DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

November 6, 1987

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

SUBJECT: Office of Device Evaluation Annual Report for Fiscal Year 1987

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

The Office of Device Evaluation is pleased to report that at the end of Fiscal Year (FY) 1987 there were no applications or supplements for Premarket Approvals, Investigational Device Exemptions or Premarket Notifications (510(k)) in this office that were overdue beyond statutory deadlines.

Approval times for applications in all categories were reduced significantly below those in FY 1985 and 1986.

We believe that the quality of the scientific reviews has also been strengthened substantially. This is due to more guidance documents issued in the last two years, including eighteen in FY 1987, than had probably been issued in the previous history of the program, and through strengthened training and performance tracking efforts.

We look forward to your continuing support and encouragement.

Kshitij Mohan

Kshitij Mohan, Ph.D.

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1987

Center for Devices and Radiological Health
Food and Drug Administration

This report was typed and produced on a desk top computer system by Candace Hamilton and Linda Noel. It was formatted by Richard Wromble and compiled and edited by Carl Demarco.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

Fiscal Year 1987

Dear ODE Colleague:

In Fiscal Year (FY) 1986, you set a new standard of excellence for a product evaluation program. In FY 1987, you surpassed it.

Your accomplishments were noted and commended by most sectors of the community concerned with the treatment and protection of patients through the timely availability of safe and effective medical devices. These "impressive" improvements were described in the President's Report, Management of the United States Government: Fiscal Year 1988, in hearings in the Congress, in the trade press and in legal and industry forums. The Center's leadership has also encouraged and commended your dedication and competence. Furthermore, your achievements have fulfilled the past goals of the Commissioner's Action Plan for the device program, and ODE and the Center have received his strong support.

The comfort of past accomplishments, however, pales in the light of our awesome responsibilities for the present and the future. Your decisions potentially affect life or death questions for every person in the U.S. and, in some cases, throughout the world. The vocation we have chosen for ourselves does not allow us the right to any degree of complacency.

The scrutiny we provide for new medical technologies must be scientifically and medically impeccable, but we cannot slip into the bureaucratically safe and defensive posture of erecting unreasonable and unnecessarily high barriers that destroy technological innovation. Human suffering or death resulting from the unavailability of new medical technologies are as troubling as those due to failure of a particular technology. We must continue to strive for a balance that is uncompromising on the scientific and medical proof of new medical technologies but which is intolerant of unnecessary procedural and bureaucratic delays.

In the coming years, we must continue the momentum we have gained by further enhancing the quality and timeliness of our reviews. I know that your dedication and competence will ensure success.

Sincerely yours,

Kshitij Mohan

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

TABLE OF CONTENTS

TABLE OF CONTENTS
(Continued)

EXECUTIVE SUMMARY
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
FISCAL YEAR 1987

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 1987 (FY 87), beginning on October 1, 1986 and running through September 30, 1987. These highlights are explained more fully in the body of the report.

In General

- The backlog of all active overdue submissions in the five major document review programs (PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s) were eliminated during FY 87. This is the first time this has been accomplished in the medical device program and, perhaps, in any FDA review program. It is even more significant in light of the all time record number of major submissions received (9,100 submissions).

- Average review times went down in all of the program areas (PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s).

- A large number (18) of guidance documents for reviewers and manufacturers were issued to strengthen the quality of reviews.

Premarket Approval

- There were no overdue active PMAs or PMA supplements at the end of the year.

- We received a combined record number of PMAs (81) and PMA Supplements (700) compared to a combined total receipt of 490 such applications in FY 85 and 547 in FY 86. The program responded by completing the review of more PMA originals and supplements than in any previous year (414 in FY 85, 549 in FY 86, and 611 in FY 87).

- Original PMAs were reviewed in an average of 337 days during FY 87, down from 395 days in FY 86 and PMA supplements, including 8 "panel track" supplements, were reviewed in an average of 148 days, down from 186 days in FY 86. If average review times were calculated on the basis of the time keeping rule in the new PMA

regulation, they would be 257 days for original PMAs and 138 days for PMA supplements.

- o We successfully organized a "SWAT" team to process the backlog of 20 relatively complex contact lens PMA supplements.

- o The new procedural regulation for premarket approval of medical devices was published on July 22, 1986 and became effective on November 19. The *Premarket Approval (PMA) Manual*, an instruction manual on this new regulation, was published in October 1986.

- o We approved PMAs for four devices that represent advances in medical device technology: a synthetic ligament for permanent implantation in the knee, an opaque tinted contact lens for extended wear, a programmable pacemaker for supraventricular tachyarrythmias, and a fiberoptic laser system for removing fatty deposits from certain arteries in the leg.

Investigational Devices

- o No pending original IDEs or IDE supplements were overdue at the end of FY 87.

- o Original IDE decisions (224) outnumbered IDE receipts (218) for the second year in a row. These are the only two times IDE decisions have out numbered receipts since 1980.

- o Original and supplemental IDEs were reviewed in an average of 28 and 22 days, respectively. These are significant reductions from the 35 and 116 days respectively for FY 86 and are comparable to FY 86 if the backlogged intraocular lens (IOL) applications that were processed in FY 86 are excluded from the analysis. The percentage of original IDE decisions made within 30 days continued to rise for the second year in a row (97 percent in FY 87, 91 percent in FY 86, and 82 percent in FY 85) and the percentage of supplemental decisions made within 30 days rose to 95 percent from 72 percent for FY 86 and 78 percent in FY 85.

- o The number of pending (but not overdue) original IDEs continued to shrink, from 17 at the end of FY 86 to 11 at the end of FY 87. The number of IDE supplements under review rose from 139 at the end of FY 86 to 175 at the end of this reporting period. The IDE supplement review rate is well above the 1985 rate (2,784 in FY 87 versus 2,190 in FY 85) and is comparable to the 1986 rate if the clean-up of the IOL supplement backlog is excluded from the 1986 supplement reviews.

Premarket Notification (510(k)

- o There were no active and overdue 510(k)s as of the end of FY 87.
- o Average review time for 510(k)s was reduced from 76 days in FY 85 and 72 days in FY 86 to 69 days in FY 87.
- o The percentage of 510(k)s reviewed within the 90 day statutory period rose from 93% in FY 86 to 96% for the current fiscal year.

Classification of Medical Devices

- o During the year, five final classification rules were published for: ear, nose, and throat devices; clinical chemistry and clinical toxicology devices; dental devices; ophthalmic devices; and orthopedic devices.

Reclassification

- o During the year, the bilirubin test kit was reclassified from Class III to Class II.
- o We published in the *Federal Register* notices announcing the reclassification of stainless steel sutures from Class III to Class II and proposing the reclassification of infant radiant warmers from class III to class II.
- o Our advisory panels recommended three devices be reclassified from Class III to Class II: absorbable gut sutures; absorbable poly (glycolide/L-lactide) sutures; and, magnetic resonance imaging (MRI) devices.
- o Reviews were conducted and formal responses were prepared for two reclassification petitions.

Call for PMAs for Pre-Amendments Devices

- o This year we published two final rules requiring PMAs for the replacement heart valve and the transabdominal amnioscope.
- o We finalized three other final rules for the contraceptive tubal occlusion device, the automated blood cell separator, and the subcortical stimulator.
- o Two devices, the automated differential cell counter and the infant radiant warmer, became the subject of reclassification actions following the call for PMAs.

Exemptions from Premarket Notification

- We published a final rule exempting four class I ear, nose, and throat devices from the premarket notification requirement.

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

  -21 clinical chemistry and clinical toxicology devices
  -23 dental devices
  -55 ophthalmic devices
  - 7 orthopedic devices

Guidance for Industry and Reviewers

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

- *Premarket Approval (PMA) Manual*
- *Executive Secretaries Guidance Manual*
- Tripartite Biocompatability Guidance
- ODE Regulatory Information for the Office of Compliance
- PMA Supplements for New Contact Lens Configurations
- PMA Supplements for Expansion of Contact Lens Parameters
- Reporting Mechanisms for Contact Lens Packaging Material
- Reporting Mechanisms for Contact Lens Solution Packaging Materials
- Report to the Congress on Intraocular Lenses (IOLs) Adjunct Studies
- New Requirements for Investigations of Anterior Chamber Intraocular Lenses
- PMA Requirements for Preamendment Prosthetic Heart Valves
- Labeling for Drugs of Abuse Screening Tests

- o Premarket Notification (510(k)) Requirements for Diagnostic Ultrasound
- o Strategy for the Regulation of Condoms
- o Media Contacts
- o Industry Representatives on Advisory Panels
- o PMA/IDE Requirements for Ligaments
- o PMA Review Schedule

Automation and Communication

- o We commissioned, and are implementing, a study conducted by the General Services Administration on automation and document handling efficiency within ODE.

Staff Resources

- o Administrative efficiencies and increased effort in ODE have already contributed to past increases in productivity in the Office and increased resources are a principal solution to future workload increases. The Commissioner and the Center had, therefore, increased ODE's staffing from 190 staff years at the end of FY 86 to 202 by the end of FY 87. The office has been allowed to hire beyond its ceiling in anticipation of future attrition and adjustments.

- o During FY 87, ODE hired 87 full-time permanent employees, including 66 scientists and engineers.

- o Recruitment during FY 87 emphasized EEO goals. For example, 29% of total hires were minorities. Over 21% of the 66 professionals hired were minorities (seven were Blacks), and 62% were women.

- o In addition to a three-day training course for all new reviewers, ODE staff participated in training courses in office automation, seminars on supervisory techniques, seminars on the state-of-the-art for selected devices, credit and non-credit courses at local universities, continuing education at professional meetings, and a work/experience program for ODE reviewers.

OFFICE OF DEVICE EVALUATION
ANNUAL REPORT
FISCAL YEAR 1987

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 1987 (FY 87) 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.

The final rule for Premarket Approval of Medical Devices (21 CFR Parts 16 and 814) became effective on November 19, 1986. With the promulgation of this important regulation, the Center for Devices and Radiological Health has articulated the procedures it considers essential in reviewing premarket approval applications. This clarification of procedures should facilitate the approval of PMAs for devices that are safe and effective while ensuring the denial of PMAs for devices that are not.

To further the understanding and implementation of this regulation, the Office of Device Evaluation, with major contributions by the Office of Standards and Regulations and the Office of Science and Technology, issued, in October 1986, the *Premarket Approval (PMA) Manual* which is described under "Guidance for Industry and Reviewers", below.

This report includes, for the first time, average FDA review times as calculated in accordance with the provisions of the new PMA regulation. These averages can be found in Tables 2 and 3, Part IV 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.

During the year, 81 original PMAs were submitted and a total of 46 were approved. Average FDA review time was reduced from 395 days in FY 86 to 337 days. If review time is computed according to the new PMA regulation, average review would be 257 days. Of the 50 PMAs under active review at the end of FY

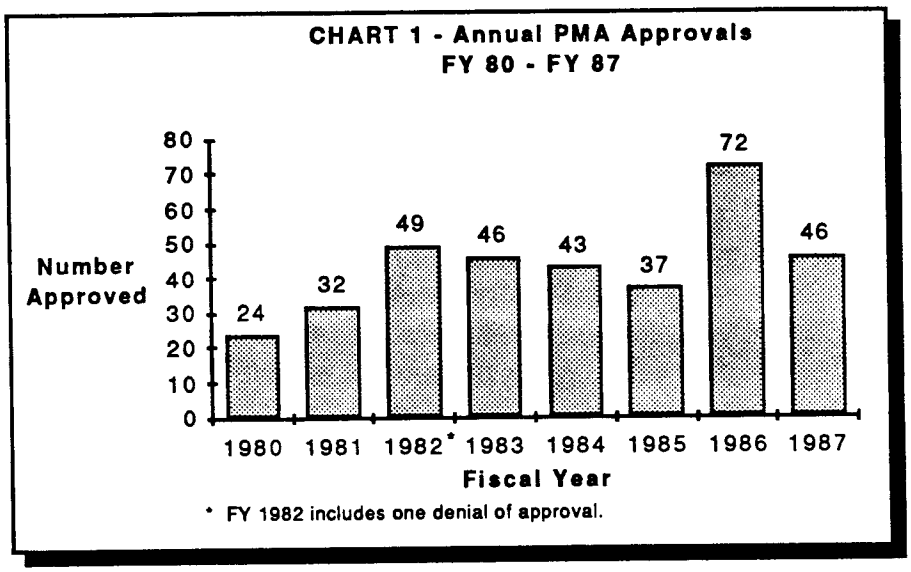


CHART 1 - Annual PMA Approvals
FY 80 - FY 87
Number Approved
80
70
60
50
40
30
20
10
0
24
32
49
46
43
37
72
46
1980 1981 1982* 1983 1984 1985 1986 1987
Fiscal Year
* FY 1982 includes one denial of approval.

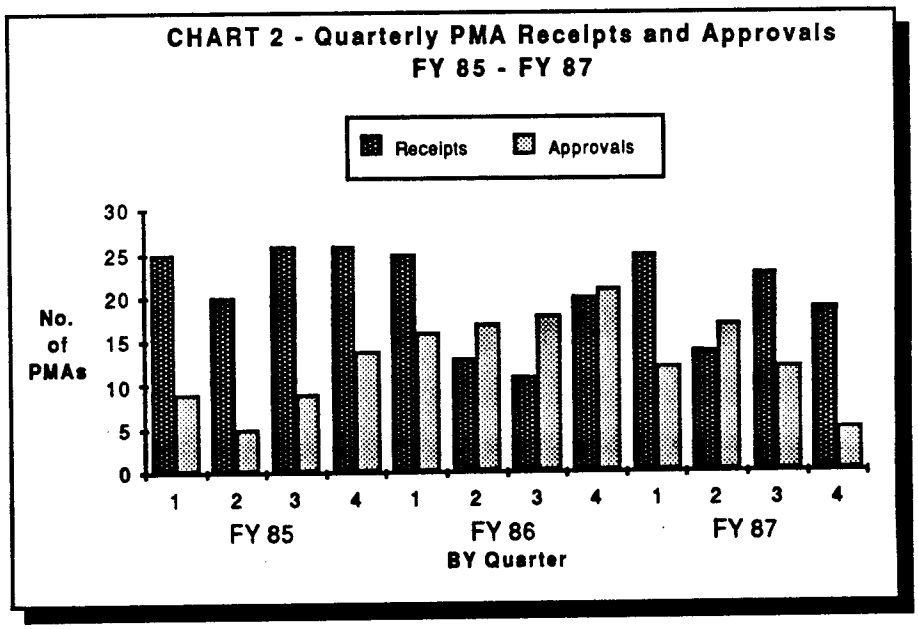
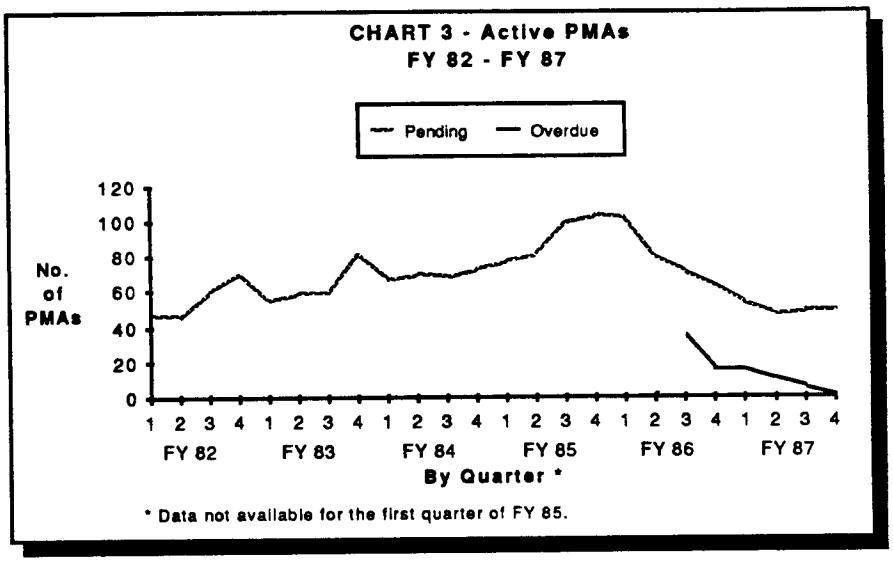


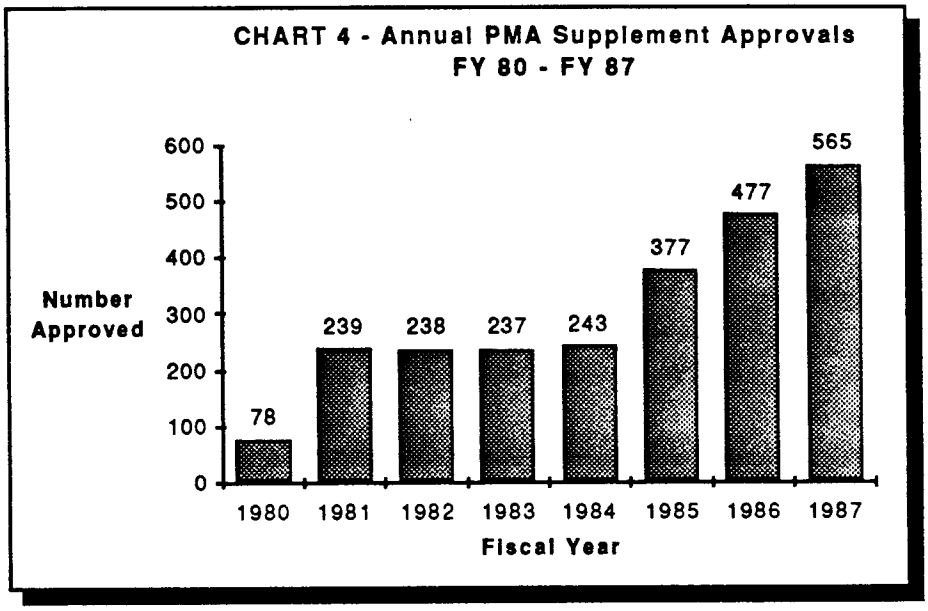
CHART 2 - Quarterly PMA Receipts and Approvals
FY 85 - FY 87
Receipts
Approvals
No. of PMAs
30
25
20
15
10
5
0
1 2 3 4 1 2 3 4 1 2 3 4
FY 85
FY 86
FY 87
BY Quarter

87, none is beyond the 180 day maximum review period required by law. Thus, the PMA program shared the distinction with ODE's other review programs of eliminating all active overdue PMAs at the end of FY 87.



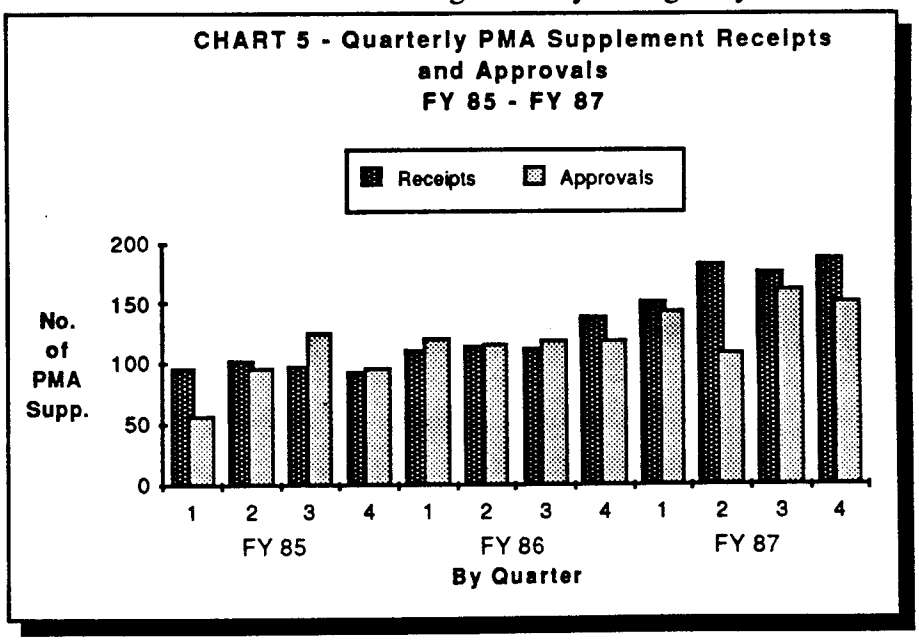
2. PMA Supplements

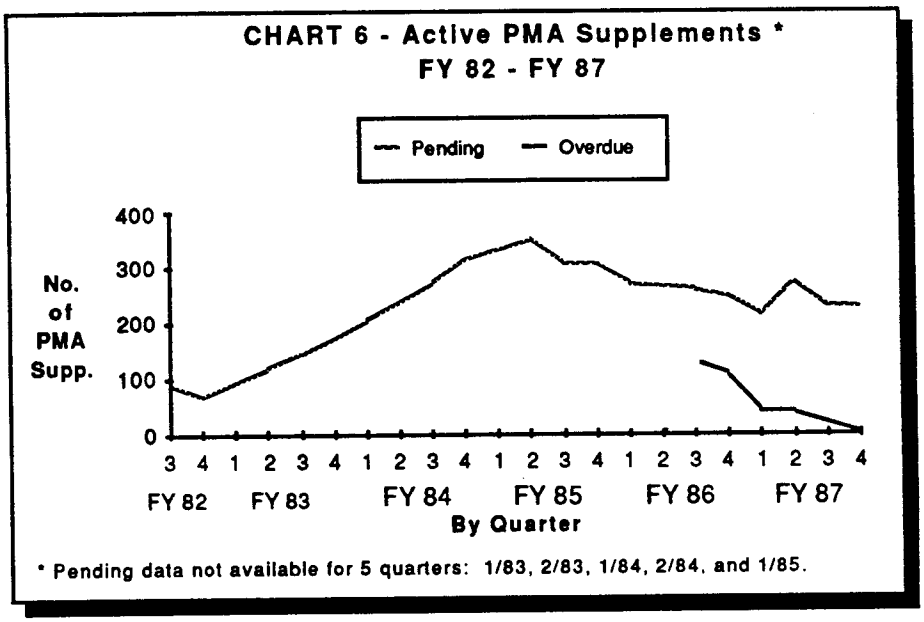
After a PMA is approved, the PMA holder may request FDA approval of changes to be made to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the new PMA procedural regulation, those changes that could affect 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, 700 compared to 478 in FY 86, an increase of 48%. We also approved an all time record number of supplements, 565 compared to 477 in FY 86, the previous all time high. The number of approvals in FY 87 also includes 8 "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 eight panel track supplements, from 186 days in FY 86 to 148 days in the current fiscal year. If review time were calculated according to the new PMA regulation, it would fall to 138 days. Furthermore, none of the 224 PMA supplements under active review at the end of FY 87 is beyond the 180 day statutory review period.

3. Significant Medical Device Breakthroughs Approved

We cleared for marketing four new devices during FY 87 that represent significant advances in medical device technology.

- The GORE-TEX Cruciate Ligament Prosthesis™ is the first synthetic ligament approved for use as a permanent replacement for the Anterior Cruciate Ligament (ACL) of the knee in those patients who have had at least one failed autogenous intra-articular reconstruction of their ACL.

- For the first time, an opague tinted contact lens for extended wear, the DURASOFT COLORS (phemfilcon A) Hydrophilic Contact Lens™, was approved. These lenses provide an ability to change the appearance of the iris color as opposed to the traditional enhancement tints previously approved.

- The Inter-Tach Antitachycardia Implantable Pacemaker™ represents a new and advanced technology in treating rapid heart beats originating in the upper chambers of the heart, i.e., supraventricular tachyarrythmias (SVTs). The physician can program this pacemaker to a primary a secondary detection mode to increase the probability of correct diagnosis of the patient's SVTs and to properly correct them.

- We approved the first laser device used to treat a vascular disorder. The Laserprobe-PLR™ Catheter and Optilase™ Contact Laser System combine a metal-tipped fiberoptic probe with an argon laser for use in removing fatty deposits obstructing certain arteries in the leg. This procedure will allow use of balloon angioplasty, which is far less expensive and risky than surgery, by burning a small hole through the fatty obstruction so that the balloon can enter.

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 reviewboard (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 fourth year in a row both the number of original IDEs received and the number of decisions rose slightly, ending the year at 218 receipts and 224 decisions. The number pending under

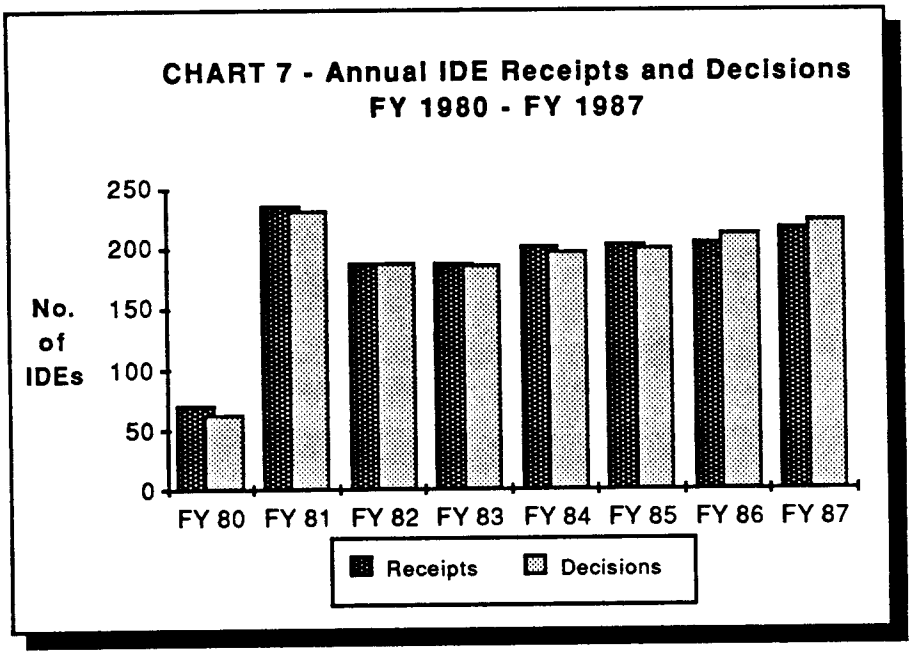


CHART 7 - Annual IDE Receipts and Decisions
FY 1980 - FY 1987
No. of IDEs
250
200
150
100
50
0
FY 80
FY 81
FY 82
FY 83
FY 84
FY 85
FY 86
FY 87
Receipts
Decisions

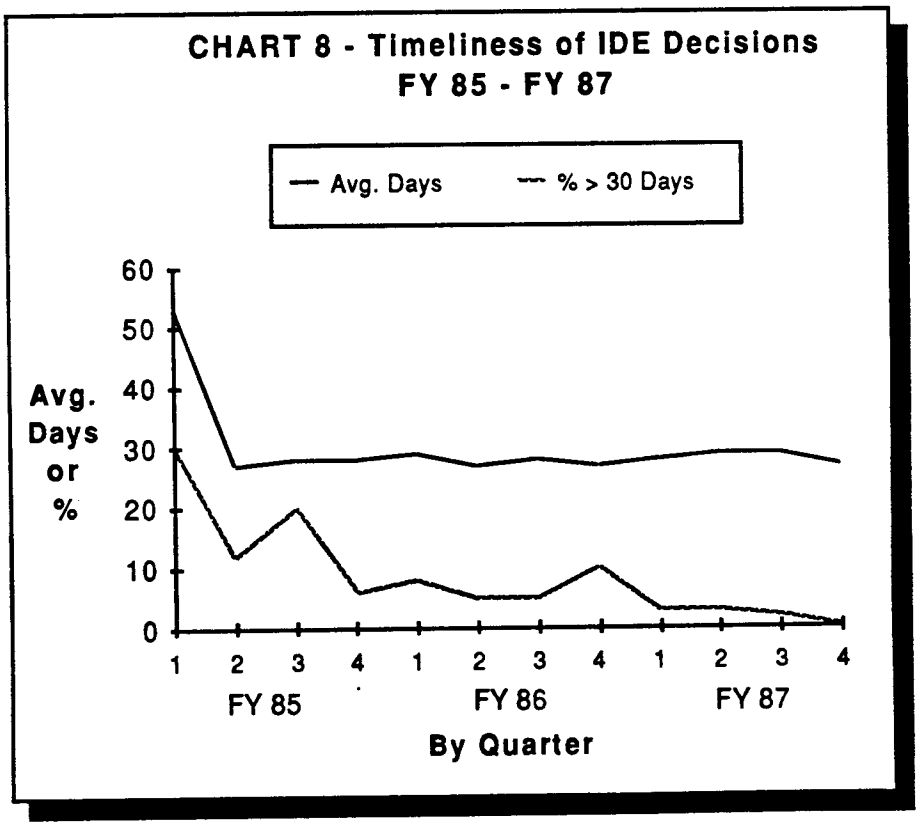
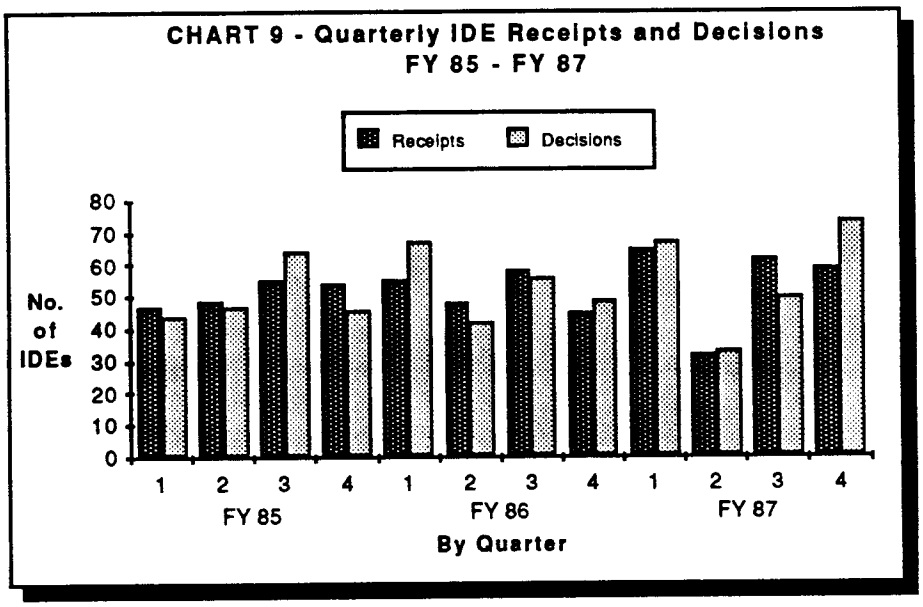


CHART 8 - Timeliness of IDE Decisions
FY 85 - FY 87
Avg. Days
% > 30 Days
Avg. Days or %
60
50
40
30
20
10
0
1 2 3 4 1 2 3 4 1 2 3 4
FY 85
FY 86
FY 87
By Quarter

review at the end of the year dropped to 11 and none of these was overdue. Average review time was reduced to 28 days while the number of IDEs approved within 30 days rose to 97% for the year, as compared to 82% in FY 85 and 91% in FY 86.

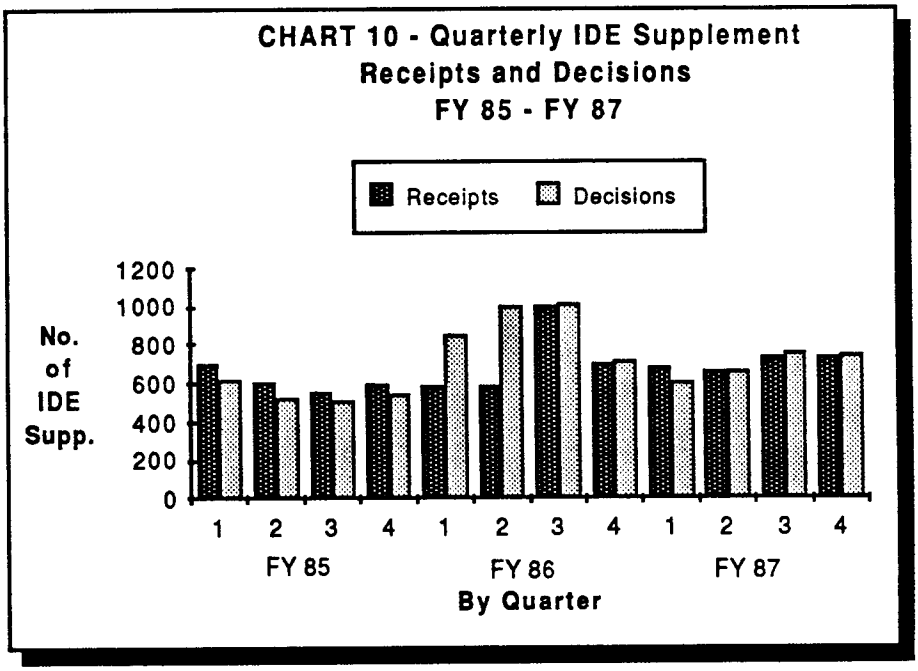
2. IDE Supplements



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.

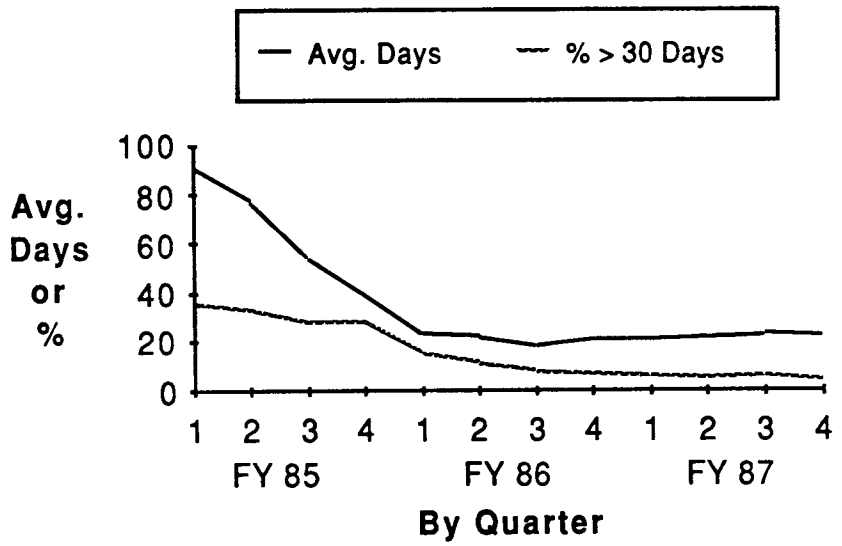
This regulation also requires submission of various reports which are logged in as supplements to the IDE applications. These include reports on unanticipated adverse device effects, recall and device disposition, and failure to obtain informed consent, as well as annual progress reports, final reports,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

The number of IDE supplements received went down slightly



from 2,884 in FY 86 to 2,836 in FY 87. There were 2,784 supplement decisions in FY 87 as compared to 3,599 decisions in FY 86. The FY 86 decisions include approximately 1,000 intraocular lens IDE supplements, the majority of which had been pending for a significant period of time prior to their approval. During FY 86 these were reviewed by a special team assigned to eliminate this backlog. Without these reviews, the FY 87 review rate compares favorably with the FY 86 and earlier review rates. Average review time dropped to 22 days and the number of

CHART 11 - Timeliness of IDE Supplement Decisions FY 85 - FY 87 *

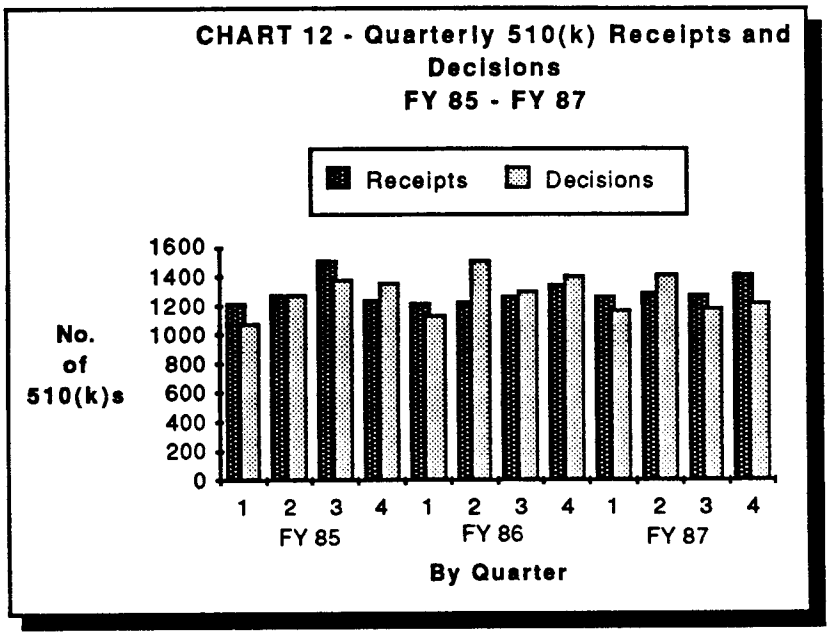


* FY 86 data excluded 728 applications that were overdue when the fiscal year began.

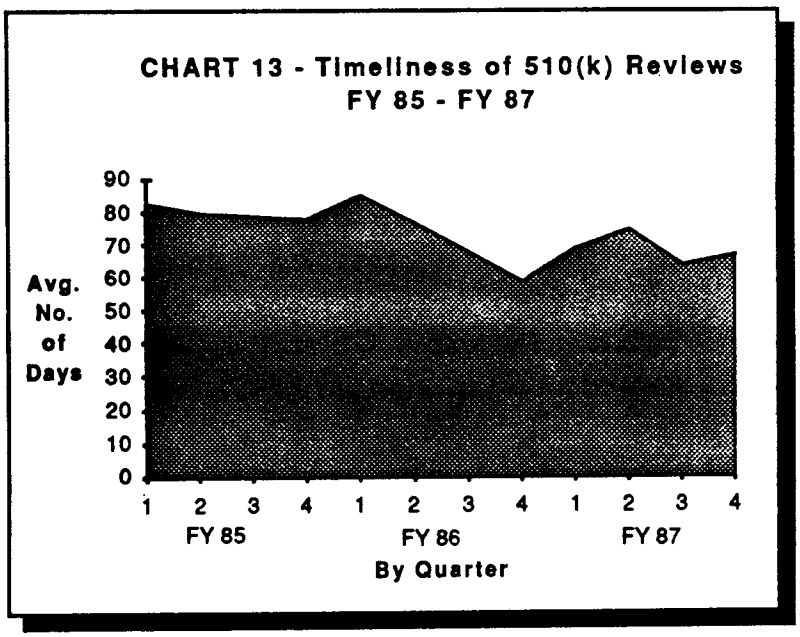
decisions made within the statutory review time of 90 days has made a dramatic improvement over earlier periods, i.e., 78% in FY 85, 72% in FY 86, and 95% in FY 87. The number under review rose somewhat in FY 87 to 175 from 139 in FY 86 but there were no overdue IDE supplements at the end of the year.

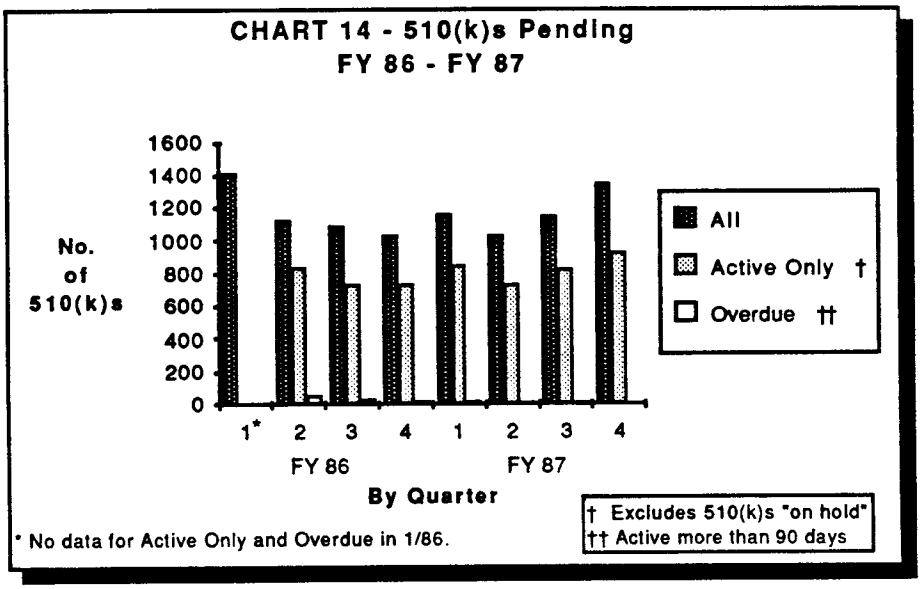
C. PREMARKET NOTIFICATION (510(k))

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.

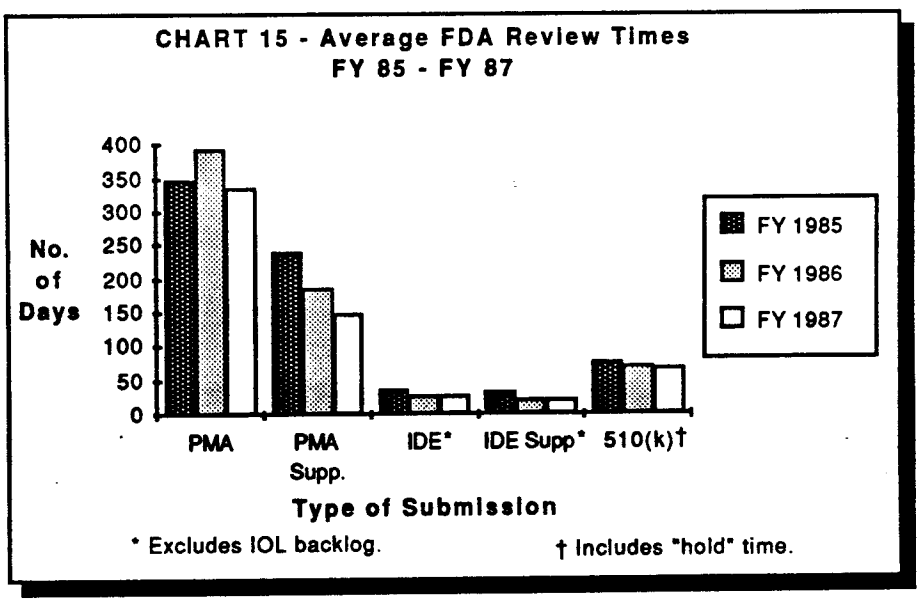


The number of 510(k)s received rose significantly to 5,265 during FY 87 from 5,063 in FY 86. Although the number of decisions made during this reporting period was off somewhat, from 5,359 in FY 86, to 4,992, the average review time dropped to 69 days, from 76 and 72 in FY 85 and FY 86, respectively.





Furthermore, the percent of decisions made within the statutory review period of 90 days rose to 96% from 93% in FY 86. As in our other review programs, there were no overdue submissions pending at the end of FY 87.



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 87, with the assistance of the Office of Standards and Regulations, we published five final classification rules.

- o Ear, Nose & Throat Devices. The final rule classifying ear, nose & throat (ENT) devices was published in the *Federal Register* on November 6, 1986, page 40378, and it became effective on December 8, 1986. This rule classifies 47 devices. Of the total number of devices classified, 14 devices are in Class I, 26 are in Class II, and 5 devices are in Class III. Two devices received dual classification depending upon their intended use. The classification of six generic types of ENT devices was postponed in order to review additional data on electrical safety.

- o Clinical Chemistry and Clinical Toxicology Devices. The final rule classifying clinical chemistry and clinical toxicology devices (CCT) was published in the *Federal Register* on May 1, 1987 at page 16102 and it became effective on July 30, 1987. This rule classifies 206 CCT devices. Of the total number of devices classified, 138 devices are in Class I and 68 are in class II.

- o Dental Devices. The final rule classifying dental devices was published in the *Federal Register* on August 12, 1987, at page 30082 and became effective on September 11, 1987. This rule classifies 110 dental devices. Of the total number of devices classified, 53 are in Class I, 42 devices are in Class II, and 10 devices are in Class III. Five devices appear in more than one class depending upon their intended use or composition. The classification of 10 generic types of dental devices was postponed pending review of additional data on electrical safety.

- o Ophthalmic Devices. The final rule classifying ophthalmic devices was published in the *Federal Register* on September 2, 1987 at page 33346 and it became effective on October 2, 1987. This rule classifies 109 ophthalmic devices. Of the total number of devices classified, 65 devices are in Class I, 33 are in Class II, and 11 devices are in Class III. The classification of 36 generic types of ophthalmic devices was postponed pending review of additional data on electrical safety.

- o Orthopedic Devices. The final rule classifying orthopedic devices was published in the *Federal Register* on September 4, 1987 at page 33686, and became effective on October 5, 1987. This rule classifies 77 orthopedic devices. Of the total number of devices classified, 15 devices are in Class I, 37 are in Class II, and 24 devices are in Class III. One device appears in more than one class depending upon its intended use. The classification of two generic types of orthopedic devices was postponed pending review of additional data on electrical safety.

Also during this fiscal year, ODE completed its work on the two remaining classification rules, general and plastic surgery devices and radiology devices, which, hopefully, will be published during the next fiscal year.

B. RECLASSIFICATION OF CLASSIFIED DEVICES

Reclassification of medical devices received special attention during FY 87. A new policy guide, currently titled "Guidance on the Center for Devices and Radiological Health's Reclassification Program," was drafted during this time and is presently being revised based on comments received from the Office of General Counsel and other offices. It embodies the new approach that has arisen out of discussions among ODE and other Center and Agency offices. This new approach should standardize and streamline reclassification actions so that devices can be reclassified more efficiently into that class whose controls are necessary to assure safety and effectiveness. This could relieve unnecessary regulatory burdens on both ODE and the industry. For example, after reclassification from Class III to Class II or I, a 510(k) can be submitted in lieu of a PMA.

In addition to the development of the reclassification policy, ODE has moved ahead with the following specific reclassification actions.

- Reclassified the bilirubin test kit from Class III to Class II.
- Published a *Federal Register* notice announcing the reclassification of stainless steel sutures from Class III to Class II.
- Published a proposed rule to reclassify automated differential cell counters from Class III to Class II.
- Redrafted a proposed rule to reclassify infant radiant warmers from Class III to Class II.
- Drafted a proposed rule to reclassify ophthalmic Nd:YAG lasers from Class III to Class II.
- Drafted a proposed rule to reclassify ceramic hip prostheses from Class III to Class II.
- Drafted a proposed rule to reclassify PcCO2 monitors from Class III to Class II.

- o Obtained Panel recommendations to reclassify absorbable gut and absorbable poly (glycolide/L-lactide) sutures from Class III to Class II.

- o Obtained a Panel recommendation to reclassify MRI devices from Class III to Class II.

- o Analyzed information requested by the Panel from a petitioner regarding reclassification of the heparin analyzer from Class III to Class II.

- o Sent a deficiency letter to a petitioner regarding reclassification of rigid gas permeable contact lenses from Class III to Class I.

- o Requested further information from a petitioner regarding reclassification of the inductive nasal device from Class III to Class I.

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.

Nearly 150 generic types of devices have been proposed for, or have final 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.

Under this program, in a previous fiscal year, FDA identified in a *Federal Register* notice 13 generic types of pre-Amendments class III devices with the highest priority for the development of 515(b) regulations. Since the 13 high priority devices were identified, the following actions have been taken.

- o Prior to FY 87:

  —Implantable Cerebellar Stimulator. Final rule published on June 28, 1984.

  —Implanted Diaphramatic/Phrenic Nerve Stimulator. Final rule published on April 8, 1986.

  —Contraceptive Intrauterine Device. Final rule published April 5, 1986.

- o During FY 87:

  —Transabdominal Amnioscope. Final rule published October 31, 1986.

  —Replacement Heart Valve. Final rule published May 13, 1987.

  —Contraceptive Tubal OcclusionDevice. Redrafted the final rule. (The final rule, in fact, was published in October, 1987.)

  —Automated Blood Cell Separator. Redrafted the final rule.

  —Subcortical Stimulator. Redrafting final rule.

  —Automated Differential Cell Counter. (Subject of a reclassification action as of December 17, 1986. See "Reclassification," above.

  —Infant Radiant Warmer. (Subject of a reclassification action as of May 27, 1987. See "Reclassification," above.)

A rule calling for PMAs for the automated heparin analyzer is under development. Action on the implantable pacemaker pulse generator and the pacemaker programmer has been postponed until the PMAs on the replacement heart valve have been completed.

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 to FDA a premarket notification (510(k)). 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 87, 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.

- o Ear, Nose & Throat Devices. Final rule published on August 25, 1987. Exempts four devices.
- o Clinical Chemistry and Clinical Toxicology Devices. Proposed rule published on May 1, 1987. Proposes to exempt 21 devices.
- o Dental Devices. Proposed rule published on August 12, 1987. Proposes to exempt 23 devices.
- o Ophthalmic Devices. Proposed rule published on September 2, 1987. Proposes to exempt 55 devices.
- o Orthopedic Devices. Proposed rule published on September 4, 1987. Proposes to exempt seven 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 2,300 FOI requests during FY 87.

IV. POLICY AND PROGRAM IMPLEMENTATION

A. GUIDANCE FOR INDUSTRY AND REVIEWERS

During FY 87, 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.

- o *Premarket Approval (PMA) Manual*. The final rule for Premarket Approval of Medical Devices (21 CFR Parts 16 and 814) became effective on November 19, 1986. To further the understanding and implementation of this regulation, the Office of Device Evaluation, with major contributions by the Office of Standards and Regulations and the Office of Science and Technology, prepared the *Premarket Approval (PMA) Manual*. This manual, which describes the required arrangement and content of a PMA, is intended to aid applicants in the preparation of a PMA as required by the Medical Device Amendments of 1976 and the PMA procedural regulation. The *PMA Manual* details the type of information needed in a PMA so that the FDA can evaluate the safety and effectiveness of a medical device. Sufficient flexibility is allowed for the applicant to submit all relevant information in a format suitable for review by FDA. The submission of a PMA that contains all of the necessary information and follows the guidance in this manual will facilitate its review.

- o *Executive Secretaries Guidance Manual*. In order to improve the operation of our advisory committees, we prepared, this fiscal year, an *Executive Secretaries Guidance Manual* which consists of FDA's *Public Advisory Committees Handbook*, FDA regulations on advisory committees, and "Executive Secretary Advisories" (ESAs). These ESAs expand and clarify the information contained in the FDA publications and will assist the executive secretaries in conducting panel meetings. New ESAs will be issued periodically, as needed, in a manner similar to the ODE "Blue Book" memoranda. The manual is currently being printed.

- o Tripartite Biocompatability Guidance. On April 24, 1987 ODE issued guidance to establish a uniform approach for the evaluation of the toxicity of medical devices. This guidance is based on the September 1986 issue of the "Tripartite Biocompatability Guidance for Medical Devices".

- o ODE Regulatory Information for the Office of Compliance. On May 15, 1987 we issued instructions to the ODE review staff to provide information to the Office of Compliance concerning ODE activities with regulated manufacturers, distributors, investigators, etc., regarding devices cleared or approved for marketing or clinical investigations. This information will enable the office of Compliance to keep FDA field offices informed of ODE activities that might have regulatory implications.

- o PMA Supplements for New Contact Lens Configurations. On November 18, 1986 we issued a guidance that provides for a 30 day approval of PMA supplements for contact lenses to correct astigmatism and presbyopia. Under this new procedure the manufacturer of a contact lens that is the subject of a currently approved PMA may submit confirmatory clinical data for certain new, alternate lens designs in a PMA supplement for FDA review. Because data is set forth in specified summary table formats, it can be reviewed on an expedited basis and the PMA supplement can be deemed approved within 30 days of receipt, provided there are no deficiencies in the application.

- o PMA Supplements for Expansion of Contact Lens Parameters. On November 14, 1986 we revised our program requirements to eliminate the need for certain PMA supplements to increase the power range, base curve, and diameter of daily wear lenses within an approved indication. The purpose of this revision is to allow for the expansion of lens parameters used as fitting criteria which go beyond the clinical population encountered in the original clinical study. These changes have no bearing on the device's safety or performance.

- o Reporting Mechanisms for Contact Lens Packaging Material. On November 18, 1986 we issued a program change that substitutes a reporting mechanism in lieu of a PMA supplement for changes made by a contact lens PMA-holder in the types of buffers used in lens packaging solutions, closure materials for lens containers, lens packaging container materials, and labeling changes necessary to make the device labeling correspond to the new packaging and expiration dating. In all other respects, the contact lens and packaging materials must conform to the terms and conditions of the PMA.

- o Reporting Mechanisms for Contact Lens Solution Packaging Materials. On November 18, we initiated an additional change for contact lens solution packaging materials similar to the change for contact lens packaging materials. Reporting may be substituted for a PMA supplement for changes in the resin material of the lens solution bottle or closure and any labeling necessary to make the labeling correspond to the new packaging and expiration dating. Other terms and conditions of the approved PMA continue to apply.

- o Report on Intraocular Lenses (IOLs) Adjunct Studies. The ODE issued a report, dated December, 1986, announcing a plan to phase out adjunct studies of IOLs. An adjunct study is a clinical investigation peculiar to IOLs which permits unlimited IOLs to be implanted under conditions requiring minimal data (adverse reaction) collection. The adjunct study was permitted to comply with provisions in the Medical Device Amendments designed to ensure reasonable availability of IOLs. While this purpose was fulfilled, these studies have provided little benefit from a safety monitoring or data collection perspective. The new approach to IOL adjunct studies is designed to improve control over the investigation of IOLs while ensuring that the availability of IOLs is not severely restricted, that innovation in IOL technology is not stifled, and that the impact of these changes on ophthalmic care and the industry is as minimal as possible. The plan calls for a three year phase out of IOL adjunct studies. During the first year, ODE will eliminate adjunct studies for IOLs of new styles or materials, expedite the PMA approval process, and streamline the IOL investigational process by clarifying and, where necessary, changing the IOL investigational requirements. During the second year, FDA will require the submission of PMAs or the

termination of investigations of unuseful IOL models.. During the third year, adjunct studies for most IOLs will be eliminated, except for those IOLs that have a filed PMA and are currently in adjunct. From this point on, no IOLs will be permitted into adjunct. Implementation of this plan was initiated in February 1987.

- o New Requirements for Investigations of Anterior Chamber Intraocular Lenses (IOLs). On December 18, 1986 ODE issued guidance letters to all IOL sponsors describing new requirements for investigations of anterior chamber IOLs. A public discussion of the long-term safety and effectiveness of these IOLs had been held at the October 20 meeting of the Ophthalmic Devices Panel. This letter was to inform sponsors of FDA's concurrence with the Panel's recommendations arising from that discussion and of specific modifications to ongoing investigations which sponsors must make.

- o PMA Requirements for Preamendment Prosthetic Heart Valves. Last year, FDA published a proposed 515(b) regulation to require PMAs for preamendment prosthetic heart valves. On October 24, 1986 ODE issued a guidance document outlining the preclinical and clinical data requirements for submission of preamendment heart valve PMAs. This guidance will enable industry to submit appropriately documented PMAs and will facilitate the FDA review process. The final 515(b) regulation was published May 13, 1987.

- o Labeling for Drugs of Abuse Screening Tests. On January 27, 1987 ODE issued a letter concerning revised requirements for professional use screening tests for drugs of abuse. Revised labeling was recommended to meet the needs of consumers and the public concerning interpretation and use of screening test results. Within 180 days of the date of the letter or at the time of the next printing of labeling, whichever occurs first, all drugs of abuse test kits for drugs referenced in the letter must display a prescribed warning, clearly and prominently, on all outside package labels, inserts, and promotional materials. In addition, the limitations section of each package insert must contain a list of all prescription drugs, OTC medication, foods, and other substances or clinical conditions known to interfere with the assay which may cause a false-positive reaction.

- Premarket Notification (510(k)) Requirements for Diagnostic Ultrasound. On January 30, 1987, the Center for Devices and Radiological Health issued further guidance to industry concerning the submission of 510(k)s for diagnostic ultrasound devices. Under this updated guidance, and effective immediately, the acoustic output criteria of ultrasound devices that may be marketed through the 510(k) process has been raised for certain clinical conditions, and a set of conditions was established under which certain system and transducer modifications would not require the submission of additional 510(k)s. A third major modification calls for all 510(k)s submitted on or after November 1, 1987, to include product labeling that demonstrates compliance with the guidance for operator manual labeling. Labeling for transducers of the system was included in this guidance but is being deferred. Also, the use of doppler ultrasound devices for fetal use remains investigational.

- Strategy for the Regulation of Condoms. This strategy paper deals with preventing STDs, including AIDS, through the use of condoms. It adopts a two pronged approach: improved consumer information, through labeling and education; and, enhanced product monitoring, through inspection and testing. The paper was developed during the first half of FY 87 and distributed on April 7, 1987.

- Media Contacts. This document sets forth general guidelines for ODE reviewers who have contacts with the trade press, print reporters other than the trade press, and radio or TV reporters. It does not apply to media contacts that have been cleared by the FDA press office or Center managers and supervisors.

- Industry Representatives on Advisory Panels. On March 23, 1987, ODE provided guidance to the Health Industry Manufacturers Association (HIMA) and ODE Executive Secretaries regarding the role of industry representatives on FDA advisory committees. This guidance was developed as a result of questions and concerns raised by the industry representatives and HIMA.

- PMA/IDE Requirements for Ligaments. On September 1, 1987, we issued guidance on the preparation of IDE studies and PMA applications for ligaments.

- o PMA Review Schedules. This guidance requires ODE divisions to prepare, for each PMA, a schedule that identifies key milestones and the planned completion date for each milestone. The schedule is due when the filing letter is prepared and it is to be updated each time the applicant submits a major amendment.

B. PUBLICATIONS

During FY 86 the Information Clearance Committee processed eleven articles authored by ODE staff for publication in professional/scientific journals and 25 presentations to be delivered by ODE staff at professional/scientific and trade association meetings.

C. ONGOING ACTIVITIES

There were a number of activities begun during FY 87 that are "ongoing" projects.

- o Proposed Guidelines for the Investigation of Electrical Bone Growth Stimulators. On October 31, 1986, the Orthopedic and Rehabilitation Devices panel considered and reached consensus on guidelines for the investigation of electrical bone growth stimulators. When finalized, these guidelines will assist industry in designing preclinical and clinical test protocols and facilitate FDA review of submissions for these devices.

- o Review of Approved Electrical Bone Growth Stimulators. This project involves the review and analysis of the labeling, current literature, and four year postmarket follow-up data on all electrical bone growth stimulators.

- o Review of Safety Data From Collagen Studies. This new project involves the review of safety data from collagen studies to provide a better understanding of complex immunology questions and to establish a database that will assist in the review of submissions for collagen products. It will also help to determine whether reactions to collagen devices increase the risk of developing autoimmune diseases.

- o Development of Panel Evaluation Criteria for "Me Too" Contact Lens Heaters for Disinfection of Soft Contact Lens and Sterile Nonpreserved Saline Solutions. These criteria are being developed to permit FDA approval, without Panel review, of new applications for "me too" contact lens heaters and sterile nonpreserved saline solutions. Panel review is not required because the criteria endorsed and approved by the panel establish for ODE staff the minimum acceptable values for objective measurements of safety and effectiveness. In this case the "me too" devices are not technologically different, to any significant degree, from the "pioneer" device, the indications for use are identical to those contained in a PMA previously reviewed by the panel, and the labeling contains no less stringent warnings and contraindications. Testing criteria for these devices were developed by the Division of Ophthalmic Devices and presented to the Ophthalmic Device Panel for its consideration at the December 4 and February 26-27 Panel meetings. After receipt and consideration of further Panel comments, a final recommendation will be prepared.

- o Effectiveness of the Radioallergosorbent Immunological Test System (RAST). ODE is developing a protocol for studying the effectiveness of the Radioallergosorbent Immunological Test System (RAST) used in the management of allergy patients. The study is planned to be performed in conjunction with a study planned by the Center for Drugs and Biologics to assess skin testing to detect allergies. The studies, also known as the HANES III study, are to be conducted by the National Center for Health Statistics.

D. OTHER ACTIVITIES

The Office of Device Evaluation has coordinated and contributed to the solution of a number of product specific issues that have a direct impact on public health and safety. These issues have been the subject of Congressional hearings, Department level debate, and extensive news media coverage.

- o ODE played a significant scientific and policy role along with other offices in the center in the market withdrawal of the Shiley 60° convexo-concave (cc) heart valve. For several years the Shiley 60° cc valves have been suffering a small but persistent rate of strut fractures. In 1985 the company, in cooperation with the

Center, withdrew the 29-33mm sizes of these valves. This action focused considerable media attention on Shiley and FDA. This attention continued through 1986 with the TV program 20/20 and CBS, among others, doing features on the subject. In the summer of 1986 ODE sought to bring the Shiley issue to a decision point by: (a) curtailing the long drawn out but inconclusive engineering review of Shiley's manufacturing practices and, (b) obtaining actuarial data on thrombus and thromboembolism related mortalities. ODE then arranged for an advisory panel meeting to consider the new data in order to determine if the valves may still be considered safe and effective. In November 1986, Shiley, Inc., ceased production and withdrew from the market the 21-27mm sizes of its 60° cc valves. The advisory panel meeting was, therefore, canceled.

- Another issue that has attracted much attention from both the public and the medical profession is the number of problems with the Garren Edwards Gastric Bubble for obesity control. ODE worked with the Office of Compliance and the manufacturer to revise the labeling of the device to clarify the indications of use for the device and to reduce the risk of deflation. ODE also issued a letter requesting detailed information from the manufacturer on the present clinical experience with the device to ascertain whether further action should be taken. The firm responded to our letter by (1) submitting a PMA supplement for the modification of the device to facilitiate its safe use and (2) by making the sale of the device conditional upon the collection and submission of clinical data by the physician as required in our letter to the manufacturer.

- A third issue, that resulted in a public hearing on April 27, 1987, resulted from the nonapproval of a PMA for Simplex P antibiotic bone cement. In its reconsideration of our action, the advisory committee considered whether a well-controlled clinical investigation in humans is necessary to demonstrate a reasonable assurance that the device is safe and effective. This was the first formal test of what constitutes "valid scientific evidence" under the Medical Device Amendments and FDA's regulations. The committee recommendation is currently under consideration by the Commissioner.

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 the Appendix for an organizational chart.

B. STAFFING

ODE started the fiscal year with 190 FTEs (full-time equivalents). By March 1987, ODE had received 12.6 additional FTEs reflecting increased agency emphasis on product review. Continuation of the aggressive recruitment program begun in the last few months of FY 86 resulted in the hiring of 87 full-time permanent employees in FY 87, including 66 exceptionally well-qualified scientists and engineers. The office had been allowed to hire beyond its ceiling in anticipation of future attrition and additional allocations. At the end of FY 87, ODE had an allocation of 202.6 FTEs.

C. TRAINING

Employees had a variety of opportunities for training during FY 87. These included, for example, office automation courses, supervisory training, seminars devoted to state-of-the-art presentations on selected devices, credit and non-credit courses at local universities, continuing education activities at professional meetings, and a work/experience program for ODE reviewers. In addition, there were several seminars at which leading scientists presented information about their research or about emerging technologies. A three-day training course designed specifically for new reviewers was presented on two occasions.

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 completed during the fiscal year.

1. Hardware

The Divisions' hardware needs were prioritized and requisitions were issued for over $195,700 in equipment and software.

Chart 16 - ODE Computer Hardware Status
FY 86 - FY 87

HARDWARE	On Hand in FY 86	Received in FY 87	On Hand in FY 87
DECmate II Word Processors	54	1	55
DECmate III Word Processors	13	25	38
LQPO2 Letter Quality Printers	28	2	30
LQPO3 Letter Quality Printers	5	0	5
LA50 Draft Quality Printers	38	1	39
LA100 Draft Quality Printers	6	2	8
LA210 Draft Quality Printer	1	1	2
LNO3 LASER Printers	8	11	19
VT220 Terminals	20	21	41
CP/M Boards for DECmates	22	23	45
Electrohome Projector	1	0	1
Compaq 286 PCs	0	3	3
Fujitsu Draft Printers	0	3	3
Macintosh Plus PCs	0	2	2
Laserwriter printers	0	2	2

2. Software

- o ODE Basic Tracking System. Last year, the major emphasis in software was 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. During FY87, all of the programming was completed, except for continuing minor adjustments.

- o Division Tracking System. In addition to the Basic Tracking System, the Division Tracking System was completed this year and is being fine-tuned. Each division maintains their portion of this system which enables them to mark and report the progress of applications through their individual organizations.

  The Office of Information Systems (OIS) programming staff has been very responsive in providing the additional reports identified as being needed by divisions during a series of meeting held during the fiscal year.

  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.

- o Other Tracking Systems. In addition to the two major tracking systems, a number of micro-computer and VAX-based systems were developed within ODE during the fiscal year. These systems supplement a number that are already in use within ODE divisions. A DECmate-based datafile was completed for the Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices (DOED) to enable more effective tracking of Freedom of Information requests. Division of Cardiovascular Devices (DCD) staff developed a special report using tracking system data. The report will be worked into the Division Tracking System by the OIS programming staff. Summer student employees and staffs in DOED, DCD, and the Division of Gastroenterology/Urology and General Use Devices developed specialized tracking systems and data bases.

During the year a spreadsheet program was developed to better enable the Office to track FTE usage and project year-end balance.

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 13 transmissions of draft summaries of safety and effectiveness were received during this fiscal year. Last year there were two transmissions received.

Even with the protocol developed by the Health Industry Manufacturers Association and the Center, micro-computer telecommunications is more of an art than science. The variations in personal computers, word processing applications, communications software, and telecommunications hardware make every transmission a challenge. And even when the transmission is successful, the document received normally requires extensive "cleaning up" by a secretary proficient with the DECmate word processor.

ODE has started to purchase IBM compatible personal computers. The telecommunications problems may be reduced or entirely eliminated if ODE can more closely match the systems in use by applicants. The new equipment will enable applicants to send diskettes from IBM or compatible PCs that can be read on similar ODE systems and, from there, transfered to DECmates, possibly through conversion programs resident on the Center's VAX computers.

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, two group training courses were presented during FY 87.

- o December 1986. Eleven trainees received basic word processing training. The training was conducted in Silver Spring by members of the OIS office automation staff.

- o March 1987. Thirteen trainees received instruction in basic word processing from OIS staff at Silver Spring Plaza.

5. Interagency Agreement

An Interagency Agreement (IAG) with the General Services Administration was completed in FY87. The IAG was for a study of the document handling processes involved in the review of 510(k), IDE, and PMA applications. The report identified 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. 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 87

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

[a] Estimate based on incomplete data.

Table 2. Original PMAs
FY 85 - FY 87

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

N/A Not available.

[a] Average FDA review time for FY 87 (in parenthesis) is the average FDA review time 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 87

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

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 notice in the *Federal Register*.

[b] Average FDA review time for FY 87 (in parenthesis) is the average FDA review time 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 atthe 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 87

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

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

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

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 thistime.

[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 87

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

Table 8. Major Submissions Reviewed
FY 80 - FY 87

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

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