

United States General Accounting Office

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GAO

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

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October 1995

# MEDICAL DEVICES

## FDA Review Time







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

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**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.

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## Background

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### 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.<sup>1</sup> 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.<sup>2</sup>

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

<sup>2</sup>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.

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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.<sup>3</sup> However the answers to the fundamental questions of safety and effectiveness are determined from data derived from clinical trials.<sup>4</sup>

FDA also regulates research conducted to determine the safety and effectiveness of unapproved devices. FDA approval is required only for “significant risk” devices.<sup>5</sup> 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.

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## 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.

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## 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

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<sup>3</sup>Nonclinical data may include microbiological, toxicological, immunological, biocompatibility, shelf life, animal, engineering (stress, wear, fatigue) data.

<sup>4</sup>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.

<sup>5</sup>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.

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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).<sup>6</sup> 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.<sup>7</sup>

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.)

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## 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

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<sup>6</sup>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.

<sup>7</sup>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).

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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.<sup>8</sup>

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.<sup>9</sup>

Under the class and tier systems, approximately 20 percent of the different types of medical devices are exempted from premarket notification.<sup>10</sup> 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.<sup>11</sup>

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## 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

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<sup>8</sup>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.

<sup>9</sup>These exempted devices remain subject to other requirements of the act. (See footnote 8.)

<sup>10</sup>Our 20-percent figure was determined by obtaining a frequency distribution by tiers of the information FDA provided.

<sup>11</sup>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.

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continue to grow as the remaining open cases (13 percent) are completed.<sup>12</sup>

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.

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## Principal Findings

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### Premarket Notifications (510(k)s)

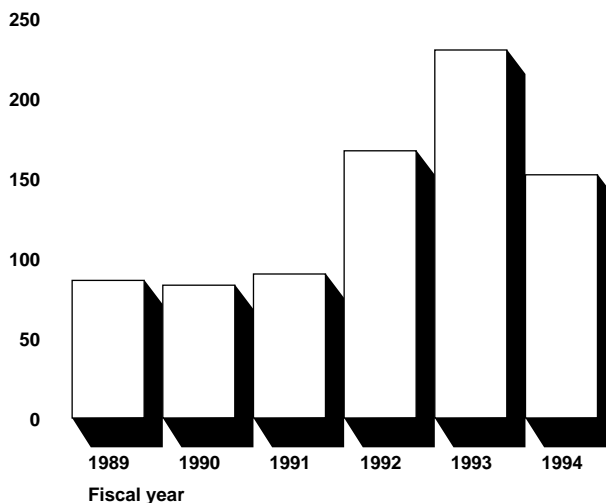
From 1989 through 1991, the median time between the submission of a 510(k) application and FDA's decision (total elapsed time) was relatively stable at about 80 to 90 days. The next 2 years showed a sharp increase that peaked at 230 days in 1993. Although the median review time showed a decline in 1994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

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<sup>12</sup>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<sup>a</sup>**

300 Days



<sup>a</sup>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.)

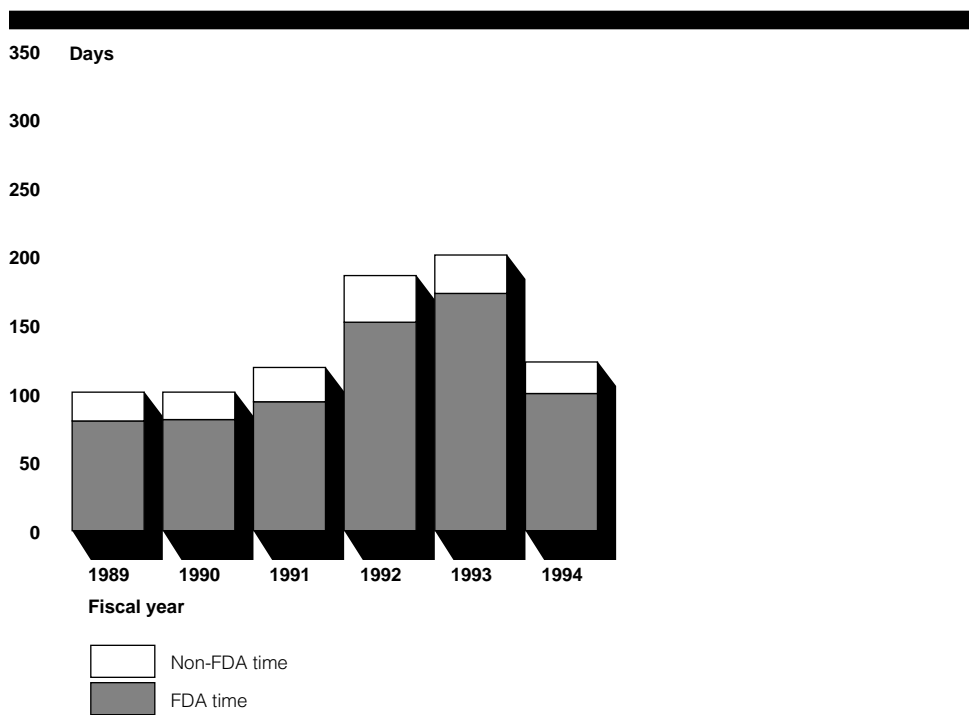
Of all the applications submitted to FDA to market new devices during the period under review, a little over 90 percent were for 510(k)s. Between 1989 and 1994, the number of 510(k) applications remained relatively stable, ranging from a high of 7,023 in 1989 to a low of 5,774 in 1991. In 1994, 6,446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

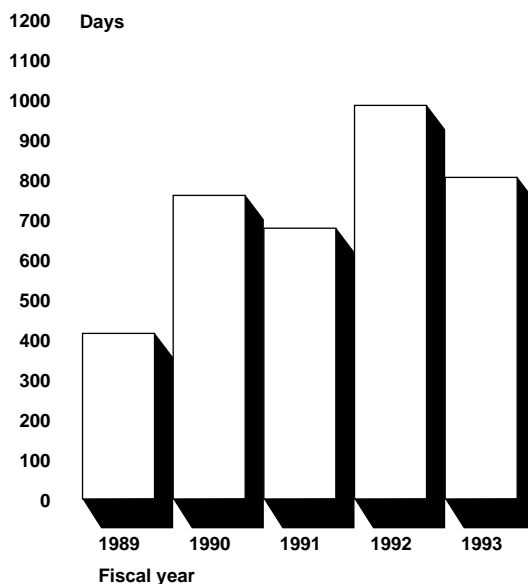


<sup>a</sup>Open cases are not included. The means shown will increase when open cases are completed.

**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<sup>a</sup>**

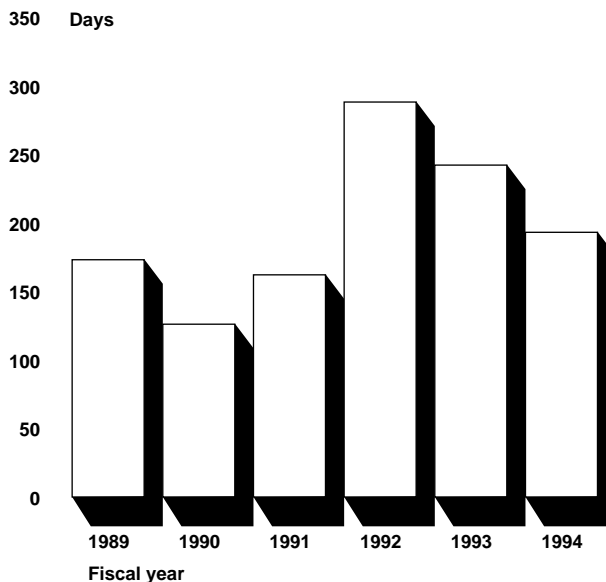


<sup>a</sup>The median includes open cases. Data for 1994 are omitted because less than 50 percent of the applications submitted had been completed.

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<sup>a</sup>**



<sup>a</sup>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.

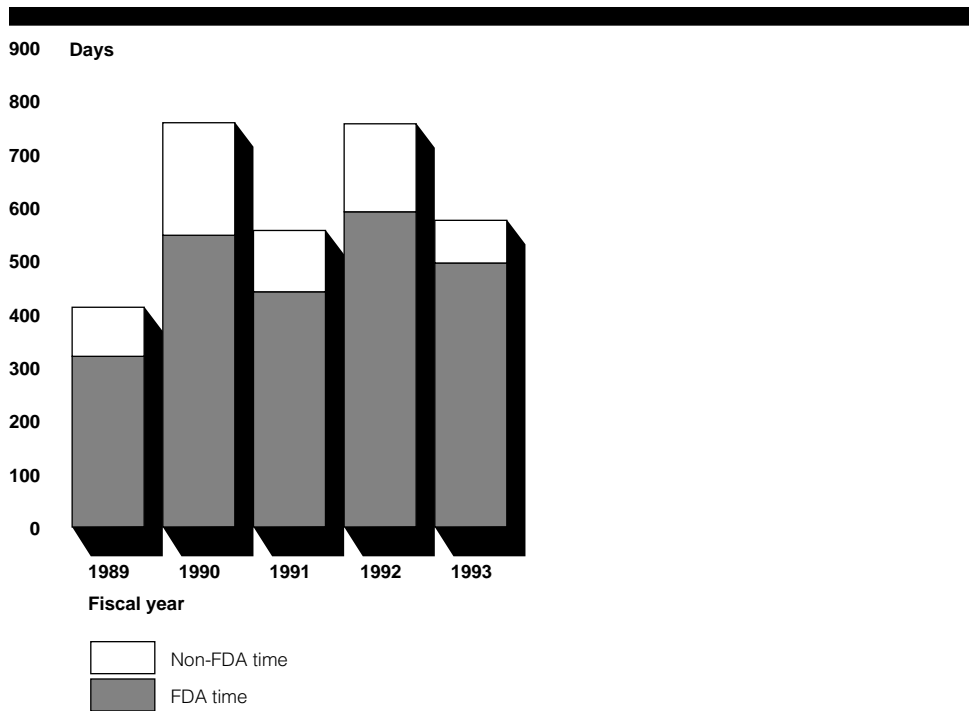
The number of applications submitted for PMA review declined each year. In 1989, applications for original PMAs numbered 84. By 1994, they were down to 43. Similarly, PMA supplements decreased from 804 in 1989 to 372 in 1994. (See tables III.1 and III.7.)

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.

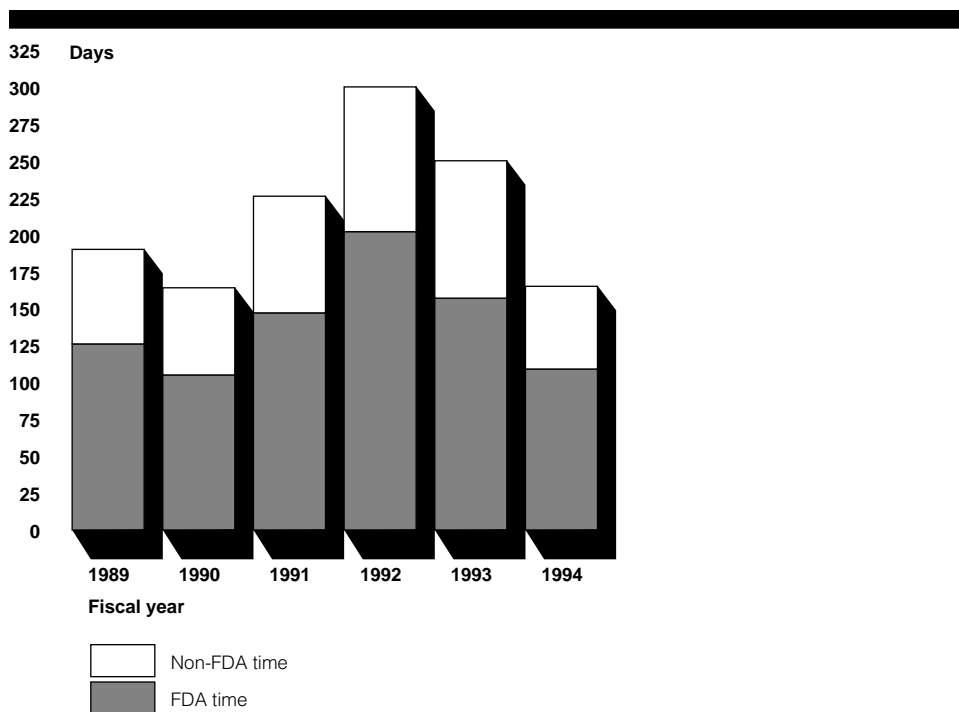
For PMA reviews that resulted in approval, non-FDA time constituted approximately one-fourth of the total elapsed time for original PMAs and about one-third for PMA supplements. The mean FDA time for original PMAs ranged from 155 days in 1994 to 591 days in 1992. Non-FDA times for those years were 34 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<sup>a</sup>**



<sup>a</sup>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<sup>a</sup>**



<sup>a</sup>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

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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.

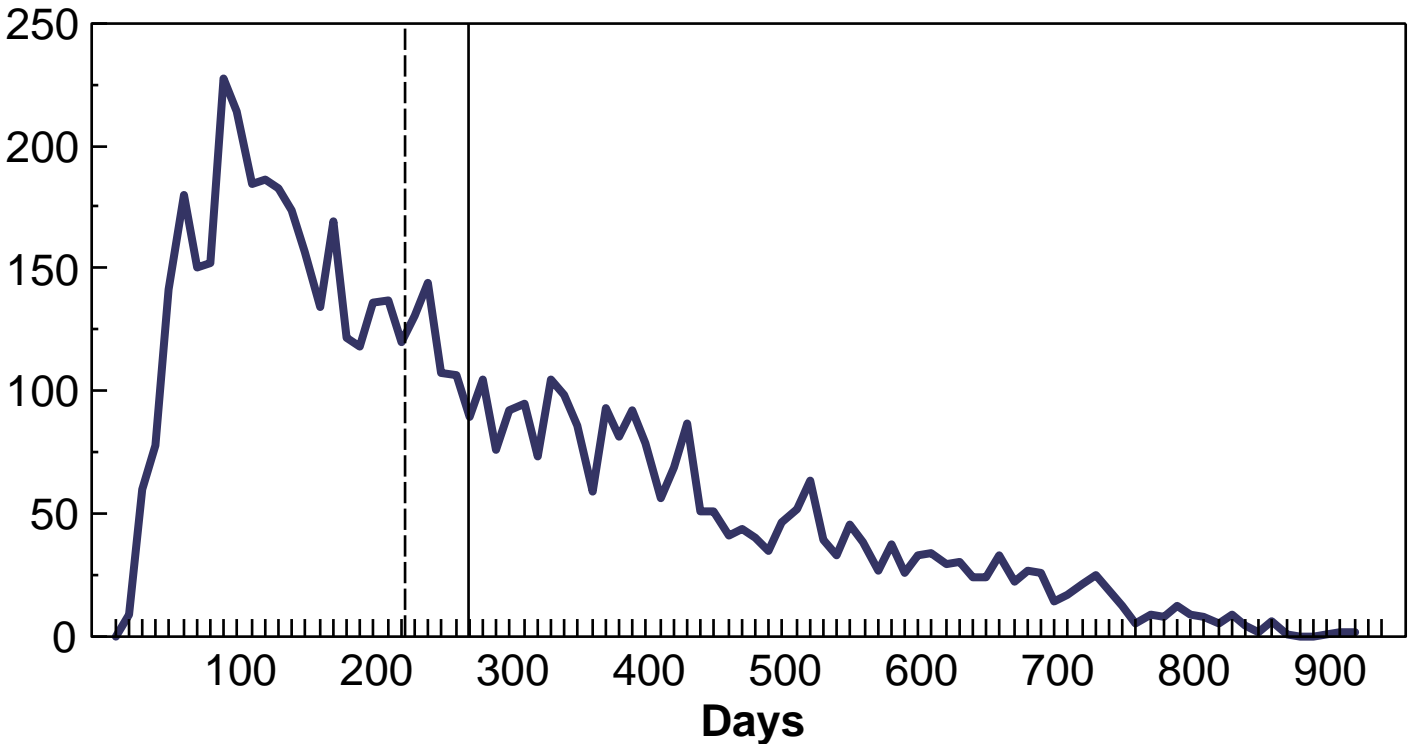
The second reason for using the median is that the distributions of review time for 510(k), original PMA, and PMA supplement applications are not symmetric, that is, having about the same number of applications requiring short reviews as lengthy reviews. The median is less sensitive to extreme values 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.<sup>13</sup>

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<sup>13</sup>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<sup>a</sup>

**Frequency**



—— Mean = 269  
 - - - - Median = 222

<sup>a</sup>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.<sup>14</sup> Another reason we report

<sup>14</sup>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.

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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.<sup>15</sup> 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.<sup>16</sup> 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.

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## Agency Comments

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

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<sup>15</sup>Using date-of-decision cohorts obviates the problem of open cases. Both means and medians can be easily determined.

<sup>16</sup>FDA has indicated that it plans to include statistics on review time based on the year of submission in its reports.



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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.

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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,

A handwritten signature in black ink, appearing to read 'Kwai-Cheung Chan'. The signature is fluid and cursive, with a long horizontal stroke at the end.

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

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**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

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# 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	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	
Premarket approval	Approved	Refuse to accept	
		Reconditioner/remanufacturer	
	Denied	Transitional device	
		Withdrawn by applicant	
	Withdrawn	Approved	
		Denied	
	Other	Abandoned	
		Converted	
		Reclassified	
		Other	

(continued)



**Appendix I**  
**FDA Decision Codes and GAO's Categories**

<b>Type of application</b>	<b>GAO category</b>	<b>FDA decision code</b>
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
	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		

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## 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.

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

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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).

**Appendix II  
 Premarket Notification (510(k)) Tables II.1 -  
 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		Nonequivalent		Other		Percentile				Open		Grand total
	N	Days	N	Days	N	Days	5	50	95	Mean	N	Days	
<b>1989</b>	5258	98	108	167	1655	205	19	86	336	124	2	2188	7023
<b>1990</b>	4633	100	142	162	1060	207	15	83	347	121	0	0	5835
<b>1991</b>	4513	124	140	225	1110	263	18	90	466	153	11	1458	5774
<b>1992</b>	4888	204	203	260	1388	387	32	164	685	245	54	1086	6533
<b>1993</b>	4654	233	108	296	1340	391	52	222	651	269	204	749	6306
<b>1994</b>	4342	141	86	182	1207	254	26	126	427	166	811	363	6446
<b>1995</b>	1429	70	16	73	260	49	14	58	153	67	1328	122	3033
<b>Total</b>	<b>29717</b>	<b>146</b>	<b>803</b>	<b>217</b>	<b>8020</b>	<b>278</b>	<b>21</b>	<b>111</b>	<b>518</b>	<b>175</b>	<b>2410</b>	<b>285</b>	<b>40950</b>

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

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

Class	Equivalent			Nonequivalent			Other			Percentile				Open		Grand total
	N	Percent	Days	N	Percent	Days	N	Percent	Days	5	50	95	Mean	N	Percent	
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
<b>Tier</b>																
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
<b>Medical specialty</b>																
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
<b>Division</b>																
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
<b>Total</b>	<b>29717</b>	<b>72.2</b>	<b>146</b>	<b>803</b>	<b>2.0</b>	<b>217</b>	<b>8020</b>	<b>19.6</b>	<b>278</b>	<b>21</b>	<b>111</b>	<b>518</b>	<b>175</b>	<b>2410</b>	<b>5.9</b>	<b>40950</b>

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

**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		Nonequivalent		Other		Total		Open N
		N	Days	N	Days	N	Days	N	Days	
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
	<b>Total</b>	<b>5258</b>	<b>98</b>	<b>108</b>	<b>167</b>	<b>1655</b>	<b>205</b>	<b>7021</b>	<b>124</b>	<b>2</b>
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
	<b>Total</b>	<b>4633</b>	<b>100</b>	<b>142</b>	<b>162</b>	<b>1060</b>	<b>207</b>	<b>5835</b>	<b>121</b>	<b>0</b>
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
	<b>Total</b>	<b>4513</b>	<b>124</b>	<b>140</b>	<b>225</b>	<b>1110</b>	<b>263</b>	<b>5763</b>	<b>153</b>	<b>11</b>
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
	<b>Total</b>	<b>4888</b>	<b>204</b>	<b>203</b>	<b>260</b>	<b>1388</b>	<b>387</b>	<b>6479</b>	<b>245</b>	<b>54</b>
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
	<b>Total</b>	<b>4654</b>	<b>233</b>	<b>108</b>	<b>296</b>	<b>1340</b>	<b>391</b>	<b>6102</b>	<b>269</b>	<b>204</b>
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
	<b>Total</b>	<b>4342</b>	<b>141</b>	<b>86</b>	<b>182</b>	<b>1207</b>	<b>254</b>	<b>5635</b>	<b>166</b>	<b>811</b>
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
	<b>Total</b>	<b>1429</b>	<b>70</b>	<b>16</b>	<b>73</b>	<b>260</b>	<b>49</b>	<b>1705</b>	<b>67</b>	<b>1328</b>
<b>Total</b>		<b>29717</b>	<b>146</b>	<b>803</b>	<b>217</b>	<b>8020</b>	<b>278</b>	<b>38540</b>	<b>175</b>	<b>2410</b>

**Appendix II**  
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**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		Nonequivalent		Other		Total		Open N
		N	Days	N	Days	N	Days	N	Days	
<b>1989</b>	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
	<b>Total</b>		<b>5258</b>	<b>98</b>	<b>108</b>	<b>167</b>	<b>1655</b>	<b>205</b>	<b>7021</b>	<b>124</b>
<b>1990</b>	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
	<b>Total</b>		<b>4633</b>	<b>100</b>	<b>142</b>	<b>162</b>	<b>1060</b>	<b>207</b>	<b>5835</b>	<b>121</b>
<b>1991</b>	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
	<b>Total</b>		<b>4513</b>	<b>124</b>	<b>140</b>	<b>225</b>	<b>1110</b>	<b>263</b>	<b>5763</b>	<b>153</b>
<b>1992</b>	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
	<b>Total</b>		<b>4888</b>	<b>204</b>	<b>203</b>	<b>260</b>	<b>1388</b>	<b>387</b>	<b>6479</b>	<b>245</b>
<b>1993</b>	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
	<b>Total</b>		<b>4654</b>	<b>233</b>	<b>108</b>	<b>296</b>	<b>1340</b>	<b>391</b>	<b>6102</b>	<b>269</b>
<b>1994</b>	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
	<b>Total</b>		<b>4342</b>	<b>141</b>	<b>86</b>	<b>182</b>	<b>1207</b>	<b>254</b>	<b>5635</b>	<b>166</b>
<b>1995</b>	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
	<b>Total</b>		<b>1429</b>	<b>70</b>	<b>16</b>	<b>73</b>	<b>260</b>	<b>49</b>	<b>1705</b>	<b>67</b>
<b>Total</b>		<b>29717</b>	<b>146</b>	<b>803</b>	<b>217</b>	<b>8020</b>	<b>278</b>	<b>38540</b>	<b>175</b>	<b>2410</b>



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

**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		Nonequivalent		Other		Total		Open N
		N	Days	N	Days	N	Days	N	Days	
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
	<b>Total</b>	<b>5258</b>	<b>98</b>	<b>108</b>	<b>167</b>	<b>1655</b>	<b>205</b>	<b>7021</b>	<b>124</b>	<b>2</b>
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
	<b>Total</b>	<b>4633</b>	<b>100</b>	<b>142</b>	<b>162</b>	<b>1060</b>	<b>207</b>	<b>5835</b>	<b>121</b>	<b>0</b>
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
	<b>Total</b>	<b>4513</b>	<b>124</b>	<b>140</b>	<b>225</b>	<b>1110</b>	<b>263</b>	<b>5763</b>	<b>153</b>	<b>11</b>
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
	<b>Total</b>	<b>4888</b>	<b>204</b>	<b>203</b>	<b>260</b>	<b>1388</b>	<b>387</b>	<b>6479</b>	<b>245</b>	<b>54</b>
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
	<b>Total</b>	<b>4654</b>	<b>233</b>	<b>108</b>	<b>296</b>	<b>1340</b>	<b>391</b>	<b>6102</b>	<b>269</b>	<b>204</b>
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
	<b>Total</b>	<b>4342</b>	<b>141</b>	<b>86</b>	<b>182</b>	<b>1207</b>	<b>254</b>	<b>5635</b>	<b>166</b>	<b>811</b>
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
	<b>Total</b>	<b>1429</b>	<b>70</b>	<b>16</b>	<b>73</b>	<b>260</b>	<b>49</b>	<b>1705</b>	<b>67</b>	<b>1328</b>
<b>Total</b>		<b>29717</b>	<b>146</b>	<b>803</b>	<b>217</b>	<b>8020</b>	<b>278</b>	<b>38540</b>	<b>175</b>	<b>2410</b>

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

**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		Nonequivalent		Other		Total		Open N
		N	Days	N	Days	N	Days	N	Days	
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
	<b>Total</b>		<b>5258</b>	<b>98</b>	<b>108</b>	<b>167</b>	<b>1655</b>	<b>205</b>	<b>7021</b>	<b>124</b>
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
	<b>Total</b>		<b>4633</b>	<b>100</b>	<b>142</b>	<b>162</b>	<b>1060</b>	<b>207</b>	<b>5835</b>	<b>121</b>
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
	<b>Total</b>		<b>4513</b>	<b>124</b>	<b>140</b>	<b>225</b>	<b>1110</b>	<b>263</b>	<b>5763</b>	<b>153</b>
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
	<b>Total</b>		<b>4888</b>	<b>204</b>	<b>203</b>	<b>260</b>	<b>1388</b>	<b>387</b>	<b>6479</b>	<b>245</b>
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
	<b>Total</b>		<b>4654</b>	<b>233</b>	<b>108</b>	<b>296</b>	<b>1340</b>	<b>391</b>	<b>6102</b>	<b>269</b>
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
	<b>Total</b>		<b>4342</b>	<b>141</b>	<b>86</b>	<b>182</b>	<b>1207</b>	<b>254</b>	<b>5635</b>	<b>166</b>
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
	<b>Total</b>		<b>1429</b>	<b>70</b>	<b>16</b>	<b>73</b>	<b>260</b>	<b>49</b>	<b>1705</b>	<b>69</b>
<b>Total</b>		<b>29717</b>	<b>146</b>	<b>803</b>	<b>217</b>	<b>8020</b>	<b>278</b>	<b>38540</b>	<b>175</b>	<b>2410</b>

**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
<b>Total</b>	<b>24917</b>	<b>108</b>	<b>25</b>	<b>133</b>	<b>21</b>	<b>90</b>	<b>378</b>

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

<b>Class</b>	<b>N</b>	<b>Total FDA time</b>	<b>Non-FDA time</b>	<b>Time lapse</b>
I	6839	85	19	104
II	16726	115	25	140
III	917	144	46	189
N/A	435	144	33	177
<b>Tier</b>				
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
<b>Medical specialty</b>				
General hospital	2773	108	31	139
General/plastic surgery	3093	109	17	125
Other	19044	108	25	133
N/A	7	66	12	77
<b>Division</b>				
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
<b>Total</b>	<b>24917</b>	<b>108</b>	<b>25</b>	<b>133</b>

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

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

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**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
<b>1989</b>	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
	<b>Total</b>	<b>5149</b>	<b>80</b>	<b>21</b>	<b>101</b>
<b>1990</b>	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
	<b>Total</b>	<b>4518</b>	<b>81</b>	<b>20</b>	<b>102</b>
<b>1991</b>	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
	<b>Total</b>	<b>4275</b>	<b>94</b>	<b>25</b>	<b>119</b>
<b>1992</b>	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
	<b>Total</b>	<b>4368</b>	<b>152</b>	<b>34</b>	<b>185</b>
<b>1993</b>	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
	<b>Total</b>	<b>3123</b>	<b>173</b>	<b>28</b>	<b>201</b>
<b>1994</b>	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
	<b>Total</b>	<b>2650</b>	<b>100</b>	<b>23</b>	<b>122</b>
<b>1995</b>	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
	<b>Total</b>	<b>834</b>	<b>60</b>	<b>7</b>	<b>66</b>
<b>Total</b>		<b>24917</b>	<b>108</b>	<b>25</b>	<b>133</b>

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

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

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

<b>Fiscal year</b>	<b>Division</b>	<b>N</b>	<b>Total FDA time</b>	<b>Non-FDA time</b>	<b>Time lapse</b>
<b>1989</b>	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
	<b>Total</b>	<b>5149</b>	<b>80</b>	<b>21</b>	<b>101</b>
<b>1990</b>	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
	<b>Total</b>	<b>4518</b>	<b>81</b>	<b>20</b>	<b>102</b>
<b>1991</b>	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
	<b>Total</b>	<b>4275</b>	<b>94</b>	<b>25</b>	<b>119</b>
<b>1992</b>	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
	<b>Total</b>	<b>4368</b>	<b>152</b>	<b>34</b>	<b>185</b>
<b>1993</b>	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
	<b>Total</b>	<b>3123</b>	<b>173</b>	<b>28</b>	<b>201</b>
<b>1994</b>	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
	<b>Total</b>	<b>2650</b>	<b>100</b>	<b>23</b>	<b>122</b>
<b>1995</b>	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
	<b>Total</b>	<b>834</b>	<b>60</b>	<b>7</b>	<b>66</b>
<b>Total</b>		<b>24917</b>	<b>108</b>	<b>25</b>	<b>133</b>



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## 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.<sup>1</sup> 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.)

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<sup>1</sup>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		Filing to panel		Panel to decision		Submission to panel		Submission to decision		Total applications
	N	Days	N	Days	N	Days	N	Days	N	Days	
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
<b>Total</b>	<b>289</b>	<b>148</b>	<b>87</b>	<b>216</b>	<b>77</b>	<b>444</b>	<b>87</b>	<b>379</b>	<b>275</b>	<b>591</b>	<b>401</b>

**PMA supplements**

Fiscal year	Submission to filing		Filing to panel		Panel to decision		Submission to panel		Submission to decision		Total applications
	N	Days	N	Days	N	Days	N	Days	N	Days	
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
<b>Total</b>	<b>35</b>	<b>164</b>	<b>9</b>	<b>174</b>	<b>9</b>	<b>309</b>	<b>9</b>	<b>325</b>	<b>3332</b>	<b>238</b>	<b>3640</b>

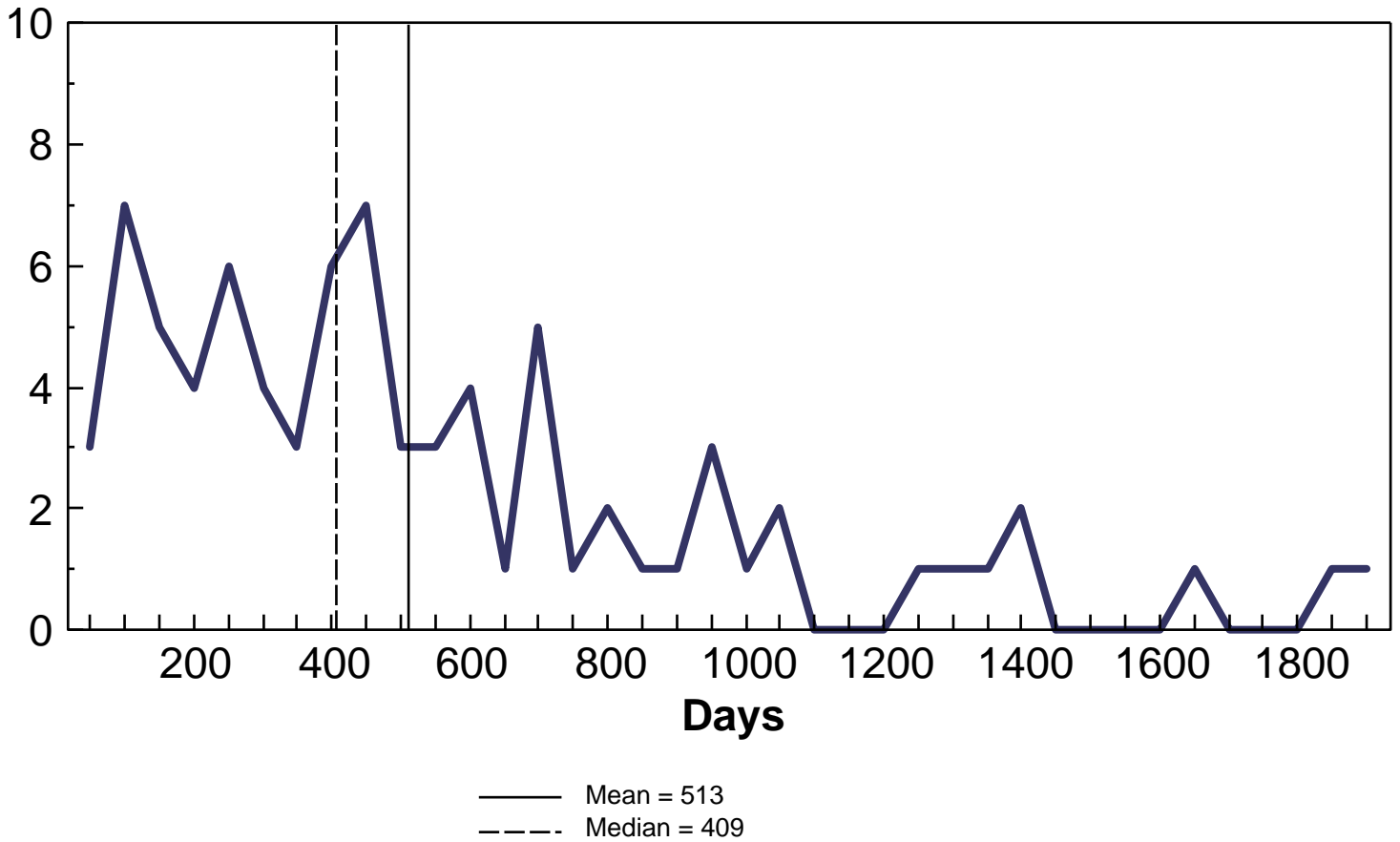
The following tables present information on review time for PMA applications for fiscal years 1989 through 1995. Original PMA applications are distinguished from PMA supplements. Some observations were deleted from our data because of apparent data entry errors. The first set of tables (tables III.1 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<sup>a</sup>

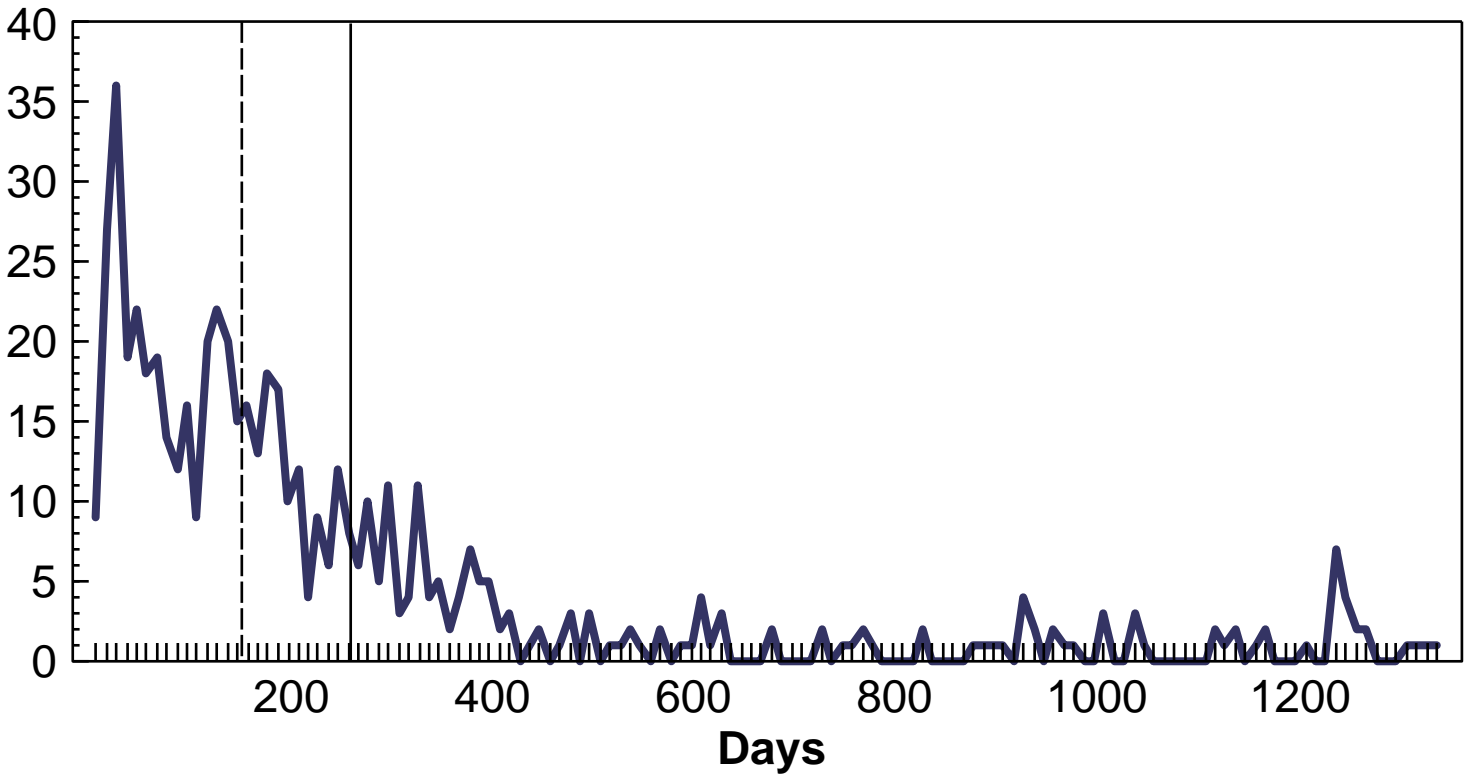
## Frequency



<sup>a</sup>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<sup>a</sup>

## Frequency



——— Mean = 261  
----- Median = 154

<sup>a</sup>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 specialties 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 through III.18 provide the details for these two summary tables.



Appendix III  
 Premarket Approval Tables III.1 - III.18

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

**Appendix III  
Premarket Approval Tables III.1 - III.18**

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

Class	Approved			Withdrawn			Other			Percentile				Open		Grand total
	N	Percent	Days	N	Percent	Days	N	Percent	Days	5	50	95	Mean	N	Percent	
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
<b>Tier</b>																
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
<b>Medical specialty</b>																
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
<b>Division</b>																
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
<b>Total</b>	<b>133</b>	<b>33.2</b>	<b>586</b>	<b>105</b>	<b>26.2</b>	<b>602</b>	<b>37</b>	<b>9.2</b>	<b>581</b>	<b>42</b>	<b>513</b>	<b>1455</b>	<b>591</b>	<b>126</b>	<b>31.4</b>	<b>401</b>

Appendix III  
 Premarket Approval Tables III.1 - III.18

**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		Withdrawn		Other		Total		Open N
		N	Days	N	Days	N	Days	N	Days	
<b>1989</b>	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
	<b>Total</b>	<b>45</b>	<b>412</b>	<b>27</b>	<b>747</b>	<b>9</b>	<b>320</b>	<b>81</b>	<b>513</b>	<b>3</b>
<b>1990</b>	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
	<b>Total</b>	<b>36</b>	<b>758</b>	<b>22</b>	<b>740</b>	<b>9</b>	<b>698</b>	<b>67</b>	<b>744</b>	<b>10</b>
<b>1991</b>	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
	<b>Total</b>	<b>21</b>	<b>556</b>	<b>27</b>	<b>528</b>	<b>12</b>	<b>741</b>	<b>60</b>	<b>580</b>	<b>12</b>
<b>1992</b>	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
	<b>Total</b>	<b>21</b>	<b>756</b>	<b>11</b>	<b>583</b>	<b>5</b>	<b>529</b>	<b>37</b>	<b>674</b>	<b>29</b>
<b>1993</b>	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
	<b>Total</b>	<b>7</b>	<b>575</b>	<b>12</b>	<b>406</b>	<b>2</b>	<b>402</b>	<b>21</b>	<b>462</b>	<b>19</b>
<b>1994</b>	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
	<b>Total</b>	<b>3</b>	<b>189</b>	<b>5</b>	<b>241</b>	<b>0</b>	<b>0</b>	<b>8</b>	<b>222</b>	<b>35</b>
<b>1995</b>	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
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>23</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>23</b>	<b>18</b>
<b>Total</b>		<b>133</b>	<b>586</b>	<b>105</b>	<b>602</b>	<b>37</b>	<b>581</b>	<b>275</b>	<b>591</b>	<b>126</b>

Appendix III  
 Premarket Approval Tables III.1 - III.18

**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 Days		Withdrawn N Days		Other N Days		Total N 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
	<b>Total</b>		<b>45</b>	<b>412</b>	<b>27</b>	<b>747</b>	<b>9</b>	<b>320</b>	<b>81</b>	<b>512</b>
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
	<b>Total</b>		<b>36</b>	<b>758</b>	<b>22</b>	<b>740</b>	<b>9</b>	<b>698</b>	<b>67</b>	<b>744</b>
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
	<b>Total</b>		<b>21</b>	<b>556</b>	<b>27</b>	<b>528</b>	<b>12</b>	<b>741</b>	<b>60</b>	<b>580</b>
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
	<b>Total</b>		<b>21</b>	<b>756</b>	<b>11</b>	<b>583</b>	<b>5</b>	<b>529</b>	<b>37</b>	<b>674</b>
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
	<b>Total</b>		<b>7</b>	<b>575</b>	<b>12</b>	<b>406</b>	<b>2</b>	<b>402</b>	<b>21</b>	<b>462</b>
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
	<b>Total</b>		<b>3</b>	<b>189</b>	<b>5</b>	<b>241</b>	<b>0</b>	<b>0</b>	<b>8</b>	<b>222</b>
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
	<b>Total</b>		<b>0</b>	<b>0</b>	<b>1</b>	<b>23</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>23</b>
<b>Total</b>		<b>133</b>	<b>586</b>	<b>105</b>	<b>602</b>	<b>37</b>	<b>581</b>	<b>275</b>	<b>591</b>	<b>126</b>

Appendix III  
 Premarket Approval Tables III.1 - III.18

**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)**

<b>Fiscal year</b>	<b>Medical specialty</b>	<b>Approved N Days</b>		<b>Withdrawn N Days</b>		<b>Other N Days</b>		<b>Total N Days</b>		<b>Open N</b>
<b>1989</b>	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
	<b>Total</b>	<b>45</b>	<b>412</b>	<b>27</b>	<b>747</b>	<b>9</b>	<b>320</b>	<b>81</b>	<b>513</b>	<b>3</b>
<b>1990</b>	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
	<b>Total</b>	<b>36</b>	<b>758</b>	<b>22</b>	<b>740</b>	<b>9</b>	<b>698</b>	<b>67</b>	<b>744</b>	<b>10</b>
<b>1991</b>	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
	<b>Total</b>	<b>21</b>	<b>556</b>	<b>27</b>	<b>528</b>	<b>12</b>	<b>741</b>	<b>60</b>	<b>580</b>	<b>12</b>
<b>1992</b>	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
	<b>Total</b>	<b>21</b>	<b>756</b>	<b>11</b>	<b>583</b>	<b>5</b>	<b>529</b>	<b>37</b>	<b>674</b>	<b>29</b>
<b>1993</b>	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
	<b>Total</b>	<b>7</b>	<b>575</b>	<b>12</b>	<b>406</b>	<b>2</b>	<b>402</b>	<b>21</b>	<b>462</b>	<b>19</b>
<b>1994</b>	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
	<b>Total</b>	<b>3</b>	<b>189</b>	<b>5</b>	<b>241</b>	<b>0</b>	<b>0</b>	<b>8</b>	<b>222</b>	<b>35</b>
<b>1995</b>	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
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>23</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>23</b>	<b>18</b>
<b>Total</b>		<b>133</b>	<b>586</b>	<b>105</b>	<b>602</b>	<b>37</b>	<b>581</b>	<b>275</b>	<b>591</b>	<b>126</b>

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 Premarket Approval Tables III.1 - III.18

**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 Days	Withdrawn N Days	Other N Days	Total N Days	Open N
<b>1989</b>	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
	<b>Total</b>	<b>45 412</b>	<b>27 747</b>	<b>9 320</b>	<b>81 513</b>	<b>3</b>
<b>1990</b>	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
	<b>Total</b>	<b>36 758</b>	<b>22 740</b>	<b>9 698</b>	<b>67 744</b>	<b>10</b>
<b>1991</b>	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
	<b>Total</b>	<b>21 556</b>	<b>27 528</b>	<b>12 741</b>	<b>60 580</b>	<b>12</b>
<b>1992</b>	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
	<b>Total</b>	<b>21 756</b>	<b>11 583</b>	<b>5 529</b>	<b>37 674</b>	<b>29</b>
<b>1993</b>	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
	<b>Total</b>	<b>7 575</b>	<b>12 406</b>	<b>2 402</b>	<b>21 462</b>	<b>19</b>
<b>1994</b>	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
	<b>Total</b>	<b>3 189</b>	<b>5 241</b>	<b>0 0</b>	<b>8 222</b>	<b>35</b>
<b>1995</b>	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
	<b>Total</b>	<b>0 0</b>	<b>1 23</b>	<b>0 0</b>	<b>1 23</b>	<b>18</b>
<b>Total</b>		<b>133 586</b>	<b>105 602</b>	<b>37 581</b>	<b>275 591</b>	<b>126</b>

**Appendix III  
 Premarket Approval Tables III.1 - III.18**

**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		Withdrawn		Other		Percentile				Open		Grand total
	N	Days	N	Days	N	Days	5	50	95	Mean	N	Days	
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
<b>Total</b>	<b>2822</b>	<b>211</b>	<b>420</b>	<b>404</b>	<b>89</b>	<b>305</b>	<b>21</b>	<b>167</b>	<b>749</b>	<b>238</b>	<b>309</b>	<b>527</b>	<b>3640</b>

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

Class	Approved			Withdrawn			Other			Percentile				Open		Grand total
	N	Percent	Days	N	Percent	Days	N	Percent	Days	5	50	95	Mean	N	Percent	
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
<b>Tier</b>																
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
<b>Medical specialty</b>																
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
<b>Division</b>																
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
<b>Total</b>	<b>2822</b>	<b>77.5</b>	<b>211</b>	<b>420</b>	<b>11.5</b>	<b>404</b>	<b>89</b>	<b>2.4</b>	<b>305</b>	<b>21</b>	<b>167</b>	<b>749</b>	<b>238</b>	<b>309</b>	<b>8.5</b>	<b>3640</b>



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 Premarket Approval Tables III.1 - III.18

**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		Withdrawn		Other		Total		Open N
		N	Days	N	Days	N	Days	N	Days	
<b>1989</b>	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
	<b>Total</b>	<b>640</b>	<b>190</b>	<b>137</b>	<b>363</b>	<b>26</b>	<b>167</b>	<b>803</b>	<b>219</b>	<b>1</b>
<b>1990</b>	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
	<b>Total</b>	<b>557</b>	<b>164</b>	<b>70</b>	<b>442</b>	<b>23</b>	<b>142</b>	<b>650</b>	<b>193</b>	<b>10</b>
<b>1991</b>	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
	<b>Total</b>	<b>493</b>	<b>226</b>	<b>72</b>	<b>462</b>	<b>12</b>	<b>479</b>	<b>577</b>	<b>261</b>	<b>18</b>
<b>1992</b>	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
	<b>Total</b>	<b>474</b>	<b>300</b>	<b>84</b>	<b>478</b>	<b>13</b>	<b>747</b>	<b>571</b>	<b>336</b>	<b>34</b>
<b>1993</b>	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
	<b>Total</b>	<b>311</b>	<b>250</b>	<b>30</b>	<b>403</b>	<b>10</b>	<b>372</b>	<b>351</b>	<b>266</b>	<b>43</b>
<b>1994</b>	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
	<b>Total</b>	<b>269</b>	<b>165</b>	<b>22</b>	<b>141</b>	<b>4</b>	<b>75</b>	<b>295</b>	<b>162</b>	<b>77</b>
<b>1995</b>	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
	<b>Total</b>	<b>78</b>	<b>80</b>	<b>5</b>	<b>74</b>	<b>1</b>	<b>39</b>	<b>84</b>	<b>79</b>	<b>126</b>
<b>Total</b>		<b>2822</b>	<b>211</b>	<b>420</b>	<b>404</b>	<b>89</b>	<b>305</b>	<b>3331</b>	<b>238</b>	<b>309</b>

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 Premarket Approval Tables III.1 - III.18

**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 Days		Withdrawn N Days		Other N Days		Total N Days		Open N
<b>1989</b>	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
	<b>Total</b>	<b>640</b>	<b>190</b>	<b>137</b>	<b>363</b>	<b>26</b>	<b>167</b>	<b>803</b>	<b>219</b>	<b>1</b>
<b>1990</b>	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
	<b>Total</b>	<b>557</b>	<b>164</b>	<b>70</b>	<b>442</b>	<b>23</b>	<b>142</b>	<b>650</b>	<b>193</b>	<b>10</b>
<b>1991</b>	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
	<b>Total</b>	<b>493</b>	<b>226</b>	<b>72</b>	<b>462</b>	<b>12</b>	<b>479</b>	<b>577</b>	<b>261</b>	<b>18</b>
<b>1992</b>	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
	<b>Total</b>	<b>474</b>	<b>300</b>	<b>84</b>	<b>478</b>	<b>13</b>	<b>747</b>	<b>571</b>	<b>336</b>	<b>34</b>
<b>1993</b>	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
	<b>Total</b>	<b>311</b>	<b>250</b>	<b>30</b>	<b>403</b>	<b>10</b>	<b>372</b>	<b>351</b>	<b>266</b>	<b>43</b>
<b>1994</b>	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
	<b>Total</b>	<b>269</b>	<b>165</b>	<b>22</b>	<b>141</b>	<b>4</b>	<b>75</b>	<b>295</b>	<b>162</b>	<b>77</b>
<b>1995</b>	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
	<b>Total</b>	<b>78</b>	<b>80</b>	<b>5</b>	<b>74</b>	<b>1</b>	<b>39</b>	<b>84</b>	<b>79</b>	<b>126</b>
<b>Total</b>		<b>2822</b>	<b>211</b>	<b>420</b>	<b>404</b>	<b>89</b>	<b>305</b>	<b>3331</b>	<b>238</b>	<b>309</b>

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 Premarket Approval Tables III.1 - III.18

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 Days		Withdrawn N Days		Other N Days		Total N 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
	<b>Total</b>	<b>640</b>	<b>190</b>	<b>137</b>	<b>363</b>	<b>26</b>	<b>167</b>	<b>803</b>	<b>219</b>	<b>1</b>
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
	<b>Total</b>	<b>557</b>	<b>164</b>	<b>70</b>	<b>442</b>	<b>23</b>	<b>142</b>	<b>650</b>	<b>193</b>	<b>10</b>
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
	<b>Total</b>	<b>493</b>	<b>226</b>	<b>72</b>	<b>462</b>	<b>12</b>	<b>479</b>	<b>577</b>	<b>261</b>	<b>18</b>
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
	<b>Total</b>	<b>474</b>	<b>300</b>	<b>84</b>	<b>478</b>	<b>13</b>	<b>747</b>	<b>571</b>	<b>336</b>	<b>34</b>
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
	<b>Total</b>	<b>311</b>	<b>250</b>	<b>30</b>	<b>403</b>	<b>10</b>	<b>372</b>	<b>351</b>	<b>266</b>	<b>43</b>
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
	<b>Total</b>	<b>269</b>	<b>165</b>	<b>22</b>	<b>141</b>	<b>4</b>	<b>75</b>	<b>295</b>	<b>162</b>	<b>77</b>
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
	<b>Total</b>	<b>78</b>	<b>80</b>	<b>5</b>	<b>74</b>	<b>1</b>	<b>39</b>	<b>84</b>	<b>79</b>	<b>126</b>
<b>Total</b>		<b>2822</b>	<b>211</b>	<b>420</b>	<b>404</b>	<b>89</b>	<b>305</b>	<b>3331</b>	<b>238</b>	<b>309</b>

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**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 Days		Withdrawn N Days		Other N Days		Total N Days		Open N
<b>1989</b>	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
	<b>Total</b>	<b>640</b>	<b>190</b>	<b>137</b>	<b>363</b>	<b>26</b>	<b>167</b>	<b>803</b>	<b>219</b>	<b>1</b>
<b>1990</b>	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
	<b>Total</b>	<b>557</b>	<b>164</b>	<b>70</b>	<b>442</b>	<b>23</b>	<b>142</b>	<b>650</b>	<b>193</b>	<b>10</b>
<b>1991</b>	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
	<b>Total</b>	<b>493</b>	<b>226</b>	<b>72</b>	<b>462</b>	<b>12</b>	<b>479</b>	<b>577</b>	<b>261</b>	<b>18</b>
<b>1992</b>	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
	<b>Total</b>	<b>474</b>	<b>300</b>	<b>84</b>	<b>478</b>	<b>13</b>	<b>747</b>	<b>571</b>	<b>336</b>	<b>34</b>
<b>1993</b>	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
	<b>Total</b>	<b>311</b>	<b>250</b>	<b>30</b>	<b>403</b>	<b>10</b>	<b>372</b>	<b>351</b>	<b>266</b>	<b>43</b>
<b>1994</b>	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
	<b>Total</b>	<b>269</b>	<b>165</b>	<b>22</b>	<b>141</b>	<b>4</b>	<b>75</b>	<b>295</b>	<b>162</b>	<b>77</b>
<b>1995</b>	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
	<b>Total</b>	<b>78</b>	<b>80</b>	<b>5</b>	<b>74</b>	<b>1</b>	<b>39</b>	<b>84</b>	<b>79</b>	<b>126</b>
<b>Total</b>		<b>2822</b>	<b>211</b>	<b>420</b>	<b>404</b>	<b>89</b>	<b>305</b>	<b>3331</b>	<b>238</b>	<b>309</b>

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

<b>Original PMAs</b>										
<b>Fiscal year</b>	<b>FDA review time</b>		<b>Total FDA time</b>	<b>Non-FDA time</b>	<b>Time lapse</b>	<b>Percentiles for time lapse</b>			<b>Number of amendments</b>	<b>Requests for information</b>
	<b>N</b>	<b>time</b>				<b>5</b>	<b>50</b>	<b>95</b>		
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
<b>Total</b>	<b>133</b>	<b>280</b>	<b>449</b>	<b>137</b>	<b>586</b>	<b>72</b>	<b>501</b>	<b>1421</b>	<b>10</b>	<b>3</b>

<b>PMA supplements</b>										
<b>Fiscal year</b>	<b>FDA review time</b>		<b>Total FDA time</b>	<b>Non-FDA time</b>	<b>Time lapse</b>	<b>Percentiles for time lapse</b>			<b>Number of amendments</b>	<b>Requests for information</b>
	<b>N</b>	<b>time</b>				<b>5</b>	<b>50</b>	<b>95</b>		
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
<b>Total</b>	<b>2822</b>	<b>115</b>	<b>137</b>	<b>74</b>	<b>211</b>	<b>22</b>	<b>151</b>	<b>639</b>	<b>1</b>	<b>1</b>

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

Class	Original PMAs					PMA supplements				
	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
<b>Tier</b>										
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
<b>Medical specialty</b>										
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
<b>Division</b>										
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
<b>Total</b>	<b>133</b>	<b>280</b>	<b>449</b>	<b>137</b>	<b>586</b>	<b>2822</b>	<b>115</b>	<b>137</b>	<b>74</b>	<b>211</b>

**Appendix III  
Premarket Approval Tables III.1 - III.18**

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

Fiscal year	Class	Original PMAs					PMA supplements				
		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
	<b>Total</b>	<b>45</b>	<b>230</b>	<b>320</b>	<b>92</b>	<b>412</b>	<b>640</b>	<b>113</b>	<b>126</b>	<b>64</b>	<b>190</b>
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
	<b>Total</b>	<b>36</b>	<b>327</b>	<b>547</b>	<b>211</b>	<b>758</b>	<b>557</b>	<b>85</b>	<b>105</b>	<b>59</b>	<b>164</b>
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
	<b>Total</b>	<b>21</b>	<b>264</b>	<b>441</b>	<b>115</b>	<b>556</b>	<b>493</b>	<b>117</b>	<b>147</b>	<b>79</b>	<b>226</b>
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
	<b>Total</b>	<b>21</b>	<b>346</b>	<b>591</b>	<b>165</b>	<b>756</b>	<b>474</b>	<b>164</b>	<b>202</b>	<b>98</b>	<b>300</b>
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
	<b>Total</b>	<b>7</b>	<b>264</b>	<b>495</b>	<b>80</b>	<b>575</b>	<b>311</b>	<b>135</b>	<b>157</b>	<b>93</b>	<b>250</b>
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
	<b>Total</b>	<b>3</b>	<b>138</b>	<b>155</b>	<b>34</b>	<b>189</b>	<b>269</b>	<b>96</b>	<b>109</b>	<b>56</b>	<b>165</b>
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
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>78</b>	<b>29</b>	<b>29</b>	<b>51</b>	<b>80</b>
<b>Total</b>		<b>133</b>	<b>280</b>	<b>449</b>	<b>137</b>	<b>586</b>	<b>2822</b>	<b>115</b>	<b>137</b>	<b>74</b>	<b>211</b>

**Appendix III  
Premarket Approval Tables III.1 - III.18**

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

Fiscal year	Tier	Original PMAs					PMA supplements				
		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
	<b>Total</b>	<b>45</b>	<b>230</b>	<b>320</b>	<b>92</b>	<b>412</b>	<b>640</b>	<b>113</b>	<b>126</b>	<b>64</b>	<b>190</b>
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
	<b>Total</b>	<b>36</b>	<b>327</b>	<b>547</b>	<b>211</b>	<b>758</b>	<b>557</b>	<b>85</b>	<b>105</b>	<b>59</b>	<b>164</b>
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
	<b>Total</b>	<b>21</b>	<b>264</b>	<b>441</b>	<b>115</b>	<b>556</b>	<b>493</b>	<b>117</b>	<b>147</b>	<b>79</b>	<b>226</b>
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
	<b>Total</b>	<b>21</b>	<b>346</b>	<b>591</b>	<b>165</b>	<b>756</b>	<b>474</b>	<b>164</b>	<b>202</b>	<b>98</b>	<b>300</b>
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
	<b>Total</b>	<b>7</b>	<b>264</b>	<b>495</b>	<b>80</b>	<b>575</b>	<b>311</b>	<b>135</b>	<b>157</b>	<b>93</b>	<b>250</b>
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
	<b>Total</b>	<b>3</b>	<b>138</b>	<b>155</b>	<b>34</b>	<b>189</b>	<b>269</b>	<b>96</b>	<b>109</b>	<b>56</b>	<b>165</b>
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
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>78</b>	<b>29</b>	<b>29</b>	<b>51</b>	<b>80</b>
<b>Total</b>		<b>133</b>	<b>280</b>	<b>449</b>	<b>137</b>	<b>586</b>	<b>2822</b>	<b>115</b>	<b>137</b>	<b>74</b>	<b>211</b>



**Appendix III  
Premarket Approval Tables III.1 - III.18**

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

Fiscal year	Medical specialty	Original PMAs					PMA supplements				
		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
	Ophthalmic	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
	<b>Total</b>	<b>45</b>	<b>230</b>	<b>320</b>	<b>92</b>	<b>412</b>	<b>640</b>	<b>113</b>	<b>126</b>	<b>64</b>	<b>190</b>
1990	Cardiovascular	7	238	632	310	942	180	65	90	59	149
	Ophthalmic	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
	<b>Total</b>	<b>36</b>	<b>327</b>	<b>547</b>	<b>211</b>	<b>758</b>	<b>557</b>	<b>85</b>	<b>105</b>	<b>59</b>	<b>164</b>
1991	Cardiovascular	8	218	603	156	759	177	84	101	67	168
	Ophthalmic	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
	<b>Total</b>	<b>21</b>	<b>264</b>	<b>441</b>	<b>115</b>	<b>556</b>	<b>493</b>	<b>117</b>	<b>147</b>	<b>79</b>	<b>226</b>
1992	Cardiovascular	7	283	614	143	757	171	110	156	99	255
	Ophthalmic	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
	<b>Total</b>	<b>21</b>	<b>346</b>	<b>591</b>	<b>165</b>	<b>756</b>	<b>474</b>	<b>164</b>	<b>202</b>	<b>98</b>	<b>300</b>
1993	Cardiovascular	2	164	506	39	545	139	122	153	82	235
	Ophthalmic	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
	<b>Total</b>	<b>7</b>	<b>264</b>	<b>495</b>	<b>80</b>	<b>575</b>	<b>311</b>	<b>135</b>	<b>157</b>	<b>93</b>	<b>250</b>
1994	Cardiovascular	1	168	168	57	225	140	96	120	66	186
	Ophthalmic	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
	<b>Total</b>	<b>3</b>	<b>138</b>	<b>155</b>	<b>34</b>	<b>189</b>	<b>269</b>	<b>96</b>	<b>109</b>	<b>56</b>	<b>165</b>
1995	Cardiovascular	0	0	0	0	0	43	16	17	61	78
	Ophthalmic	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
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>78</b>	<b>29</b>	<b>29</b>	<b>51</b>	<b>80</b>
<b>Total</b>		<b>133</b>	<b>280</b>	<b>449</b>	<b>137</b>	<b>586</b>	<b>2822</b>	<b>115</b>	<b>137</b>	<b>74</b>	<b>211</b>

**Appendix III  
Premarket Approval Tables III.1 - III.18**

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

Fiscal year	Division	Original PMAs					PMA supplements				
		N	FDA review time	Total FDA time	Non-FDA time	Time lapse	N	FDA review time	Total FDA time	Non-FDA time	Time lapse
<b>1989</b>	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
	<b>Total</b>	<b>45</b>	<b>230</b>	<b>320</b>	<b>92</b>	<b>412</b>	<b>640</b>	<b>113</b>	<b>126</b>	<b>64</b>	<b>190</b>
<b>1990</b>	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
	<b>Total</b>	<b>36</b>	<b>327</b>	<b>547</b>	<b>211</b>	<b>758</b>	<b>557</b>	<b>85</b>	<b>105</b>	<b>59</b>	<b>164</b>
<b>1991</b>	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
	<b>Total</b>	<b>21</b>	<b>264</b>	<b>441</b>	<b>115</b>	<b>556</b>	<b>493</b>	<b>117</b>	<b>147</b>	<b>79</b>	<b>226</b>
<b>1992</b>	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
	<b>Total</b>	<b>21</b>	<b>346</b>	<b>591</b>	<b>165</b>	<b>756</b>	<b>474</b>	<b>164</b>	<b>202</b>	<b>98</b>	<b>300</b>
<b>1993</b>	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
	<b>Total</b>	<b>7</b>	<b>264</b>	<b>495</b>	<b>80</b>	<b>575</b>	<b>311</b>	<b>135</b>	<b>157</b>	<b>93</b>	<b>250</b>
<b>1994</b>	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
	<b>Total</b>	<b>3</b>	<b>138</b>	<b>155</b>	<b>34</b>	<b>189</b>	<b>269</b>	<b>96</b>	<b>109</b>	<b>56</b>	<b>165</b>
<b>1995</b>	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
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>78</b>	<b>29</b>	<b>29</b>	<b>51</b>	<b>80</b>
<b>Total</b>		<b>133</b>	<b>280</b>	<b>449</b>	<b>137</b>	<b>586</b>	<b>2822</b>	<b>115</b>	<b>137</b>	<b>74</b>	<b>211</b>

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# Investigational Device Exemption Tables

## IV.1 - IV.6

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## **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.

**Appendix IV**  
**Investigational Device Exemption Tables**  
**IV.1 - IV.6**

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

**Appendix IV**  
**Investigational Device Exemption Tables**  
**IV.1 - IV.6**

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

Class	Approved			Denied			Withdrawn			Other			Total N	Percentile			Mean
	N	Percent	Days	N	Percent	Days	N	Percent	Days	N	Percent	Days		5	50	95	
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
<b>Tier</b>																	
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
<b>Medical specialty</b>																	
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
<b>Division</b>																	
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
<b>Total</b>	<b>488</b>	<b>33.0</b>	<b>29</b>	<b>886</b>	<b>59.9</b>	<b>29</b>	<b>23</b>	<b>1.6</b>	<b>31</b>	<b>81</b>	<b>5.5</b>	<b>38</b>	<b>1478</b>	<b>21</b>	<b>30</b>	<b>31</b>	<b>30</b>

**Appendix IV**  
**Investigational Device Exemption Tables**  
**IV.1 - IV.6**

**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 Days		Denied N Days		Withdrawn N Days		Other N Days		Total N Days	
<b>1989</b>	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
	<b>Total</b>	<b>89</b>	<b>31</b>	<b>142</b>	<b>30</b>	<b>6</b>	<b>25</b>	<b>7</b>	<b>45</b>	<b>244</b>	<b>31</b>
<b>1990</b>	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
	<b>Total</b>	<b>95</b>	<b>29</b>	<b>150</b>	<b>29</b>	<b>2</b>	<b>29</b>	<b>17</b>	<b>49</b>	<b>264</b>	<b>30</b>
<b>1991</b>	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
	<b>Total</b>	<b>71</b>	<b>28</b>	<b>133</b>	<b>29</b>	<b>0</b>	<b>0</b>	<b>17</b>	<b>64</b>	<b>221</b>	<b>32</b>
<b>1992</b>	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
	<b>Total</b>	<b>74</b>	<b>29</b>	<b>136</b>	<b>29</b>	<b>4</b>	<b>29</b>	<b>14</b>	<b>26</b>	<b>228</b>	<b>29</b>
<b>1993</b>	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
	<b>Total</b>	<b>58</b>	<b>29</b>	<b>161</b>	<b>27</b>	<b>4</b>	<b>50</b>	<b>18</b>	<b>22</b>	<b>241</b>	<b>27</b>
<b>1994</b>	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
	<b>Total</b>	<b>42</b>	<b>28</b>	<b>120</b>	<b>29</b>	<b>5</b>	<b>27</b>	<b>4</b>	<b>13</b>	<b>171</b>	<b>28</b>
<b>1995</b>	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
	<b>Total</b>	<b>59</b>	<b>30</b>	<b>44</b>	<b>30</b>	<b>2</b>	<b>26</b>	<b>4</b>	<b>18</b>	<b>109</b>	<b>30</b>
<b>Total</b>		<b>488</b>	<b>29</b>	<b>866</b>	<b>29</b>	<b>23</b>	<b>31</b>	<b>81</b>	<b>38</b>	<b>1478</b>	<b>30</b>

**Appendix IV**  
**Investigational Device Exemption Tables**  
**IV.1 - IV.6**

**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		Denied		Withdrawn		Other		Total	
		N	Days	N	Days	N	Days	N	Days	N	Days
<b>1989</b>	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
	<b>Total</b>		<b>89</b>	<b>31</b>	<b>142</b>	<b>30</b>	<b>6</b>	<b>25</b>	<b>7</b>	<b>45</b>	<b>244</b>
<b>1990</b>	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
	<b>Total</b>		<b>95</b>	<b>29</b>	<b>150</b>	<b>29</b>	<b>2</b>	<b>29</b>	<b>17</b>	<b>49</b>	<b>264</b>
<b>1991</b>	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
	<b>Total</b>		<b>71</b>	<b>28</b>	<b>133</b>	<b>29</b>	<b>0</b>	<b>0</b>	<b>17</b>	<b>64</b>	<b>221</b>
<b>1992</b>	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
	<b>Total</b>		<b>74</b>	<b>29</b>	<b>136</b>	<b>29</b>	<b>4</b>	<b>29</b>	<b>14</b>	<b>26</b>	<b>228</b>
<b>1993</b>	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
	<b>Total</b>		<b>58</b>	<b>29</b>	<b>161</b>	<b>27</b>	<b>4</b>	<b>50</b>	<b>18</b>	<b>22</b>	<b>241</b>
<b>1994</b>	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
	<b>Total</b>		<b>42</b>	<b>28</b>	<b>120</b>	<b>29</b>	<b>5</b>	<b>27</b>	<b>4</b>	<b>13</b>	<b>171</b>
<b>1995</b>	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
	<b>Total</b>		<b>59</b>	<b>30</b>	<b>44</b>	<b>30</b>	<b>2</b>	<b>26</b>	<b>4</b>	<b>18</b>	<b>109</b>
<b>Total</b>		<b>488</b>	<b>29</b>	<b>886</b>	<b>29</b>	<b>23</b>	<b>31</b>	<b>81</b>	<b>38</b>	<b>1478</b>	<b>30</b>



**Appendix IV**  
**Investigational Device Exemption Tables**  
**IV.1 - IV.6**

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

**Appendix IV**  
**Investigational Device Exemption Tables**  
**IV.1 - IV.6**

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

Fiscal year	Division	Approved		Denied		Withdrawn		Other		Total	
		N	Days	N	Days	N	Days	N	Days	N	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
	<b>Total</b>		<b>89</b>	<b>31</b>	<b>142</b>	<b>30</b>	<b>6</b>	<b>25</b>	<b>7</b>	<b>45</b>	<b>244</b>
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
	<b>Total</b>		<b>95</b>	<b>29</b>	<b>150</b>	<b>29</b>	<b>2</b>	<b>29</b>	<b>17</b>	<b>49</b>	<b>264</b>
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
	<b>Total</b>		<b>71</b>	<b>28</b>	<b>133</b>	<b>29</b>	<b>0</b>	<b>0</b>	<b>17</b>	<b>64</b>	<b>221</b>
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
	<b>Total</b>		<b>74</b>	<b>29</b>	<b>136</b>	<b>29</b>	<b>4</b>	<b>29</b>	<b>14</b>	<b>26</b>	<b>228</b>
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
	<b>Total</b>		<b>58</b>	<b>29</b>	<b>161</b>	<b>27</b>	<b>4</b>	<b>50</b>	<b>18</b>	<b>22</b>	<b>241</b>
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
	<b>Total</b>		<b>42</b>	<b>28</b>	<b>120</b>	<b>29</b>	<b>5</b>	<b>27</b>	<b>4</b>	<b>13</b>	<b>171</b>
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
	<b>Total</b>		<b>59</b>	<b>30</b>	<b>44</b>	<b>30</b>	<b>2</b>	<b>26</b>	<b>4</b>	<b>18</b>	<b>109</b>
<b>Total</b>		<b>488</b>	<b>29</b>	<b>886</b>	<b>29</b>	<b>23</b>	<b>31</b>	<b>81</b>	<b>38</b>	<b>1478</b>	<b>30</b>

# Comparison 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)**

Fiscal year	510(k)				Original PMA				PMA supplement				IDE			
	Decision N Days		Submission N Days		Decision N Days		Submission N Days		Decision N Days		Submission N Days		Decision N Days		Submission N 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
<b>Total</b>	<b>38539</b>	<b>175</b>	<b>38540</b>	<b>175</b>	<b>275</b>	<b>591</b>	<b>275</b>	<b>591</b>	<b>3331</b>	<b>237</b>	<b>3331</b>	<b>237</b>	<b>1478</b>	<b>30</b>	<b>1478</b>	<b>30</b>
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

AUG 02 1995

Date

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*  
Diane E. Thompson

Attachment

Appendix VI  
Comments From the Food and Drug  
Administration

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

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

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.

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

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See comment 5.

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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

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

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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

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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).

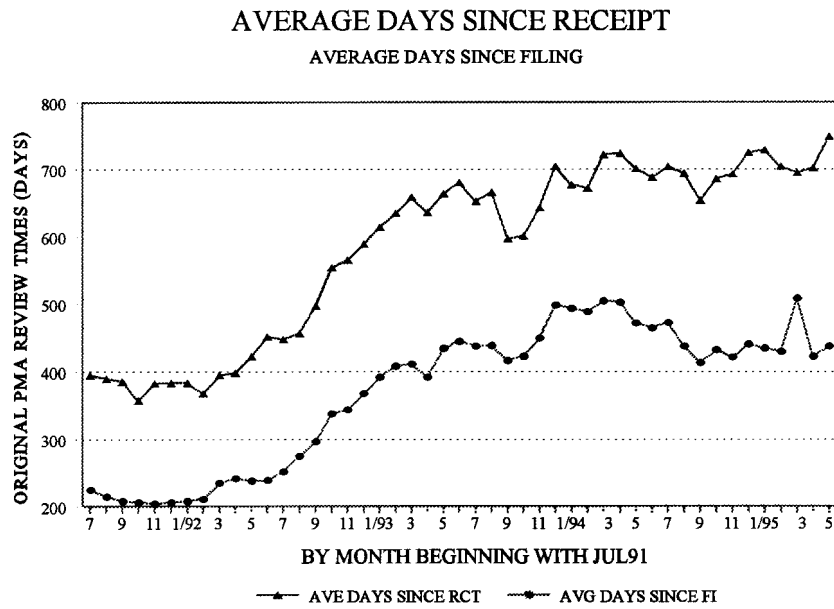
**IDE REVIEW**

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.

See comment 10.

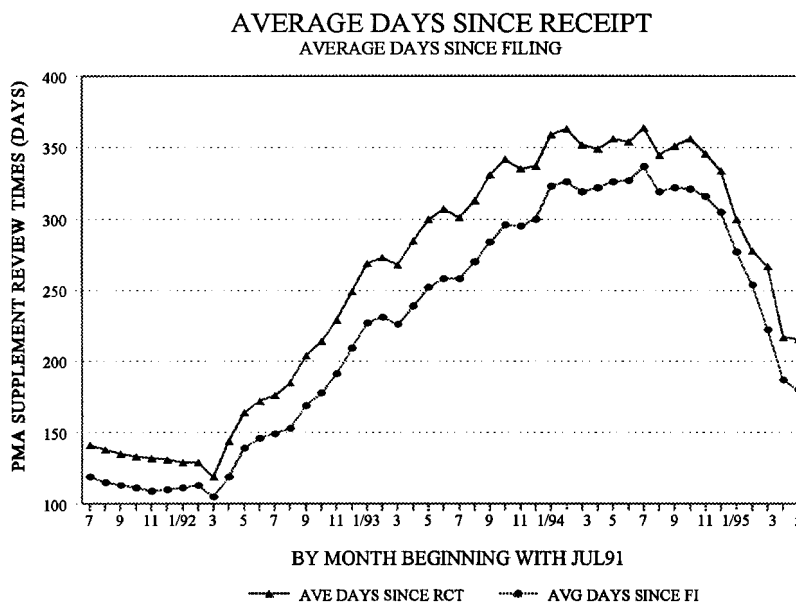
FDA also provided technical comments, which have been incorporated into the text where appropriate but have not been reprinted here.

Figure 1



INSERT 1

Figure 2



INSERT 2

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

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## 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.

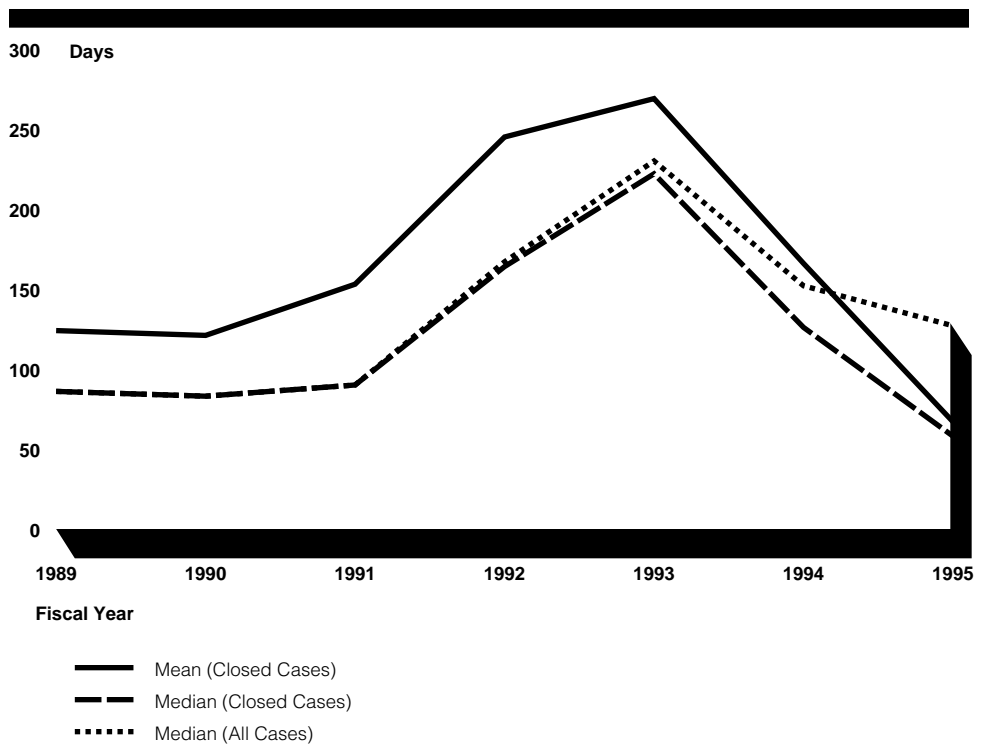
2. In discussing our methodology in the draft report, we noted the differences between FDA's typical method of reporting review time according to the year in which action on applications is finalized, as opposed to our method of assigning applications to the year in which they were submitted. We also 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<sup>a</sup>



<sup>a</sup>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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