OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1996

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

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(October 1, 1995 - September 30, 1996)

Acknowledgements

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

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PREFACE

Fiscal Year 1996 has proven to be a year of outstanding accomplishments for the Office of Device Evaluation (ODE). Our goals to increase efficiency and productivity were achieved due to the continued support of a dedicated and hard working staff. Together, we -

- approved 43 PMAs, 16 more than FY 95, 9 via expedited review;
- reduced both the FDA and total average review time and average elapsed time for PMA supplements;
- initiated a "real-time review" pilot for PMA supplements;
- called for PMAs for 41 class III devices in accordance with the 515(b) regulation;
- approved or cleared 43 devices (24 PMAs and 19 510(k)s) which represent significant medical device breakthroughs;
- eliminated the active and overdue backlog in the 510(k) program;
- initiated a third-party review pilot program for 510(k)s for select device types;
- significantly reduced the FDA and total average review and median review times for 510(k)s;
- changed 510(k) clearance letters to include indications for use;
- approved 73% of IDEs on the first review cycle;
- reduced the FDA and total average approval time for original IDEs with amendments;
- issued 36 guidance documents;
- implemented new procedures for the development and use of guidance documents;
- implemented an humanitarian device exemption program; and
- made information on ODE's activities available on the CDRH Home Page.

It gives me great pleasure to present this year's annual report because it reflects the exceptional achievements of the ODE staff. Appreciation is also expressed to Center management and the other CDRH Offices for their support during FY 96.

Susan Alpert, Ph.D., M.D.
Director, Office of Device Evaluation

HIGHLIGHTS
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
Fiscal Year 1996

The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research or marketing. (See Appendix A for further information on ODE's program activities.).

ODE's Major Program Initiatives (Humanitarian Device Exemption Program, Real-Time Review Pilot Program, Major Revision of IDE Manual, Third-Party Review Pilot, 510(k) Exemptions, Indications for Use in 510(k)s, IVD Tier/Triage Management Initiative, and CDRH World Wide Web) are discussed in detail in the next section of this report. This section also discusses Significant Jurisdictional Issues.

Following are the highlights of ODE's activities for Fiscal Year 1996 (FY 96):

Workload/Resources

- During FY 96, ODE received 20,236 submissions, compared to 21,990 in FY 95.
- On the output side, ODE completed the processing of 9,667 major submissions, compared to 12,013 major submissions in FY 95.
- ODE ended the year with 368 employees on board. During the year, ODE lost 22 full-time employees (21 scientific reviewers and 1 medical officer) through resignation or retirement but added 37 new employees (17 scientific reviewers, 9 medical officers, and 11 support staff). Eleven new hires (30%) were members of minority groups (6 were women).

Chart 1. Major Submissions, Reviews and Total Actions

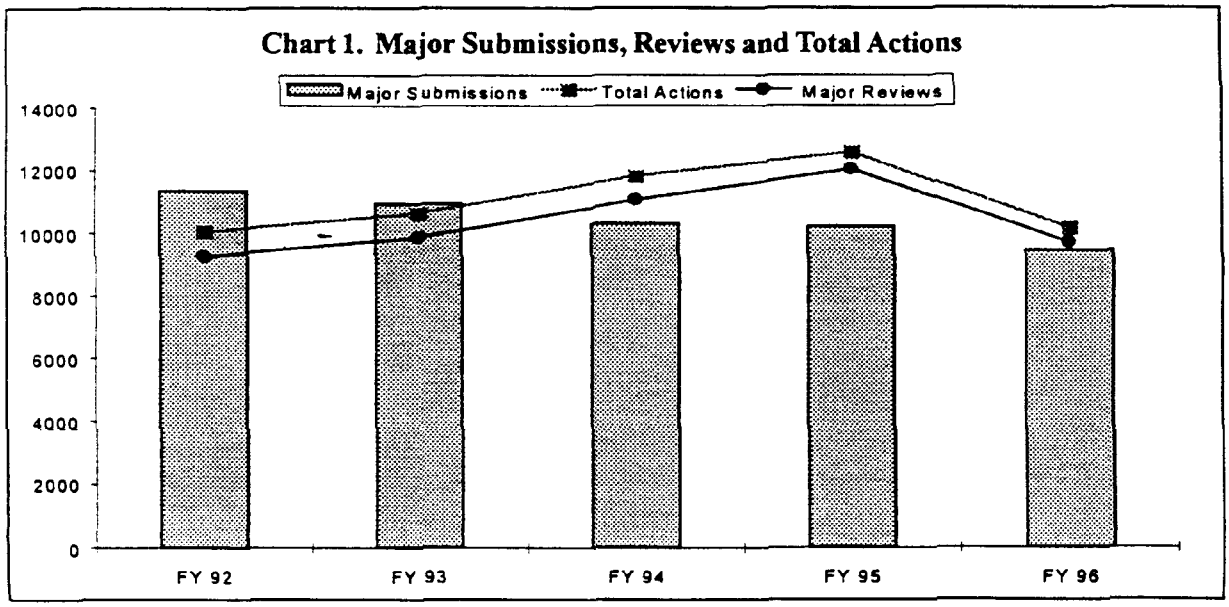
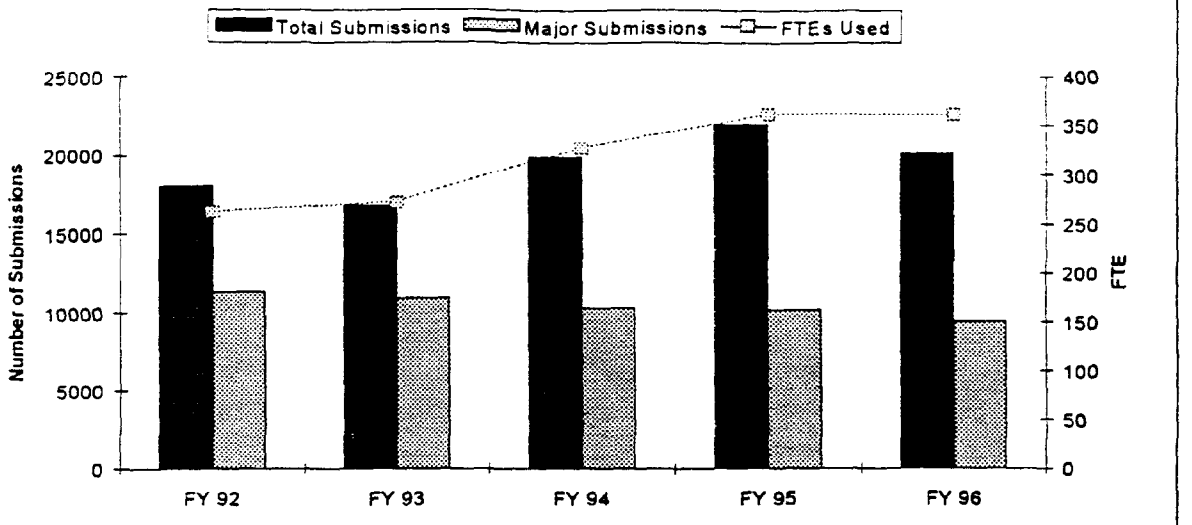


Chart 2. Submissions Received and FTEs Used



Premarket Approval Applications (PMAs)

- ODE received 44 original PMAs, 5 more than the number received in FY 95.

- The total number of PMAs under review at the end of this fiscal year dropped for the fourth year in a row, from 125 last year to 96. The number of active PMAs under review decreased at the end of FY 96 to 57 compared to 69 last year, and those on hold decreased from last year, from 56 to 39. The number of PMAs that were active and overdue decreased from 26 last year to 17 at the end of FY96, the lowest it has been for the past five years.

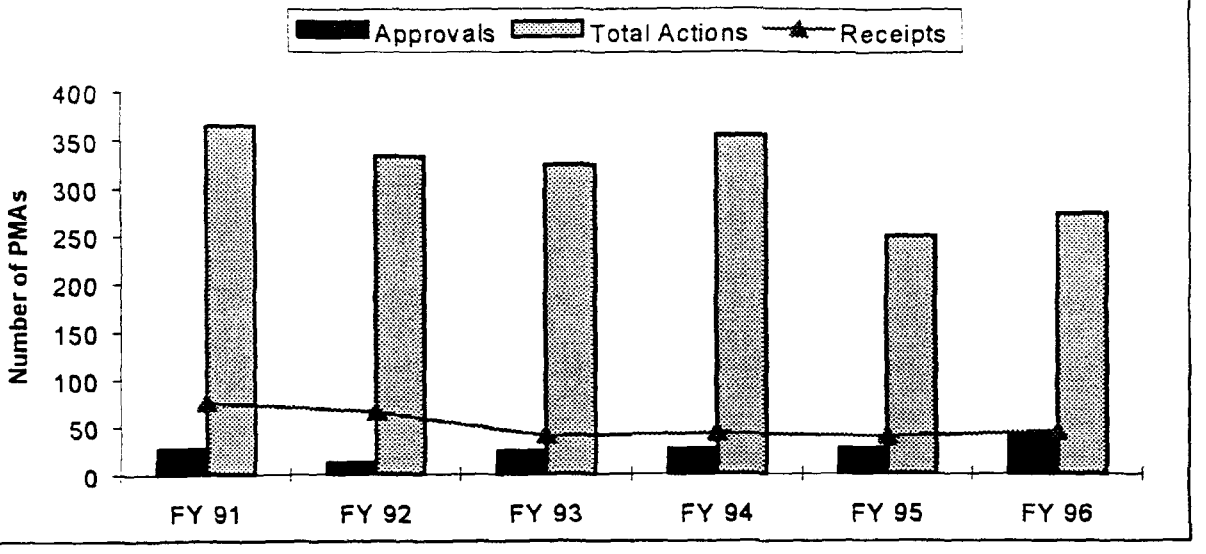
- The total number of 272 PMA actions increased from 249 PMA actions last year. These actions included 62 filing decisions, 134 review activity determinations, and 76 approval decisions.

- The 76 PMA decisions consisted of 43 approvals (16 more than the number of approvals in FY 95), 27 original PMAs were found to be approvable, and 6 nonapprovables (an increase from 4 in FY 95). Nine of the 43 approvals were expedited PMAs.

- Average FDA review time for original PMAs reaching final action increased from 276 days in FY 95 to 289 days in FY 96. The non-FDA component of review time decreased slightly from 81 days in FY 95 to 55 days this fiscal year. On balance, the combined average review time remained nearly constant at slightly less than 12 months. There were 17 PMAs active and overdue at the end of this fiscal year, down from 26 at the end of FY 95.

- The number of PMA supplements received decreased from last year's 499 to 415. The total number of PMA supplement actions, which includes 9 panel track filing decisions, 151 review activity determinations, and 543 approval decisions, was 703, down from last year's 744 total actions.

Chart 3. Annual PMA Receipts and Actions



- ODE reduced both the average review time, from 228 days in FY 95 to 182 days, and the average elapsed time, from 275 days to 216 days for PMA supplements.

- The number of PMA supplements that were active and overdue dropped from 49 at the end of the last fiscal year to 17. The number of active supplements was further reduced to 162 from 226 last year, and the number of supplements on hold decreased from 151 to 74.

Chart 4. Average Review Time for PMA Approvals

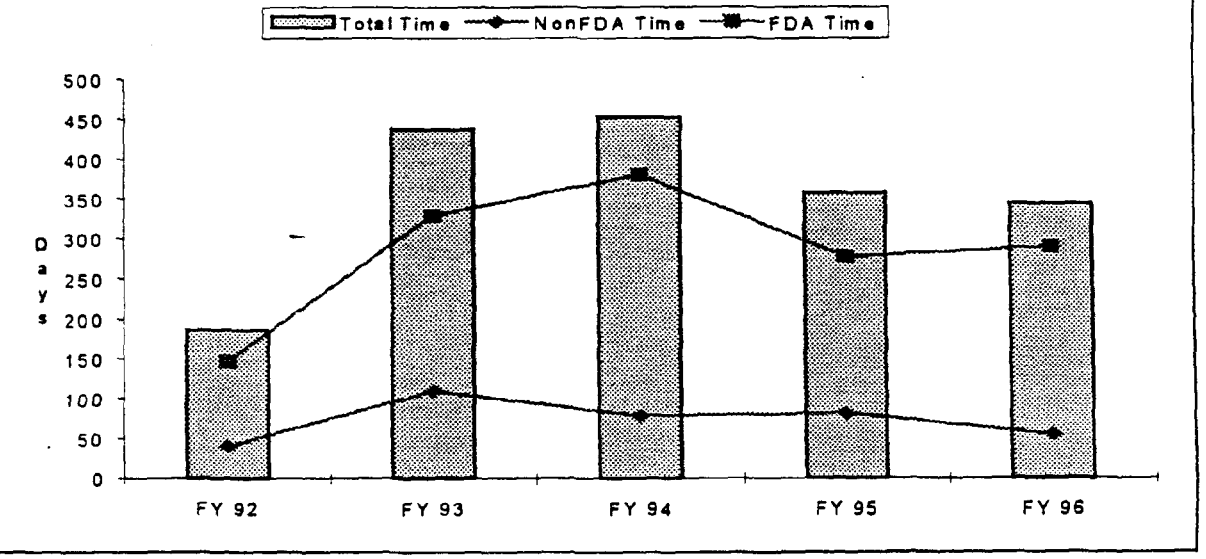


Chart 5. Annual PMA Supplement Receipts and Actions

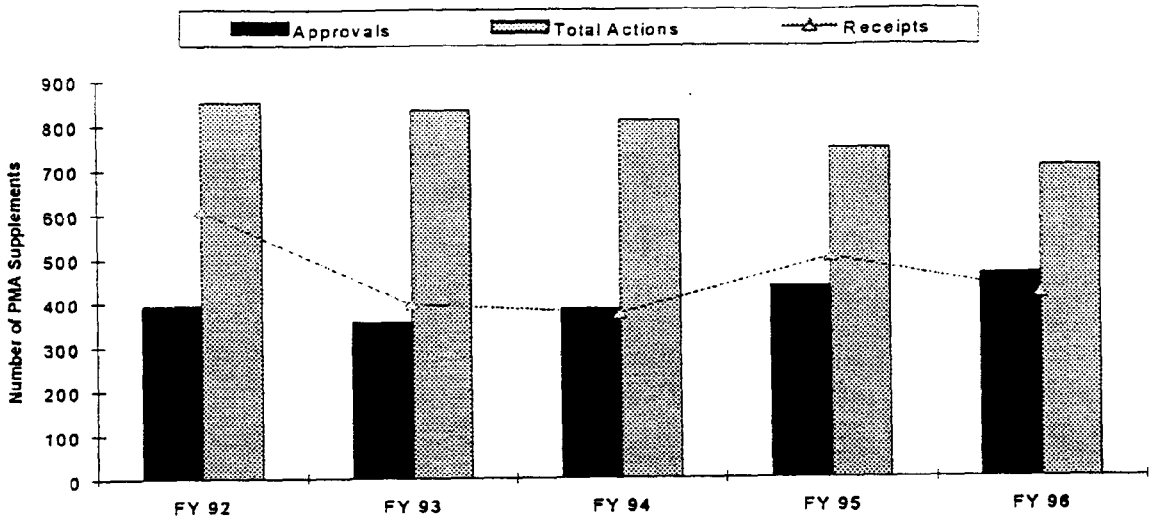
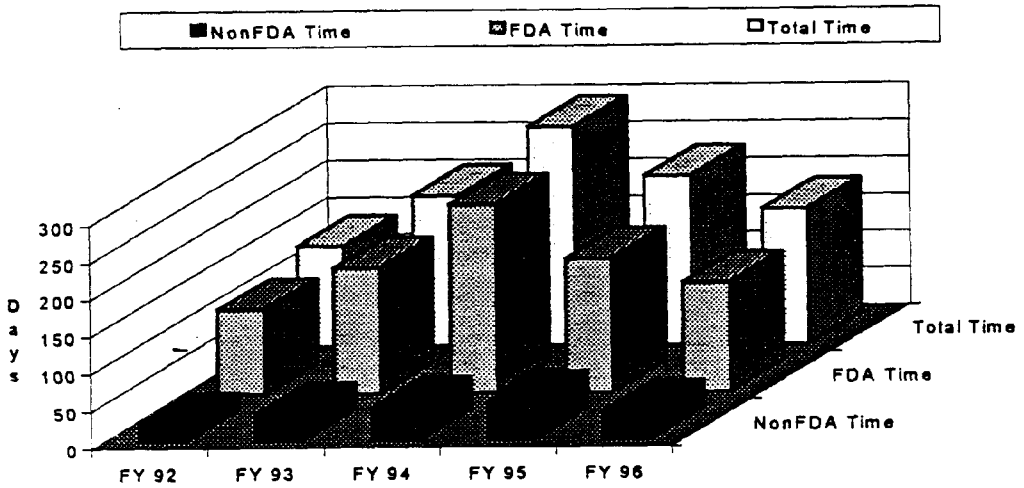


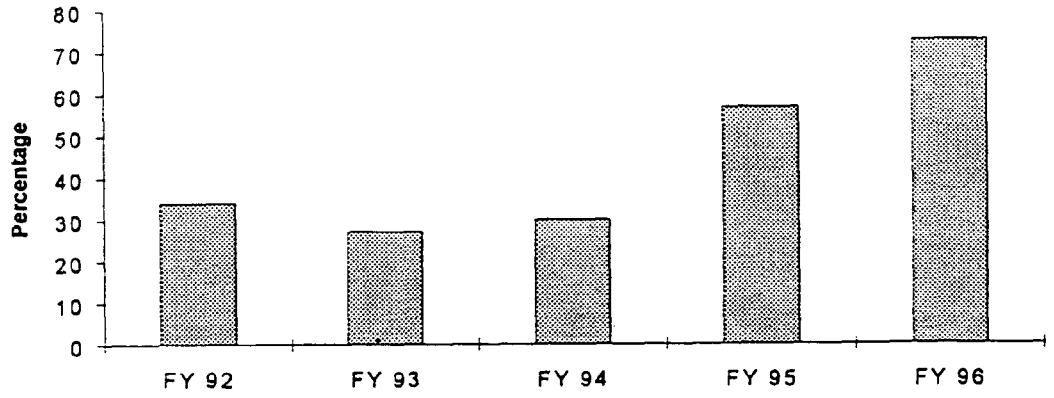
Chart 6. Average Review Time for PMA Supplements



Investigational Device Exemptions (IDEs)

- ODE received 253 original IDEs, a significant increase from the 214 received in FY 95. The same holds true for IDE decisions; 260 decisions were made on original IDEs, an increase from 210 last year.

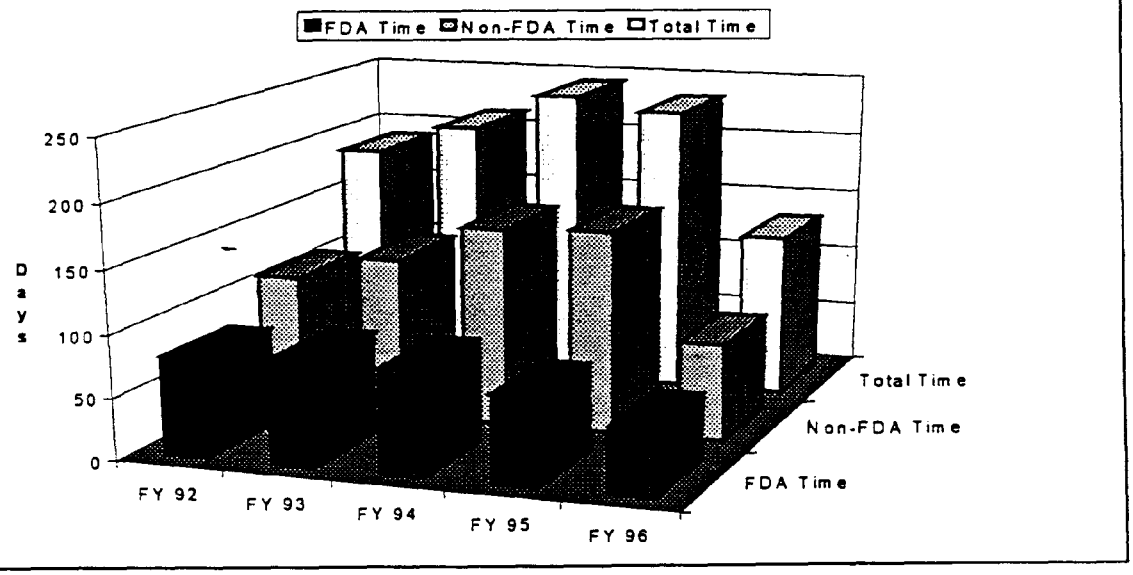
Chart 7. Percentage of IDEs Approved on First Review Cycle*



*Based on those IDEs complete enough to permit substantive review.

- Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 96, up from 92 percent in FY 95. Of the IDEs which were complete enough to permit substantive review, the percentage of IDEs approved on the first review cycle increased from 57 percent in FY 95 to 73 percent during FY 96.

Chart 8. Average Approval Time for IDEs with Amendments

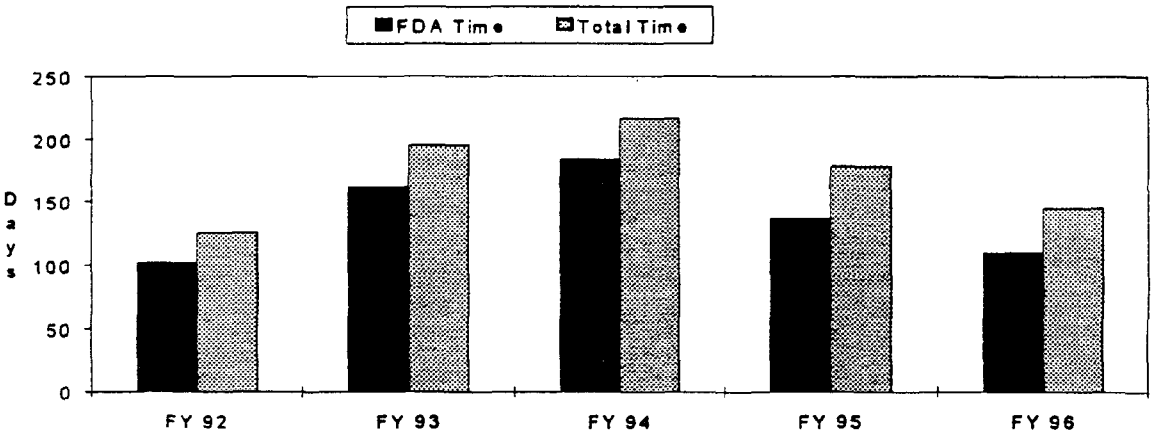


- During this fiscal year, 219 IDE amendments were received. Decisions were made on 218 amendments: 98 approvals (45%); 29 disapprovals (13%); and 91 other administrative actions (42%). Ninety-eight percent of these decisions were made within 30 days.

- It took an average total time of 131 days to approve original IDEs with amendments, down from 232 days in FY 95. This average approval time consisted of 53 days for FDA time, down from 70 days last year, and 78 days for non-FDA time, down from 162 days in FY 95.

- ODE received 3,189 IDE supplements during FY 96. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe is slightly up at 99 percent in FY 96. The average review time for completing the review of IDE supplements dropped to 21 days.

Chart 9. Average 510(k) Review Time*



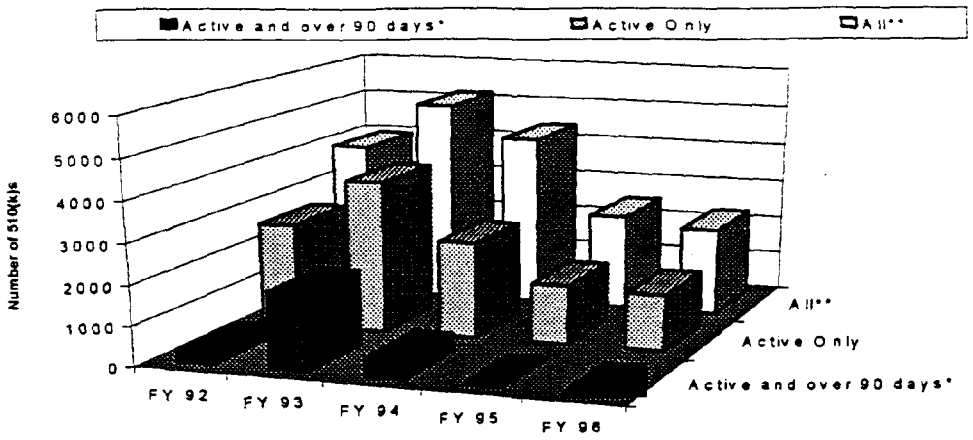
*Without withdraws and deletes

Premarket Notifications (510(k))

- ODE received 5,297 original 510(k)s, 3,246 510(k) supplements (responses to hold letters, the receipt of which restart the review clock), and 5,343 amendments (additional information, the receipt of which does not affect the review clock).

- The total average review time declined from 178 days in FY 95 to 145 days in FY 96, and the FDA review time was 110 days, down from 137 days in FY 95. The median review time, i.e., the time it took to review 50% of the 510(k)s, has been falling from a high of 164 days in FY 93 to a current low of 88 days in FY 96.

Chart 10. Pending 510(k)s



*in the current review cycle, includes those over 90 days
** under review and on hold

- There were 2,229 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year, which is a significant decrease from the 2,450 510(k)s that were in FY 95's end-of-year inventory. The number on hold declined from 964 at the end of FY 95 to 821. Most important, at the end of this reporting period there were no 510(k)s active and overdue as compared to 1,894 in FY 93, 460 in FY 94, and 9 in FY 95.

Significant Medical Device Breakthroughs

During FY 96, ODE approved 24 PMAs and cleared 19 510(k)s that represent significant medical device breakthroughs. See Appendix B for a complete list.

Final Reclassification Actions

- Published a final rule in the *Federal Register* on January 16, 1996, reclassifying 111 devices from class II to class I and exempting them from premarket notification and reclassifying 11 devices from class I to class I exempt from premarket notification.

- Issued an order on March 29, 1996, to the Acupuncture Coalition reclassifying Acupuncture Needles from class III to class II.

- Issued an order on September 19, 1996, to Centocor Inc. reclassifying Tumor Associated Antigen Immunological Test System from class III to class II.

- Issued an order on September 24, 1996, to Incstar Inc. reclassifying Vitamin D I^{125} RIA Assay from class III to class II.

Proposed Reclassification Actions

- Published a proposed rule in the *Federal Register* on October 4, 1995, to classify/reclassify Pedicle Screw Spinal Systems from class III to class II.

- Published a proposed rule in the *Federal Register* on March 8, 1996, to reclassify the Neodymium: Yttrium:Aluminum:Garnet (Nd:YAG) Laser for Peripheral Iridotomy from class III to class II.

- Published a proposed rule in the *Federal Register* on March 14, 1996, to classify/reclassify Analyte Specific Reagents from class III to class I and class III.

- Published a proposed rule in the *Federal Register* on April 1, 1996, to reclassify Rigid Gas Permeable Contact Lens Solution; Soft (Hydrophilic) Contact Lens Solutions; and Contact Lens Heat Disinfecting Unit from class III to class II.

- Published a proposed rule in the *Federal Register* on June 14, 1996, to classify/reclassify Immunohistochemistry Reagents and Kits from class III to class II or class I.

- Published a proposed rule in the *Federal Register* on August 27, 1996, to reclassify the Infant Radiant Warmer from class III to class II.

Other Reclassification Activities

- On March 11, 1996, the General Hospital and Personal Use Devices Advisory Panel recommended the classification of the Long-Term Percutaneous Intravascular Catheter and the Subcutaneously Implanted Intravascular Infusion Ports and Catheters into class II and identified special controls for both devices.

- On May 9 and 13, 1996, ODE conducted a reclassification training for reviewers in conjunction with Staff College.

- On June 7, 1996, ODE, in cooperation with the Health Industry Manufacturers Association, the Medical Device Manufacturers Association, and the National Electrical Manufacturers Association, conducted a workshop on reclassification of pre-amendment class III devices.

- On July 26, 1996, the Ophthalmic Devices Advisory Panel recommended the classification of Corneal Storage Media in class II, and identified special controls for the device.

PMA's for Pre-Amendments Devices (515(b) Regulation)

- During FY 96, FDA published a 515(b) Final Rule in the *Federal Register* on September 27, 1996, for 41 class III preamendments devices.

Guidance for Industry and Reviewers

In FY 96, ODE issued 36 Guidance Documents. See Appendix C for a complete listing.

Advisory Panel Activities

The Medical Devices Advisory Committee provides advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification of devices into one of three regulatory categories, the review of premarket approval applications, and the content of guidelines or guidance documents designed to improve the interaction between the Agency and sponsors of medical devices. The Committee is divided into 16 panels according to medical device specialty.

In FY 96, ODE held 25 panel meetings. Each panel met at least once. There were 10 formal training sessions held for new panel members. The Executive Secretaries attended monthly meetings, and, in addition, seminars were scheduled which covered a variety of topics regarding the advisory committees.

Announcements of panel meetings are publicized in several ways: FDA Advisory Committee Information Line (1-800-741-8138); *Consumer Quarterly Report, Federal Register*, and the Internet. The panel meetings are open to the public and time is provided for public comment on the topic under consideration. Persons who wish to present their views must contact the Executive Secretary and request time in advance.

Panel meetings are now announced and summarized via internet and can be accessed by typing "http://www.fda.gov/cdrh/index.html" and then selecting 'General Information' followed by 'CDRH Advisory Committees.' Detailed information on any one of ODE's panels can be accessed by selecting specific highlighted information.

Female and minority representation are encouraged; currently females make up 40% of our membership and minorities 32%.

ODE continuously recruits highly qualified experts to serve on its panels. Interested individuals should send their resume to the Advisory Panel Coordinator, Office of Device Evaluation, 9200 Corporate Boulevard, Rockville, Maryland 20850.

ODE Integrity Program

During this fiscal year, ODE investigated 39 cases concerning the integrity of data submitted to the agency in premarket applications and handled 42 instances related to questions arising under the standards of conduct for employees.

A particular issue arose during FY 96 which received special attention under the Integrity Program. An unauthorized disclosure of proprietary information concerning ophthalmic lasers occurred during the year. There were articles in the *Wall Street Journal* and the trade press discussing this disclosure, and it was the subject of a Congressional hearing on July 31, 1996. Upon learning of this disclosure in November of 1995, the matter was referred immediately to the agency's Office of Internal Affairs, who conducted an initial investigation of the matter. During the summer of 1996, the investigation was turned over to the Federal Bureau of Investigation and remains under investigation. Internally, the ODE Integrity Officer issued a memorandum to the ODE staff concerning the need to protect nonpublic confidential information, and the Center Director issued a memorandum to all Center staff concerning the protection of privileged information. In addition, various steps, such as the installation of locks for offices, desks, and file cabinets, were

taken to increase the security of files within ODE. Clarification of procedures for security in the Document Control Unit (DCU) was provided to ODE staff. These procedures included how to correctly check out documents and access DCU contractual staff.

Freedom of Information Requests

ODE staff received 1,794 FOI requests during FY 96 indicating a significant increase from previous years (1,378 in FY 95, 943 in FY 94, 976 in FY 93, and 1,052 in FY 92). During FY 96, the number of FOI requests closed were 2,140; the total number of FOI requests pending in ODE is 1,229.

Congressional Inquiries

Congressional interest in ODE programs continued to be strong during FY 96. ODE staff responded to 20 Congressional letters. Most inquiries related to excimer lasers, the Sensor Pad, and anti-snoring devices. Congressional hearings held during FY 96 dealt with FDA's use of authority, the product approval process, off-label use, improvement in review times, patient access to medical treatment, and home drug testing.

Publications

During FY 96, ODE cleared 1 abstract, 2 manuscripts, and 1 letter authored by ODE staff for publication in professional and scientific journals, and 13 presentations delivered by ODE staff at professional and scientific and trade association meetings.

ODE Vendor Days

In FY 96, ODE continued to sponsor informational exchange seminars with device manufacturers. On March 14-15, 1996, ODE sponsored a "Vendor Day" with manufacturers of Patient Monitoring devices. This 4-hour seminar included an open session for device viewing and demonstrations of multi-parameter and arrhythmia monitors. This is the fifth Vendor Day since the Vendor Day program began.

Site Visits

In FY 96, ODE continued its "Site Visit" program which was developed to enhance reviewer knowledge of how specific regulated devices are manufactured and tested. The 10 FY 96 site visits included visits to manufacturers of devices for hips and spines, ear implants, ENT surgical instruments, various catheters, stents and generators.

In-House Training

The CDRH Staff College sponsored seminars, lectures, and grand rounds throughout the year. Specific ODE training courses included Basic Optics, Clinical Practice in the Management of Patients with Cardiac Pacemakers and/or Defibrillators, and Software Validation. Supervisors continued to participate in monthly

meetings to discuss current management issues, and all employees attended in-house workshops to learn about current technologies and new policies and procedures.

Computer Tracking Systems

ODE tracking system changes and additions included: the modification of the 510(k) tracking system to capture Indications for Use information; the completion of receipt/cohort tracking reports for 510(k)s, PMAs, and IDEs that allow for performance monitoring based on collections of submissions received during a specified time period; and the capture of data on recognized third parties and the products they are authorized to review. The programming to support these computer tracking systems was completed by staff from the Office of Systems and Management. In addition, a new PMA Expedited Review Module was programmed and implemented to support the expedited review of PMAs. Two new "net productivity" reports were programmed for 510(k)s and PMAs to indicate the net workload per month based on input/ output. Finally, programming commenced on a new tracking system to monitor the document process for Humanitarian Device Exemptions.

Electronic Submissions

ODE reviewers continued to receive electronic submissions in FY 96. Six manufacturers participated by submitting electronic submissions. ODE received 3 510(k)s, 1 IDE, 18 PMA supplements and 1 PMA. However, this program remains in its initial stages. PC limitations, the current infrastructure, and reviewer knowledge and aptitude for this new procedure limit the widespread use within ODE.

Video Conferencing

While continuing to use video conferencing for label reviews and other interactions with device sponsors, ODE conducted four "Real Time" PMA supplement reviews, via video conferencing, which were all approved within the next five working days. ODE also linked a conference on Surfaces in Biomaterials in Phoenix with a group of ODE experts in Rockville. The experts responded to questions raised at the conference. The conference organizers received high praise for FDA's participation and, in particular, for the interactive nature of the video conference.

Office Automation

ODE continued to improve its base of equipment and its computer systems in FY 96 with the installation of 150 new AST P/100s, 4 faxsimile machines, secretarial printer upgrades and computer memory upgrades. ODE's computer staff connected all of ODE's PCs to the Center's Pathworks LAN which facilitated document sharing among Center Offices and allowed ODE employees access to the Internet through Netscape or Mosaic. Plans are underway for the installation of Windows 95 and the migration to Microsoft Office. In addition, ODE Tracking Systems received considerable attention, and electronic submissions activity continued. In summary, ODE reviewers obtained additional tools needed to assist them in an ever-expanding review process.

MAJOR PROGRAM INITIATIVES
Fiscal Year 1996

Humanitarian Device Exemption Program (HDEs)

On June 26, 1996, FDA issued a final rule to implement the provisions of the Safe Medical Devices Act of 1990 (SMDA) regarding humanitarian use devices (HUDs). Pursuant to the SMDA and this regulation, we established the Humanitarian Device Exemption (HDE) Program within ODE. An HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. A device manufacturer's research and development costs could exceed its market returns for diseases or conditions affecting small patient populations. The Agency, therefore, developed and published this regulation in order to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

According to new Subpart H of *21 CFR Part 814*, an HUD is exempt from the effectiveness requirements of sections 514 and 515 of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360j(m)) provided that: (1) The device is used to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year; (2) the device would not be available to a person with such a disease or condition unless the exemption is granted; (3) no comparable device (other than another approved HUD or a device being studied under an approved IDE) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Under Subpart H, marketing approval for an HUD is accomplished in two distinct steps. First, the sponsor of an HUD submits a request to FDA's Office of Orphan Products Development (OOPD) seeking a determination that the disease or condition which the device is intended to treat or diagnose affects or is manifested in fewer than 4,000 individuals in the United States per year. Within 45 days of receiving a request for HUD designation, OOPD will issue its determination. If OOPD determines that a device is eligible for designation as an HUD, a sponsor may submit an HDE application, including a copy of this designation, to the Office of Device Evaluation.

An HDE application is similar in both form and content to a premarket approval application (PMA) but is exempt from the effectiveness requirements of a PMA. Even though the HDE is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose, the application must contain sufficient information for FDA to determine, as required by statute, that the device does not pose an unreasonable risk of illness or injury to patients and that the probable benefit outweighs the risk of injury or illness from its use. An HDE application must also contain information that will allow FDA to make the other determinations required by the act as enumerated above.

Subpart H references many of the procedures and requirements set forth in Part 814; thus, the review procedures for HDEs will be largely the same as those for PMAs. As for PMAs, the Agency will notify the submitter of an HDE within 45 days whether the application is sufficiently complete to permit a substantive

review. If the HDE is filed, the Agency will act upon the application within 180 days from the time such application is received by ODE.

Because an HUD is exempt from the effectiveness requirements, there are several specific requirements for HUDs that do not apply to devices that are reviewed for both safety and effectiveness. For instance, an approved HDE authorizes marketing of the device for a term of only 18 months from the date of approval. Beyond that date, if an extension request is not submitted and approved, the HUD is no longer considered a legally marketed device. If an extension request is submitted, however, the original approval may be extended at 18-month intervals. Also, an HUD may not be sold for an amount that exceeds the costs of research and development, fabrication, and distribution. In addition, an HUD may only be used in facilities that have established a local institutional review board (IRB) to supervise clinical testing of devices and after an IRB has approved the use of the device to treat or diagnose the specific disease. Finally, labeling for an HUD device must state that, although use of the device is authorized by Federal Law, the device is an humanitarian use device and that the effectiveness of the device for the specific indication has not been demonstrated.

This regulation became effective October 24, 1996. For further information regarding the HUD designation process, please contact the Office of Orphan Products Development at (301) 827-3666. For further information regarding the HDE program, please contact the HDE Staff at (301) 594-1190. HDE applications may be submitted after the effective date of the regulation and should be submitted to: HDE Document Mail Center (HFZ-401), ODE, CDRH, 9200 Corporate Boulevard, Rockville, MD 20850.

Real-Time Review Pilot Program

ODE's Division of General and Restorative Devices (DGRD) initiated a six-month pilot to process medical device applications more quickly. A "real-time" review pilot program for some types of Premarket Approval Applications (PMA) supplements (not including clinical studies, manufacturing site changes, and panel-track supplements) began in April 1996. The Orthopedic Devices Branch and the Plastics and Reconstructive Surgery Branch in DGRD assessed the possibility of conducting document reviews in "real-time" in meetings or teleconference formats.

Seven PMA supplements were reviewed under this program during FY 96. These reviews were conducted during the meetings, with data presentation by the sponsors, and scientific discussion of the issues. DGRD was able to review these supplements in less than five working days. The program results in rapid review times for manufacturers of these devices. In FY97, the real-time review program will be implemented in all ODE Divisions.

Major Revision of the IDE Manual

The Investigational Device Exemptions (IDE) Manual was revised and updated in a cooperative effort between the Office of Device Evaluation (ODE) and the Division of Small Manufacturers Assistance (DSMA). The manual was revised to be more informative for persons unfamiliar with medical device regulations. Two new sections were added to the manual to help the first time submitter. The first is an introduction which includes an overview of the medical device regulations, identifies proposed regulations that would affect investigational device studies, and identifies how additional information can be obtained

from DSMA. The second new section is entitled "How to Submit an IDE" and includes a suggested format for an IDE application, an administrative checklist, and suggestions for the content of the cover letter. The new manual also includes current policy and guidance documents that relate to the submission of IDE applications and the conduct of clinical investigations of medical devices. Copies of the new IDE Manual may be obtained by contacting the Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041 and asking for publication #FDA 96-4159.

Third-Party Review Pilot Program for 510(k)s

On August 1, 1996, the Center commenced a 2-year, voluntary pilot program to test the feasibility of using third-party reviews to improve the efficiency of the Center's review of premarket notifications for selected low and moderate risk devices. Under the pilot program, which was announced in the *Federal Register* on April 3, 1996, manufacturers of more than 250 eligible Class I and Class II devices may elect to submit 510(k)s to CDRH-recognized third-party review organizations, in lieu of CDRH. On July 11, 1996, seven third parties were recognized for this pilot program. Third parties may assess manufacturers a fee for their review services. The third-party reviews the 510(k) and forwards its documented review and recommendation to ODE, along with the manufacturer's 510(k). ODE retains final decision-making authority under the pilot and has established a 30-day performance goal for its issuance of final decisions based on third-party reviews. Manufacturers that do not wish to participate in the pilot may continue to submit 510(k)s directly to ODE. If the pilot approach is successful, it will: (1) provide manufacturers of eligible devices an alternative review process that may yield more rapid marketing clearance decisions; and (2) enable CDRH to target its scientific review resources at higher-risk devices while maintaining confidence in the review by third parties of low and moderate risk devices. Receipt of 510(k)s from third-party reviewers are expected to begin in early FY97. CDRH will evaluate the pilot during its second year to determine whether it should be continued beyond the planned 2-year period.

510(k) Exemptions

During FY94, ODE established a Triage program as described in the ODE Annual Report for FY94. The policy of assigning devices to tiers is a continuing effort to allocate the Center's resources in the most efficient way to advance FDA's public health mission. FDA is continuing in its efforts to exempt Tier 1 devices from premarket notification procedures. FDA has determined that manufacturers' submissions of premarket notifications for the devices proposed for exemption are unnecessary for the protection of public health and, accordingly, FDA published a final rule in the *Federal Register* on January 16, 1996, to exempt 11 class I, Tier 1 devices from premarket notification and to reclassify into class I and exempt from premarket notification †11 class II Tier 1 devices. As of February 13, 1996, 572 of the 1700 device types are now exempt from premarket notification requirements. This represents 74% of all class I devices and 33% of all classified devices.

Indications for Use in 510(k)s

In February 1996, ODE announced a change in the way we handle premarket notifications. Clearance letters for devices found to be substantially equivalent to a legally marketed predicate device now include the indications for use, written by the 510(k) holder, as an attachment. This procedural change facilitates the submitter's and agency's identification of specific indications for use that are the subjects of each clearance.

IVD Tier /Triage Management Initiative

On October 30, 1995, ODE conducted a public workshop to reassess the 1993 tier/triage management initiative within the Division of Clinical Laboratory Devices (DCLD) to improve the efficiency of its administrative work process. FDA had received suggestions from the Health Industry Manufacturers Association (HIMA), professional societies, laboratory professionals, the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Health Care Financing Administration (HCFA) on categorization of IVDs. A decision-chart for assigning products into a low risk category was developed to aid in the reassessment and presented at the public workshop. On June 1, 1996, DCLD implemented a management action plan for improving the efficiency of its administrative work process by additng 18% more products into the Tier 1 category and issued a revised decision-chart, using an assessment of the risk to the patient associated with the use of the device. Products listed in Tier 1 undergo a focused administrative but non-scientific review allowing DCLD to redirect review resources to high risk, new devices. The decision-chart and expanded Tier 1 list are available through the Division of Small Manufacturers Association (DSMA).

CDRH World Wide Web

With the assistance of the Office of Systems and Management and the Division of Information Dissemination, information pertinent to ODE's activities were made available on the CDRH Home Page (http://www.fda.gov/cdrh/index.html). The CDRH Home Page will replace the Electronic Docket formerly operated by DSMA (The Division of Small Manufacturers Assistance). A sample of information that can be found on the CDRH Home Page include:

- ODE's Guidances
- Monthly PMA Approval List
- PMA and 510(k) Summaries of Safety and Effectiveness Data
- ODE's Panel Meetings

Significant Jurisdictional Issues Involving Devices in FY 96

Title 21 of the *Code of Federal Regulations Part 3* - Product Jurisdiction describes the procedure the agency uses to assign jurisdiction among its Centers for medical products whose jurisdiction is not clear or is in dispute. Requests for Designations (RFDs) may be filed by manufacturers for such products by writing to the Office of the Chief Mediator and Ombudsman. An RFD describes the requester's product and/or products and a proposal regarding which Center should be given lead designation over the product and which review authority, i.e., biological, device or drug, should apply.

FY 96 was a busy year for the receipt and handling of RFDs by CDRH. Of the 31 such requests sent to the FDA Ombudsman's Office, 27 were forwarded to CDRH for determination. DGRD and DCLD received 7 RFDs each. DCRND received 5, DDIGD 4, and DRAERD 3 RFDs, respectively. One RFD was not assigned to any Division since it was not CDRH's. Ultimately, 14 RFDs were assigned to CDRH as lead reviewing Center, 8 were assigned to other Centers, and 5 decisions are still pending.

STATISTICAL TABLES
Fiscal Year 1996

[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
FY92 - FY96

Type of Submission	No. Received				
	FY92	FY93	FY94	FY95	FY96
Premarket Approval (PMAs)					
Original Applications	65	40	43	39	44
Amendments	740	665	704	812	883
Supplements	606	395	372	499	415
Amendments to Supplements	897	782	788	838	823
Reports for Orig. Applications	483	442	407	487	435
Reports for Supplements	21	17	12	8	24
Master Files	41	71	130	92	65
PMA Subtotal	2,853	2,412	2,456	2,775	2,689
Investigational Device Exemptions (IDEs)					
Original Appplications	229	241	171	214	253
Amendments	297	320	254	210	219
Supplements	3,644	3,668	3,020	3,171	3,189
IDE Subtotal	4,170	4,229	3,445	3,595	3,661
Premarket Notification (510(k)s)					
Original Notifications	6,509	6,288	6,434	6,056	5,297
Supplements	4,555	3,940	4,571	4,552	3,246
Amendments	N/A	N/A	3,057	5,012	5,343
510(k) Subtotal	11,064	10,228	14,062	15,620	13,886
PMA/IDE/510(k) Total	18,086	16,869	19,963	21,990	20,236

Table 2. Original PMAs
FY92 - FY96

Action	FY92	FY93	FY94	FY95	FY96
Number Received	65	40	43	39	44
PMA Actions					
Filing Decisions					
Filed (%)	46(54)	33(62)	38(60)	33(60)	45(73)
Not Filed (%)	28(33)	16(30)	25(40)	22(40)	17(27)
Others(%)	11(13)	4 (8)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	85	53	63	55	62
Review Activities					
Major Deficiencies	31	21	30	29	32
Minor Deficiencies	5	10	4	7	5
Other[a]	162	171	191	111	97
Review Activity Subtotal	198	202	225	147	134
Approval Decisions					
Approvals(%)	12(24)	24(35)	26(39)	27(57)	43(57)
Approvable(%)	18(37)	23(34)	22(33)	16(34)	27(35)
Not Approvable(%)	15(31)	21(31)	18(27)	4 (9)	6 (8)
Denials	4 (8)	0 (0)	0 (0)	0 (0)	0 (0)
Approval Decision Subtotal	49	68	66	47	76
Total PMA Actions	332	323	354	249	272
Average Review Time (Days:Months) for Approvals[b]					
FDA	146:4.8	328:10.8	374:12.3	276:9.1	289:9.5
Non-FDA	40:1.3	109:3.6	78:2.6	81:2.7	55:1.8
Total	186:6.1	437:14.4	452:14.9	357:11.7	343:11.3
Average Elapsed Time (Days:Months) for Approvals[c]					
FDA	236:7.8	547:18.0	649:21.3	606:19.9	572:18.8
Non-FDA	74:2.4	252:8.3	174:5.7	167:5.5	214:7.0
Total	310:10.2	799:26.3	823:27.1	773:25.4	786:25.9
Number under Review at End of Period[d]					
Active[e]	87	94	67	69	57
(Active and overdue)	(36)	(45)	(22)	(26)	(17)
On hold[f]	77	56	72	56	39
Total	164	150	139	125	96

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

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 FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock. Number of months based upon 30.4 day/month and rounded to one decimal point.

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 its filing date until it receives final approval. Number of months based upon 30.4 day/month and rounded to one decimal point.

(Continued on next page.)

Table 2. Original PMAs
FY 92 - FY 96

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 not reflected in the table.
e/ FDA responsible for processing application.
f/ FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 3. PMA Supplements
FY 92 - FY 96

Action	FY92	FY93	FY94	FY95	FY96
Number Received	606	395	372	499	415
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed(%)	4 (27)	1 (10)	3 (60)	4 (0.8)	8 (89)
Not Filed(%)	11 (73)	6 (90)	2 (40)	1 (0.2)	1 (11)
Other(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	15	7	5	5	9
Review Activities[a]					
Major Deficiencies	2	5	1	3	9
Minor Deficiencies	0	0	0	1	1
Other[b]	196	251	219	147	141
Review Activities Subtotal	198	256	220	151	151
Approval Decisions					
Panel track approvals(%)[c]	1 (1)	2 (1)	3 (1)	3 (1)	0 (0)
Nonpanel track approvals(%)	393 (62)	352 (62)	382 (65)	432 (73)	462 (85)
Approvable(%)	120 (18)	91 (16)	95 (16)	78 (13)	33 (6)
Not approvable(%)	122 (19)	124 (21)	104 (18)	75 (13)	48 (9)
Approval Decision Subtotal	636	569	584	588	543
Total PMA Supplement Actions	849	832	809	744	703
Average Review Time (Days:Months) for Approvals[d]					
FDA	113 : 3.7	168 : 5.5	253 : 8.3	179 : 5.9	146 : 4.8
Non-FDA	22 : .7	35 : 1.2	42 : 1.4	49 : 1.6	36 : 1.2
Total	135 : 4.4	203 : 6.7	295 : 9.7	228 : 7.5	182 : 6.0
Average Elapsed Time (Days:Months) for Approvals[e]					
FDA	135 : 4.4	213 : 7.0	301 : 9.9	209 : 6.9	167 : 5.5
Non-FDA	32 : 1.1	56 : 1.8	70 : 2.3	66 : 2.2	49 : 1.6
Total	167 : 5.5	269 : 8.8	371 : 12.2	275 : 9.0	216 : 7.1
Number under Review at End of Period[f]					
Active[g]	341	346	243	226	162
(Active and overdue)	(98)	(173)	(110)	(49)	(17)
On hold[h]	144	119	133	151	74
Total	485	465	376	377	236

a/ Filing, not filing, major, and minor deficiency letters are issued for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

b/ Includes actions that did not result in an approval/denial decision, such as GMP letters prior to inspection, an applicant 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 are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this

(Continued on next page.)

Table 3. PMA Supplements
FY 92 - FY 96

regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock. Number of month based upon 30.4 day/month and rounded to one decimal point

e/ 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 its filing date until it receives final approval. Number of months based upon 30.4 day/month and rounded to one decimal point.

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 92 - FY 96

Action	FY92	FY93	FY94	FY95	FY96
Number Received	229	241	171	214	253
Number of Decisions					
Approved	68	60	47	109	171
Not approved	130	166	109	81	63
Other[a]	17	22	18	20	26
Total	215	248	174	210	260
Percent (%) of Approvals made during first review cycle[b]	34	27	30	57[d]	73
Average FDA Review Time (days)	30	28	29	29	28
Percent (%) of Decisions made within 30 Days	97	97	95	92[e]	99
Number under Review at End of Period[c]	21	14	11	15	8
Number Overdue at End of Period	0	3	0	0	0

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

b/ Based on "approved" and "not approved" decisions only.

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

d/ During the first half of FY 95 this percentage was 49%; during the second half of FY 95, after the establishment of new policies and procedures, it rose to 65%.

e/ In October 1995, ODE moved its offices from Piccard Drive to Corporate Boulevard in Rockville, Maryland. ODE accepted premarketing submissions during the 14-day moving period but added 2 weeks to the due dates of IDEs. This 2-week delay is reflected in the percent of decisions made within the 30 days for original IDEs and amendments. This policy was announced in two notices in the *Federal Register* of October 14, 1994 (pg. 52170) and November 29, 1994 (pg. 60092).

Table 5. IDE Amendments
FY 92 - FY 96

Action	FY92	FY93	FY94	FY95	FY96
Amendments Received[a]	297	320	254	210	219
Decisions on Amendments					
Approved(%)	127(43)	93(29)	109(43)	106(50)	98(45)
Not approved (%)	92(31)	131(40)	68(27)	38(18)	29(13)
Other (%)[b]	78(26)	100(31)	77(30)	69(32)	91(42)
Total	297	324	256	213	218
Average FDA Review Time (days)	24	25	24	22	18
Percent (%) of Decisions made within 30 Days	99	96	97	92[e]	98
Average Approval Time (days) for IDEs with Amendments					
FDA time	79	83	83	70	53
Non-FDA time	109	129	159	162	78
Total time[c]	188	212	242	232	131
Number of Amendments per Approved IDE	N/A	2.2	2.3	1.8	1.4
Amendments under Review at End of Period[d]	21	16	11	8	9
Amendments Overdue at End of Period	1	2	0	0	0

a/ Submissions received after the original IDE and prior to approval of the IDE application.

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 the date the original IDE was received to the date of 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 October 1995, ODE moved its offices from Piccard Drive to Corporate Boulevard in Rockville, Maryland. ODE accepted premarketing submissions during the 14-day moving period but added 2 weeks to the due dates of IDEs. This 2-week delay is reflected in the percent of decisions made within the 30 days for original IDEs and amendments. This policy was announced in two notices in the *Federal Register* of October 14, 1994 (pg. 52170) and November 29, 1994 (pg. 60092).

Table 6. IDE Supplements
FY 92 - FY 96

Action	FY92	FY93	FY94	FY95	FY96
Number Received	3,644	3,668	3,020	3,171	3,189
Number of Decisions	3,469	3,814	3,070	3,181	3,121
Average FDA Review Time (days)	23	24	23	22	21
Percent (%) of Decisions made within 30 Days	99	97	98	98	99
Number under Review at End of Period[a]	359	213	160	149	148
Number Overdue at End of Period	4	8	1	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.

Table 7. 510(k)s
FY92 - FY96

Action	FY92	FY93	FY94	FY95	FY96
Number Originals Received	6,509	6,288	6,434	6,056	5,297
Number of Decisions					
Substantially equivalent	3,776	4,007	5,498	5,594	4,501
Not substantially equivalent	130	135	135	101	64
Other[a]	956	931	1502	2,253	998
Total	4,862	5,073	7,135	7,948	5,563
Percent(%) not substantially					
Equivalent[b]	3.3	3.3	2.4	1.8	1.4
Average Review Time (days)					
FDA time[c]	102	162	184	137	110
Total time[d]	126	195	216	178	145
Median Review Time (days)					
FDA time[c]	88	144	134	91	85
Total time[d]	90	164	155	102	88
Percent (%) of Decisions made within 90 Days, based on					
FDA time[e]	94	46	45	62	80
Total time[d]	45	20	27	36	50
Number under Review at End of Period[f]					
Active[g]	2,599	3,822	2,414	1,486	1,408
(Active and overdue)	(331)	(1,894)	(460)	(9)	0
On hold[h]	1,352	1,335	1,960	964	821
Total	3,951	5,157	4,374	2,450	2,229

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 time includes all increments of time FDA reviewed a 510(k), so long as the 510(k) document number did not change; changes in 510(k) document numbers occur rarely.

d/ Includes all time from receipt to final decision, i.e., does not exclude time 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(k)).

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 decisions) because of deletions and conversions which are not reflected in the table.

g/ FDA responsible for processing notification.

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

Table 8. Major Submissions Received
FY 86 - FY 96

Type of Submission	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996
Orig. PMAs	69	81	96	84	79	75	65	40	43	39	44
PMA Supp.	478	700	727	810	660	593	606	395	372	499	415
Orig. IDEs	206	218	268	241	252	213	229	241	171	214	253
IDE Amend.	365	265	316	271	288	283	297	320	254	210	219
IDE Supp.	2,884	2,836	3,391	3,038	3,043	3,647	3,644	3,668	3,020	3,171	3,189
510(k)s	5,063	5,265	5,536	7,022	5,831	5,770	6,509	6,288	6,434	6,056	5,297
Total	8,974	9,365	10,334	11,466	10,153	10,581	11,350	10,952	10,293	10,189	9,417

Table 9. Major Submissions Completed
FY 86 - FY 96

Type of Submission	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996
Orig. PMAs	72	46	46	56	47	27	12	24	26	27	43
PMA Supp.	477	565	652	519	700	479	394	354	385	434	462
Orig. IDEs	213	224	260	245	248	220	215	248	174	210	260
IDE Amend.	330	253	327	280	270	287	297	324	256	213	218
IDE Supp.	3,599	2,784	3,405	3,023	2,968	3,705	3,469	3,814	3,070	3,181	3,121
510(k)s	5,359	4,992	5,513	6,136	6,197	5,367	4,862	5,073	7,135	7,948	5,563
Total	10,050	8,864	10,203	10,259	10,430	10,085	9,249	9,837	11,045	12,013	9,667

APPENDIX A. MAJOR ODE PROGRAMS
Fiscal Year 1996

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 clinical trials and marketing. This Appendix provides summary information about the major programs administered by ODE and includes a brief description of the premarket approval, humanitarian device exemption, investigational device exemption, and premarket notification programs.

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 Class III 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 the review process, FDA may present the PMA to an expert advisory panel for its recommendations. After obtaining the panel recommendations, the agency makes a 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 make available a summary of the safety and effectiveness data upon which the decision is based. This publicly available summary does not include proprietary data or information submitted by the applicant.

PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made; for example, changes to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the PMA regulation, changes that affect the safety or effectiveness of the device require FDA premarket 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. PMA supplements can be as complex as an original application.

Humanitarian Device Exemption Program (HDEs)

An HDE application is similar in both form and content to a PMA but is exempt from the effectiveness requirement of a PMA. Even though the HDE is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose, the application must contain sufficient information for FDA to determine, as required by statute, that the device does not pose an unreasonable or significant risk of illness or injury to patients and that the probable benefit to health outweighs the risk of injury or illness from its use. An HDE application must also contain information that will allow FDA to make the other determinations required by the act. An approved HDE authorizes marketing of the humanitarian use device (HUD) for a period of 18 months from the date of approval, and this approval may be renewed.

Investigational Device Exemptions (IDEs)

Under the Act and Regulations, an individual, institution or company 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) as well as informed consent from the study subjects at the time of their enrollment in the study. If the investigational device study presents a significant risk to the subjects, the sponsor also must obtain FDA's approval of an "investigational device exemption" application (IDE) under 21 CFR 812. The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject informed consent form, device labeling, cost of the device, and other matters related to the study. FDA has 30 calendar days from the date of receipt of the application to approve or disapprove an IDE submission.

IDE Amendments

Although not provided for in the IDE regulations, all submissions related to an original IDE that has been submitted, but not approved, are referred to as "IDE amendments". After an IDE is approved, related submissions are called "supplemental applications" under the regulations. Identification of IDE amendments enables FDA to track each IDE from the time it is orginally submitted until the time it is approved.

IDE Supplements

The IDE regulation requires the sponsor of an investigation of a significant risk device to submit a supplemental application for a number of reasons. For example, a sponsor must submit a supplement if there is a change in the investigational plan when such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. Supplemental applications also are required for the addition of investigational sites. This regulation also requires the submission of various reports, which are logged in as supplements to IDE applications. These include reports on unanticipated adverse effects of the device; recall and device disposition; failure to obtain informed consent; and annual progress reports, final reports, investigator lists, and other reports requested by FDA.

Premarket Notification (510(k))

At least 90 days before placing a medical device into commercial distribution, a person required to register 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, a 510(k) summary or a 510(k) statement of safety and effectiveness information, the 510(k) must include data to substantiate the 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 510(k) submitter 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 application. A device may not be marketed pursuant to a 510(k) until it receives clearance from FDA.

APPENDIX B. SIGNIFICANT MEDICAL DEVICE BREAKTHROUGHS
Fiscal Year 1996

The following devices were approved via the Premarket Approval (PMA) process or cleared via the 510(k) process during FY96. They represent significant medical breakthroughs because they are first-of-a kind, e.g., they use a new technology or energy source, or they provide a major diagnostic or therapeutic advancement, such as reducing hospital stays, replacing the need for surgical intervention, reducing the time needed for a diagnostic determination, etc. The information for each device includes the trade name and/or classification name, firm, PMA/510(k) number and date of approval.

Devices Approved via PMA

Division of General and Restorative Devices (DGRD)

- Photodynamic Therapy Units by QLT Phototherapeutics Inc. (P940010, P940011, and P940012, December 27, 1995)
- Integra Artificial Skin by Integra LifeSciences Corp. (P900033, March 1, 1996)
- Seprafilm Bioresorbable Membrane by Genzyme Corp. (P950034, August 12, 1996)
- BAK Interbody Fusion Device by Spine Tech (P950002, September 20, 1996)

Division of Ophthalmic Devices (DOD)

- Perfluoron (perfluoro-n-octane) Intraocular Fluid by Infinitech, Inc. (P950018, February 29, 1996)
- Excimer Lasers for Photorefractive Keratectomy (PRK) by Summit Technology Inc. (P930034, October 20, 1995) and by VISX (P930016, March 27, 1996)
- Refresh CL Lubricating and Rewetting Drops by Allergan Optical (P960012, September 25, 1996)

Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices (DRAERD)

- Liposorber® LA-15 by Kaneka America Corp. (P910018, February 21, 1996)
- Ultramark® 9 High Definition (HFI™) Ultrasound System by Advanced Technology Laboratories, Inc. (P940005, April 11, 1996)
- Prostatron™ by EDAP Technomed Group (U.S.A.) Inc. (P950014, May 3, 1996)
- UroLume™ Endourethral Prosthesis by American Medical Systems, Inc. (P920023, May 6, 1996)
- Reliance® Urinary Control Insert and Sizing Device by Uromed Corp. (P960020, August 16, 1996)
- Xillix LIFE-Lung Fluorescence Endoscopy System by Xillix Technologies Corp. (P950042, September 19, 1996)

Division of Clinical Laboratory Devices (DCLD)

- PAPNET Testing System by Neuromedical Systems, Inc. (P940029, November 8, 1995)
- Bladder Tumor Associated (BTA) Analytes by Bard Diagnostic Sciences, Inc. (P940018, November 29, 1995)
- Amplified Mycobacterium Tuberculosis Direct Test (MTD) by Gen-Probe Inc. (P940034, December 15, 1995)

- ThinPrep Model Processor Model TP2000 by Cytyc Corp. (P950039, May 20, 1996)
- NMP22 Test Kit by Matritech (P940035, July 2, 1996)
- Chemoresponse Assay by Bartel Prognostics Inc. (P940036, August 1, 1996)

Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)

- Ventricular Assist Device System by Thoratec Laboratories Corp. (P870072, December 20, 1995)
- Implantable Cardioverter Defibrillators (ICDs) by Guidant (P910073/SO20, P930035/SO05, P910077/SO15, May 15, 1996)
- Capsure® Epi Pacing Lead by Medtronic (P950024, September 6, 1996)

Division of Dental, Infection Control, and General Hospital Devices (DDIGD)

- Model 3000 Constant Flow Implantable Pump with Bolus Safety Valve by Therex Corp. (P890055, March 11, 1996)
- Emdogain by Biora (P930021, September 30, 1996)

Devices Cleared via 510(k)

DGRD

- Ceramic Hemi-Endo Modular Head Hip Prosthesis by BIOPRO (K954768, January 18, 1996)
- Varifix System by Advanced Spine Fixation Systems Inc. (K954770, January 25, 1996)
- Suture Cord by Phoenix Biomedical Corp. (K953128, February 9, 1996)
- Carbon Dioxide Laser Scanner System (Silktouch) by Sharplan Laser, Inc. (K960521, April 25, 1996)
- Rapi-Seal by Fusion Medical Technologies (K961440, May 31, 1996)
- Wright Plaster of Paris Pellets by Wright Medical Technology, Inc. (K960978, June 21, 1996)
- Dexterity Pneumo Sleeve Set by Medical Creative Technology (K962147, July 9, 1996)
- Saline Breast Implant by Poly Implants Prostheses (K960419, September 4, 1996)

DRAERD

- PPX Tissue Quantification Output by Lunar Corp. (K935454, October 18, 1995)

DCLD

- VOLUMET CD4 Positive T Lymphocyte Absolute Count Test Kit by Buckman Company Inc. (K940003, October 19, 1995)
- FACE (Fluorophore Assisted Carbohydrate Electrophoresis) Qualitative Urinary Carbohydrate Analysis kit by Pharmquest Corp. (K945519, November 3, 1995)
- Lcx Chlamydia Trachomatis Assay by Abbott (K934622, December 8, 1995)
- hemoSTATUS Platelet Function Test Cartridges by Medtronic Hemotec Inc. (K954202, June 20, 1996)
- Safestrip by Firehouse Medical (K955107, August 16, 1996)
- MERETEK UBT Breath Test Collection Kit (K952220, September 17, 1996)

DCRND

- Cardiac Electrophysiological Mapping System, CARTO, by Biosense, Ltd. (K954395, December 20, 1995)
- Automatic External Defibrillator, the ForeRunner, by Heartstream (K955628, July 26, 1996)

DDIGD

- Acupuncture Needles by Helio Medical Supplies Inc. (K961339, July 2, 1996)
- Total Temporomandibular Joint Prosthesis by Anspach Effort Inc. (K954224, July 17, 1996)

APPENDIX C. ODE GUIDANCE DOCUMENTS
Fiscal Year 1996

All ODE guidance documents are available from the Division of Small Manufacturers Assistance (DSMA, HFZ-220) on the Center's Electronic Docket, a computer-based bulletin board system, via telefax and in hard copy at: FACTS-ON-DEMAND (telefax): (800) 899-0381 or (301) 827-0111; MAIL: 1350 Piccard Drive, Rockville, Maryland 20850-4307; VOICE: (800) 638-2041 or (301) 443-6597; or CDRH World Wide Web home page: http://www.fda.gov/cdrh.

Office of Device Evaluation (ODE)

- 510(k) Requirements During Firm-Initiated Recalls (#K95-1, November 21, 1995)
- 510(k) Quality Review Program (#I96-1, March 29, 1996)
- Document Review by the Office of the Chief Counsel (#G96-1, June 6, 1996)
- ODE Standard Operating Procedures for the Development and Use of Guidance Documents (#G96-2, June 6, 1996)
- Continued Access to Investigational Devices During PMA Preparation and Review (#D96-1, July 15, 1996)
- Memorandum of Understanding Regarding Patient Labeling Review (#G96-3, August 9, 1996)

Division of General and Restorative Devices (DGRD)

- Bone Anchor Devices (April 20, 1996)
- Biodegradable Polymer Implant Devices (April 20, 1996)
- Saline Breast Implant Devices (June 13, 1996)

Division of Ophthalmic Devices (DOD)

- Potential Reclassification of Eye Valve Implants Letter (November 16, 1995)
- Availability of Aniridia IOLs and Endocapsular Rings in the US Letter (March 29, 1996)
- Review Criteria for Assessment of Phacofragmentation System Device (August 16, 1996)
- Review Criteria for Assessment of Vitreous Aspiration and Cutting Device (August 16, 1996)
- Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers (September 27, 1996)
- Humanitarian Device Exemptions and Ophthalmic Devices Letter (September 6, 1996)

Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices (DRAERD)

- Hemodialyzer Reuse Labeling (October 6, 1995)
- MRI Guidance Update for dB/dt (October 11, 1995)
- Urethral Stents (November 2, 1995)
- Urethral Bulking Agents (November 29, 1995)
- Hysteroscopes and Gynecologic Laparoscopes (March 7, 1996)
- Thermal Endometrial Ablation (March 14, 1996)
- Digital Mammography (June 19, 1996)

Division of Clinical Laboratory Devices (DCLD)

- In Vitro Diagnostic Devices That Utilize Cytogenetic In Situ Hybridization (ISH) Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic) (October 1995)
- Cholesterol In Vitro Diagnostic Devices for Clinical Laboratories, Physicians' Office Laboratories and Home Use Cholesterol Devices (November 1995)
- Estrogen or Progesterone Receptors In Vitro Diagnostic Devices (November 1995)
- Calibration and Quality Control Labeling for In Vitro Diagnostic Devices (February 1996)
- Portable Blood Glucose Monitoring In Vitro Diagnostic Devices (February 1996)
- Original Equipment Manufacturer, Secondary and Generic In Vitro Diagnostic Reagents for Use with Automated Analyzers (June 1996)
- Tumor Associated Antigen Assays (September 1996)

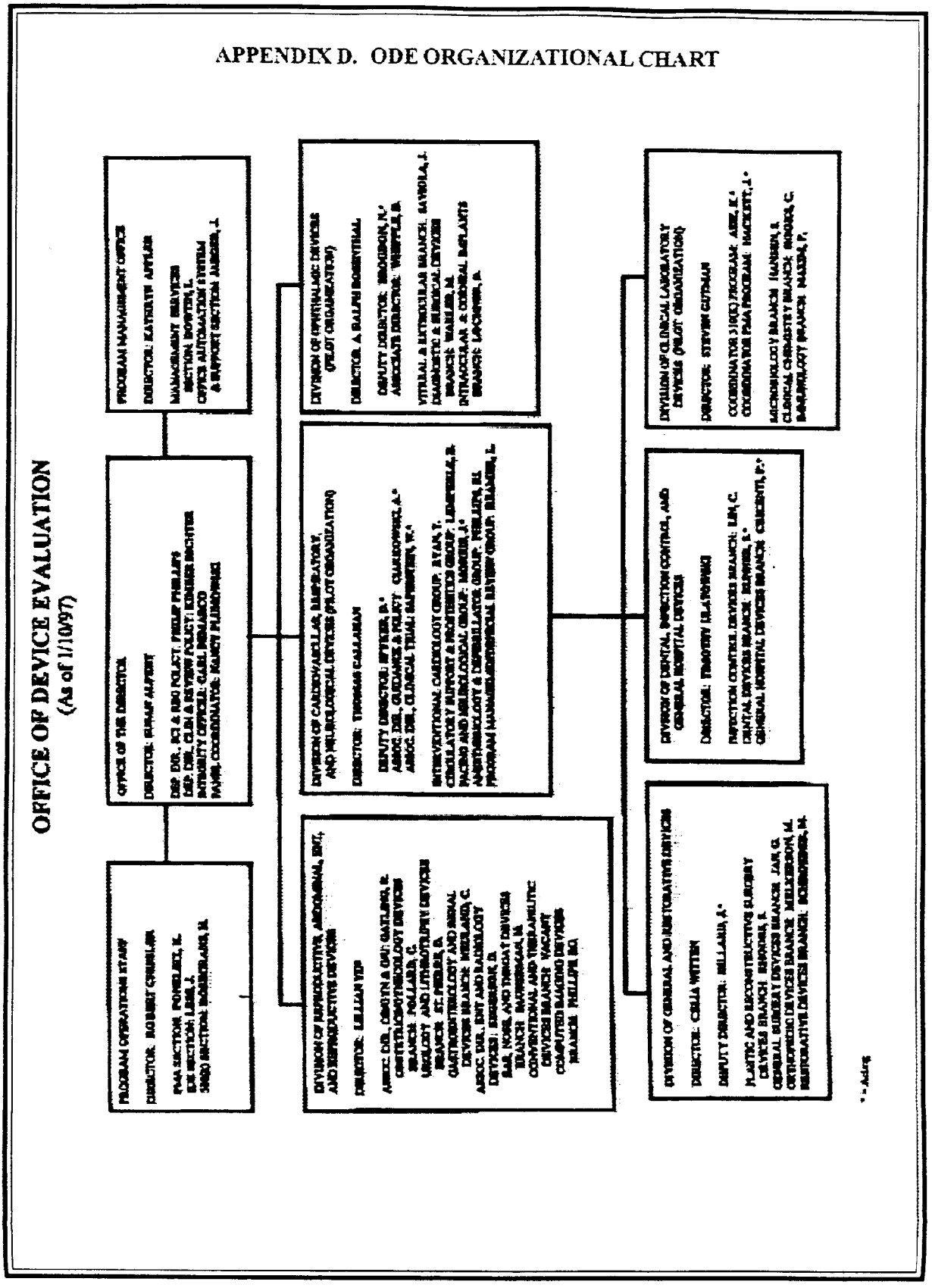
Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)

None were issued in FY96.

Division of Dental, Infection Control, and General Hospital Devices (DDIGD)

- Draft Guidance of the Content of Premarket Notification [510(k)] Submissions for Protective restraints. (December 28, 1995)
- Draft Guidance for the Preparation of Premarket Notifications [510(k)'s] for Direct Filling Dental Composites (January 2, 1996)
- Protective Restraints (Final Rule March 4, 1996)
- Draft Guidance on the Preparation of PMA Applications for Sharps Needle Destruction Devices. (June 1, 1996)
- Guidance for Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities; Draft; Availability (Federal Register June 15, 1995)
- Latex -containing Devices (Proposed Rule June 24, 1996)
- Draft Guidance on the Content and Format of Premarket Approval Applications (PMA) for Absorbable Dusting Powder for Surgical Gloves (July 1, 1996)

APPENDIX D. ODE ORGANIZATIONAL CHART



APPENDIX E. ODE STAFF ROSTER
Fiscal Year 1996

Office of the Director

Acker, Rita
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Richter, Kimber

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Clingerman, Angie
Dowtin, Lesa
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Moran, Shelly
Robins, Lisa
Trammell, Dan
Wedlock, Chuck
Wright, Mark
Yakubik, Janet

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Division of Clinical Laboratory Devices

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Dubois, Woody
Fugate, Kearby
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Gaines, Kessia
Gonzalez, Augustin
Gutman, Steven
Hackett, Joe
Hanna, Nancy
Hansen, Sharon
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Heyliger, Marian
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Jones, Doris
Lappalainen, Sharon
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Rao, Prasad

Reeves, Pat
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Rogers, Liz
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Rubin, Fran
Selepak, Sally
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Division of Cardiovascular, Respiratory, and Neurological Devices

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Donelson, Jan
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Ho, Charles
Ho, Nathan
Huynh, Ann
Hwang, Shang
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Massi, Mark
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Reamer, Lynne
Roberts, Anne
Roy, Joydeb
Ryan, Tara
Sapirstein, Wolf
Shanker, Rhona
Shein, Mitchell
Sloan, Chris
Smallwood, Senora
Spyker, Dan
Stuhlmuller, John
Subramanian, Ramiah
Terry, Doris
Trinh, Hung
Truesdale, Curtis
Turtil, Steven
Wang, Emil
Weitershausen, Joanna
Wentz, Catherine
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Zimmerman, Barabara
Zuckerman, Bram

Division of Dental, Infection Control, and General Hospital Devices - formerly the DGRD Pilot Division

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Mills, George
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Peters, Kim
Robinson, Mary Jo
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Division of General and Restorative Devices

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Goode, John
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Horbowyj, Roxolana
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Krause, David
Lee, Kevin
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McDermott, Ken
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Novick, Andy
Ogden, Neil
Phillips, Mary Ellen
Ponnapalli, Murty
Rhodes, Holly
Rhodes, Stephen
Riegel, Elizabeth
Riley, Theresa
Schmidt, Sharon
Schroeder, Marie
Sloan, Nadine
Sternchak, Richard
Stevens, Theodore
Sung, Pei
Torres-Cabassa, Angel
Townsend, Barbara

Vinson, Priscilla
Vishnuvajjala, Lakshmi
Watson, Tony
Weiblinger, Richard
Wilkerson, Paula
Williams, Berry
Williams, Paul
Witten, Celia
Wolf, Beverly
Yen, Dwight

Division of Ophthalmic Devices

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Boulware, Ashley
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Burns, Adrienne
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Calogero, Don
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Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Felton, Eleanor
Fox, Greg
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Krawczyk, Claudine
Lepri, Bernie
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Lochner, Donna
Massimilla, Glenn
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Mischou, Bruce
Moore, Shirley
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Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

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Daws-Kopp, Kathryn
Doyle, Robert
Eba, Felisa
Flack, Marilyn
Foy, Keith
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Gammell, Paul
Gatling, Robert
Gonzalez, Gema
Harvey, Brian
Harvey, Elisa
Herrera, Hector
Jaffee, Sydney
Jasper, Susan
Jevtich, Milorad
Kammula, Raju
Kang, Andrew
Kuchinski, Mike
Mahall, Melissa
Mallis, Elias
Malshet, Vasant
McCool, Barbara
McGee, Leah
Miller, Linda
Miller, Pat
Monahan, Jack
Montgomery, Al
Neuland, Carolyn
Nimmagadda, Rao
Nutter, Cathy

Olveyt, Kathleen
Provost, Miriam
Relacion, Cheryl
Rohr, Jennifer
Rubendall, Rita
Sauberman, Harry
Sauls, Mattie
Schultz, Dan
Segerson, Dave
Seiler, Jim
Sharpe, Skip
Shuping, Ralph
Smith, Ernest
St. Pierre, Don
Tillman, Donna-Bea
Tsai, Miin-Rong
Virmani, Mridulika
Warren, Jim
Williams, Dick
Williams, Eugene
Yin, Lillian
Zaremba, Loren
Zaudtke, Peter