OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

Fiscal Year 1985

Center for Devices and Radiological Health
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date MAY 15 1986

From Director, Office of Device Evaluation (HFZ-400)

Subject ODE Annual Report for Fiscal Year 1985

To Director
Center for Devices and Radiological Health (HFZ-1)

I am pleased to share with you the attached Annual Report which covers the activities of the Office of Device Evaluation for FY 1985. In the future, we will be issuing annual and periodic reports on our activities.

I am distributing the Annual Report to the ODE staff. ODE staff members should be proud of our collective accomplishments during FY 1985. Without their efforts, these achievements would not have been possible. As we apply new policies and procedures and continue to work hard and reach for individual and organizational excellence, 1986 should be even better.

Kshitij Mohan

Kshitij Mohan, Ph.D.

CONTENTS

TABLES

EXECUTIVE SUMMARY
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
FISCAL YEAR 1985

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In FY 85, ODE received more than 12,000 submissions, a slightly lower total than for FY 84. The resource demands for reviewing the submissions were far greater in FY 85, however, because of increases in the most resource-intensive types of submissions:

- ODE received 97 premarket approval applications (PMAs) in FY 85 as compared to 65 PMAs in FY 84, an increase of 49 percent.

- ODE received 5,261 510(k) notifications, more than in any previous fiscal year.

- ODE received 206 original Investigation Device Exemption (IDE) applications, more than in any fiscal year since FY 81.

ODE staff worked on the Center's criticism task forces to develop recommendations to improve program areas administered by ODE, and significant task force recommendations were incorporated in FDA's Action Plan, published in July 1985. ODE strived to cope with a burgeoning workload and insufficent resources by developing ways to reduce the workload and to streamline its review processes to the extent possible without compromising the protection of the public health. ODE's efforts to improve the review process resulted in the following:

- A policy reducing requirements for adding investigational sites that led to a 20 percent decrease in IDE supplements submitted.

- Procedures for adding contact lens finishing laboratories to an approved PMA for a rigid gas permeable contact lens.

- A task force to develop ways to reduce the backlog of PMAs and PMA supplements for intraocular lenses.

- Two new policies to allow annual reporting of certain changes in devices that previously required prior FDA approval of a PMA supplement.

- An initial reduction in the Office of the General Counsel's involvement in reviewing certain routine PMA summaries of safety and effectiveness.

- Delegation of authority for approval of many types of PMA supplements from the ODE office director to the division directors.

- A fast-track review process for simple PMA supplements for contact lenses.

- Improvement in the ODE document tracking systems and increased capabilities in office automation, both in acquisition of equipment and training of staff.

- Increased review and scientific support from other CDRH offices, particularly the Office of Science and Technology.

ODE was instrumental in achieving other results which clarified FDA policy or authority in the area of device evaluation. These included:

- Completion of most work on the pending classification rules and forwarding the "final" drafts to the office of the Associate Commissioner for Regulatory Affairs and the Office of the General Counsel.

- *Federal Register* notices proposing to require PMAs for three pre-Amendments class III devices: implanted intracerebral/subcortical stimulators; implanted diaphragmatic/phrenic nerve stimulators; and contraceptive intrauterine devices and introducers.

Despite the objectives achieved in FY 85, ODE's review backlogs continued to grow. This occurred because, as in previous years, the incoming workload exceeded the resources needed to perform all the work. While ODE is optimizing its staff through new efficiencies, it will be virtually impossible to eliminate the backlog until the available resources exceed the needs of the incoming workload. Nevertheless, the effect of new policies that have been established and others that will be established should result in some improvements in 1986.

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I. INTRODUCTION

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This report provides information about major programs administered by ODE during fiscal year 1985 (FY 85), 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 FY 84 and trend analyses. The report also discusses, in lesser detail, the classification project, freedom of information activities, the "issues" task force process, and development of "515(b) regulations" for pre-Amendments devices. Major issues in the scientific and regulatory/legal areas are identified and discussed as well as major management issues and initiatives.

This is the first of what will be a series of annual reports on the status of the approval programs administered by ODE.

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). Together these program areas resulted in ODE's receipt of more than 12,000 submissions in FY 85. Although this total is slightly lower than for FY 84, the resource demands for reviewing the submissions were greater in FY 85 because of increases in the most resource-intensive types of submissions.

The following table provides an overview of PMA, IDE, and 510(k) submissions received by ODE in FY 84 and FY 85. The remainder of this section describes the major review activities in more detail. (Additional data are contained in the referenced appendices.)

Table 1. PMA/IDE/510(k) Submissions Received
FY 84 - FY 85

TYPE OF SUBMISSION	No. RECEIVED FY 84	FY 85
Premarket Approval:		
Original Applications	65	97
Amendments	586	597
Supplements	435	393
Amendments to Supplements	520	628
Reports for Original Applications	205	236
Reports for Supplements	91	132
PMA Subtotal:	1,902	2,083
Investigational Device Exemption:		
Pre-Original Applications	9	22
Original Applications	203	206
Amendments	380	371
Supplements	3,077	2,463
IDE Subtotal:	3,669	3,062
Premarket Notification:		
Original Notifications	5,004	5,261
Supplements	2,000*	1,800*
510(k) Subtotal:	7,004	7,061
PMA/IDE/510(k) TOTAL:	12,575	12,206

*Estimate based on incomplete data.

A. PREMARKET APPROVAL

1. Premarket Approval Applications

Under the Food, Drug, and Cosmetic Act (the act), a manufacturer or others (the applicant) must submit a premarket approval application (PMA) for FDA review and approval before marketing a new device. The application 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 review panel for its recommendations on the application. After obtaining the panel recommendation, the agency makes its determination to approve the application, 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.

During FY 85, sponsors submitted 97 PMA applications compared to 65 applications submitted in FY 84, an increase of 49 percent. More PMAs were submitted in FY 85 than in any previous fiscal year.

The number of final approvals decreased from 43 in FY 84 to 37 in FY 85, continuing recent years' decline from a high of 48 approvals in FY 82. The decline in the number of PMA approvals since FY 82 reflects growth in PMA, IDE, and 510(k) workloads compared to resources, as discussed later in this report. The number of PMA approvals surged at the end of FY 85, however, with 13 occurring in the last two months of the year. This may be a result of recent ODE resource increases and initiatives to streamline the approval processes, also discussed later in this report. The following table provides additional comparisons between FY 84 and FY 85.

Table 2. Original PMAs
FY 84 - FY 85

ACTION	FY 84	FY 85	CHANGE	
Number Received	65	97	+ 32	(+49%)
Number of Final Approvals	43	37	− 6	(−14%)
Average FDA Review Time (Days) for Final Approvals	470	347	−123	(−26%)
Number Under Review at End of Year				
Active*	73	103	+ 30	(+41%)
On Hold**	55	60	+ 5	(+ 9%)
Total	128	163	+ 35	(+27%)

* FDA responsible for processing application.
** FDA's processing of application officially suspended pending receipt of additional information from the applicant.

The charts in Appendices A and B provide more of a historical perspective on incoming submissions and review times.

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. 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 upon the type of device, the significance of the change, and the complexity of the technology.

During FY 85, PMA holders submitted 393 PMA supplements as compared with 435 supplements in FY 84 (see following table). This decrease contrasts with past years during which the number of submissions increased rapidly. The reason for the decrease in submissions is uncertain, but the decrease occurred in the contact lens area where PMA supplement submissions historically have undergone alternating years of growth and retreat. The initiatives described later in this report also may have contributed to the decrease. Appendix A shows the trend in submissions of PMA supplements since FY 80.

Table 3. PMA Supplements
FY 84 - FY 85

ACTION	FY 84	FY 85	CHANGE	
Number Received	435	393	− 42	(−10%)
Number of Final Approvals	245	377	+132	(+54%)
Average FDA Review Time (Days) for Final Approvals	140****	240	+100	(+71%)
Number Under Review at End of Year*				
Active**	315	306	− 9	(− 3%)
On Hold***	74	80	+ 6	(+ 8%)
Total	389	386	− 3	(− 1%)

* The Center is aware of historical problems in the existing PMA data system that currently prevent us from obtaining accurate information on the number of "active" and "on hold" PMA supplements by year and by quarter. The numbers above are the most accurate available at this time. Work on new data systems should correct this problem, but, as a result, the numbers appearing above may ultimately be modified.

** FDA responsible for processing application.

*** FDA's processing of application officially suspended pending receipt of additional information from applicant.

**** Based on 9 months' data.

As shown in the above table, the number of PMA supplement approvals increased significantly from FY 84 to FY 85. More PMA supplements were approved in FY 85 than in any previous fiscal year. The increase in approvals, in conjunction with the decrease in submissions, resulted in the first reduction in the number of PMA supplements pending at year's end since at least FY 82.

3. Approvals of New Technologies

Several innovative devices resulting from new medical device technologies,including those described below, were approved for commercial distribution during FY 85.

- Lithotripter: The extracorporeal shockwave (ECSW) lithotripter is a major innovation for treatment of kidney stones. The device focuses shock waves on the stones, crumbling them into sand-like bits that can be passed in the urine. In most cases, treatment by ECSW lithotripter will be less painful, require less hospitalization, and may save about $2000 per case compared with surgery. This was the first approval of a device of this type.

- Cochlear Implant System: This innovative, single-channel device provides sensation of sound for profoundly deaf adults who cannot benefit from a hearing aid. Instead of amplifying sound and delivering it to the outer ear, the device converts sound to an electrical signal, processes it, and then broadcasts it through the skin to an implanted receiver. The receiver provides direct electrical stimulation to auditory nerve fibers in the inner ear. A multichannel cochlear implant that permits perception of a range of sound, rather than only the presence of sound, was reviewed during FY 85 and was approved during the first quarter of FY 86.

- Garren Gastric Bubble: This new device is a free floating balloon which is placed into the stomach through the esophagus and then inflated. The inflated device is about the size of a small juice can and is used as an adjunct to diet and behavior modification therapy for aiding weight loss in seriously overweight individuals.

- Ophthalmic Nd:YAG Lasers: Four PMAs for these lasers were approved during FY 85. Posterior capsulotomy using a YAG laser is a noninvasive operation in which the laser ruptures the capsular membrane left behind after extracapsular cataract extraction. The alternative procedure for posterior capsulotomy is invasive surgery. These were not the first ophthalmic Nd:YAG laser approvals (three others were approved in FY 84), but they are noteworthy for making more widely available this substitute for invasive surgery. Invasive surgery carries the added risk of infection and is more difficult when an intraocular lens is present, as is increasingly the case.

- Magnetic Resonance Imagers (MRIs): Two PMAs for MRIs were approved during FY 85. An MRI device uses radio waves and a strong magnetic field to produce a picture of the body that can differentiate between adjacent soft tissues that might look the same on an x-ray image. In addition, bones do not obscure underlying tissues in MRI imaging as they do with x-rays. These also were not the first MRIs approved, but are noteworthy.

B. INVESTIGATIONAL DEVICES

1. Investigational Device Exemptions

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

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

During FY 85, sponsors submitted 206 original IDE applications compared to 203 applications submitted in FY 84, as shown in the following table. More original IDE applications were submitted in FY 85 than in any fiscal year since FY 81, when ODE received 237 applications. A large number of applications received in FY 81 concerned investigations that were ongoing when the IDE regulation took effect. Appendix C shows the trend in submissions since FY 80.

Table 4. Original IDEs
FY 84 - FY 85

ACTION	FY 84	FY 85	CHANGE	
Number Received	203	206	+ 3	(+1%)
Number of Decisions	198	200	+ 2	(+1%)
Average Review Time (Days)	38	37	− 1	(−3%)
Proportion of Decisions Made Within 30 Days	62%	82%		+20%

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 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.

During FY 85, sponsors submitted 2,463 IDE supplements compared to 3,077 supplements submitted during FY 84 (see following table). This 20 percent decrease in IDE supplement submissions reversed years of rapid growth. The decrease resulted primarily from a new waiver policy that was instituted by ODE in FY 85 to reduce requirements for adding new sites to approved investigations. The waiver policy is described in Section V of this report. Appendix C shows the trend in submissions since FY 80.

Table 5: IDE Supplements
FY 84 - FY 85

ACTION	FY 84	FY 85	CHANGE
Number Received	3,077	2,463	−614 (−20%)
Number of Decisions	(not avail.)	2,126	(not avail.)
Average FDA Review Time (Days)	45*	33	− 12 (−27%)
Proportion of Decisions Made Within 30 Days	32%*	78%	+46%

* Estimate based on sample.

3. Approved Investigations of Innovative Technologies

FDA cannot disclose the existence of specific IDE applications. However, the sponsors of two investigations of innovative medical devices approved during FY 85 have disclosed their investigations' existence:

- Pennsylvania State University's artificial heart (the "Hershey Heart") is being investigated for use as a "bridge" for patients awaiting human heart transplants.

- The Jarvik-7 artificial heart was approved for investigational use as a bridge-to-transplant during FY 85. The IDE application for permanent use of the Jarvik-7 was approved in FY 81.

C. PREMARKET NOTIFICATION

1. 510(k) Reviews

Before placing a medical device into commercial distribution, a manufacturer or distributor must file a premarket notification, commonly known as a 510(k), with FDA at least 90 days before marketing. The 510(k) must include, among other items, a description of the device, the class under which it is to be regulated, and whether it is in compliance with any applicable performance standard. The 510(k) may also include a claim that the device is substantially equivalent to a pre-Amendments device. "Substantially equivalent" devices may be marketed subject to the same regulatory controls as their pre-Amendments predecessors. FDA reviews the submission to determine if the classification of the device is correct and whether the device is substantially equivalent to a device marketed before enactment of the Medical Device Amendments. If the device is not substantially equivalent, the manufacturer may petition for reclassification, submit a PMA to market the device, or submit an IDE to conduct a clinical investigation.

During FY 85, manufacturers and distributors submitted 5,261 510(k) notifications as compared with 5,004 510(k)s submitted in FY 84. More 510(k)s were submitted in FY 85 than in any previous fiscal year. (See Appendix D for information on submissions since FY 80.) As shown in the following table, 2.7 percent of 510(k) reviews in FY 85 resulted in "not substantially equivalent" determinations, an increase from 2.0 percent in FY 84.

Table 6. 510(k)s
FY 84 - FY 85

ACTION	FY 84	FY 85	CHANGE
Number Received	5,004	5,261	+257 (+ 5%)
Number of Decisions*	4,262	4,699	+437 (+10%)
Proportion "Not Substantially Equivalent"	2.0%	2.7%	(+ 0.7%)
Average Review Time (Days)	70	76	+ 6 (+ 8%)
Proportion of Decisions Made Within 90 Days	74%	68%	(– 6%)

* Includes "substantially equivalent" and "not substantially equivalent" decisions but does not include deletions, withdrawals, and other administrative actions.

2. Examples of Substantial Equivalency Findings

Noteworthy examples of devices found substantially equivalent during FY 85 include a DNA probe for the identification of bacterium Legionella, a DNA probe for the identification of herpes, and many in vitro diagnostic devices using hybridoma technology.

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. By the end of 1983, FDA had published final classification rules for the devices grouped under nine medical specialty panels. The agency had also published proposed classification rules for the remaining seven panels. During FY 85, ODE made a substantial effort to revise and complete these remaining rules for publication in the *Federal Register*. By the end of calendar year 1985, the bulk of the Center's work on pending classification rules was finished and the "final" drafts were forwarded to the office of the Associate

Commissioner for Regulatory Affairs and the Office of General Counsel for review. After review by these offices, the documents will be returned to ODE for final revisions before publication.

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

C. Activities of the Criticisms Task Forces/FDA's Action Plan

Because of criticisms leveled against FDA's implementation of the Medical Device Amendments, the Center established eleven task forces in FY 84 to analyze these charges and FDA's implementation of the Amendments, and to develop recommendations to improve the programs. This activity continued through FY 85.

Significant task force recommendations were incorporated into FDA's Action Plan, published in July 1985. ODE had major staff involvement in the task force process as many of the issues concerned program areas administered by ODE, and the office has expended significant effort in carrying out the Action Plan objectives. This effort will continue until appropriate actions have been implemented to accommodate valid criticisms and to make review processes more effective and efficient.

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

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

Nearly 150 generic types of devices have been 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. Accordingly, in a previous fiscal year, FDA published a *Federal Register* notice identifying the first 13 generic types of pre-Amendments

class III devices that had been assigned a high priority by FDA for the development of 515(b) regulations.

A 515(b) regulation was proposed and issued for one high priority pre-Amendments class III device (the implanted cerebellar stimulator) before FY 85 began. During FY 85, ODE continued development of 515(b) regulations. This effort resulted in the publication of three proposed 515(b) regulations during the fiscal year: implanted intracerebral/subcortical stimulators; implanted diaphragmatic/phrenic nerve stimulators; and contraceptive intrauterine devices and introducers. In addition, the agency received and began processing a petition to reclassify one other high priority device (automated heparin analyzers). Substantial progress was made in developing proposed 515(b) regulations for six of the remaining high priority devices.

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

IV. ODE ORGANIZATIONAL STRUCTURE

ODE is comprised of seven divisions grouped according to medical specialty: cardiovascular devices; anesthesiology, neurology, and radiology devices; surgical and rehabilitation devices; gastroenterology/urology and general use devices; obstetrics/gynecology, ear, nose, throat, and dental devices; clinical laboratory devices; and ophthalmic devices. Several small offices report directly to the ODE director: an administrative office as well as offices that coordinate the review of PMAs, IDEs, and 510(k)s. See Appendix E for an organizational chart.

At the end of FY 85, the equivalent of 184 full-time employees were working for ODE. This included 119 professionals (both administrative staff and scientific reviewers), 43 clericals, and 22 supervisors. (Because not all of these employees were on board for the entire year, ODE actually used about 176 FTEs during FY 85.)

ODE is located in the Silver Spring office of the Center. This causes a lot of lost time and frequent difficulties in travel and transfer of workload when consulting and coordinating work with other CDRH offices in Rockville. These problems were lessened in FY 85 through improvements in automation and communication described in Section V.

V. ISSUES AND INITIATIVES THAT IMPACT ON PROGRAM IMPLEMENTATION

The Center addressed a number of substantive issues affecting the policies and procedures of the approval programs during FY 85. The effort to resolve these issues was intensive and time consuming but was desirable because of the importance of these issues to the agency, the public, and the industry. The resolution of these issues and subsequent policy and procedural changes have had a significant impact on ODE resources and will make long-term contributions to the more efficient implementation of ODE programs. This in turn will enable safe and effective medical devices to be available for use sooner.

Many FDA offices contributed to the resolution of these issues, including various ODE staffs, other CDRH offices, the offices of the Associate Commissioners for Regulatory Affairs and for Health Affairs, the Office of General Counsel, and the Executive Secretariat. In many cases, the work begun in FY 85 will continue into the next fiscal year in order to complete agency policy or action on these issues.

A. GROWING WORKLOAD

Over the years, ODE's workload has increased dramatically, from the sheer volume of applications received to the complexity of the technologies that must be evaluated. As the medical device program matures, there is also an increase in ancillary activities such as reclassification petitions, requests for information and guidance, IDE waivers, policy modification, and general administrative support. The chart below vividly demonstrates the increase in applications submitted for review and action since FY 80.

Table 7. Submissions for ODE Review
FY 80 - FY 85

APPLICATIONS	NUMBER RECEIVED FY 80	FY 85	INCREASE	ANNUAL GROWTH RATE
510(k)s	3,167	5,261	+ 66%	11%
IDEs	71	206	+190%	24%
IDE Supplements	460	2,463	+435%	40%
PMAs	62	97	+ 54%	9%
PMA Supplements	165	393	+138%	19%

In the past, ODE was able to keep pace with the growing workload through increases in resources and declining resource needs in other program areas, such as device

classification. After FY 82, however, growth in workload began to outpace resources.

Appendix F shows ODE's incoming workload from FY 82 to FY 85, in terms of FTEs of effort necessary to review each year's submissions, and compares this workload to ODE's resources for each of these years. The incoming workload figures were derived from modules that convert numbers of different applications (e.g., PMAs, PMA supplements, etc.) into FTEs needed in ODE to review them. An additional number of FTEs was added for ODE's growing ancillary activities as well. The area between the workload curve and the resource curve represents the workload that surpasses the availability of resources. The short-fall in resources has resulted in increasing numbers of pending submissions, higher review times, and greater frequency of missed deadlines.

Because of the tremendous increase in workload, ODE has made a number of changes to streamline policies and procedures and to promote greater efficiency in the approval programs. These changes are discussed individually below. Other administrative initiatives were also instituted and these are discussed below as well.

B. POLICY AND PROCEDURAL CHANGES

1. Exemption from Premarket Notification

The act authorizes FDA to exempt a generic type of class I device from premarket notification if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of a device.

During FY 85, the Premarket Notification Criticism Task Force looked at exemptions from premarket notification and found that too few exemptions had been granted. To assist in remedying this situation, the task force developed criteria for determining whether an exemption from premarket notification is appropriate for a generic type of class I device.

During FY 85, ODE applied these criteria to class I devices in the seven medical specialty areas for which device classification is not yet final. Notices proposing these exemptions will be published along with these seven final classification regulations.

2. Waiver of Certain IDE Supplements

In previous years, the sponsor of an approved investigation was required to submit an IDE supplement to obtain FDA approval before adding investigational sites to the study. During FY 85, ODE adopted a policy that allows sponsors to add investigational sites to a study provided that the total number of sites does not exceed a specified number, the IRB at the new site approves the study without significant modification to the protocol or the informed consent procedures, and certain records are maintained and reports made to FDA.

This change has reduced submissions of IDE supplements by 20% without compromising the safety and protections provided to the public through the IDE program. At the same time, it has relieved the sponsors/industry of obtaining additional approvals.

3. Automatic Approval of Certain PMA Supplements

In May 1985, ODE streamlined the procedures for adding contact lens finishing laboratories to an approved PMA for a rigid gas permeable contact lens. The procedures allow the laboratories to begin manufacturing, selling, and shipping an approved lens 30 days after a PMA supplement containing certain required information is filed with FDA, if the original PMA application has an approved protocol for assessing the adequacy of new lens finishing laboratories and the PMA holder has not received a notice from FDA requesting additional information or denying approval. Under the previous procedures, the laboratories were not allowed to start manufacturing, selling, or shipping the lenses until the PMA holder received written FDA approval of the PMA supplement.

4. PMAs and Supplements for Intraocular Lenses

During FY 85, ODE established a task force to develop ways to reduce the backlog of PMAs and supplements for IOLs. As a result of this emphasis, 36 PMA supplements for IOLs were approved in FY 85 and at least 12 submissions were withdrawn after discussions with the applicants.

5. Annual Report in Place of PMA Supplements

During FY 85, ODE instituted two new policies intended to reduce delays for PMA applicants who wish to make certain changes in their devices. These policies allow annual reporting of the changes in place of the previous requirement of prior FDA approval of a PMA supplement. The first policy allows an applicant to annually report extensions in the shelf-life for an approved device, if the applicant has

received prior approval of a protocol for establishing shelf-life and follows that protocol. This policy change was accomplished by modifying the standard conditions of approval for PMAs. The second policy allows implementation of labeling changes for additional private labels and trade names for approved contact lenses, provided these changes are included in the next required annual report. Previous policies did not allow implementation of these changes until the applicant received written FDA approval of a PMA supplement. This new policy was instituted through a letter to contact lens manufacturers.

6. Eliminating Steps in the PMA Process

In an effort to speed PMA reviews while maintaining current quality, ODE eliminated some steps in the PMA and PMA supplement review processes. Early in FY 85, ODE reached agreement with the agency's Office of General Counsel (OGC) to modify OGC's participation in the review of certain routine PMA summaries of safety and effectiveness. This procedural change initially applied to PMAs for frequently reviewed devices such as cardiac pacemakers, contact lens heat disinfection units, and salt tablets for use in heat disinfection of soft (hydrophilic) contact lenses.

7. Fast-track Review of Simple PMA Supplements for Contact Lenses

In FY 85, resources were set aside in ODE's Contact Lens Branch for rapid processing of simple PMA supplements. The fast-track process helped to alleviate the backlog in PMA supplement reviews and was a major reason for the large increase in the number of decisions on contact lens PMA supplements during FY 85. The number of final decisions on PMA supplements for contact lenses, solutions, and accessories increased 58 percent from FY 84 to FY 85.

C. INTRA-CENTER DETAILS

Some of ODE's resource needs could be addressed with temporary reassignments of CDRH staff from other offices. At the end of FY 85, ODE management evaluated ODE's needs and requested details of staff with specific expertise, including engineers, statisticians, virologists, chemists, and generalists in the biological sciences. These details will occur in FY 86.

D. INTEROFFICE SUPPORT

In addition to actually detailing people within the Center to ODE, steps were taken to assure interoffice cooperation and support for the approval process. During FY 85, a protocol between ODE and the Office of Science and Technology (OST) was implemented to foster interoffice communication and to augment resources available for the review of applications. Under the protocol, the two offices agreed upon the general concepts which apply to the review of applications received by ODE and to the transfer of knowledge and skills concerning medical device technologies and their review between the two offices. OST provides ODE with engineering and scientific support in the review of applications, particularly those involving precedent-setting or unique issues, and in the development of guidelines for testing, analysis, or preparation of submissions.

The protocol has increased the cooperation and communication between the Offices and between Center scientists and thereby increased the scientific capabilities available for the review of submissions.

E. 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. In October 1984, ODE hired an individual to spend full time on these office automation activities.

1. Hardware

Based on the manner in which data systems are being developed and the desire on the part of Center management for electronic mail access to all Center employees, ODE's strategy is to obtain word processors for each secretary, terminals for each manager, and word processors or terminals for at least every two professional reviewers. The following table lists hardware acquired by ODE during FY 85.

Table 8. ODE Computer Hardware Status

HARDWARE	Ordered in FY 85	Received in FY 85
DECmate II Word Processors	10	15*
DECmate III Word Processors	10	10
LQP02 Letter Quality Printers	5	5
LQP03 Letter Quality Printers	5	5
LA50 Draft Quality Printers	20	20
LA100 Draft Quality Printers	1	1
LN03 LASER Printers	4	6**
VT220 Terminals	10	10
CP/M Boards for DECmate IIs	20	0
Hard Disk Drives for DECmates	21	0

* The 15 DECmate IIs received in FY 85 were ordered in FY 84.
** Two of the LASER Printers were provided to ODE by the Division of Computer Services.

2. Software

Throughout FY 85, a great deal of emphasis has been placed on developing software for the three major document tracking systems, PMA, IDE, and 510(k), that run on the Center's Rockville, Maryland computer systems. Nearly all of the programming is being done by the Center's Division of Computer Services (DCS) staff. The basic tracking systems have been conceptualized and under development since before October 1984. During FY 85, however, a major effort was undertaken to consolidate the systems into one computer system specifically reserved for data processing applications. The basic IDE tracking system has been functioning throughout the year, primarily because the IDE staff has been able to assist with computer program development.

3. Training

ODE's greatest continuing need in office automation is to make its staff comfortable with office automation and capable of seeing and taking advantage of the capabilities available to them. Training is one of the keys to accomplishing this. A number of efforts were undertaken in FY 85. First, ODE made available a full time office automation specialist who could help individual users as, and at the time, problems arose.

In addition, in February 1985, 91 ODE staff members received training in office automation at 36 training sessions averaging 3 hours each.

4. Telecommunications

Through most of FY 85, ODE staff communicated with the Center's Rockville-based computers using their terminals or word processors connected via modems and standard telephone lines. Because of many problems relating to conditions beyond the control of users, such as electrical surges, construction vibrations, "noisy" telephone lines, and faulty equipment, the quality of transmissions left much to be desired. Consequently, the Center decided to replace the modem-operated system with an ETHERNET network which uses smart electronic circuits to control the flow of data at eight times the rate possible over standard telephone lines and with a very low level of distortion. Installation of ETHERNET in ODE will begin in FY 86.

ODE has been involved in one other aspect of telecommunications. The Health Industry Manufacturers Association (HIMA) in June 1985 requested that ODE participate in developing a protocol for transmitting documents between non-DEC microcomputers and an ODE DECmate II word processor. A number of test transmissions have been conducted successfully and a protocol on electronic data transmission will be developed by HIMA for use by its membership.

VI. SUMMARY

During FY 85, ODE received more than 12,000 PMA, IDE, and 510(k) submissions -- over 100 submissions per technical reviewer. Although the total number of submissions was slightly lower than for FY 84, ODE's resource demands were higher due to increases in the types of submissions that require the most resource-intensive reviews. ODE received more original PMAs and 510(k)s in FY 85 than in any previous fiscal year, and more IDEs than in any fiscal year since FY 81. Decreases in supplemental submissions, which are relatively less resource-intensive, accounted for the decline in the total number of submissions received.

ODE undertook numerous initiatives during FY 85 to reduce workload growth and to streamline its review processes, to the extent possible without compromising public health protection. New or modified policies and procedures were put into effect in FY 85. One impact of these initiatives was the reduction in supplemental submissions described above. For example, a new IDE waiver policy instituted by ODE in FY 85 resulted in a 20 percent decrease in IDE supplement submissions from FY 84 to FY 85. Other steps taken to improve the review process include increases

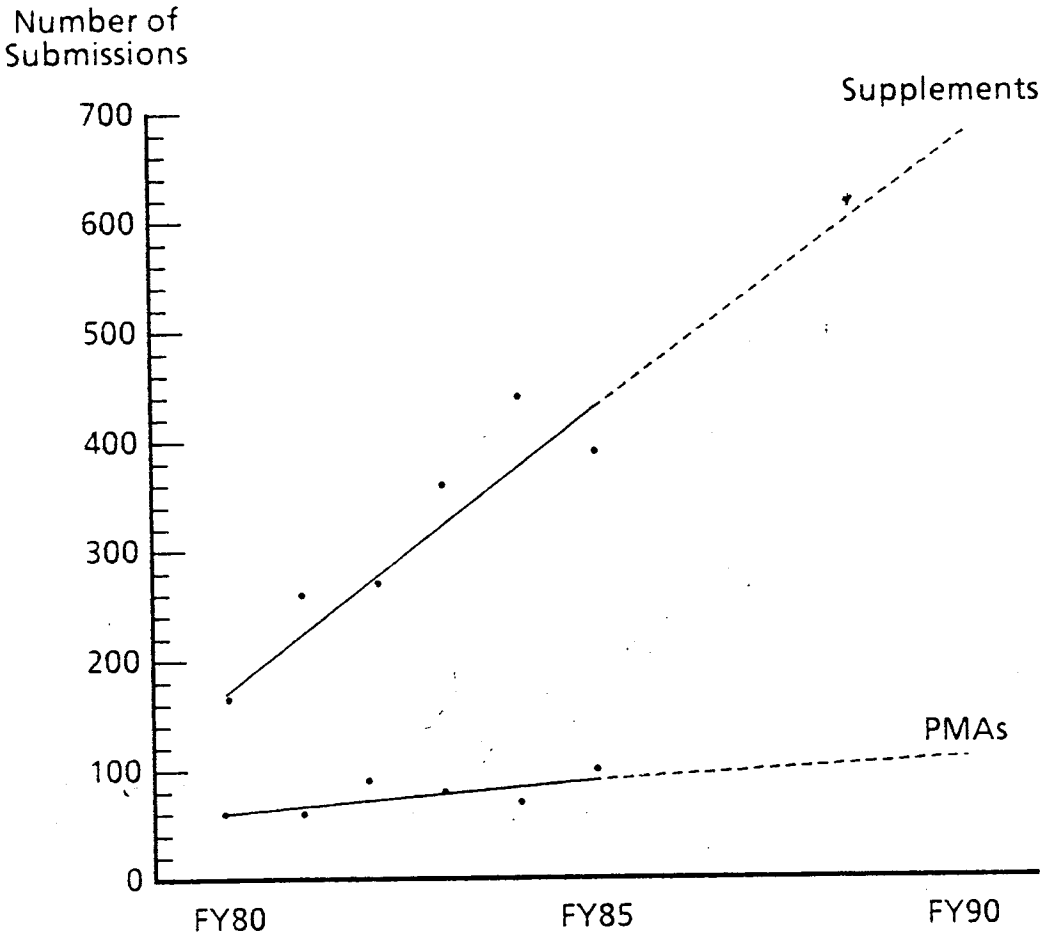
in interoffice support, initiatives to improve public and internal guidance about the device review processes, and continued increases in office automation. These efforts provided some immediate benefits and will make significant long-term contributions to the efficiency and quality of ODE programs.

Despite the efficiencies achieved in FY 85, review backlogs continued to grow. This occurred because the FY 85 incoming workload exceeded the resources needed to perform all the work. This condition has persisted for a number of years. Until the available resources, optimized through new efficiencies, exceed the needs of the incoming workload, it will be virtually impossible to eliminate the backlog.

On balance, ODE has a basically sound system for the processing of submissions. The staff is well qualified and hard working. It has made progress against a tremendous workload under conditions that were far from ideal. Nevertheless, the current system can benefit from policy and procedural changes and management initiatives that will improve efficiency and output.

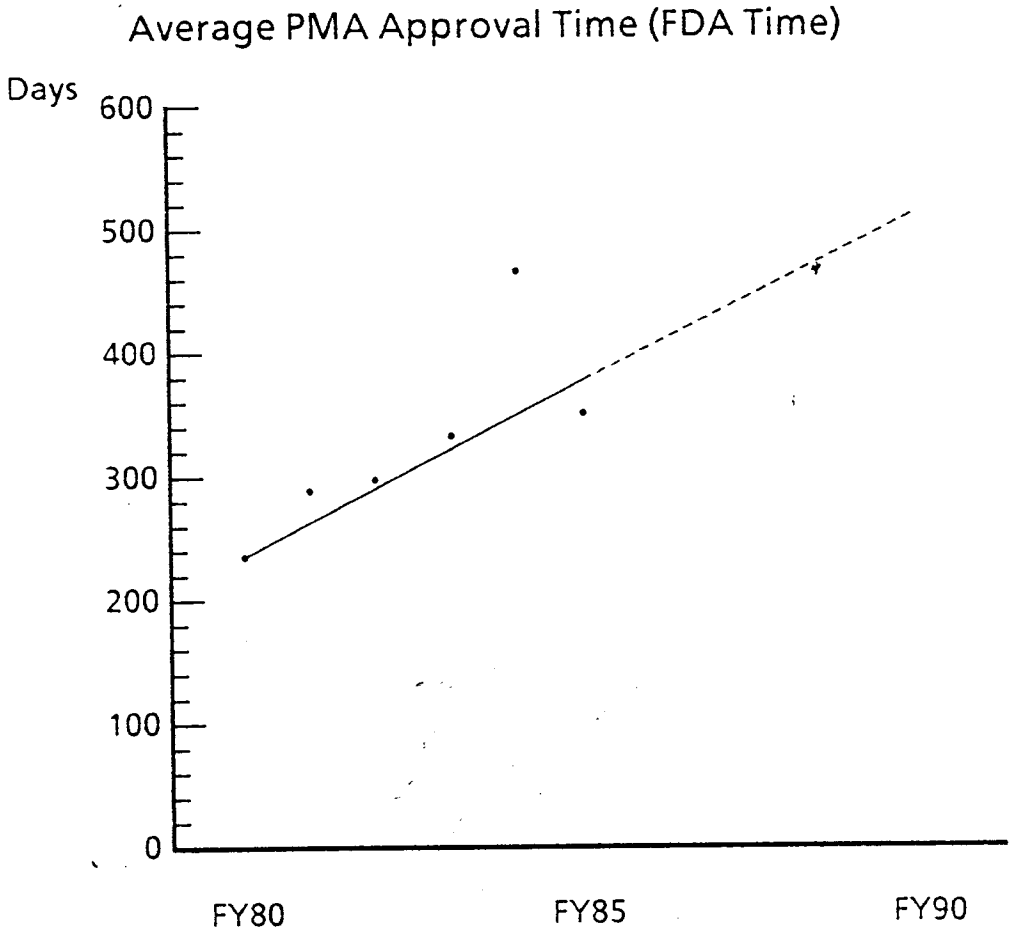
The improvements that were initiated in FY 85 are already having a positive effect and they will be continued and expanded in FY 86 to obtain optimum performance within available resource constraints.

PMA and PMA Supplement Submissions



FY	PMAs Received	PMA Supplements Received
80	62	165
81	60	259
82	90	277
83	76	360
84	65	435
85	97	393
Annual growth rate FY80-FY85:	+ 9%	+ 19%

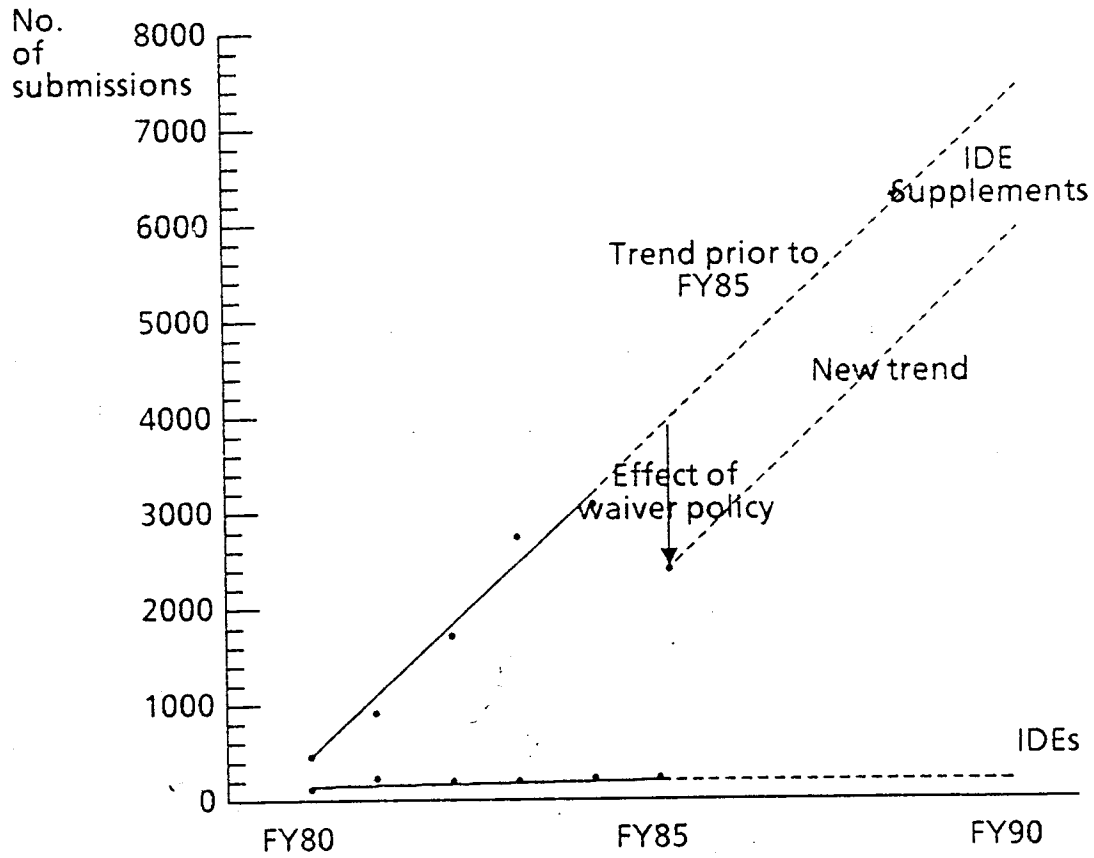
APPENDIX B



FY	Average Number of Days Required to Review PMAs
80	230 (Data are not currently
81	290 available for some PMAs
82	294 approved during FY80-FY82)
83	329
84	470 High due to approval of AFP PMAs
85	347

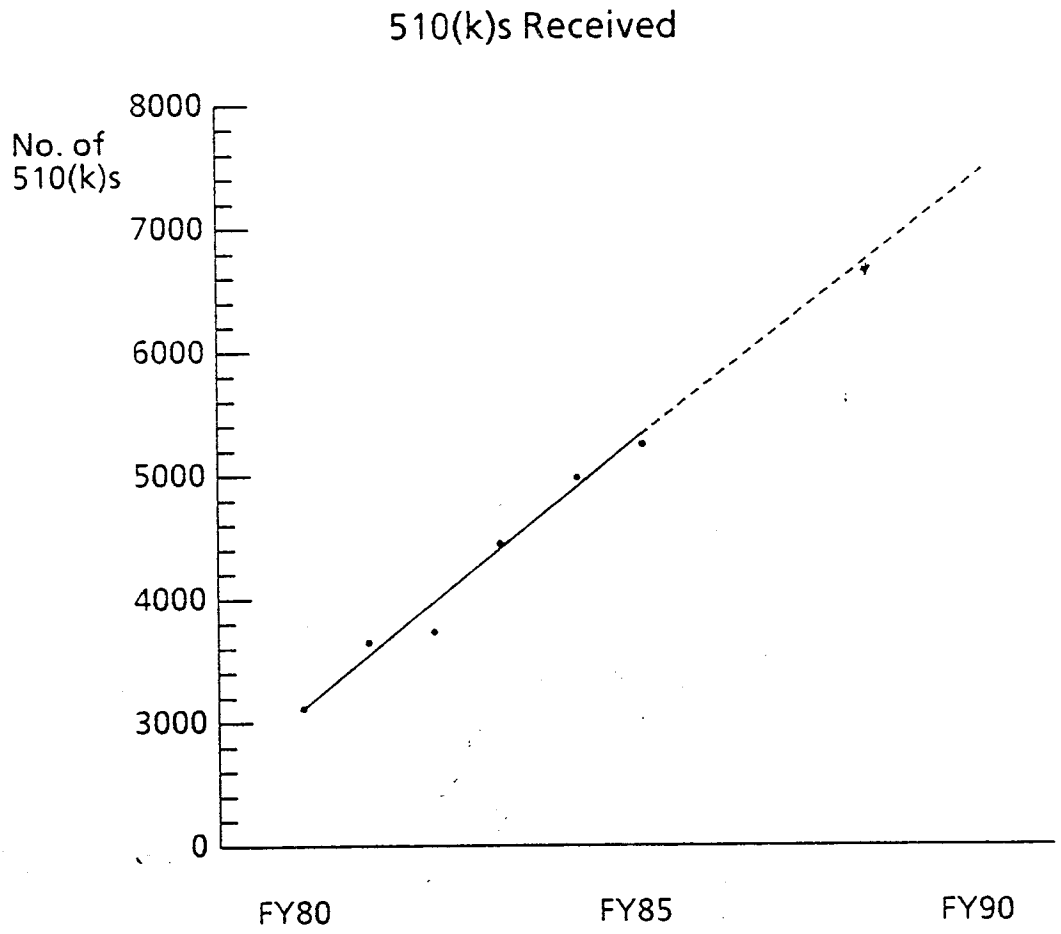
APPENDIX C

IDEs and IDE Supplements Received



FY	IDEs Received	IDE Supplements Received
80	71	460
81	237	924
82	189	1694
83	189	2750
84	203	3077
85	206	2463

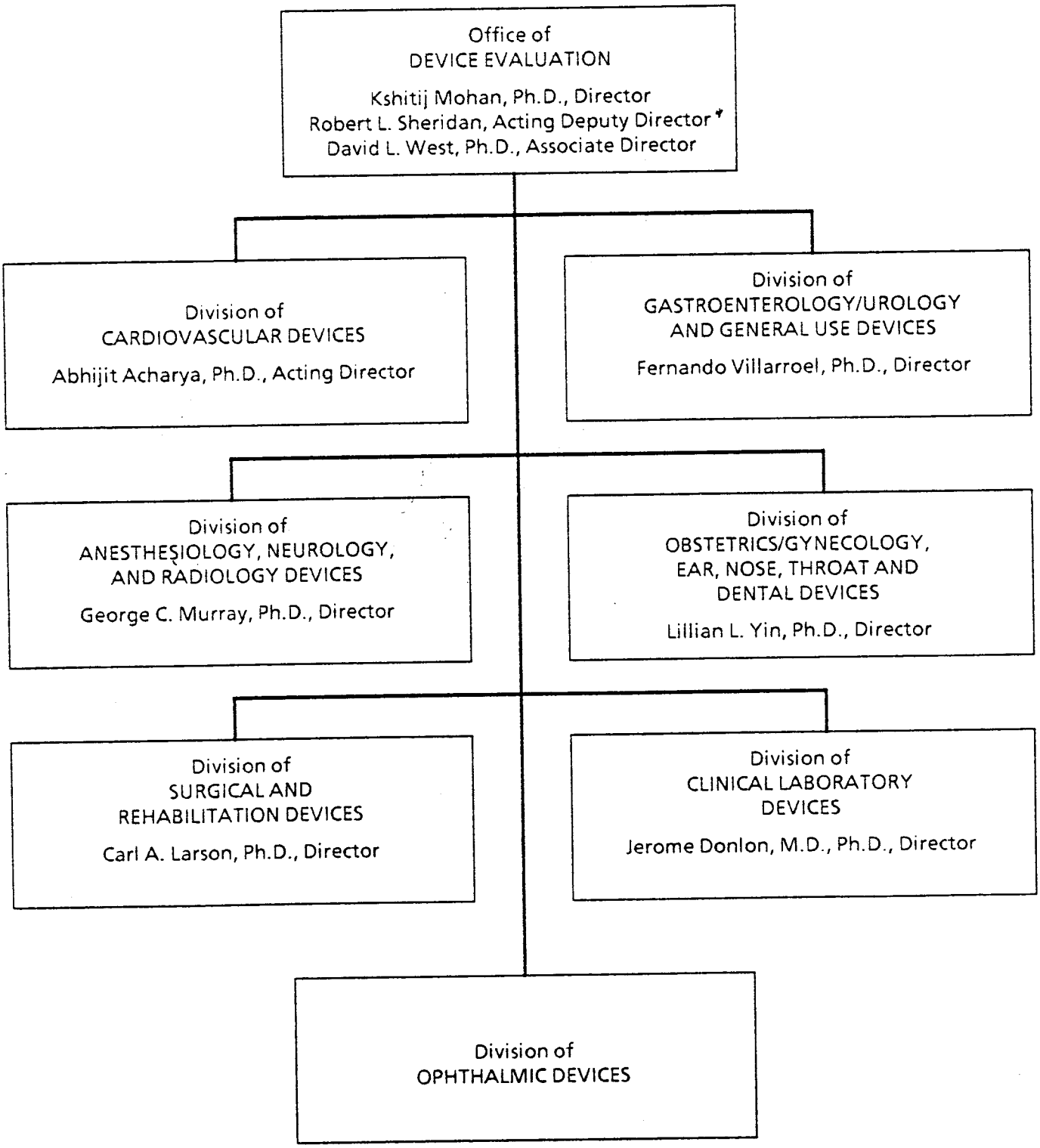
APPENDIX D



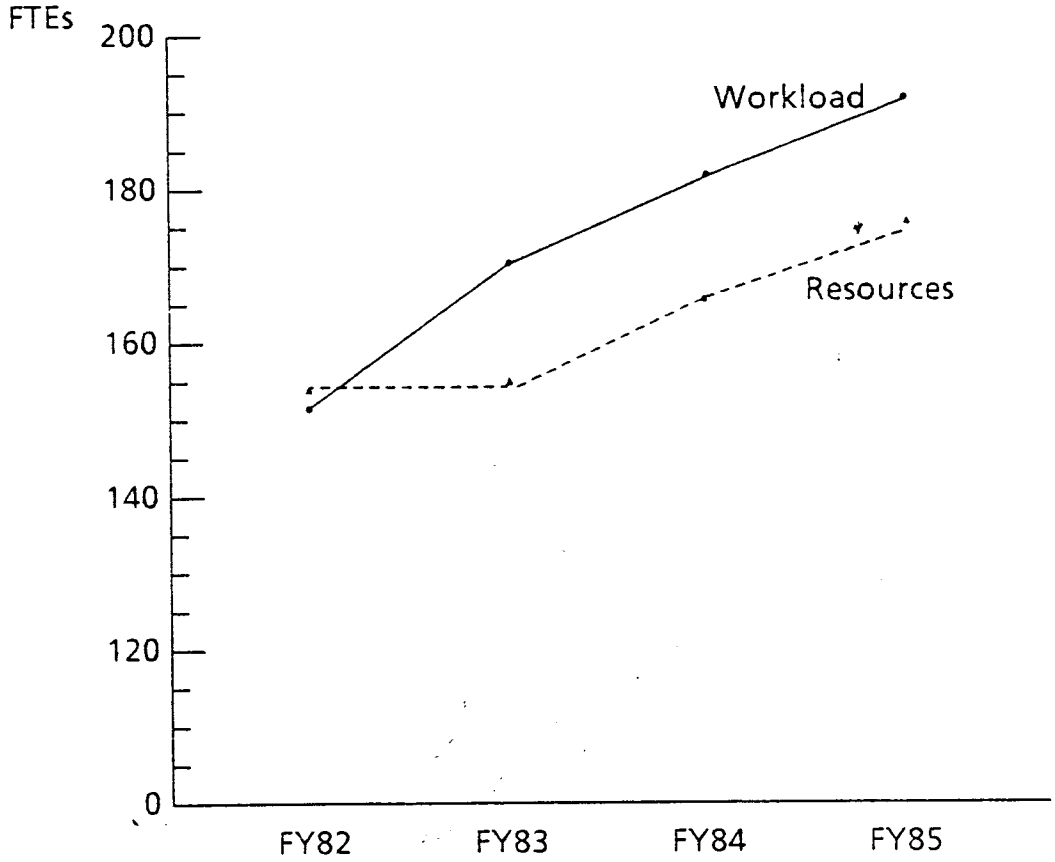
FY	510(k)s Received
80	3167
81	3684
82	3798
83	4477
84	5004
85	5261

APPENDIX E

Office of Device Evaluation



Incoming ODE Workload vs. Resources FY82 - FY85



FY	Estimated Incoming ODE Workload (FTEs)	Resources (FTEs)*
82	152	154
83	170	155
84	182	166
85	192	176

* FY 82 and FY 83 resource and workload figures adjusted to include functions shifted to ODE in FY 84 (e.g., document control).