DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date · JAN 25 1991

From Director, Office of Device Evaluation
Center for Devices and Radiological Health

Subject Office of Device Evaluation Annual Report for Fiscal Year 1990

To Acting Director and Acting Deputy Director
Center for Devices and Radiological Health

I am pleased to present to you the ODE Annual Report for Fiscal Year 1990. During FY 90, we saw a stable and solid performance by the ODE staff. We received an all time high of 10,430 major submissions. Furthermore, FY 90 is only the second year in which the number of reviews exceeded the number of submissions. Despite this high level of output, virtually all IDE and 510(k) decisions were made within statutorily mandated time frames. We ended the year with no active and overdue IDE or 510(k) documents. There was a general reduction in the numbers of documents awaiting action with a significant reduction in the number of pending PMA supplements. The overdue PMAs (24) and PMA Supplements (62) that remained from last year were reduced to five PMAs and seven PMA supplements by the end of FY 90. As we expected, some average review times rose due to the factors identified and discussed in the report.

In the program development area, we completed the final stage of phasing out IOL adjunct studies, we issued many new guidance documents for reviewers and industry, and we instituted an enhanced documentation system in support of 510(k) decisions.

On behalf of the ODE staff and management, I wish to thank you and the other CDRH offices that helped make possible our accomplishments in FY 90.

Robert L. Sheridan

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1990

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

Acknowledgements

The Office of Health Affairs, CDRH, provided valuable assistance by reviewing this report . Carl T. DeMarco compiled and edited the report. The PMA, IDE, and 510(k) staff officers, in conjunction with Eileen Marshall of the Office of Information Systems, provided the data, and each ODE division provided divisional information used in the report. Margretann N. Alvarado provided data input support using desktop computer equipment and software.

OFFICE OF DEVICE EVALUATION
ANNUAL REPORT
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Dear ODE Colleague:

Attached is the ODE Annual Report for Fiscal Year 1990. As in the past, it contains statistical data for our three major program activities (premarket approval, investigational devices, and premarket notification), as well as other program areas, divisional data and highlights, and management programs. This year, the report also includes an expanded analysis of resources and production data.

In terms of performance in FY 90, the report reflects a stable and solid effort by the ODE staff. We averaged 46 major reviews per FTE last year. This rate of review has been relatively steady over the past four years, ranging from 44 to 46 reviews per FTE. Moreover, we reviewed an all time high 10,430 major submissions and, for only the second time since 1980, we reviewed more submissions than we received. This resulted in virtually eliminating the number of PMAs and PMA supplements that are awaiting decision or that were active and overdue. There was also a significant reduction in the number of pending 510(k)s. While there was a rise in the average review times in the PMA and 510(k) program areas, this resulted primarily from the reduction in overdue PMAs and from the exemption of certain Class I devices from submission requirements.

Looking at production figures alone does not reveal the true depth and dimensions of your accomplishments. The data in this report do not document the numerous program improvements and operational enhancements that were instituted throughout ODE. They do not illustrate the difficulty of the issues that had to be resolved, the impact of the scientific decisions that were made on a day-to-day basis and the quality of the judgments that were needed to render our decisions in a quality and timely manner. These are the intrinsic qualities of the ODE staff that cannot be measured but, nevertheless, constitute our most valuable resource.

The ODE management team knows how hard the staff has worked throughout the year and we appreciate your support. Congratulations on a job well done.

Robert L. Sheridan
Director

David L. West
Deputy Director

Abhijit Acharya
Cardiovascular Devices

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Obsterics, Gynecology, Ear,
Nose, Throat and Dental
Devices

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The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health is responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research or marketing. The following are the highlights of the activities of ODE for fiscal year 1990 (FY 90). These highlights are explained more fully in the body of the report.

Workload

After experiencing a tremendous surge of submissions during FY 89, the number of submissions received during FY 90 returned to levels experienced in prior years. We received 15,879 total submissions and 10,153 major submissions during FY 90.

On the output side, ODE reviewed an all-time high of 10,430 major submissions. Records were set for the number of PMA supplements(700) and 510(k)s(6,197) reviewed in one fiscal year. This also is only the second fiscal year in which the number of documents reviewed exceeded the number of major documents received.

Resources

During the past fiscal year, ODE's actual FTE usage grew modestly from 222 to 227. ODE staffing levels increased from 218 people on board at the end of FY 89 to 276 as of September 30, 1990. Most of these new hires took place during the second half of the fiscal year and were not a major factor in productivity during FY 90. On balance, ODE lost 30 employees (14 scientific reviewers and 16 support staff) and hired 88 new full-time employees (66 of whom are scientific reviewers) both to replace those who resigned or retired and to fill the increase in authorized FTEs.

Premarket Approval

During FY 90 we received 79 original and 660 supplemental PMAs. We approved 47 PMAs, which is consistent with the PMA approval rates in FY 87 and FY 88. This year's approval of 47 PMAs is 9 fewer than the 56 PMAs approved in FY 89, which was the second highest number of PMAs ever approved in one fiscal year. The number of PMA supplements approved rose dramatically over last year's 519 to 700 for the current year, an increase of 35% in productivity in this area. This year's approved supplements included five''panel track'' supplements.

The number of PMAs pending at the end of this fiscal year was in line with the last two years but the number of supplements pending was reduced from 531 last year to 335 at the end of this year. This represents a 37% reduction in the number of supplements pending. The 5 PMAs and 7 supplements that were active and overdue at the end of this fiscal year represents a dramatic reduction from the end of last year, when there were 24 original and 62 supplements active and overdue. This reversal in the number of active and overdue PMAs was due to in large part to the special management attention that

was applied, through a specially created IOL Task Force, to the unusual influx of IOL PMAs during the first quarter of FY 89. The reversal was also made possible during this fiscal year through the eventual recovery of FTEs lost to the prior year's move from Silver Spring to Gaithersburg.

The average review time for original PMAs and PMA supplements was up from the average review times for the last fiscal year and are about level with review times in FY 87. The increase in the average FDA review time was due primarily to the virtual elimination of original and supplemental backlogs which contained overdue submissions. In particular, eight original PMAs that were part of the backlog at the end of FY 89 were approved with long review times. These PMAs included six IOL PMAs that had an average review time of 350 days and two PMAs for surgical products that averaged 429 days. Another factor that is becoming an increasing problem and has a negative effect on PMA approval rates and review times is the failure of a substantial number of manufacturers to meet GMP requirements during the PMA approval process.

Investigational Devices

We received the second highest number of IDE originals(252), amendments(288), and supplements (3,043) ever received in one fiscal year. Despite this increased volume of work, average review times for each of these submission types remained virtually constant with the last few years and 99% of all decisions were made within the prescribed 30 days. There were no IDEs, amendments, or supplements active and overdue as of this reporting date. For the third year in a row we were able to increase the percentage of original IDEs approved, 38% for FY 90, which is the highest percentage of original IDE approvals for the last five years. This is important because of the savings in cost and time for FDA and industry alike when an IDE can be approved upon its first review.

Premarket Notification (510(k))

After the record number of 510(k)s received in FY 89, we received, in FY 90, what might be considered a "normal" number of submissions when compared to prior fiscal years. We reviewed a record number of 510(k)s for the third year in a row. Both FDA and total average review times went up because of a general change in circumstances in the 510(k) program. FY 90 was the first full year in which approximately 40% of Class I devices, the ones that took very little time to review, were exempted from 510(k) premarket notification review. Review times also rose due to three specific factors discussed in the report. The number of 510(k)s pending at the end of the year were reduced 16% and there were no active and overdue 510(k)s as of the end of FY 90. For the first time ever in the 510(k) program we can report that 100% of the decisions were made within the specified 90-day time frame.

Guidance for Industry and Reviewers

ODE and its divisions developed 30 guidance documents on the following subjects for use by industry and ODE reviewers.

- Implantable Pacemaker Lead Testing
- Integrity of the Medical Device Review Process

- Meetings with the Regulated Industry
- 510(k) Sterility Review Guidance
- Policy Development and Review Procedures
- Explant Protocol
- Heart Valve Annual Report Guidance
- Content and Organization of Premarket Notification for Medical Lasers
- Approval of Speaking Engagements
- ODE Peer Review Promotion Process
- When PMA Supplements are Required
- Cochlear Implants in Adults at least 18 years of Age
- Cochlear Implants in Children Ages 2 through 17 years
- Replacement Heart Valves
- Endolymphatic Shunt Tube with Valve
- ODE Mentor Program
- Vascular Graft
- Training Checklist for New Reviewers
- PMA Filing Decisions
- Intraortic Balloon (IAB) Catheter Guidance
- Testing and Development of Female Barrier Contraceptives Guidelines
- Ultrasound Device Guidance
- Biliary Lithotripsy Studies
- Assignment of Review Documents
- Document Control Procedures
- Implantable Port Guidance
- Consolidated Review of Submissions for Laser and Accessories
- Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories, and Related Measurement Devices
- Review of Approval of Licensee PMAs
- 510(k) Independent Quality Review Program

Classification of Medical Devices

We received a panel recommendation to classify human dura mater as a Class II pre-amendments medical device.

Reclassification

During the year, we reclassified the following devices from class III to class II:

- the nonabsorbable polyamide surgical suture;

- the nonabsorbable poly(ethylene terephthalate) surgical suture;
- the nonabsorbable polypropylene surgical suture;
- the automated differential cell counter; and,
- the ceramic head hip prosthesis.

We also published in the *Federal Register* a proposal to reclassify the electroconvulsive therapy device for severe depression from class III to class II.

An advisory panel recommended the argon laser for rhinology and larygology be reclassified from class III to class II.

Call for PMAs for Pre-Amendments Devices

This year we published three proposed 515(b) rules requiring PMAs for endosseous implants, endolyphatic shunts, and silicone gel-filled breast implants.

Advisory Panel Activities

We held 29 medical device panel meetings during the past fiscal year, revised the panel charter to create one omnibus committee that will include the current 16 panels, and instituted a major orientation and training program for panel members and executive secretaries.

Freedom of Information Requests

ODE processed 1,214 Freedom of Information requests.

Publications

During FY 90 the Information Clearance Committee cleared 12 articles (three abstracts and nine manuscripts) authored by ODE staff for publication in professional and scientific journals and 14 presentations to be delivered by ODE staff at professional and scientific and trade association meetings.

Office Management and Automation

The major office management event of this fiscal year was the recruiting and hiring of 88 new employees. Along with the new hires came the somewhat difficult tasks of providing office space, furniture and training.

The Office of Device Evaluation continued to enhance its office automation capability as a means to process device applications and prepare review documents as quickly as possible. With the purchase of IBM compatible personal computers during the past two years, the foundation has been set for the use of continuously improved personal computer software and optical disk technology in ODE. To orient the ODE employee to the new PCs and the emerging technology, a *Personal Computer Guide* for ODE was developed by the Program Management Office.

ANNUAL REPORT
OFFICE OF DEVICE EVALUATION
FISCAL YEAR 1990

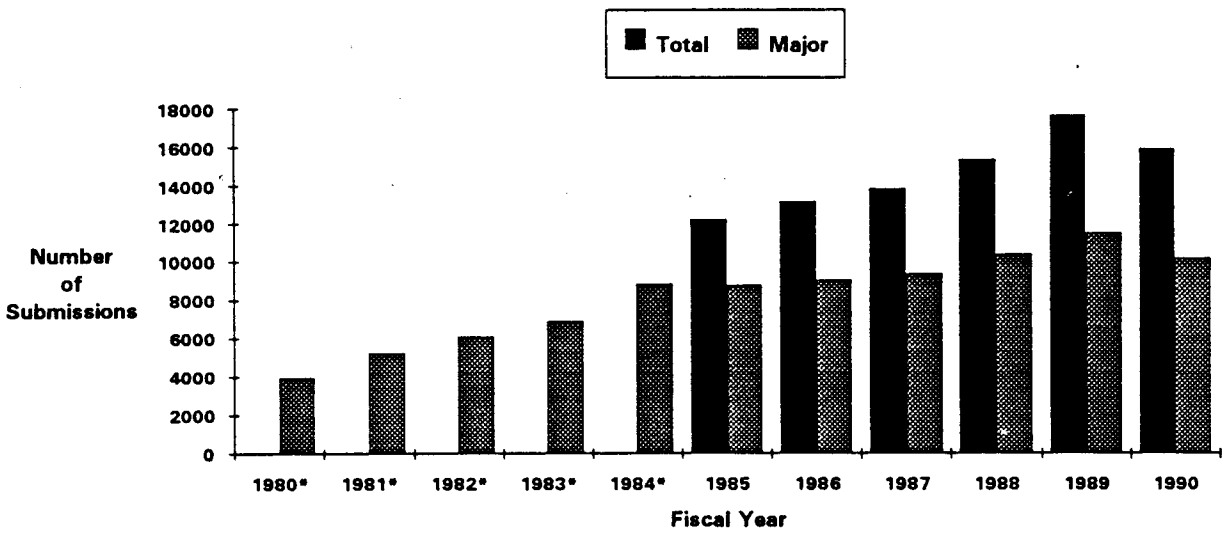
I. Introduction

The Office of Device Evaluation(ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health is responsible for the program areas through which medical devices are evaluated and cleared for human clinical trials or marketing. This report provides information about major programs administered by ODE during Fiscal Year 1990 (FY 90), beginning on October 1, 1989 and running through September 30, 1990. It emphasizes activities of the premarket approval, investigational device exemption, and premarket notification programs. The report contains comparative performance data from previous fiscal years and trend analyses. Procedure and policy guidance that was issued during the year and major management initiatives to further implement our policy and program goals and to streamline our practices and procedures are discussed. It also addresses device reclassification, 515(b) regulations, advisory panel activities, and freedom of information. Specific information about ODE divisional activities is also presented in this report.

II. Overall Workload and Resources

A. Workload

CHART 1 - Submissions Received by ODE
FY 80 - FY 90



* Data on Total Submissions for FY 80 - FY 84 is not available.

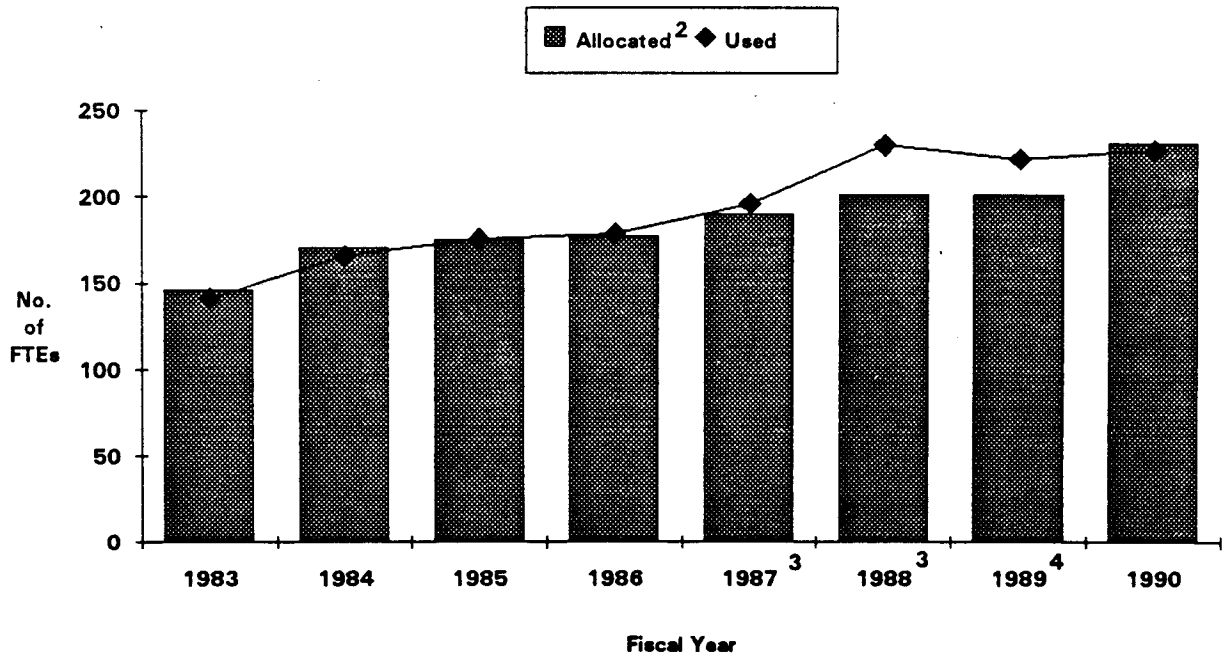
After experiencing a tremendous surge of total incoming submissions during FY 89, the number of total submissions received during FY 90 returned to normal. We received 15,879 total submissions for the year which is in line with the number of total submissions received in years prior to FY 89. The same is true for the number of major submissions: PMAs, PMA supplements, IDEs, IDE amendments and supplements, and 510(k)s. We received a total of 10,153 major submissions during FY 90, which is comparable to the pre-FY 89 submission rate.

On the output side, ODE reviewed an all-time high of 10,430 major submissions. Records were set for the number of PMA supplements (700) and 510(k)s (6,197) reviewed within one fiscal year. This also is only the second fiscal year in which the number of documents reviewed exceeded the number of major documents received.

B. Resources

During the past fiscal year, ODE's actual FTE usage grew modestly from 222 to 227. Our staffing level increased from 218 people on board at the end of FY 89 to 276 as of September 30 , 1990. This growth is a direct result of the authorization from FDA for ODE to recruit new personnel during the second half of FY 90. Since most of these new hires took place near the end of FY 90, they were not a major factor in productivity during this past fiscal year.

CHART 2 - ODE Full -Time Equivalents (FTEs) [1]
FY 83 - FY 90



1. This chart does not include resources in other Center officies that applied to product approval.
2. The allocated FTEs are official ceilings at the beginning of each fiscal year.
3. ODE was allowed to use FTEs in excess of its official ceiling because of FTE under-utilization elsewhere in FDA.
4. ODE was allowed to use FTEs in excess of its official ceiling because of FTE under-utilization elsewhere in FDA. The number of FTEs used in FY 89 includes 14 FTEs which were not available due to the relocation of ODE offices.

In FY 90, ODE lost 30 employees (14 scientific reviewers and 16 support staff) through resignation or retirement. Some of this loss relates to the ODE office relocation from Silver Spring in July 1989 and to delays in some employees finding alternative employment. However, this attrition was more than offset by the successful hiring of 88 new full-time employees in FY 90 (66 of whom are scientific reviewers) both to replace those who resigned or retired and to fill the increase in authorized FTEs.

C. Analysis

For the first time, this report includes charts that analyze some of the relationships between workload, resources, and output. For example, Chart 3, Workload versus Resources, shows that since FY 83 the resources available to ODE have increased at a rate that closely parallels the rate of increase in major submissions. If total submissions were compared, the rate of increase in the number of FTEs would not be quite so comparable.

CHART 3 - Workload versus Resources
FY 83 - FY 90

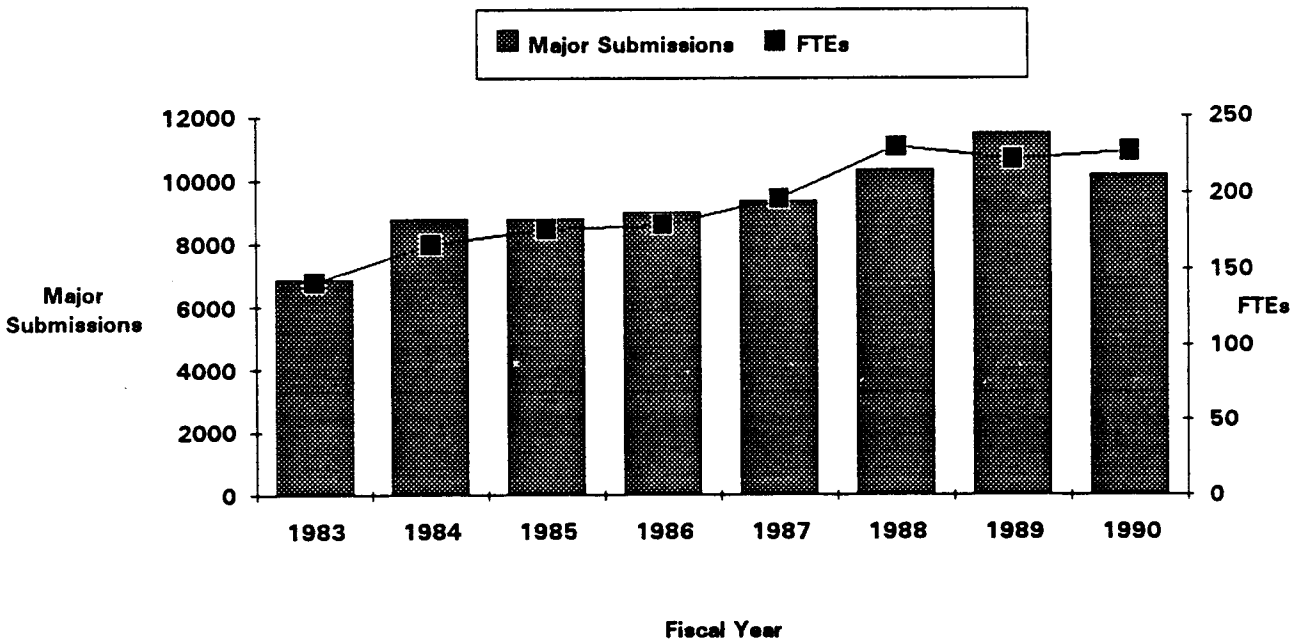
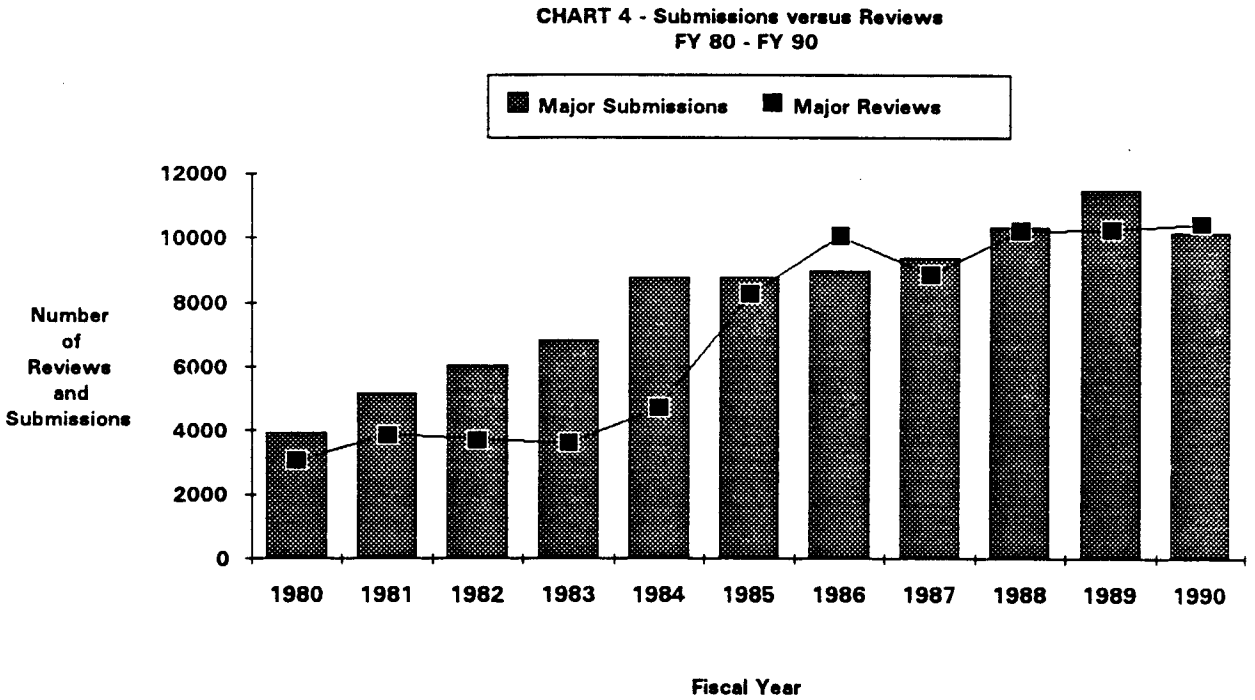
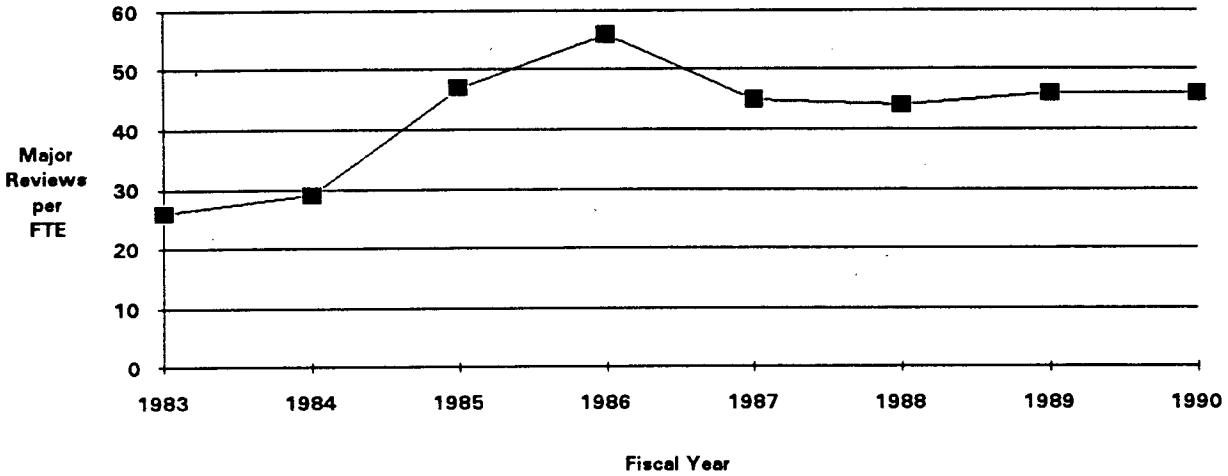


Chart 4, Submissions versus Reviews, illustrates a major jump in productivity. Prior to FY 85, the number of reviews per year fell far short of the number of annual submissions. Then, from FY 85 to present, the annual number of reviews is almost equal to the number of submissions each year. In two years during that time span, in FY 86 and FY 90, major reviews out-numbered the major submissions.



This leap in productivity is confirmed in Chart 5, Submissions Review Efficiency. Prior to FY 85 the number of major reviews per FTE was between 20 and 30. In FY 85 the number of reviews per FTE jumped to the upper 40s and has remained between 40 and 50 reviews per FTE every fiscal year since, except FY 86 in which case the rate rose to an all-time high of 56. Based on the review rate since 1985, there seems to be a stable rate of 40-50 reviews per FTE per year. During this time span, 510(k) exemptions have taken effect for as many as 50% of the Class I devices. This has removed from the review cycle most of the "easier" 510(k) submissions and left ODE with the relatively more difficult and complicated reviews. Maintaining output at about 40 to 50 reviews per FTE indicates improved and stable efficiency over the last few years.

CHART - 5 Submissions Review Efficiency*
FY 80 - FY 90



* The efficiency rate is calculated by dividing the number of major submissions reviewed by the total ODE FTEs used during the fiscal year.

III. Major Program Activities and Performance

This section describes and analyzes activities in the three major program areas which are ODE's primary responsibility, i.e., Premarket Approval, Investigational Devices, and Premarket Notification. Reference data are contained in the statistical tables in Part VII of the report and comparative data are displayed graphically throughout the report.

A. Premarket Approval

1. Premarket Approval Applications (PMAs)

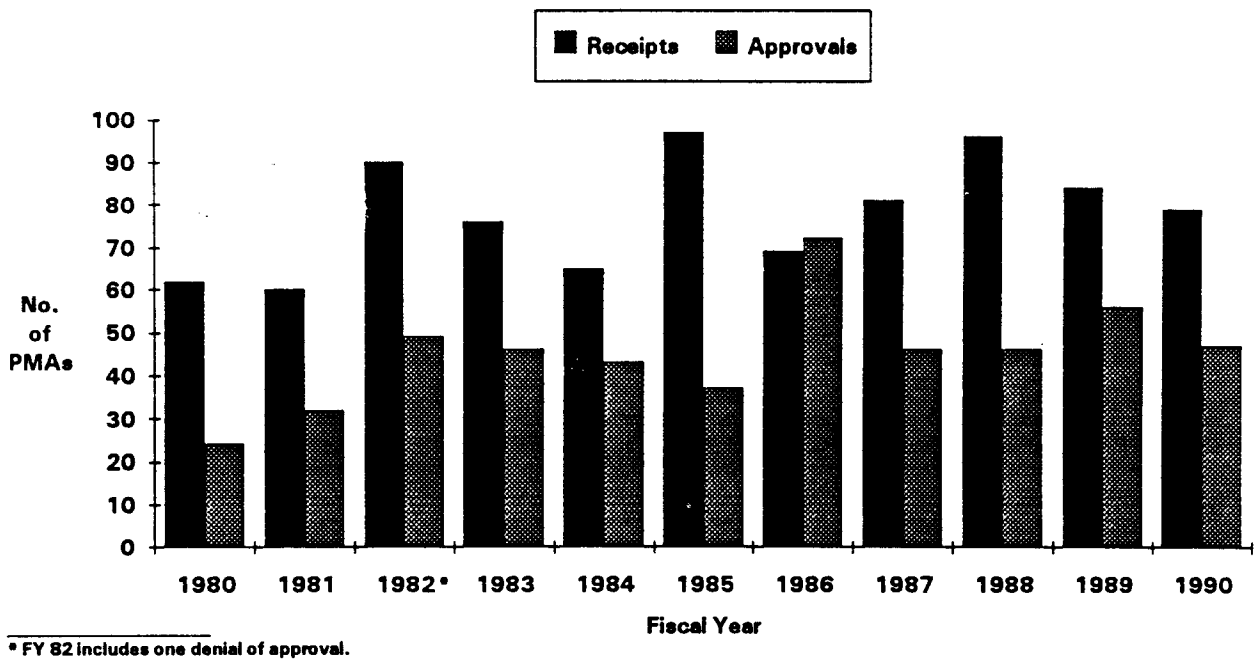
Under the Federal Food, Drug, and Cosmetic Act (the act) and the FDA regulations, *Code of Federal Regulations, Title 21* (the regulations), a manufacturer or others must submit a PMA for FDA review and approval before marketing certain new devices. The PMA must provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufactured in accordance with current good manufacturing practices. As part of its review process FDA must present the PMA to an expert advisory panel for its recommendations on the application. After obtaining the panel recommendations, the agency makes its determination to approve the PMA, deny it, or request additional information. If the PMA is approved or denied approval, FDA must publish a notice in the *Federal Register* to inform the public of the decision and to make available a summary of the safety and effectiveness data upon which the decision is based.

This report includes average FDA review times as calculated in accordance with the provisions of the 1986 PMA regulation, 21 *CFR* Part 814. These averages can be found in Tables 2 and 3, Part VII of this report. This regulation establishes a new methodology by which to calculate the statutory time within which FDA must complete its review of original and supplemental PMAs. Under this regulation, the method for calculating PMA review time is now the same as that used to calculate review time for new drug applications. In addition, this report continues to carry PMA review times as calculated under the old system so that comparisons can be made between current performance and performances in previous years.

During this fiscal year, 79 original PMAs were submitted. A total of 47 were approved which is consistent with the PMA approval rates in FY 87 and FY 88. This year's approval of 47 PMAs is 9 fewer than the 56 PMAs approved in FY 89, which was the second highest number of PMAs ever approved in one fiscal year.

The average review times for PMAs went up from last year and was about level with the review times in FY 87. Both the average FDA and nonFDA review days for PMAs rose from 247 to 302 and from 101 to 113, respectively. The same holds true for these average review

CHART 6 - Annual PMA Receipts and Approvals
FY 80 - FY 90



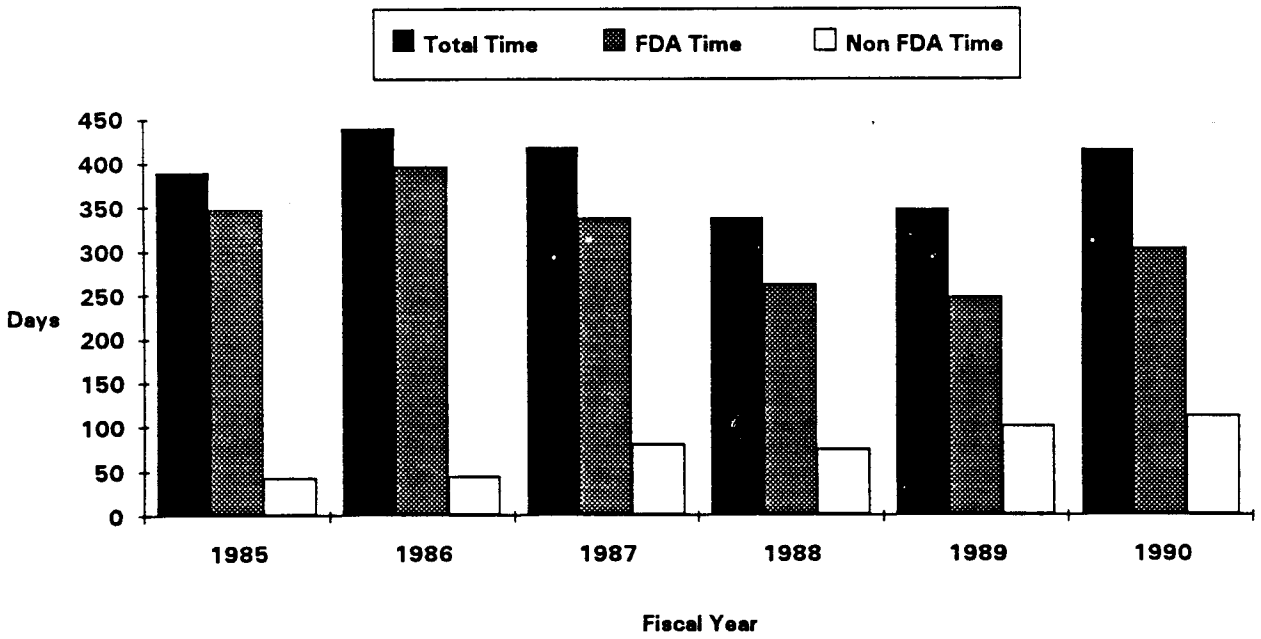
* FY 82 includes one denial of approval.

times when calculated under the PMA regulation. The FDA average review time went from 145 days in FY 89 to 228 days in FY 90 and nonFDA days rose from 42 to 55 over this same time period. This increase in the average FDA review time was due primarily to the completion of work on 19 PMAs that were active and overdue with long review times at the time they were approved. In particular, this backlog included six IOL PMAs that had an average review time of 350 days and two PMAs for surgical products that averaged 429 days. Another factor that is becoming an increasing problem and has a negative effect on PMA approval rates and review times is the failure of a substantial number of manufacturers to meet Good Manufacturing Practices requirements during the PMA approval process.

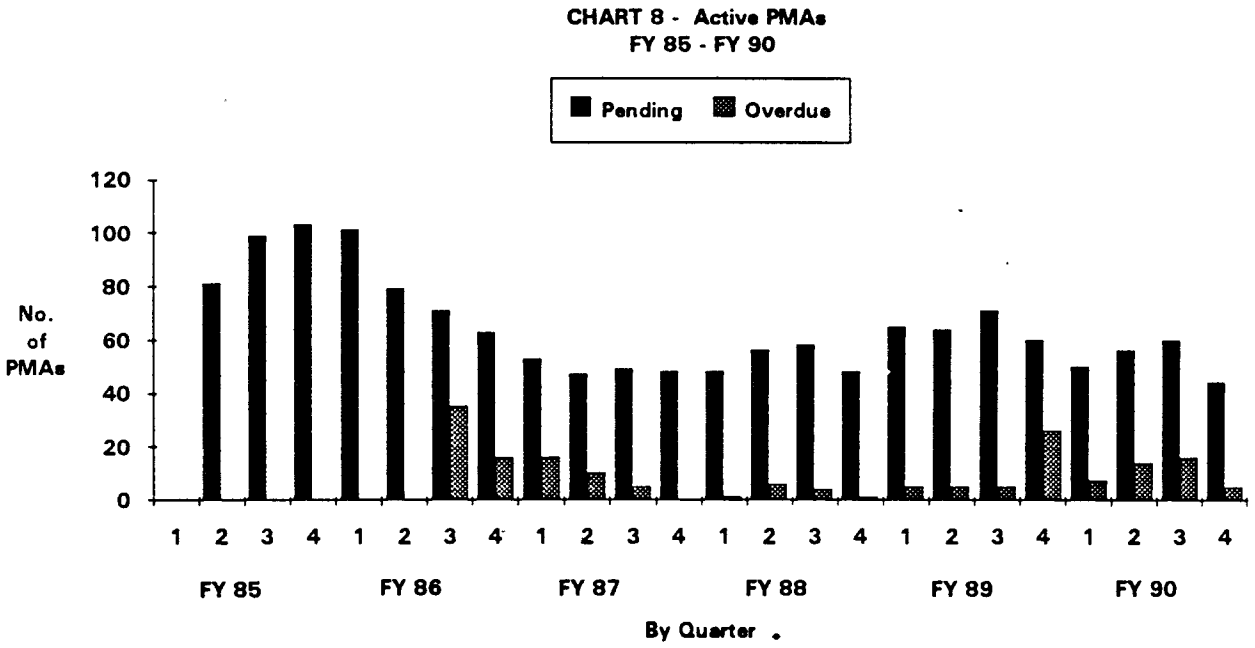
The total number of PMAs under review at the end of the fiscal year has remained almost constant for the last three years at 114, 114 and 116. The active PMAs under review at the end of this fiscal year was reduced to 44 from last year's 62, while those on hold went up a bit from last year, from 52 to 72.

The number of PMAs that were active and overdue was reduced dramatically from 24 last year to 5 at the end of FY 90. This reversal in the number of active and overdue PMAs was

CHART 7 - Average Approval Time for PMAs
FY 85 - FY 90



due to in large part to the special management attention that was applied, through a specially created IOL Task Force, to the unusual influx of IOL PMAs during the first quarter of FY 89. The reversal was also possible during this fiscal year through the eventual recovery of FTEs lost to the prior year's move from Silver Spring to Gaithersburg.



* Pending data not available for 1/85 quarter; overdue data not available prior to 3/86 quarter.

2. PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the new PMA procedural regulation, those changes affecting the safety or effectiveness of the device require FDA approval. FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology.

CHART 9 - Annual PMA Supplement Receipts and Approvals
FY 80 - FY 90

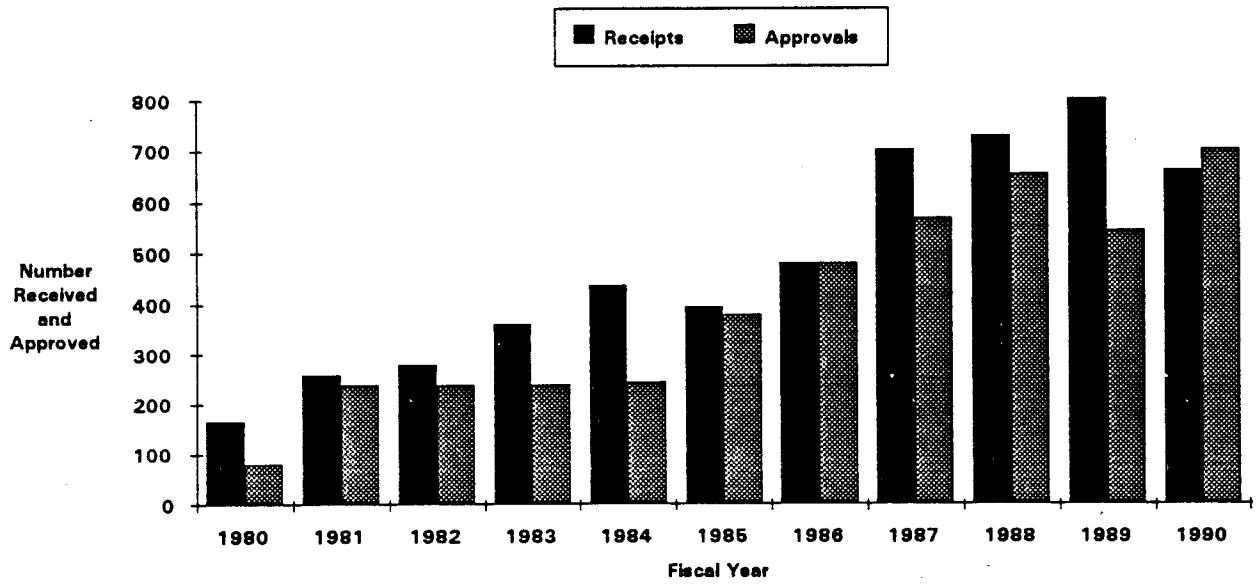
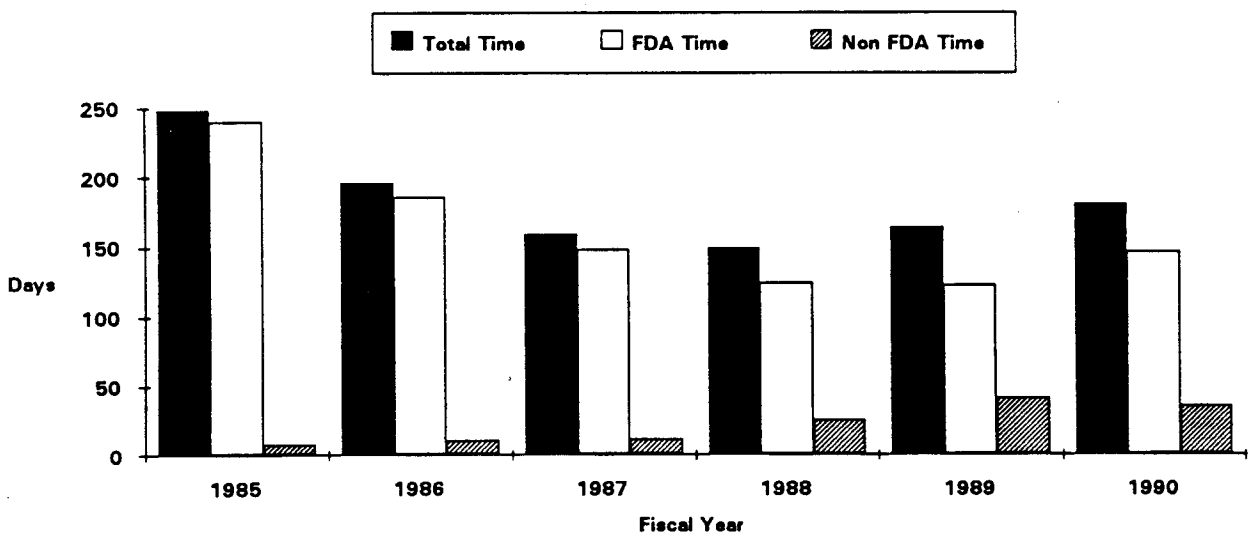


CHART 10 - Average Approval Time for PMA Supplements
FY 85 - FY 90

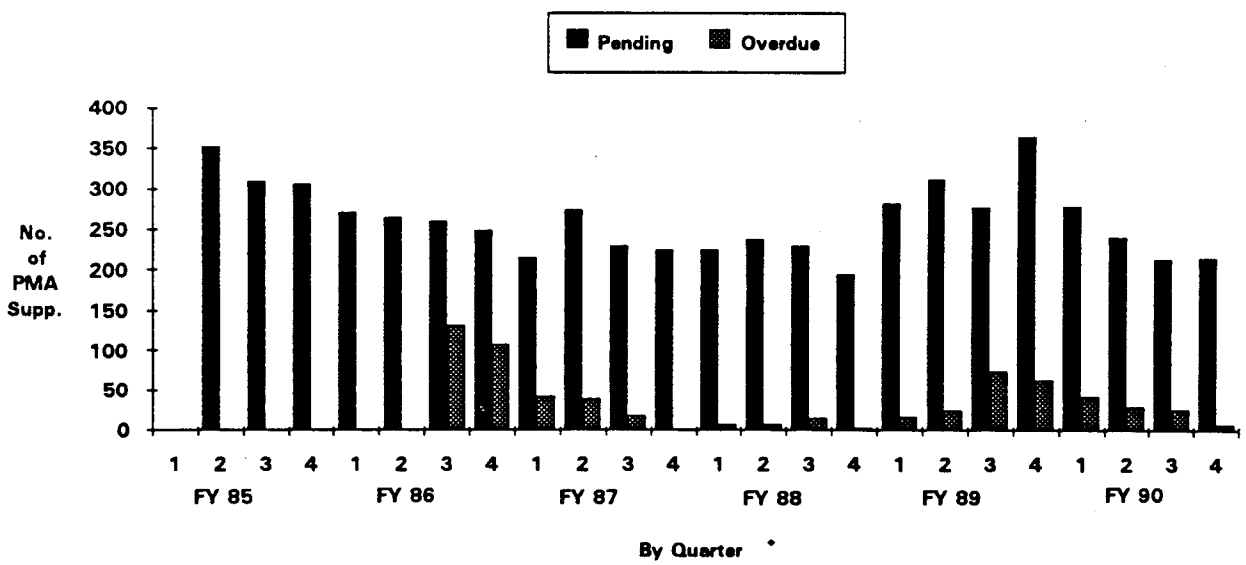


The number of PMA supplements submitted during FY 90 has fallen from last year's record of 810 to 660. This lower rate is more consistent with the 700 received in FY 87 and the 727 received in FY 88. On the other hand, the number of PMA supplements approved rose dramatically over last year's 519 to 700 for the current year, an increase of 35% in productivity in this area. This year's approvals included five "panel track" supplements. Panel track supplements require the full administrative procedures normally associated with original PMAs, i.e., Panel review, preparation of a summary of safety and effectiveness, and publication of a *Federal Register* notice.

The 531 total number of PMA supplements under review at the end of last year was reduced to 335 this year. This represents a 37% reduction in the number of supplements awaiting decisions. The number of PMA supplements that were active and overdue were practically eliminated, being reduced from 62 at the end of the last fiscal year to 7 at the end of this year. Likewise, the number of active supplements and the number of supplements on-hold were dramatically reduced.

Total average review time for PMA supplements as calculated under the old system, rose from 163 days in FY 89 to 180 days in FY 90. Under the PMA regulation, this average rose from 140 days last year to 159 days for the current year. These review times are about level with the review times in FY 87. A major factor in this rise in the average review time for PMA supplements was the processing of 55 overdue applications. The longer review times of these applications contributed to this increase in the average review time.

CHART 11 - Active PMA Supplements
FY 85 - FY 90



* Pending data not available for 1/85 quarter; overdue data not available prior to 3/86 quarter.

B. Investigational Devices

1. Investigational Device Exemptions (IDEs)

Under the act and regulations, a person may sponsor the clinical investigation of a medical device to establish its safety and effectiveness. Before conducting a clinical trial, however, the sponsor must obtain the approval of an institutional review board (IRB). If the investigational device study presents a significant risk to subjects, the sponsor also must obtain FDA's approval of an investigational device exemption application (IDE). The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject informed consent, device labeling, cost of the device, and other matters related to the study. FDA has 30 days from the date of receipt to approve or disapprove an IDE application. If the agency does not act within the 30-day period, the application is deemed to be approved.

During FY 90, ODE issued 11 letters withdrawing approval or proposing the withdrawal of approval of 14 IDE applications. While specific information about these withdrawals is not discloseable, the charts below summarize information about these actions. Chart 12, Summary of Grounds Cited in IDE Withdrawal Letters , identifies the grounds upon which the withdrawal actions were based. Chart 13, Summary of Types of Devices Subject to IDE Withdrawal Letters, lists the types of devices that were the subject of these IDE withdrawal notices.

Chart 12 - Summary of Grounds Cited in IDE Withdrawal Letters
FY 90

	Immediate Withdrawal	Proposed Withdrawal	Total
812.30(b)(1)	4	6	10
812.30(b)(3)	0	1	1
812.30(b)(4)			
risk/benefit	2	1	3
inadequate consent	1	0	1
unsound	2	0	2
ineffective	1	0	1
812.30(b)(5)(ii)			
manufacturing	4	1	5
812.30(b)(5)(iii)			
monitoring and review	4	3	7
813.35(a)(7)	0	3	3

Also during this fiscal year, ODE initiated steps to enhance the follow-up on overdue IDE progress reports. In the past, the IDE staff sent reminder letters on an irregular basis to sponsors who had not submitted their progress reports. This year, we sent letters requesting overdue reports to approximately 638 sponsors. This will be done on an annual basis following a search for overdue progress reports. In the request letter for a progress report, ODE identified the following four situations and explained what the sponsor should do to fulfill the reporting requirement.

1. If your study is ongoing and you have not submitted a marketing application, you must submit a progress report to FDA which references your IDE application.

2. If your study is ongoing and you have submitted a premarket approval (PMA) application which is under review and contains a summary of the progress of the study, you must submit a letter to FDA stating this fact, and submit a copy of that portion of the PMA application or state where this information can be located in the PMA application (i.e., PMA number, date of submission, volume and pages).

3. If you have received marketing approval for the device studied under your IDE, either through a PMA application or premarket notification (510(k)) submission which contains a summary of the progress of your device investigation, you must submit a letter to FDA stating that a marketing application has been approved and that the progress report can be located in the marketing application (i.e., PMA or 510(k) number, date of submission, volume and pages). Alternatively, you may submit a copy of that portion of the marketing application. This summary report should also serve as a final report since an IDE is no longer required once a marketing application, for the same device and indication for use as granted in the IDE, is approved. If the 510(k) submission does not contain a summary of the progress of the study, a separate final report must be submitted to FDA in order for FDA to consider your file closed.

4. If your study has been terminated or completed and no marketing application is being pursued, you must submit either a progress report or a final report of your study to FDA. That is, when all subjects have been followed for the time period designated in the investigational plan, this complete information must be submitted to FDA in a final report. FDA will not consider your file closed until a complete report regarding the findings of your study are satisfactorily submitted. If all subjects have not been followed according to the investigational plan, a progress report must be submitted to FDA accompanied with a statement as to when you anticipate submission of a final report.

Chart 13 -Summary of Types of Devices Subject to IDE Withdrawal Letters, FY 90

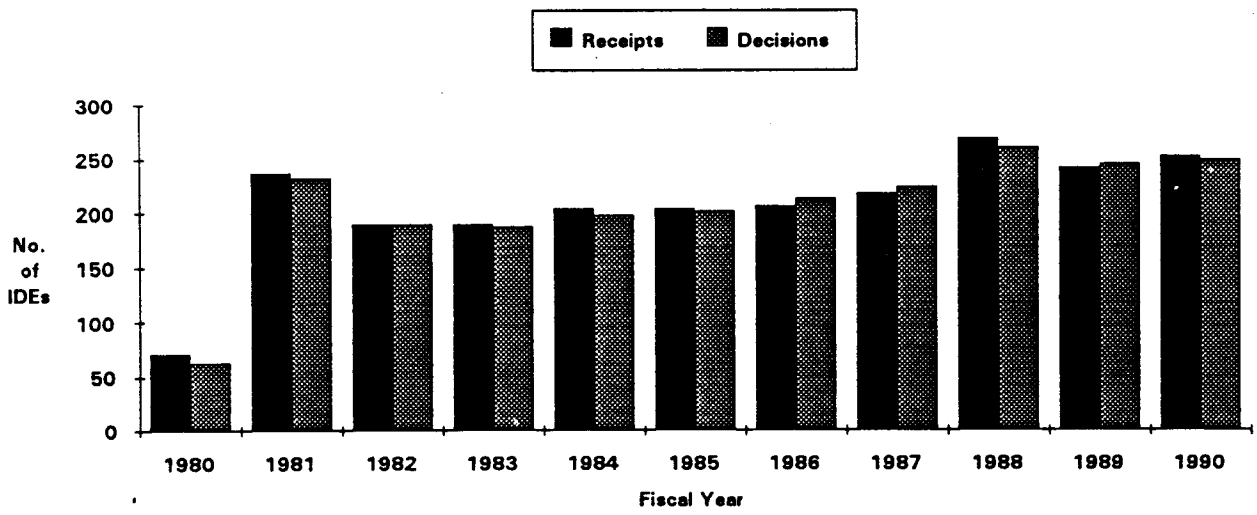
Immediate Withdrawal (Six Letters Affecting 8 IDEs.)

Panel	Device Type
Radiological	Hyperthermia
Neurological	Stimulation for Chronic Pain Relief
Cardiovascular	Total Artificial Heart, permanent
	Total Artificial Heart , bridge to transplant
	Ventricular Assist Device
Ophthalmology	Surgical Laser
Orthopedic	Spinal Fixation System
	Bone Cement

Proposed Withdrawal (Five letters affecting 6 IDEs.)

Panel	Device Type
Cardiovascular	Vascular Graft

CHART 14 - Annual IDE Receipts and Decisions
FY 80 - FY 90



We received 252 original IDEs during FY 90, the second largest number ever received in one fiscal year. This number is exceeded only by the 268 IDEs received in FY 88. The same holds true for IDE approvals; the 248 original IDE decisions made during FY 90 are the second highest number of IDE decisions ever made within a fiscal year, exceeded only by the record-setting 260 decisions made in FY 88. The average FDA review time for original IDEs remained constant since last year at 29 days. Also, 99% of all original IDE decisions were completed within 30 days. The number of IDEs under review at the end of this fiscal year rose slightly to 20, up from 16 at the end of last year. No IDEs were overdue at the end of the year.

Of the total original IDE decisions made this year, the percentage of decisions that resulted in approval has continued to rise, from 36% last year to 38% this year. This represents the third year in a row that the percentage of original IDE approvals has increased. It went from a 27% rate in FY 87 to the current 38% which represents an all-time high. This is important because of the savings in cost and time for the FDA and industry alike when IDEs are approved upon their first submission.

CHART 15 - Timeliness of IDE Decisions
FY 85 - FY 90

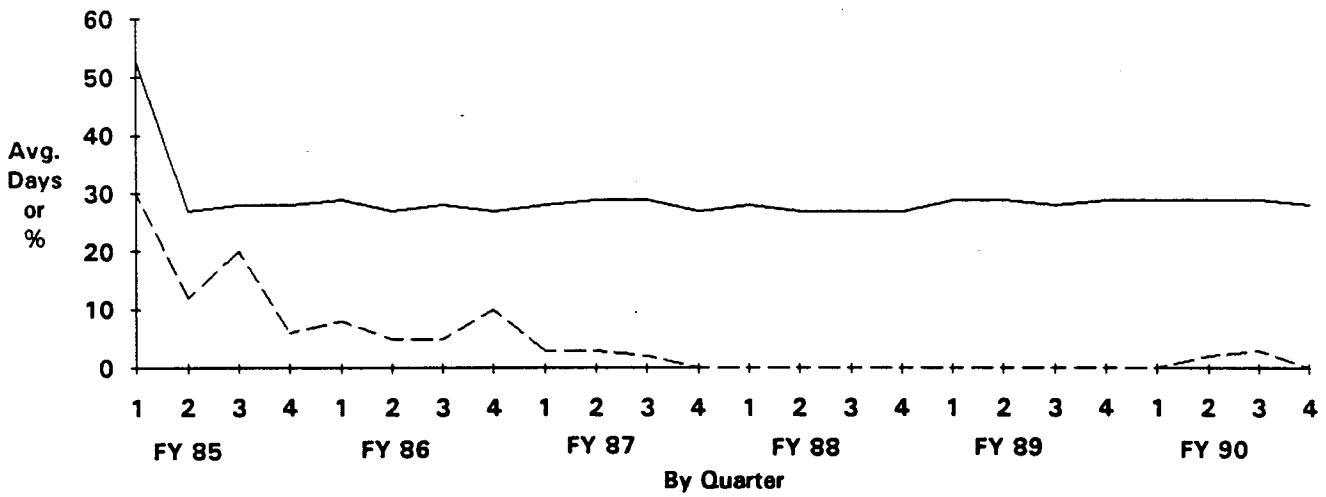
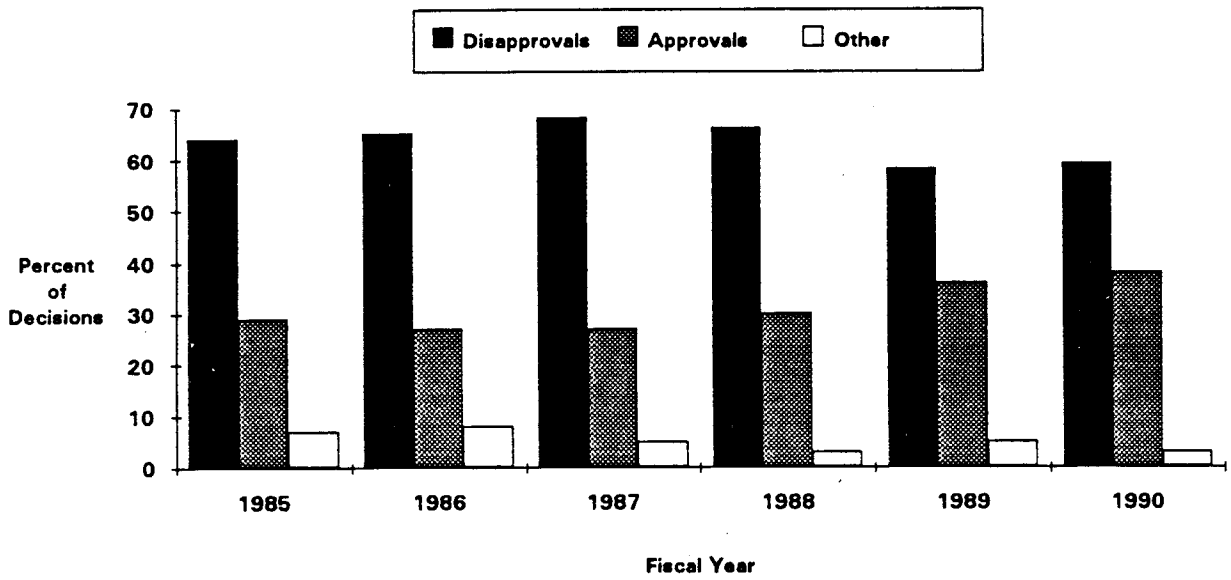


CHART 16 - Analysis of Original IDE Decisions
FY 85 - FY 90



2. IDE Amendments

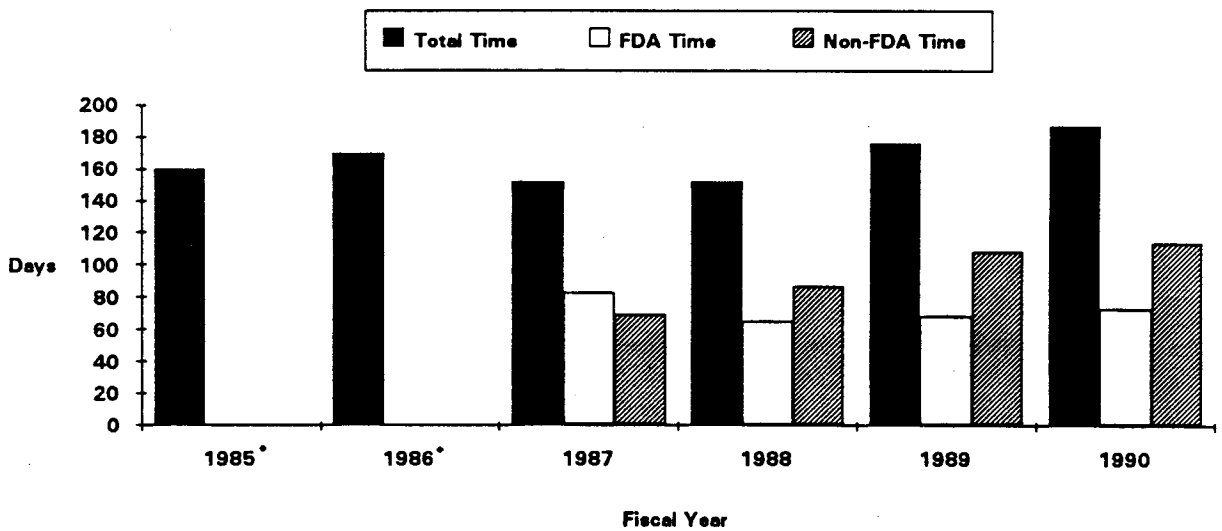
Although not provided for in the IDE regulations, we refer to all submissions related to an original IDE that has been submitted but not approved as an IDE amendment. Submissions related to an IDE after it is approved are supplemental applications under the regulations. Identification of IDE amendments enables FDA to track each IDE from the time it is originally submitted to the time it is approved. The content of an amendment may relate to any matter that is the subject of an original IDE. Thus, an amendment may be initiated by the sponsor or it may be submitted in response to FDA's disapproval letter.

During this fiscal year we received 288 amendments, up from 271 during the last fiscal year. This was the second largest number of amendments ever received in a fiscal year. We made 270 decisions on amendments: 123 approvals(46%); 79 disapprovals(29%); and 68(25%) other administrative actions. Ninety-nine percent of these decisions were made within 30 days. The 29 IDE amendments pending at the end of this fiscal year was up slightly from the 11 that were pending at the end of last year but none of these was overdue.

Each amendment is associated with an original IDE. Thus, the approval of an amendment constitutes the approval of an original IDE and the proposed investigation may begin. During FY 90, the 123 amendments approved were related to 115 original IDEs. The additional 8 amendments were related to some of the same original IDEs and were approved simultaneously. The oldest amendment that was approved this year was submitted as an original IDE in August, 1986. The most amendments associated with an original IDE approved this year was fourteen. This number may seem high when compared to last years high of five, but it is unrelated to the way ODE does business or to ODE's overall performance. It will fluctuate independently each year depending upon the specific IDE to which the amendment is related. The average number of amendments per originally disapproved IDE that was approved in FY 90 was 1.8, as compared to an average last year of 2.7.

It took an average total time of 187 days to approve amended IDEs this year, up somewhat from 176 days last year. This total approval time consisted of 73 days for FDA, up from 68 days last year, and 114 days for nonFDA time, also up from 108 days in FY 89. For the last four years, the only time for which such data is available, the FDA time has fluctuated between a low of 65 days to a high of 83 days. The nonFDA time has been rising steadily from 69 days in FY 87 to its current high of 114 days. An increase in average review times can be expected as the percentage of original IDE approvals rises. This is due to the fact that the "easier" or "better prepared" IDEs are being approved upon the first review. This leaves the more difficult ones, with longer review times, to be approved as amendments.

Chart 17 - Average Approval Time for IDEs with Amendments
FY 85 - FY 90



* FDA and Non-FDA Times not available.

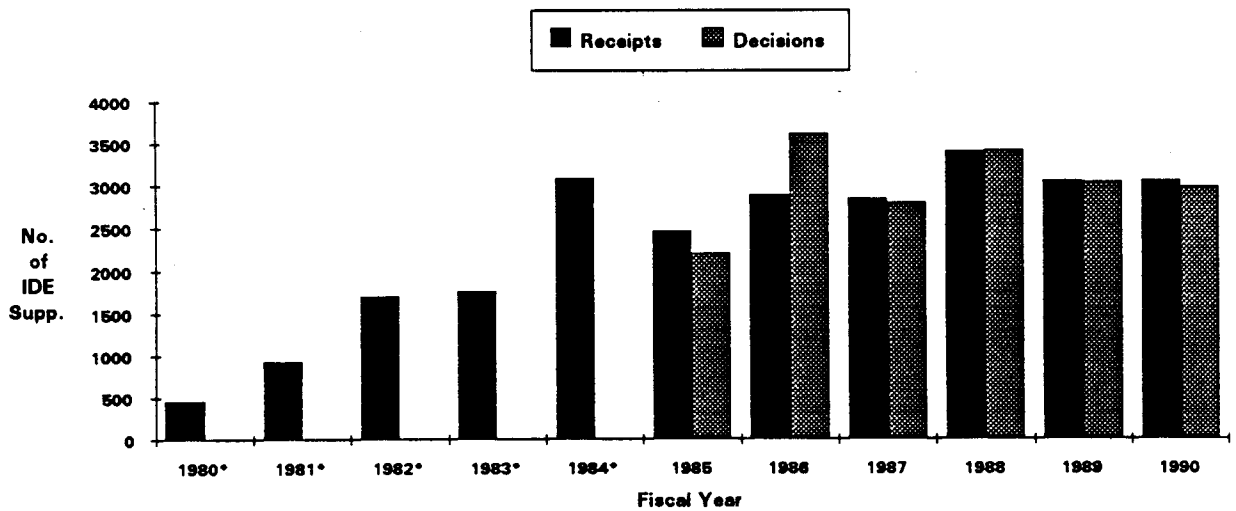
3. IDE Supplements

The IDE regulation requires that the sponsor of an investigation of a significant risk device investigation submit a supplemental application if there is a change in the investigational plan, whenever such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. Supplemental applications are also required for the addition of investigational sites. The supplements must update information previously submitted in the IDE application, including any modifications to the investigation.

This regulation also requires the submission of various reports which are logged in as supplements to IDE applications. These include reports on unanticipated adverse device effects, recall and device disposition, and failure to obtain informed consent, as well as annual progress reports, final reports, investigator lists, and other reports requested by FDA.

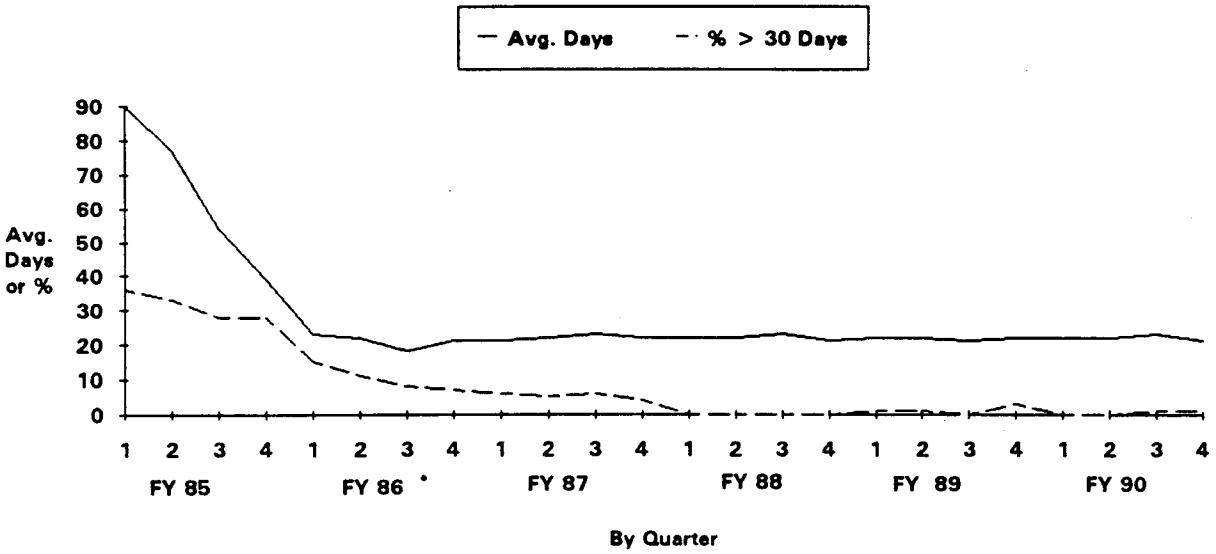
We received the second highest number of IDE supplements last year, 3,043, which represents a slight increase over the 3,038 received in FY 89. The number reviewed, 2,968, represents a small reduction from the 3,023 reviewed last fiscal year. The number under review at the end of FY 90 rose to 245 from last years 170. There were, however, no overdue supplements at the end of the year and the number of supplements reviewed within the 30 day statutory time frame remained constant at 99 percent. The average review time for completing the review of IDE supplements also remained constant at 22 days.

CHART 18 - Annual IDE Supplement Receipts and Decisions FY 80 - FY 90



* Data on decisions not available.

CHART 15 - Timeliness of IDE Supplement Decisions
FY 85 - FY 90



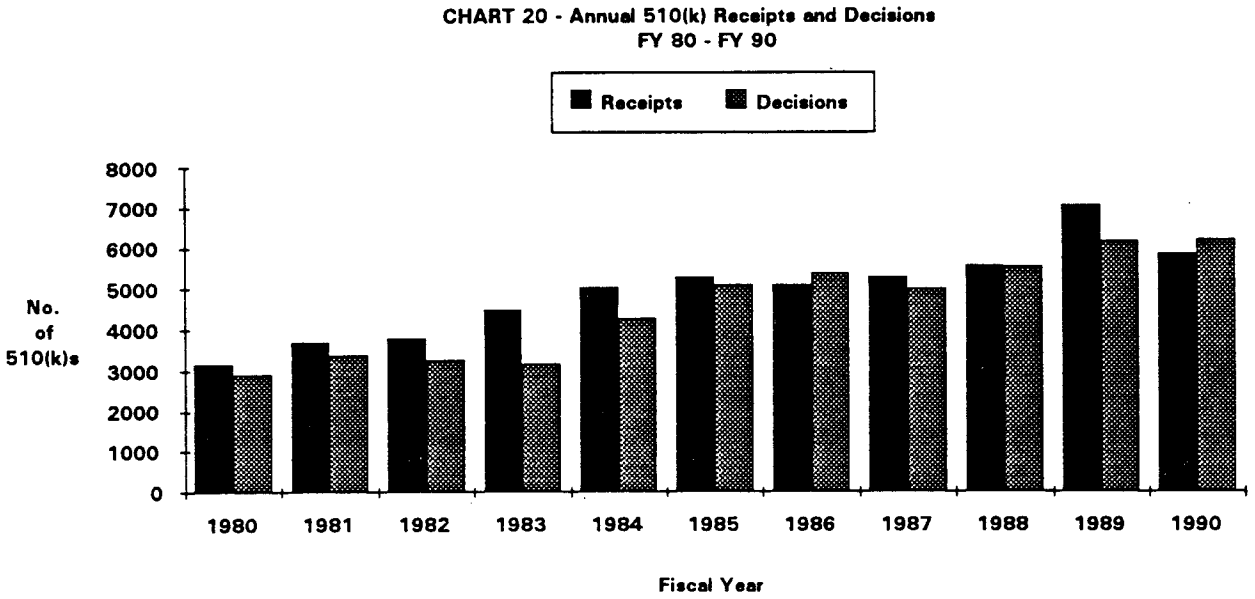
* FY 86 data excluded 728 applications that were overdue when the fiscal year began.

C. Premarket Notification (510(k))

At least 90 days before placing a medical device into commercial distribution, a manufacturer or distributor must file with FDA a premarket notification, commonly known as a 510(k). In addition to a description of the device, the 510(k) may also include a claim that the device is "substantially equivalent" to a legally marketed device. Substantially equivalent devices may be marketed subject to the same regulatory controls as their pre-Amendments predecessors. If the device is not substantially equivalent, the manufacturer may petition for reclassification, submit a PMA to market the device, or submit an IDE to conduct a clinical investigation.

During 1990 a new documentation requirement to record the 510(k) decision-making process was developed and implemented throughout ODE. Training courses were conducted on the new requirements for all ODE reviewers and managers. Also during this fiscal year, the Department's Office of the Inspection General reviewed the ODE 510(k) program and issued a report of their findings. The report concluded that although minor potential vulnerabilities existed, the overall program was sound and proper.

After an extraordinary surge of 7,022 510(k) submissions last fiscal year, the 5,831 received during FY 90 is in line with earlier fiscal year receipts. The number of final decisions rendered during FY 90, on the other hand, set a new record for the 510(k) program at 6,197. This is the third year in a row that a record number of 510(k)s have been reviewed.

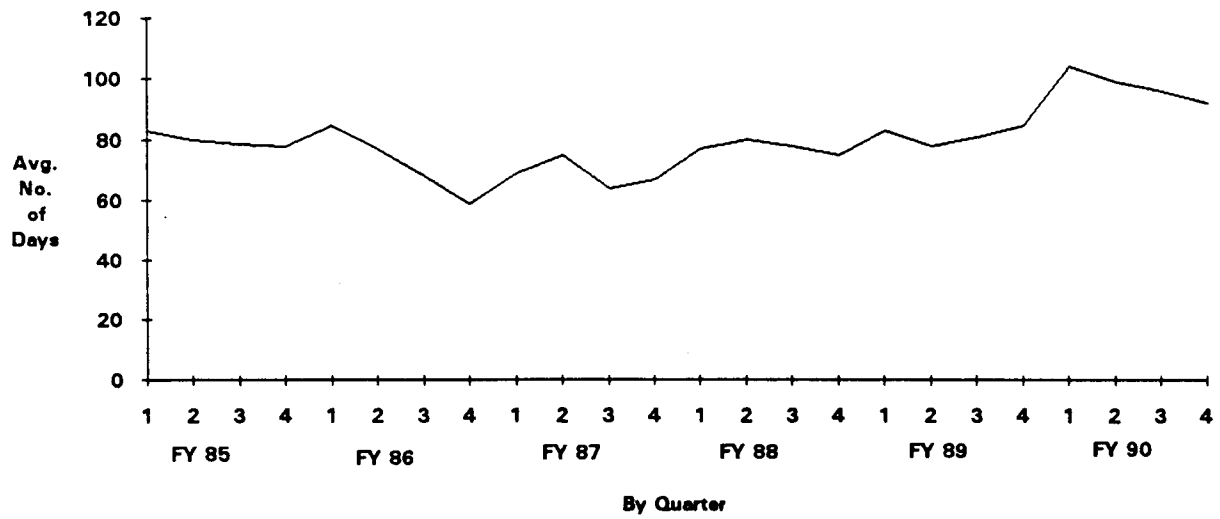


There are two average review times that traditionally have been reported for 510(k)s. The average review time based on total time is calculated, in part, by totaling all the times each 510(k) is reviewed by FDA plus all of the times the 510(k) is on hold while it is under revision by the submitter. This average is useful to manufacturers who wish to estimate how long it may take to get a final decision from the time a 510(k) is originally submitted. The FDA average review time is based only on the total of all of the times each 510(k) is reviewed by FDA. Both of these average review times were adversely affected during FY 90. The total average review time rose to 98 days from 82 days in FY 89 and the FDA review time went up to 78 days from 66 days in FY 89.

FY 90 was the first full year that there were two general programmatic factors that have had a negative impact on 510(k) average review times. Nearly 40% of Class I 510(k)s have been exempted from 510(k) review. These were the "easier" submissions that took less review time. Removing these exempted products from review left the more difficult and time consuming 510(k)s which raises the average review time. Also, there has been an increase in the reviewer documentation of decisions for 510(k)s in order to improve consistency among 510(k) decisions. This has caused an increase in the time required to complete each 510(k) review.

In addition to programmatic changes, there were three operational factors that contributed to increased 510(k) review times. One of the main reasons was the effect of the deluge of examination glove 510(k)s that we experienced during the past year. About 70% of the approximately 1500 glove submissions were found to be deficient. Communicating the deficiencies to so many submitters was compounded by the fact that as many as 85% were foreign manufacturers. Although we called local intermediaries when known, a major portion of these communications had to be made via the mails which consumed inordinate amounts of time. Additionally, many manufacturers never responded and the 510(k)s were carried on hold which increased the average total elapsed time for these submissions. Another factor contributing to the increase in the FDA average review time was the review of ultrasound 510(k)s. Because of the varying expertises required to review these submissions, the 510(k)s had to be routed to different divisions for input. This system resulted in delays that drove up review times. The third major factor was the increase in review times we experienced in the cardiovascular device area. There are more IDEs for cardiovascular devices than in any other area. These submissions have a 30 day turn-around time and necessitate the postponement of work on 510(k)s.

CHART 21 - Timeliness of 510(K) Reviews *
FY 85 - FY 90

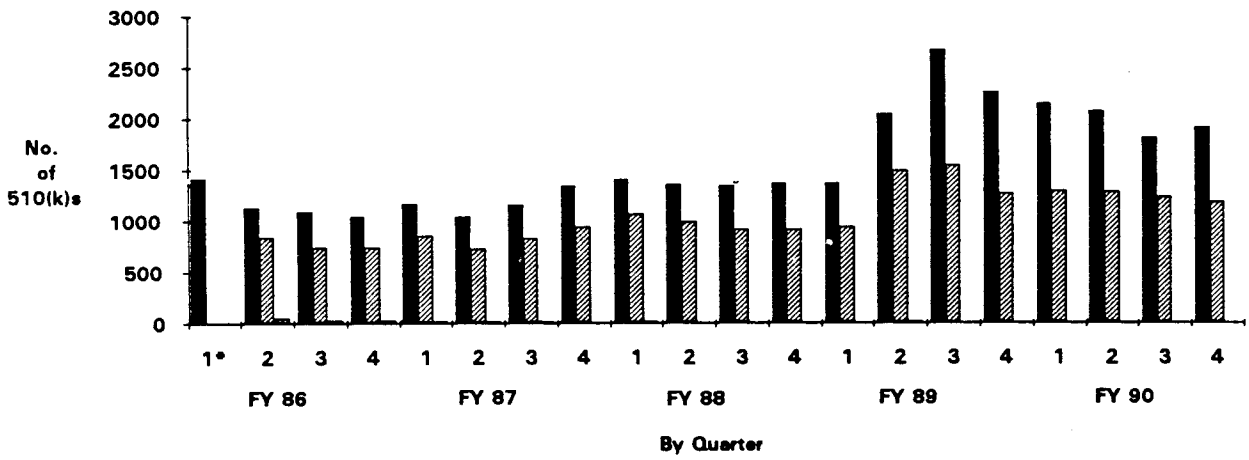


* Based on "total " time which includes all time from receipt to final decision, i.e., does not exclude time while a submission is on hold pending receipt of additional information.

During the second half of FY 90 we took steps to overcome some of the factors that were leading to increases in the average review time for 510(k)s. We increased our recruitment efforts in the Division of Cardiovascular Devices. We established new review policies for ultrasound devices. The review of 510(k)s for ultrasound devices is now consolidated in one division to reduce administrative delays in the review of these submissions. In addition to these management initiatives, the surge in 510(k)s for examination gloves has subsided and the pending submissions have been virtually completed. The effect of these changes during the second half of FY 90 can already been seen when the average review times at the midyear point are compared to end-of-year figures, which show that the average review times have started to come down.

The picture is somewhat different when we look at the number of 510(k)s completed within the 90 day review period allowed by law. For the first time ever in the 510(k) program, we are able to report in Table 7, Part VII, that 100% of the 510(k)s were reviewed within 90 days. The 100% figure in Table 7 is derived by rounding off 99.88%. In reality, of 6,197 510(k) decisions rendered during the year, seven decisions went over the 90 day review period. The rounding off of the percentage yields a first time ever performance figure of 100%. This calculation is based upon the time FDA takes to review a 510(k) each time it is received and represents a measurement of FDA's turn-around time on 510(k)s.

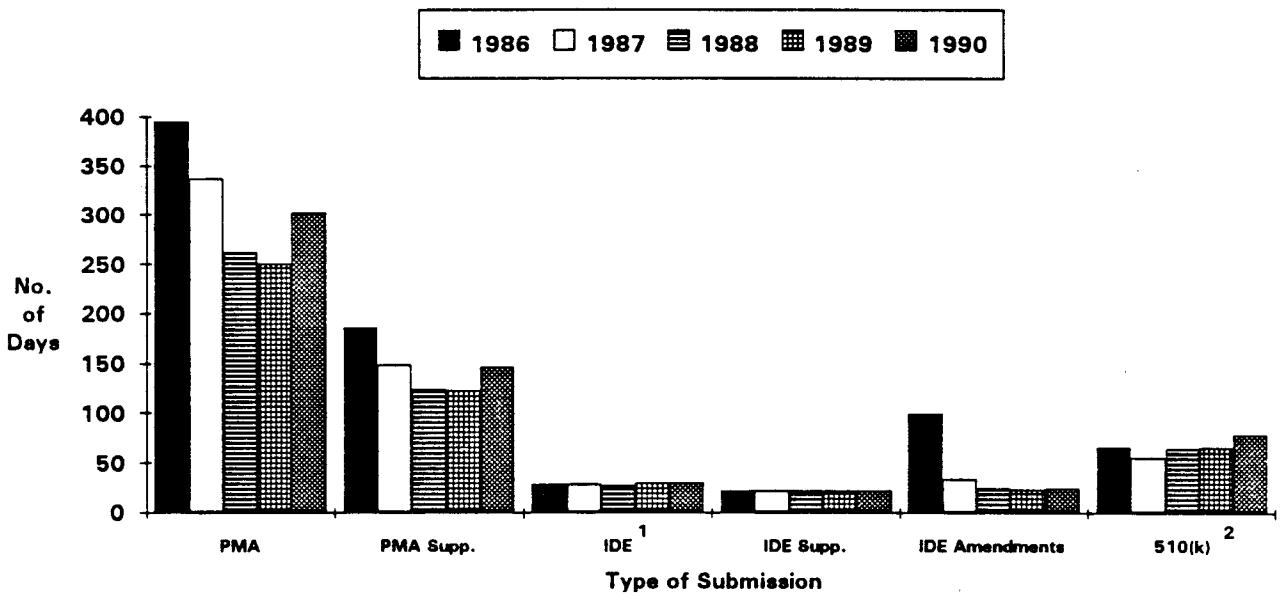
CHART 22 - 510(k)s Pending
FY 86 - FY 90



* No data for Active Only and over 90 days in 1/86.
1. Excludes 510(k)s "on hold."

There were 1900 510(k)s pending at the end of this fiscal year, which represents a 16% reduction from the 2,259 pending at the end of FY 89. The number on hold was also reduced since last year from 989 to 726, a 27% reduction. At the end of this reporting period, there were no 510(k)s that were active and overdue.

CHART 23 - Average FDA Review Time
FY 85 - FY 90



1. Excludes IOL Backlog.
2. Includes "hold" time.

D. Significant Medical Device Breakthroughs

We cleared for marketing nine devices during FY 90 that represent significant advances in medical device technology.

- The OSI[R] Transprobe-1[TM] was approved for marketing on October 3, 1989. It is used for the detection of the presence of the BCR 210 Philadelphia (PH(1)) translocation in bone marrow or peripheral blood cells as an aid in the diagnosis of chronic myleogenous leukemia.

- The CellIfree[R] Interleukin-2 Receptor Bead Assay Kit was approved on October 6, 1989. The kit, an enzyme immunometric assay for the quantitative measurement of interleukin-2 receptor (IL-2R) levels in human serum, is indicated for use as an aid in evaluating and monitoring response to treatment in hairy cell leukemia patients in whom elevated levels of serum IL-2 have been confirmed.

- The Oncor B-T Gene Rearrangement Test was approved for marketing on October 10, 1989. The test detects clonal populations of lymphoid cells in mixed cell populations from tissues and body fluids to aid in the differential diagnosis of lymphocytic leukemia and lymphoid malignancies from other neoplasms. The test provides information about the B-cell and T-cell lineage of the neoplasm which can aid in the selection of appropriate therapy. Moreover, the test identifies rearranged genes (specific tumor markers), so that a physician can qualitatively examine a clonal population during relapse to determine if the same population is present as an aid in evaluation of therapeutic effectiveness.

- VH8500 Hyperthermia Treatment System was approved on October 10, 1989. It is intended for use in the palliative management of certain malignant brain tumors that are progressive, recurrent or viable.

- The Nucleus 22 Channel Cochlear Implant was approved for marketing on June 27, 1990. It is intended for use in patients 2 through 17 years of age who have bilateral profound sensorineural deafness and demonstrate little or no benefit from a hearing (or vibrotactile) aid, as demonstrated by the inability to improve on an age-appropriate closed-set word identification task. This is the first cochlear implant available for commercial distribution for use in children.

- The Trophocan[TM] Chorionic Villus Sampling (CVS) Catheter was approved for marketing on August 9, 1990. It is a device for the sampling of chorionic villi to diagnose genetic abnormalities during the first trimester of pregnancy. It is the first device approved for marketing for this intended use. The approval was based on several studies, most of which were supported by NIH.

- The Genesis[TM] Home Uterine Activity Monitoring System was approved for marketing on September 12, 1990. This system is used to monitor uterine

contractions of pregnant women at home. It is the first device approved for the detection of preterm labor.

- The Simpson Coronary Atherocath™ was approved for commercial distribution on September 14, 1990. This device is intended for use in atherectomy in patients with coronary disease accessible to the atherocath.

- The Mansfield Aortic Valvuloplasty Balloon Dilation Catheter, (standard and low profile) was approved on September 19, 1990. It is used for percutaneous transluminal valvoplasty of aortic stenosis in patients who are determined to be inoperative.

IV. Other Program Activities

In addition to the review of PMAs, IDEs, and 510(k)s, ODE has been heavily involved in other significant program activities. Several of these are discussed below.

A. Guidance for Industry and Reviewers

Many new guidance documents were developed by ODE and its operating units during FY 90. These documents are designed to promote uniformity and to improve the efficiency, administration and quality of ODE programs. They also serve as guidance to manufacturers. In addition to dissemination of these guidance documents to appropriate ODE staff members, they have been distributed to the affected industry and made available to interested members of the public. Most of these guidance documents are available through the Division of Small Manufacturers Assistance (HFZ-220), 5600 Fisher Lane, Rockville, Maryland 20857, telephone (800)638-2041.

- Implantable Pacemaker Lead Testing. In October, 1989, the Division of Cardiovascular Devices issued the implantable Pacemaker Lead Testing guidance which specifies testing requirements for the submission of applications for implantable cardiac pacemaker leads. The purpose of this guidance is to ensure that leads intended for human use are supported by appropriate qualification data, to facilitate the review process, and to facilitate the manufacturer's planning of test protocols and preparation of the required regulatory submissions.

- Integrity of the Medical Device Review Process. On October 25, 1989, we issued this "Blue Book" memorandum to establish a program to assure the integrity and equity of the medical device review program. It establishes policies that will provide assurances to the public, industry, and agency officials that our approval program is operating in a fair and equitable manner.

- Meetings with the Regulated Industry. On November 20, 1989, we issued a "Blue Book" memorandum to set forth procedures to be followed when meeting with representatives of medical device firms or trade associations. As a matter of practice, ODE staff has been applying most of these principles for many years now, but they had not been formalized in a written policy or procedure.

- 510(k) Sterility Review Guidance. On February 12, 1990, we issued this "Blue Book" guidance on the respective roles of the Office of Compliance and Surveillance and the Office of Device Evaluation in regard to the review of 510(k)s for certain sterile devices.

- Policy Development and Review Procedures. On February 15, 1990, we issued a "Blue Book" memorandum to establish a procedure to assure the regular and timely establishment and review of ODE guidance documents and policies.

- Explant Protocol. In March, 1990, the Division of Cardiovascular Devices issued a revised explant protocol entitled "Analysis of Explanted Replacement Heart Valves." This draft is a modification of a general protocol developed for explant retrieval of implanted devices. This protocol is now an appendix to the heart valve guidance. It is being issued separately since the protocol has utility beyond prosthetic heart valves.

- Heart Valve Annual Report Guidance. In April, 1990, the Division of Cardiovascular Devices issued this guidance to provide consistency and uniformity to annual reports for prosthetic heart valves that is within the framework of the PMA conditions of approval.

- Content and Organization of Premarket Notification for Medical Lasers. On April 5, 1990, the Division of Surgical and Rehabilitation Devices issued a guidance document to accomplish two goals: a) to guide applicants in preparing premarket notifications for medical lasers; and, b) serve as a guide for our staff in their reviews of these notifications.

- Approval of Speaking Engagements. On April 24, 1990, we issued this "Blue Book" guidance to establish a procedure for the approval of speaking engagements by ODE staff members prior to the preparation and submission of clearance forms required by the Center.

- ODE Peer Review Promotion Process. On April 24, 1990, we issued a "Blue Book" memorandum on the peer review promotion process. The

Regulatory Review Committee for peer review of proposed promotions to Non-Supervisory Review Scientist GS-14 or GS-15 meets approximately four times each year. This memorandum clarified for the ODE staff the procedures used within ODE whereby staff members are nominated for such promotions.

- When PMA Supplements are Required. On April 24, 1990, we issued a "Blue Book" memorandum to provide guidance on when a PMA holder must submit a PMA supplement.

- Cochlear Implants in Adults at least 18 years of Age. During May 1990, this guidance was issued, after review by the Ear, Nose, and Throat Devices Panel, to assist applicants in the preparation of PMAs for cochlear implants in adults at least 18 years of age.

- Cochlear Implants in Children Ages 2 through 17 years. During May 1990, this guidance was issued to aid applicants in the preparation of PMAs for cochlear implants in children ages 2 through 17. FDA received comments from industry and the Ear, Nose, and Throat Devices Panel.

- Replacement Heart Valves. On May 1, 1990, the Division of Cardiovascular Devices made available the revision of the heart valves guidance. This document is intended for those organizations and individuals who are developing a heart valve and intend to submit an IDE or PMA application to FDA. This revision includes provisions for using Doppler Ultrasound to assess the hemodynamic performance of prosthetic heart valves. Previously, cardiac catheterization was required for this assessment. This revision also made several technical changes to modify or clarify FDA requirements.

- Endolymphatic Shunt Tube with Valve. On May 4, 1990, this guidance was announced in the Federal Register. It is intended to aid applicants in the preparation of PMAs for endolymphatic shunt tube with valves. The shunt tube with valves is placed in the endolymphatic sac to relieve symptoms such as vertigo.

- ODE Mentor Program. On May 4, 1990, ODE issued this "Blue Book" memorandum to announce the establishment of the Office of Device Evaluation Mentor Program. This program has to provide a framework within which to orient ODE's new employees to their jobs and work place and in some instances, to the local community. Each division was provided

with a copy of the ODE Mentor Program and became responsible to implement the program

- Vascular Grafts. On May 11, 1990, the Division of Cardiovascular Devices distributed this guidance to interested parties. In addition to outlining the types of data needed to support submissions for vascular grafts , the guidance establishes a policy regarding the technologies that CDRH will consider new or old for the purpose of determining the type of submission that is required.

- Training Checklist for New Reviewers. On May 18, 1990, we issued a "Blue Book" memorandum to disseminate the ODE Training Checklist for New Reviewers. The checklist provides guidance on the training that is expected to be provided to each new reviewer who joins the ODE staff.

- PMA Filing Decisions. On May 18, 1990, we issued a new "Blue Book" memorandum to describe the three available decisions that may result from the filing review of premarket approval applications. The memorandum also provides guidance on the appropriateness of each decision. A flow chart was included to help clarify this process.

- Intraortic Balloon (IAB) Catheter Guidance. On May 25, 1990, the Division of Cardiovascular Devices released this guidance as a replacement for the reviewer checklist of items to consider in an evaluation of IAB catheter equivalency via a 510(k). It is distributed to industry upon request.

- Testing and Development of Female Barrier Contraceptives Guidelines. On June 7, 1990, the Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices, with combined joint efforts of NIH and CDC, announced in the *Federal Register* a development guideline for expedited testing and development of barrier contraceptive devices with potential to prevent AIDS and other STDs. These guidelines allow manufacturers to bring their barrier devices with potential to prevent AIDS to the market in an expedited manner. These guidelines were reviewed and endorsed by the OB-GYN Devices Panel.

- Ultrasound Device Guidance. On June 12, 1990, the Division of Obstetrics/ Gynecology, Ear, Nose, Throat, and Dental Devices issued new industry guidance on diagnostic ultrasound premarket notifications that integrates guidance over the last five years, as well as updating the current guidance.

The primary goal of the guidance was to simplify the reporting of information on ultrasound systems without sacrificing key review concerns.

- Biliary Lithotripsy Studies. On August 7, 1990 the Office of Drug Evaluation and the Office of Device Evaluation issued a jointly developed guidance for the study and data requirements needed to support PMAs and NDAs for lithotripters used in combination with ursodiol. It was released to the National Electrical Manufacturers Association and manufacturers.

- Assignment of Review Documents. In August 24, 1990, we issued a "Blue Book" memorandum that revises and replaces Integrity Memorandum #I89-2, entitled "Reassignment of Review Documents." This revised memorandum sets forth procedures for the assignment of review documents (PMAs, PMA supplements and amendments, IDEs, IDE supplements and amendments, and 510(k)s) to ODE staff. It also covers reassignment of such documents from primary reviewers to other reviewers.

- Document Control Procedures. On September 26, 1990, we issued a new "Blue Book" memorandum to set forth procedures for receipt, tracking, and security of documents received by ODE. It covers document log-in, "desk copies," telephonic and facsimile transmissions, and work at home. These procedures are designed to assure fair and equal treatment for all members of the regulated industry. They also help assure the authenticity and security of submissions to ODE for review and decision.

- Implantable Port Guidance. The Division of Gastroenterology/Urology and General Use Devices issued a document entitled, "Guidance on 510(k) submissions for Implanted Infusion Ports." This revised guidance outlines recommended documentation and testing to establish equivalence for implantable ports, and outlined conditions where additional *in vivo* performance testing was necessary. This guidance was first issued in January, 1990 and revised in October, 1990.

- Consolidated Review of Submissions for Lasers and Accessories. On October 19, 1990, we issued a new "Blue Book" memorandum to promote uniformity and efficiency in the review of submissions for lasers and their accessories. 510(k) submissions for these devices may have been reviewed in different divisions depending upon the intended use of a specific device. This guidance assures the consolidation of responsibility for review of 510(k) submissions and their supporting IDEs for these devices within one division, while at the same time maintaining inter-divisional consultations, as necessary, to assure the high level of expert review that has been applied

in the past. This memorandum clarifies the roles and responsibilities of the primary reviewing division and the consulting divisions and sets forth the procedures they will use for this review process.

- Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories, and Related Measurement Devices. On October 19, 1990, we issued a "Blue Book" memorandum to promote uniformity and efficiency in the review of submissions for Diagnostic Ultrasound Equipment, Accessories, and Related Measurement Devices. 510(k) submissions for these devices may have been reviewed in different divisions depending upon the intended use of a specific device. This guidance assures the consolidation of responsibility for review of 510(k) submissions and their supporting IDEs for these devices within one division, while at the same time maintaining interdivisional consultations, as necessary, to assure the high level of expert review that has been applied in the past. This memorandum clarifies the roles and responsibilities of the primary reviewing division and the consulting divisions and sets forth the procedures they will use for this review process.

- Review and Approval of Licensee PMAs. On October 19, 1990, we issued this "Blue Book" guidance that revises and supersedes PMA Memorandum #P86-4, entitled "Review and Approval of PMAs of Licensees." This memorandum provides for an expedited review procedure for certain PMAs subject to license agreements in order to conserve resources without sacrificing protection of the public health. The present revision incorporates additional guidance regarding the licensing procedure and content of licensee PMAs subsequently prepared by ODE and included in the Premarket Approval Manual.

- 510(k) Independent Quality Review Program. On October 31, 1990, we issued this "Blue Book" memorandum to establish an independent quality review system to enhance management oversight of the premarket notification (510(k)) review process and to further ensure the integrity and fairness of the process and the propriety of the 510(k) decisions that are made.

B. Classification of Medical Devices

Based on an ODE proposal for a regulatory process presented at a panel meeting, the Neurological Devices Panel recommended that human dura mater be classified as a Class II pre-Amendments medical device.

C. Reclassification of Classified Devices

ODE took the following actions during FY 90 concerning the reclassification of medical devices.

- Issued an order to reclassify the nonabsorbable polyamide surgical suture from class III to class II on February 15, 1990
- Issued an order to reclassify the nonabsorbable poly(ethylene terephthalate) surgical suture from class III to class II on July 5, 1990.
- Issued an order to reclassify the nonabsorbable polypropylene surgical suture from class III to class II on July 5, 1990.
- Published a final rule in the *Federal Register* on June 8, 1990 announcing the reclassification of the automated differential cell counter from class III to class II, effective August 7, 1990.
- Published a final rule in the *Federal Register* on November 22, 1989 announcing the reclassification of the ceramic head hip prosthesis from class III to class II. Reclassification was effective on December 5, 1989.
- Published a proposed rule in the *Federal Register* on September 5, 1990 to reclassify the electroconvulsive therapy device for severe depression from class III to class II.
- Obtained a Panel recommendation on October 14, 1989 to reclassify the argon laser for rhinolaryngology from class III to class II.

D. PMAs for Pre-Amendments Devices (515(b) Regulations)

Pre-Amendments devices classified in Class III, and substantially equivalent post-amendments devices, are not immediately subject to premarket approval under the act. Instead, the act directs FDA to publish regulations, known as "515(b) regulations," calling for PMAs for these devices. A 515(b) regulation may not require the filing of PMAs for a device until 30 months after the device is classified in class III, or 90 days after the 515(b) regulation is promulgated, whichever is later.

Nearly 150 generic types of devices have been proposed for, or have been finally classified in, class III. Recognizing that FDA could not issue 515(b) regulations simultaneously for all pre-Amendments class III devices, Congress authorized FDA to establish priorities which may be used in applying premarket approval requirements to these devices. On January 6, 1989, FDA published an advanced notice of proposed rulemaking to announce its intent to issue 515(b)

CHART 24 - ODE Advisory Panel Meetings
FY 90

Panel (Executive Secretary)	Number of Meetings	Meeting Days
Dental (Gregory Singleton)	2	2
Obstetrics and Gynecology (Colin Pollard)	4	6
Ear, Nose, and Throat (Celeste Bove')	1	2
General and Plastic Surgery (Paul R. Tilton)	1	1
Orthopedic and Rehabilitation (Marie Schroeder)	2	2
Gastroenterology and Urology (Ruth W. Hubbard)	4	5
General Hospital and Personal Use (Amalie Mattan)	-	-
Opththalmic (Daniel W. C. Brown)	4	7
Radiology (Adrianne Galdi)	0	0
Neurology (Robert F. Munzer)	1	1
Anesthesia and Respiratory Therapy (Michael Gluck)	1	1
Circulatory Systems (Wolf Sapirstein)	4	6
Microbiology (Joseph L. Hackett)	2	2
Hematology and Pathology (Larry Brindza)	1	1
Clinical Chemistry and Toxicology (Kaiser J. Aziz)	2	3
Immunology (Srikrishna Vadlamudi)	-	-
Totals	29	39

regulations for an additional 31 Class III preAmendments devices having a high priority for the application of premarket approval requirements.

In prior years, 515(b) rules have been promulgated for various high priority devices. During this fiscal year, we published the following proposed rules to require the filing of a PMA for each of these three devices.

Proposed 515(b) Rules:

- Endosseous Implants, 54 F.R. 50592 (December 7, 1989)
- Endolyphatic Shunts, 55 F.R. 18830 (May 4, 1990)
- Silicone Gel-filled Breast Implants, 55 F.R. 20568 (May 17, 1990)

E. Advisory Panel Activities

ODE held 29 medical device advisory panel meetings during the past year as identified in Chart 24. During this past year we developed an orientation/training workshop; two-hour workshops were conducted for seven of the device panels. ODE participated on the CDRH/Health Industry Manufacturers Association committee to develop educational videotapes for future training of panel members. We revised the panel charter which will subsume the current sixteen advisory panels under one omnibus committee. The goal of this charter revision is to create a more flexible panel review system whereby the expertise of panel members could be used more effectively by all of the panels. In support of ODE panel activities, the Center was successful in procuring the services of a logistical support contractor; the contractor has provided services to the panel executive secretaries for 8 panel meetings. Another major activity in this area was the development of panel management policies and procedures that will increase consistency among panels and improve general functioning of panel meetings; this includes issuance of Executive Secretary Advisories and periodic group meetings with executive secretaries.

F. Responding to FOI Requests

Under the Freedom of Information (FOI) Act, FDA must respond within 10 days to requests for information contained within agency files, with the exception of trade secret data and confidential commercial information. Requested documents must be "purged" of such privileged information before release. ODE staff processed more than 1,214 FOI requests during FY 90.

G. Publications

During FY 90 the Information Clearance Committee cleared 12 articles (three abstracts and nine manuscripts) authored by ODE staff for publication in professional and scientific journals and 14 presentations to be delivered by ODE staff at professional and scientific and trade association meetings.

V. ODE Divisional Reports

A. General Responsibilities

Divisions within ODE are the main units that review applications and evaluate the safety and effectiveness of medical devices, the appropriateness of clinical investigations, and whether a device is substantially equivalent. The bulk of our scientific and professional expertise resides in the divisions. The divisions are comprised of branches and, in one case, the branches are broken down into sections. The organizational chart in Appendix B identifies ODE's divisional structure and each division's leadership.

ODE has seven divisions, each responsible for devices that fall within certain medical specialty areas. There is some overlap in the review of certain devices for which the indications of use fall within different medical specialty areas or for the review of which a particular scientific or professional expertise is required, e.g., lasers, ultrasound, and a few others. Each division and the highlights of its activities for the past fiscal year are discussed below.

B. Division Reports

The following summaries were prepared by each ODE division to highlight the major events within the division during FY 90.

1. Division of Anesthesiology, Neurology and Radiology Devices (DANRD)

DANRD finished FY 90 with a record of quality reviews with all submissions and actions completed by the division within or before the required times. Several additional noteworthy initiatives are summarized here.

The need for regulation of human dura mater was addressed this fiscal year. DANRD offered a proposal for a regulatory process at a public meeting of the Neurological Devices Panel. This led to a Panel recommendation to classify human dura mater as a Class II device. The active participation of the tissue bank organizations is leading to a smooth introduction of necessary regulations.

A proposed rule to reclassify the electroconvulsive therapy (ECT) device for severe depression was published in the *Federal Register* of September 5, 1990. Also considerable work has been put into emerging new standards and revision of older ones, including the development of standards within the European Community for MRI devices.

The DANRD has worked closely with the CDER on the process and criteria for joint reviews of nebulizer devices including those for the delivery of drugs to control respiratory infections

in AIDS patients. The Division also was involved in several expedited reviews of special equipment needed for use in the Persian Gulf activity, including transportable oxygen concentration facilities, and battle field anesthesia vaporizers.

2. Division of Cardiovascular Devices (DCD).

DCD in its reviews and in its interactions with manufacturers continues to emphasize the importance of scientific soundness of submissions as being the most reliable predictor of expeditious device approval. Toward that end, DCD staff reviewed IDE protocols in great detail and assisted sponsors in designing clinical protocols to address the questions that would need answers prior to device approval. This was an onerous task since DCD made over 1200 IDE decisions in FY 90 but one that is of benefit to FDA and the public since better clinical characterization is likely to result from well designed clinical trials. In order to communicate FDA's expectations of preclinical testing and clinical trials, DCD issued or updated seven device-specific guidance documents and is working on another nine.

DCD workload, in terms of the number of final decisions on documents, increased by about 32% over the FY 89 workload. The Surgical Devices Branch, one of three DCD branches, accounted for 50% of the division's output and is dealing effectively with a flood of new interventional cardiology device applications.

An area of increasing complexity has been software and microprocessor controlled EKG devices and monitoring systems with signal processing, data compression, data transmission and diagnostic capabilities. The 510(k) process is being strained to accommodate these complex and rapidly changing devices.

DCD is preparing to initiate the regulation of allograft heart valves in the near future. In FY 90 DCD staff addressed two meetings of the American Association of Tissue Banks and had several working meetings with members of the tissue banking community, followed by a special meeting of the Cardiovascular System Devices Panel to address the issues and to generate a guidance document for allograft heart valves. DCD lost 7 reviewers in FY 90 and was able to recruit ten new reviewers. This small net increase in reviewer strength will prove insufficient if the workload maintains its present rate of growth.

3. Division of Clinical Laboratory Devices (DCLD)

DCLD engaged in several important public policy issues during FY 90. One area of increasing activity related to the Clinical Laboratory Improvement Act of 1988 (CLIA '88). Another issue involved the development of a policy concerning the exemption of drugs of abuse test kits as prescription devices for certain indications of use. In addition, the Division continued to be challenged by the introduction of new biotechnology devices.

With regard to CLIA '88, DCLD staff met with staff from HCFA and CDC during the year to assist in the development of proposed implementing regulations. These proposed regulations were published in the *Federal Register* on May 21, 1990. During the comment period, DCLD staff participated in a three day "National Congress" sponsored by the National Committee for Clinical Laboratory Standards (NCCLS). The congress was attended by representatives from various health professional groups, industry, and government for the purpose of identifying key concerns raised by the proposed regulations and recommending alternatives to specific proposed requirements. In addition, the DCLD director participated as a member of an internal CDC technical advisory committee charged with assisting HCFA in responding to the over 44,000 comments submitted on the proposed regulations. To assist the director in this activity, a CDRH technical advisory committee was formed in late summer which comprised representatives from various CDRH offices.

In the area of drugs of abuse test kits (DATs), DCLD assisted in the development of a strategy to exempt DATs from the prescription requirements of test kits cleared for nonmedical professional use, e.g., for forensic purposes or in law enforcement settings. This initiative was undertaken in response to a manufacturer's concern that application of prescription requirements for DATs, i.e., requiring distribution and use upon the order of a licensed practitioner as defined by individual states, impeded the use of DATs in law enforcement and other settings and, thus, was contrary to national drug testing policy. This initiative has important precedent setting implications for other similar *in vitro* tests such as DNA tests used as evidence to link suspects to crimes, e.g., DNA semen analysis of suspects in rape cases.

In keeping with past trends, DCLD was involved in the scientific review of several marketing applications for biotechnology based IVDs. For example, the division completed work on a PMA for a cell-free interleukin-2 receptor bead assay kit. The kit, an enzyme immunometric assay for the quantitative measurement of interleukin-2 receptor (IL-2R) levels in human serum, is indicated for use as an aid in evaluating and monitoring response to treatment in hairy cell leukemia patients in whom elevated levels of serum IL-2R have been confirmed. In addition, DCLD completed work on a PMA B-cell/T-cell gene rearrangement test. The test detects clonal populations of lymphoid cells in mixed cell populations from tissues and body fluids to aid in the differential diagnosis of lymphocytic leukemia and lymphoid malignancies from other neoplasms. The test provides information about the B-cell and T-cell lineage of the neoplasm which can aid in the selection of appropriate therapy. Moreover, the test identifies rearranged genes (specific tumor markers), so that a physician can qualitatively examine a clonal population during relapse to determine if the same population is present as an aid in evaluation of therapeutic effectiveness.

In addition, DCLD completed the reviews of three DNA probe based 510(k) submissions. Two submissions were for the culture confirmation of Cryptococcus neoformans and Listeria

monocytogenes. The third submission was for the detection of Streptococcus pneumonia in clinical specimens.

4. Division of Gastroenterology/Urology and General Use Devices (DGGD)

During FY 90, DGGD was characterized by increases in staff, a change in the structure of the Division, and the successful management of several ongoing scientific and regulatory issues.

The Division had an increase of 12 positions, nearly a 50% increase in staff. This includes one Branch Chief position, one secretarial position, and 9 scientific reviewer positions. Eight of these positions were female, with two being minorities and one a supervisor.

In April 1990, the Division was reorganized into three Branches. The General Hospital and Personal Use Devices Branch was unchanged, but the Gastroenterology/Urology Devices Branch was split into two branches: GU-I Devices Branch and GU-II Devices Branch. This reorganization allows the management of the Division to be better aligned with the staff and workload increases, and permits greater scientific and technical focus of the product areas and more effective management of the workload and staff.

There were several significant issues that were managed by the Division during FY 90. DGGD facilitated, reviewed, and approved a National Electrical Manufacturers Association sponsored protocol to study long-term effects of lithotripsy on hypertension. This represents an innovative effort where a group of competitors have agreed to study a potential long-term effect jointly, using the same protocol and the same study monitor. The likely result will be information that authoritatively addresses the risk of hypertension following lithotripsy and will be able to address any possible different effects caused by a specific machine. DGGD managed the development of a regulatory and scientific review policy for lithotripters used in treating gallstones. This involved a public discussion by the Gastroenterology/Urology Advisory Panel of the issue, the review of two controversial PMAs for this application of lithotripsy, and the development of improved working relations between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health. This process culminated in the issuance of an FDA draft guidance on Biliary Lithotripsy.

DGGD continued its ongoing effort for increased interactions with the professional and clinical community including the American Urological Association, the American Society of Gastrointestinal Endoscopy, and several lithotripsy groups. DGGD also continued its interactions with the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research on drug/device and biologic/device issues.

5. Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices (DOED)

Many public health and policy issues demanded DOED's scientific and regulatory expertise in FY 90. A significant policy change within ODE is a modification of DOED's responsibility for the review of diagnostic ultrasound 510(k)s. ODE's previous practice was to coordinate concurrent divisional reviews of diagnostic ultrasound 510(k)s at the office level. DOED now will be responsible for the entire review of diagnostic ultrasound applications, both technically and clinically. DOED will consult with other Divisions if there are new or unfamiliar technology issues under their purview. This consolidated ultrasound review policy is similar to the laser review guidance policy.

The increasing spread of the HIV infection necessitated the need to expedite testing and development of barrier contraceptive devices with potential to prevent AIDS. As a result, DOED, in collaboration with experts from CDRH, NIH, CDC and from across the country, completed the development of guidelines for female barrier contraceptives intended to prevent AIDS and other sexually transmitted diseases (STDs).

In collaboration with OST, DOED developed a computerized decision support system for aiding reviewers in processing 510(k) submissions for air conduction hearing aids. The system is currently being tested. The system is based on the Computer-Assisted Review and Evaluation (CARE) system which is a computer program to assess routine device applications, identify deficiencies, and prepare correspondence. Nonroutine or more complex applications are rejected by the computer for evaluation by the expert reviewer.

A reclassification petition to reclassify endosseous implants (a minimum of 21 different types of implants) from class III to Class II was submitted by the Dental Implant Manufacturers Association (DIMA). FDA has responded to DIMA's petition, noting several major deficiencies. The petition will be reviewed by the Dental Products Panel on March 14, 1991. DIMA has until December 31, 1990, to submit additional clinical data supporting reclassification.

DOED has reconvened its Amalgam Task Force and is presently reviewing new information related to the potential consequences of the use of dental amalgams. Studies have been conducted on sheep which raise new questions related to the migration of mercury from the fillings in the sheep's mouth to other organ systems in the animal. The Task Force will review these data along with anecdotal information from persons who claim to have had adverse effects from their amalgam fillings. CDRH will review this new information and present its conclusions to the Dental Products Panel on March 15, 1991. The Panel will be asked for recommendations for needed FDA action.

Our staff increased in FY 90. We hired 7 professional staff, one FOI Technician, and a new Branch Chief for the ENTD Branch. DOED has also instituted a monthly narrative and statistical table reporting system which has strengthened our ability to resolve problems involving review times and helped maintain a high level of productivity.

6. Division of Ophthalmic Devices (DOD)

The Division of Ophthalmic Devices had several issues that either arose or came to conclusion during FY 90. These involved the treatment of new technologies such as excimer lasers for keratectomy, multifocal intraocular lenses for the treatment of aphakia, responding to public comment on the use of laboratory techniques in place of animal studies, and the completion of the phase-out of adjunct investigational studies for IOLs.

The division responded to sponsor needs for guidance in the study of new technologies such as excimer lasers for producing therapeutic and refractive changes in the eye and multifocal intraocular lens replacement of the natural lens in patients where it has been removed due to cataract. Draft guidance documents were initiated during the fiscal year on these issues.

An animal rights group commented on animal device testing indicating that laboratory tests could be used in place of certain tests performed on animals (Draize Test). The division coordinated the FDA response to this proposal.

FY 90 marked the end of a three year phase-out plan of adjunct IOL investigations. The plan was designed to bring investigations of intraocular lens models into better compliance with established IDE regulation.

Additional areas of activity and accomplishments within the division include:

- support of the medical community for certain orphan devices
- provided major support to OCS, OGC, and the Department of Justice on an IOL related grand jury case
- issued a letter to all IOL PMA holders warning about advertising and promotional activities
- contributed to the goal statement for OTA/CDRH sponsored Consortium conference on contact lens care

- contributed to development of ODE policy on the promotion in labeling for contact lens products

- contributed to development of precedent setting correspondence to contact lens manufacturers regarding misleading/misrepresentations in PMA applications

- established requirements for new 510k contact lens device accessories, and new criteria for streamlining toxicology review under 510k for certain products

- developed new internal policy on use of tinted lenses as "custom" devices

- developed a working policy on definitions regarding disposable contact lenses and their permutations

- developed precedent setting correspondence to contact lens solution manufacturers requesting approval of effectiveness claims for disinfection of AIDS virus and effectiveness against acanthamoeba

- developed working policy for inclusion of "public service messages" in contact lens product labeling

- issued branch policy for revision of testing requirements for RGP lens solution manufacturers

- issued draft policy for ODE review and concurrence for adding new RGP finishing labs to annual report mechanism

The Division continues to process a large number of PMA applications with 18 original PMAs being approved during FY 90. The workload in the PMA supplemental area and IDE areas also reflect high numbers of decisions all made within the statutory review times established by regulation.

The Division was able to fill the position of Branch Chief, Surgical and Diagnostic Devices Branch. This enabled the Division to sustain its ability to process documents in a timely manner and deal with emerging complex scientific issues. During the fiscal year twelve new employees were hired, 5 support staff and 7 scientific reviewers.

7. Division of Surgical and Rehabilitation Devices (DSRD)

DSRD has progressed in its work on several public health policy issues in FY 90. These issues are related to both surgical and rehabilitation devices and included suture reclassification, health risks associated with mammary implants, and scalp cooling caps for chemotherapy patients.

During FY 90, three further suture materials were successfully reclassified: polyamide, polypropylene, and polyethylene terephthalate. The silk suture reclassification is in the final stage of receiving agency approval. Several 510(k)s for these newly reclassified transitional devices have been successfully processed, and permanent review guidelines for suture 510(k)s are being developed. It should be noted that this effort is precedent setting and forges the mechanism for future reclassification efforts within CDRH.

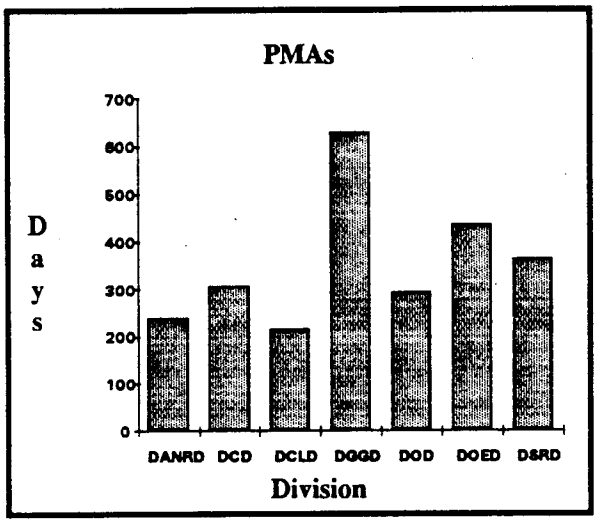
Work on the proposed 515(b) call for PMAs for silicone gel breast implants has continued and the proposed rule was published in the *Federal Register* on May 5, 1990. The division is now in the process of reviewing comments received on the published proposal. Additional work in this area has included the ongoing development of a patient information brochure regarding these implants. It was developed in conjunction with other CDRH offices, physicians, consumer groups and the State of Maryland. DSRD staff also participated in the planning of the Silicone Conference to be sponsored by the Agency and scheduled to take place in Baltimore in February, 1991.

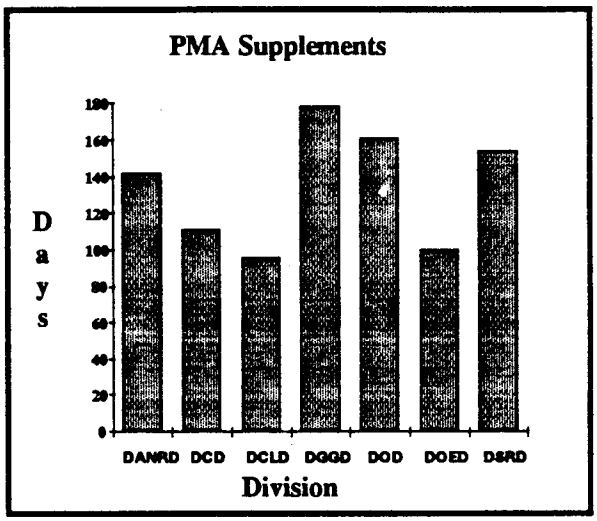
During FY 90, significant advances in laser technology continued through expansion of minimal invasive surgical techniques. Surgeons, using endoscopes and laparoscopes, coupled with laser fiber optics or waveguides or special manual instruments, can perform closed-body surgery for a variety of purposes. As an example, laser laparoscopic cholecystectomy (removal of the gall bladder) reportedly reduces hospital stay from 7-10 days for the open procedure to 1 - 1 1/2 days for the laparoscopic procedure. In addition, patients may return to work and other activities within 7 days as opposed to several weeks following open surgery. Many of the endoscopic or laparoscopic procedures may be performed on an outpatient basis.

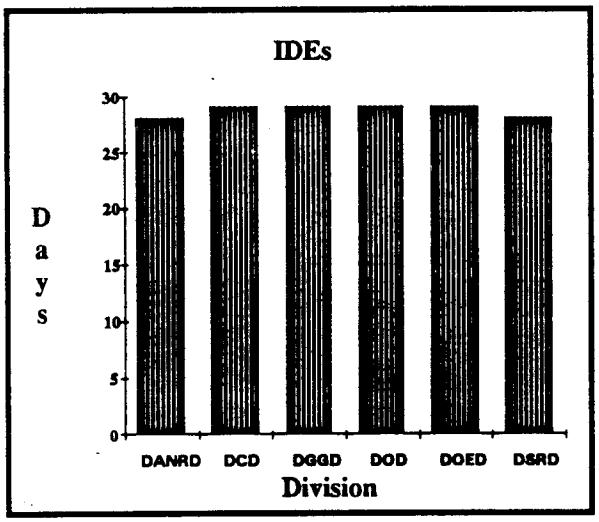
Work has continued on reclassification of Biologically Fixed Porous Coated Total Hip Prostheses from Class III to Class II. A reclassification petition was filed in September 1989. In that same month the FDA Orthopedic Advisory Panel recommended that FDA reclassify these devices. FDA believes that the data provided by the petitioner and other persons constitute valid scientific evidence that the regulatory controls of Class II are sufficient for these devices and has tentatively agreed with the recommendation of the panel pending review of any public comments on the recommendation.

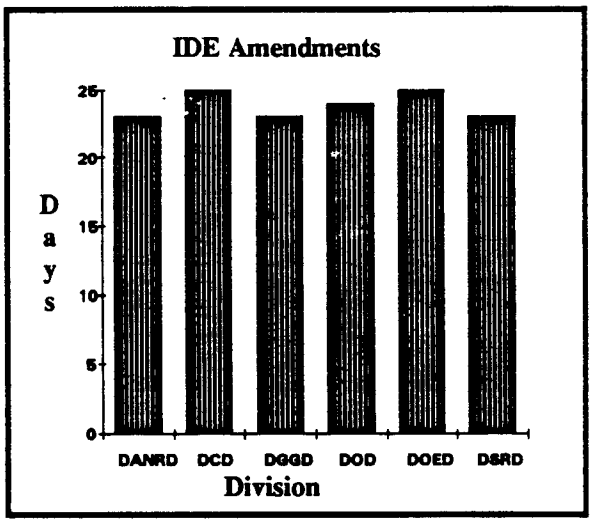
C. Division Performance Data

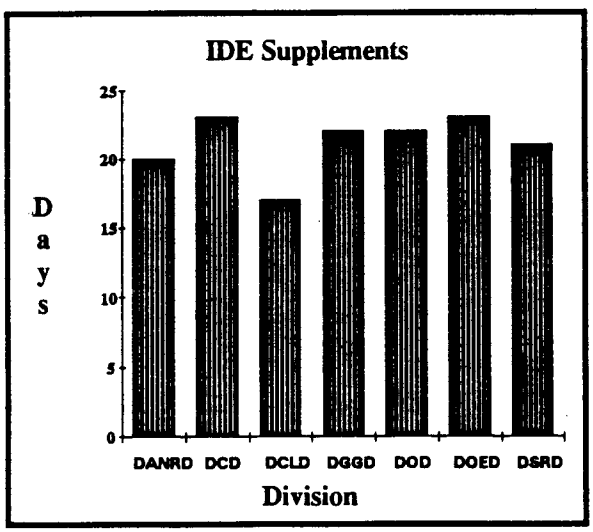
CHART 25 - Average FDA Review Time for Major Submissions by ODE Division - FY 90











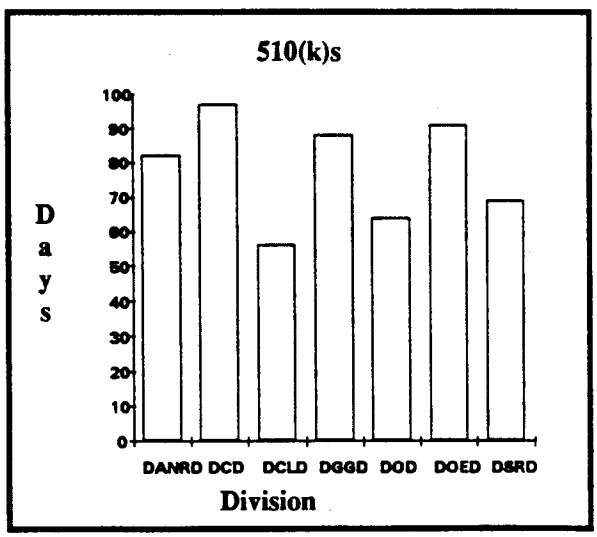
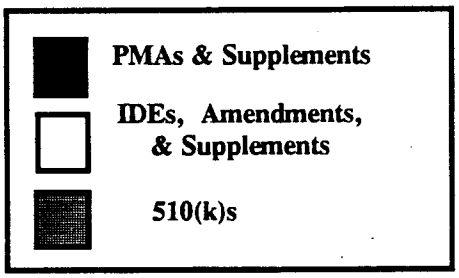
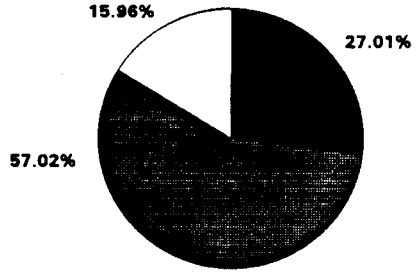


CHART 26 - Major Submissions Received by ODE Division - FY 90

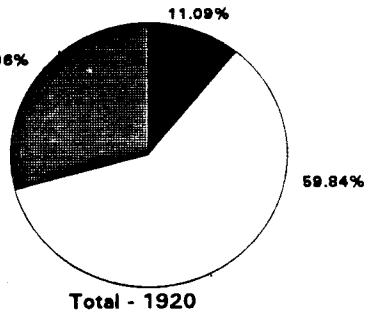




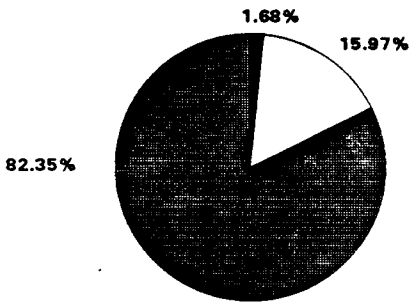
DOD

Total - 1303

DCD



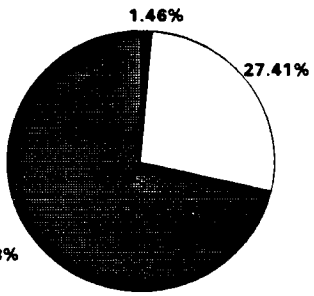
Total - 1920



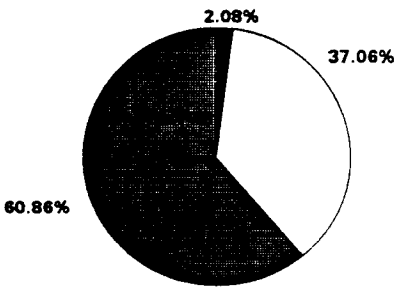
DOED

Total - 1190

DANRD



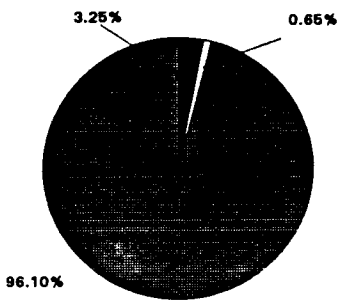
Total - 1233



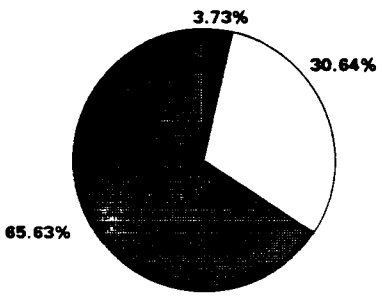
DGGD

Total - 1635

DCLD



Total - 1077



DSRD

Total - 1795

VI. Office Management

A. Organizational Structure

ODE is comprised of seven divisions grouped according to medical specialty: cardiovascular devices; anesthesiology, neurology, and radiology devices; surgical and rehabilitation devices; gastroenterology/urology and general use devices; obstetrics/gynecology, ear, nose, throat, and dental devices; clinical laboratory devices; and, ophthalmic devices. In addition, two offices report directly to the ODE director: the Program Management Office, which administers ODE management and administrative functions, and the Program Operations Staff, which coordinates the review of PMAs, IDEs, and 510(k)s. See Appendix B, ODE Organizational Chart.

B. New Employees

FY 90 management directions added a new dimension when we received word in late December that our hiring freeze had been lifted and we could hire again. Ultimately, the resulting growth spurt produced 88 new employees, all hired in FY 90 and all requiring space, furniture, equipment, training, and multiple adjustments.

Two initiatives addressed the problems of indoctrinating the new employees into the ODE workforce: the ODE Mentor Program (Blue Book Memo # A90-3) and the Training Checklist for New Reviewers (Blue Book Memo # A90-4). Also, we recognized the need for more focused training for our new reviewers by assigning to one of our most able and experienced employees the task of providing an in-house reviewer training course and working with industry and other non-government officials to provide for site visits and joint seminars. We believe these endeavors will extend beyond the education and professional enrichment of the individual employees and will enhance the entire review process as well.

C. Training

Although the greatest emphasis was placed on the training needs of our new employees, we continued to encourage and support training for all ODE employees. During FY 90 there were 212 ODE employees involved in 557 training instances which included coursework directed towards advanced degrees, courses in office automation and scientific-based subjects, and seminars on research and emerging medical device technologies. Our total expenditures for this training was $178,000.

Special training was provided for our supervisors this past year. We emphasized improving their management skills by bringing trainers on site for the following half day or all day courses: Time Management; Interviewing Skills; and, Performance Management - Making It Work.

Chart 27 - ODE Computer Hardware Status
FY 89 - FY 90

HARDWARE	On hand in FY 89	Received in FY 90	On hand in FY 90
DECmate II Word Processors	55	15	70
DECmate III Word PRocessors	35	1	36
LQP02 Letter Quality Printers	31	2	33
LQP03 Letter Quality Printers	6	-3	3
LA50 Draft Quality Printers	38	5	43
LA75 Draft Quality Printers	39	1	40
LA100 Draft Quality Printers	7	-6	1
LA210 Draft Quality Printers	2	-1	1
LN03 LASER Printers	23	-	23
VT102/125	0	9	9
VT220 Terminals	43	-	43
VT320 Terminals	7	-	7
PRO 350 Terminals	4	-4	0
Ricoh FAX 1000L	1	1	2
CP/M Boards for DECmates	67	-	67
Electrohome Projectors	1	-	1
Compaq 286 PCs	11	-	11
AST 286 PCs	69	-	69
AST 386 SX	0	29	29
AST 386 PCs	7	2	9
Fujitsu Draft Printers	70	-	70
Fujitsu Letter Quality Printers	11	-	11
Macintosh Plus/SE PCs	5	-	5
Apple Laserwriter Printers	5	-	5
Apple Imagewriter Printers	1	-	1
HP LaserJet II Printers	8	-	8
DEST DECmate Document Scanner	1	-	1
DEST PC Document Scanner	1	-	1

D. Office Automation

The Office of Device Evaluation continued to enhance its office automation capability as a means to process device applications and prepare review documents as quickly as possible. With the purchase of IBM compatible personal computers during the past two years, the foundation has been set for the use of continuously improved personal computer software and optical disk technology in ODE. To orient the ODE employee to the new PCs and the emerging technology, a *Personal Computer Guide for ODE* was developed by the Program Management Office.

1. Equipment and Software

During FY 90, requisitions for over $364,000 were submitted for additional equipment and software. Orders were placed for 74 personal computers. After final delivery, sixty percent of the ODE computer terminals available for word processing will be IBM compatible PCs.

When all the PCs are delivered, forty percent of the ODE computer terminals will be Digital Equipment Corporation DECmates and DEC terminals. This mixture of PCs and DEC equipment has presented logistical problems as it relates to final document preparation. Many reviewers now have PCs and most secretaries still have DECmates. To alleviate this problem, ODE PC users converted documents between WordPerfect and DECmate formats through conversion software on the Center's VAX computer. Software conversion was also performed by a document converter in the ODE Program Management Office.

Eighty-eight people were hired in FY 90 and the large influx of new employees prevented the replacement of older DECmates since the DECmates were given to new employees. Regardless, the existence of the DECmates and various DEC computer terminals afforded all but 6 of the new employees an opportunity to have a computer terminal. The purchase of the AST PCs addressed the equipment compatibility issue since at least half of the secretaries within each ODE Division will soon have PCs and the logistical problems with final document preparation will be reduced. Our next step is to purchase more PCs and replace the older DECmates where compatibility with PCs is needed and within fiscal constraints.

The software used on the ODE PCs included word processing, database, statistical, and graphical software. The WordPerfect word processing software enhanced a reviewer's capability for review document preparation with the increased functionality and speed with which these functions were performed. Database, statistical, and graphical software provided new tools for the reviewer and the manager to perform their designated responsibilities. PC databases were developed to track the flow of device applications and to record information for quick retrieval. Data pertaining to the review of device applications was also displayed graphically and prepared as reports for management. With these features, the PC afforded an opportunity for gains in productivity and new ways to manage the device application process.

2. Tracking Systems

Despite the great strides in the introduction of PC technology, the ODE Document Tracking System on the Center's VAX remained vital to the successful operation of this organization. Individuals within ODE continued to work with the analysts and programmers in the Office of Information Systems to resolve problems which developed with the system and to request system modifications. Additional management reports were recently requested to more completely utilize the existing data.

3. Optical Storage and Retrieval

With the continued purchase of IBM compatible personal computers, the office automation foundation was expanded with computers that can be upgraded to optical disk workstations for accessing images stored on the Center's VAX computer. Rapid access to archival documents will reduce the time needed to research historical documents that pertain to new device applications. Eventually, ODE's PCs will be upgraded with the necessary hardware and software to allow PC users ready access to documents stored on optical disk.

To initiate the scanning of ODE documents to optical disk, the Office of Information Systems signed a contract for scanning by a local contractor. The first ODE documents placed on an optical disk will be completed 510(k)s and the most recently completed PMAs. To perform in-house scanning of selected documents, ODE received a scanning PC workstation.

4. Local Area Network

PC connectivity is vital for the effective operation of an organization with over 160 PCs. Connectivity allows the sharing of expensive peripherals such as laser printers and also the sharing of information. While ODE PC users have access to the DEC laser printers through Ethernet, easy access to the Hewlett Packard laser printers is an immediate need. Therefore, the hardware and software to establish a local area network (LAN) to link the PCs was purchased. A LAN with 5 PCs was established and underwent testing prior to full scale implementation. Two AST 386/25 PCs were used as LAN servers and the application software was the 3 COM 3+Open LAN Manager.

5. Training

ODE employees continued to receive training in the use of the VAX-based systems, DEC word processors and PC application software. Most of the training was provided by the Office of Information Systems training staff but non-government training sources were used when necessary. Training of this type will continue to receive emphasis so that ODE employees can obtain the proficiency needed to utilize the office automation resources.

VII. STATISTICAL TABLES

[NOTE: Although accurate at the time of publication, the data in the following tables may change slightly in subsequent reports to reflect changes in the regulatory status of submissions or verification of data entry. For example, if an incoming PMA supplement is later converted to an original PMA, changes are made in the appropriate tables. Likewise, some data from earlier reporting periods may have been changed to reflect similar corrections in data entry. These adjustments are not likely to have a significant effect on conclusions based on these data.]

Table 1. PMA/IDE/510(k) Submissions Received
FY 86 - FY 90

Type of Submission	No. Received				
	FY86	FY 87	FY 88	FY 89	FY 90
Premarket Approval:					
Original Applications	69	81	96	84	79
Amendments	853	748	754	856	569
Supplements	478	700	727	810	660
Amendments to Supplements	714	871	919	999	1,069
Reports for Orig. Applications	297	514	535	466	479
Reports for Supplements	174	162	59	57	22
Master Files	36	43	41	32	37
PMA Subtotal	2,621	3,119	3,131	3,304	2,915
Investigational Device Exemptions:					
Pre-original Applications	20	15	8	7	19
Original Appplications	206	218	268	241	252
Amendments	274	265	316	271	288
Supplements	2,884	2,836	3,391	3,038	3,043
IDE Subtotal:	3,384	3,334	3,983	3,557	3,602
Premarket Notification:					
Original Notifications	5,063	5,265	5,536	7,022	5,831
Supplements	2,050	2,113	2,713	3,752	3,531
510(k) Subtotal:	7,113	7,378	8,249	10,774	9,362
PMA/IDE/510(k) Total:	13,118	13,831	15,363	17,635	15,879

Table 2. Original PMAs
FY 86 - FY 90

Action	FY 86	FY 87	FY 88	FY 89	FY 90
Number received	69	81	96	84	79
Number of final approvals	72	46	46	56	47
Average review time (days) for final approvals;[a]					
FDA	395	337(257)	262(142)	247(145)	302(228)[e]
Non-FDA	44	81 (27)	75 (17)	101 (42)	113 (55)[e]
Total	439	418(284)	337(159)	348(187)	415(283)[e]
Number under review at end of period:[b]					
Active[c]	63	50	48	62	44
(Active and overdue)	(16)	0	(1)	(24)	(5)
On hold[d]	72	77	66	52	72
Total	135	127	114	114	116

a/ Average review times in parentheses are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814).

b/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

c/ FDA responsible for processing application.

d/ FDA's processing of applications officially suspended pending receipt of additional information from the applicant.

e/ Average review times have gone up primarily because of the completion of work on 19 PMAs that were active and overdue in FY 89 (see active and overdue) with long review times at the time they were approved. In particular, this backlog included six IOL PMAs that had an average review time of 350 days and two PMAs for surgical products that averaged 429 days.

Table 3. PMA Supplements
FY 86 - FY 90

Action	FY 86	FY 87	FY 88	FY 89	FY 90
Number received	478	700	727	810	660
Number of final approvals:					
Panel track[a]	9	8	9	13	5
Others	468	557	643	506	695
Total	477	565	652	519	700
Average review time (days) for final approvals:[b]					
FDA	186	148(138)	124(95)	122(109)	146(133)[f]
Non-FDA	10	11 (5)	25 (12)	41 (31)	35 (26)[f]
Total	196	159(143)	149(107)	163(140)	180(159)[f]
Number under review at end of period:[c]					
Active[d]	249	224	195	364	215
(Active and overdue)	(107)	0	(2)	(62)	(7)
On hold[e]	54	120	107	167	120
Total	303	344	302	531	335

a/ Panel track supplements require the full administrative procedures normally associated with original PMAs, i.e., Panel review, preparation of a summary of safety and effectiveness, and publication of a *Federal Register* notice.

b/ Average review times in parentheses are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814).

c/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

d/ FDA responsible for processing application.

e/ FDA's processing of application officially suspended pending receipt of additional information from the applicant.

f/ These average review times have gone up primarily because of the completion of work on 55 PMA supplements that were overdue at the beginning of this fiscal year (see active and overdue). The longer review times of these applications contributed to these increased average review times.

Table 4. Original IDEs
FY 86 - FY 90

Action	FY 86	FY 87	FY 88	FY 89	FY 90
Number received	206	218	268	241	252
Number of decisions:					
Approved(%)	58(27)	60(27)	79(30)	89(36)	95(38)
Not approved (%)	138(65)	153(68)	172(66)	143(58)	146(59)
Other (%)[a]	17 (8)	11 (5)	9 (3)	13 (5)	7 (3)
Total	213	224	260	245	248
Average FDA review time (days)	35(28)[b]	28	27	29[c]	29
Percent (%) of decisions made within 30 days	91(93)[b]	97	99	100[c]	99
Number under review at end of period[d]	17	11	19	16	20
Number overdue at end of period	0	0	0	0[c]	0

a/ Includes deletions, withdrawals, and other administrative actions not resulting in an approval/disapproval decision.

b/ FY 86 performance reflects completion of 4 applications that were already overdue when FY 86 began. Excluding these applications from the analysis yields an average review time of 28 days and 93 % of decisions made within 30 days.

c/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no IDEs were logged out and the clock was suspended for purposes of counting the 30 day review period. For IDEs that were in ODE during the closed period and for which the review period exceeded 30 days, up to 18 days were subtracted from the review time to determine average review times and to determine whether the document was overdue. This policy was announced in two letters to submitters of IDEs and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377

d/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

Table 5. IDE Amendments
FY 86 - FY 90

Action	FY 86	FY 87	FY 88	FY 89	FY 90
Amendments received[a]	274	265	316	271	288
Decisions on amendments:					
Approved(%)	192(58)	132(52)	170(52)	127(45)	123(46)
Not approved (%)	61(18)	71(28)	88(27)	78(28)	79(29)
Other (%)[b]	77(23)	51(20)	68(21)	75(27)	68(25)
Total	330	253	327	280	270
Average FDA review time (days)	99	33	24	23[c]	24
Percent (%) of decisions made within 30 days	74	96	98	99[c]	99
Average approval time (Days) for IDEs with amendments:					
Total time[d]	169	152	152	176	187[e]
FDA time	N/A	83	65	68	73[e]
Non-FDA time	N/A	69	87	108	114[e]
Amendments under review at end of period[f]	19	31	20	11	29
Amendments overdue at end of period	2	0	0	0[c]	0

N/A - Not available.

a/ Includes only those submission received subsequent to and as a result of the disapproval of an original IDE.

b/ Includes deletions, withdrawls, and other administrative actions not resulting in an approval/disapproval decision.

c/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no IDEs were logged out and the clock was suspended for purposes of counting the 30 day review period. For IDEs that were in ODE during the closed period and for which the review period exceeded 30 days, up to 18 days were subtracted from the review time to determine average review times and to determine whether the document was overdue. This policy was announced in two letters to submitters of IDEs and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377.

d/ The average IDE approval time represents the total time it has taken, on average, for an original IDE that was initially disapproved, to be approved after the submission of amendments to correct deficiencies. The time being measured here covers the priod from which the original IDE was received to the final approval of an IDE amendment.

e/ An increase in average review times can be expected as the percentage of original IDE approvals rises. This is due to the fact that the "easier" or "better prepared" IDEs, with their shorter review times, are not included with IDE amendments.

f/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

Table 6. IDE Supplements
FY 86 - FY 90

Action	FY 86	FY 87	FY 88	FY 89	FY 90
Number received	2,884	2,836	3,391	3,038	3,043
Number of decisions	3,599[a]	2,784	3,405	3,023	2,968
Average FDA review time (days)	116(21)[b]	22	22	22[c]	22
Percent (%) of decisions made within 30 days	72(90)[b]	95	99	99[c]	99
Number under review at end of period[d]	139	175	157	170	245
Number overdue at end of period	0	0	0	0[c]	0

a/ These decisions include approximately 1,000 intraocular lens IDE supplements, the majority of which had been pending for a significant period of time when FY 86 began and which were reviewed by a special team assigned to eliminate this backlog; without these reviews, the FY 86 review rates are comparable to review rates in other years.

b/ FY 86 performance reflects completion of 728 applications that were already overdue when FY 86 began. Excluding these application from the analysis yields an average review time of 21 days and 90% of decisions made within 30 days.

c/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no IDEs were logged out and the clock was suspended for purposes of counting the 30 day review period. For IDEs that were in ODE during the closed period and for which the review period exceeded 30 days, up to 18 days were subtracted from the review time to determine average review times and to determine whether the document was overdue. This policy was announced in two letters to submitters of IDEs and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377.

d/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

Table 7. 510(k)s
FY 86 - FY 90

Action	FY86	FY 87	FY 88	FY 89	FY 90
Number received	5,063	5,265	5,536	7,022	5,831
Number of decisions:					
Substantially equivalent	4,388	4,105	4,432	4,867	4,748
Not substantially equivalent	78	103	82	92	117
Other[a]	873	784	999	1,177	1,332
Total	5,359	4,992	5,513	6,136	6,197
Percent(%) not substantially Equivalent[b]	2.2	2.4	1.8	1.9	2.4
Average review time(days):					
Total time[c]	72	69	78	82[e]	98[f]
FDA time[d]	66	56	64	66[e]	78[f]
Percent(%) of decisions made within 90 days, based on:					
Total time[c]	65	71	67	70[e,g]	57
FDA time[h]	93[i]	96	99	99	100[j]
Number under review at end of period:					
Active[k]	733	934	913	1,270	1,174
(Active and overdue)	(25)	0	0	0[e]	0
On hold[l]	308	409	445	989	726
Total	1,041	1,343	1,358	2,259[m]	1900

a/ Includes withdrawals, deletions, and other administrative actions.

b/ Based on "substantially equivalent" and "not substantially equivalent" decisions only.

c/ Includes all time from receipt to final decision, i.e., does not exclude time while a submission is on hold pending receipt of additional information.

d/ FDA average review time includes all increments of time FDA reviewed a 510(k) so long as the 510(k) document number did not change, which occurs rarely.

e/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document MailCenter was closed from June 26 to July 13, for a total of 18 days. During this time, no 510(k)s were logged out and the clock was suspended for our Center was closed from June 26 to July 13, for a total of 18 days. During this time, no 510(k)s were logged out and the clock was suspended for purposes of counting the 90 day review period. In FY 89 and FY 90, for 510(k)s that were in ODE during the closed period and for which the review period

(Continued on next page)

Table 7. 510(k)s
FY 86 - FY 90

(Continued from previous page.)

exceeded 90 days, up to 18 days were subtracted from the review time to determine the average review time and to determine whether the document was overdue. This policy was announced in two letters to submitters of 510(k)s and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and, September 8, 1989, at page 37,377.

f/ Both FDA and total average review times went up because of two general programmatic changes that occurred. FY 90 was the first full year in which approximately 40% of Class I devices, the ones that took very little time to review, were exempted from 510(k) review. Removing these exempted products from review left the more time consuming 510(k)s which raised the average review time. Also, there has been an increase in the reviewer documentation of decisions for 510(k)s in order to improve consistency among 510(k) decisions. This has also caused an increase in the time required to complete each 510(k) review.

g/ Based on 10 month data, which is representative of this performance had the Document Mail Center not been closed for 18 days as explained in footnote e, above.

h/ Considers whether FDA review time remained within 90 days, with FDA's review clock being reset to zero whenever additonal information was received (in accordance with 21 *CFR* 807.87(h)).

i/ Based on final two quarters only.

j/ The percent of decisions made within 90 days based on FDA review time is 100% rounded off from 99.9%. Only seven decisions out of the 6,197 total decisions were completed in more than 90 days.

k/ FDA responsible for processing notification.

l/ FDA's processing of notification officially suspended pending receipt of additional information from the applicant.

m/ This total includes a large number of submissions for examination gloves submitted immediately before the close of the reporting period.

Table 8. Major Submissions Received
FY 80 - FY 90

Type of Submissions	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990
Orig. PMAs	62	60	90	76	65	97	69	81	96	84	79
PMA Supp.	165	259	277	360	435	393	478	700	727	810	660
Orig. IDEs	71	237	189	189	203	204	206	218	268	241	252
IDE Amend.	N/A	N/A	N/A	N/A	N/A	365	274	265	316	271	288
IDE Supp.	460	924	1,694	1,750	3,077	2,457	2,884	2,836	3,391	3,038	3,043
510(k)s	3,167	3,684	3,798	4,477	5,004	5,254	5,063	5,265	5,536	7,022	5,831
Total	3,925	5,164	6,048	6,852	8,784	8,770	8,974	9,365	10,334	11,466	10,153

Table 9. Major Submissions Completed
FY 80 - FY 90

Type of Submissions	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990
Orig. PMAs	24	32	49[a]	46	43	37	72	46	46	56	47
PMA Supp.	78	239	238	327	243	377	477	565	652	519	700
Orig. IDEs	63	232	189	187	198	201	213	224	260	245	248
IDE Amend.	N/A	N/A	N/A	N/A	N/A	361	330	253	327	280	270
IDE Supp.	N/A	N/A	N/A	N/A	N/A	2,190	3,599[b]	2,784	3,405	3,023	2,968
510(k)s	2,908	3,381	3,256	3,162	4,262	5,095	5,359	4,992	5,513	6,136	6,197
Total	3,073	3,884	3,732	3,632	4,746	8,261	10,050	8,864	10,203	10,259	10,430

N/A - Not available.

a/ Includes one denial of approval.

b/ These decisions include approximately 1,000 intraocular lens IDE supplements that had been pending for a significant period of time when FY 86 began and which were reviewed by a special team assigned to eliminate this backlog; without these reviews, the FY 86 review rates are comparable to review rates for other years.

Appendix A

ODE STAFF ROSTER
FY 90

OFFICE OF THE DIRECTOR

Alvarado, Margretann
DeMarco, Carl
Donlon, Jerome
Robinson, Mary Jo
Sheridan, Robert
West, David

PROGRAM MANAGEMENT OFFICE

Appler, Kathryn
Cavanaugh, Sharon
Clingerman, Angela
Cornelius, Elizabeth
Ingraham, Samuel
Jaeger, Jeff
Trammell, Dennis
Vaughan, Sharyn
Vinson, Priscilla
Wedlock, Charles

PROGRAM OPERATIONS STAFF

Allen, Gene
Alpert, Arnold
Alonge, Laura
Bagley, Tammy
Calhoun, Elizabeth
Chissler, Robert
Cole-Fisher, Lisa
Davis, Lisa
Dillard, Sharon
Dorsey, Leslie
Falls, Deborah
Fishbein, Linda
Huff, William
Jackson, Barbara
Kyper, Charles
Lewis, Jessica
Lundsten, Kathy
Parker, Mervin
Perticone, Diane
Phillips, Phil
Rosecrans, Heather
Shulman, Marjorie
Socks, Betty
Sterniolo, Michael
Sutton, William
Teague, Nancy

DIVISION OF ANESTHESIOLOGY, NEUROLOGY, AND RADIOLOGY DEVICES

Arnaudo, Joesph
Bowie, Kim
Bradley-Allen, Cheryl
Burdick, William
Costello, Ann
Cress, Larry
Dawson, John
Dillard, Christina
Dillard, James
Galdi, Adrianne
Gantt, A. Doyle
Glass, John
Gluck, Michael
Harrison, Maria
Hinckley, Stephen
Kaltovich, Florence
Keely, Levering
Kirschenmann, Pam
Maloney, William
McCarthy, Elizabeth
Morris, Janine
Mosely, Tom
Munzner, Robert
Murray, George
O'Neill, Carroll
Porter, Barbara
Shuping, Ralph
Smallwood, Senora

Tran, Ann
Trinh, Hung
Wolf, Beverly
Zaremba, Loren
Zier, David

DIVISION OF
CARDIOVASCULAR DEVICES

Abel, Dorothy
Acharya, Abhijit
Astor, Brad
Brown, Lorraine
Byrd, Glen
Carey, Carole
Cheng, James
Ciarkowski, Arthur
Cromwell, Sybil C.
Cronin, Veronica
Dahms, Donald
Danielson, Judith
Donelson, Jan
Hoang, Quynh
Hoard, Renita
Hwang, Shang
Justice, Dina
Kennell, Lisa
Lemperle, Bette
Letzing, William
Loew, William
Lusted, Keith
Massi, Mark
MacCulloch, Diane
McKenna, Joyce
Michaloski, Cathleen
Paulson, Kirsten
Reamer, Lynne
Roy, Joydeb
Ryan, Tara
St. Pierre, Donald
Sapirstein, Wolf
Shanker, Rhona
Shein, Mitchell
Scheppan, Jeanette
Sliwiak, Joan
Sloan, Chris
Terry, Doris

DIVISION OF CLINICAL
LABORATORY DEVICES

Appell, Ray
Atwood, Pamela
Aziz, Kaiser
Berko, Retford
Blagmon, Djuana
Brindza, Larry
Bucher, Betty
Chace, Nina
Cricenti, Pat
Fugate, Kearby
Garland, June
Hackett, Joesph
Hanna, Naziha
Hansen, Sharon
Hawthorne, C. Ann
Huff, LaVerne
Jones, Doris
Lappalainen, Sharon
Magruder, Louise
Maxim, Peter
Moore, Nancy
Nutter, Cathy
Ohrmundt, Jan
Poole, Freddie
Rahda, Edappallath
Rao, Prasad
Rechen, Kathy
Robinowitz, Max
Rooks, Corneilia
Selfon, Nathaline
Sellman, Viola
Shively, Roxanne
Simms, Thomas
Sliva, Clara
Staples, Broden
Stewart, Willard
Temel, Seniye
Tsakeris, Thomas
Vadlamudi, Srikrishna
Wilson, Theresa
Yoder, Freda

DIVISION
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UROLOGY AND GENERAL USE
DEVICES

Acker, Rita
Barrett, Susanna
Baxley, John
Bolden, Brenda
Breslawec, Halyna

Byrd, Laura
Conklin, Glenn
Cornelius, Mary Joan
Dart, Linda
Derrer, E. Carolyn
Foster, Felisa
Gatling, Robert
Guest, John
Harris, Christine
Hubbard, Ruth
Lang, John
Mattan, Amalie
Melvin, Marsha
Mills, George
Nessen, Leonard
Neuland, Carolyn
Nimmagadda, Venkat
Park, James
Pfister, Richard
Purvis-Wynn, Sherry
Rubendall, Rita
Schools, Trenna
Scudiero, Janet
Seiler, James
Trybus, Chet
Ulatowski, Timothy
Williams, Richard
Wong, Linh

DIVISION OF
OPHTHALMIC DEVICES

Arras, Carol
Batra, Karaam
Brogdon, Nancy
Brown, Daniel
Burke-Nicholas, Marsha
Calogero, Don
Carbone, Josephine
Chen, Tzeng
Choy, Joanne
Clark, Geoff
Cohen, Linda
Coleman, Yvette
Duvall, Anita
Felton, Eleanor
Fox, Patricia
Gelles, Muriel
Gerondakis, Rose
Gouge, Susan
Grygier, Debra
Hammerman, Cynthia
Jan, George
Jankowski, Pamela
Jones, Susanna
Kaufman, Daryl
Lewis, Debra
Lippman, Richard
Maurey, Karen
McCarthy, Denis
Moyal, Albert
Pettinato, Mark
Phillips, Robert
Rogers, Donna
Saviola, James
Sloane, Walter
Smith, Myra
Stalbaum, Karen
Storer, Patricia
Thornton, Sara
Tilgman, Gwendolyn
Weiblinger, Richard
Whipple, David
Wilkerson, Paula
Yoza, Alice
Zollo, Mary Jo

DIVISION OF OBSTETRICS/
GYNECOLOGY, EAR, NOSE,
THROAT, AND DENTAL DEVICES

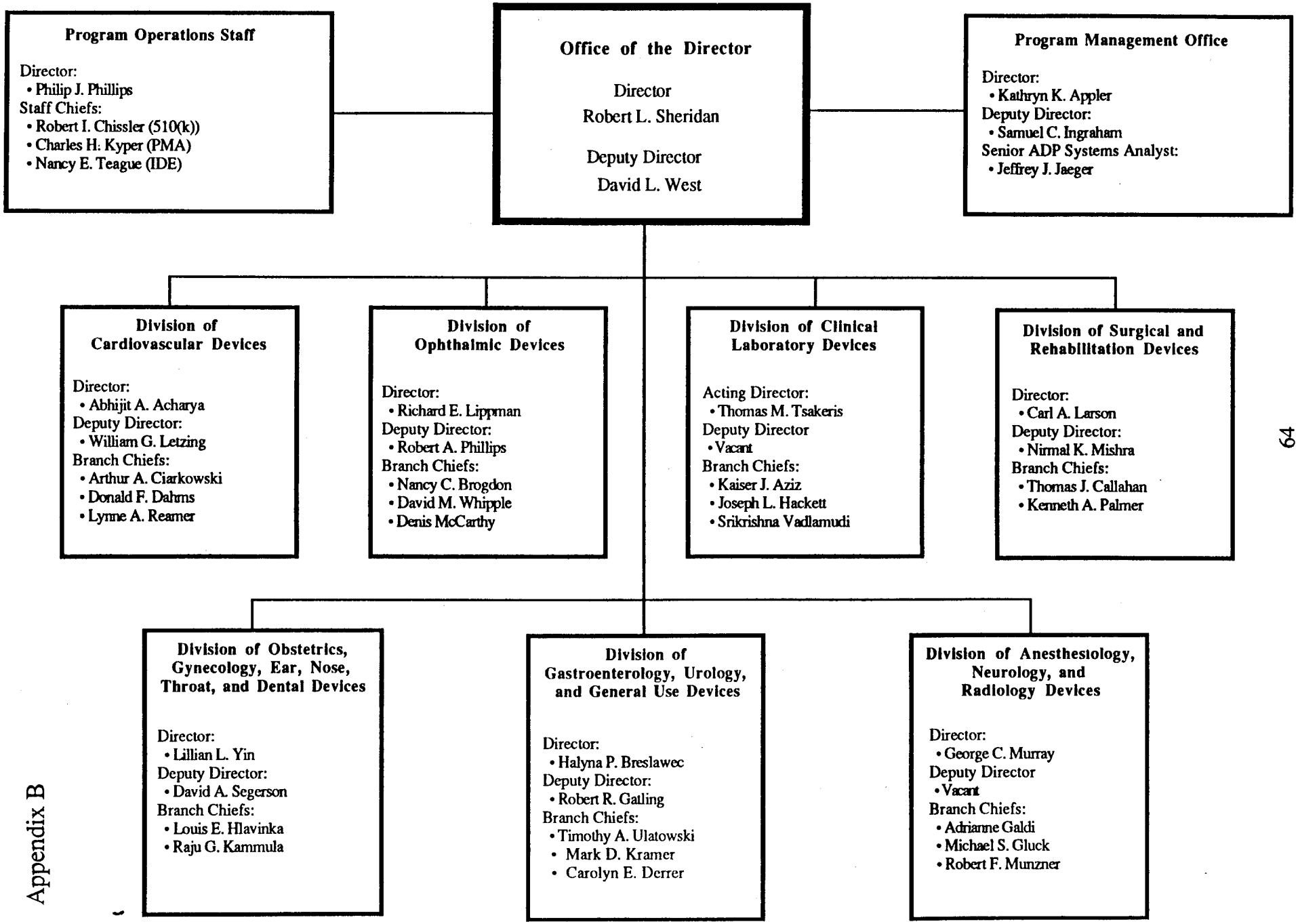
Bove', Celeste
Brauer, Christine
Browne, Myra
Cunningham, Melody
Goodman, Suzanne
Hlavinka, Louis
Jasper, Susan
Jefferies, Melpomeni
Kammula, Raju
Kuchinski, John (Mike)
Lockhart (Lamb), Joyce
Miller, Patricia
Perez, Rodrigo
Pollard, Colin
Purohit, Vishnudutt
Relacion, Cheryl
Sanchez, Rafael
Sands, Barry
Scott, Pamela
Segerson, David
Sharpe, Ellsworth

Singleton, Darryl (Greg)
Tsai, Miin-Rong
Tylenda, Caroyln
Whipp, Lori
Yin, Lillian
Yaffe, Leah
Yurawecz, Jane

DIVISION OF SURGICAL AND REHABILIATATION DEVICES

Adams, Tonja
Barnes, Roger
Basu, Sankar
Berne, Bernard
Bhatnagar, Gopal
Blackwell, Michael
Callahan, Thomas
Clark, Tracey
Donoghue, Mary
Einberg, Elmar
Gantenberg, Julie
Hadley, Kaelyn
Hastings, Robert
Hemeon-Heyer, Sheila
Howell, Heather
Johnson, Ramona
Kawin, Leslie
Kim, Hyuan
Larson, Carl
Luu, Hoan My Doo
McCuin, Sandra
McDermott, Kenneth
McGunagle, Daniel
Melkerson, Mark
Minear, Diane
Mishra, Nirmal
Moreland, Francis
Niver, Samie
Ogden, Neil
Palmer, Kenneth
Parkhurst, Louis (John)
Randolph, Joseph
Rhodes, Stephen
Riegel, Elizabeth
Rosile, Nadine
Saas, Hollace
Schroeder, Marie
Smith, Gwendolyn
Sternchak, Richard
Stevens, Theodore
Thomas, David U.
Tilton, Paul
Torres-Cabassa, Angel
Trisler, Patsy
Walker, Kathleen
Wei, Tena

ODE ORGANIZATIONAL CHART



Appendix B