OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1991

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

Acknowledgements

Carl T. DeMarco compiled and edited the report. The PMA, IDE, and 510(k) staff offices, in conjunction with Eileen Marshall of the Office of Information Systems, provided the data used in the report. The Office of Health Affairs, CDRH, provided valuable assistance by reviewing this report .

OFFICE OF DEVICE EVALUATION
ANNUAL REPORT
Fiscal Year 1991

Dear ODE Colleague:

Attached is the ODE Annual Report for Fiscal Year 1991. It contains statistical tables for our three major program areas: premarket approval; investigational devices; and, premarket notification. In addition to the statistical data, the summary analysis highlights important program and production information. Unlike previous annual reports, this report does not contain divisional data and statistics. During this fiscal year, ODE reorganized from seven divisions to five divisions so we do not have a full year of data for either organizational structure. We believe this new structure will improve the quality and efficiency of our review programs.

On November 28, 1990, the Safe Medical Devices Act became law. These changes in the law will improve the implementation and enforcement of our review programs and ensure the safer use of medical devices. At the operational level, the requirements of this law and other programmatic changes related to the review and processing of submissions have already had a significant impact on ODE operations and we expect this to continue into the foreseeable future.

In FY 91, we received 16,639 total submissions, which represents the second largest number of total sumbissions ever received. On the output side, we completed the review of 10,085 major submissions. Average review times were reduced or remained stable for all document types except 510(k)s, for which they went up. Average review times are likely to continue to rise for 510(k)s because of the programmatic changes discussed in the report. The total number of documents under review at the end of this fiscal year remained stable or went down for all but two categories of documents, PMAs and 510(k)s. There were only two PMAs, one PMA supplement and one original IDE active and overdue at the end of the year.

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Executive Summary
Office of Device Evaluation Annual Report
Fiscal Year 1991

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 1991 (FY 91). These highlights are explained more fully in the body of the report.

General

On November 28, 1990, the President signed into law the Safe Medical Devices Act of 1990(SMDA). This new law has significant implications for various CDRH and, specifically, ODE programs, especially the premarket approval and 510(k) program areas. It will, however, take some years before the law is fully implemented. As the various provisions of the law are implemented, the effect upon ODE programs will be described in the Annual Report. The implementation of the law will be discussed under each program area that is affected by the specific implementing regulations or policy/procedural changes. For this fiscal year, both the PMA and 510(k) sections of this report contain descriptions of the implementation actions that have taken place in each program area.

Workload

During FY 91 ODE received 16,639 total submissions, an increase of 760 over last fiscal year. This represents the second largest number of total submissions ever received during one fiscal year. The record number of total submissions received in FY 89 was due to exceptional circumstances that year. This year's increase represents a normal increase in line with our experience in other fiscal years. The same is true for the number of major submissions: PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s. We received a total of 10,581 major submissions during FY 91, which represents an increase of 428 over last year.

Along with an ever increasing number of submissions being received, there are related program factors that have increased the difficulty and time required to process submissions. The specific factors are discussed under each program area, as appropriate, and include implementation of the SMDA, 510(k) exemptions, participating in the Congressional hearing process, cooperating with program audits by the General Accounting Office, Office of the HHS Inspector General, and various outside consultants. All of these activities have had an impact on the time ODE staff has to deal with applications. The time consumed by some of these activities is transitory, but some of them, such as implementation of the new requirements of the SMDA, will have an enduring effect.

On the output side, ODE reviewed 10,085 major submissions, which represents a small decrease of 345(3%) from last year's all time high of 10,430. This fiscal year ended with virtually no active and overdue submissions.

Resources

ODE's authorized FTEs went from 227 in FY 90 to 251 in FY 91. The actual FTE usage during this fiscal year was 259, but ODE ended the year with 266 employees on board, down from the 276 employees on board at the end of last year. In FY 91, ODE lost 25 employees (14 scientific reviewers and 11 support staff) through resignation or retirement. This attrition was offset somewhat by the addition of 10 new full-time employees and three part time employees during the year; however, only four of the new hires were scientific reviewers and nine were support personnel.

Premarket Approval

During this fiscal year, PMA productivity increased. We received 75 original PMAs. The total number of PMA actions, including filing decisions(104), review activity determinations(160) and review decisions(100), rose significantly from 315 last year to 364 for FY 91. This number of total PMA actions is a better indication of the level of output in the PMA area than just the number of approvals. There were 27 PMAs that received final approval and another 15 original PMAs for which approval packages were prepared but could not be approved because of the applicants' inability to meet manufacturing inspection requirements.

Average FDA review time for original PMAs was reduced from 228 days in FY 90 to 199 days during FY 91. Total review time, however, rose from 283 days last year to 285 days in FY 91 because nonFDA review time rose from 55 days in FY 90 to 87 days this fiscal year. This is the third year in a row in which nonFDA time has risen.

Unlike the stability of average review times, average elapsed time rose dramatically from 415 days last year to 633 days in the current reporting period. There was a modest increase in the FDA component of the total elapsed time but the nonFDA component nearly tripled, from 113 in FY 90 to 298 this year.

The total number of PMAs under review at the end of the fiscal year rose somewhat from 116 to 135. The active PMAs under review at the end of this fiscal year numbered 49, compared to 44 last year, while those on hold went up a bit from last year, from 72 to 86. Most importantly, the number of PMAs that were active and overdue was reduced from 5 last year to 2 at the end of FY 91.

During FY 91, PMA supplement activity returned to normal after last year's record setting pace. The number of supplements received has fallen from last year's 660 to 593. The total number of PMA supplement actions, including panel track filing decisions(13), review activity determinations(265), and review decisions(752), likewise, dropped to 1,030 from the record 1,258 total actions taken in FY 90. This level of total actions is comparable, and somewhat higher than, the total actions taken in the years prior to last year's record output in this program area. There were a total of 480 PMA supplements that received final approval. These approvals included two "panel track" supplements.

The FDA average review time for PMA supplements was reduced from 133 days in FY 90 to 111 days this year and total average review time dropped from 159 days last fiscal year to 143 days by the end of this year, despite a rise in the nonFDA review time from 26 to 32 days since FY 90.

Average elapsed time also dropped from 180 days in FY 90 to 175 days this year, due to the reduction in FDA elapsed time from 146 to 131 over the same period of time. NonFDA elapsed time rose from 35 to 44 days in FY 91.

The 339 total number of PMA supplements under review at the end of this year remained essentially identical to last year's 335. The number of PMA supplements that were active and overdue were practically eliminated, being reduced from seven at the end of the last fiscal year to one at the end of this year. The number of active supplements and the number of supplements on hold remained virtually the same as last year.

Investigational Devices

Although we received a fewer number of IDEs(213) and amendments(283), we experienced a record number of supplements(3,647). The total number of original IDE decisions dropped slightly from last year and the amendment decisions rose somewhat over last fiscal year; however, the number of decisions on supplemental IDEs rose dramatically from 2,968 in FY 90 to 3,705 in FY 91, a 25% jump in productivity. Average review times for each of these submission types remained virtually constant with the last few years and 99% of all decisions were made within the prescribed 30 days. There was one original IDE, but no amendments, or supplements, active and overdue at the end of FY 91.

Premarket Notification (510(k))

During this reporting period, ODE received 5,770 original 510(k)s as compared to 5,831 received during FY 90. There were also 3,917 510(k) supplements that came in during this fiscal year. Both original and supplemental 510(k)s total 9,687 submissions, the second highest number of 510(k) submissions ever received in one fiscal year. The number of final decisions rendered on original 510(k)s during FY 91 was down from the previous two years during which time we saw a record number of receipts and decisions.

Both the total and FDA average review times were adversely affected during FY 91. The total average review time rose from 98 days in FY 90 to 102 days for FY 91 and the FDA review time went up to 81 days from 78 days in FY 90. FY 90 was the first full year in which the first two of the following programmatic factors had a negative impact on 510(k) average review times. These two factors, plus the new requirements of the SMDA were present in FY 91 as well. In fact, these three factors are likely to have a significant impact on 510(k) review times for the foreseeable future.

- Nearly 40% of Class I 510(k)s have been exempted from 510(k) review. These were the "easier" submissions that took less review time, did not wait in a cue, and were processed without delay. Removing these exempted products from review left the more difficult and time consuming 510(k)s which raises the average review time.

- There has been an increase in the reviewer documentation of decisions for 510(k)s in order to improve consistency among 510(k) decisions. This has caused an increase in the time required to complete each 510(k) review.

- New requirements of the SMDA, as discussed in the report, below.

Guidance for Industry and Reviewers

ODE and its divisions developed 23 guidance documents on the following subjects for use by industry and ODE reviewers.

- Review and Approval of Licensee PMAs
- Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements
- Picture Archiving and Comunications Systems (PACS) and Related Devices
- Device Labeling Guidance
- Air Conduction Hearing Aid Guidance
- Diagnostic Ultrasound Guidance Update
- Antimicrobial Sensitivity Devices
- Clinical Utility and Premarket Approval
- Panel Review of Premarket Approval Applications
- PMA Compliance Program
- Hyperthermia Devices used for the Treatment of Benign Prostatic Hyperplasia (BPH)
- Document Review Processing
- Integrity of Data and Information Submitted to ODE
- Cytogenetic Analysis
- Blood Culture Systems
- Borrelia Burgdorferi (Lyme Disease)
- Review of Final Draft Medical Device Labeling
- Review of 510(k)s for Computer Controlled Medical Devices
- Cholesterol
- Cyclosporine
- Self-Monitoring Blood Glucose Devices
- Glycohemoglobin(glycated hemoglobin)
- Lymphocyte Immunophenotyping Monoclonal Antibodies

Reclassification

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

- Microsurgical argon laser for use in rhinology and laryngology
- Natural nonabsorbable surgical silk suture

FDA also published final rules on the following devices previously reclassified from class III to II:

- Nonabsorbable poly(ethylene terephthalate) surgical suture
- Nonabsorbable polypropylene surgical suture
- Nonabsorbable polyamide surgical suture
- Absorbable poly(Glycolide/l-lactide) surgical suture

In addition to the foregoing final actions, FDA published a proposed rule in the *Federal Register* to reclassify the hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis from class III to class II.

Call for PMAs for Pre-Amendments Devices

FDA published a notice of applicability of a final rule in the *Federal Register* of June 26, 1991 to clarify that replacement heart valve allografts are subject to the final rule that had been published in the *Federal Register* of May 13, 1987 requiring the filing of PMAs for all pre-Amendments replacement heart valves. Manufacturers of currently marketed replacement heart valve allograghs were required to have an approved PMA or IDE in effect on or before August 26, 1991, or cease distribution of the device. On July 29, 1991, we published a notice in the *Federal Register* to extend this effective date to November 25, 1991. Subsequent to this action, a petition was filed and the effective date is under reconsideration.

Advisory Panel Activities

During FY 91, ODE held 26 medical device advisory panel meetings. In FY 91, the sixteen independently chartered advisory panels were rechartered as subcommittees of an omnibus Medical Devices Advisory Committee. The result of the rechartering is that the logistics of scheduling meetings is simplified and, more importantly, the appropriate voting expertise that is so critical to credibility is more attainable. ODE is in the process of creating a database for use within the Center that will provide quick access to the speciality areas represented by all of the approximately 340 panel members and consultants. This will be especially useful in taking advantage of the increased flexibility available under the new charter for moving panelists around within the committee system.

ODE Integrity Program

During FY 90, ODE initiated an ODE Integrity Program. During FY 91, the program attained a new level of maturity and activity. It currently consists of four major components: Enforcement, Ethics, 510(k) Performance Monitoring, and 510(k) Quality Reviews. Each of these components is described in the report, below. Under the Integrity Program, ODE issued the following Blue Book Guidance Memoranda during FY 91:

- 510(k) Independent Quality Review Program
- Document Review Processing
- Integrity of Data and Information Submitted to ODE

Under the enforcement component of the Integrity program, ODE referred 20 submissions to the Office of Compliance for investigation. Under the ethics component, we referred 5 complaints to the FDA Ethics Branch for resolution.

Freedom of Information Requests

ODE received for processing 1,098 Freedom of Information requests.

Office Management and Automation

The major office management event of this fiscal year was the reorganization of ODE from seven to five divisions. The new organizational structure is an attempt to respond to both growth and technological change that have resulted in an increased and diversified workload. These changes provide greater scientific and technical focus, better alignment of functions and staff, and improved management control and more effective supervision. Review procedures have been enhanced by the improved management structure and the proper realignment of product specialties.

Despite a significantly reduced office automation budget, we continued to build upon a foundation of installed equipment to improve office automation capabilities. We received PCs that were ordered in FY 90 which expanded our base of PCs. This expanded base helped reduce the equipment incompatibilities between PCs and DECmates and provided a computer capable of word processing to each individual needing this equipment. We expanded our LAN capabilities through the purchase of LAN hardware and commenced the process of having 510(k)s and recently completed PMAs scanned to the CDRH IMAGE system.

ANNUAL REPORT
OFFICE OF DEVICE EVALUATION
FISCAL YEAR 1991

I. Introduction

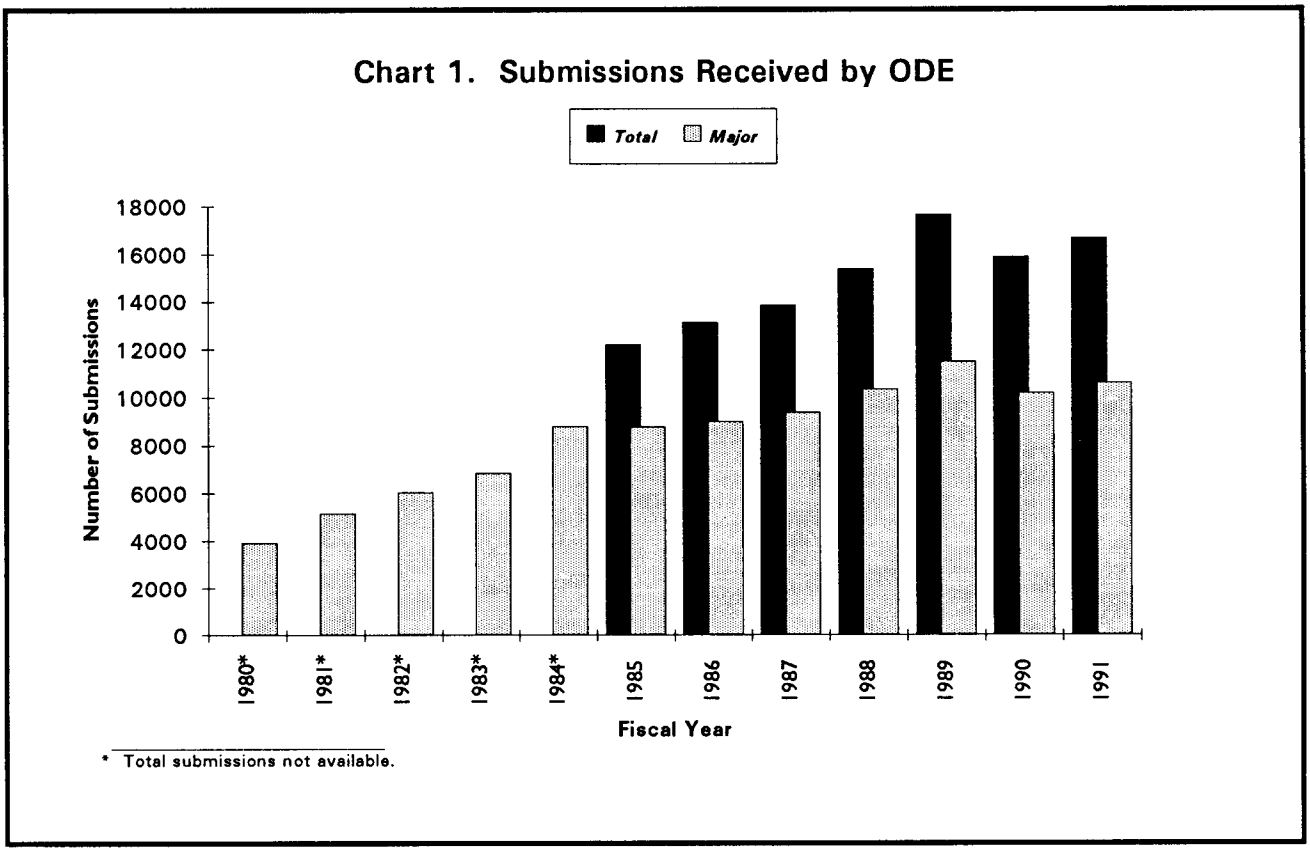
The Office of Device Evaluation(ODE) in the Food and Drug Administration's(FDA) Center for Devices and Radiological Health is responsible for the program areas through which medical devices are evaluated and cleared for human clinical trials or marketing. This report provides information about major programs administered by ODE during Fiscal Year 1991(FY 91), beginning on October 1, 1990 and running through September 30, 1991. It emphasizes activities of the premarket approval, investigational device exemption, and premarket notification programs. The report contains comparative performance data from previous fiscal years and trend analyses. Procedure and policy guidance and other major management initiatives to further implement our policy and program goals and to streamline our procedures are discussed in detail. The report also discusses device reclassification, freedom of information, and PMAs for pre-Amendments devices under Section 515(b).

On November 28, 1990, the President signed into law the Safe Medical Devices Act of 1990(SMDA). This new law has significant implications for various CDRH and, specifically, ODE programs, especially the premarket approval and 510(k) program areas. It will, however, take some years before the law is fully implemented. As the various provisions of the law are implemented, the effect upon ODE programs will be described in the Annual Report. The implementations of the law will be discussed under each program area that is affected by the specific implementing regulations or policy/ procedural changes. For this fiscal year, both the PMA and 510(k) sections of this report, below, contain descriptions of the implementation actions that have taken place in each program area.

II. Overall Workload and Resources

A. Workload

During FY 91 ODE received 16,639 total submissions, an increase of 760 over last fiscal year. This represents the second largest number of total submissions ever received during one fiscal year. The record number of total submissions received in FY 89 was due to exceptional circumstances that year. This year's increase represents a normal increase in line with our experience in other fiscal years. The same is true for the number of major submissions: PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s. We received a total of 10,581 major submissions during FY 91, which represents an increase of 428 over last year. On the output side, ODE reviewed 10,085 major submissions, which represents a decrease of 345 from last year's all time high of 10,430.



Along with an ever increasing number of submissions being received, there are related program factors that have increased the difficulty and time required to process submissions. The specific factors are discussed under each program area, as appropriate, and include implementation of the SMDA, 510(k) exemptions, participating in the Congressional hearing process, cooperating with program audits by the General Accounting Office, Office of the HHS Inspector General, and various outside consultants. All of these activities have had an impact on the time ODE staff had to deal with submissions. This can be seen in Chart 5, which indicates a drop in the number of major submissions completed per FTE during FY 91. The time consumed by some of these activities is transitory, but some of them, such as implementation of the new requirements of the SMDA, will have an enduring effect. This may become a trend that will persist into the foreseeable future.

B. Resources

During the past fiscal year, ODE's authorized FTEs went from 227 in FY 90 to 251 in FY 91. The actual FTE usage during this fiscal year was 259, but ODE ended the year with 266 employees on board, down from the 276 employees on board at the end of last year. In FY 91, ODE lost 25 employees (14 scientific reviewers and 11 support staff) through resignation or retirement. This attrition was offset somewhat by the addition of 10 new full-time employees and three part time employees during the year; however, only four of the new hires were scientific reviewers and nine were support personnel.

Chart 2. ODE Full Time Equivalents

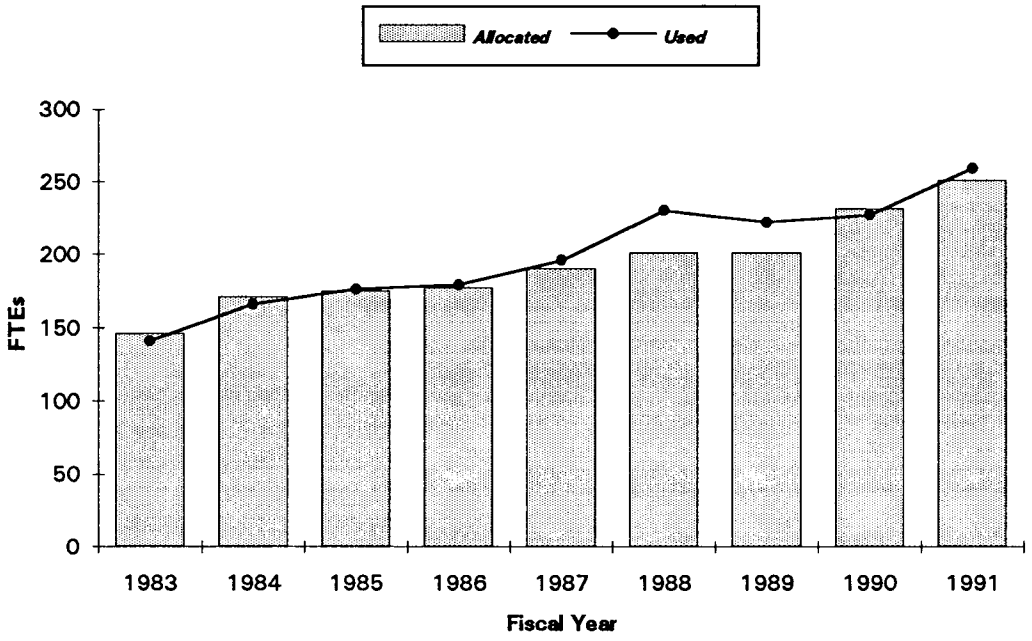


Chart 3. Workload vs. Resources

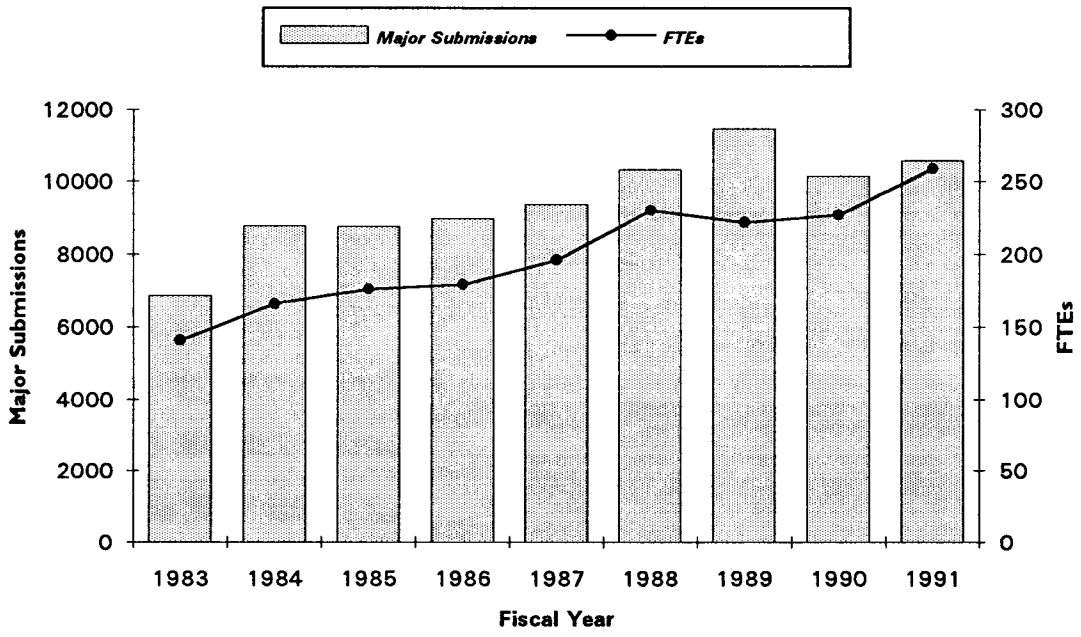


Chart 4. Major Submissions vs. Major Reviews

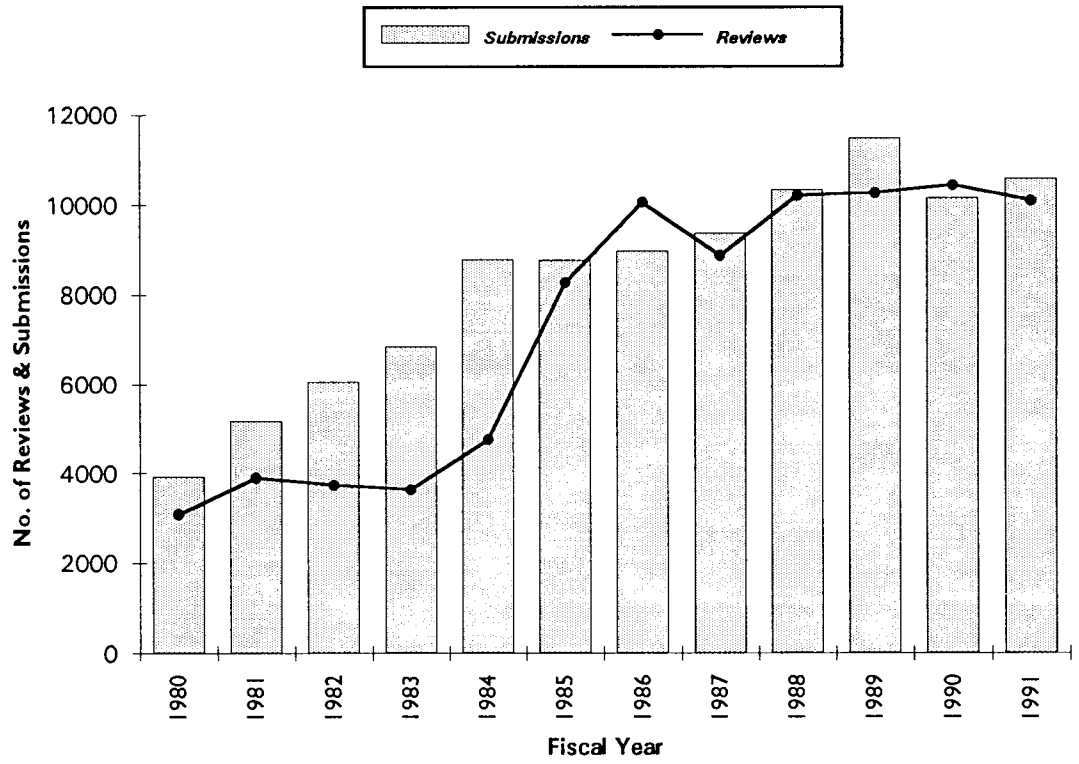
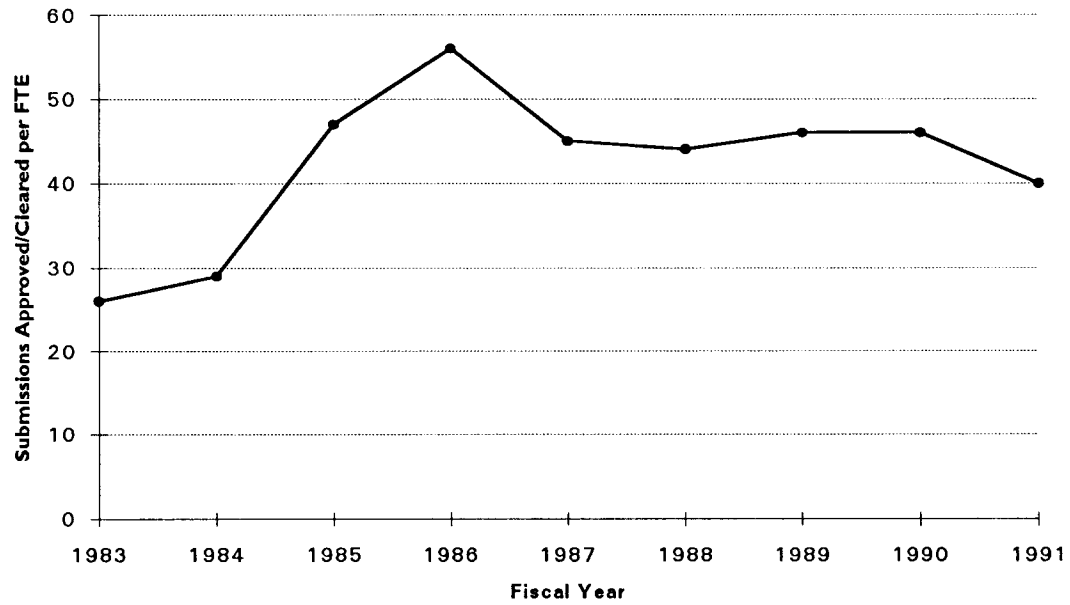


Chart 5. Submissions Approved/Cleared vs. Resources



III. Major Program Activities and Performance

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

A. Premarket Approval

1. Premarket Approval Applications (PMAs)

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

During FY 91, the enactment of the SMDA brought about a number of changes related to the PMA requirements and authorities under the act. For example, the SMDA:

- authorizes the temporary suspension of the premarket approval of a device;
- no longer requires panel review of every PMA;
- requires the review of transitional and other specified class III devices that presently do not require a PMA to determine whether any of these devices should be reclassified;
- authorizes, upon certain conditions, the granting of a humanitarian device exemption for devices intended for use in fewer than 4,000 individuals;
- requires the establishment of new procedures to regulate products that constitute a combination of a drug, device or biological product;
- provides specific authority to include preproduction design validation of devices under GMPs; and,
- incorporates many new postmarket surveillance requirements, some of which involve the direct participation of the ODE staff.

These changes in the law will improve the Agency's implementation and enforcement of the PMA program and ensure the safer use of PMA devices. At the operational level, they will have a significant impact on ODE staff time, which, in turn will have an ultimate effect upon the review of PMAs.

For FY 91, some changes have been instituted in the statistical tables for original PMAs and PMA supplements, Tables 2 and 3, respectively, as set forth in Part VI. In previous reports, we reported average reviews times as calculated by two methods, the method that was in use prior to the promulgation of the PMA regulation and the method that was prescribed in the PMA regulation. In this report, both methods are provided, but in a different format.

The first averages, identified as average review time, represent the calculation of review times as specified in the PMA regulation. Under this regulation, the review clock is reset upon the receipt of a major amendment. The review clock may also be stopped but not reset for minor amendments and other actions. Thus, these average review times may exclude review time that occurred prior to the receipt of a major amendment. They will include, however, all increments of review that occurred after the receipt of the last major amendment, if any. This average is a good indication of how well FDA is doing in reference to the 180 day review period allowed by law.

The second averages, identified as the average elapsed time, is the average review time as calculated according to the method that was in use prior to the promulgation of the PMA

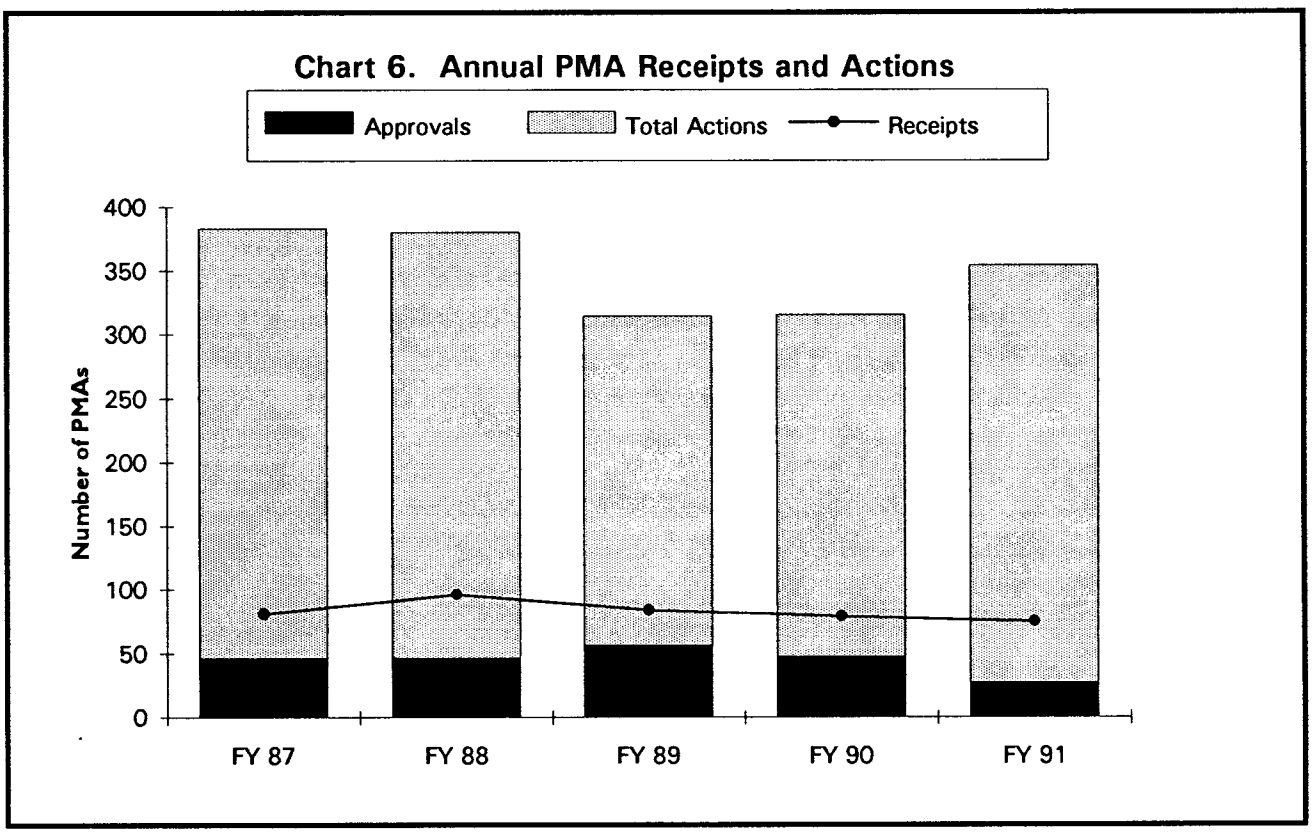
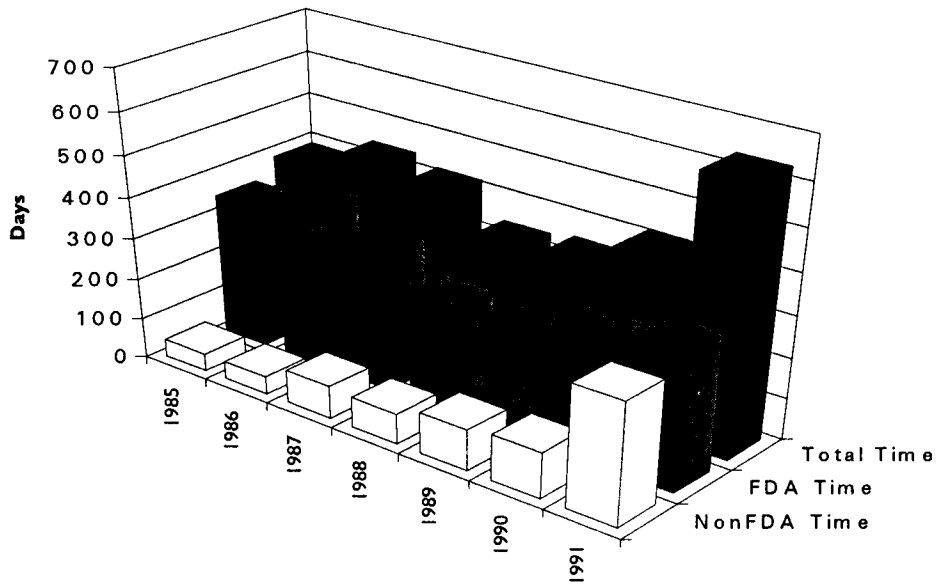


Chart 7. Average Approval Times for PMAs

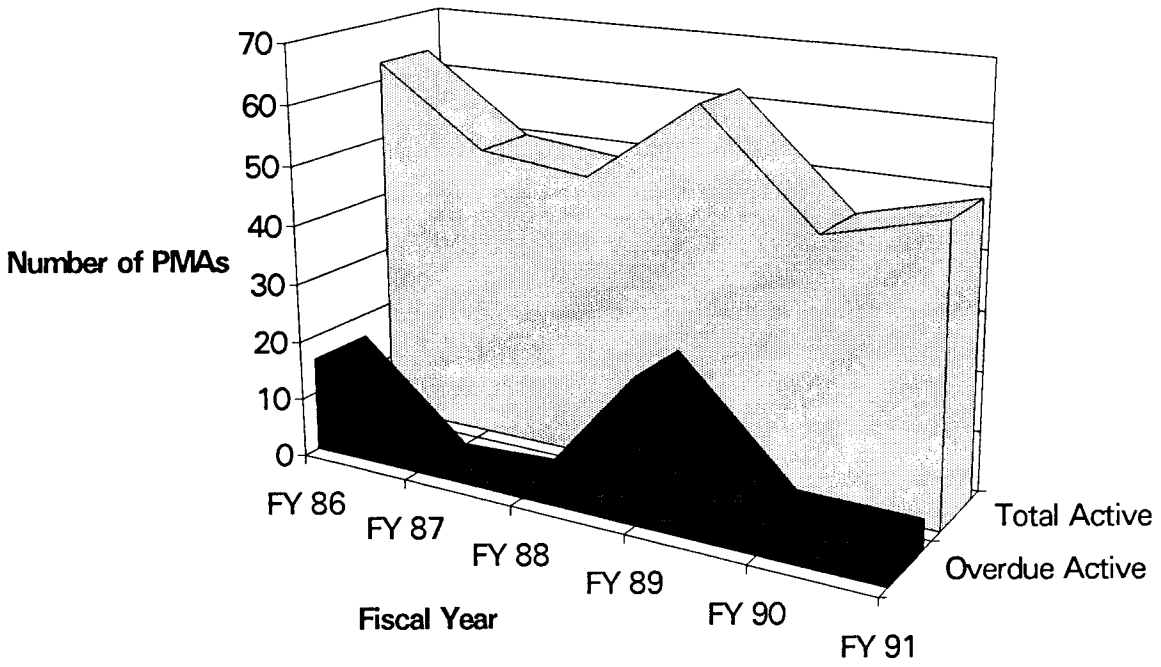


regulation. It includes all increments of time the PMA was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. This average will continue to be reported because it indicates the average time it takes to get final approval of a PMA from the date it was filed.

In addition to the foregoing, these tables now include statistics on the number of PMAs and PMA supplements that were filed , not filed, and other filing actions. The tables also include data on review activities, i.e., major and minor deficiency determinations and other administrative actions that are made between the time an application is filed and approved or disapproved. Along with filing and review data, these tables include data on the number of approval, approvable, and not approvable review decisions, and other decisions. This data is similar to the data we started reporting for the IDE program last year.

During this fiscal year, PMA productivity increased. We received 75 original PMAs. The total number of PMA actions, including filing decisions(104), review activity determinations(160) and review decisions(100), rose significantly from 315 last year to 364 for FY 91. This number of total PMA actions is a better indication of the level of output in the PMA area than just the number of approvals. There were 27 PMAs that received final approval and another 15 original PMAs for which approval packages were prepared but could not be approved because of the applicants' inability to meet manufacturing inspection requirements.

Chart 8. End-of-Year Active PMAs



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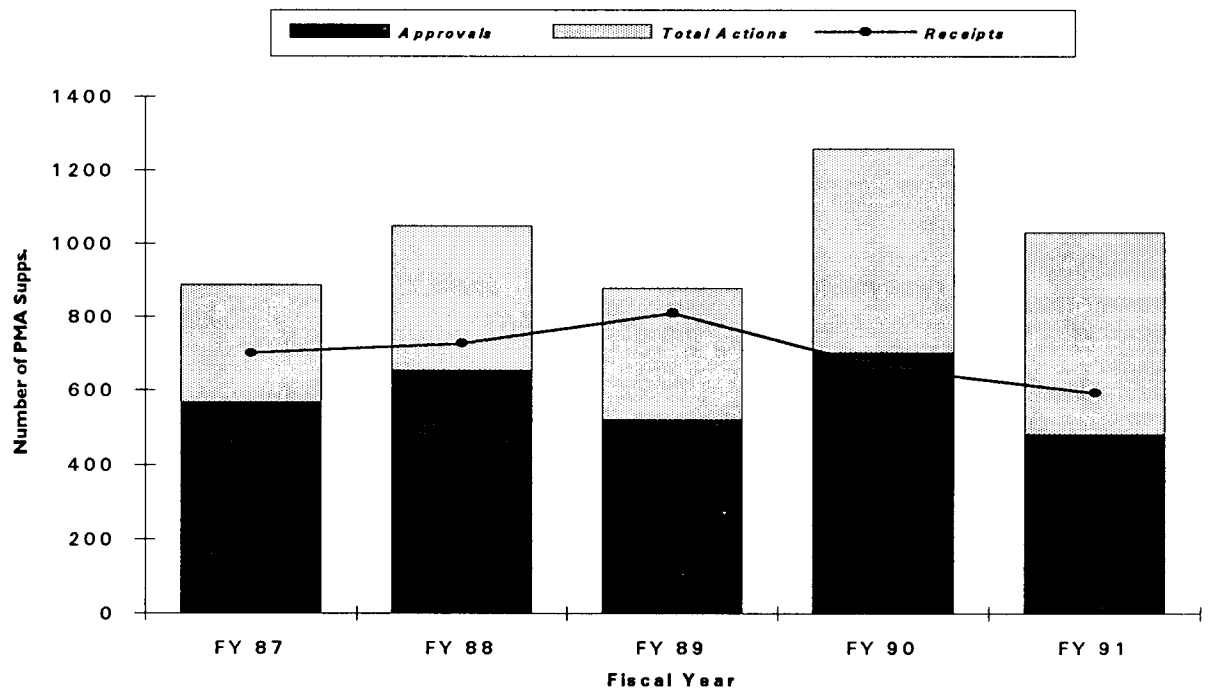
The total number of PMAs under review at the end of the fiscal year rose somewhat from 116 to 135. The active PMAs under review at the end of this fiscal year numbered 49, compared to 44 last year, while those on hold went up a bit from last year, from 72 to 86. Most importantly, the number of PMAs that were active and overdue was reduced from 5 last year to 2 at the end of FY 91.

2. PMA Supplements

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

Chart 9. Annual PMA Supplement Receipts and Actions



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higher than, the total actions taken in the years prior to last year's record output in this program area. This number of total PMA supplement actions is a better indication of the level of output than just the number of PMA supplement approvals. There were a total of 480 PMA supplements that received final approval. These approvals included two "panel track" supplements. Panel track supplements require the full administrative procedures normally associated with original PMAs, i.e., Panel review, preparation of a summary of safety and effectiveness, and publication of a *Federal Register* notice.

The FDA average review time for PMA supplements was reduced from 133 days in FY 90 to 111 days this year and total average review time dropped from 159 days last fiscal year to 143 days by the end of this year, despite a rise in the nonFDA review time from 26 to 32 days since FY 90.

Chart 10. Average Approval Times for PMA Supplements

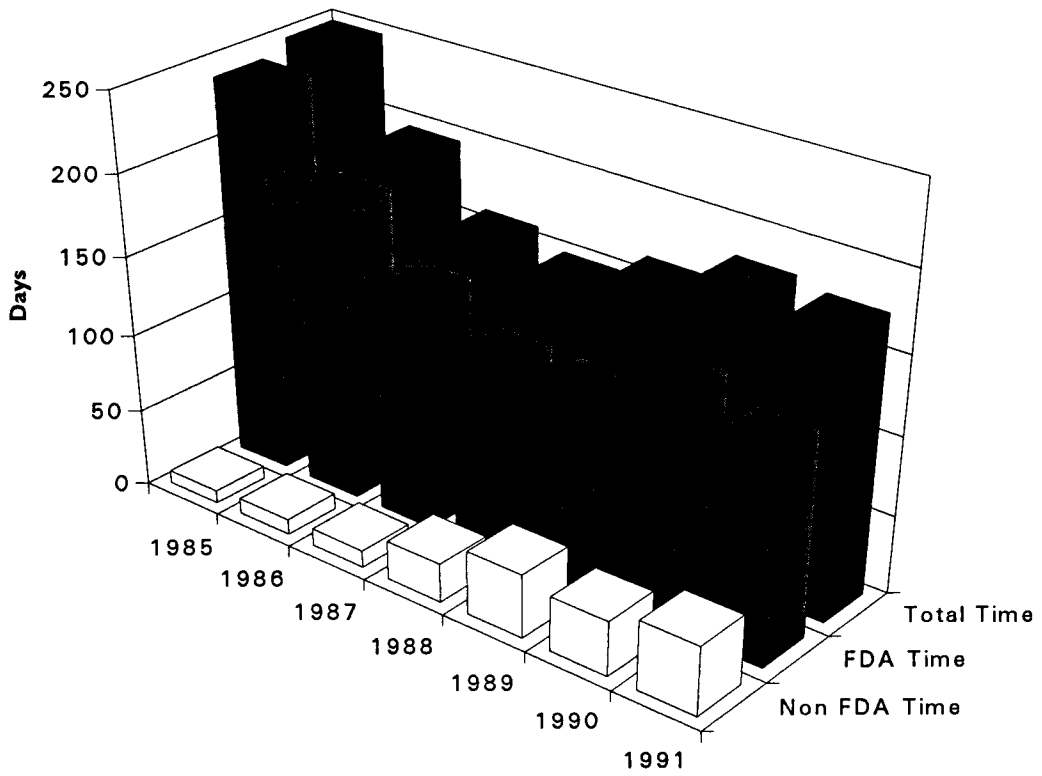
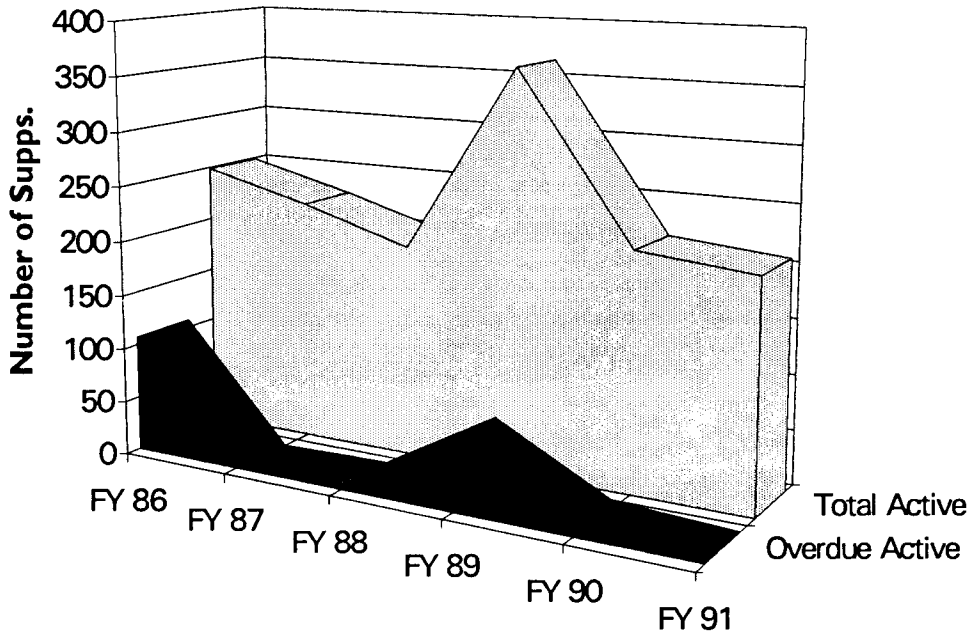


Chart 11. End-of-Year Active PMA Supplements



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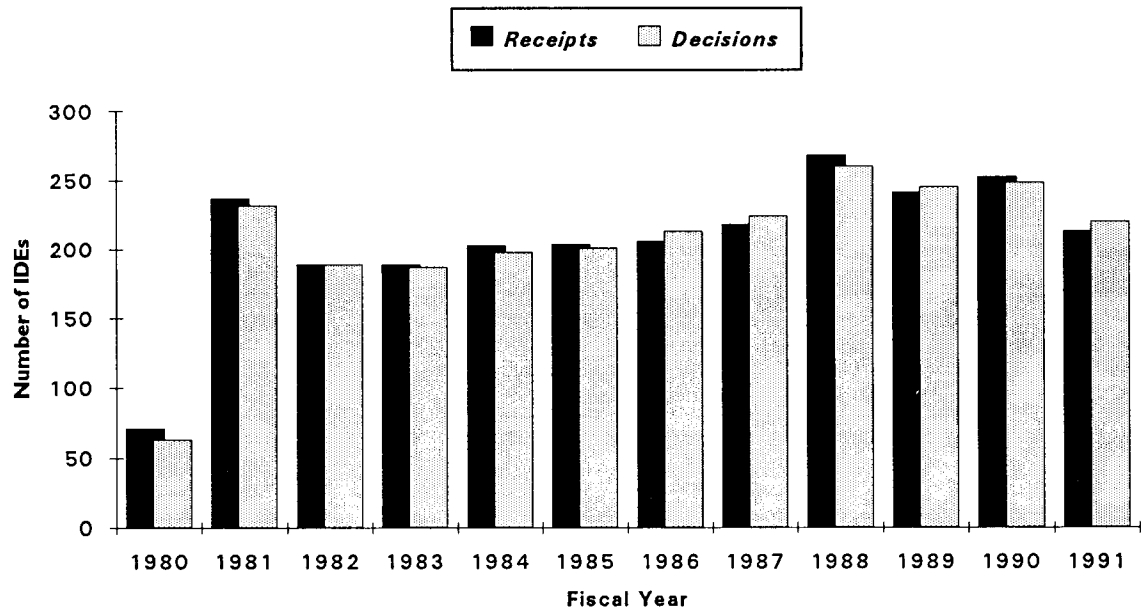
The 339 total number of PMA supplements under review at the end of this year remained essentially identical to last year's 335. The number of PMA supplements that were active and overdue were practically eliminated, being reduced from seven at the end of the last fiscal year to one at the end of this year. The number of active supplements and the number of supplements on-hold remained virtually the same as last year.

B. Investigational Devices

1. Investigational Device Exemptions (IDEs)

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

Chart 12. Annual IDE Receipts and Decisions



We received 213 original IDEs during FY 91, which is 39 fewer than last fiscal year and represents a return to the pre-FY 88 level of IDE submissions. The same holds true for IDE approvals; the 220 original IDE decisions made during FY 91, down from 248 last year, is comparable to the pre-FY 88 output. This is expected because the output closely parallels the input because of the short turn around times involved with IDE reviews. The average FDA review time for original IDEs remained constant since last year at 29 days. Also, 99% of all original IDE decisions were completed within 30 days. The number of IDEs under review at the end of this fiscal year dropped slightly to 12, down from 20 at the end of last year. There was one IDE overdue at the end of the year.

Chart 13. Timeliness of IDE Decisions, by Quarter

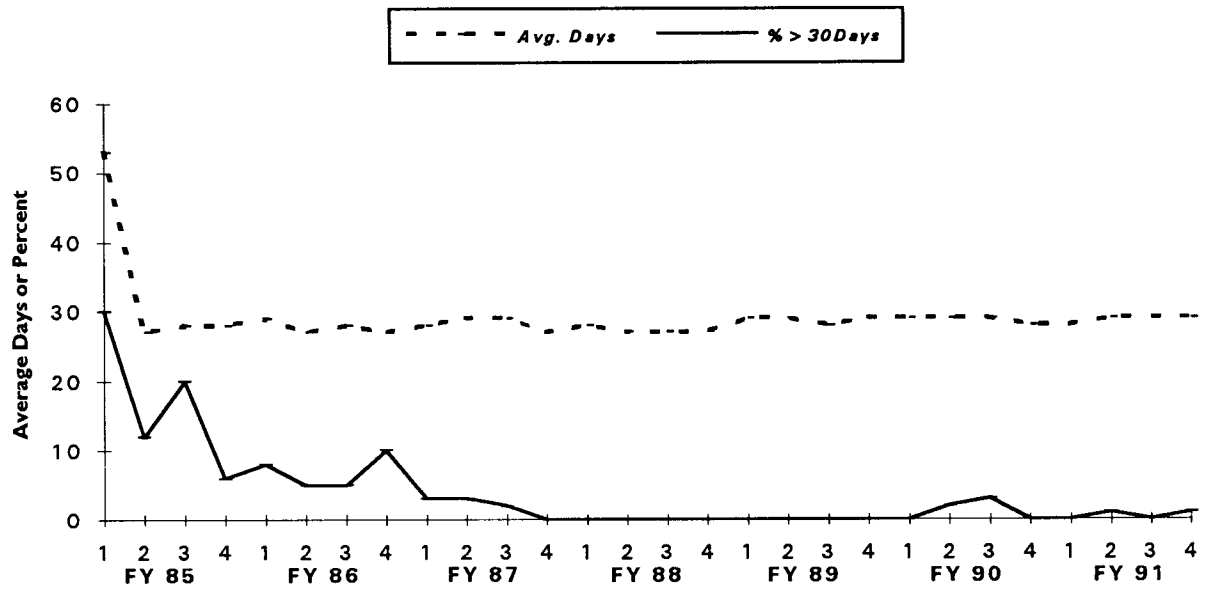
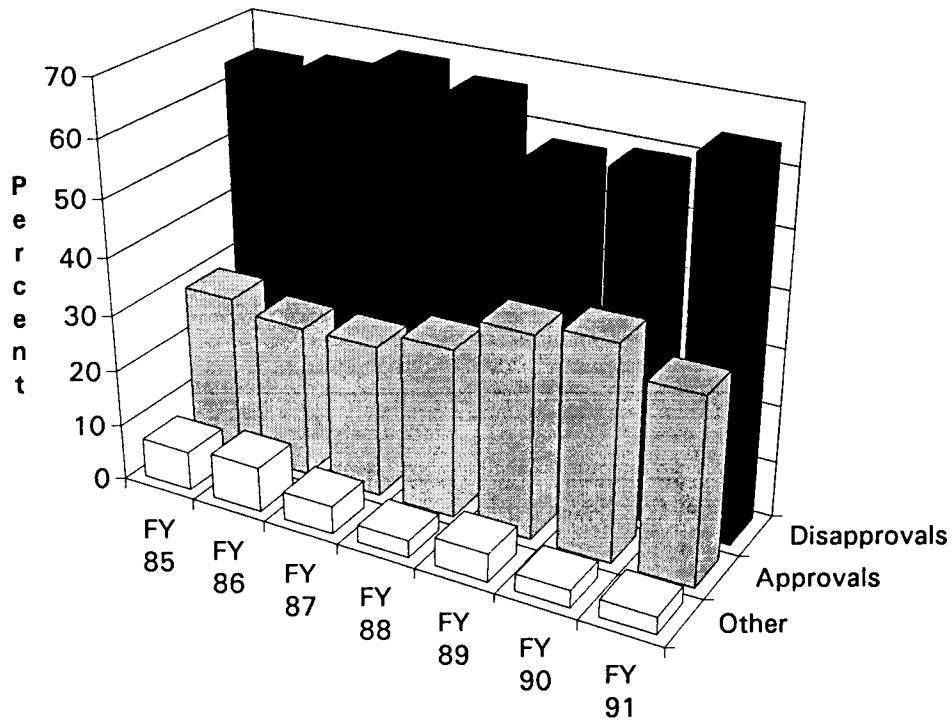


Chart 14. Percentages of Types of Actions on IDE Decisions



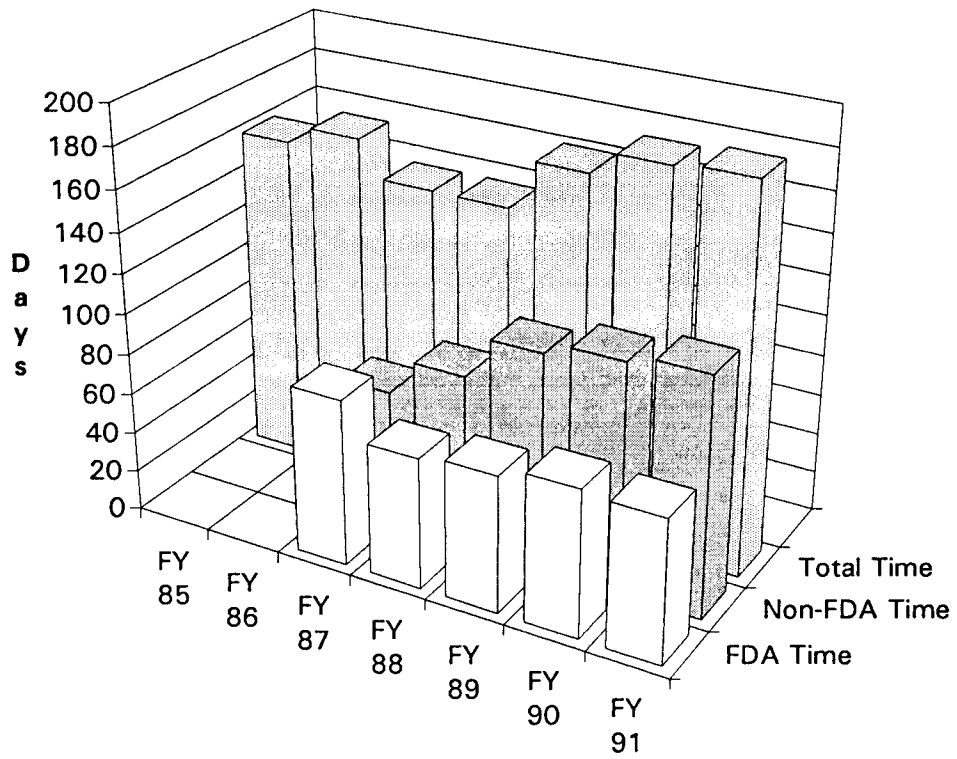
Of the total original IDE decisions made this year, the percentage of decisions that resulted in approval has dropped for the first time in two years, from 38% last year to 33% this year. Since FY 88 the percentage of approvals has ranged from a low of 30% to a high of 38%. It is important that the device industry and ODE do all that they can to keep this rate of approval as high as possible because of the savings in cost and time for the FDA and industry alike when IDEs are approved upon their first submission.

2. IDE Amendments

Although not provided for in the IDE regulations, we refer to all submissions related to an original IDE that has been submitted but not approved as an IDE amendment. Submissions related to an IDE after it is approved are supplemental applications under the regulations. Identification of IDE amendments enables FDA to track each IDE from the time it is originally submitted to the time it is approved.

During this fiscal year we received 283 amendments, down slightly from 288 during the last fiscal year. This was the third largest number of amendments ever received in a fiscal year. We made 287 decisions on amendments, up from 270 last year. These decisions were broken

Chart 15. Average Approval time for IDEs with Amendments



down into: 133 approvals(46%); 80 disapprovals(28%); and 74 other administrative actions(26%). Ninety-nine percent of these decisions were made within 30 days. The 25 IDE amendments pending at the end of this fiscal year was down slightly from the 29 that were pending at the end of last year but none of these was overdue.

Each amendment is associated with an original IDE. Thus, the approval of an amendment constitutes the approval of an original IDE and the proposed investigation may begin. During FY 91, the 133 amendments approved were related to 110 original IDEs. The additional 23 amendments, above the 110 original IDEs, were related to some of the same original IDEs and were approved simultaneously. The oldest amendment that was approved this year was submitted as an original IDE in Decenber, 1987. The most amendments associated with an original IDE approved this year was six. This number is low when compared to last year's high of fourteen, but it is unrelated to the way ODE does business or to ODE's overall performance. It will fluctuate independently each year depending upon the specific IDE to which the amendment is related. The average number of amendments per originally disapproved IDE that was approved in FY 91 was 1.8, the same as last year.

It took an average total time of 189 days to approve amended IDEs this year, almost the same as the 187 days last year. This total approval time consisted of 71 days for FDA, down from 73 days last year, and 118 days for nonFDA time, up slightly from 114 days in FY 90.

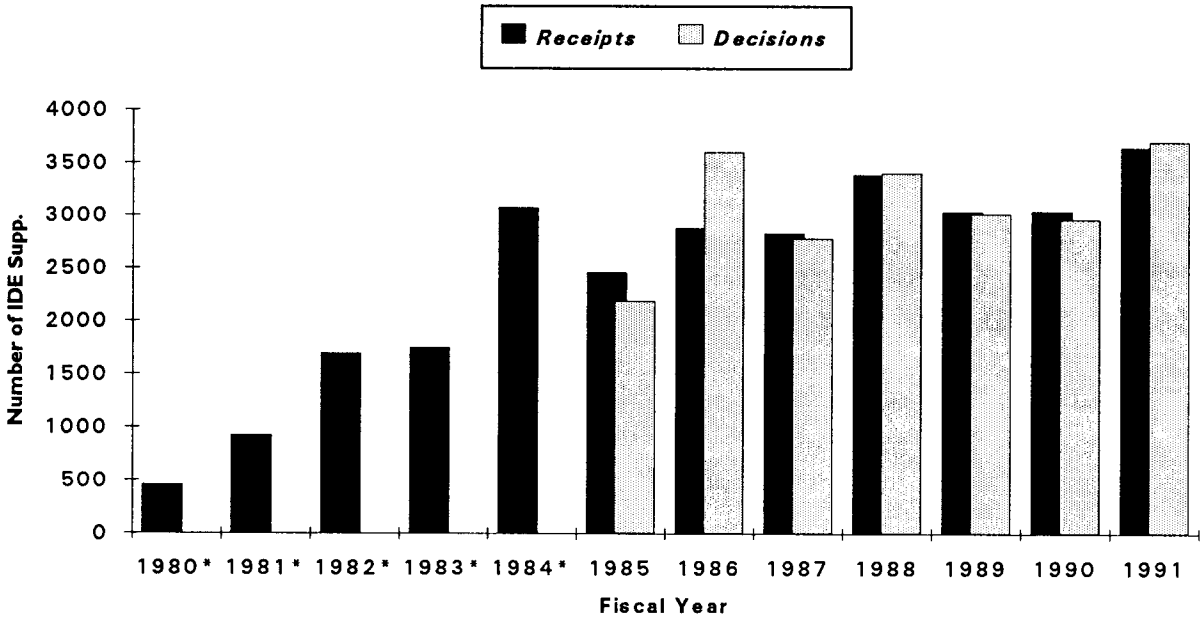
3. IDE Supplements

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

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

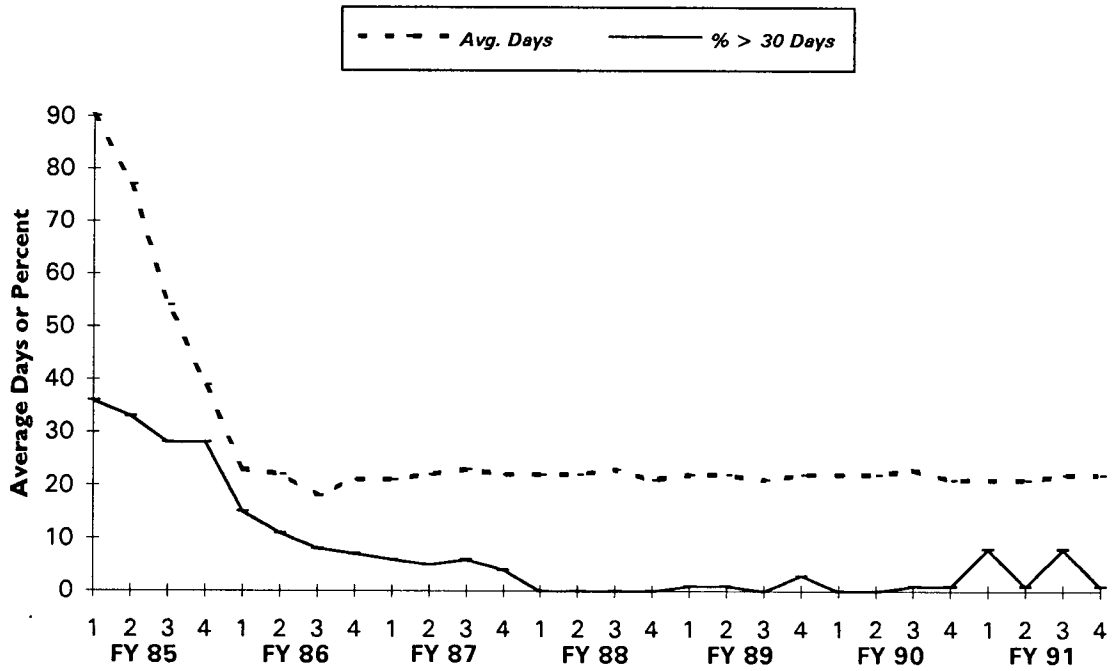
We received a record number of IDE supplements last year, 3,647, which represents an increase of 604 submissions over the 3,043 received in FY 90. The number reviewed, 3,705, also represents a record number of reviews up 737 from the 2,968 reviewed last fiscal year. The number under review at the end of FY 91 was reduced to 189 from last years 245. There were no overdue supplements at the end of the year and the number of supplements reviewed within the 30 day statutory time frame remained constant at 99 percent. The average review time for completing the review of IDE supplements dropped to 21 days after remaining constant at 22 days for the previous four years.

Chart 16. Annual IDE Supplement Receipts and Decisions



* Data on decisions not available.

Chart 17. Timeliness of IDE Supp. Decisions, by Quarter



C. Premarket Notification (510(k))

At least 90 days before placing a medical device into commercial distribution, a manufacturer must submit to FDA a premarket notification, commonly known as a 510(k). In addition to other information concerning the device, e.g., a description of the device, the 510(k) must also include data to substantiate any claim that the device is "substantially equivalent" to a legally marketed device that is not subject to premarket approval. A substantially equivalent device is marketed subject to the same regulatory controls as the device to which it is substantially equivalent. If the device is found to be not substantially equivalent, the manufacturer may submit a petition for reclassification of the device from class III to class I or II, submit a PMA to market the device, or submit an IDE to conduct a clinical investigation to obtain data or information to support a new 510(k) or PMA.

During FY 91, the enactment of the SMDA brought about a number of changes related to 510(k) requirements and authorities under the act. These changes will raise the quality and consistency of reviews, enhance enforcement of 510(k) requirements, and monitor the postmarket use of these devices. For example, the SMDA:

- prohibits substantially equivalent decisions to misbranded or adulterated devices;
- allows a finding of substantial equivalency to a post-Amendments device in lieu of a specifically marketed pre-Amendments device so long as the new device is within a type of pre-Amendments device;
- provides specific authority to ask for clinical data;
- provides a mechanism for judicial review of a substantially equivalent determination;
- requires manufacturers to receive an FDA order permitting commercial distribution before marketing a device;
- permits technological growth under the 510(k) program;
- allows for postmarket surveillance of certain 510(k) devices (this will be implemented during FY 92); and,
- codified current FDA practices regarding how 510(k) decisions are made;

In addition to the foregoing changes, the SMDA also instituted the following changes that directly and significantly impact on the 510(k) program's operations:

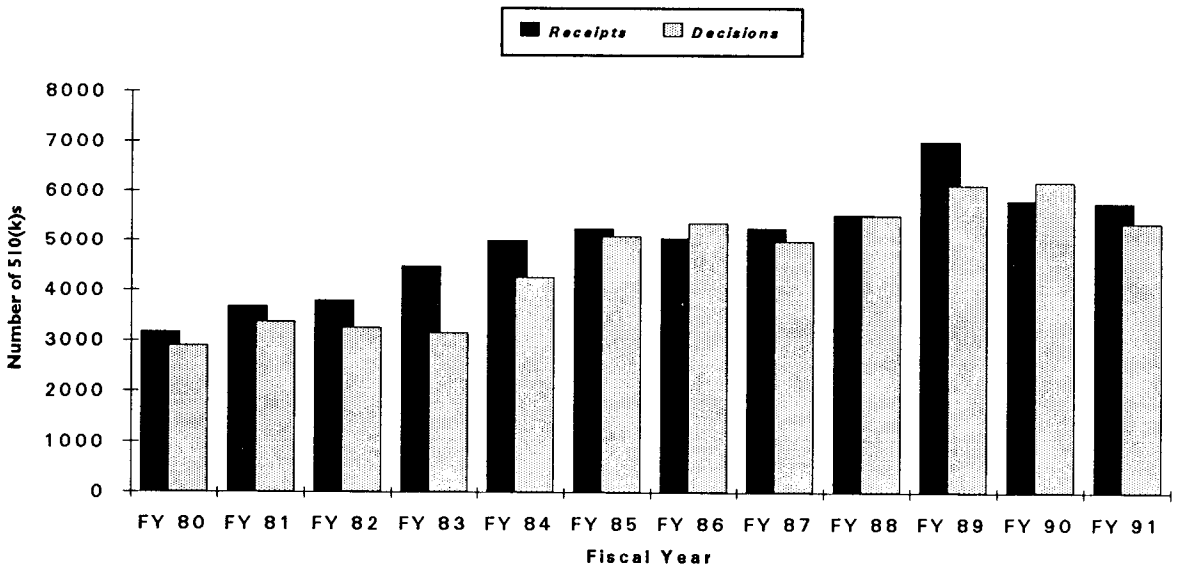
- each 510(k) claiming a device to be substantially equivalent to a class III or unclassified device requires: (1) the certification of a reasonable search of all information known or available about the types and causes of safety and effectiveness problems with that type of device, and (2) a complete and accurate summary of the types and causes of safety and effectiveness problems with that type of device; and,

- each 510(k) regardless of the class of the device, also requires either a summary of safety and effectiveness information upon which a substantially equivalent determination could be based or a statement that safety and effectiveness information will be made available by the manufacturer when requested by an interested party.

In addition to the program and public health benefits that will be derived from these changes, they will require a significant increase in the staff time required to complete the review and processing of each 510(k) submission. This, in turn, will contribute to increased review times that are expected to grow over the next few years.

During this reporting period, ODE received 5,770 original 510(k)s as compared to 5,831 received during FY 90. There were also 3,917 510(k) supplements that came in during this fiscal year. Both original and supplemental 510(k)s total 9,687 submissions, the second highest number of 510(k) submissions ever received in one fiscal year. The number of final decisions rendered on original 510(k)s during FY 91 was down from the previous two years during which time we saw a record number of receipts and decisions.

Chart 18. Annual 510(k) Receipts and Decisions



There are two average review times that traditionally have been reported for 510(k)s. The average review time based on total time is calculated, in part, by totaling all the times each 510(k) is reviewed by FDA plus all of the times the 510(k) is on hold while it is under revision by the submitter. This average is useful to manufacturers who wish to estimate how long it may take to get a final decision from the time a 510(k) is originally submitted. The FDA average review time is based only on the total of all of the times each 510(k) is reviewed by FDA. Both of these average review times were adversely affected during FY 91. The total average review time rose from 98 days in FY 90 to 102 days for FY 91 and the FDA review time went up to 81 days from 78 days in FY 90.

FY 90 was the first full year in which the first two of the following programmatic factors had a major impact on 510(k) average review times. These two factors, plus the new requirements of the SMDA were present in FY 91 as well. In fact, these three factors are likely to have a significant impact on 510(k) review times for the foreseeable future.

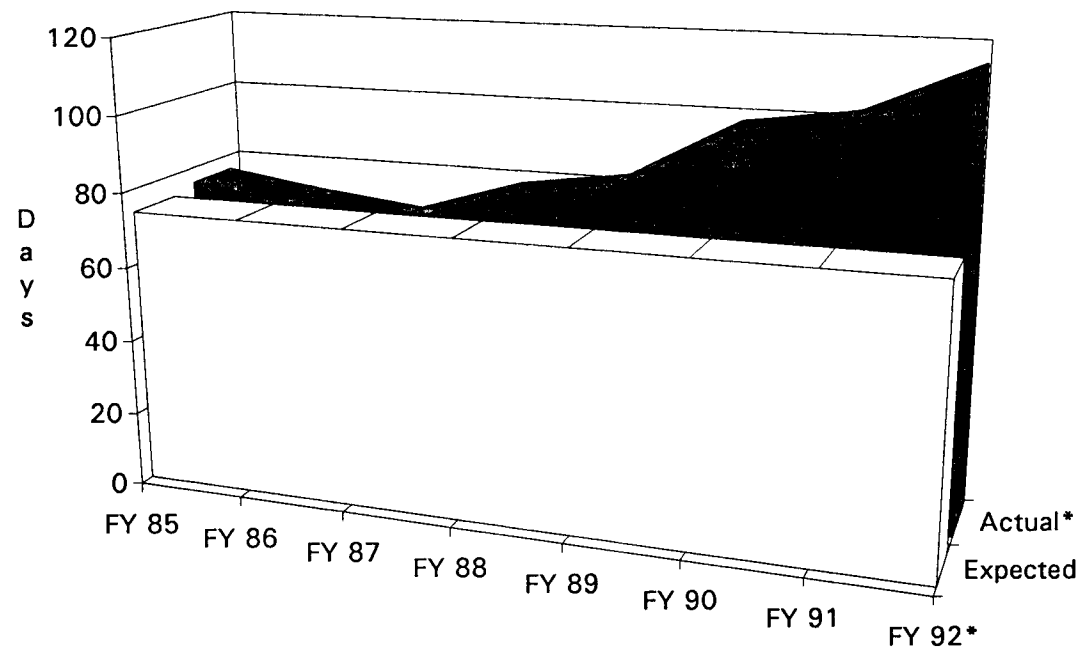
- Nearly 40% of Class I 510(k)s have been exempted from 510(k) review. These were the "easier" submissions that took less review time, did not wait in a cue, and were processed without delay. Removing these exempted products from review left the more difficult and time consuming 510(k)s which raises the average review time.

- There has been an increase in the reviewer documentation of decisions for 510(k)s in order to improve consistency among 510(k) decisions. This has caused an increase in the time required to complete each 510(k) review.

- New requirements of the SMDA, as discussed above.

Chart 19 demonstrates the effect of these factors on average total review time. It is reasonable to expect that these programmatic changes will result in higher average review times for the foreseeable future. Prior to FY 89, actual total review times ranged from 69 to 78 days. These average review times are

Chart 19. Average Total 510(k) Review Time.

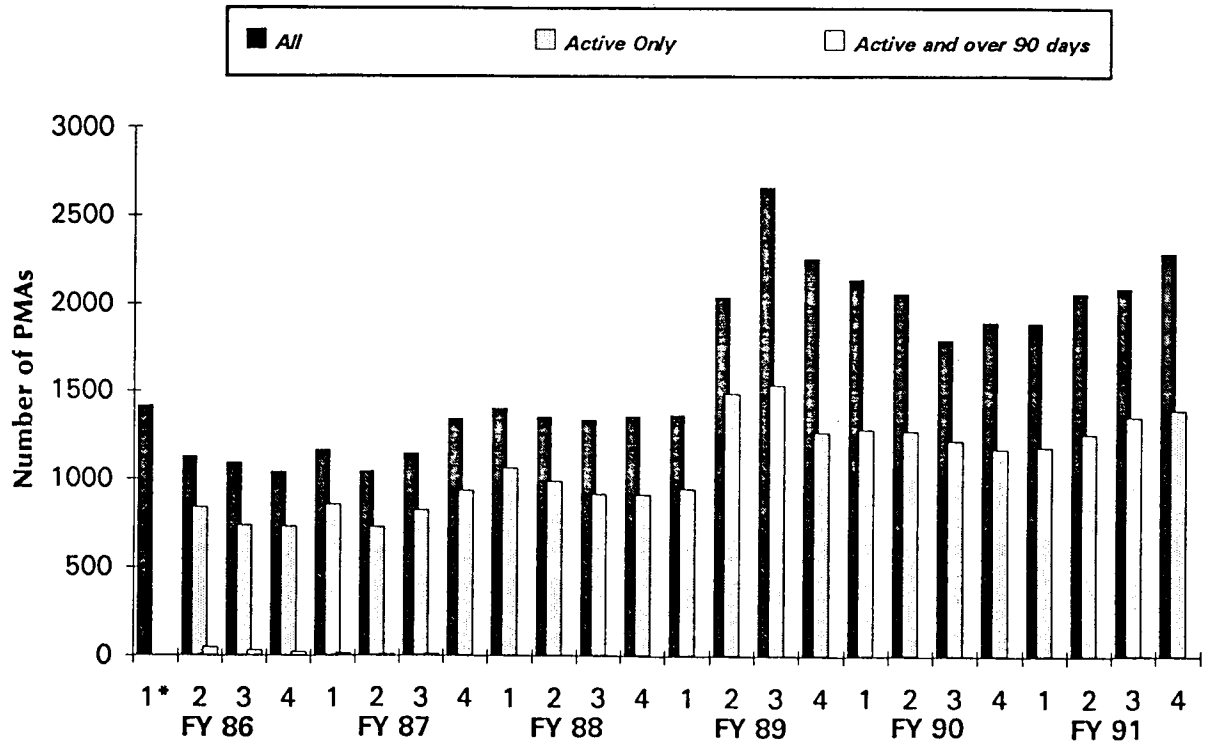


Note: For explanation of chart, see accompanying text.
* Estimate for FY 92 based on average review times at the end of FY 91.

the basis of the expected average review time. The average of these four years(FY 85 through FY 88) is 74 days, which was used as a baseline for the expected value for FY 85 through FY 92 for purposes of comparison. The actual values used in the chart are the actual average total review times for FY 85 to FY 91. There is no actual value for FY 92. The value used for FY 92, 115 days, is based upon the average review times at the end of FY 91. In FY 89, actual review times started to rise noticable. This was the year in which the flood of 510(k)s for examination gloves were received and some of the "easy" class I exemptions were not received. In FY 90, the rising slope grew stepper because of the full impact of the examination gloves 510(k)s, the complete impact of the exemptions was felt, and new documentation for 510(k)s was initiated. In FY 91, the curve continues due to the exemptions, the new documentation, and the new SMDA requirements for Class III summaries and all 510(k) summaries or statements. Because of the continuation of the SMDA factors, we predict a continued rise in these average review times in FY 92. It is difficult to predict exactly where average review times will plateau, but we expect it to be well above 100 days.

The picture is somewhat different when we look at the number of 510(k)s completed within 90 days of review. One of the provisions of the SMDA removed the mandatory 90 day review period for 510(k)s. Nevertheless, ODE, as a matter of policy, will operate on a 90 day turn around time for as

Chart 20. Pending 510(K)s, by Quarter

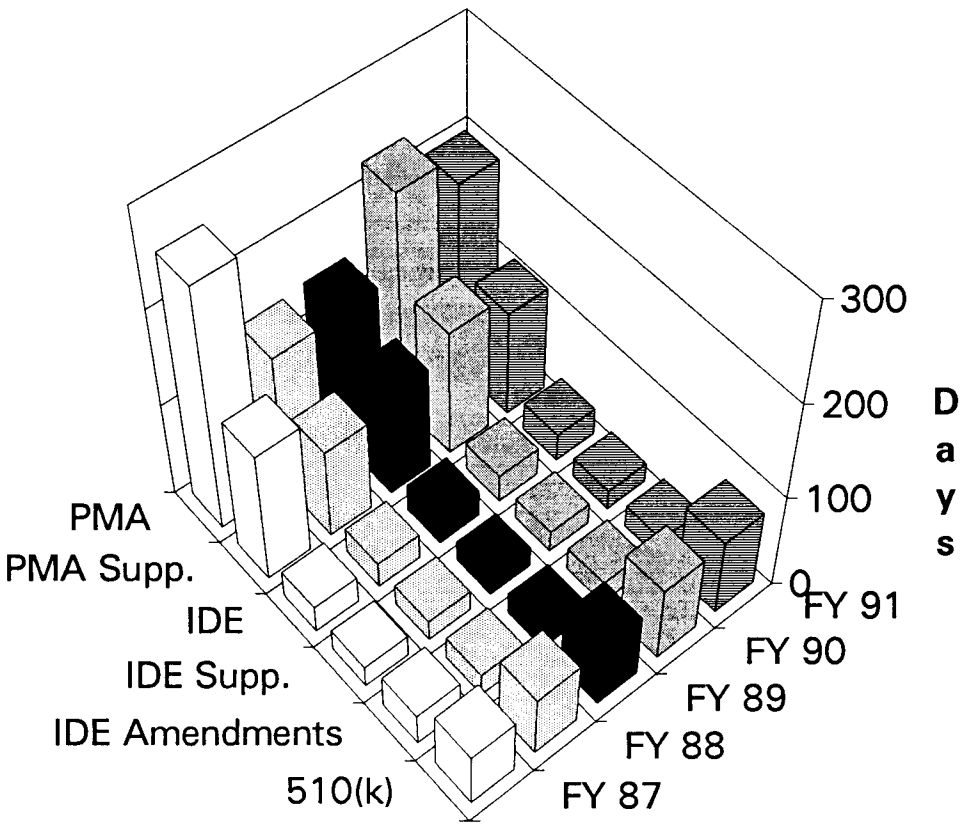


long as possible. For the second year in a row, we are able to report in Table 7, Part VI, that 100% of the 510(k)s were reviewed within 90 days. The 100% figure in Table 7 is derived by rounding off 99.6%. In reality, of 5,367 510(k) decisions rendered during the year, 23 decisions went over the 90 day review period. The rounding off of the percentage yields a performance figure of 100%. This calculation is based upon the time FDA takes to review a 510(k) each time it is received and represents a measurement of FDA's turn-around time on 510(k)s.

There were 2,291 510(k)s pending at the end of this fiscal year, which represents an increase of 391 over last year's end-of-year inventory. The number on hold also rose somewhat since last year from 726 to 889. At the end of this reporting period, there were no 510(k)s that were active and overdue.

Below is a chart that summarizes the average FDA review times for major ODE program areas.

Chart 21. Average FDA Review Times



D. Significant Medical Devices Cleared for Marketing

We cleared five devices for marketing during FY 91 that represent significant advances in medical device technology.

- On October 1, 1990, the PREMIER *Clostridium Difficile* Toxin A Assay became the first enzyme immunoassay to be cleared by the FDA for detection of Toxin A in stool specimens. Detection of this enterotoxin aids in the diagnosis of *Clostridium difficile* associated diarrheal disease. Test results can be available within 2 1/2 hours of taking the sample instead of the usual three days required by previous methods.

- The ICA Plasma HDL and LDL Measurement System was cleared on January 15, 1991. This is the first device to be cleared that uses proton nuclear magnetic resonance spectroscopy to separate and quantitate simultaneously high density lipoproteins (HDL) and low density lipoproteins (LDL) in human plasma specimens. Previously cleared similar devices only quantify total cholesterol and HDL and estimate LDL concentration by indirect calculation. Direct quantitation is expected to be more accurate.

- On April 17, 1991, the FDA cleared the Quidel *Helicobacter Pylori* Test, the first enzyme immunoassay (EIA) for qualitative detection of IgG antibodies to *Heliocobacter pylori* in human serum and plasma. EIA tests are specific for cytotoxin A, more reproducible than cytotoxicity assays, and eliminate the necessity of the high-risk invasive sampling procedure required by previous test methodologies.

- The E Test for determination of the discrete minimum inhibitory concentration of individual antibiotics against a wide variety of bacteria was cleared on September 25, 1991. The E Test is the first test that is based on graduated concentrations of antibiotics on a single test strip. This allows for selection of individual antibiotics for testing on the basis of the bacteria isolated from the patient sample instead of requiring testing of a preselected panel of antibiotics. This can result in savings in materials, costs and labor.

- The PALMAZ™ Balloon-Expandable Stent was approved for marketing on September 29, 1991. It is indicated for use in patients who have undergone an angioplasty of the iliac artery with inadequate angiographic and/or hemodynamic results. It is the first device approved for marketing for this intended use.

IV. Other Program Activities

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

A. Guidance for Industry and Reviewers

Many new guidance documents were developed by ODE and its operating units during FY 91. These documents are designed to promote uniformity and to improve the efficiency, administration, and quality of ODE programs. They also serve as guidance to manufacturers. In addition to dissemination of these guidance documents to appropriate ODE staff members, they have been distributed to the affected industry and made available to interested members of the public. Most of these guidance documents are available through the Division of Small Manufacturers Assistance (HFZ-220), 5600 Fisher Lane, Rockville, Maryland 20857, telephone (800)638-2041.

- Review and Approval of Licensee PMAs. This guidance memorandum, issued on October 19, 1990, revises and replaces the original memorandum #P86-4 dealing with the same subject. The present revision incorporates additional guidance regarding the licensing procedure and content of licensee PMSs subsequently prepared by ODE and included in the Premarket Approval Manual.

- Heated Humidifiers. In November 1990, the Division of Cardiovascular, Respiratory, and Neurological devices revised a draft guidance document, "Guidance for Reviewing 510(k) Applications for Heated Humidifiers", to deal with increased problems of overheating in patient breathing circuits. The revised guidance document addresses safety features such as limiting mechanisms, shut down mechanisms, alarms, and electrical safety that may eliminate, reduce, or warn of events that may lead to burning of patient airway and electrical shock.

- Nebulizers/Metered Dose Inhalers (MDI). In November 1990, the Division of Cardiovascular, Respiratory, and Neurological devices updated the draft, "Guidance for Reviewing 510(k) Applications for Nebulizers/Metered Dose Inhalers", due to an increased awareness that nebulizers, MDIs, spacers, and actuators may affect the therapeutic effect of the drugs they deliver due to the particle size distribution they provide. The revised guidance document includes a description of the in vitro particle size distribution testing to be performed on these devices.

- Ventilator Testing. In November 1990, the Division of Cardiovascular, Respiratory, and Neurological devices added an addendum to the "Guidance for Reviewing 510(k) Applications for Ventilators", because of the increase in the number of modifications made to ventilators due to mechanical and electrical failures of components, software modifications, and additional modes of ventilation. The addendum discusses the need for appropriate qualification testing for these changes.

- Pulmonary Function Data Calculator. In November 1990, the Division of Cardiovascular, Respiratory, and Neurological devices issued an addendum to the "Guidance for Reviewing 510(k) Applications for Pulmonary Function Data Calculator". Although the product code is different for those that are predictive or interpretive, this is applicable to pulmonary function data calculators in general. This framework includes testing that follow the American Thoracic Society recommendations for Spirometry and requires that data derived from patient inputs is identical to a legally marketed device or is supported clinically.

- Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements. On January 18, 1991, the Division of Abdominal, Reproductive, Ear, Nose and Throat, and Radiological Devices issued this "draft" PMA guidance which outlines information required by lithotripter manufacturers in characterizing the shock waves of their devices. Manufacturers should describe the instruments (e.g. hydrophones) and procedures use to measure shock waves, present the results of the tests and use the numbering scheme in the guidance.

- Picture Archiving and Comunications Systems (PACS) and Related Devices. In February 1991, the Division of Abdominal, Reproductive, Ear, Nose and Throat, and Radiological Devices issued this "draft" 510(k) guidance which is applicable to picture archiving and communications systems, such as image digitizers (video and film digitizers), image communications equipment (networks and interfaces), image storage devices (video recorders and digital storage media), workstations and their components (video monitors, image processors, and image processing software), image hardcopy devices (laser printers and multiformat cameras). It does not apply to general purpose devices if they are not specifically indicated or promoted for use in conjunction with medical images.

- Device Labeling Guidance. The primary purpose of this memorandum, which was issued on March 8, 1991, is to formalize guidance to ODE reviewers concerning their review of labeling in device marketing submissions, especially premarket approval applications (PMAs). This guidance is intended to ensure the adequacy of, and consistency in, device labeling information. The guidance is also intended for industry use in preparing labeling.

- Preparation of PMA Manufacturing Information. On March 22, 1991, CDRH, through the Office of Device Evaluation and the Office of Compliance and Surveillance, issued the Guidance for the Preparation of PMA Manufacturing Information. This guidance should assist device manufacturers in preparing and maintaining manufactuing information required in premarket approval applications(PMA) and PMA supplements.

- Air Conduction Hearing Aid Guidance. In April 1991, the Division of Abdominal, Reproductive, Ear, Nose and Throat, and Radiological Devices issued this guidance, based on the hearing aid regulation, 21 CFR 801.420 and 801.421, to enable industry to utilize a standardized format for applications for air conduction hearing aids. Standardized forms

which coincide with the computerized format were issued to industry. When the standardized format for a hearing aid 510(k) is received, a technician, assisted by a reviewer, is able to insert the provided information into the computer program. The efficiency of the computerized review of hearing aid 510(k)s has dramatically reduced review time.

- Diagnostic Ultrasound Guidance Update. On April 26, 1991, the Division of Abdominal, Reproductive, Ear, Nose and Throat, and Radiological Devices issued this "draft" 510(k) guidance which is an update of previously issued ultrasound guidances. The guidance includes indications for use, general device description, acoustic output reporting (TRACK 1 - based on application-specific comparisons to pre- Amendment levels and must be below pre-Amendment levels; TRACK 2 - an alternate approach for systems with fetal Doppler capability whose overall acoustic output may exceed the pre-Amendments levels for fetal applications; TRACK 3 - based upon conformance with the ``Standard for Real Time Display of Thermal and Mechanical Indices of Diagnostic Ultrasound Equipment.''), general clinical safety and effectiveness and labeling, and lists those guidance documents now in effect.

- Antimicrobial Sensitivity Devices. In May 1991, the Division of Clinical Laboratory Devices issued "Review Criteria for Assessment of Antimicrobial Susceptibility Devices". This guidance specifies requirements for submission of applications for generic type devices for use in the clinical laboratories as an *in vitro* test for measurement of susceptibility of bacteria to antimicrobial agents.

- Clinical Utility and Premarket Approval. The "clinical Utility" of all devices undergoing review in a premarket approval application (PMA) must be established prior to approval. The purpose of this memorandum, dated May 3, 1991, is to provide some general written guidance on the regulatory meaning of the term "clinical utility" in the context of PMA review. This memorandum will hopefully enhance consistency in the review of PMAs and heighten the awareness of this important concept.

- Panel Review of Premarket Approval Applications. The Safe Medical Devices Act of 1990 (SMDA) has provided the Food and Drug Administration much needed discretion in the use of advisory panels in the review of premarket approval application (PMAs). The purpose of this memorandum, issued May 3, 1991, is to establish points to consider when deciding whether to take a PMA before an advisory panel for review and recommendations. This memorandum does not specifically address the situation in which an applicant disagrees with our decision not to obtain panel review and requests that their PMA be referred to the appropriate panel for a formal review and recommendation.

- PMA Compliance Program. The purpose of this guidance memorandum, which issued on May 3, 1991, is to make available to ODE reviewers an interoffice agreement regarding Office of Device Evaluation (ODE)/ Office of Compliance and Surveillance (OCS) roles

in supporting the PMA compliance program. It outlines each office's responsibility for the implementation of the PMA compliance program.

- Hyperthermia Devices used for the Treatment of Benign Prostatic Hyperplasia (BPH). On May 10, 1991, the Division of Abdominal, Reproductive, Ear, Nose and Throat, and Radiological Devices issued this "draft" guidance which outlines the features of the clinical investigations for the treatment of Benign Prostatic Hyperplasia (BPH) using hyperthermia therapy (heating the prostate through the use of microwave or RF radiation) that FDA would find acceptable in support of IDEs and PMAs.

- Anesthesia Catheters. On May 15, 1991, the Division of Cardiovascular, Respiratory, and Neurological devices created a draft guidance document, "Guidance for Reviewing 510(k) Applications for Anesthesia Catheters", to deal with an increase in reported catheter breakage and neurologic deficits (Cauda Equina Syndrome). The guidance covers areas such as biocompatibility, flexural and tensile strength tests, sterilization, intended use, length of use, and gauge size.

- Document Review Processing. The purpose of this memorandum, dated May 29, 1991, is to reaffirm the basic principle within ODE that we will attempt to initiate the review of documents on the basis of their dates of submission, i.e., we will attempt to review first the documents that were received first. There will, however, be many exceptions to this principle which are discussed in the memorandum. Nevertheless, our underlying goal is to maintain a review process that is fair and without preferential treatment for any applicant.

- Integrity of Data and Information Submitted to ODE. The purpose of this Blue Book Memorandum issued on May 29, 1991, is to specify the procedures to be followed by the ODE staff if there is a question concerning the integrity of data and information contained in any PMA, IDE, or 510(k) submission. We want to encourage reviewers to be sensitive to the possibility of inaccurate, withheld or otherwise false data in submissions reviewed by them.

- Human Heart Valve Allografts. The "Guidance for Human Heart Valve Allografts", dated June 21, 1991, outlines the *in-vitro*, processing, and clinical information that must be addressed in an Investigational Devices Exemption or Premarket Approval Application. It represents the collaborative effort of Office of Device Evaluation staff, the tissue banking community, heart valve allograft processors, and the Circulatory System Devices Advisory Panel. The guidance was released in conjunction with the *Federal Register* notice that announced the FDA decision to actively regulate these products.

- Cytogenetic Analysis. In July 1991, the Division of Clinical Laboratory Devices issued "Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers". This guidance specifies requirements for submission of applications for

generic type devices for use in the cytogenetics laboratory to aid laboratory personnel in the performance of certain procedures used in karyotyping human metaphase/prometaphase cells for *in vitro* cytogenetic analysis.

- Blood Culture Systems. In August 1991, the Division of Clinical Laboratory Devices issued "Review Criteria for Assessment of *In Vitro* Blood Culturing System Diagnostic Devices". This guidance specifies requirements for submission of applications for generic type devices for use in the clinical laboratories as an *in vitro* test for detection of microorganisms from human blood or other normally sterile body fluids.

- *Borrelia Burgdorferi* (Lyme Disease). In August 1991, the Division of Clinical Laboratory Devices issued "Guidance Criteria for 510(k) Submissions Review Criteria for Assessment of Serological *In Vitro* Diagnostic Devices for Detection of Serum Antibodies to *Borrelia Burgdorfern"* . This guidance specifies requirements for submission of applications for generic type devices for use in clinical laboratories as an *in vitro* test for detection of antibodies to *Borrelia burgdorferi*, the causative agent of Lyme disease (Lyme borreliosis). The diagnosis of Lyme disease is based on clinical signs and symptoms; serological tests are an adjunct to other clinical evidence in the diagnosis of Lyme disease.

- Review of Final Draft Medical Device Labeling. The purpose of this memorandum of August 29, 1991 is to establish a policy to assure that the labeling of a medical device in commercial distribution is consistent with the labeling approved during the review of the PMA submission.

- Review of 510(k)s for Computer Controlled Medical Devices. The purpose of this Blue Book Memorandum, issued on August 29, 1991, is to establish a framework for use by ODE reviewers in the review of software aspects of 510(k) submissions for computer controlled medical devices. The specific guidance is contained in the document "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review" and is incorporated into this memorandum by reference.

- Magnetic Resonance Compatible Ventilators. On August 29, 1991, the Division of Cardiovascular, Respiratory, and Neurological Devices issued a draft guidance document, "Guidance for Reviewing 510(k) Applications for Magnetic Resonance(MR) Compatible Ventilators", to guide applicants in preparing premarket notifications for these devices and to serve as a guide for FDA staff in their review of these applications.

- Oxygen Concentrators. On August 30, 1991, the Division of Cardiovascular, Respiratory, and Neurological devices issued a draft "Guidance for Reviewing 510(k) Applications for Oxygen Concentrators" for these devices. The guidance includes sections on comparative output characteristics, electrical characteristics, alarms, environmental testing, and technical descriptions of the pneumatics and filtering systems.

- PTCA Catheter and Coronary Guidewire. The guidance, "Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter and Coronary Guidewire Testing Guidance for the Submission of an Investigational Device Exemptions Application and a Premarket Approval Application", dated September, 1991, describes the general framework to be followed in developing and testing a safe and effective PTCA catheter and its accompanying guidewire. The tests are grouped into (A) material biocompatibility and toxicity tests, (B) in vitro physical tests, (C) animal tests, (D) cadaver tests, and (E) clinical tests.

- Cholesterol. In September 1991, the Division of Clinical Laboratory Devices issued "Review Criteria for Assessment of Cholesterol *In Vitro* Diagnostic Devices Using Enzymatic Methodology for Clinical Laboratories, Physicians' Office laboratories and Home Use". This guidance specifies requirements for submission of applications for generic type devices that measure cholesterol in whole blood, serum, or plasma quantitatively or qualitatively by chemical or enzymatic methods. The guidance covers manual and automated methods.

- Cyclosporine. In September 1991, the Division of Clinical Laboratory Devices issued "Guidance Criteria for Cyclosporine PMAs". This guidance specifies requirements for submission of applications for generic type devices for use in the monitoring of cyclosporine therapy. Several methodologies are covered in this guidance (FPIA, HPLC, and RIA).

- Self-Monitoring Blood Glucose Devices. In September 1991, the Division of Clinical Laboratory Devices issued "Review Criteria for Assessment of Self-Monitoring Blood Glucose *In Vitro* Diagnostic Devices Using Glucose Oxidase Methodology". This generic type device is intended for use over-the-counter as an *in vitro* monitoring test for quantitative measurement of glucose by the glucose oxidase methodology.

- Glycohemoglobin (glycated hemoglobin). In September 1991, the Division of Clinical Laboratory Devices issued "510(k) Review Criteria for Assessment of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin *In Vitro* Diagnostic Devices". This guidance specifies requirements for submission of applications for generic type devices for use in clinical laboratories for the quantitative determination of the fraction (expressed as percent) of glycohemoglobin (glycated or glycosylated) hemoglobin in blood samples. All commercially available methodologies are covered in this guidance (affinity chromatography, cation exchange column, HPLC, electrophoresis, and immunoassay).

- Lymphocyte Immunophenotyping Monoclonal Antibodies. In September 1991, the Division of Clinical Laboratory Devices issued "Guidance Criteria for 510(k) Submission of Diagnostic Devices for Lymphocyte Immunophenotyping Monoclonal Antibodies". This guidance specifies requirements for submission of applications for generic type devices for use in clinical laboratories as an *in vitro* test for the quantitative measurement of lymphocytes and their subsets using monoclonal antibodies by flow cytometry, light, and fluorescence microscopy.

B. Reclassification of Classified Devices

ODE took the following actions during FY 91 concerning the reclassification of medical devices.

- Issued an order to reclassify the microsurgical argon laser for use in rhinology and laryngology from class III to class II on July 16, 1991.

- Issued an order to reclassify the natural nonabsorbable surgical silk suture from class III to class II on November 9, 1990.

- Published a final rule in the *Federal Register* on July 15, 1991, announcing the reclassification of the nonabsorbable poly(ethylene terephthalate) surgical suture from class III to class II. The reclassification was effective on July 5, 1990.

- Published a final rule in the *Federal Register* on July 15, 1991, announcing the reclassification of the nonabsorbable polypropylene surgical suture from class III to class II. The reclassification was effective on July 5, 1990.

- Published a final rule in the *Federal Register* on July 15, 1991, announcing the reclassification of the nonabsorbable polyamide surgical suture from class III to class II. The reclassification was effective on February 15, 1990.

- Published a final rule in the Federal Register on September 18, 1991, announcing the reclassification of the absorbable poly(Glycolide/l-lactide) surgical suture from class III to class II. The reclassification was effective on October 4, 1989.

- Published a proposed rule in the *Federal Register* on July 15, 1991, to reclassify the hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis from class III to class II.

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

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

Nearly 150 generic types of devices have been proposed for, or have been finally classified in, class III. Recognizing that FDA could not issue 515(b) regulations simultaneously for all pre-Amendments class III devices, Congress authorized FDA to establish priorities which may be used

in applying premarket approval requirements to these devices. On January 6, 1989, FDA published an advanced notice of proposed rulemaking to announce its intent to issue 515(b) regulations for an additional 31 Class III preAmendments devices having a high priority for the application of premarket approval requirements.

In prior years, 515(b) rules have been promulgated for various high priority devices. During this fiscal year, we published a final rule in the *Federal Register* of April 10, 1991 requiring the filing of PMAs for silicone gel-filled breast prostheses on or before July 9, 1991. Such devices that were not the subject of a PMA by the specified date could no longer be distributed commercially. FDA received 10 PMAs from six manufacturers of these devices on or before the deadline.

FDA published a notice of applicability of a final rule in the *Federal Register* of June 26, 1991 to clarify that replacement heart valve allografts are subject to the final rule that had been published in the *Federal Register* of May 13, 1987 requiring the filing of PMAs for all pre-Amendments replacement heart valves. Manufacturers of currently marketed replacement heart valve allograghs were required to have an approved PMA or IDE in effect on or before August 26, 1991, or cease distribution of the device. On July 29, 1991, we published a notice in the Federal Register to extend this effective date to November 25, 1991. Subsequent to this action, a petition was filed necessitating the reconsideration of this effective date.

D. Advisory Panel Activities

ODE held 26 medical device advisory panel meetings during the past year as identified in Chart 24. In FY 91, the sixteen independently chartered advisory panels were rechartered as subcommittees of an omnibus Medical Devices Advisory Committee. The purpose of the rechartering was to allow greater flexibility in the use of the expertise represented among the voting panel members and non-voting consultants. Under the old charter system, a voting member of one advisory panel could not vote on an issue coming before another panel. Under the new system, all panelists are members of the same formal committee; therefore, even though they will be appointed to a specific subcommittee (panel), they may serve as voting members on any other subcommittees as needed. In addition, in the past meetings were sometimes delayed simply because we could not get a quorum of voting members; now we can borrow a qualified member from another panel for a needed review and attendance at the meeting. Likewise, the new charter allows us to appoint a consultant to serve as a voting panelist for a very limited period of time.

The result of the rechartering is that the logistics of scheduling meetings is simplified and, more importantly, the appropriate voting expertise that is so critical to credibility is more attainable. ODE is in the process of creating a database for use within the Center that will provide quick access to the speciality areas represented by all of the approximately 340 panel members and consultants. This will be especially useful in taking advantage of the increased flexibility available under the new charter for moving panelists around within the committee system.

Chart 22. ODE Advisory Panel Meetings FY 91

Panel (Executive Secretary)	Number of Meetings	Meeting Days
Dental (Gregory Singleton)	1	1
Obstetrics and Gynecology (Colin Pollard)	2	2
Ear, Nose, and Throat (Celeste Bove')	1	2
General and Plastic Surgery (Paul R. Tilton)	1	1
Orthopedic and Rehabilitation (Marie Schroeder)	2	2
Gastroenterology and Urology (Ruth W. Hubbard)	2	2
General Hospital and Personal Use (Amalie Mattan)	2	2
Opththalmic (Daniel W. C. Brown)	3	3
Radiology (Adrianne Galdi)	0	0
Neurology (Robert F. Munzer)	1	1
Anesthesia and Respiratory Therapy (Michael Gluck)	1	1
Circulatory Systems (Wolf Sapirstein)	5	7
Microbiology (Joseph L. Hackett)	2	2
Hematology and Pathology (Larry Brindza)	1	1
Clinical Chemistry and Toxicology (Kaiser J. Aziz)	0	0
Immunology (Srikrishna Vadlamudi)	2	2
Totals	26	29

Prior to FY 90 device advisory panel members received no training and very little orientation for their roles as advisors to FDA. In FY 90 we developed a training workshop which, by the end of FY 91, had been conducted for eleven of the sixteen panels. Panel training has become an endless process because panel membership is not static. The voting and non-voting members are appointed for four-year terms; consultants are appointed on one or two-year renewable terms. Furthermore, because of the need for continuity, members' terms are staggered. . It is logistically very difficult to bring all new panelists in for a personal two-hour training session. Therefore, we are in the process of producing a videotape training and orientation program. The scripting process is complete and the initiation of production should begin soon. When completed, the three short videotapes and supporting materials will be provided to each new panel member and consultant as they are appointed.

E. ODE Integrity Program

During FY 90, ODE initiated an ODE Integrity Program. During FY 91, the program attained a new level of maturity and activity. It currently consists of four major components: Enforcement, Ethics, 510(k) Performance Monitoring, and 510(k) Quality Reviews. Each of these components is described below. Under the Integrity Program, ODE issued the following Blue Book Guidance Memoranda:

Prior to FY 91 (These were described in the FY 90 ODE Annual Report.)

- Integrity of the Medical Device Review Process
- Meetings with the Regulated Industry
- Policy Development and Review Procedures
- Assignment of Review Documents
- Document Control Procedures

During FY 91 (These are described under Subsection A, above.)

- 510(k) Independent Quality Review Program
- Document Review Processing
- Integrity of Data and Information Submitted to ODE

1. Enforcement Program

This part of the Integrity Program involves follow-up actions on those submissions that contain questionable data or information. When such a submission is identified, the case is referred to the Office of Compliance and Surveillance(OCS) for necessary action. Typically, once a submission is referred to OCS, all further review of that submission is suspended until OCS finishes its investigation. If the situation falls within the FDA Fraud Policy, review of all submissions by that company may be suspended until FDA is convinced that the firm has undertaken the appropriate rehabilitation actions. During FY 91, ODE referred 20 submissions to OCS for investigation under this aspect of the Integrity Program.

2. Ethics Program

This component of the Integrity Program involves follow-up action on allegations concerning favorable or discriminatory actions by the ODE staff toward a firm that has submissions pending before the agency. When such a case arises, it is referred to the FDA Ethics Branch for appropriate investigation and action. During FY 91, ODE referred 5 cases to the Ethics Branch for resolution.

3. 510(k) Performance Monitoring

This aspect of the Integrity program involves the analysis of review times for competing 510(k)s under the same product code to determine whether the review time or the number of holds of any 510(k) has deviated significantly from the norm for review times or holds for all of the 510(k)s for devices within the product code. Exceptionally long or short review times or number of holds for a specific 510(k) may be an indication of preferential or discriminatory treatment. Such cases are investigated to determine whether there is a satisfactory explanation for the deviation. In order to accomplish this monitoring of the system, a computer program was developed in conjunction with the Office of Information Systems. The program is currently being tested and refined. After the necessary testing is completed, the program will become operational.

4. 510(k) Quality Reviews

This part of the Integrity Program involves the evaluation of a random sampling of completed 510(k)s to determine whether the reviews have been objective, complete, properly documented, consistent with other reviews, and absent evidence of bias and preferential or discriminatory treatment. To implement this process, a checklist is being developed that will be used to assure the review of each 510(k) is complete and consistent with the review of other 510(k)s. Once the checklist and procedures are finalized, this component of the program will become operational.

F. Responding to FOI Requests

Under the Freedom of Information (FOI) Act, FDA must respond within 10 days to requests for information contained within agency files, with the exception of trade secret data and confidential commercial information. Requested documents must be "purged" of such privileged information before release. ODE staff received 1,098 FOI requests during FY 91.

V. Office Management

A. Organizational Structure

Effective May 20, 1991, a major reorganization of the Division-level structure within the Office of Device Evaluation (ODE) was implemented. Appendix A contains the new ODE organizational chart. ODE is now comprised of five divisions which contain all of the previously existing branches and ODE's overall responsibilities remain unchanged. Each of the five Division Directors is now supported by either two or three Associate Division Directors, who each oversee the management and operations of two or three branches. The cardiovascular, respiratory and neurological devices specialty areas are now combined in one division; the urology, lithotripsy, gastroenterology, renal and radiological devices areas have been combined with obstetrics/gynecology, and ear nose and throat devices areas in a single division; and the general hospital and infection control devices, along with dental devices have been combined with surgical, reconstructive, restorative and orthopedic devices in a single division. Responsibilities at the branch level remain largely unchanged, although a number of new branches have been created to better isolate and address specific device specialty areas.

The new organizational structure is an attempt to respond to both growth and technological change that have resulted in an increased and diversified workload. These changes provide greater scientific and technical focus, better alignment of functions and staff, and improved management control and more effective supervision. Review procedures have been enhanced by the improved management structure and the proper realignment of product specialties.

B. Training

A comprehensive effort was undertaken in FY 91 to identify the training needs of ODE employees. Input was obtained from ODE staff members and managers as well industry representatives. A focal point for this training was designated and support was provided to develop and direct training activities to meet these needs..

In-house training programs developed and instituted this past year were:

- Two 3-day training courses on the policies and procedures of IDE, 510(k), and PMA activities were held for 62 new reviewers and several employees from other Center offices. There were guest speakers who presented industry and consumer views of ODE activities as they affect their groups.

- Training focusing on the provisions and impact of the Safe Medical Devices Act (SMDA) of 1990 was provided to all ODE reviewers and technical support staff.

- Several training sessions covering the 510(k) and IDE program areas were presented to reviewers. Topics included the impact of IG and GAO reports and recommendations affecting these program areas as well as changes reflecting the SMDA of 1990.

- A 2-day training course in diagnostic ultrasound was presented to 37 reviewers. This course included lecture and hands-on experience using devices supplied by several manufacturers.

- A 2-day course covering review of software in medical devices was offered to ODE reviewers who will be focal points for implementing the software guidance document and review policies.

- A 1-day contract course covering how to give effective presentations and briefings was presented to all ODE supervisors and managers and some panel executive secretaries.

- A training session was provided to all ODE supervisors on changes in the EPMS system and general information on conducting EPMS and PMRS reviews.

- A 1-day seminar titled Stress Management was presented to ODE secretaries and support personnel. This course sought to enable participants to identify and handle stress factors in their professional lives.

- A 1-and-1/2 day course, Projecting a Professional Image, was presented to secretaries. This course enhanced the secretaries' ability to identify and understand the dynamics of a positive self-image and to display a professional image within the office and with the general public.

- A training session on the policy "First in - First Reviewed" (as specified in a recent Blue Book Memorandum) was given to all ODE supervisors and managers. This policy was one of several directed to program integrity in the review process.

- A course on team-building was presented to employees of DCLD. The division staff learned techniques for managing both agreement and conflict and became familiar with negotiation techniques that improved their team meetings.

- A 1-day workshop, Communication, was provided to employees of DRAERD. This course included material and exercises to help participants handle crucial encounters with others, to resolve conflicts, and to create a work environment favorable to building a team spirit.

An ongoing training activity for all ODE employees is the "ODE POTPOURRI" which is designed to encourage the sharing of information within the Office. The program is not intended to be highly technical but to cover interesting or novel policy issues or to present information on devices of broad general interest. Sessions in FY 91 have included:

- home use diagnostic kits

- dental amalgams
- UV light sources (tanning devices) and sun screens
- videotapes of the New Lawyer Lecture Series

A separate initiative in the broad training efforts of FY 91 was the development of an ODE Employee Handbook (using as a base a similar effort initiated by OST). The handbook is intended to provide to all employees important day-to-day information about activities, policies and procedures in ODE, CDRH, and FDA.

In addition to the in-house training activities mentioned above, ODE continues to generously support employee off-site training and career development to the extent possible given a limited budget. In FY 91, ODE expended approximately 220K for employee training.

C. Office Automation

Despite a significantly reduced office automation budget, we continued to build upon a foundation of installed equipment to improve office automation capabilities. We received PCs that were ordered in FY 90 which expanded our base of PCs. This expanded base helped reduce the equipment incompatibilities between PCs and DECmates and provided a computer capable of word processing to each individual needing this equipment. We expanded our LAN capabilities through the purchase of LAN hardware and commenced the process of having 510(k)s and recently completed PMAs scanned to the CDRH IMAGE system.

1. Equipment and Software

The expenditure for equipment and software for FY91 was $61,000. The equipment included laser printers for PCs and the document tracking system, 2 additional PCs, LAN communication hardware, and a poster maker. The software included database, spreadsheet, and graphics software.

We received 43 AST 386/SX20 PCs that were ordered in FY90. With this equipment all employees needing a computer terminal for word processing had either a PC, a DEC word processor, or a DEC terminal. Sixty percent of the computer terminals assigned to ODE employees are PCs.

Seventy-two percent of the ODE secretaries now have PCs. With the arrival of the 11 Hewlett-Packard IIP laser printers that were ordered in FY90, the ODE secretaries with PCs have dedicated laser printers. With dedicated printers, the secretaries are positioned to use the form generating software ordered by the Office of Management Services.

With the purchase of the additional LAN hardware, most of the PC users will have a LAN connection. The PC users can access boilerplate letters stored on the LAN server and use the

laser printers on the LAN. When the new LAN software arrives, PC users will have access to Harvard Graphics and dBase IV on the LAN server.

The Program Management Office provided color graphics capability for ODE employees with the arrival of a Hewlett- Packard PaintJet printer.

A Poster Maker was acquired to enlarge documents to poster size. This device has proved helpful to ODE employees when making presentations.

2. Tracking Systems

With the restructuring of ODE from 7 Divisions to 5 Divisions, a change to the Document Tracking Systems was needed. Individuals from the Program Management Office, the Program Operations Staff and the ODE Divisions worked with the systems analyst from the Office of Information Systems to effect the change to the division/branch codes to reflect the new ODE structure. Individuals within ODE continued to work with the analysts and programmers in OIS on tracking system issues.

PC database software was provided to ODE PC users. Many users developed their own database applications to track device applications. The Program Management Office also developed PC database applications for PC users.

3. Document Imaging

As a result of the new device legislation, 510(k) summaries must be made available to the public for 510(k)s received after April 18, 1991 and found to be substantially equivalent. Individuals from ODE, the FOI staff and OIS developed a procedure to use the CDRH IMAGE system to satisfy the requirement of the legislation. The 510(k) summary is scanned by the Program Management Office to the IMAGE system. The FOI staff retrieves and prints the 510(k) summary when needed to satisfy a request.

The scanning of 510(k)s to the IMAGE system by a contractor was started in October 1990. By the end of FY91, 3,987 510(k)s were loaded on the optical disk. In April 1991, the first PMA was scanned to optical disk and in September, 1991 the PMA scanning instructions were developed for the contractor to do routine scanning of recently completed PMAs.

4. Shared Folders

The Program Management Office is committed to the use of computer technology to eliminate the abundance of paper in a government office. The availability of shared folder on the Center's All-in-1 system affords an excellent way to make documents available for viewing and copying by All-in-1 users. The ODE Blue Book Memoranda are now available to all CDRH VAX users.

The Personal Computer Guide, the ODE Employee Handbook, boilerplate letters, conference room schedules and helpful hints are also available.

5. Remote Control Statistical Consulting

ODE participated in a pilot project with OST for remote control statistical consulting by computer. In this project, two Apple Macintosh computers were linked by 9600 baud dial modems and the same image was displayed on both computers. The OST statistician ran programs and displayed graphics with the results displayed on both computer monitors simultaneously. Both individuals were in contact by telephone and discussed the information on the screens. Through remote consulting additional analysis could be requested by the ODE reviewer and the result of the analysis would be displayed on the reviewer's screen.

This type of consulting eliminates the need to travel between buildings and encourages consulting for those short questions. Also, the OST statistician could provide advice on ways to process or present data and show the method on the screen. The pilot project was successful and ODE and OST jointly funded the purchase of the modems and the remote control software.

6. Training

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

Chart 23. ODE Computer Hardware Status FY 90 - FY 91

HARDWARE	On hand In FY 90	Received in FY 91	On hand in FY 91
DECmate II Word Processors*	70	-	70
DECmate III Word Processors*	36	-	36
LQP02 Letter Quality Printers	33	-7	26
LQP03 Letter Quality Printers	3	-2	1
LA50 Draft Quality Printers	43	-	43
LA75 Draft Quality Printers	40	-	40
LA210 Draft Quality Printers	1	-	1
LN03 Laser Printers	23	1	24
VT220 Terminals*	43	-	43
VT320 Terminals*	7	-	7
Ricoh Fax 1000L	2	-	2
Electrohome Projector	1	-	1
Compaq 286 PCs	11	-	11
AST 286 PCs	69	-	69
AST 386 SX/16	29	-	29
AST 386 SX/20	0	43	43
AST 386 PCs	9	-	9
Fujitsu Draft Printers	70	-	70
Fujitsu Letter Quality Printers	11	-	11
Epson LQ510 Printers	0	10	10
Macintosh Plus/SE PCs	5	-	5
Apple Laserwriter Printers	5	-	5
Apple Imagewriter Printers	1	-	1
HP LaserJet II Printers	9	-	9
HP LaserJet IIP Printers	0	17	17
HP LaserJet III Printers	3	2	5
HP LaserJet IIIP Printers	0	2	2
HP PaintJet Printer	0	1	1
DEST DECmate Document Scanner	1	-	1
DEST PC Document Scanner	1	-	1

* Some DECmates/VT Terminals held for possible new hires.

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 may have been changed to reflect similar corrections in data entry. These adjustments are not likely to have a significant effect on conclusions based on these data. Percentages of actions are presented in some tables. They may not add up to 100% in all cases due to the rounding off of fractions.]

Table 1. PMA/IDE/510(k) Submissions Received
FY 87 - FY 91

Type of Submission	No. Received				
	FY 87	FY 88	FY 89	FY 90	FY 91
Premarket Approval:					
Original Applications	81	96	84	79	75
Amendments	748	754	856	569	680
Supplements	700	727	810	660	593
Amendments to Supplements	871	919	999	1,069	954
Reports for Orig. Applications	514	535	466	479	441
Reports for Supplements	162	59	57	22	15
Master Files	43	41	32	37	42
PMA Subtotal	3,119	3,131	3,304	2,915	2,800
Investigational Device Exemptions:					
Pre-original Applications	15	8	7	19	9
Original Appplications	218	268	241	252	213
Amendments	265	311	271	288	283
Supplements	2,836	3,391	3,038	3,043	3,647
IDE Subtotal	3,334	3,978	3,557	3,602	4,152
Premarket Notification:					
Original Notifications	5,265	5,536	7,022	5,831	5,770
Supplements	2,113	2,713	3,752	3,531	3,917
510(k) Subtotal	7,378	8,249	10,774	9,362	9,687
PMA/IDE/510(k) Total	13,831	15,358	17,635	15,879	16,639

Table 2. Original PMAs
FY 87 - FY 91

Action	FY 87	FY 88	FY 89	FY 90	FY 91
Number received	81	96	84	79	75
PMA Actions:					
Filing Decisions:					
Filed (%)	59(47)	78(52)	61(62)	53(52)	52(50)
Not Filed (%)	67(53)	71(48)	37(38)	49(48)	42(40)
Others(%)	N/A	N/A	N/A	N/A	10(10)
Filing Decision Subtotal	126	149	98	102	104
Review Activities:					
Major Deficiencies	32	41	8	33	28
Minor Deficiencies	1	5	8	2	5
Other[a]	137	78	85	67	127
Review Activities Subtotal	170	124	101	102	160
Review Decisions:					
Approvals(%)	46(53)	46(43)	56(49)	47(42)	27(27)[g]
Approvable(%)	36(41)	55(51)	52(45)	45(41)	46(46)
Not approvable(%)	5 (6)	6 (6)	7 (6)	19(17)	27(27)
Approval Decision Subtotal	87	107	115	111	100
Total PMA Actions	383	380	314	315	364
Average review time(days) for approvals:[b]					
FDA	257	142	145	228	199
Non-FDA	27	17	42	55	87
Total	284	159	187	283	285
Average elapsed time(days) for approvals:[c]					
FDA	337	262	247	302	335
Non-FDA	81	75	101	113	298
Total	418	337	348	415	633
Number under review at end of period:[d]					
Active[e]	50	48	62	44	49
(Active and overdue)	0	(1)	(24)	(5)	(2)
On hold[f]	77	66	52	72	86
Total	127	114	114	116	135

a/ Includes actions that did not result in an approval/disapproval decision, such as a sponsor directed hold, reclassification of the device and conversion of the PMA to another regulatory category, and official correspondence concerning the abandonment or withdrawal of the PMA, placing the PMA on hold, and other miscellaneous administrative actions.

(Continued on next page.)

Table 2. Original PMAs
FY 87 - FY 91

(Continued from previous page.)

b/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is reset upon receipt of a major amendment. Thus, these average review times may exclude review time that accurred prior to the receipt of a major amendment. The review clock also may be stopped and resumed, but not reset, for minor amendments and other minor actions. This average review time will include all such incremenrs of review that occurred after the receipt of the last major amendment, if any.

c/ The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus, the average elapsed time is the average time taken to obtain approval of a PMA from the time it was filed until it receives final approval.

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

e/ FDA responsible for processing application.

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

g/ Does not include 15 PMAs that had approval packages prepared but were awaiting clearance of GMP inpections.

Table 3. PMA Supplements
FY 87 - FY 91

Action	FY 87	FY 88	FY 89	FY 90	FY 91
Number received	700	727	810	660	593
PMA Supplement Actions:					
Panel Track Filing decisions:[a]					
Filed(%)	9(43)	15(75)	21(81)	6(35)	5(38)
Not Filed(%)	12(57)	5(25)	5(19)	11(65)	8(62)
Fileable(%)	N/A	N/A	N/A	N/A	0 (0)
Filing Decision Subtotal	21	20	26	17	13
Review Activities:					
Major Deficiencies	7	5	18	30	14
Minor Deficiencies	6	0	1	0	0
Other[b]	104	133	171	292	251
Review Activities Subtotal	117	138	190	322	265
Review Decisions:					
Panel track approvals(%)[c]	8 (1)	9 (1)	13 (2)	5 (1)	2 (1)
Nonpanel track approvals(%)	557(74)	643(72)	506(76)	695(76)	478(64)
Approvable(%)	99(13)	184(21)	119(18)	138(15)	138(18)
Not approvable(%)	102(14)	72 (8)	47 (7)	87 (9)	134(18)
Approval Decision Subtotal	749	890	662	919	752
Total PMA Supplement Actions	887	1,048	878	1,258	1,030
Average review time(days) for approvals:[d]					
FDA	138	95	109	133	111
Non-FDA	5	12	31	26	32
Total	143	107	140	159	143
Average elapsed time(days) for approvals:[e]					
FDA	148	124	122	146	131
Non-FDA	11	25	41	35	44
Total	159	149	163	180	175
Number under review at end of period[f]					
Active[g]	224	195	364	215	206
(Active and overdue)	0	(2)	(62)	(7)	(1)
On hold[h]	120	107	167	120	133
Total	344	302	531	335	339

a/ Filing decisions are made for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

(Continued on next page.)

Table 3. PMA Supplements
FY 87 - FY 91

(Continued from previous page.)

b/ Includes actions that did not result in an approval/disapproval decision, such as a sponsor directed hold, reclassification of the device and conversion of the PMA supplement to another regulatory category, and official correspondence concerning the abandonment or withdrawal of the supplement, the status of the supplement as a special(changes being effected) or 30 day submission, and other miscellaneous administrative actions.

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

d/ Average review times in parentheses are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock id reset upon receipt of a major amendment. Thus, these average review times may exclude review time that accurred prior to the receipt of a major amendment. The review clock also may be stopped and resumed, but not reset, for minor amendments and other minor actions. This average review time will include all such incremenrs of review that occurred after the receipt of the last major amendment, if any.

e/ The average elapsed time includes all increments of time a PMA was under review, including all of the in rements of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus, the average elapsed time is the average time talken to obtain approval of a PMA from the time it was filed until it receives final approval.

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

g/ FDA responsible for processing application.

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

Table 4. Original IDEs
FY 87 - FY 91

Action	FY 87	FY 88	FY 89	FY 90	FY 91
Number received	218	268	241	252	213
Number of decisions:					
Approved(%)	60(27)	79(30)	89(36)	95(38)	72(33)
Not approved (%)	153(68)	172(66)	143(58)	146(59)	141(64)
Other (%)[a]	11 (5)	9 (3)	13 (5)	7 (3)	7(3)
Total	224	260	245	248	220
Average FDA review time (days)	28	27	29[c]	29	29
Percent (%) of decisions made within 30 days	97	99	100[c]	99	99
Number under review at end of period[b]	11	19	16	20	12
Number overdue at end of period	0	0	0[c]	0	1

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

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

Table 5. IDE Amendments
FY 87 - FY 91

Action	FY 87	FY 88	FY 89	FY 90	FY 91
Amendments received[a]	265	316	271	288	283
Decisions on amendments:					
Approved(%)	132(52)	170(52)	127(45)	123(46)	133(46)
Not approved (%)	71(28)	88(27)	78(28)	79(29)	80(28)
Other (%)[b]	51(20)	68(21)	75(27)	68(25)	74(26)
Total	253	327	280	270	287
Average FDA review time (days)	33	24	23[e]	24	23
Percent (%) of decisions made within 30 days	96	98	99[e]	99	99
Average approval time (Days) for IDEs with amendments:					
FDA time	83	65	68	73[f]	71
Non-FDA time	69	87	108	114[f]	118
Total time[c]	152	152	176	187[f]	189
Amendments under review at end of period[d]	31	20	11	29	25
Amendments overdue at end of period	0	0	0[e]	0[e]	0

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

b/ Includes actions that did not result in an approval/disapproval decision, such as withdrawal of the IDE or the amendment by the sponsor, and other administrative actions, e.g., acknowledgement letters concerning the submission of information that did not require independent approval/disapproval and other administrative information, such as a change of address.

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

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

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

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

Table 6. IDE Supplements
FY 87 - FY 91

Action	FY 87	FY 88	FY 89	FY 90	FY 91
Number received	2,836	3,391	3,038	3,043	3,647
Number of decisions	2,784	3,405	3,023	2,968	3,705
Average FDA review time (days)	22	22	22[b]	22	21
Percent (%) of decisions made within 30 days	95	99	99[b]	99	99
Number under review at end of period[a]	175	157	170	245	189
Number overdue at end of period	0	0	0[b]	0	0

a/ 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.

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

Table 7. 510(k)s
FY 87- FY 91

Action	FY87	FY 88	FY 89	FY 90	FY 91
Number received	5,265	5,536	7,022	5,831	5,770
Number of decisions:					
Substantially equivalent	4,105	4,432	4,867	4,748	4,294
Not substantially equivalent	103	82	92	117	122
Other[a]	784	999	1,177	1,332	951
Total	4,992	5,513	6,136	6,197	5,367
Percent(%) not substantially Equivalent[b]	2.4	1.8	1.9	2.4	2.8
Average review time(days):					
FDA time[c]	56	64	66[h]	78[k]	81
Total time[d]	69	78	82[h]	98[k]	102
Percent(%) of decisions made within 90 days, based on:					
FDA time[e]	96	99	99	100[l]	100[l]
Total time[d]	71	67	70[h,i]	57	57
Number under review at end of period:					
Active[f]	934	913	1,270	1,174	1,402
(Active and overdue)	0	0	0[h]	0	0
On hold[g]	409	445	989	726	889
Total	1,343	1,358	2,259[j]	1,900	2,291

a/ Includes final administrative actions that did not result in a substantially equivalent/not substantially equivalent decision because the 510(k) or device/product was: withdrawn by the applicant, deleted due to lack of response, a duplicate, not a device, a transitional device, regulated by CBER, a general purpose article, exempted by regulation, and other miscellaneous actions.

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

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

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

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

f/ FDA responsible for processing notification.

(Continued on next page.)

Table 7. 510(k)s
FY 87 - FY 91

(Continued from previous page.)

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

h/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no 510(k)s were logged out and the clock was suspended for our Center was closed from June 26 to July 13, for a total of 18 days. During this time, no 510(k)s were logged out and the clock was suspended for purposes of counting the 90 day review period. In FY 89 and FY 90, for 510(k)s that were in ODE during the closed period and for which the review period exceeded 90 days, up to 18 days were subtracted from the review time to determine the average review time and to determine whether the document was overdue. This policy was announced in two letters to submitters of 510(k)s and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and, September 8, 1989, at page 37,377.

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

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

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

l/ The percent of decisions made within 90 days based on FDA review time is 100% rounded off from 99.6%. Only 23 decisions out of the 5,367 total decisions were completed in more than 90 days.

Table 8. Major Submissions Received FY 81- FY 91

Type of Submissions	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991
Orig. PMAs	60	90	76	65	97	69	81	96	84	79	75
PMA Supp.	259	277	360	435	393	478	700	727	810	660	593
Orig. IDEs	237	189	189	203	204	206	218	268	241	252	213
IDE Amend.	N/A	N/A	N/A	N/A	N/A	365	265	316	271	288	283
IDE Supp.	924	1,694	1,750	3,077	2,457	2,884	2,836	3,391	3,038	3,043	3647
510(k)s	3,684	3,798	4,477	5,004	5,254	5,063	5,265	5,536	7,022	5,831	5770
Total	5,164	6,048	6,852	8,784	8,974	8,974	9,365	10,334	11,466	10,153	10,581

Table 9. Major Submissions Completed FY 81- FY 91

Type of Submissions	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991
Orig. PMAs	32	49[a]	46	43	37	72	46	46	56	47	27
PMA Supp.	239	238	327	243	377	477	565	652	519	700	479
Orig. IDEs	232	189	187	198	201	213	224	260	245	248	220
IDE Amend.	N/A	N/A	N/A	N/A	361	330	253	327	280	270	287
IDE Supp.	N/A	N/A	N/A	N/A	2,190	3,599	2,784	3,405	3,023	2,968	3,705
510(k)s	3,381	3,256	3,162	4,262	5,095	5,359	4,992	5,513	6,136	6,197	5,367
Total	3,884	3,732	3,632	4,746	8,261	10,050	8,864	10,203	10,259	10,430	10,085

N/A - Not available.

a/ Includes one denial of approval.

Appendix A. ODE Staff Roster
FY 91

Office of the Director

Acker, R.
Alvarado, M.
Breslawec, H.
DeMarco, C.
Grygier, D.
Kyper, C.
Murray, G.
Sheridan, R.
Trisler, P.
West, D.

Program Management Office

Appler, K.
Barnes, R.
Clingerman, A.
Cornelius, E.
Link, J.
McGheehan, R.
Ingraham, S.
Jaeger, J.
Schools, T.
Trammell, D.
Vaughan-Dowtin, S.
Wedlock, C.

Program Operations Staff

Allen, G.
Alpert, A.
Alonge, L.
Chissler, R.
Cole-Fisher, L.
Dorsey, L.
Falls, D.
Fishbein, L.
Huff, W.
Jackson, B.
Lewis, D.
Lewis, J.
Lundsten, K.
Parker, M.
Perticone, D.
Phillips, P.
Robinson, M.
Rosecrans, H.
Shulman, M.
Socks, B.
Spade, J.
Sterniolo, M.
Sutton, W.
Zafra, M.

Division of Clinical Laboratory Devices

Appell, R.
Aziz, K.
Berko, R.
Blagmon, D.
Brindza, L.
Bucher, B.
Chace, N.
Cricenti, P.
Fugate, K.
Hackett, J.
Hanna, N.
Hansen, S.
Harris, P.
Hawthorne, C.
Huff, L.
Jones, D.
Lappalainen, S.
Magruder, L.
Maxim, P.
Moore, N.
Nutter, C.
Ohrmundt, J.
Poole, F.

Rahda, E.
Rao, P.
Robinowitz, M.
Rooks, C.
Selfon, N.
Sellman, V.
Shively, R.
Simms, T.
Sliva, C.
Staples, B.
Stewart, W.
Tsakeris, T.
Vadlamudi, K.
Wilson, T.
Yoder, F.

Division of Cardiovascular, Respiratory, and Neurological Devices

Abel, D.
Acharya, A.
Astor, B.
Bowie, K.
Burdick, W.
Byrd, G.
Carey, C.
Cheng, J.
Ciarkowski, A.
Costello, A.
Cronin, V.
Dahms, D.
Danielson, J.
Davis, L.
Dillard, C.
Dillard, J.
Donelson, J.
Gantt, D.
Glass, J.
Gluck, M.
Gornick, M.
Harrison, M.
Hinckley, S.
Hoang, Q.
Hwang, S.
Justice, D.
Keely, L.
Kennell, L.
Lemperle, B.
Letzing, W.
Massi, M.
McCullough, D.
Morris, J.
Moyal, A.
Munzner, R.
Muse, M.
O'Neill, C.
Palmer, K.
Reamer, L.
Roy, J.
Ryan, T.
St. Pierre, D.
Sapirstein, W.
Shein, M.
Sliwiak, J.
Sloan, C.
Smallwood, S.
Teague, N.
Terry, D.
Tran, A.
Trinh, H.
Twardochleb-Shanker, R.
Wentz, C.
Zier, D.

Division of General and Restorative Devices

Adams, T.
Barrett, S.
Basu, S.
Berne, B.
Blackwell, M.
Bolden, B.
Brower, A.
Browne, M.
Callahan, T.
Clark, T.
Donoghue, M.
Einberg, E.

Felten, R.
Ferl, J.
Gantenberg, J.
Hadley, K.
Harris, C.
Hlavinka, L.
Hoard, R.
Jan, G.
Lang, J.
Larson, C.
Lin, C.
Mattan, A.
McCuin, S.
McDermott, K.
McGunagle, D.
Melkerson, M.
Minear, D.
Mishra, N.
Moreland-Curtis, F.
Nessen, L.
Niver, S.
Ogden, N.
Parkhurst, J.
Purvis-Wynn, S.
Rhodes, S.
Riegel, E.
Rosile, N.
Saas, H.
Sands, B.
Schroeder, M.
Scott, P.
Scudiero, J.
Singleton, G.
Smith, G.
Sternchak, R.
Stevens, T.
Thomas, D.
Tilton, P.
Torres-Cabassa, A.
Tylenda, C.
Ulatowski, T.
Vinson, P.
Wei, T.
Williams, R.
Wolf, B.
Wong, L.
Yahiro, M.

Division of Opthalmic Devices

Arras, C.
Batra, K.
Brogdon, N.
Brown, D.
Buas, C.
Burke-Nicholas, M.
Calogero, D.
Chen, T.
Cohen, L.
Coleman, Y.
Felton, E.
Fox, P.
Gelles, M.
Gouge, S.
Hammerman, C.
Jankowski-Miller, P.
Jones, S.
Kaufman, D.
Lippman, R.
Maurey, K.
McCarthy, D.
Meads, L.
Pettinato, M.
Rogers, D.
Saviola, J.
Schwartz, T.
Sloane, W.
Smith, M.
Storer, P.
Thornton-WIlburn, S.
Weiblinger, R.
Whipple, D.
Wilkerson, P.
Yoza, A.
Zollo, M.

Division of Reproductive, Abdominal, ENT, and Radiological Devices

Arnaudo, J.
Baxley, J.
Bove', C.
Bradley-Allen, C.
Brauer, C.
Byrd, L.
Conklin, G.
Cornelius, M.
Cress, L.
Dart, L.
Derrer, C.
Foster, F.
Fredericksen, J.
Galdi, A.
Gatling, R.
Geiger, F.
Guest, J.
Howell, H.
Hubbard, R.
Jasper, S.
Jefferies, M.
Kaltovich, F.
Kammula, R.
Kramer, M.
Kuchinski, J.
Maloney, W.
Melvin, M.
Miller, P.
Mills, G.
Mosely, T.
Neuland, C.
Nimmagadda, R.
Perez, R.
Phillips, R.
Pollard, C.
Relacion, C.
Rubendall, R.
Sauberman, H.
Segerson, D.
Seiler, J.
Sharpe, E.
Shuping, R.
Tsai, M.
Williams, E.
Yin, L.
Yaffe, L.
Zaremba, L.

Left Before Re-Organization

Bhatnagar, G.
Kawin, L.
Dawson, J.
Michaloski, C.
Loew, W.
Pfister, R.
Park, J.
Cromwell, S.
Brown, L.
Garland, J.
Trybus, C.
Stalbaum, K.
Choy, J.
Sanchez, R.
Purohit, V.
Lockhart, J.
Goodman, S.

OFFICE OF DEVICE EVALUATION