OFFICE OF DEVICE EVALUATION
ANNUAL REPORT
Fiscal Year 1988

Dear ODE Colleague:

I am pleased to present to you the ODE Annual Report for Fiscal Year 1988. Congratulations to all of you on having another year of outstanding performance. Your performance has been outstanding not only in view of the "numbers" but also in terms of the difficulty of the issues you have had to deal with and the quality of the work that has been performed.

We would be remiss if we did not acknowledge the contribution that had been made by Dr. Mohan who recently resigned as Director of the Office of Device Evaluation. Dr. Mohan's leadership over the past few years has inspired us and brought greater visibility to ODE. Under his leadership our efforts have been recognized throughout FDA and other government agencies and we heartily thank him and wish him well in his new endeavors.

During the next fiscal year we hope to put renewed emphasis on our divisional activities. Exciting and noteworthy things are happening within our operating units and we hope to highlight the fine efforts that are being made and their impact on our product approval programs.

Robert L. Sheridan
Acting Director

David L. West
Acting Deputy Director

Abhijit Acharya
Director, Division of Cardiovascular Devices

Halyna P. Breslawec
Director, Division of Gastroenterology, Urology and General Use Devices

Jerome A. Donlon
Director, Division of Clinical Laboratory Devices

Carl A. Larson
Director, Division of Surgical and Rehabilitation Devices

Richard E. Lippman
Director, Division of Ophthalmic Devices

George C. Murray
Director, Division of Anesthesiology, Neurology and Radiology Devices

Lillian L. Yin
Director, Division of Obstetrics, Gynecology, Ear, Nose, Throat and Dental Devices

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1988

Center for Devices and Radiological Health
Food and Drug Administration

Acknowledgements

The Office of Health Affairs, CDRH, provided valuable assistance by reviewing this report. Carl DeMarco compiled and edited the text, and the PMA, IDE, and 510(k) staff offices of the Program Operations Staff compiled and verified the quantitative data. Leslie Dorsey produced the report on a desk top publishing system.

November 10, 1988

FROM: Acting Director, Office of Device Evaluation
Center for Devices and Radiological Health

SUBJECT: Office of Device Evaluation Annual Report for Fiscal Year 1988

TO: Director, Center for Devices and Radiological Health
Acting Deputy Director, Center for Devices and Radiological Health

I am pleased to present to you the ODE Annual Report for FY 88. We all appreciate the cooperation and support of the Office of the Center Director and the other offices within the Center during this past year.

Robert L. Sheridan

TABLE OF CONTENTS

TABLE OF CONTENTS
(Continued)

EXECUTIVE SUMMARY

OFFICE OF DEVICE EVALUATION ANNUAL REPORT

FISCAL YEAR 1988

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 1988 (FY 88), beginning on October 1, 1987 and running through September 30, 1988. These highlights are explained more fully in the body of the report.

In General

- Despite the receipt of a record number of major submissions, at the end of this fiscal year we had only three active overdue submissions (one PMA and two PMA supplements) in the five major document review programs (PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s).

- Average review times went down or remained steady in all of the program areas (PMAs, PMA supplements, IDEs, IDE supplements) except for 510(k)s, where the average review time rose from 69 to 78 days.

- We issued eleven guidance documents for reviewers and manufacturers.

Premarket Approval

- We had one PMA and two PMA supplements overdue at the end of the year.

- We received a combined record number (823) of PMAs and PMA Supplements in FY 88. The program responded by completing the review of more PMA originals and supplements (698) than in any previous year.

- Original PMAs were reviewed in an average of 262 days during FY 88, down from 337 days in FY 87, and PMA supplements, including 9 "panel track" supplements, were reviewed in an average of 124 days, down from 148 days in FY 87. If average review times were calculated on the basis of the time keeping rule in the new PMA regulation, they would be 142 days for original PMAs and 95 days for PMA supplements.

- We cleared eleven devices for marketing that represent advances in medical device technology: two recombinant DNA derived in-vitro diagnostic test kits; a plasma immunoadsorption column; a temperature sensitive pacemaker; a laser and a catheter used together for peripheral occlusive vascular disease; a contraceptive cervical cap; four nucleic acid probes for detection of campylobacter and herpes simplex virus type 1 and 2.

Investigational Devices

- No pending original IDEs or IDE supplements were overdue at the end of FY 88.

- Original and supplemental IDEs were reviewed in an average of 27 and 22 days, respectively. In FY 88, 99% of all IDE decisions (originals and supplements)were made within 30 days of receipt.

- The number of pending (but not overdue) original IDEs rose slightly to 19 at the end of FY 88, up from 11 at the end of FY 87. The number of IDE supplements under review was reduced to 157 at the end of FY 88, down from 175 at the end of the previous reporting period. The IDE supplement review rate is well above the 1987 rate (2,784 in FY 87 versus 3,405 in FY 88).

Premarket Notification (510(k))

- There were no active and overdue 510(k)s as of the end of FY 88.

- Average total review time for 510(k)s rose somewhat to 78 days in FY 88, up from 69 days in FY 87. Average FDA review time rose from 56 days in FY 87 to 64 days in FY 88.

- The percentage of 510(k)s reviewed within the 90 day statutory period rose from 96% in FY 87 to 99% for the current fiscal year.

Classification of Medical Devices

- During the year, the last two remaining final classification rules were published for general and plastic surgery devices and radiology devices.

Reclassification

- During the year, the ophthalmic Nd:YAG laser, the magnetic resonance imaging device, and the absorbable surgical gut suture were reclassified from class III to class II.

- We published in the *Federal Register* a proposal to reclassify $PcCO_2$ monitors from class III to class II.

- FDA published a notice on May 27, 1988 of the Panel recommendation and FDA's tentative findings on reclassifying the ceramic hip prosthesis from class III to class II.

- Our advisory panels recommended that the heparin analyzer and the nonabsorbable polyamide surgical suture be reclassified from class III to class II.

Call for PMAs for Pre-Amendments Devices

- This year we published a final rule requiring a PMA for the contraceptive tubal occlusion device and introducer.

Exemptions from Premarket Notification

- We published two final rules exempting the following types of class I devices from the premarket notification requirements:

  — 55 ophthalmic devices

  — 21 clinical chemistry and clinical toxicology devices

- We also published proposals to exempt the following types of class I devices from 510(k) requirements:

  — 8 general and plastic surgery devices

  — 6 radiology devices

Guidance for Industry and Reviewers

ODE and its divisions developed 11 new guidance documents for use by industry and our reviewers:

- Class II Contact Lens Solutions for Class III Contact Lenses
- Salt Tablets
- Enzyme Products for Contact Lens Care
- Ultraviolet Blockers in Class III Contact Lenses
- Intraocular Lens (IOL) Adjunct Study Phase Out Plan
- Alternate Design Policy for Class III Daily Wear Contact Lenses
- Bone Growth Stimulator Devices
- Balloon Valvuloplasty Guidance
- Review of Laser Submissions
- PMA Review Schedule
- Delegation of IDE Actions

Automation and Communication

- Major activities in office automation included the procurement and installation of hardware and software, the modification of the tracking system, training of users, and improvement of telecommunication capabilities. Also, ODE participated in the testing and evaluation of an optical storage and retrieval prototype initiated by the Office of Information Systems.

Staff Resources

- ODE started FY 88 with approximately 242 employees (equivalent to 236 FTEs)

and ended the year having used 229.9 FTEs. Of the 22 new full-time employees hired in FY 88, 8 were scientific reviewers. ODE lost 27 employees (17 scientific reviewers and 10 support staff) during FY 88.

- In FY 88 ODE continued to emphasize the availability of training opportunities as part of its personnel development and retention program. The dollar amount spent on training over the last few years reflects ODE's increased support of training: FY 86-$31,700; FY 87-$58,900; and, FY 88-$104,839.

ANNUAL REPORT

OFFICE OF DEVICE EVALUATION

FISCAL YEAR 1988

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 1988 (FY 88) 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, development of regulations to require premarket approval applications for certain pre-Amendments devices ("515(b) regulations") and exemptions from 510(k) requirements. Procedure and policy guidance and other 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.

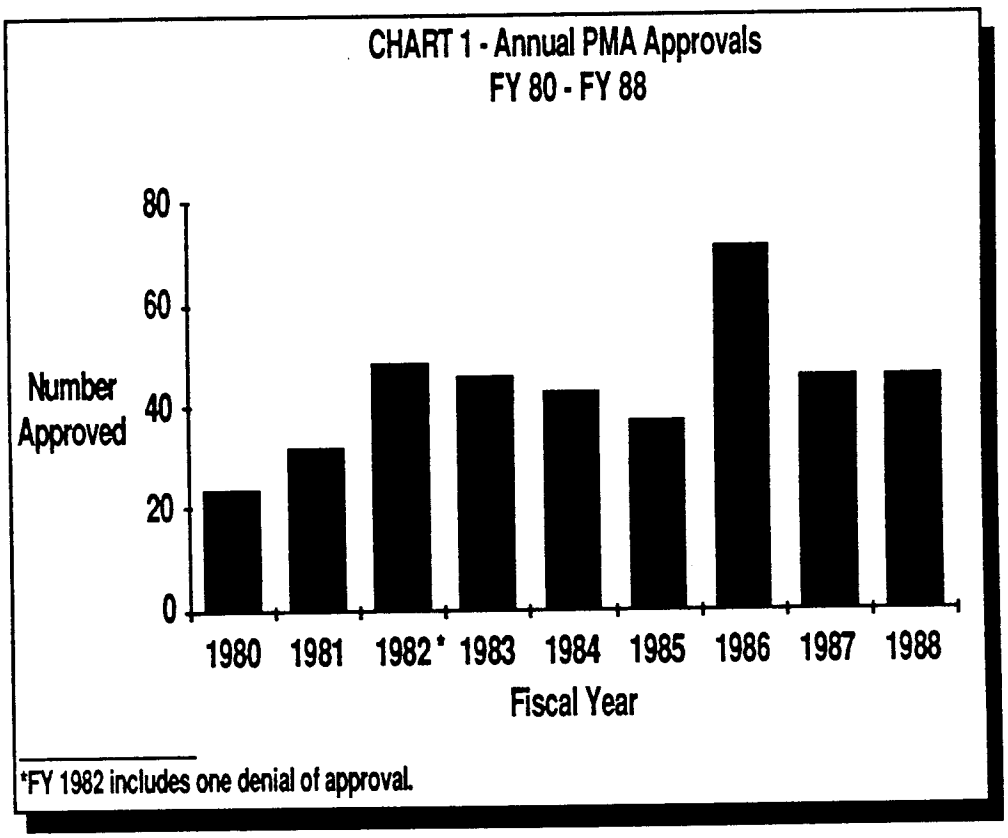
A. PREMARKET APPROVAL

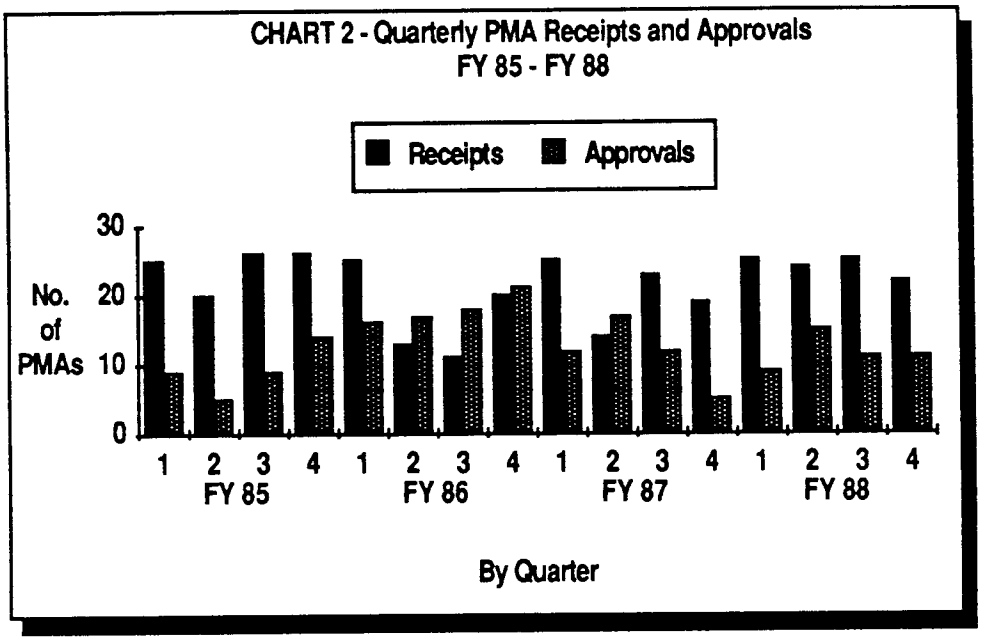
1. Premarket Approval Applications (PMAs)

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

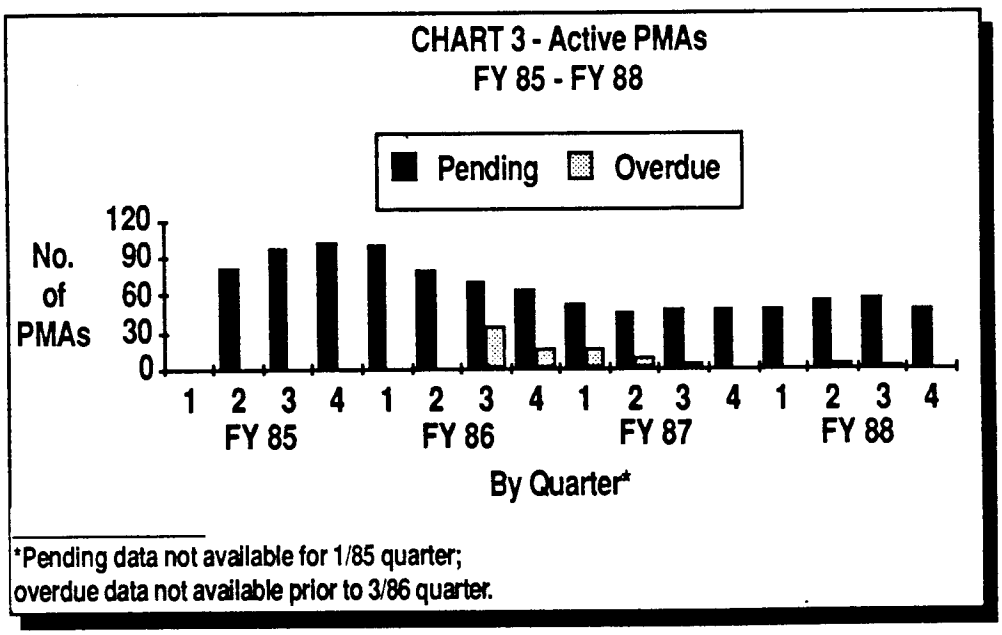
panel for its recommendations on the application. After obtaining the panel recommendation, the agency makes its determination to approve the PMA, deny it, or request additional information. If the PMA is approved or denied approval, FDA must publish a notice in the Federal Register to inform the public of the decision and to make available a summary of the safety and effectiveness data upon which the decision is based.

This report includes average FDA review times as calculated in accordance with the provisions of the PMA regulation. [The final rule for Premarket Approval of Medical Devices (21 CFR Parts 16 and 814) became effective on November 19, 1986.] These averages can be found in Tables 2 and 3, Part VI 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. 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.



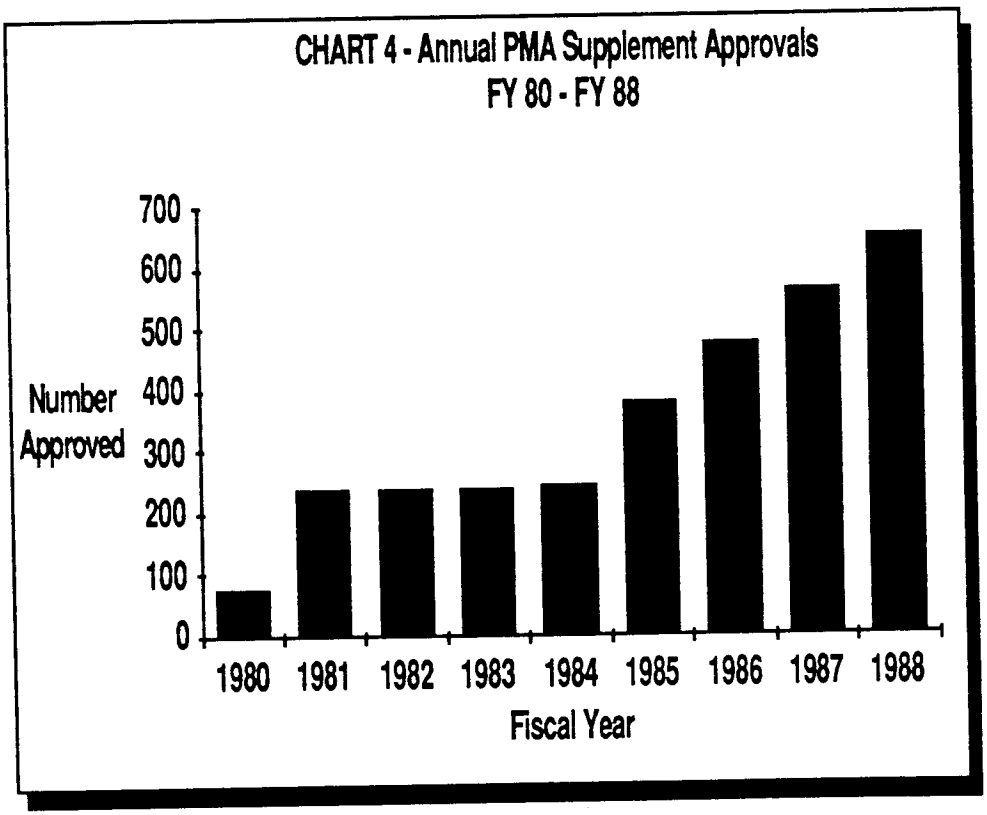


During the year, 96 original PMAs were submitted and a total of 46 were approved. Average FDA review time was reduced from 337 days in FY 87 to 262 days for FY 88. If review time is computed according to the new PMA regulation, average review time would be 142 days this past year. Of the 48 PMAs under active review at the end of FY 88, only one is beyond the 180 day review period specified by law.

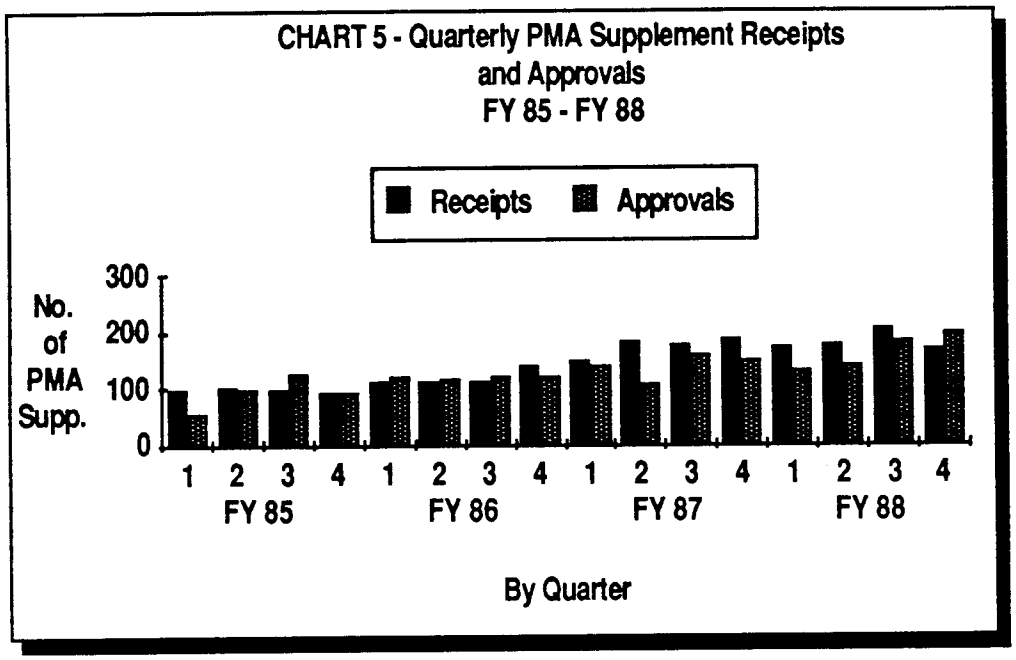


2. PMA Supplements

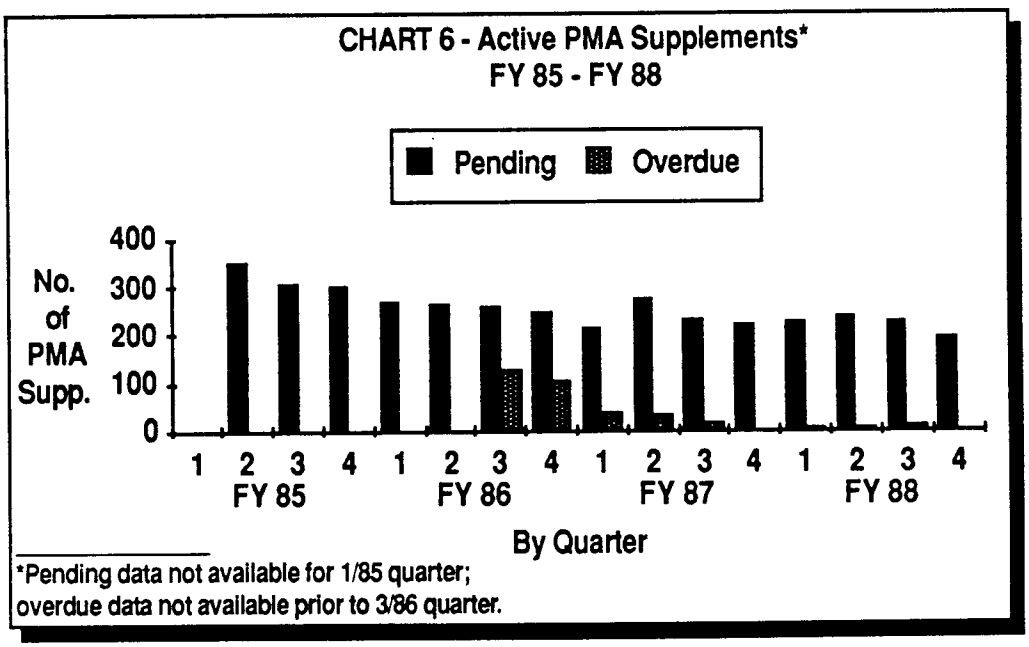
After a PMA is approved, the PMA holder may request FDA approval of changes to be made to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the new PMA procedural regulation, those changes that could affect 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.



During the year, we received an all time record number of supplements, 727 compared to 700 in FY 87. We also approved an all time record number of supplements, 652 compared to 565 in FY 87, the previous all time high. The number of approvals in FY 88 also includes 9 "panel track" supplements which are equal to an original PMA in the time and effort required for review, including consideration and recommendation by our review panels.



Review time was reduced significantly during the year for PMA supplements, including the nine panel track supplements, from 148 days in FY 87 to 124 days in the current fiscal year. If review times were calculated according to the new PMA regulation, it would fall to 95 days. Furthermore, only two of the 195 PMA supplements under active review at the end of FY 88 are beyond the 180 day statutory review period.



3. Significant Medical Device Breakthroughs

We cleared for marketing eleven new devices during FY 88 that represent significant advances in medical device technology.

- The La Antibody Test™ and RNP Antibody Test™, two in-vitro diagnostic test kits, are the first of such devices to utilize a protein fusion (recombinant DNA) method to develop the critical components of these kits. These products, cleared in February and May, 1988, respectively identify nuclear antibodies (La and RNP) which aid in detection of autoimmune disease, particularly for patients with Systemic Lupus Erythamatosis.

- The Prosorba (R) Column™ , approved on December 23, 1987, is the first immunoadsorption column approved for commercial distribution as a medical device. This technology is used to remove specific components from plasma. The Prosorba (R) Column™ is specifically indicated for the therapeutic removal of immunoglobulin G (Ig G) and Ig G-containing circulating immune complexes from plasma in patients with idiopathic thrombocytopenic purpura.

- The Kelvin® Model 500 pacing system, approved on April 29, 1988, is the first approved pulse generator to use temperature, as measured in the right ventricle, as an indicator of physiological stress for the purpose of regulating a patient's heart rate.

- The Spectraprobe - PLR™ Catheter and Model 900 Optilase™ Contact Laser Source System was approved on June 30, 1988. This is the second laser approved for treatment of peripheral occlusive vascular disease and has an expanded indication. It is indicated as the sole therapeutic procedure or as an adjunct to peripheral vascular surgical procedures for the treatment of total occlusions and severe stenosis in the iliac, femoral, popliteal and tibial arteries.

- The Prentif™ Cavity-Rim Cervical Cap was approved May 23, 1988. The Prentif™ Cap is the first contraceptive medical device given premarket approval by FDA since the 1976 amendments. The Cap is indicated for use by women of child-bearing age as a barrier method of contraception. It is used in conjunction with a spermicidal cream or jelly to prevent pregnancy and must be left in place for a minimum of 8 hours after intercourse and may be left in place for a maximum of 48 hours (2 days).

- The SNAP™ Campylobacter Direct Specimen Diagnostic Kit and the SNAP™ Campylobacter Culture Identification kit were cleared for marketing in June and August, respectively. These represent the first synthetic nucleic acid probes for the detection of Campylobacter species directly from patient specimens or as a culture identification test. Campylobacter currently is estimated to be the number one cause of gastroenteritis in the U.S. and the use of nucleic acid probes enables a clinical laboratory to make a faster diagnosis of this human pathogen.

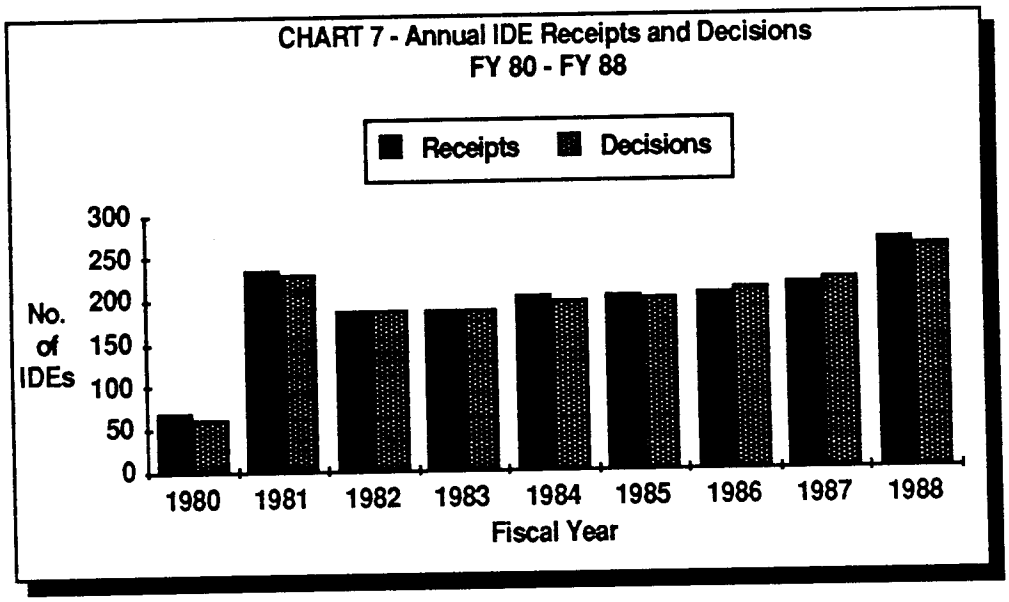
- The ColorGene™ Hybridization Test, the first nucleic acid probe for the detection of Herpes Simplex Virus type 1 and 2, was cleared for marketing in March. In May, the SNAP™ Rotavirus Diagnostic Kit was also cleared. These DNA probes enable the clinical laboratory to speed up identification of these significant human viral pathogens which, in turn, allows the physician to more rapidly and correctly diagnose his patient's condition.

B. INVESTIGATIONAL DEVICES

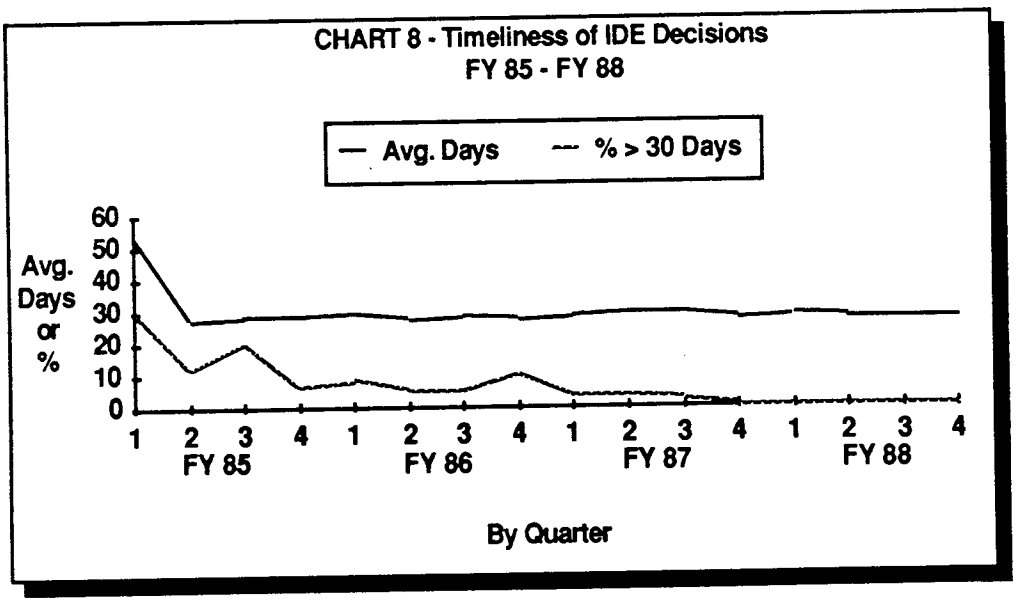
1. Investigational Device Exemptions (IDEs)

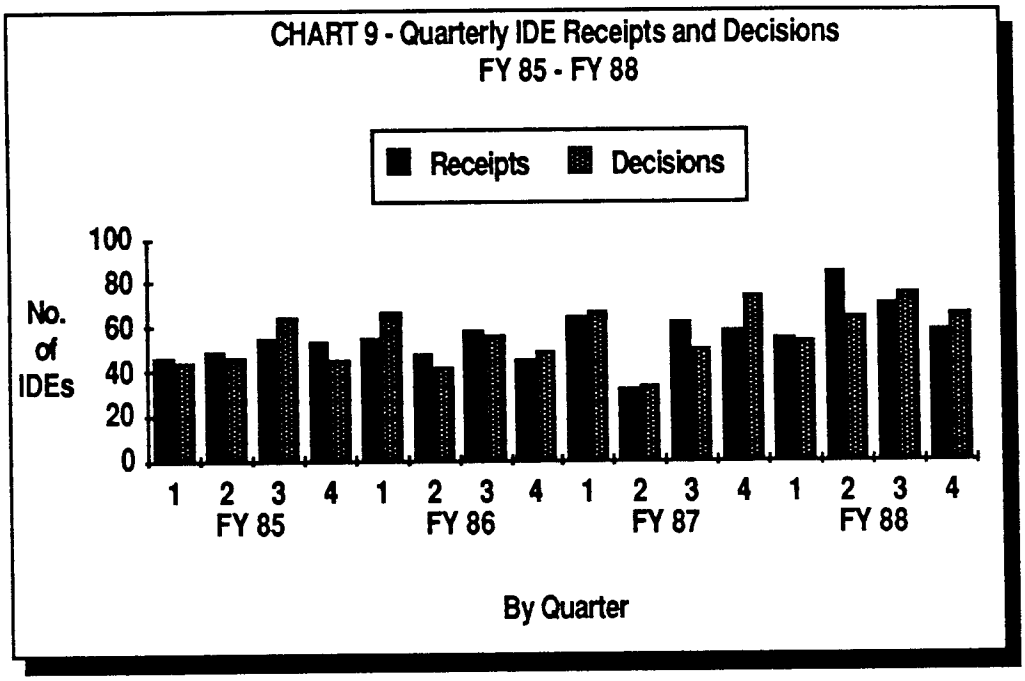
Under the act and regulations, a person may sponsor the clinical investigation of a medical device to establish its safety and effectiveness for a use that has not been approved by FDA. Before conducting clinical trials,however, the sponsor must obtain the approval of an institutional review board (IRB), 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, investigator 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 application. If the agency does not act within the 30-day period, the application is deemed to be approved.



For the fifth year in a row both the number of original IDEs received and the number of decisions increased, ending the year at 268 receipts and 260 decisions. The number of original IDEs pending at the end of the year rose slightly to 19. This year is the third consecutive year in which we have had no overdue original IDEs pending at the end of the year. Average review time was reduced to 27 days while the number of IDEs approved within 30 days rose to 99% for the year, as compared to 82% in FY 85, 91% in FY 86, and 97% in FY 87.



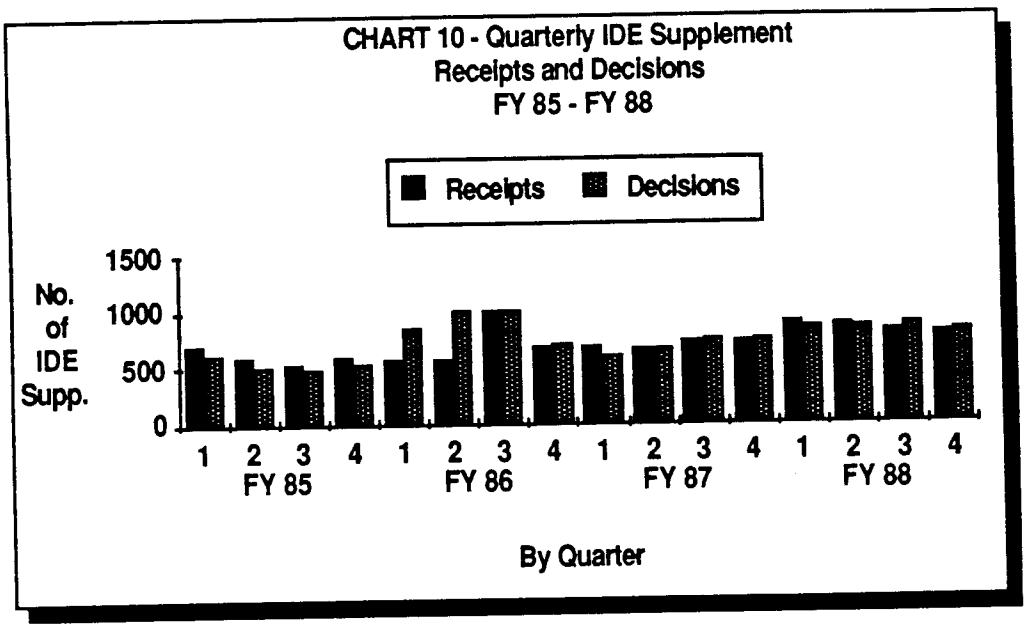


2. IDE Supplements

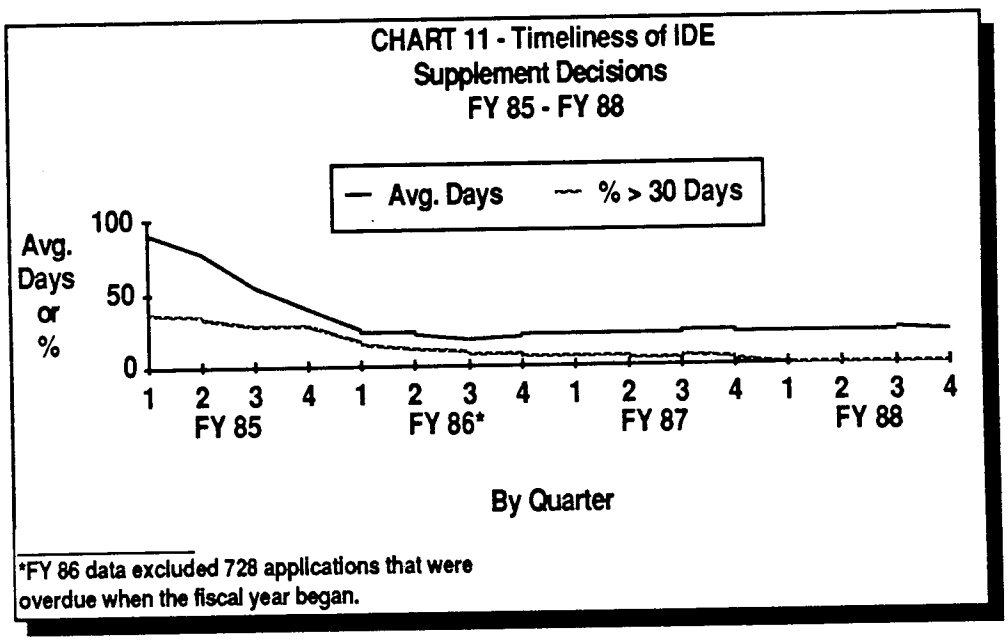
The IDE regulation requires that the sponsor of an investigation of a significant risk device submit a supplemental application if there is a change in the investigational plan, whenever such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. 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 application, including any modifications to the investigation.

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

The number of IDE supplements received rose dramatically from 2,836 in FY 87 to 3,391 in FY 88. There was a similar jump in IDE supplement decisions, 2,784 supplement decisions in FY 87 as compared to 3,405

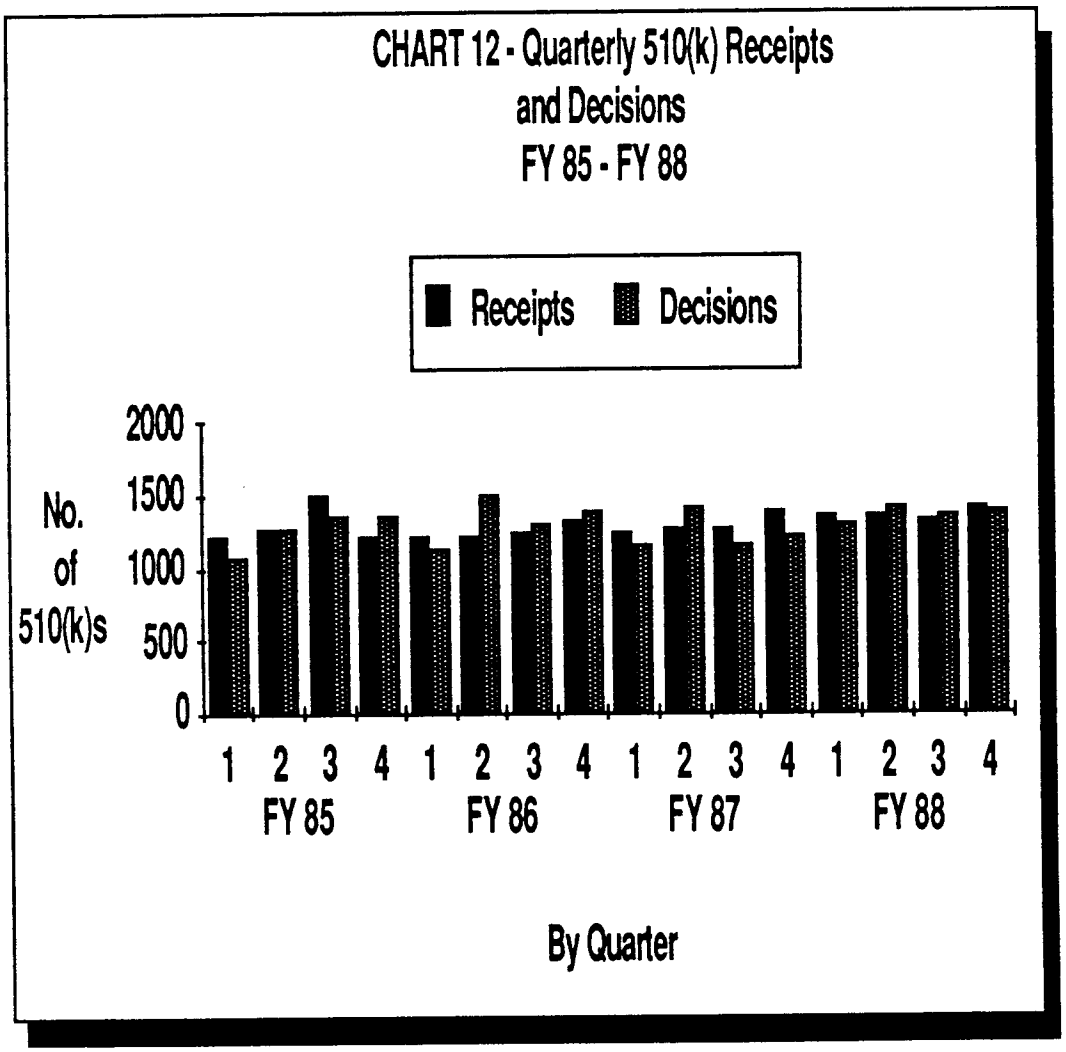


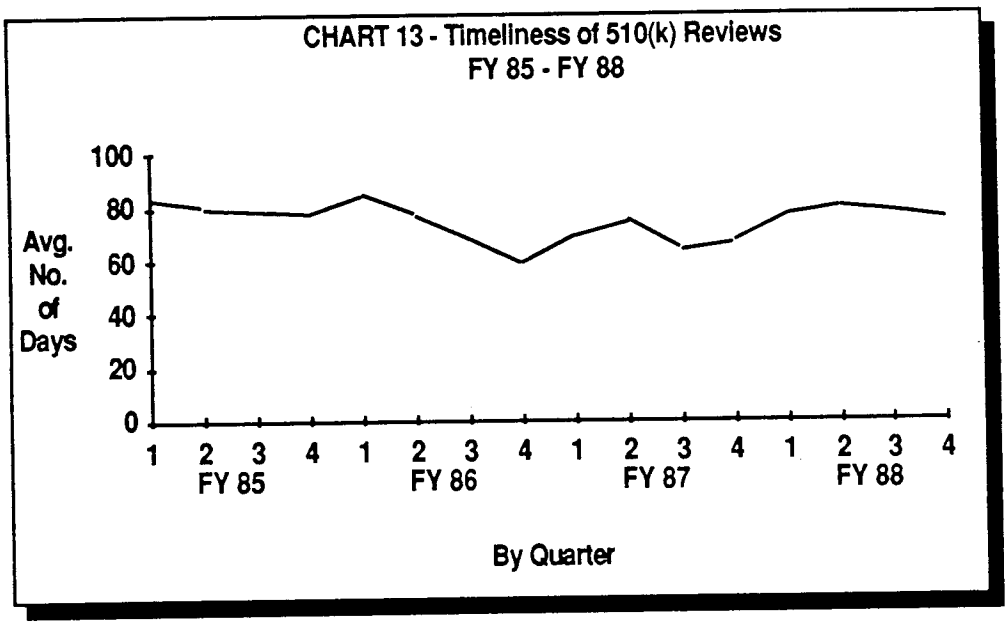
decisions in FY 88. Average review time remained steady at 22 days and the number of decisions made within the statutory review time of 90 days continued to rise, i.e., 78% in FY 85, 72% in FY 86, 95% in FY 87 and 99% in FY 88. The number of supplements under review was reduced somewhat from 175 in FY 87 to 157 in FY 88, and there were no overdue IDE supplements at the end of the year.



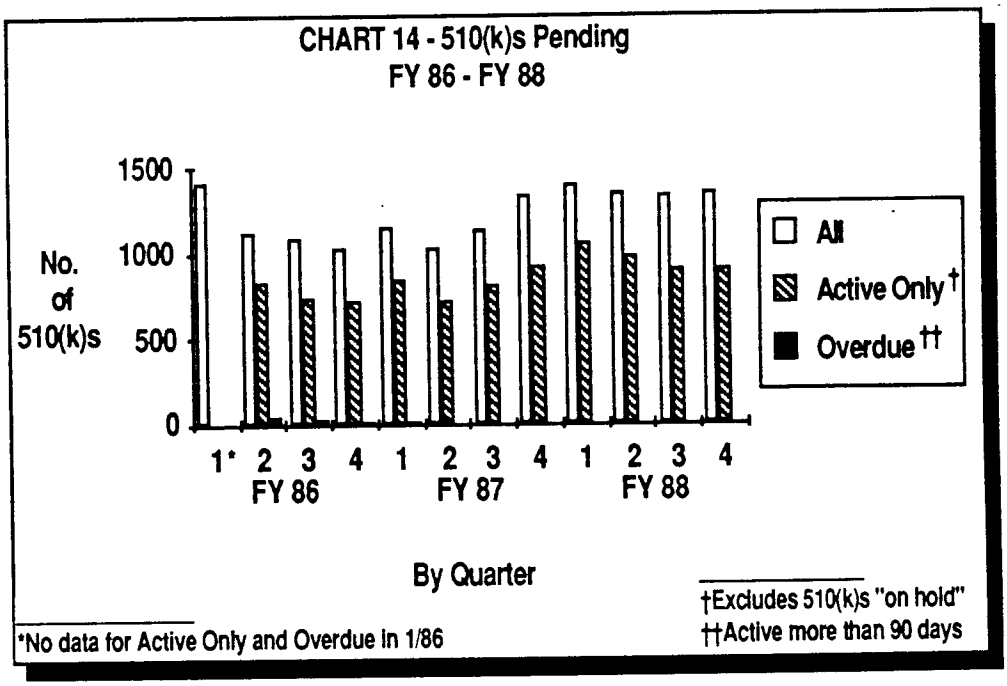
C. PREMARKET NOTIFICATION (510(K))

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 pre-Amendments 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.





We experienced another significant rise in the number of 510(k)s received, from 5,265 in FY 87 to 5,536 in FY 88. The number of decisions made during this reporting period also rose significantly, from 4,992 in FY 87, to 5,513 in FY 88. The average review time rose from 69 days in FY 87 to 78 days in FY 88, but the percent of decisions made within the statutory review period of 90 days increased from 96% in FY 87 to 99% in FY 88.



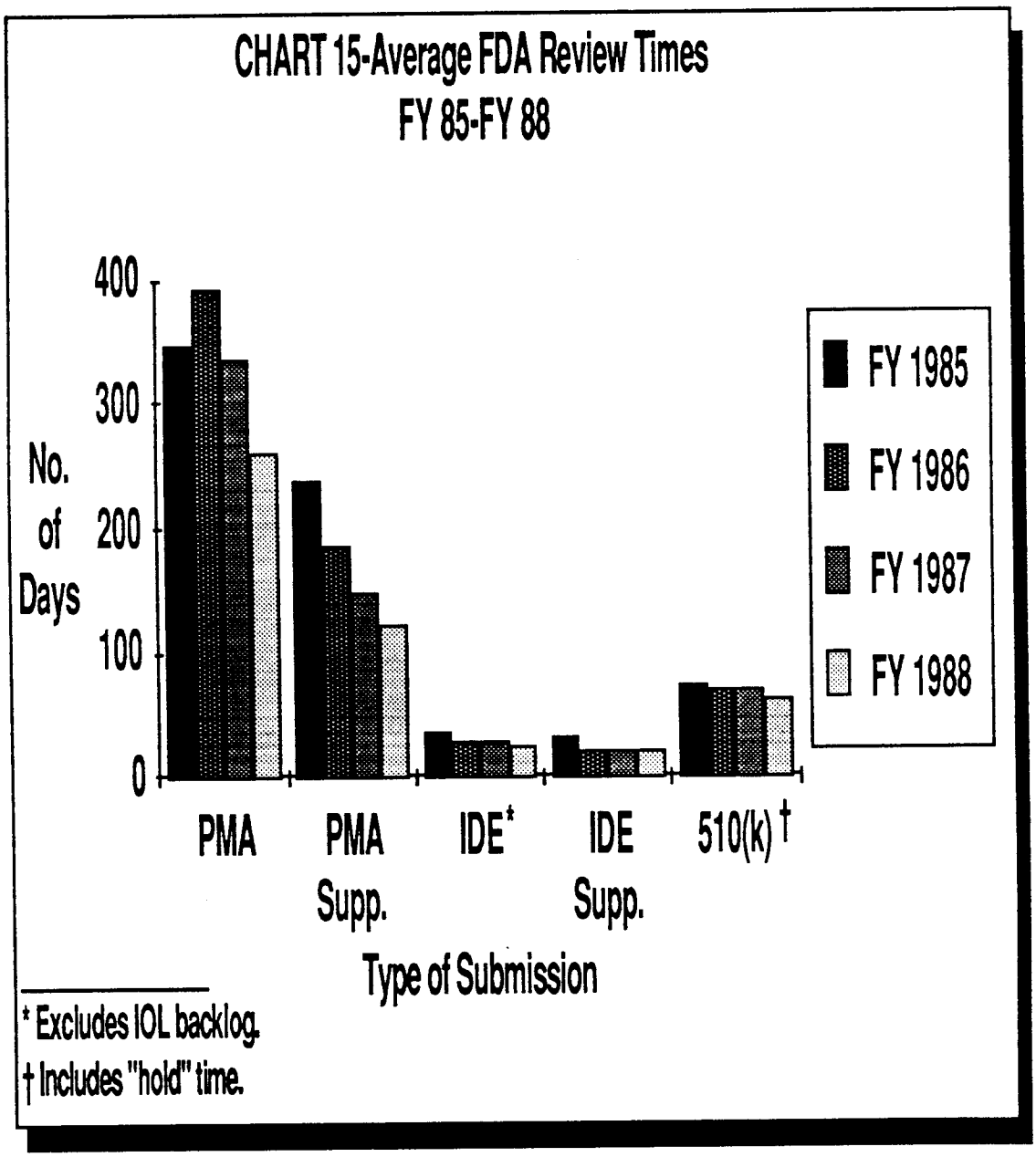


CHART 15-Average FDA Review Times
FY 85-FY 88
400
300
200
100
0
No. of Days
FY 1985
FY 1986
FY 1987
FY 1988
PMA
PMA Supp.
IDE*
IDE Supp.
510(k)†
Type of Submission
* Excludes IOL backlog.
† Includes "hold" time.

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 of 1976 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.

During FY 88, we assisted the Office of Standards and Regulations in the publication of the two remaining final classification rules.

- General and Plastic Surgery Devices. The final rule classifying general and plastic surgery devices (GPS) was published in the Federal Register on June 24, 1988, at page 23856 and became effective on July 25, 1988. This rule classifies 49 GPS devices. Of the total number of devices classified, 23 devices are in class I, 18 devices in class II, and 9 devices in class III. One device appears in more than one class depending upon its specific characteristics. The classification of four generic types of GPS devices was postponed pending review of additional data on electrical safety.

- Radiology Devices. The final rule classifying radiology devices was published in the *Federal Register* on January 20, 1988, page 1554, and it became effective on February 19, 1988. This rule classifies 59 devices. Of the total number of devices classified, 14 devices are in class I, 44 devices are in class II, and 2 devices are in class III. One device received dual classification depending upon its intended use. The classification of all versions of 14 devices was postponed to provide the agency time to review additional data on electrical safety.

B. RECLASSIFICATION OF CLASSIFIED DEVICES

The following actions occurred during FY 88 on reclassification proposals.

- Reclassified the ophthalmic Nd:YAG laser from class III to class II on March 31, 1988.
- Reclassified magnetic resonance imaging devices from class III to class II under the generic name magnetic resonance diagnostic device on July 28, 1988.
- Issued the order on reclassifying the absorbable surgical gut suture from class III to class II, on September 19, 1988 to become effective 20 days from September 19.
- Published a proposed rule in the Federal Register on July 25, 1988, to reclassify $PcCO_2$ monitors from class III to class II.
- Published a notice on May 27, 1988 of the Panel recommendation and FDA's tentative findings on reclassifying the ceramic hip prosthesis from class III to class II.
- Obtained a Panel recommendationon on June 24, 1988 to reclassify the nonabsorbable polyamide (nylon) surgical suture from class III to class II.
- Obtained a Panel recommendation to reclassify the heparin analyzer from class III to class II.
- Drafted a proposed rule to address the issue of reclassifying the automated differential cell counter from class III to class II.

C. 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.

With the publication of the last final classification rule, approximately 130 generic types of devices have been 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. In prior years, 515(b) rules have been proposed or published for various high priority devices. During this fiscal year, on October 1, 1987, we published a final rule requiring the filing of a PMA for the contraceptive tubal occlusion device and introducer. This rule became effective on December 30, 1987.

D. EXEMPTIONS FROM PREMARKET NOTIFICATION

Under Section 513 of the Federal Food, Drug, and Cosmetic Act, (the act), FDA may exempt, by regulation, a generic type of class I device from the requirements of, among other things, premarket notification in section 510(k) of the act and 21 CFR Part 807, Subpart E. Such an exemption allows manufacturers to introduce devices into commercial distribution without first submitting a premarket notification (510(k)) to FDA. Recently, FDA developed criteria for exempting certain class I devices from the 510(k) requirement to reduce the number of 510(k)s on relatively innocuous devices while freeing agency resources for the review of more complex devices. Based on these criteria, FDA has published, during FY 88, the following proposed or final 510(k) exemption notices for certain class I devices in the Federal Register. These notices set forth certain limitations on exemptions depending upon the device's intended use or the fundamental scientific technology used in the device.

- Ophthalmic Devices. Final rule published on September 14, 1988. Exempts 55 devices.
- Clinical chemistry and Clinical Toxicology Devices. Final rule published on June 8, 1988. Exempts 21 devices.
- General and Plastic Surgery Devices. Proposed rule published on June 24, 1988. Proposes to exempt 8 devices.
- Radiology Devices. Proposed rule published on January 20, 1988. Proposed to exempt 6 devices.

E. 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 1,371 FOI requests during FY 88.

IV. POLICY AND PROGRAM IMPLEMENTATION

A. GUIDANCE FOR INDUSTRY AND REVIEWERS

During FY 88, ODE and its operating units issued the following instructional materials for use by manufacturers and ODE reviewers. These guides identify changes in procedures and policies and clarify requirements applicable to our approval program. They are intended to promote uniformity and efficiency in program implementation. Most of these guidance documents are available through the Division of Small Manufacturers Assistance (HFZ-220), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (800) 638-2041.

- Class II Contact Lens Solutions for Class III Contact Lenses.* On June 19, 1987, the Division of Ophthalmic Devices (DOD) issued a policy regarding the use of class II contact lens solutions with class III contact lenses. Class II has not been shown to be adequate to insure the safety and effectiveness of contact lens solutions indicated for use with class III lenses. Furthermore, contact lens solutions indicated for use with class III contact lenses are, by definition, class III products due to their transitional status.

- Salt Tablets.* On September 21, 1987, ODE issued a letter to manufacturers concerning the indications for use of salt tablets used to prepare saline for use with class III soft contact lenses. Revised labeling was recommended to delete the indication for the prepared solution as a rinse prior to chemical disinfection, and to heighten the warning statements that the product is not to be used as a rinse after heat disinfection or as an eyedrop directly in the eye. This is in response to concerns raised by the Ophthalmic Device Panel and information reviewed by the DOD regarding microbial contamination of saline prepared from salt tablets.

- Enzyme Products for Contact Lens Care.* On September 21, 1987, ODE issued a letter to the manufacturers of enzyme tablet products for contact lens use. Revised labeling was recommended to delete the indication for the dilution of the enzyme tablets using distilled water, particularly when the procedure was to be followed by chemical disinfection of contact lenses.

*Not included in FY 87 Annual Report.

This is in response to the concern raised by the Ophthalmic Device Panel and the DOD regarding the potential for microbial contamination of distilled water and subsequent use of disinfection systems that may not be totally effective against certain microorganisms on contact lenses.

- Ultraviolet Blockers in Class III Contact Lenses.* On September 21, 1987, ODE issued a draft guidance document to assist in the development of labeling for ultraviolet light absorbing contact lenses. This guidance includes listing requirements for spectral transmittance curves, a descriptive statement to be placed in the label, and a description for the restrictive elements on advertising.

- Intraocular Lens (IOL) Adjunct Study Phase Out Plan. Further steps in the implementation of this three year phase out plan were taken during this fiscal year. On October 16, 1987, ODE issued a letter to IOL sponsors revising the current tier system for investigation of new, modified posterior chamber IOLs and shortening the investigational period for certain types of lenses. On March 17, 1988, a revision of the previous letter was issued to clarify the tier designations with specific examples and conditions.

  On August 31, 1988, we issued a letter to industry which outlined the rules to be applied for the final year of phase out of adjunct studies for intraocular lenses. A new "modified core" limitation was described which defines the parameters under which investigative IOLs may continue to be distributed, and the data that will be collected for additional safety and efficacy information.

  At the same time, a draft letter to investigators was distributed to the professional ophthalmic societies to explain the changes that will affect investigators who conduct studies of IOLs for safety and efficacy evaluations. This draft letter was made available to these organizations so their members may be notified of the changes about to be implemented beginning January 1, 1989.

- Alternate Design Policy for Class III Daily Wear Contact Lenses. During this fiscal year we completed work on a policy document for contact lenses that was published in the *Federal Register* on April 12, 1988. This document describes conditions under which a manufacturer of class III daily wear contact lenses may apply for approval of alternate designs of their approved lenses without necessarily conducting a prospective clinical trial.

*Not included in FY 87 Annual Report.

- Bone Growth Stimulator Devices. On September 9, 1988, DSRD issued a guidance document for the preparation of IDE and PMA applications for bone growth stimulators. This document addresses specific information needed to support the safety and effectiveness of bone growth stimulators and outlines the concerns of DSRD in conducting clinical trials which gather valid scientific evidence.

- Balloon Valvuloplasty Guidance. On August 8, 1988, the Division of Cardiovascular Devices issued the Balloon Valvuloplasty Guidance. This document provides guidance for the manufacturer to follow in testing and developing a safe and effective percutaneous balloon valvuloplasty catheter for aortic, mitral and pulmonary valves. A public discussion of this guidance had been held at the January 15, 1988 Circulatory System Devices Panel and their recommendations were incorporated in the August 8, 1988 guidance.

- Review of Laser Submissions. On April 15, 1988, ODE issued a "Blue Book" memorandum to consolidate and streamline the review of submissions for medical lasers and laser accessories. Laser reviews will be conducted primarily in a new unit established for this purpose in the Division of Surgical and Rehabilitation Devices (DSRD). This new policy and the newly established procedures will reduce multi-divisional reviews and establish uniformity of labeling while at the same time maintaining the high level of expert review we have applied in the past.

- PMA Review Schedule. This "Blue Book" memorandum of March 31, 1988 revises the "PMA Review Schedule" procedure established May 15, 1987 to assure the completion of PMA reviews in a timely and orderly manner. This revision provides to the review staff a standardized form that is completed along with the PMA filing letter. This form is then used to track the progress of the PMA or panel-track PMA supplement.

- Delegation of IDE Actions. On April 26, 1988, ODE issued a "Blue Book" memorandum to detail the delegation of several IDE actions from the Director, ODE, to Division Directors. These delegations will result in more expeditious handling of many IDEs.

B. ONGOING ACTIVITIES

There were a number of activities begun during FY 88 that are "ongoing" projects.

- Diagnostic Ultrasound. On May 27, 1988, the Center for Devices and Radiological Health issued a letter to industry which addressed tentative perspectives regarding the regulatory approaches used for fetal Doppler ultrasound equipment. These perspectives were discussed in a May 13th meeting of the Center with representatives from the National Electrical Manufacturers Association (NEMA) and the American Institute for Ultrasound in Medicine (AIUM). On August 29, 1988, the OB-GYN Devices Panel met to discuss the effectiveness of Doppler ultrasound instrumentation for fetal evaluation. FDA is considering the recommendations from the Panel and will continue the dialogue with AIUM and NEMA on this matter.

- Pediatric Cochlear Implant. On February 17, 1988, the Center for Devices and Radiological Health sent a draft Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Children to sponsors of cochlear implant investigations and the industry. It was also made available to the public via the agency's electronic bulletin board and discussed at a July 29, 1988 public meeting of the Ear, Nose, and Throat Devices Panel meeting. The draft guideline is intended to aid applicants in the preparation of PMAs for cochlear implants for children. The guideline describes the kind of data needed to allow the agency to evaluate the safety and effectiveness of these devices in children. Comments and suggestions which have been received in response to the draft are presently being reviewed and a second draft will be issued in the near future.

- In-Vitro Fertilization (IVF) Devices. The Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices (DOED) is in the process of gathering information concerning IVF devices. On January 29, 1988, the Obstetrics and Gynecology Devices Panel met to identify and discuss IVF devices and to identify the data required for the evaluation of the safety and effectiveness of these devices.

- Dental Implant. The DOED released to the public, on September 28, 1988, a draft Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant for Prosthetic Attachment. The guidance describes the kind of information needed to allow the Agency to evaluate the safety and effectiveness of these devices. An endosseous implant for prosthetic attachment is a class III, pre-Amendment dental device that is intended to replace a human tooth.

- Testing Requirements for Class III Contact Lenses. This project involves the revision of testing criteria for class III contact lenses in configurations, other than spherical, which previously required data from confirmatory trials and subsequent FDA review and approval. The proposal eliminates the requirement for confirmatory trials in cases where the original clinical information remains applicable to the new configuration. The proposal includes a plan to review, on a case by case basis, these requests with their scientific rationale via PMA supplements.

- Review of Contact Lens Guidance to the Industry. The Division of Ophthalmic Devices (DOD) is currently revising its guidance document to the industry for class III contact lenses. The Ophthalmic Device Panel will review it at its Panel meeting on April 13-14, 1989. This review will be followed by a comment period for the public and industry to respond to recommended changes. We anticipate finalization of the guidance at the June 29-30, 1989 Panel meeting.

- Review of Contact Lens Solution Guidance to the Industry. The DOD is reviewing changes for the solutions guidance document and plans to present its recommended revision for consideration to the Ophthalmic Device Panel before its meeting on June 29-30, 1989. Following that meeting, comments will be solicited from the industry and other members of the public for consideration and a final draft will be prepared by autumn 1989.

- Ventricular Assist Devices and Total Artificial Hearts. In December 1987, draft guidance for the preparation and content of applications for ventricular assist devices (VAD) and total artificial hearts (TAH) was issued. This guideline addresses specific information that must be collected to support the safety and effectiveness of a VAD or TAH and covers both temporary and permanent use. The Division of Cardiovascular Devices (DCD) is currently soliciting further comments before finalizing the draft.

- Testing Implantable Pacemakers. In November 1987, a draft of the Implantable Pacemaker Testing Guidance was circulated for review. This guideline describes a framework for design verification testing of a safe and effective implantable cardiac pulse generator. The DCD is continuing to receive comments for consideration in a final document.

- Lithotripters. The Division of Gastroenterology/Urology and General Use Devices is developing a draft guidance for reporting shockwave measurements of extracorporeal shockwave lithotripter (ESWL) devices. This guidance provides information to manufacturers on the suggested information to be reported on shockwave measurements of extracorporeal shockwave lithotripters. This guidance will discuss the type of testing of ESWL devices and the reporting format for the test data.

- Excimer Lasers for Ophthalmic Use. A draft guidance document on the preparation and content of an investigational device exemption application for studying excimer lasers in ophthalmic surgery has been circulated within ODE and the Ophthalmic Device Panel for comment. The purpose of these studies is to evaluate the effects of refractive surgery to the cornea by several methods utilizing the subject device.

- Radiological Health Data Base. Prior to the merger of the Bureau of Radiological Health (BRH) and the Bureau of Medical Devices, BRH reviewed and tracked 510(k) submissions for a variety of radiation emitting medical devices. The 510(k) Staff has researched and begun development of a "phase-in" process for adding the former BRH 510(k) data base to the current CDRH 510(k) data base.

- Master Files. The 510(k) Staff aided in the development of, and is in the process of implementing, an ADP system for master file documents. The 510(k) staff also set up an independent master file document section within the Document Mail Center.

- Product Codes. A product code update project was initiated to evaluate the accuracy and validity of the product codes assigned to devices cleared through the 510(k) process. To accomplish this task individuals were identified to address all devices associated with each device panel, to review product codes that have been previously used, and to make certain that all new descriptive product codes can be related to product codes for pre-amendments devices. The 510(k) Staff has completed the first phase of the product code update project. This portion of the project established the predicate product code for each device subject to a classification regulation.

- Treatment Use Investigations. The IDE Staff has begun the development of a treatment use policy regarding investigational medical devices. The approach to be taken will be as consistent as possible with the investigational new drug treatment use requirements.

- Document Mail Center Initiative. During the first half of FY 88 ODE initiated major changes in the way controlled PMA documents are processed to improve the overall operation of the Document Mail Center. All files are currently being inventoried and a decision on long term storage will be made. The inventory process will continue through FY 88 and into FY 89. As a result of the changes made, incoming documents are being processed in 24 hours or less and stored documents will be easier to retrieve. Additional staff was also hired to support this activity.

- Review of Laser Submissions. The Division of Surgical and Rehabilitation Devices (DSRD), specifically the General and Plastic Surgery Devices Branch, will be reviewing all 510(k) submissions and "panel track" IDEs for lasers. A memorandum of understanding was developed by Directors of ODE Divisions that provided laser reviews. The transfer of these laser reviews to DSRD became effective March 31, 1988.

- Surgeons Gloves. In August 1988, DSRD issued a draft guidance document for the Content and Organization of a Premarket Notification (510(k)) for Surgeons Gloves. This guidance will assist industry in providing essential information in a 510(k) submission. It facilitates the conduct of a review by FDA staff and provides consistency in the 510(k) requirements.

- Glove Dusting Powder. In August, 1988, DSRD distributed a draft guidance document for PMAs for glove absorbable dusting powder. This guidance will assist industry in providing the essential information in a PMA which is needed by the Agency to evaluate the safety and effectiveness of glove absorbable dusting powders.

- Computer-Controlled Medical Devices. On July 25, 1988, ODE issued a draft guidance for the review of software aspects of 510(k) submissions for medical devices that are not exempt from regulation either according to the FDA Draft Policy for the Regulation of Computer Products or other FDA action. The guidance, developed in concert with the Center's Office of

Science and Technology focuses attention on the software development process to assure that potential hazardous failures have been addressed, effective performance has been defined, and means of verifying both safe and effective performance have been planned and carried out. The draft guidance presents an overview of the kind of information FDA reviewers may expect for the software aspect of 510(k) submissions and the approach FDA reviewers should take in reviewing computer-controlled devices.

- Magnetic Resonance Diagnostic Devices. On August 2, 1988, the Division of Anesthesiology, Neurology, and Radiology Devices issued a draft Guidance for Content and Review of a Magnetic Resonance Diagnostic Device. This document spelled out the suggested information to be contained in a 510(k) premarket notification for reclassified magnetic resonance diagnostic devices.

C. PUBLICATIONS

During FY 88 the Information Clearance Committee processed eight articles authored by ODE staff for publication in professional/scientific journals and 30 presentations to be delivered by ODE staff at professional/scientific and trade association meetings.

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. In addition, two offices report directly to the ODE director: an administrative office as well as the newly organized office that coordinates the review of PMAs, IDEs, and 510(k)s.

In order to exercise greater control over the device evaluation and review processes, the Premarket Approval Staff and the Investigational Device Exemption Staff have been reorganized into two of the the three organizational sections of the newly created Program Operations Staff (POS). To focus greater attention in the 510(k) area, a third section, the Premarket Notification Section, has been created. The PMA, IDE and 510(k) document mail centers have been consolidated and are being managed within the Premarket Notification Section, POS. Additionally, one individual in POS has been given the lead responsibility for coordinating the evaluation of incoming petitions for reclassification.

The Division of Surgical and Rehabilitation Devices also reorganized to be better aligned with the increase in staff and workload. The Division's three branches were reduced to two, and two sections were added to each branch. This permitted delegation of the major responsibility for technical/scientific review and documentation to the section chief and staff. It is expected that reduced review times and a more efficient use of staff will result.

B. STAFFING

ODE started FY 88 with approximately 242 employees (equivalent to 236 FTEs) and ended the year having used 229.9 FTEs. Of the 22 new full-time employees hired in FY 88, 8 were scientific reviewers. ODE lost 27 employees (17 scientific reviewers and 10 support staff) during FY 88.

C. TRAINING

In FY 88 ODE continued to emphasize the availability of training opportunities as part of its personnel development and retention program. The dollar amount spent on training over the last few years reflects ODE's increased support of training: FY 86-$31,700; FY 87-$58,900; and FY 88-$104,839. Training opportunities included support of coursework directed towards advanced degrees, courses in office automation, supervisory training, seminars on research and emerging technologies relating to medical devices, courses at local universities, continuing education at professional meetings, and a work/experience program for ODE reviewers. A three-day training course for new reviewers was presented in November 1987.

D. OFFICE AUTOMATION

Major activities in office automation included the procurement and installation of hardware and software, the modification of the tracking system, training of users, and improvement of telecommunication capabilities. Also, ODE participated in the testing and evaluation of an Optical Storage and Retrieval prototype initiated by the Office of Information Systems.

1. Hardware and Software

The Divisions' hardware needs were prioritized and requisitions were issued for over $405,000 in equipment and software. Of the total, $331,000 was used to purchase personal computer hardware and software.

Chart 16 - ODE Computer Hardware Status
FY 87 - FY 88

HARDWARE	On Hand in FY 87	Received in FY 88	On Hand in FY 88
DECmate II Word Processors	55	0	55
DECmate III Word Processors	35	0	35
LQPO2 Letter Quality Printers	30	0	30
LQPO3 Letter Quality Printers	6	0	6
LA50 Draft Quality Printers	38	0	38
LA75 Draft Quality Printers	10	29	39
LA100 Draft Quality Printers	7	0	7
LA210 Draft Quality Printers	2	0	2
LNO3 LASER Printers	21	0	21
VT220 Terminals	41	1	42
VT320 Terminals	0	7	7
PRO 350 Terminals	2	2	4
Ricoh FAX 1000L	0	1	1
CP/M Boards for DECmates	57	10	67
Electrohome Projector	1	0	1
Compaq 286 PCs	3	8	11
Fujitsu Draft Printers	3	7	10
Macintosh Plus/SE PCs	2	3	5
Apple Laserwriter printers	2	2	4
Apple Imagewriter printer	0	1	1

2. Tracking Systems

   - ODE Basic Tracking System. The ODE Basic Tracking System, which consists of three major components (510(k), IDE, and PMA), runs on the Center's VAX computers in Rockville, Maryland. The ODE Document Control Center staffs maintain data in this System. During FY 88, short names for manufacturers were added to eliminate name variation and facilitate the retrieval of device information.

   - Division Tracking System. Last year, the development of the Division Tracking System was completed. Each division maintains their portion of this system which enables them to mark and report the progress of applications through their individual organizations.

3. Telecommunications - Summaries of Safety and Effectiveness

   Occasionally, applicants for medical devices wish to send 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. Because most of those applicants have word processing different from the Offices' DECmates, it has not been possible to accept the diskettes. One way around this has been to accept electronic transmissions from the applicant's word processor directly to a DECmate. Approximately 15 transmissions of draft summaries of safety and effectiveness were received during this fiscal year. Last year 13 transmissions were received.

   ODE has purchased IBM compatible personal computers. The new equipment will enable applicants to send diskettes for IBM or compatible PCs that can be read on similar ODE systems and, from there, transferred to DECmates through conversion programs resident on the Center's VAX computers. Also, the new equipment will receive electronic transmissions from the applicant's computer; one transmission was received last year using a new PC.

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 is now provided by another organization within CDRH, the Office of Information Systems. During FY 88, 29 employees received basic word processing training and 17 employees received advanced word processing training. In addition, 31 employees were trained in the use of the Center's databases and 17 employees were trained in the use of the Device Experience Network, the Office of Compliance's Medical Device Reporting and Product Problem Reporting systems.

5. Optical Storage and Retrieval

ODE continues to seek ways of increasing efficiency, accuracy, and timeliness in the review process. In conjunction with the Office of Information Systems, ODE is examining the possibility of an Optical Storage and Retrieval System for future use.

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. Likewise, some data from earlier reporting periods has 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 85 - FY 88

Type of Submission	No. Received			
	FY 85	FY 86	FY 87	FY 88
Premarket Approval:				
Original Applications	97	69	81	96
Amendments	597	853	748	754
Supplements	393	478	700	727
Amendments to Supplement	628	714	871	919
Reports for Orig. Applications	236	297	514	535
Reports for Supplements	132	174	162	59
PMA Subtotal:	2,083	2,585	3,076	3,090
Investigational Device Exemptions:				
Pre-original Applications	21	20	15	8
Original Applications	204	206	218	268
Amendments	366	275	265	311
Supplements	2,457	2,884	2,836	3,391
IDE Subtotal:	3,048	3,385	3,334	3,978
Premarket Notification:				
Original Notifications	5,254	5,063	5,265	5,536
Supplements	1,800[a]	2,050	2,113	2,713
510(k) Subtotal:	7,054	7,113	7,378	8,249
PMA/IDE/510(k) Total:	12,185	13,083	13,788	15,317

a/ Estimate based on incomplete data.

Table 2. Original PMAs
FY 85 - FY 88

Action	FY 85	FY 86	FY 87	FY 88
Number received	97	69	81	96
Number of final approvals	37	72	46	46
Average FDA review time (days) for final approvals[a]	347	395	337(257)	262(142)
Number under review at end of period:[b]				
Active[c]	103	63	50	48
(Active and overdue)	N/A	(16)	0	(1)
On hold[d]	60	72	77	66
Total	163	135	127	114

N/A - Not available.

a/ Average FDA review times in parentheses are the average FDA review times calculated under the new 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 application officially suspended pending receipt of additional information from the applicant.

Table 3. PMA Supplements
FY 85 - FY 88

	FY 85	FY 86	FY 87	FY 88
Number received	393	478	700	727
Number of final approvals				
"Panel track"[a]	7	9	8	9
Others	370	468	557	643
Totals	377	477	565	652
Average FDA review time (days) for final approvals[b]	240	186	148(138)	124(95)
Number under review at end of period:[c]				
Active[d]	306	249	224	195
(Active and overdue)	N/A	(107)	0	(2)
On hold[e]	80	54	120	107
Total	386	303	344	302

N/A - Not available.

a/ 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 *Federal Register* notice.

b/ Average FDA review times in parentheses are the average FDA review times calculated under the new 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

Table 4. Original IDEs
FY 85 - FY 88

Action	FY 85	FY 86	FY 87	FY 88
Number received	204	206	218	268
Number of decisions	201	213	224	260
Average review time (days)	37	35(28)[a]	28	27
Percent (%) of decisions made within 30 days	82	91(93)[a]	97	99
Number under review at end of period[b]	24	17	11	19
Number overdue at end of period	4	0	0	0

a/ 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.

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.

Table 5. IDE Supplements
FY 85 - FY 88

Action	FY 85	FY 86	FY 87	FY 88
Number received	2,457	2,884	2,836	3,391
Number of decisions	2,190	3,599[a]	2,784	3,405
Average review time (days)	33	116(21)[b]	22	22
Percent (%) of decisions made within 30 days	78	72(90)[b]	95	99
Number under review at end of period[c]	854	139	175	157
Number overdue at end of period	728	0	0	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 87 and FY 86 review rates are comparable.

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

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.

Table 6. 510(k)s
FY 85 - FY 88

Action	FY 85	FY 86	FY 87	FY 88
Number Received	5,254	5,063	5,265	5,536
Number of Decisions:				
Substantially Equivalent	4,491	4,388	4,105	4,432
Not Substantially Equivalent	132	98	103	82
Other[a]	472	873	784	999
Total	5,095	5,359	4,992	5,513
Percent (%) Not Substantially Equivalent[b]	2.8	2.2	2.1	1.8
Average Total Elapsed Time(Days)[c]	76	72	69	78
Average FDA Review Time	N/A	66	56	64
Percent (%) of Decisions Made Within 90 Days, Based on:				
Total Elapsed Time[c]	68	65	71	67
FDA Review Time[d]	N/A	93[e]	96	99
Number Under Review at End of Period:[f]				
Active[g]	N/A	733	934	913
(Active and Overdue)	N/A	(25)	0	0
On Hold[h]	N/A	308	409	445
Total	1,337	1,041	1,343	1,358

N/A - Not available.

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/ 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)).

e/ Based on final 2 quarters only.

f/ 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.

g/ FDA responsible for processing notification.

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

Table 7. Major Submissions Received
FY 80 - FY 88

Type of Submissions	Fiscal Year								
	1980	1981	1982	1983	1984	1985	1986	1987	1988
Original PMAs	62	60	90	76	65	97	69	81	96
PMA Supplements	165	259	277	360	435	393	478	700	727
Original IDEs	71	237	189	189	203	204	206	218	268
IDE Supplements	460	924	1,694	1,750	3,077	2,457	2,884	2,836	3,391
510(k)s	3,167	3,684	3,798	4,477	5,004	5,254	5,063	5,265	5,536
Total Submissions	3,925	5,164	6,048	6,852	8,784	8,405	8,700	9,100	10,018

Table 8. Major Submissions Reviewed
FY 80 - FY 88

Type of Submissions	Fiscal Year								
	1980	1981	1982	1983	1984	1985	1986	1987	1988
Original PMAs	24	32	49[a]	46	43	37	72	46	46
PMA Supplements	78	239	238	327	243	377	477	565	652
Original IDEs	63	232	189	187	198	201	213	224	260
IDE Supplements	N/A	N/A	N/A	N/A	N/A	2,190	3,599[b]	2,784	3,405
510(k)s[c]	2,908	3,381	3,256	3,162	4,262	5,095	5,359	4,992	5,513
Total Reviews	3,073	3,884	3,732	3,632	4,746	7,900	9,720	8,611	9,876

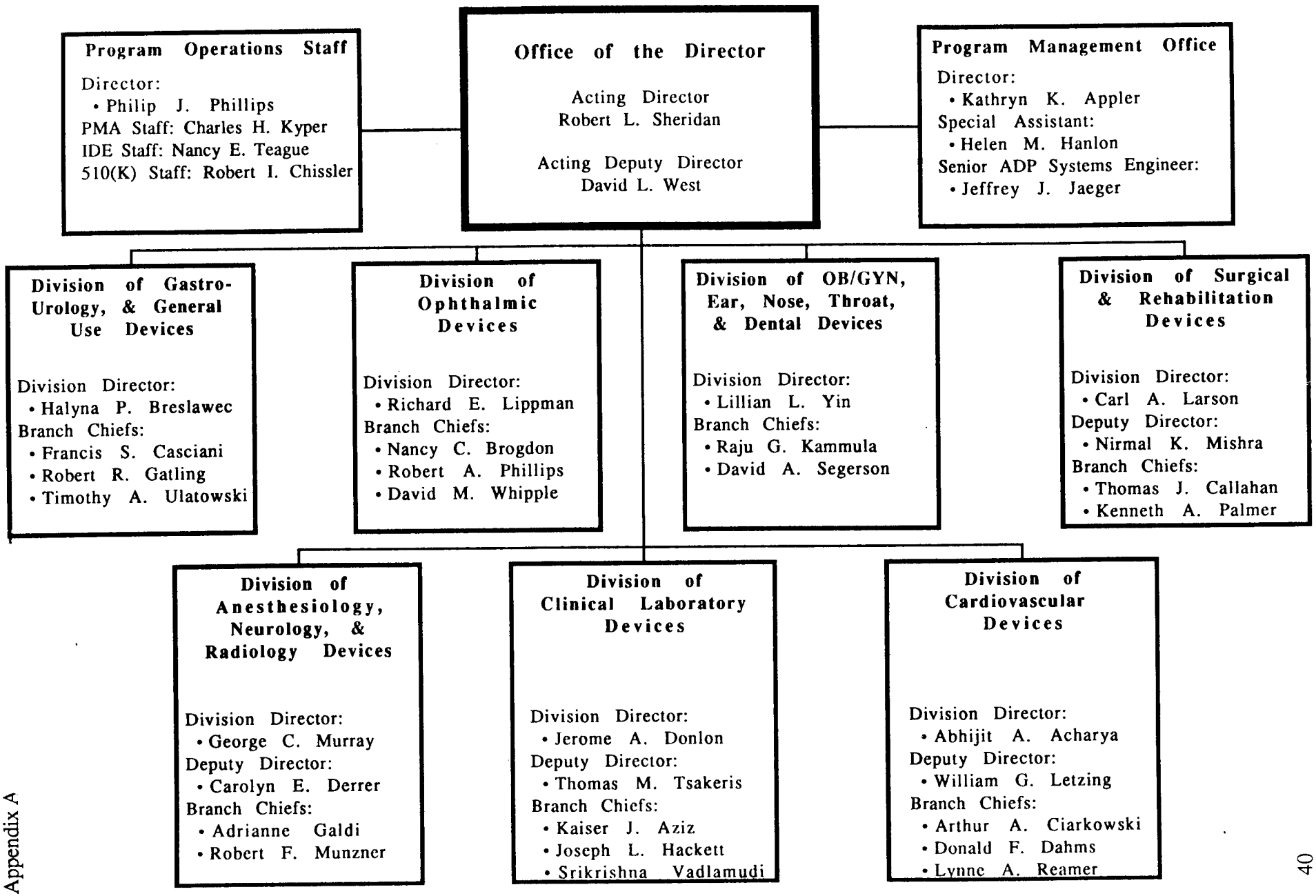
N/A - Not available.

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 87 and FY 86 review rates are comparable.

c/ Data for FY 80-84 does not include withdrawals and deletions.

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



ODE STAFF ROSTER
FY 1988

OFFICE OF THE DIRECTOR

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Mohan, Kshitij
Noel, Linda
Robinson, Mary Jo
Sheridan, Robert
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