** | **30** |
| **Total** | | **488** | **29** | **886** | **29** | **23** | **31** | **81** | **38** | **1478** | **30** |

**Table IV.6: Average Days to Decision on Investigational Device Exemptions by Reviewing Division (October 1, 1988 - May 18, 1995)**

| Fiscal year | Division | Approved N | Approved Days | Denied N | Denied Days | Withdrawn N | Withdrawn Days | Other N | Other Days | Total N | Total Days |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | DCLD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | DCRND | 41 | 30 | 65 | 29 | 0 | 0 | 2 | 64 | 108 | 30 |
| | DGRD | 14 | 41 | 41 | 30 | 4 | 24 | 1 | 21 | 60 | 32 |
| | DOD | 18 | 27 | 14 | 31 | 1 | 27 | 1 | 18 | 34 | 28 |
| | DRAER | 16 | 29 | 22 | 30 | 1 | 30 | 3 | 50 | 42 | 31 |
| | **Total** | **89** | **31** | **142** | **30** | **6** | **25** | **7** | **45** | **244** | **31** |
| 1990 | DCLD | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 95 | 2 | 95 |
| | DCRND | 31 | 28 | 55 | 29 | 0 | 0 | 5 | 36 | 91 | 29 |
| | DGRD | 17 | 29 | 36 | 29 | 2 | 29 | 2 | 19 | 57 | 29 |
| | DOD | 29 | 29 | 25 | 29 | 0 | 0 | 2 | 29 | 56 | 29 |
| | DRAER | 18 | 30 | 34 | 29 | 0 | 0 | 6 | 63 | 58 | 33 |
| | **Total** | **95** | **29** | **150** | **29** | **2** | **29** | **17** | **49** | **264** | **30** |
| 1991 | DCLD | 1 | 29 | 0 | 0 | 0 | 0 | 1 | 29 | 2 | 29 |
| | DCRND | 24 | 28 | 51 | 29 | 0 | 0 | 8 | 71 | 83 | 33 |
| | DGRD | 16 | 29 | 41 | 29 | 0 | 0 | 5 | 61 | 62 | 32 |
| | DOD | 16 | 25 | 17 | 29 | 0 | 0 | 1 | 36 | 34 | 28 |
| | DRAER | 14 | 29 | 24 | 29 | 0 | 0 | 2 | 74 | 40 | 31 |
| | **Total** | **71** | **28** | **133** | **29** | **0** | **0** | **17** | **64** | **221** | **32** |
| 1992 | DCLD | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 30 | 1 | 30 |
| | DCRND | 17 | 28 | 64 | 29 | 1 | 15 | 5 | 26 | 87 | 29 |
| | DGRD | 13 | 28 | 30 | 29 | 3 | 33 | 3 | 25 | 49 | 29 |
| | DOD | 32 | 30 | 15 | 28 | 0 | 0 | 3 | 29 | 50 | 29 |
| | DRAER | 12 | 28 | 27 | 29 | 0 | 0 | 2 | 19 | 41 | 28 |
| | **Total** | **74** | **29** | **136** | **29** | **4** | **29** | **14** | **26** | **228** | **29** |
| 1993 | DCLD | 0 | 0 | 1 | 27 | 0 | 0 | 0 | 0 | 1 | 27 |
| | DCRND | 10 | 29 | 60 | 29 | 1 | 56 | 3 | 22 | 74 | 29 |
| | DGRD | 2 | 30 | 36 | 29 | 0 | 0 | 3 | 27 | 41 | 29 |
| | DOD | 37 | 29 | 36 | 19 | 1 | 30 | 9 | 19 | 83 | 23 |
| | DRAER | 9 | 29 | 28 | 29 | 2 | 56 | 3 | 24 | 42 | 30 |
| | **Total** | **58** | **29** | **161** | **27** | **4** | **50** | **18** | **22** | **241** | **27** |
| 1994 | DCLD | 0 | 0 | 1 | 29 | 1 | 29 | 1 | 28 | 3 | 29 |
| | DCRND | 25 | 28 | 55 | 30 | 2 | 28 | 1 | 8 | 83 | 29 |
| | DGRD | 2 | 27 | 25 | 29 | 0 | 0 | 1 | 11 | 28 | 28 |
| | DOD | 6 | 30 | 11 | 27 | 0 | 0 | 0 | 0 | 17 | 28 |
| | DRAER | 9 | 29 | 28 | 29 | 2 | 25 | 1 | 3 | 40 | 28 |
| | **Total** | **42** | **28** | **120** | **29** | **5** | **27** | **4** | **13** | **171** | **28** |
| 1995 | DCLD | 2 | 29 | 0 | 0 | 0 | 0 | 1 | 9 | 3 | 22 |
| | DCRND | 21 | 29 | 23 | 31 | 1 | 29 | 2 | 30 | 47 | 30 |
| | DGRD | 15 | 30 | 10 | 30 | 1 | 22 | 0 | 0 | 26 | 30 |
| | DOD | 3 | 29 | 3 | 24 | 0 | 0 | 0 | 0 | 6 | 26 |
| | DRAER | 18 | 31 | 8 | 30 | 0 | 0 | 1 | 3 | 27 | 30 |
| | **Total** | **59** | **30** | **44** | **30** | **2** | **26** | **4** | **18** | **109** | **30** |
| **Total** | | **488** | **29** | **886** | **29** | **23** | **31** | **81** | **38** | **1478** | **30** |

# Comparision in Table V of Alternative Methods for Determining Average Days to Decision by Fiscal Year

## Alternative Calculation of Review Time by Year of Decision

We reported our findings according to the fiscal year in which the applications were submitted to FDA (date-of-submission cohort). By contrast, FDA commonly reports review time according to the fiscal year in which the review was completed (date-of-decision cohort). This led to discrepancies between our results and those reported by FDA. The following table illustrates the differences in calculating total elapsed time by the year that the application was submitted and the year that a decision was rendered. Comparisons are provided for 510(k)s, PMA supplements, original PMAs, and IDEs.

Our dataset did not include applications submitted before October 1, 1988. Consequently, the results presented in the following table understated the number of cases, as well as the elapsed time, when calculated by the year of decision. That is, an application submitted in fiscal year 1988 and completed in 1989 would not have been in our dataset.

**Table V: Comparison of Alternative Methods for Determining Average Days to Decision by Fiscal Year (October 1, 1988 - May 18, 1995)**

| | 510(k) | | | | Original PMA | | | | PMA supplement | | | | IDE | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fiscal year | Decision N | Decision Days | Submission N | Submission Days | Decision N | Decision Days | Submission N | Submission Days | Decision N | Decision Days | Submission N | Submission Days | Decision N | Decision Days | Submission N | Submission Days |
| 1989 | 4819 | 82 | 7021 | 124 | 25 | 138 | 81 | 513 | 359 | 107 | 803 | 219 | 228 | 31 | 244 | 31 |
| 1990 | 6148 | 120 | 5835 | 121 | 46 | 324 | 67 | 744 | 780 | 176 | 650 | 193 | 259 | 30 | 264 | 30 |
| 1991 | 5374 | 122 | 5763 | 153 | 38 | 492 | 60 | 580 | 553 | 189 | 577 | 261 | 226 | 30 | 221 | 32 |
| 1992 | 4938 | 150 | 6479 | 245 | 37 | 479 | 37 | 674 | 465 | 198 | 572 | 336 | 223 | 31 | 228 | 29 |
| 1993 | 5120 | 225 | 6102 | 269 | 48 | 804 | 21 | 462 | 420 | 305 | 350 | 264 | 248 | 27 | 241 | 27 |
| 1994 | 7167 | 247 | 5635 | 166 | 58 | 846 | 8 | 222 | 466 | 394 | 295 | 162 | 174 | 29 | 171 | 28 |
| 1995 | 4973 | 256 | 1705 | 67 | 23 | 876 | 1 | 23 | 288 | 369 | 84 | 79 | 120 | 30 | 109 | 30 |
| Total | 38539 | 175 | 38540 | 175 | 275 | 591 | 275 | 591 | 3331 | 237 | 3331 | 237 | 1478 | 30 | 1478 | 30 |
| Open | 2410 | 0 | 2410 | 0 | 126 | 0 | 126 | 0 | 309 | 0 | 309 | 0 | 0 | 0 | 0 | 0 |

# Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date AUG 0 2 1995

From Associate Commissioner for Legislative Affairs, HFW-1
Through: Margaret Porter, Chief Counsel, Office of General Counsel, GCF-1

Subject Comments on GAO Draft Report Entitled "Medical Devices: FDA Review Time."

To Kwai-Cheung Chan, Director
Program Evaluator in Physical Systems Area

We have reviewed the subject draft report and have the attached comments.

Diane E. Thompson

Attachment

Food and Drug Administration Comments on the General Accounting Office Draft Report Entitled, MEDICAL DEVICES FDA Review Time

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the subject draft report. We recognize that both GAO and FDA are interested in presenting an accurate and fair analysis of FDA's performance with respect to reviewing medical devices during the past few years. As written, however, we believe the report seriously misrepresents the current state of the review program by omitting the significant progress made since the start of FY1994. Therefore, in addition to the following comments, we would appreciate the opportunity to meet with the study team to further discuss the report and changes we believe to be necessary to correct some inaccuracies and misperceptions. For your information, we are also enclosing a copy of a letter that was sent to device manufacturers on May 18, 1995 further explaining review process improvements.

FDA is particularly concerned that the report does not reflect recent improvements in device review times, nor does it acknowledge recent initiatives designed to further improve review times. It also does not correctly describe key aspects of the device evaluation program. The Agency acknowledges that during the first part of this decade, the review process became very slow for a number of reasons. However, recent management initiatives and reemphasis on doing thorough reviews in a timely manner have brought about significant performance improvements that are not evident in this report.

In the interest of clarity, we have grouped our comments into four categories: general comments, comments on the Premarket Notification {510(k)} review process, comments on the Premarket Approval (PMA) review process, and comments on the Investigational Devices Exemption (IDE) review process.

GENERAL COMMENTS

See comment 1.

As noted above, FDA has made a number of changes to the review process for PMAs, 510(k)s and IDEs that are not discussed in the report. We believe the report would be enhanced and serve the Congress better if it included a discussion of the changes that have been instituted to address the problems of backlog and extended review times. Among the changes are:

- triage/tier review of 510(k)s;
- refuse to accept/file policies for IDEs, 510(k)s, and PMAs;
- expedited review for breakthrough products;

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- delegation of decision-making authority to lower levels; and

- hiring and training new reviewers.

We also suggest that a section of the report be devoted to the increasing complexity of applications and the mix of simple versus complex applications received. FDA has recently taken steps to exempt certain low-risk devices from premarket notification or approval. This has resulted in a greater proportion of the submissions being complex rather than simple. Other factors that have impacted on the complexity of applications are advancements and innovations in medical technology. Together, the result has been applications that require significantly more time to review than was the case in past years. Simultaneously, however, the industry has benefitted by being able to market low-risk devices without prior FDA review.

See comment 2.

The report would be more useful if it provided a more comprehensive overview of the methodology used for analysis. For example, the report measures performance based on date-of-submission cohorts, whereas FDA's usual method for measuring device review performance is based on date-of-decision cohorts. While the report acknowledges that these approaches can vary substantially, it does not explain the variances or the implications of each for understanding and explaining FDA performance. We should note at this point that because the report uses date-of-submission cohorts, FDA's statistical analyses over the past several years may not agree with GAO's, although the trends should be in the same direction. This may become a source of confusion for the readers of the report.

See comment 3.

We also note that the report deals only with calculations of averages and percentiles. We believe it would be useful to include additional performance measures as well. For example, median review times can provide a better measure of "typical" performance by reducing the effects of outliers (unusually "quick" and unusually "slow" reviews).

Also, while some of the tables in the report include data for the 5th, 50th, and 95th percentiles, the text discusses only average (mean) review times. Indeed, on page 9 the report says GAO cannot determine whether review times continued to increase after 1992 for PMAs and after 1993 for 510(k)s because of the increasing number of open cases. Average time is not a helpful statistic while open cases remain in the date-of-receipt cohort. Others have used percentiles as a more meaningful statistic to interpret receipt cohort data. A comparison of percentiles can help determine whether this trend continued. For example, by May 18, 1995, GAO's cutoff date, 87.5% of 510(k)s submitted in FY1994 had received a final action. A comparison of median times (i.e.,

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the 50th percentile, or the time to complete 50% of the applications) or the 75th or 85th percentiles from FY1989 through FY1994 can help answer this question.

510(K) REVIEW

See comment 4.

As briefly introduced above, the value of the report would be enhanced if recent improvements in review performance were acknowledged. We are particularly concerned that the report concludes that, while 510(k) review time increased from 1989 to 1993, later trends "cannot be determined because of the increasing number of open cases". While it is true that review time increased in the early 1990s, the data for FY1994 shows a significant improvement. For example, using GAO's date-of-submission cohort methodology, including withdrawals and deletions, we calculate that;

- the median review time has dropped (from 169 days in FY1993, to 100 days in FY 1994 and 108 days in FY1995),
- more 510(k)s are being reviewed within 90 days (1536 in FY1993, 2461 in FY1994, and 2045 in the first seven months of FY1995),
- backlogs of 510(k)s under review over 90 days have been substantially reduced (1978 in December, 1993, versus 204 in June, 1995).

By focusing exclusively on the one measure of performance and excluding the data from 1994-1995, the report presents a distorted view of the current situation, and leaves the impression of a static review process that remains problem-ridden.

See comment 5.

The report would be more useful for analytical purposes if it also included information about FDA review times rather than just total elapsed time. The Agency has kept statistics in this manner for some time and believes this to be an important analysis for understanding how the review process works and where improvements are needed and can be made. By focusing exclusively on the total elapsed times, the report essentially faults FDA for time not under its control and for attempting to work with the sponsors to improve the quality of their submissions so they may become approvable. For example, in most cases when FDA identifies substantial problems that would justify closing out the application without approving it, as a courtesy to the applicant the file is kept open for up to a full year to allow the applicant to submit additional information rather than submitting an entirely new application. The report has not acknowledged this FDA practice, and therefore, all the time allowed for the applicant to strengthen its application is counted as FDA review time, skewing the results in an unfavorable

way. Although the report includes rough estimates of non-FDA time, the information is too general to be useful. By distinguishing between FDA review time and total elapsed time, the report will enable readers to more accurately assess FDA's performance.

See comment 6.

The report also has a built-in bias for the purposes of workload analysis because of the selection of FY1989 as the benchmark year. FDA received an unusually high number of 510(k) applications during that particular year because of the need to review applications for all existing and new patient examination gloves. Prior to FY1989, these gloves were exempt from FDA premarket notification requirements. In 1989, because of the increasing concerns relating to AIDS/HIV transmission, FDA revoked the exemption and required 510(k) submissions for all existing and new patient examination gloves. As a result, the Agency received more than 1500 applications for gloves in FY1989. This one-time surge should be taken into account in examining review performance and application receipts over time. FDA's data show that, taking patient examination gloves into account, 510(k) receipts have increased over the last few years.

See comment 7.

The report should not apply the tier-based analysis to the data for years prior to FY1994. The tier review approach was developed in FY1993 and phased into use beginning on June 30, 1993 (end of the 3rd quarter, FY1993) and extending into FY1994. In fact, the first full year of operating using the tier approach is FY1995. Statistics showing tiers should not have been used prior to that time. We acknowledge that FDA contributed to the confusion by extrapolating tier data for the prior years in the database we provided to GAO. We apologize for the confusion this caused, and suggest that we work with the study team to correct this error. It should be noted, however, that the tier approach applies only to 510(k)s, and not to PMAs or IDEs.

The report states that "FDA does not make a determination on the safety or effectiveness of the new {510(k)} device." This is not accurate. When evaluating 510(k) applications, FDA does not make a determination of the absolute safety or effectiveness of the new device, but makes a determination based on comparative safety and effectiveness to determine substantial equivalence--the device under review must be shown to be at least as safe and effective as other legally-marketed predicate devices.

PMA REVIEW

See comment 8.

The draft report inappropriately mixes data for PMAs with data for PMA supplements without recognizing the two distinctly different workloads. PMAs are entirely new; PMA supplements represent changes to existing devices. The complexity of the two are quite different. PMAs frequently involve novel technologies and issues of safety and effectiveness that FDA has not

theretofore confronted. PMA supplements always follow an approved PMA and benefit from the baseline knowledge gained during the PMA review. Original PMAs generally take considerably more time to review than do PMA supplements.

See comment 1.

As noted above, the report omits any reference to the recent management initiatives that promise to have a significant favorable impact on the time required to review the typical PMA application. Chief among these initiatives is the institution of a project management approach to reviews to help process PMAs in a more efficient and timely manner.

The report points out that there has been a reduction in the number of PMAs received by FDA, yet, it fails to explain this phenomenon. Part of the downward trend in receipts is attributable to FDA actions to reduce the regulatory burden on the industry by reclassifying devices from class III into class I or II, thereby allowing submission of 510(k)s instead of PMAs or PMA supplements. This is a significant reduction in data requirements for the affected devices. For example, magnetic resonance imaging (MRI) systems, sutures, and daily wear contact lenses have been reclassified and no longer require PMA review. The number of approved PMAs for these three devices total 147, and the number of PMA supplements for the three is 1475. Since reclassification, 513 510(k)s have been received for the three devices, representing a mixture of what would have been new PMAs and PMA supplements.

Another factor in the reduction of PMAs is market saturation, particularly in the ophthalmic area, which has reduced the incentive for manufacturers to seek to enter this market. A consequence of these two factors is that the PMAs received by FDA are proportionately more first-of-a-kind, innovative products that require more time to review as well as more expertise.

The report apparently includes some invalid data in the PMA statistics. The data tables include an "exempt" category, which is erroneous. We will be happy to work with GAO to correct this error.

See comment 9.

The report fails to use data that would allow a more accurate assessment of changes in the device review performance. The report notes that the average elapsed time for review is declining, but observes that the decline may be misleading because of the number of applications remaining open. We have analyzed the data provided to GAO and constructed the figure below, which shows the elapsed time since receipt of an original PMA application. The figure demonstrates that since the beginning of 1994, for pending PMAs the elapsed time has remained stable at approximately 700 days. This means that FDA is not accumulating an additional backlog of old PMAs, as was the case from 1991 through 1993. We recognize that the total elapsed time

for original PMAs must be reduced to a level comparable to that for PMA supplements, which has substantially decreased since October of 1994 and is now running around 200 days. See Figures 1 and 2 (inserts).

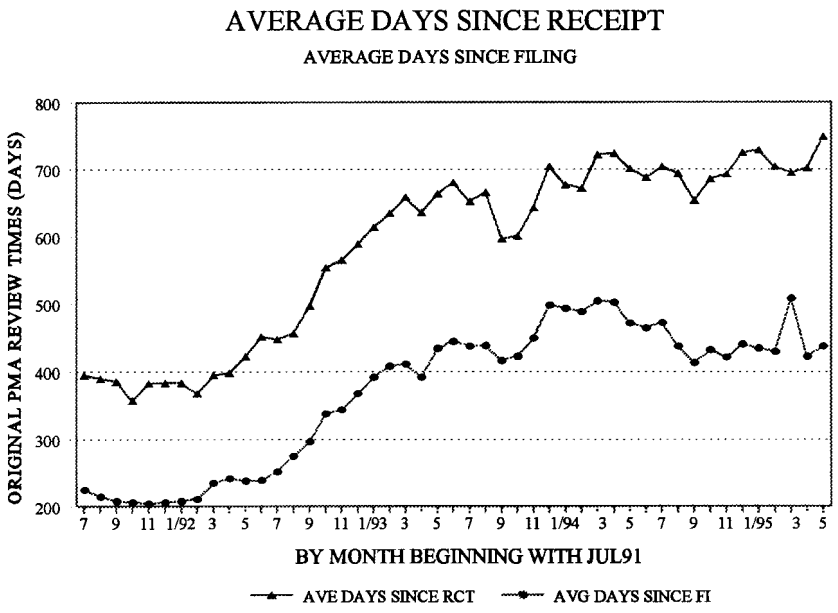
IDE REVIEW

See comment 10.

The report should describe recent management improvements in the IDE review process which have reduced the number of review cycles through which IDEs typically go. There have been substantial improvements in the IDE program which are not reflected by either the data presented in the report or in the discussion of this data in the text. For example, FDA has been encouraging sponsors to engage in pre-submission meetings with the review staff and has also been using a more interactive review process than was used in the past. Implementation of these initiatives in January, 1995, has resulted in an increase in the approval rate for initial submissions from a level of approximately 30% to over 60% as of now. In addition, the total time to approval for all original IDEs has decreased by about 50%, from approximately 200 days in recent years to just over 100 days.

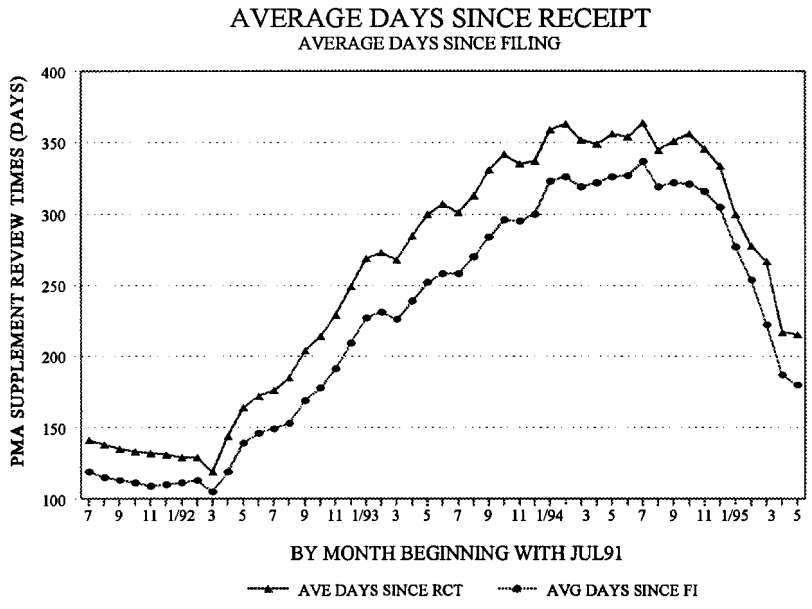
FDA also provided technical comments, which have been incorporated into the text where appropriate but have not been reprinted here.

**Figure 1**




INSERT 1

**Figure 2**




INSERT 2

The following are GAO's comments on the August 2, 1995, letter from FDA.

## GAO Comments

1. The purpose of our review was to provide to FDA's congressional oversight committee descriptive statistics on review time for medical device submissions between 1989 and May 1995. It was not to perform an audit of whether FDA was in compliance with statutory review time, nor to examine how changes in FDA management practices may have resulted in shortening (or lengthening) review times. FDA officials suggested that a number of process changes and other factors may have contributed to the trends we reported—for example, the increased complexity of the typical submission that resulted from the agency's exemption from review of certain low-risk devices. We are not able to verify the effect changes have actually had on review time, and it may be that it is still too early for their impact to be definitively assessed.

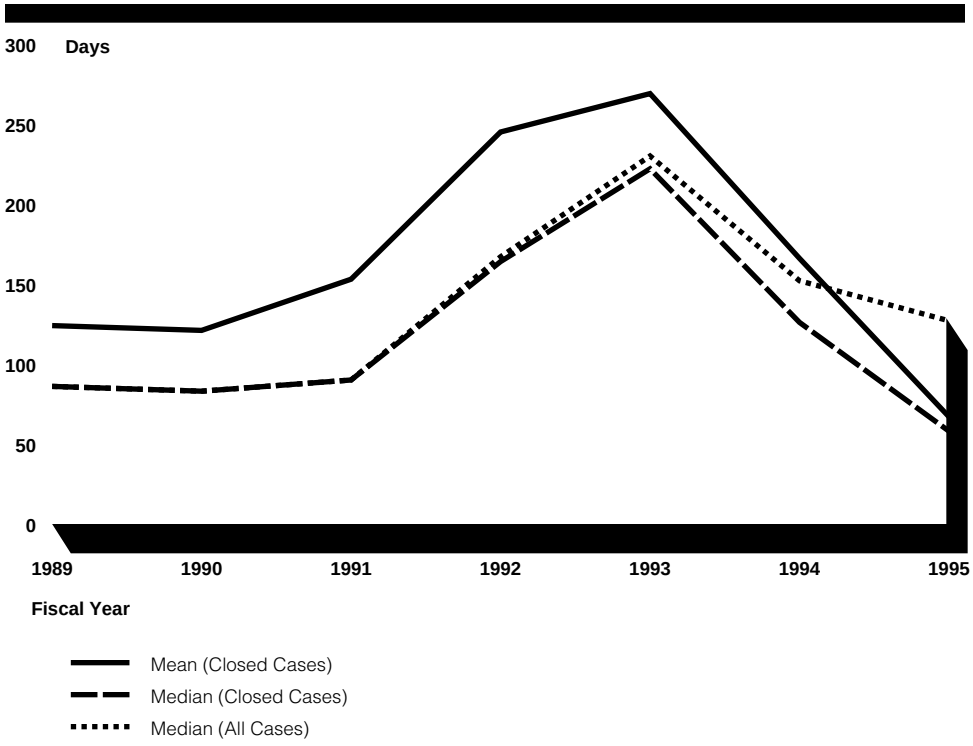
2. In discussing our methodology in the draft report, we noted the differences between FDA's typical method of reporting review time according to the year in which action on applications is finalized, as opposed to our method of assigning applications to the year in which they were submitted. We also included an appendix that compares the results of the two different approaches. (See appendix V.) We agree with FDA that it is important for the reader to understand these differences and have further expanded our discussion of methodology to emphasize this point. (See p. 14.)

3. We agree with FDA that our report "deals only with calculations of averages and percentiles"—that is, with means, medians (or 50th percentile), as well as the 5th and 95th percentiles. However, FDA's suggested additions do not extend beyond such descriptive statistics.

We also agree that mean review times in the presence of numerous open cases may not be meaningful. For this reason, we have included open cases in our tables that report review time, but we have excluded them from the calculation of means. FDA suggests that we include open cases in our calculation of medians. We have adopted this suggestion and presented our discussion of trends in terms of the median review time for all cases. It should be noted, however, that including open cases increases our estimate of review time. (For example, including open cases raises the calculation of 510(k) median review time from the 126 days we reported for 1994 to 152 days.)

Figure VI.1 depicts the relationship among the three measures of elapsed time for 510(k) submissions: the mean of closed cases, the median of closed cases, and the median of all cases. The two measures of closed cases reveal roughly parallel trends, with median review time averaging some 45 days fewer than mean review time. The two estimates of median review time are nearly identical from 1989 through 1990 since there are very few cases from that period that remain open. The divergence between the two medians increases as the number of open cases increases in recent years until 1995, when the median, including open cases, is larger than the mean of closed cases.

**Figure VI.1: Total Elapsed Time for 510(k) Reviews, 1989-95: Mean, Median for Closed Cases, and Median for All Cases[a]**




[a]Fiscal year 1995 includes actions only through May 18, 1995.

4. While we are unable to reproduce the calculations performed by FDA, we agree in general with the trends indicated by FDA. Specifically,

- Our calculations, as presented in our draft report tables II.7 and following, showed a decrease from 1993 to 1994 in FDA review time for finding a 510(k) submission substantially equivalent. By our calculation, this declined from a mean of 173 days in 1993 to 100 days in 1994.
- The proportion of 510(k) applications reaching initial determination within 90 days of submission increased from 15.8 percent in 1993 to 32 percent in 1994 and 57.9 percent between October 1, 1994, and May 18, 1995.

Clearly, since 1993, more 510(k) cases have been determined within 90 days, and the backlog of undetermined cases has been reduced. Because a review of the nature and complexity of the cases still open was beyond the scope of this study, we cannot predict with certainty whether, when these cases are ultimately determined, average review time for 1995 cases will be shorter than for cases submitted in 1993.

5. FDA time was reported in our draft report tables II.7 through II.12, and findings contrasting the differences between FDA time and non-FDA time were also included. Additional language addressing this distinction has been included in the text of the report.

6. FDA's contends that 1989 was an atypical year for 510(k) submissions and therefore a poor benchmark. However, we do not believe that starting our reporting in 1989 introduced any significant bias into our report of the 510(k) workload. Indeed, our draft report concluded that the number of 510(k) submissions had "remained relatively stable" over the 1989-94 period. If we had extrapolated the data from the first 7-1/2 months of 1995 to a full year, we would have concluded that the current fiscal year would have a substantially lower number of 510(k) submissions (16 percent to 31 percent) than any of the previous 6 years.

7. The tier classification was created by FDA to manage its review workload; however, it was not our intention to evaluate or in any way assess the use of tiers for such purposes. The tier classification was based on "the potential risk and complexity of the device." Accordingly, both class and tier provide a rough indication of a device's complexity.

8. We agree that our draft report aggregated original PMA submissions and PMA supplements in summarizing its findings. We have now disaggregated PMA statistics throughout.

9. We interpret the figures presented by FDA to represent the mean number of days elapsed between receipt (or filing) of a PMA submission and a given month for cases that have not been decided. We agree with FDA that the average review time for open original PMAs does not appear to have increased substantially since the beginning of calendar 1994 and that the average review time has decreased for PMA supplements since late 1994. Decreasing these averages is the product of either an increasing number of new cases entering the system or of closing out older cases in the backlog or both. Since the number of PMAs (originals and supplements) submitted in recent years has declined, the evidence suggests that the drop in average time for pending PMA supplements resulted from eliminating lengthy backlogged cases.

10. As noted earlier, assessing the impact of specific management initiatives is beyond the scope of this report. However, we do agree with FDA that the approval rate for initial IDE submissions doubled between 1994 and 1995; by our calculations, it increased from 25 percent to 54 percent. We have not independently examined the total time to approval for all IDEs.

# Major Contributors to This Report

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