November 10, 1986

FROM: Director, Office of Device Evaluation

SUBJECT: ODE Annual Report for Fiscal Year 1986

TO: Director, Center for Devices and Radiological Health

I am pleased to submit to you the attached Annual Report which describes the activities of the Office of Device Evaluation during fiscal year 1986.

The ODE staff and I want to convey to you and Mr. Benson, and through you, to the Commissioner and the Deputy Commissioner, our sincere appreciation for the support and encouragement that all of you have provided.

We also acknowledge, with thanks, the cooperation and help provided to ODE by other Center offices throughout the year.

Kshitij Mohan

Kshitij Mohan, Ph.D.

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

Fiscal Year 1986

Center for Devices and Radiological Health
Food and Drug Administration

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

Fiscal Year 1986

Dear ODE Colleague:

Attached is the ODE Annual Report for fiscal year 1986, which I am also submitting to the Center Director. The facts speak for themselves; your accomplishments far exceed any goals or expectations that I had, and that anyone could have reasonably desired.

This report, however, does not describe the full extent of your efforts. It cannot capture the sincere dedication with which you have approached the task of developing a rational and responsive program to protect the public health. All those who benefit from the rapid introduction of safe and effective medical devices into our marketplace owe you their thanks.

You have my personal gratitute and admiration for demonstrating what can be accomplished by a group of dedicated federal government employees.

Sincerely yours,

Kshitij Mohan

Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

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EXECUTIVE SUMMARY
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
FISCAL YEAR 1986

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 for safety and effectiveness and cleared for marketing. Set forth below are highlights of the activities and programs of ODE for fiscal year 1986 (FY 86), beginning on October 1, 1985 and running through September 30, 1986. These highlights are explained more fully in the body of the report.

In General

- In each of ODE's five major document review processes, Premarket Approvals (PMAs), PMA supplements, Investigational Device Exemptions (IDEs), IDE supplements, and Premarket Notifications (510(k)s), ODE issued more decisions in FY 86 than in FY 85. Moreover, in all five review processes, the number of pending submissions was also reduced in FY 86. This reduction is particularly important in light of the increases in the numbers of incoming submissions in three of the five document review processes from FY 85 to FY 86.

- Average review times were reduced in four of the five major document review areas.

Premarket Approval

- We approved 72 PMAs in FY 86, nearly twice the number approved in FY 85. Approvals also exceed the previous yearly high of 48 in FY 82. Annual PMA approvals are now exceeding receipts for the first time in the history of the program.

- The number of PMA applications under active review was reduced during FY 86 from 103 to 63. Of these, only 16 PMAs are over 180 days under review.

- There was a rise in PMA average review time, from 347 days in FY 85 to 395 days in FY 1986. This reflects the fact that ODE completed reviews of many long overdue applications, which raised the average. Of the 72 PMAs approved in FY 86, half were received in 1984 or before.

- We approved 477 PMA supplements in FY 86 which exceeds the number of approvals in FY 85, the previous all-time yearly high. Through the third quarter of FY 86, PMA supplement approvals have exceeded receipts for five consecutive quarters. As a result, the number of PMA supplements under active review fell during FY 86 from 306 to 249.

- Average review time for PMA supplements was reduced from 240 days in FY 85 to 186 days in FY 86.

- We approved four "technological breakthrough" medical devices: the automatic implantable cardiac defibrillator; the multichannel implantable hearing prosthesis; a variable rate single chamber pacemaker; and a transesophogeal pacemaker.

- We published a final rule on "Premarket Approval of Medical Devices" in the *Federal Register* of July 22, 1986. It becomes effective on November 19, 1986.

- To improve the PMA program, we issued guides for our reviewers on: OGC review of summaries of safety and effectiveness; early PMA reviews; PMA progress reports to applicants; criteria for panel review of PMA supplements; review and approval of PMAs for licensees; and, panel report and recommendations on PMA approvals.

Investigational Devices

- All overdue original IDEs and IDE supplements were eliminated during FY 86. These consisted of 4 original IDEs and 728 IDE supplements.

- Average review time for original IDEs was reduced from 37 days in FY 85 to 28 days in FY 86, and the percentage of decisions made within 30 days of receipt increased from 82% to 93%, when original IDEs that were already overdue when the fiscal year began are eliminated from the analysis.

- Average review time for IDE supplements was reduced from 33 days in FY 85 to 21 days in FY 86, and the percentage of decisions made within 30 days of receipt increased from 78% to 90%, when the supplements that were already overdue when the fiscal year began are eliminated from the analysis.

- We issued 213 and 3,599 decisions on original IDEs and IDE supplements, respectively. These exceed the 206 original IDEs and 2,884 IDE supplements received.

- "Guidance for the Emergency Use of Unapproved Medical Devices" was published in the *Federal Register* of October 22, 1985.

- We distributed a guidance to industry and the public that suggested the format and content of IDE progress reports.

- We issued "Guidance on Significant and Nonsignificant Risk Device Studies" to ODE reviewers. This guidance also should assist institutional review boards in determining whether a given study presents significant risk.

- Another significant document that we issued to sponsors of IOL IDEs and PMAs discussed current requirements on: adjunct studies; labeling for UV-absorbing lenses; trade names and claims; anterior chamber lens data reporting; manufacturing data in PMAs; and, PMAs for alternative materials.

Premarket Notification

- Average review time for 510(k)s was reduced from 76 days in FY 85 to 72 days in FY 86, reversing a trend of increasing review time that had existed since FY 82. The average review time dropped in each of the four quarters of FY 86 and was 59 days during the fourth quarter.

- The number of pending 510(k)s was reduced from 1,337 at the end of FY 85 to 1,041 at the end of FY 86. By the end of FY 86, only 25 pending 510(k)s were overdue.

- During FY 86, we made 5,359 510(k) decisions and received 5,063 submissions.

- To clarify and streamline the 510(k) process, we issued guidance on an expedited review process and a more efficient sign-off procedure for certain responses to premarket notifications.

- A major guidance document was issued on the premarket notification review program that contained a detailed explanation of the requirements for premarket notification review and, for the first time, discusses the factors ODE will consider in making a determination of whether a device is substantially equivalent.

Call for PMAs for Pre-Amendments Devices

- We published final rules to require premarket approval of two pre-Amendments class III devices: the contraceptive uterine device; and, the implanted diaphramatic/phrenic nerve stimulator.

- We also published proposed rules to require premarket approval of five pre-Amendments class III devices: the automated differential cell counter; infant radiant warmers; the transabdominal amnioscope; the contraceptive tubal occlusion device; and the replacement heart valve.

Reclassification

- During the year, we reclassified stainless steel sutures from class III to class II and denied a petition to reclassify the blood oxygenator.

- Our advisory panels reviewed six reclassification petitions. They recommended class I for one device, class II for four devices, and requested further information on another device.

- We published in the *Federal Register* the panel recommendations on three devices and our intent to reclassify two other devices.

- Five deficiency letters and a request for more information were sent in response to reclassification petitions.

Guidance for Reviewers and Industry

- To standardize and expedite our policies and procedures, we published ten guides for reviewers on:

  - Office of General Counsel (OGC) Review of Summaries of Safety and Effectiveness
  - Early PMA Review
  - PMA Progress Reports to Applicants
  - Criteria for Panel Review of PMA Supplements
  - Review and Approval of PMAs of Licensees
  - Panel Report and Recommendations on PMA Approvals
  - Significant and Nonsignificant Risk Device Studies
  - 510(k) Review Programs
  - 510(k) Expedited Review
  - 510(k) Sign-off Procedures

- To clarify regulatory requirements, improve compliance, and streamline procedures, ODE divisions issued guidance for the regulated industry on:

  - Safety and Labeling Requirements for Heat Disinfection Units
  - Requirements for Intraocular Lens (IOL) IDEs and PMAs
  - Annual Report in Place of PMA Supplements
  - PMA Supplements for Magnetic Resonance Imaging (MRI) Devices
  - Format for IDE Progress Reports
  - Inclusion of PMA Type Devices in Surgical Kits under 510(k)
  - Deviations in Suture Sizing

Automation and Communication

- ODE arranged to make statistical performance data publicly available through two computer accessible data bases, the BMEDSS System and Healthnetwork.

- ODE staff prepared six articles for professional/scientific journals and 21 presentations for professional and trade association meetings.

- A new PMA computer system and a computerized division-level tracking system for PMAs, IDEs, and 510(k)s were installed.

- We began distributing periodic automated reports to ODE management and review personnel that identify overdue applications and provide other performance data to help manage the timely review of PMA, IDE, and 510(k) submissions.

Staff Resources

- ODE's staff resources amounted to 179 FTEs in FY 86 as compared to 176 FTEs in FY 85. In addition, 8 FTEs were provided to ODE on detail from other Center offices in order to help with the workload and provide training to individuals from other offices. For FY 87, ODE has been allocated a total of 190 FTEs.

OFFICE OF DEVICE EVALUATION
ANNUAL REPORT
FISCAL YEAR 1986

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 for safety and effectiveness and cleared for marketing. This report provides information about major programs administered by ODE during Fiscal Year 1986 (FY 86) emphasizing activities of the premarket approval (PMA), investigational device exemption (IDE), and premarket notification (510(k)) programs. To the extent possible, we have included comparative data from previous fiscal years and trend analyses. The report also discusses the device classification program, reclassification, freedom of information, and development of regulations to require premarket approval applications for certain pre-Amendments devices ("515(b) regulations"). Major management initiatives to further implement our policy and program goals and to streamline our procedures are discussed in detail.

II. 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., PMA, IDE, and 510(k). Reference data are contained in the statistical tables in Section VI of this report. In addition to the statistical tables, some data are displayed graphically throughout this section.

A. Premarket Approval

1. Premarket Approval Applications

Under the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer or others must submit a PMA for FDA review and approval before marketing a new device. 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 recommendation, 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.

On July 22, 1986, FDA published in the *Federal Register* a final rule on "Premarket Approval of Medical Devices." This regulation prescribes the contents of a PMA and the criteria which will be used in approving, disapproving, or withdrawing approval of a PMA. The

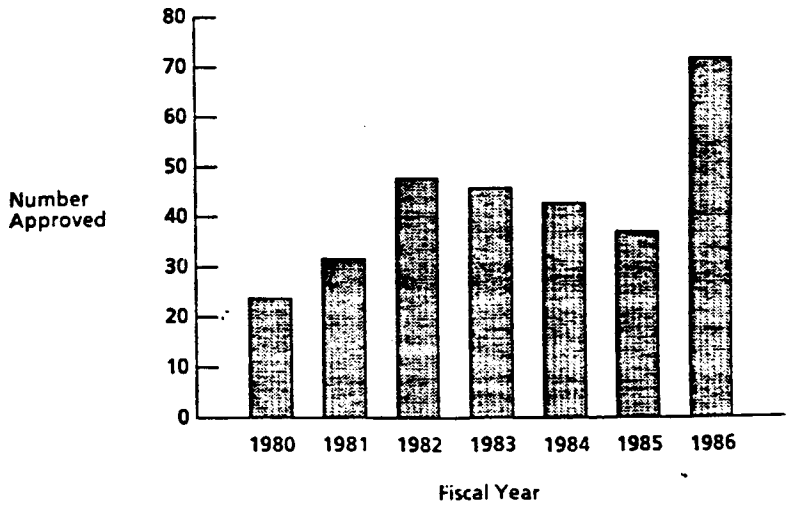
purpose of this regulation is to establish clear and uniform procedures for FDA's review of new class III medical devices. Another purpose is to facilitate the approval of PMAs for devices that have been shown to be safe and effective and that meet other criteria for approval. A final objective is to ensure the disapproval of PMAs for devices that have not been shown to be safe and effective.

The final rule includes several important policy and procedural changes that include: (a) submission of six rather than 12 copies of the PMA, (b) a more detailed discussion of the information to be included in the summary of safety and effectiveness data, (c) provision for a 30-day supplement providing for automatic approval of specified changes affecting safety or effectiveness if FDA doesn't request additional information or disapprove the supplement within 30 days of receipt, and (d) reporting of specified changes affecting safety or effectiveness in otherwise required periodic reports in lieu of awaiting FDA approval of PMA supplements for such changes. Copies of the new regulation are available from the Division of Small Manufacturers Assistance, 5600 Fishers Lane, Rockville, Maryland 20857, (800) 638-2041.

In support of this new regulation, an extensive revision of the November 1980 PMA Guideline is expected prior to the scheduled November 19, 1986 effective date of the PMA procedural regulation.

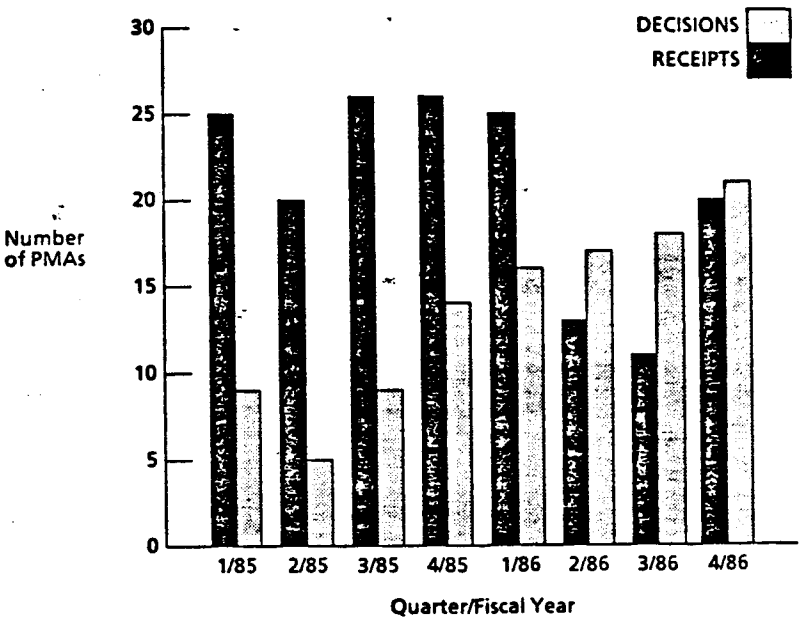
Concerning performance of the PMA program, 72 original applications were approved in FY 86 as compared to 37 in FY 85. This nearly doubling of approvals sets an all time high, representing a 50% increase over the previous high of 48 approvals in FY 82.

CHART 1 - PMA APPROVALS
FY 1980 - FY 1986



Moreover, original PMA approvals have now increased for six consecutive quarterly periods. This was accomplished despite the fact that the total number of all types of incoming PMA submissions increased by 502, from 2,083 in FY 85 to 2,585 in FY 86. This increase reflects a rise in all categories of PMA submissions (amendments, supplements, reports, etc.) except original PMAs. The submission of original PMAs decreased from 97 in FY 85 to 69.

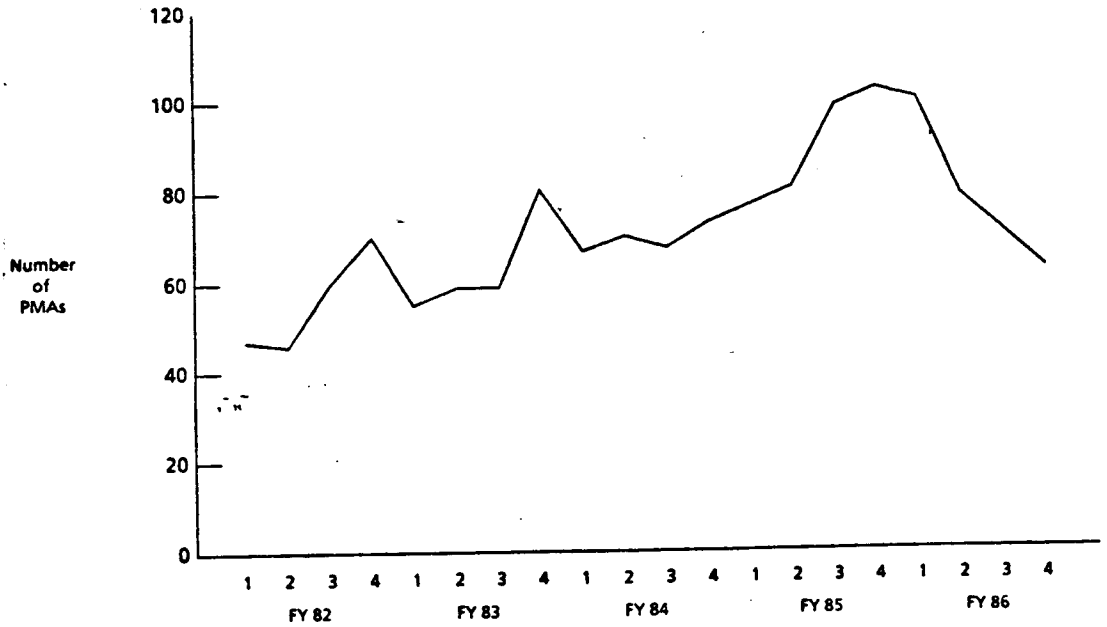
CHART 2 - PMA RECEIPTS AND DECISIONS*
FY 1985 - FY 1986, BY QUARTER



*Decisions include final approvals only.

Average FDA review time for final approval of original PMAs rose slightly from 347 days in FY 85 to 395 days in FY 86. This rise in average review time reflects the fact that we are completing reviews of long overdue applications, which raises the average. For example, of the 72 PMAs approved in FY 86, half were received in 1984 or before. Because there were still 16 PMAs active and overdue at the end of this fiscal year, the average FDA review time again may be negatively affected for FY 87 as this backlog is eliminated. The number of PMAs under active review dropped from 103 at the end of FY 85 to 63 for FY 86.

CHART 3 - PMAs PENDING (ACTIVE) AT END OF QUARTER
FIRST QTR. FY 1982 - FOURTH QTR. FY 1986



Of these, the number that were overdue dropped from 35 at end of the 3rd quarter (the first quarter for which data are available) to 16 by the end of this fiscal year.

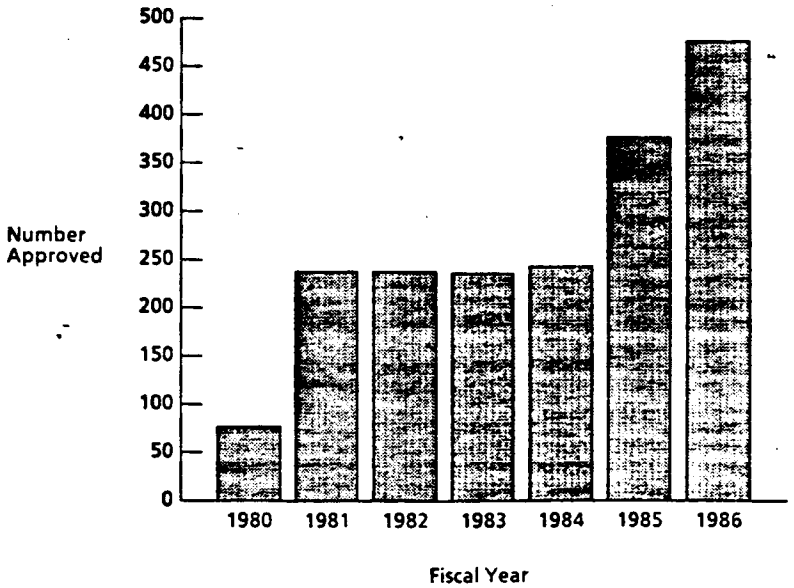
Also during FY 86, ODE and its operating units issued instructional and guidance documents affecting various procedural and policy aspects of the PMA review process. These are described below under the sections entitled "Guides for Reviewers" and "Guidance for the Regulated Industry."

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, discussed above, those changes that could affect 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.

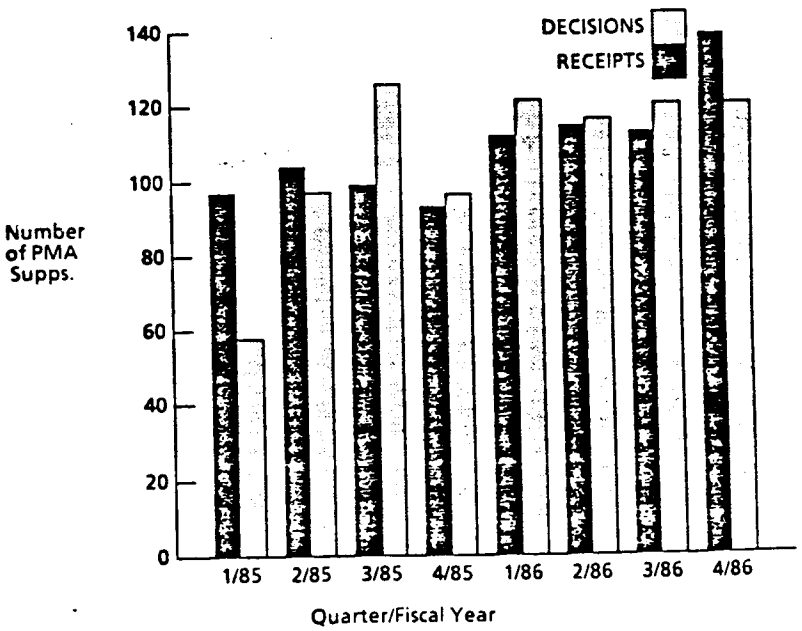
The number of PMA supplement approvals rose significantly from 377 in FY 85 to 477 in FY 86. This includes an increase in approvals of "panel track" supplements, which are equivalent in intensity of time and effort to original PMAs, from 7 in FY 85 to 9 in FY 86.

CHART 4 - PMA SUPPLEMENT APPROVALS
FY 1980 - FY 1986



Even though the total number of incoming supplements rose from 393 to 478, average FDA review time for PMA supplements has decreased from 240 days in FY 85 to 186 days for FY 86.

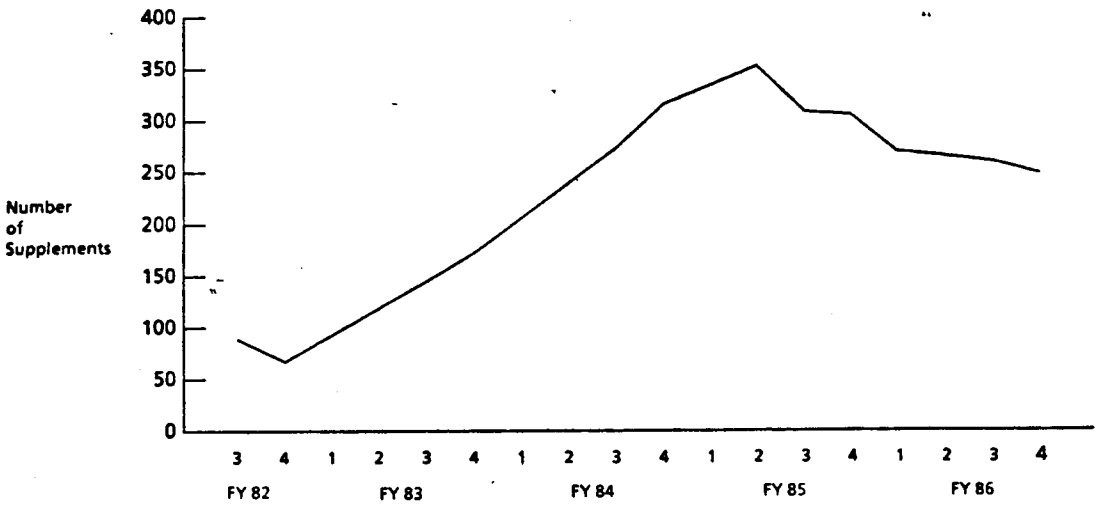
CHART 5 - PMA SUPPLEMENT RECEIPTS AND DECISIONS*
FY 1985 - FY 1986, BY QUARTER



* Decisions include final approvals only.

The number of such supplements under active review at the end of the year dropped from 306 in FY 85 to 249 in FY 86 and the number that were overdue was reduced from 131 at the end of the 3rd quarter of FY 86 (the first quarter for which data are available) to 107 by the end of the year.

CHART 6 - PMA SUPPLEMENTS PENDING (ACTIVE) AT END OF QUARTER
THIRD QUARTER FY 1982 - FOURTH QUARTER FY 1986*



* Data not available for five quarters (1/83; 2/83; 1/84; 2/84; 1/85).

3. Significant Medical Device Breakthroughs Approved

We approved PMAs for several new devices that represent significant advances in medical device technology.

- The automatic implantable cardiac defibrillator is programmed to automatically correct potentially fatal tachycardia and fibrillations. This could save some 10,000 to 20,000 lives per year.

- The multi-channel implantable hearing prosthesis is a 22-channel cochlear implant that permits perception of a range of sound, rather than only the presence of sound, as with a single-channel device.

- The Activatrax™ is the first approved single chamber pacemaker that can change its rate in response to the patient's need for cardiac output. The cardiac output need is derived by the pacemaker from the patient's body movements as detected by a piezoelectric sensor. Previously approved single chamber pacemakers ran at a fixed rate as programmed by the physician.

- The Stat-Pace II™ is the first approved transesophageal pacemaker that stimulates the heart by an electrical impulse delivered to an electrode in the esophagus in close proximity to the heart. It is effective in the temporary treatment of certain cardiac arrhythmias and assists in the differential diagnosis of certain dysrrhythmias. The use of a transesophageal pacemaker is more convenient than, and reduces certain risks associated with, the use of a transvenous pacemaker.

B. Investigational Devices

1. Investigational Device Exemptions

Under the act and regulations, a person may sponsor the clinical investigation of a medical device to establish its safety and effectiveness for a use that has not been approved by FDA. Before conducting clinical trials, however, the sponsor must obtain the approval of an institutional review board (IRB), and, if the investigational device presents a significant risk to subjects, the approval of FDA of an investigational device exemption application (IDE). The IDE must contain information concerning the study's investigational plan, report of prior investigations, IRB actions, investigators' agreements, patient consent, and other matters related to the study, including preclinical testing of the device.

FDA has 30 days from the date of receipt to approve or disapprove an IDE. If the agency does not act within the 30-day period, the IDE is deemed to be approved.

On July 25, 1986, FDA announced in the *Federal Register* that it plans to conduct a full retrospective review of the IDE regulation. In connection with this review, FDA intends to consider any comments received on the related American Society of Artificial Internal Organs petition (*FR*, April 1, 1986), guidance for the emergency use of unapproved medical devices (*FR*, October 22, 1985), and a guideline for preparing notices that investigational medical devices are available (*FR*, April 4, 1986).

In an attempt to stimulate relevant comments, data, and suggestions, FDA has identified particular areas of potential interest. These include policy and procedural issues such as: cost recovery; enforcement; investigations of less than significant risk devices (which do not now require an IDE approved by FDA); responsibilities of clinical investigators, institutional review boards, and sponsors; and, regulatory flexibility, in general. Data that can quantify the costs and benefits of the present IDE regulation are needed, as well as suggestions for alternatives to the present IDE program.

Reprints of this notice are available from either the Division of Small Manufacturers Assistance (HFZ-220), 800-638-2041, or the Office of Standards and Regulations (HFZ-80), both at 5600 Fishers Lane, Rockville, Maryland 20857.

Also during FY 86, ODE issued two major documents clarifying IDE policies and interpretations. The first one, "Guidance on Significant and Nonsignificant Risk Device Studies," is discussed below, under Guides for Reviewers. The second one, "Requirements for IOL IDEs and PMAs," is described below under Guidance for the Regulated Industry.

Both the number of original IDEs received and decided rose slightly, from 204 and 201, respectively, for FY 85, to 206 and 213 for FY 86. The net effect was a reduction in the number of IDEs under review, from 24 at the end of last fiscal year to 17 at the end of the current fiscal year.

CHART 7 - IDE RECEIPTS AND DECISIONS
FY 1985 - FY 1986

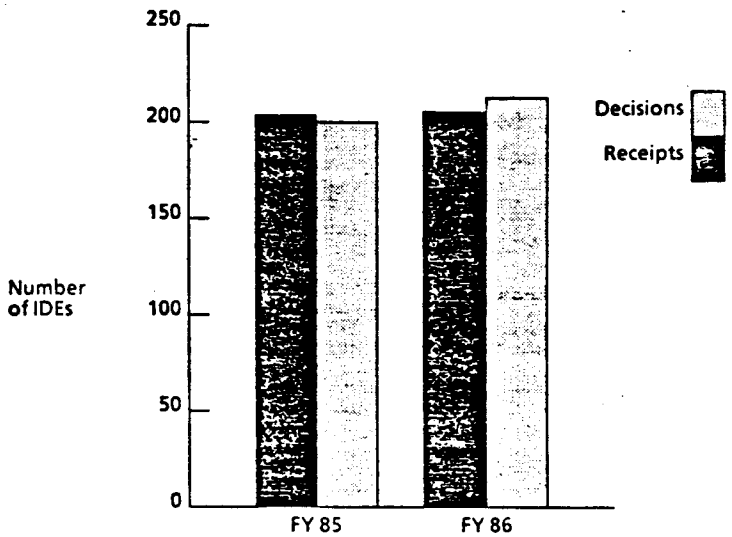
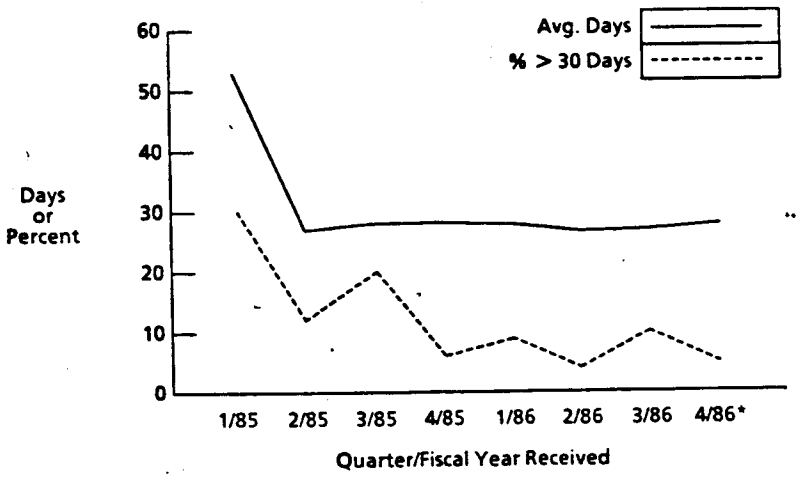


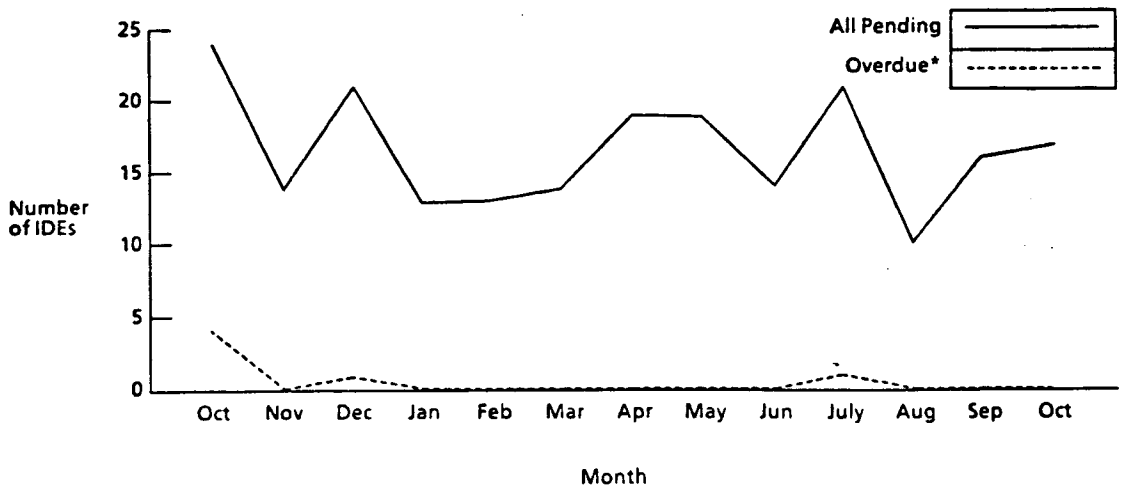
CHART 8 - TIMELINESS OF IDE DECISIONS
FY 1985 - FY 1986, BY QUARTER OF RECEIPT



* Based on 43 completed original IDEs out of 46 received during the quarter.

Average FDA review time for original IDEs dropped slightly from 37 days in FY 85 to 35 days for FY 86, and the percentage of decisions made within 30 days of receipt went up significantly from 82% in FY 85 to 91% in FY 86. These performance measures include decisions made on 4 original IDEs that were already long overdue when FY 86 began. If these decisions are excluded from the analysis, average FDA review time for original IDEs fell to 28 days in FY 86, and the percentage of decisions made within 30 days of receipt increased to 93%. No original IDEs were overdue by the end of FY 86.

CHART 9 - IDEs PENDING IN FY 1986, BY MONTH
BEGINNING OF OCTOBER 1985 - BEGINNING OF OCTOBER 1986



* Pending more than 30 days

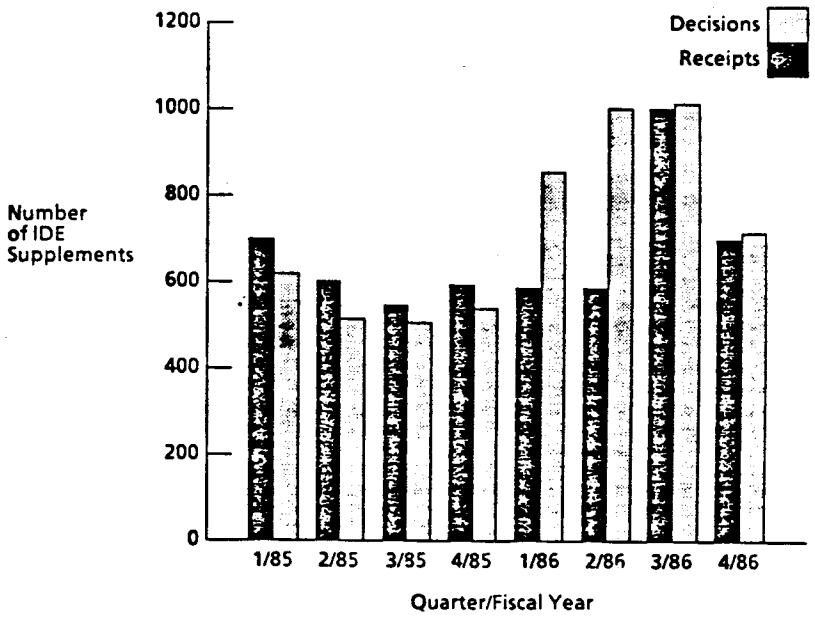
2. IDE Supplements

The IDE regulation requires that the sponsor of an investigation of a significant risk device 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. The sponsor also must submit a supplement if a new investigational site is being added, in which case certification of the reviewing IRB's approval must be submitted. The supplements must update information previously submitted in the IDE, including any modifications to the investigation.

This regulation also requires submission of various reports which are logged in as supplements to the IDE. 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.

The number of IDE supplements received went up from 2,457 in FY 85 to 2,884 for FY 86, and the number of decisions rose from 2,190 in FY 85 to 3,599 in FY 86.

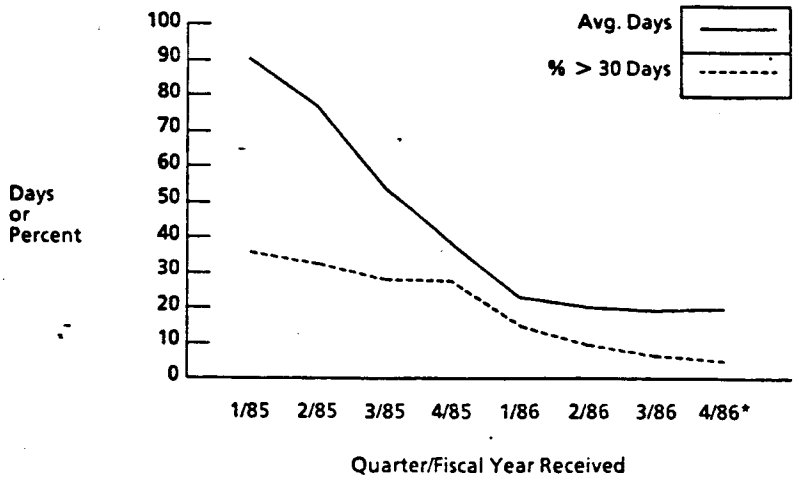
CHART 10 - NUMBER OF IDE SUPPLEMENT RECEIPTS & DECISIONS
FY 1985 - FY 1986, BY QUARTER



Because so many long overdue IDE supplements were cleared out in the first half of this fiscal year, the average FDA review time for these submissions rose from 33 days in FY 85 to an average of 116 days for

FY 86. It should be noted, however, that the average review time for the 3rd and 4th quarters of FY 86, after the long overdue IDE supplements were completed, dropped to 18 and 21 days, respectively. Furthermore, if decisions on the backlogged IDE supplements are excluded from the analysis, average review time was only 21 days for FY 86 as a whole.

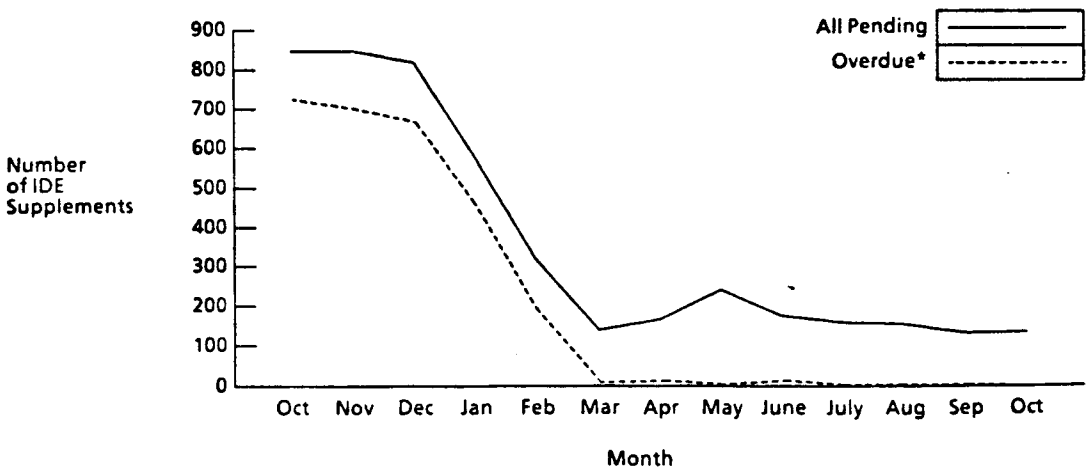
CHART 11 - TIMELINESS OF IDE SUPPLEMENT DECISIONS
FY 1985 - FY 1986, BY QUARTER OF RECEIPT



* Based on 684 completed IDE Supplements out of 700 received during the quarter.

Consistent with the elimination of the overdue IDE supplements, the number under review at the end of FY 86 fell to 139 from the 854 that were under review at the end of the last fiscal year. Just as with original IDEs, there were no overdue IDE supplements as of the end of FY 86. This was accomplished by wiping out the backlog of 728 overdue IDE supplements, primarily for intraocular lens investigations that existed when this fiscal year began.

CHART 12 - IDE SUPPLEMENTS PENDING IN FY 1986, BY MONTH
BEGINNING OF OCTOBER 1985 - BEGINNING OF OCTOBER 1986



* Pending more than 30 days

C. Premarket Notification

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). The 510(k) must include, among other items, a description of the device, the class under which it is to be regulated, and action taken to comply with any applicable performance standard. The 510(k) may also include a claim that the device is substantially equivalent to a pre-Amendments device. "Substantially equivalent" devices may be marketed subject to the same regulatory controls as their pre-Amendments predecessors. FDA reviews the submission to determine if the classification of the device is correct and whether the device is substantially equivalent to a device marketed before enactment of the Medical Device Amendments. 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 FY 86, ODE issued a number of documents to clarify and streamline the 510(k) process. They deal with an expedited review process, a more efficient sign-off procedure, and premarket notification review requirements. For a discussion of these documents see "Guides for Reviewers," below.

The 510(k) program also had an impressive record for FY 86. There were slightly fewer 510(k)s received in FY 86 (5,063) than in FY 85 (5,254), but the number of decisions rose significanly from 5,095 in FY 85 to 5,359 in FY 86 and the number of decisions for the year outnumber the submissions received by 296. The average FDA review time for 510(k)s fell slightly from 76 days in FY 85 to 72 days in FY 86; more importantly, the average review time fell steadily for each of the four quarters during FY 86 and was reduced to 59 days by the end of the 4th quarter of this fiscal year. The percentage of 510(k) decisions made within 90 days fell

CHART 13 - AVERAGE REVIEW TIMES FOR 510(K)s
OCTOBER 1985 - SEPTEMBER 1986, BY MONTH

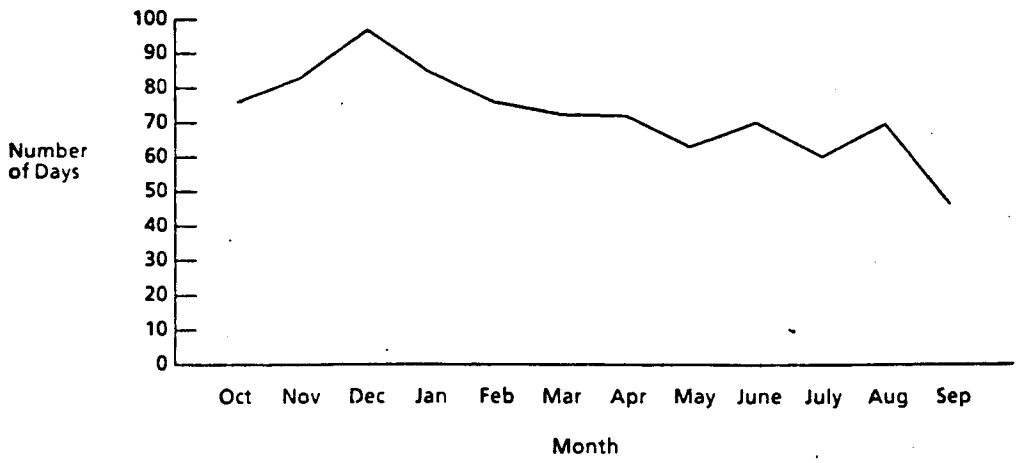
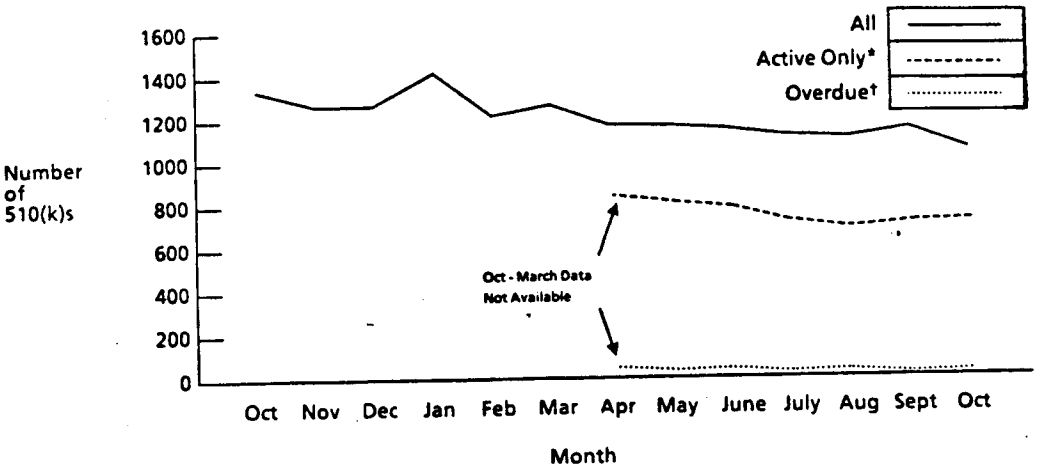


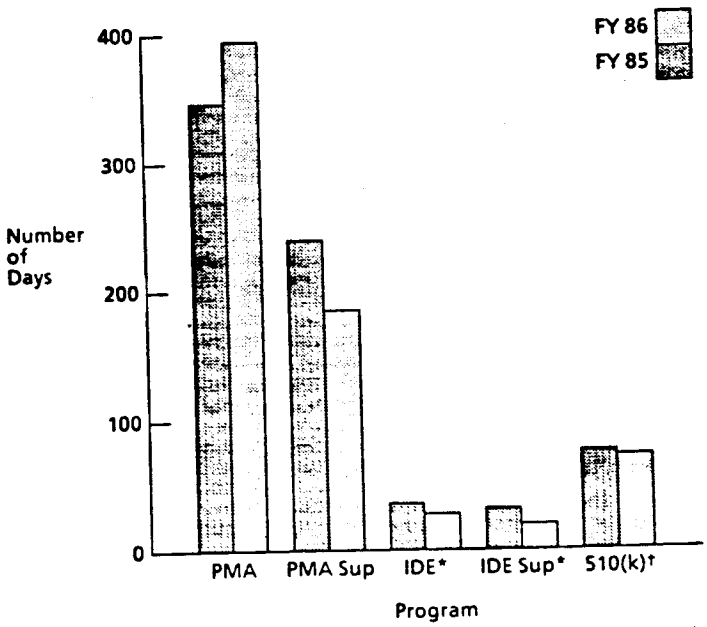
CHART 14 - 510(K)s PENDING IN FY 1986, BY MONTH
BEGINNING OF OCTOBER 1985 - BEGINNING OF OCTOBER 1986



* Excludes 510(k)s "on hold"
† Active more than 90 days

slightly from 68% for FY 85 to 65% in FY 86 when total elapsed time is measured; but, if only FDA review time is considered, 93% of decisions issued in the second half of the year (the only period for which such data are available) were made within 90 days. The percentage of devices found to be "not substantially equivalent" fell from 2.8% to 2.2% from FY 85 to FY 86.

CHART 15 - AVERAGE FDA REVIEW TIMES
FY 1985 - FY 1986



* Excludes IOL backlog
† Includes "hold" time

III. 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 highlighted below.

A. Classification of Medical Devices

When the Medical Device Amendments were enacted, Congress mandated that FDA classify each device then in commercial distribution into one of the three designated regulatory classes, i.e., class I - General Controls, class II - Performance Standards, and class III - Premarket Approval. By the end of 1983, FDA had published final classification rules for the devices grouped under nine medical specialty panels. The agency also had published proposed classification rules for the remaining seven panels. During FY 86, ODE and the Office of Standards and Regulations (OSR) made a substantial effort to revise and complete these remaining final rules for publication in the *Federal Register.* Early in FY 86, the bulk of the Center's work on pending classification rules was finished and the "final" drafts were forwarded to the office of the Associate Commissioner for Regulatory Affairs and the Office of General Counsel for review. At the end of the fiscal year, ODE and OSR continued working with these offices on final revisions before publication.

B. Reclassification of Classified Devices

Depending upon the particular device, FDA may, upon its own initiative, or in response to a petition from a manufacturer, importer, or other interested party, reclassify a device from one class to another consistent with the regulatory needs of the agency and protection of the public health. The act and regulations provide various procedures for reclassifying devices. The reclassification procedures are designed to ensure that there is valid scientific evidence to demonstrate that the controls of the class into which the device is being reclassified will provide reasonable assurance of the safety and effectiveness of the device.

During this fiscal year, there were fourteen reclassification petitions and two FDA initiated reclassification actions pending before the agency. We gratefully acknowledge the coordinating efforts by the Office of Standards and Regulations and the scientific support from the Office of Science and Technology in processing these petitions. Depending upon the reclassification proposal's status, ODE staff has to provide scientific reviews or obtain panel recommendations on the proposals. In many cases, the staff time required to complete a reclassification action is significant.

During the year, six reclassification petitions received panel review. The panels in these cases: recommended class I for one device - the neonatal bilirubin test system; recommended class II for four devices - the automated differential cell counter, the Nd:YAG laser for posterior capsulotomy, the infant radiant warmer, but only after a standard is developed and implemented, and, the pH-sensitive glass electrode cutaneous carbon dioxide (PcCO2) monitor; and, abstained from making a recommendation on the reclassification of the heparin analyzer until further information was provided.

Based on staff work and/or panel recommendation, we published three notices in the *Federal Register* announcing a panel recommendation and our intent to reclassify two devices. We also found it necessary to send five deficiency letters and a request for further information in response to petitions to reclassify six other devices. Lastly, we denied a petition to reclassify the blood oxygenator from class III to class II and we issued a reclassification order to the petitioner reclassifying stainless steel sutures from class III to class II.

C. 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 commerical information. Requested documents must be "purged" of such privileged information before release. ODE processes more than 2,000 FOI requests per year.

D. PMAs for Pre-Amendments Devices

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 classified or proposed for classification 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.

Accordingly, in a previous fiscal year, FDA identified in a *Federal Register* notice the first 13 generic types of pre-Amendments class III devices that had been assigned a high priority for the development of 515(b) regulations. Accordingly, FDA also published four proposed 515(b) regulations for: implanted cerebellar stimulators; implanted intracerebral/subcortical stimulators; implanted diaphragmatic/phrenic nerve stimulators; and contraceptive intrauterine devices and

introducers. We subsequently issued a final rule for implanted cerebellar stimulators. In addition, the agency received and began processing a petition to reclassify one other high priority device, the automated heparin analyzers.

During FY 86, FDA published five more proposed 515(b) regulations for: automated differential cell counter; infant radiant warmers; transabdominal amnioscope; contraceptive tubal occlusion device; and, replacement heart valve. As a result of these proposals, FDA received a reclassification petition for the infant radiant warmer, which is now being considered as a reclassification action. In addition to the proposals, FDA published two final rules requiring premarket approval for the contraceptive intrauterine device, and the implanted diaphramatic/phrenic nerve stimulator.

Over the next several years, ODE anticipates publication of additional 515(b) regulations. ODE expects to receive about 100 to 170 PMAs as a result of publishing final 515(b) regulations for all 13 high priority devices.

IV. POLICY AND PROGRAM IMPLEMENTATION

A. Guides for Reviewers

One of the most important management initiatives undertaken in FY 86 was the development of operating guidance to ODE staff. This guidance provides uniformity in operations and improves efficiency among ODE units. During this fiscal year we issued guidance on the following subjects. These guidance documents are available to the public through the Division of Small Manufacturers Assistance (HFZ 220), 5600 Fishers Lane, Rockville, MD 20857, telephone (800) 638-2041.

1. Premarket Approval

   - *Office of General Counsel (OGC) Review of Summaries of Safety and Effectiveness.* This guidance reflects the Deputy Commissioner's decision that the routine review of PMA summaries by OGC will be phased out. It also describes the circumstances under which OGC assistance will be sought. This procedure will reduce FDA review times, but maintain the quality of reviews.

   - *Early PMA Review.* This guidance directs ODE reviewers to: require that applicants provide summaries of safety and effectiveness in PMA submissions, prepare FDA summaries before Panel meetings (using the submitted summaries as a basis), and endeavor to identify all PMA deficiencies in one letter before the Panel meeting. These procedures will improve the quality and timeliness of our reviews.

- *PMA Progress Reports to Applicants.* This guidance directs ODE staff to inform PMA applicants on a monthly basis of the status of our review of the applicant's PMA. The status report will further contribute to our own tracking of PMA documents, improve industry understanding of our review process, and add to efficiency by eliminating certain random industry requests for status information.

- *Criteria for Panel Review of PMA Supplements.* This guidance sets forth criteria for when we will and when we will not subject PMA supplements to the full review procedures required for original PMAs. Having such criteria will enhance the efficiency of decision-making and ensure that only appropriate supplements are subjected to the full review procedures. Thus, resources will be saved and review times should improve.

- *Review and Approval of PMAs of Licensees.* This guidance establishes an expedited procedure for the review of PMAs resulting from contractual agreements in which the original PMA holder licenses to another the right to use the data in the original PMA in order to market the subject device. All the licensee must submit to FDA, assuming the indications for use have not been changed, is evidence that the new device is the same as the previously approved device, evidence that the PMA holder agrees to the licensee's use of the PMA data, and, if the manufacturing process is different than the one applied under the original PMA, the licensee must submit all the manufacturing information necessary for FDA review. In the past, these PMAs were reviewed by an advisory panel. The guidance makes it clear that panel review is no longer required because the safety and effectiveness data being relied upon have been reviewed previously by the panel. This policy should significantly reduce review times for these submissions.

- *Panel Report and Recommendations on PMA Approvals.* This guidance memorandum modifies the panel review procedures previously used in considering PMAs and certain reclassification petitions. These changes were adopted in response to the shortcomings of the panel procedures identified by the U.S. Court of Appeals in *General Medical Co. v. FDA.* As before, we shall conclude a panel's consideration of a PMA with a vote on the panel's recommendation, but we now shall augment the voting procedure with a more formal enumeration of the reasons and basis for the recommendation. This will take place during the panel meeting and will be recorded in the transcript of the panel meeting.

2. Investigational Devices

- *Significant and Nonsignificant Risk Device Studies.* This document, entitled "Guidance on Significant and Nonsignificant Risk Device Studies" is intended to assist ODE reviewers as well as sponsors and institutional review boards in determining whether device studies are significant or nonsignificant risk.

It provides examples of significant and nonsignificant risk device investigations and criteria to be used in making these determinations.

3. Premarket Notification

- *Premarket Notification Review Program.* This guidance document contains a detailed explanation of the requirements for premarket notification review and, for the first time, discusses the factors ODE will consider when making a determination that a device is, or is not, substantially equivalent. See Appendix A - 510(k) "Substantial Equivalence" Decision Making Process (Detailed). The guidance document covers the meaning of "intended use", technological changes that can be reviewed in a 510(k), and data that can be required in a 510(k). Seminars were conducted on the guidance for all ODE personnel involved in the review of 510(k)s in order to be certain that it is clear and that any needed changes are identified. A consistent application of this guidance by manufacturers and ODE review staff should foster complete and expeditious review of 510(k) submissions.

- *510(k) Expedited Review.* Under this new procedure, premarket notifications for devices that are exempt or proposed for exemption from 510(k) requirements or those devices that do not raise any question concerning substantial equivalence will be answered immediately. Notifications for devices that raise only minor questions concerning substantial equivalence will be quickly resolved and a response issued within 30 days of receipt. All other notifications that require scientific review or verification of data will be completed within 90 days of receipt.

- *510(k) Sign-off Procedures.* We changed the sign-off procedures for certain responses to premarket notifications to reduce the routing of paperwork, thereby speeding the issuance of responses while at the same time retaining necessary quality control checks in this high volume area.

B. Guidance for the Regulated Industry

During this fiscal year ODE and its operating units issued the following instructional materials to manufacturers identifying changes in procedures and policies and clarifying requirements applicable to our approval program.

1. *Safety and Labeling Requirements for Heat Disinfection Units.* On May 22 the Division of Ophthalmic Devices notified manufacturers that PMAs for heat disinfection units with an automatically controlled disinfection cycle could be approved only if the device contains a light or other indicator to show whether or not the heating element is functioning properly and if the device is labeled with an

explanation of indicator functioning. PMAs already filed would not be approved without a committment from the applicant to provide such an indicator as soon as practical and the submission of appropriate labeling. Holders of approved PMAs for heat disinfection units that do not meet these requirements are being encouraged to upgrade units currently in production to meet these requirements. PMA supplements to cover these changes will not require prior FDA approval since these changes enhance the safety of the device.

2. *Requirements for Intraocular Lens (IOL) IDEs and PMAs.* On May 16 ODE provided sponsors of IOL IDEs and PMAs with an update on current FDA requirements concerning IOLs. These requirements affect: .adjunct studies (instituting the requirement for all new investigational IOLs that all core subjects needed for PMA purposes must be enrolled before any adjunct subjects); labeling for UV-absorbing lenses (requiring UV transmission curves in labeling so that surgeons can compare UV absorbance of one manufacturer's lens with another's); trade names and claims (stating that trade names which are construed as claims may not be used unless the claims have been proven); anterior chamber lens data reporting (requiring 3-year clinical data as a condition of premarket approval for flexible and semi-flexible anterior chamber IOLs); submission of manufacturing information in PMAs (suggesting that sponsors help expedite FDA's PMA reviews by including information in their PMAs rather than nonspecifically referencing such information in IDE files); and, filing of PMAs for alternative materials (explaining that PMAs for UV-absorbing IOLs will be treated as supplements to previously approved non-UV-absorbing lens PMAs for similarly designed IOLs, and also explaining that, for these types of materials once the safety of a given material and of a given model configuration have been demonstrated in approved PMAs, the two may be combined without the need for additional cohort patients).

3. *Format for IDE Progress Reports.* In October, 1985 ODE issued to industry and the public a document entitled "Suggested Format for IDE Progress Reports." It outlines the content of progress reports and suggests that these reports provide, among other things, information on the progress of the study, new information that would impact on the changes made in manufacturing practices or in the investigational plan, and a projected date of PMA or 510(k) submissions.

4. *Annual Report in Place of PMA Supplements.* In 1985, ODE established a policy that allows annual reporting, in lieu of FDA approval of PMA supplements, for the implementation of labeling changes for additional private labels and trade names for approved contact lenses. During FY 86, ODE extended this policy to contact lens solutions or accessories, via a letter to manufacturers of these devices.

5. *PMA Supplements for Magnetic Resonance Imaging (MRI) Devices.* On April 25 we issued a document prepared by the Division of Anesthesiology, Neurology, and Radiology Devices (DANRD) to holders of PMAs for MRI devices. The document, entitled "Guidance for Submission of Premarket Approval Supplements for MRI Devices: Interpretation of the Conditions of Approval," streamlines the processing of PMA supplements for MRI devices. The new process should expedite the approval of supplements where DANRD agrees with the manufacturer's testing method and acceptance criteria for most of the modifications anticipated for approved MRI devices. This should result in significant savings of resources since there may be as many as 30-40 such applications per year.

6. *Inclusion of PMA Type Devices in Surgical Kits Under 510(k).* During April, the Division of Surgical and Rehabilitation Devices (DSRD) issued a letter providing guidance to surgical kit manufacturers that allows PMA type devices, such as sutures, to be included in surgical kits and marketed through the 510(k) process, if: (1) the only processing planned was sterilization, (2) the method of sterilization was ethylene oxide (EO), and (3) the manufacturer demonstrated that ethylene oxide did not come in direct contact with the device.

7. *Deviations In Suture Sizing.* On March 6, DSRD established a written policy allowing suture manufacturers to market sutures that deviate from United States Pharmacopeia (USP) designated diameters. The policy sets limits as to how much the suture diameter can deviate from USP. Additionally, the policy requires sutures that deviate beyond these defined limits to be labeled non-USP. This policy provides uniformity with respect to suture diameter designation(s) labeling where none existed before.

C. Public Availability of ODE Performance Data

During FY 86 ODE, through the Office of Training and Assistance, arranged to make publicly available, on a quarterly basis, statistical performance data through two computer accessible data bases, the Biomedical Engineering Decision Support Services (BMEDSS) system and the Nebraska Health Network (Healthnetwork). The data that are being made available consist of the six tables that appear in Section VI of this report. They deal with PMA/IDE/510(k) submissions, PMA and PMA supplement approvals, IDE and IDE supplement decisions, and 510(k) determinations. BMEDSS is a private integrated electronic information system for health professionals available on a subscription basis. For more information on BMEDSS, contact Jeffrey Drew, BMEDSS, Akron City Hospital, 525 East Market Street, Akron, OH 44309-2090, telephone (216) 375-3501. Healthnetwork also is a nation-wide electronic information network that facilitates the sharing of health related information. For more information on Healthnetwork, contact Arturo Coto, Healthnetwork, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NB 68509, telephone (402) 471-3494.

D. Publications

During FY 86 the Information Clearance Committee processed six articles authored by ODE staff for publication in professional/scientific journals and 21 presentations to be delivered by ODE staff at professional, scientific and trade association meetings.

E. Ongoing Activities

At the end of the fiscal year, there were a number of ongoing activities and pending actions that are noteworthy. An ODE guidance memorandum on reclassification procedures was under development. In addition, various divisions also are developing the following product specific guidance for the industry.

1. *Antimicrobial Agents for Medical Devices.* The Division of Gastroenterology, Urology, and General Use Devices (DGGD) is developing a guidance document that deals with the premarket testing and labeling of antimicrobial agents for medical devices. It should help manufacturers in the preparation of premarket notifications for such agents.

2. *Formaldehyde Use in Hemodialyzers.* DGGD is also preparing a document that deals with health risks and hazards associated with the use of formaldehyde in hemodialyzers. It is a review of literature focusing on animal and human intra-vascular exposure to formaldehyde and includes a chapter with recommendations for future research.

3. *Testing New Materials for IOLs.* The Division of Ophthalmic Devices (DOD) is revising the IOL manufacturing section of the 1980 "Guidelines for Intraocular Lenses" to make the guidelines applicable to IOLs made of new materials. The earlier version applies to lenses made of polymethylmethacrylate (PMMA) only. The document is designed to answer most preliminary questions about preclinical requirements for IOLs.

4. *Data Requirements for Contact Lens PMA Supplements.* DOD also has proposed modifications in data requirements for contact lens PMA supplements for daily wear soft (hydrophilic) and rigid gas permeable contact lenses. The proposal simplifies clinical test requirements in two major areas: (1) expansion of contact lens parameters (base curves, powers, and diameters required to meet fitting needs within a given indication), and (2) addition of design characteristics (toric, bifocal lenticular) of lenses. The proposal was discussed at the May 23, 1986 meeting of the Ophthalmic Devices Panel and is now being reviewed within the agency.

5. *Conditions of Approval for Contact Lenses and Solutions.* DOD is considering changes in supplemental PMA requirements for contact lenses and solutions. Changes being considered include the elimination of supplemental PMAs for changes in sterilization procedures and nonsignificant changes in manufacturing such as changes in buffers, packaging materials, changes in sizes, etc., for contact lens solutions based upon preapproved protocols.

6. *Requirements for Prosthetic Ligament IDEs and PMAs.* The Division of Surgical and Rehabilitation Devices (DSRD) prepared a draft document entitled "Guidelines for the Intraarticular Prosthetic Knee Ligament." These guidelines are intended to (1) inform sponsors of prosthetic ligament devices of the preclinical and clinical testing necessary for an assessment of safety and effectiveness of the device, and (2) aid sponsors in the preparation of IDEs and PMAs for prosthetic ligaments. DSRD is accepting comments on this draft document from members of the Orthopedic and Rehabilitation Devices Panel and from industry.

7. *Requirements for Bone Growth Stimulator IDEs and PMAs.* A "Guidance on Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices," in draft form, has been prepared by the DSRD. The intended purposes of this document are to (1) present FDA's perspective on issues related to electrical stimulation for the treatment of orthopedic conditions, (2) set forth FDA's recommendations and minimum requirements on the type of preclinical and clinical data necessary to support safety and effectiveness claims of these devices, and (3) assist the sponsor in preparation of IDEs and PMAs for bone growth stimulators. Included within the document is a formal definition of nonunion fractures. DSRD is accepting comments on this draft document from members of the Orthopedic and Rehabilitation Devices Panel and from industry.

8. *Definition of Skin/Skin Substitutes.* On September 30, 1986, approximately 30 representatives from industry, academia, and government met to draft definitions for Artificial/Synthetic, Temporary/Permanent, Skin/Skin Substitutes that would not be considered false and misleading. These definitions will also be reviewed by the GPS advisory panel as to the acceptability of each definition. After finalization within the agency, these labeling claims will be communicated to the wound/burn dressing manufacturers.

V. STATUS OF ODE RESOURCES

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. Several small offices report directly to the ODE director: an administrative office as well as offices that coordinate the review of PMAs, IDEs, and 510(k)s. See Appendix B for an organizational chart.

B. Staffing

ODE's actual use of staffing resources was 179 FTEs in FY 86 as compared to 176 FTEs in FY 85. This included professionals (both administrative staff and scientific reviewers), clericals, and supervisors. In addition, ODE requested and received the detail of other Center staff, equivalent to 8 FTEs, with specific expertise, including engineers, statisticians, virologists, chemists, and generalists in the biological sciences. These details learned about ODE's review processes and helped with technical reviews. The FY 87 allocations are 190 FTEs and the office was fully staffed by October 1, 1986, in anticipation of the new ceiling. This required an aggressive recruitment program during the last few months of FY 86. Several training courses are being planned for new employees.

C. Training

Over the course of the fiscal year ODE employees have participated in many varied forms of training. Two employees enjoyed the benefits of long term training (a year of full-time study) and two employees participated in a one year mid-level management training program. Other employees participated in everything from day long courses to 3 to 12 credits advanced level work at local universities. Several supervisory courses were sponsored by the ODE PMO Office and a number of product specific program seminars were conducted by the individual divisions. Plans for the future include a training program for new reviewers.

D. Office Automation

Major activities in office automation included the procurement and installation of hardware and software, the development of specialized software, training of users, and improvement of telecommunications capabilities. Also, a special study of the document handling processes involved in processing applications for medical devices was initiated during the fiscal year.

1. Hardware

The Divisions' hardware needs were prioritized and requisitions were issued for over $51,000 in equipment and software.

Chart 16 - ODE Computer Hardware Status

FY 85 - FY 86

HARDWARE	On Hand in FY 85	Received in FY 86	On Hand in FY 86
DECmate II Word Processors	54	0 [a]	54
DECmate III Word Processors	10	3	13
LQPO2 Letter Quality Printers	26	2	28
LQPO3 Letter Quality Printers	5	0	5
LA50 Draft Quality Printers	25	13	38
LA100 Draft Quality Printers	6	0	6
LA210 Draft Quality Printer	0	1	1
LNO3 LASER Printers	6	2	8
VT220 Terminals	16	4	20
CP/M Boards for DECmate IIs	20	2	22
Electrohome Projector	0	1 [b]	1

a/ ODE had ordered 7 DECmate II word processors for the Divisions. The ordered was cancelled when we learned that the DECmate II has been declared obsolete by Digital Equipment Corporation.

b/ The Electrohome Projector, which was received in August 1986, enables the video image from a VT220 or DECmate to be projected on a large screen.

2. Software

- *ODE Basic Tracking System.* During FY86 the major emphasis in software has been to complete development of the ODE Basic Tracking System, which consists of three major components (510(k), IDE, and PMA) that run on the Center's VAX computers in Rockville, Maryland. The ODE Document Control Center staffs for each application program maintain data in this System. All of the programming has been completed, except for minor adjustments. The IDE component had been functioning since 1984, the 510(k) since January 1986, and the PMA since June 1986. Additional programming was initiated and is used to generate a series of periodic reports using the data from this system for ODE management, supervisors, and reviewers. These reports identify overdue applications and provide other performance data to help manage the timely review of PMA, IDE, and 510(k) submissions.

- *Division Tracking System.* In addition to the Basic Tracking System, the Division Tracking System has been completed and is being fine-tuned. It was eased into operation in April 1986. Each division maintains their portion of this system which enables them to mark and report the progress of applications through their individual organizations. The Division Tracking System relies on information input to the Basic Tracking System, such as application ID, applicant name, device name, and due dates. It then complements the Basic Tracking System by allowing divisions to incorporate such data as division action codes, division due dates, reviewer names, and panel information. Presently, the number of management reports available from the Division Tracking System is limited. Additional programming is still required to develop a more complete series of reports.

  Both the Basic and Division Tracking Systems are interim systems until the Center develops an integrated Center-wide data base. At that time it will be possible to make additional improvements and major changes to the two systems. It is anticipated that the Center-wide data base will become available within two years.

- *Other Tracking Systems.* In addition to the two major tracking systems, a number of micro-computer based systems were developed within ODE. One was a DECmate based PMA approvals data file for the PMA staff. It was completed in February 1986. It facilitates the generation of monthly reports on PMA approvals for the FDA Drug and Device Product Approvals list and for the Center's Videotex system.

  Another DECmate based file was completed in August 1986 for the Division of Surgical and Rehabilitative Devices to enable more effective tracking of Freedom of Information requests.

3. Telecommunications

Telecommunications is the process of transfering information and data from one computer or word processor location to another. It is a process on which we are becoming increasingly dependent. For example, it makes electronic messaging possible and has become an alternative to the telephone and internal memoranda within the Center. It also makes data input by one organization readily available to other organizations via the Center's central computers. Additionally, it allows information to be communicated quickly and efficiently with organizations outside the Center.

The installation of Ethernet has been the major telecommunications improvement for ODE during the past year. Prior to the installation of Ethernet, all of ODE's word processors and terminals communicated with the central computers and each other via modems and standard telephone lines. The slow speed and sometimes poor quality of transmission was always a source of frustration to ODE users. Ethernet has increased the speed by a factor of eight and virtually

eliminated poor quality transmissions. Ethernet installation for ODE was completed on February 6, 1986.

On occasion, applicants for medical devices have expressed an interest in sending ODE reviewers diskettes containing draft copies of documents like summaries of safety and effectiveness to help speed the preparation of the final documents by doing some of the draft typing. Unfortunately, those applicants who have attempted this have word processing equipment different from ours which results in a compatibility problem. That is, either their diskettes can not be read in our DECmates or their word processing programs insert formatting codes in their documents different from those understood by our DECmate word processing systems.

One industry group, the Health Industry Manufacturers Association, has been working with the Center's Office of Information Systems (OIS) and ODE on the problem of electronic transmission of draft documents. During FY 86, a number of test transmissions were conducted between a few manufacturers and both OIS and ODE. The result has been development of a protocol for use in transmitting documents between IBM and compatible PCs and the Center's DECmates. The draft protocol is currently under consideration by the Agency.

Even without the protocol, we were able to work with two manufacturers during the fiscal year to successfully capture draft summaries telecommunicated via modems and telephone lines.

4. Training

Training is essential if staff members are to become comfortable with and take full advantage of office automation equipment capabilities available to them. Much of this training occurs on a one-on-one basis as the need arises. However, a number of training courses were presented during FY 86.

- o *October 1985.* Twelve training sessions were held during which Basic, Intermediate, and Advanced Word Processing on the DECmate II and DECmate III word processors were taught.

- o *January 1986.* Ten training seminars were held at Silver Spring Plaza to acquaint users with the features of Version 2.0 of the All-in-1 Office Automation system.

- o *January and February 1986.* Two seminars were held for ODE staff to describe the features of the Division Tracking System.

- o *July 1986.* Three training sessions were held to introduce ODE staff to word processing on the DECmate II.

5. Interagency Agreement

An Interagency Agreement was entered into in August 1986 with the General Services Administration for a study of the document handling processes involved in the review of 510(k), IDE, and PMA

applications. The study will seek to identify improvements in the processes for handling applications that will enable net processing times to be reduced while maintaining or improving the security and efficiency of the processes.

VI. 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. These adjustments are not likely to have a significant effect on conclusions based on these data.]

TABLE 1. PMA/IDE/510(k) SUBMISSIONS RECEIVED [a/]
FY 85 - FY 86

Type of Submission	No. Received					
	FY 85	FY 86				
		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Total
Premarket Approval:						
Original Applications	97	25	13	11	20	69
Amendments	597	222	211	208	212	853
Supplements	393	112	114	113	139	478
Amendments to Supplements	628	187	135	201	191	714
Reports for Orig. Applications	236	60	87	70	80	297
Reports for Supplements	132	64	38	30	42	174
PMA Subtotal:	2,083	670	598	633	684	2,585
Investigational Device Exemptions:						
Pre-Original Applications	21	1	7	1	11	20
Original Applications	204	55	48	58	45	206
Amendments	366	78	58	76	63	275
Supplements	2,457	591	588	1,005	700	2,884
IDE Subtotal:	3,048	725	701	1,140	819	3,385
Premarket Notification:						
Original Notifications	5,254	1,218	1,226	1,268	1,351	5,063
Supplements	1,800 [b/]	440	520	541	549	2,050
510(k) Subtotal:	7,054	1,658	1,746	1,809	1,900	7,113
PMA/IDE/510(k) TOTAL:	12,185	3,053	3,045	3,582	3,403	13,083

a/ Some data modified from ODE's previous activities report to reflect corrections in data entry.

b/ Estimate based on incomplete data.

TABLE 2. ORIGINAL PMAs [a]
FY 85 - FY 86

Action	FY 85	FY 86				
		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Total
Number Received	97	25	13	11	20	69
Number of Final Approvals	37	16	17	18	21	72
Average FDA Review Time (Days) for Final Approvals	347	463	320	441	365	395
Number Under Review at End of Period						
Active [b]	103	101	79	71	63	63
(Active and Overdue)	N/A	N/A	N/A	(35)	(16)	(16)
On Hold [c]	60	65	75	69	72	72
Total	163	166	154	140	135	135

N/A - Not available.

a/ Some data modified from ODE's previous activities report to reflect corrections in data entry.

b/ FDA responsible for processing application.

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

TABLE 3. PMA SUPPLEMENTS [a]
FY 85 - FY 86

Action	FY 85	FY 86				
		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Total
Number Received	393	112	114	113	139	478
Number of Final Approvals:						
"Panel Track" [b]	7	2	3	4	0	9
All Others	370	119	113	116	120	468
Total	377	121	116	120	120	477
Average FDA Review Time (Days) for Final Approvals	240	240	190	172	143	186
Number Under Review at End of Period						
Active [c]	306	270	265	260	249	249
(Active and Overdue)	N/A	N/A	N/A	(131)	(107)	(107)
On Hold [d]	80	96	88	42	54	54
Total	386	366	353	302	303	303

N/A - Not available.

a/ Some data modified from ODE's previous activities report to reflect corrections in data entry.

b/ Supplements requiring 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 notice in the FEDERAL REGISTER.

c/ FDA responsible for processing application.

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

TABLE 4. ORIGINAL IDEs [a]
FY 85 - FY 86

Action	FY 85	FY 86				
		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Total
Number Received	204	55	48	58	45	206
Number of Decisions	201	66	42	56	49	213
Average Review Time (Days) [b]	37	51	27	28	27	35
Percent (%) of Decisions Made Within 30 Days [b]	82	86	95	95	90	91
Number Under Review at End of Period	24	13	19	21	17	17
Number Overdue at End of Period	4	0	0	1	0	0

a/ Some data modified from ODE's previous activities report to reflect corrections in data entry.

b/ FY 86 performance reflects completion of 4 applications that were already overdue when FY 86 began. Excluding these applications from the analysis yields the following:

Average Review Time (Days)	37	29	27	28	27	28
Percent (%) of Decisions Made Within 30 Days	82	92	95	95	90	93

TABLE 5. IDE SUPPLEMENTS [a]
FY 85 - FY 86

Action	FY 85	FY 86				
		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Total
Number Received	2,457	591	588	1,005	700	2,884
Number of Decisions	2,190	858	1,005	1,017	719	3,599
Average Review Time (Days) [b]	33	148	252	19	22	116
Percent (%) of Decisions Made Within 30 Days [b]	78	57	50	92	92	72
Number Under Review at End of Period	854	587	170	158	139	139
Number Overdue at End of Period	728	465	20	10	0	0

a/ Same data modified from ODE's previous activities report to reflect corrections in data entry.

b/ FY 86 performance reflects completion of 728 applications that were already overdue when FY 86 began. Excluding these applications from the analysis yields the following:

Average Review Time (Days)	33	23	22	18	21	21
Percent (%) of Decisions Made Within 30 Days	78	85	89	92	93	90

TABLE 6. 510(k)s [a]
FY 85 - FY 86

Action	FY 85	FY 86 1st Qtr.	FY 86 2nd Qtr.	FY 86 3rd Qtr.	FY 86 4th Qtr.	FY 86 Total
Number Received	5,254	1,218	1,226	1,268	1,351	5,063
Number of Decisions:						
Substantially Equivalent	4,491	936	1,155	1,132	1,165	4,388
Not Substan. Equivalent	132	17	34	30	17	98
Other [b]	472	184	327	141	221	873
Total	5,095	1,137	1,516	1,303	1,403	5,359
Percent (%) Not Substantially Equivalent [c]	2.8	1.8	2.8	2.6	1.4	2.2
Average Review Time (Days) [d]	76	85	77	68	59	72
Percent (%) of Decisions Made Within 90 Days, Based On:						
Total Elapsed Time [d]	68	59	58	72	72	65
FDA Review Time [e]	N/A	N/A	N/A	91	95	93 [f]
Number Under Review at End of Period: [g]						
Active [h]	N/A	N/A	843	740	733	733
(Active and Overdue)	N/A	N/A	(50)	(31)	(25)	(25)
On Hold [i]	N/A	N/A	285	353	308	308
Total	1,337	1,418	1,128	1,093	1,041	1,041

N/A - Not available.

a/ Some data modified from ODE's previous activities report to reflect corrections in data entry.

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

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

d/ 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.

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

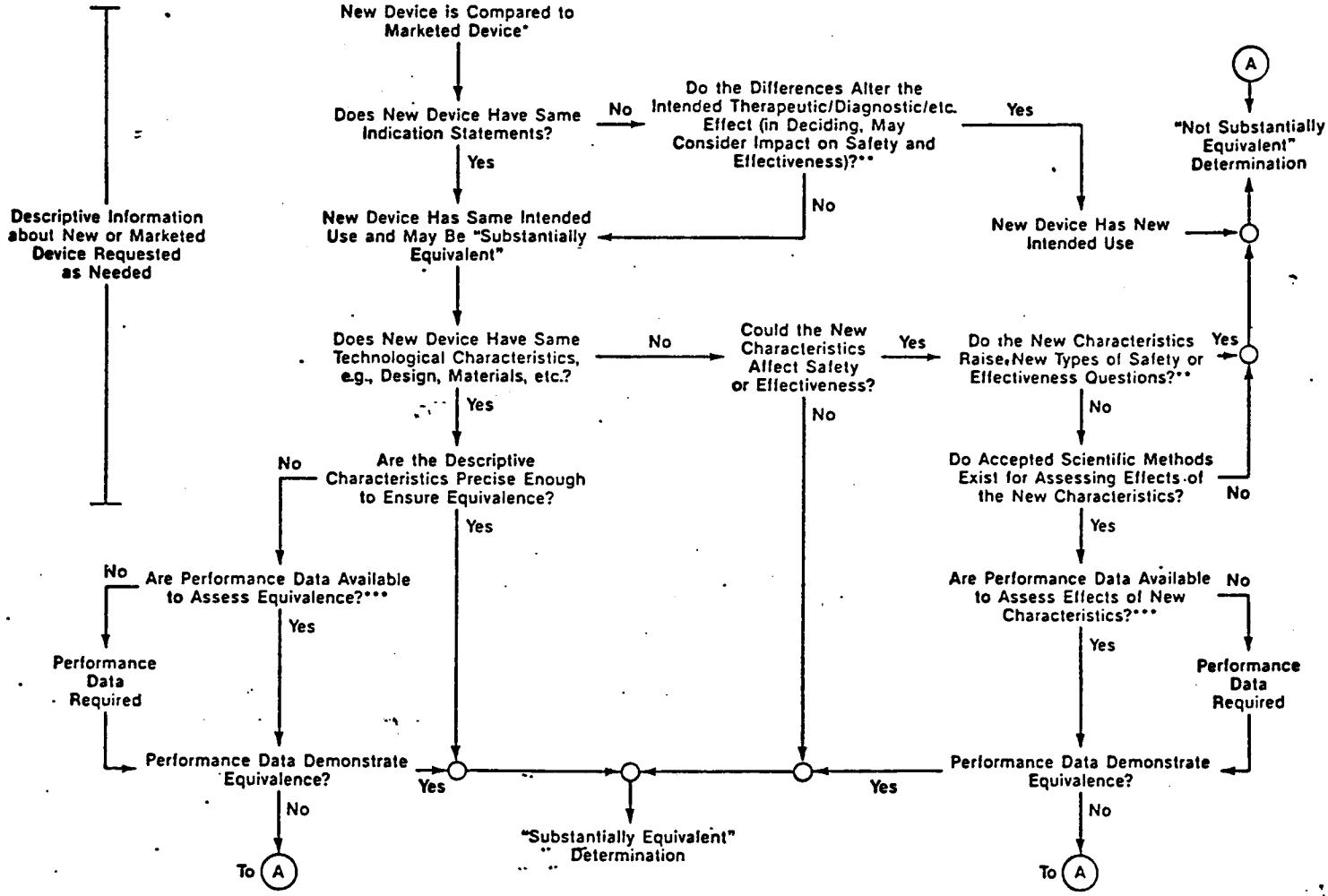
f/ Based on final 2 quarters only.

g/ Historical problems in the previous 510(k) data system currently prevent us from obtaining completely accurate information on the number of 510(k)s under review. The numbers above are the most accurate available at this time.

h/ FDA responsible for processing notification.

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

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



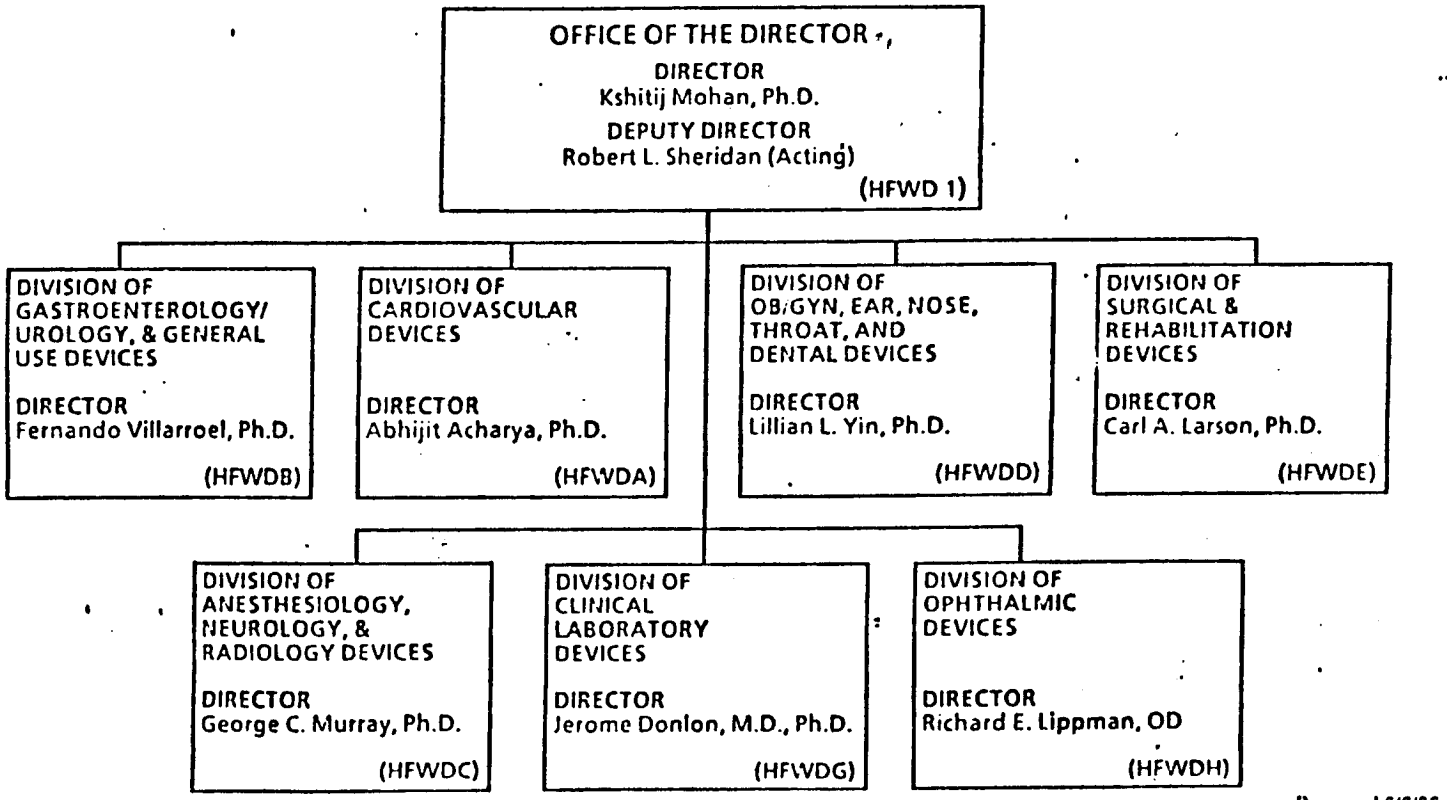
* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION



Prepared 6/6/86

APPENDIX B