OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1997

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, 1996 - September 30, 1997)

Acknowledgements

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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

The message from Fiscal Year 1997 is similar to that of Fiscal Year 1996 -- excellent performance! With the help and encouragement of Center management and other CDRH Offices, ODE finished FY97 with nothing overdue in any category--the first time since 1987 that we have had nothing overdue! In addition, ODE staff played a vital role in the Center's reengineering effort. ODE staff provided leadership in this important effort and is in the process of vigorously implementing these new procedures and processes to streamline the ODE operations.

Other performance highlights include:

- approved 48 PMAs, 5 more than FY 96, 9 under expedited review, and 2 as humanitarian device exemptions;
- reviewed 15 of the 48 PMA approvals in 180 days or less;
- significantly reduced review times for PMAs and PMA Supplements;
- reduced both the average FDA and average total review time and the average FDA and average total elapsed time for PMA supplements;
- expanded the "real-time review" program to all Divisions for PMA supplements used to reduce supplement review times from 7.1 months in FY 96 to 4.7 months in FY 97;
- reviewed 73 PMA Supplements in real time;
- approved or cleared 35 devices (19 PMAs and 17 510(k)s) which represent significant medical device breakthroughs;
- continued, for a second year, a zero backlog in the 510(k) program;
- completed the first year of the 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;
- provided pre-IDE guidance to companies on 198 applications;
- approved 69% of IDEs in the first review cycle;
- reviewed 100% of all IDEs (originals, amendments, and supplements) within 30 days; and
- issued 33 guidance documents.

ODE is looking foward to a busy and productive FY98. ODE will play an integral role in the implementation of the FDA Modernization Act of 1997. This will involve the promulgation of new regulations, issuance of new guidance documents and the development of new policies and procedures. ODE also will continue its efforts under the Center's reengineering initiative. These efforts should eventually lead to a higher level of efficiency in carrying out our primary responsibilities in the review of premarketing applications.

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

HIGHLIGHTS
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
Fiscal Year 1997

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

ODE's Major Program Initiatives (CDRH Reengineering Efforts, Canadian and U.S. Medical Device Partnering Program, and Treatment IDEs) are discussed in the next section of this report. Following are the highlights of ODE's review activities and performance for Fiscal Year 1997 (FY 97). The data below, with the exception of data related to staff resources, can be found in the tables in the Statistical Tables section of this report on pages 16 to 25. The charts below also are based on data in these same tables.

Workload/Resources

- During FY 97, ODE received a total of 19,267 submissions, compared to 20,236 in FY 96.
- On the output side, ODE completed the processing of 9,873 major submissions, compared to 9,667 major submissions in FY 96.
- ODE ended the year with 356 employees on board. During the year, ODE lost 20 full- time employees (16 scientific reviewers including 2 medical officers) through resignation or retirement and added only 7 new employees (1 scientific reviewer, 4 medical officers, and 2 office automation clerks). Two of the new hires (29%) were members of minority groups (1 Black male, 1 Hispanic male), 4 were women.

Chart 1. Submissions Received

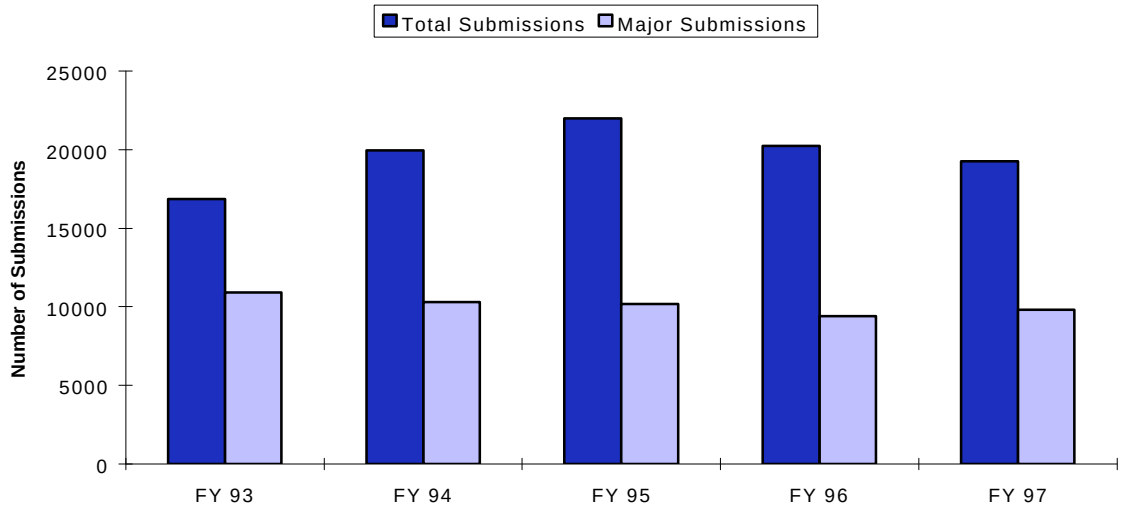
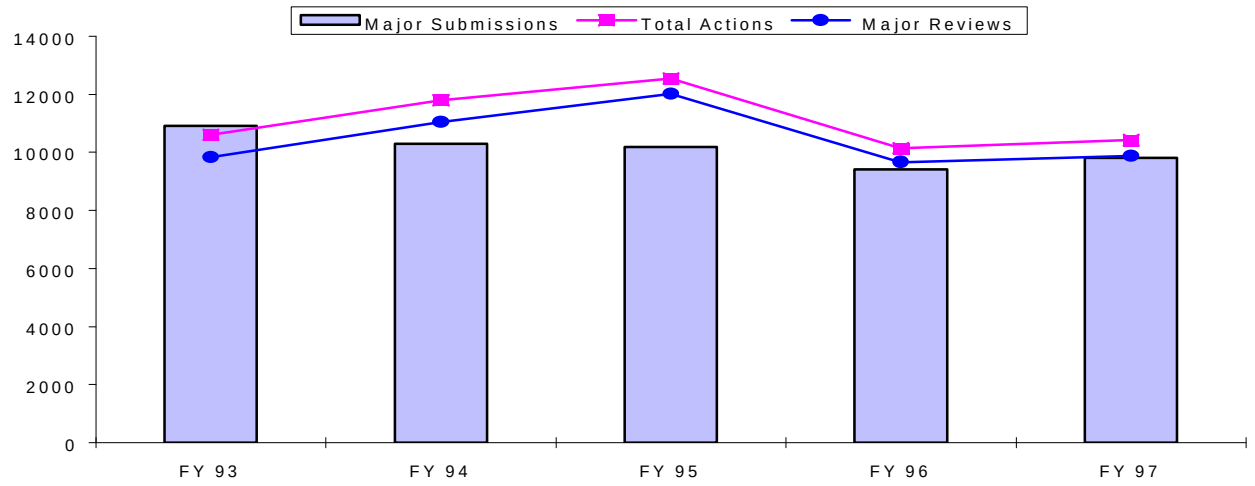


Chart 2. Major Submissions, Reviews and Total Actions



Premarket Approval Applications (PMAs)

- ODE received 70 original PMAs, 26 more than the number received in FY 96.

- The total number of PMAs in inventory (active and on hold) at the end of this fiscal year dropped for the fifth year in a row, from 96 last year to 85. The number of active PMAs under review decreased at the end of FY 97 to 44 compared to 57 last year, and those on hold increased slightly from last year, from 39 to 41. The number of PMAs that were active and overdue decreased from 17 last year to 0 at the end of FY97.

Chart 3. Annual PMA Receipts and Actions

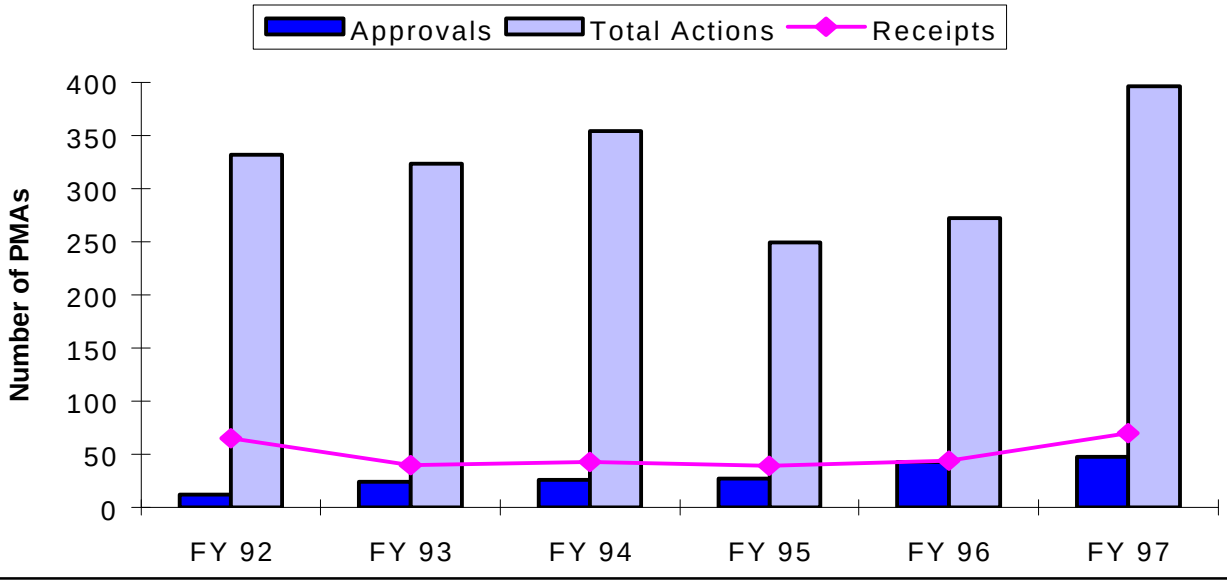
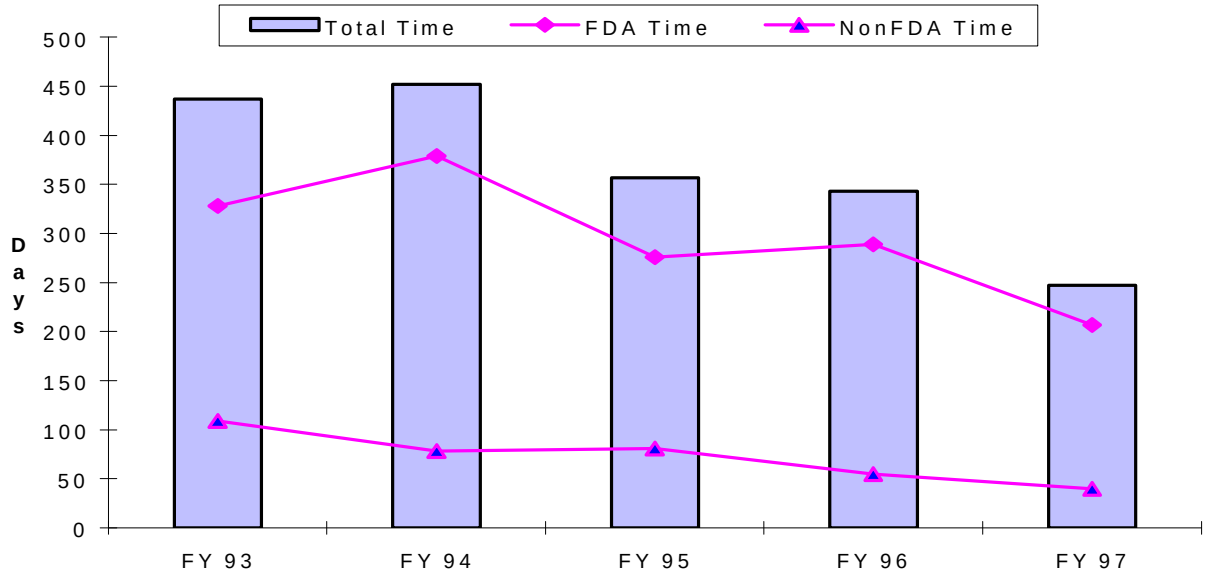


Chart 4. Average Review Time for PMA Approvals



- The total number of PMA actions increased from 272 to 322 actions. These actions included 74 filing decisions, 181 review activity determinations, and 67 approval decisions.

- Among the 67 PMA decisions were 48 approvals (5 more than the number of approvals in FY 96), 14 original PMAs were found to be approvable, and 5 were nonapprovable. Nine of the 48 approvals were expedited PMAs, and 2 were HDEs. See Appendix D for a complete list of PMA approvals.

Chart 5. Annual PMA Supplement Receipts and Actions

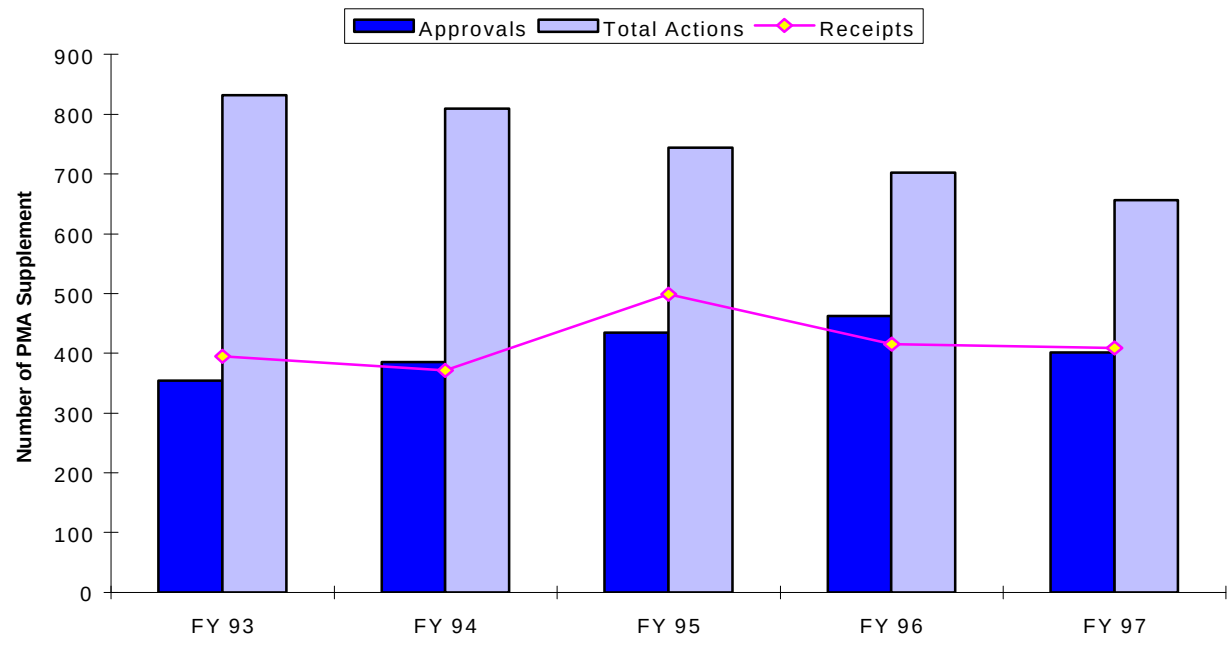
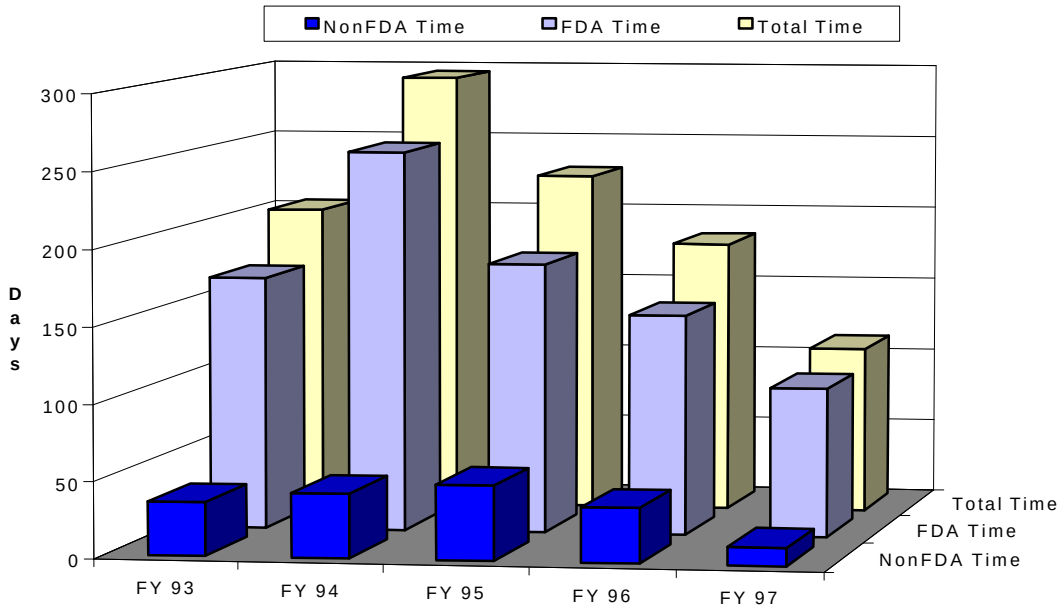


Chart 6. Average Review Time for PMA Supplements



- Average FDA review time for original PMAs reaching final action decreased from 289 days in FY 96 to 207 days in FY 97. The non-FDA component of review time decreased from 55 days in FY 96 to 40 days this fiscal year. On balance, the combined average review time decreased to 8 months. Furthermore, 15 PMAs were reviewed in 180 days or less.

- The number of PMA supplements received decreased slightly from last year's 415 to 409. The total number of PMA supplement actions, which includes 16 panel track filing decisions, 132 review activity determinations, and 526 approval decisions, was 674, down from last year's 703 total actions.

- ODE achieved major reductions for PMA supplement review in both the average review time (from 182 days in FY 96 to 112 days) and the average elapsed time (from 216 days to 143 days). There were 73 PMA Supplements in real time review.

- There were no PMA supplements active and overdue at the end of this fiscal year compared to 17 at the end of the last fiscal year. The number of active supplements was further reduced to 110 from 162 last year, and the number of supplements on hold increased from 74 to 80.

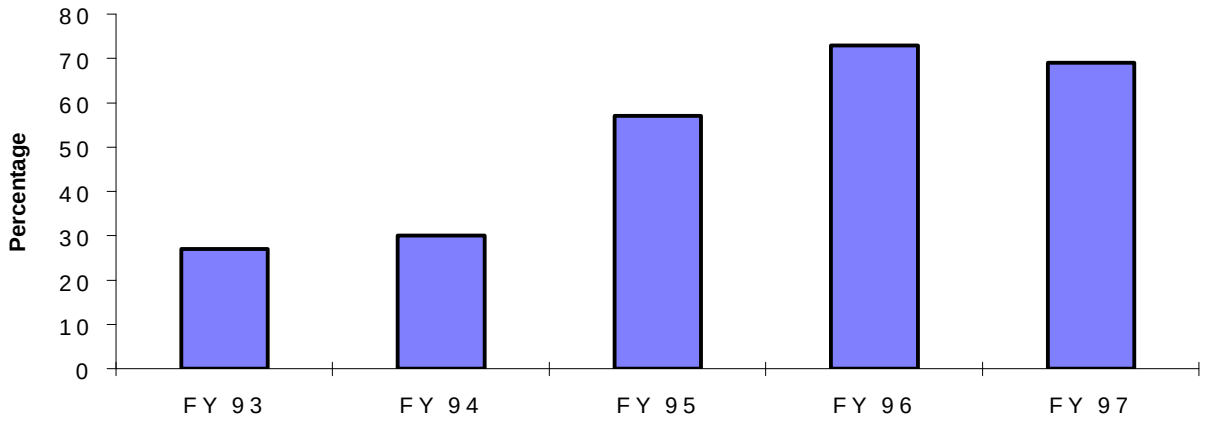
Product Development Protocols (PDPs)

- During FY 97, we received four PDPs and one was withdrawn. There were three pending PDPs at the end of FY 97 and none were overdue.

Investigational Device Exemptions (IDEs)

- During FY 97, ODE reviewed 198 pre-IDEs. Based on the review of these pre-original IDE applicatons, guidance for the original IDE was provided through meetings with the sponsor, letters, or by teleconferencing.

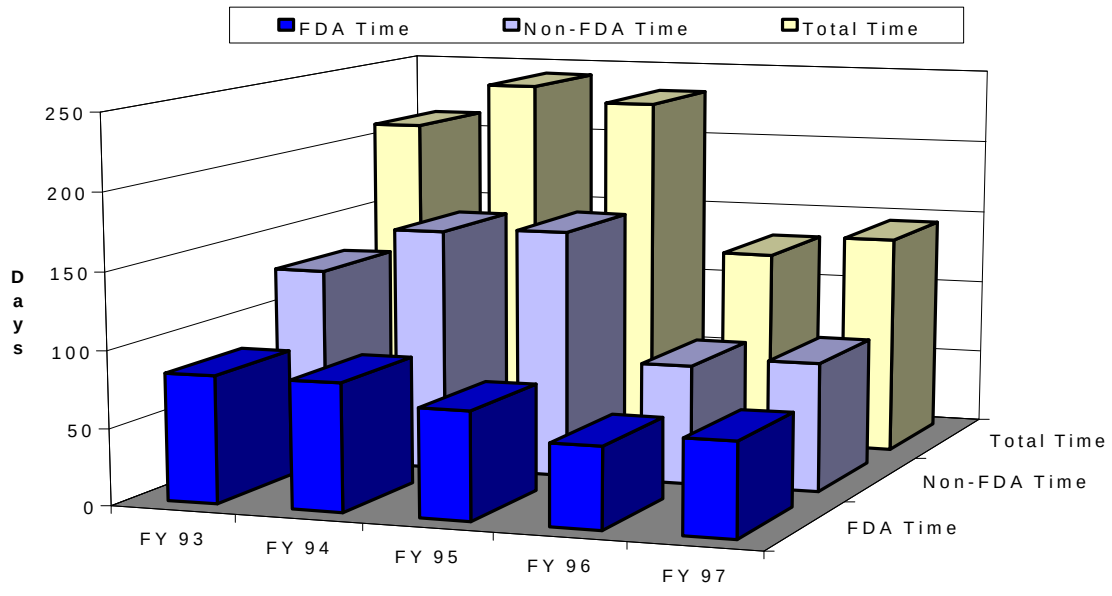
Chart 7. Percentage of IDEs Approved on First Review Cycle*



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

- ODE received 297 original IDEs, an increase from the 253 received in FY 96. There were 272 decisions made on original IDEs, an increase from 260 last year.

Chart 8. Average Approval Time for IDEs with Amendments



- One hundred percent of all original IDE decisions were issued within 30 days in FY 97. Of the IDEs which were complete enough to permit substantive review, the percentage of IDEs approved on the first review cycle decreased slightly from 73 percent in FY 96 to 69 percent during FY 97.

- During this fiscal year, 223 IDE amendments were received. Decisions were made on 220 amendments: 101 approvals (46%); 25 disapprovals (11%); and 94 other administrative actions (42%). One hundred percent of these decisions were made within 30 days.

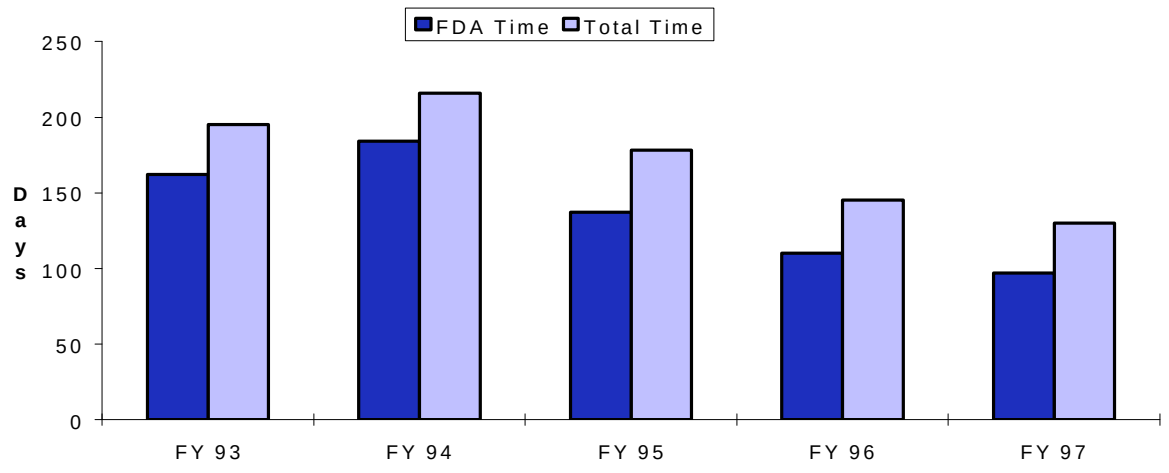
- It took an average total time of 145 days to approve original IDEs with amendments, up slightly from 131 days in FY 96. This average approval time consisted of 61 days for FDA time, up from 53 days last year, and 84 days for non-FDA time, up from 78 days in FY 96.

- ODE received 3,776 IDE supplements during FY 97. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe reached 100 percent in FY 97. The average review time for completing the review of IDE supplements remained constant at 21 days.

Premarket Notifications (510(k)s)

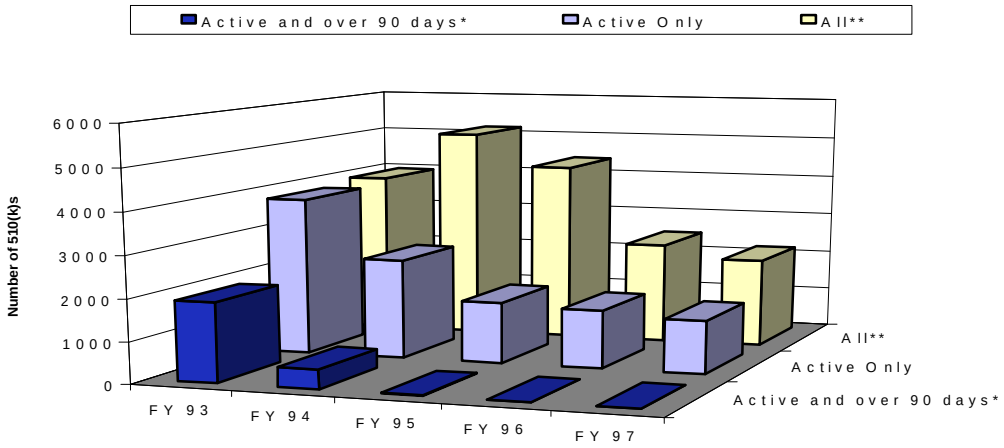
- ODE received 5,049 original 510(k)s, 2,785 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 4,433 amendments (additional information received while the 510(k) is under review, the receipt of which does not affect the review clock).

Chart 9. Average 510(k) Review Time*



*Without withdraws and deletes

Chart 10. Pending 510(k)s



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

- The total average review time declined from 145 days in FY 96 to 130 days in FY 97, and the average FDA review time was 97 days, down from 110 days in FY 96. 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 85 days in FY 97.

- There were 2,152 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year, which is a decease from the 2,229 in FY 96's end-of-year inventory. The number on hold increased from 821 at the end of FY 96 to 865. Most important, for the second consecutive fiscal year there were no 510(k)s active and overdue at the end of the reporting period.

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

On July 31, 1997, the Center completed the first year of a 2-year, voluntary pilot program to test the feasibility of using third-party review groups to improve the efficiency of the Center's review of 510(k)s for selected low and moderate risk devices. During the first year of the pilot, ODE received 10 510(k)s that had been reviewed by third parties. ODE issued substantial equivalence decisions for 9 of the 10 510(k)s received, and a final decision for the tenth submission was still pending at year's end. Based on a preliminary analysis of these 9 decisions, 510(k)s reviewed by third parties under the pilot program received marketing clearance 55 days faster, on average, than comparable 510(k)s reviewed entirely within CDRH. One of the 7 third-party review organizations originally recognized by CDRH withdrew from the pilot after conducting 3 reviews, due to the low volume of submissions. All class I devices that are not exempt from 510(k) (221 device types) have been eligible for third-party review since commencement of the pilot. The number of class II devices eligible for third-party review increased from 6 to 23, as ODE completed guidance documents for these devices.

Significant Jurisdictional Issues Involving Devices in FY 97

In FY 97, CDRH participated in the FDA Office of the Ombudsman's review of 28 out of 32 new requests received for designation of jurisdiction (RFDs). In addition , 5 RFDs received in FY 96 were completed. Of the 33 RFDs received, 12 were designated for CDRH to be the lead Center with 6 decisions pending at the close of the fiscal year. Out of the 28 new RFDs assigned to CDRH for consideration, DCLD received six, DRAERD and DDIGD each received five individual requests and shared the review of another, DGRD received four, DCRND three, and DOD one, respectively. One RFD went to the Office of Compliance for review. In addition, two RFDs were assigned to be reviewed by the Tissue Reference Group (TRG), a newly formed InterCenter reviewing committee consisting of three members each from CDRH and the Center for Biologics Evaluation and Research (CBER).

Real-Time Review Program

In FY 97, the real-time review program, initiated as a pilot in April 1996, was expanded to all ODE divisions. Designated types of Premarket Approval Application (PMA) supplements with selected, non data intense device changes (not including clinical studies, manufacturing site changes, and panel-track supplements) are reviewed during a meeting, teleconference, or video conference with the firm. ODE divisions have established criteria for real-time reviews to produce faster review times for applicants and efficient use of FDA staff time. Information about the real-time program is available on the Programs in CDRH page at *www.fda.gov/cdrh/programs.html*.

Significant Medical Device Breakthroughs

During FY 97, ODE approved 19 PMAs and cleared 17 510(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 December 6, 1996, reclassifying acupuncture needles for the practice of acupuncture from class III to class II.

- Published a final rule in the *Federal Register* on December 24, 1996, reclassifying scented or scented deodorized menstrual pads from class II to class I and exempting this device and another generic type of class I device, unscented menstrual pads, from the requirement of premarket notification, with limitations.

- Published a final rule in the *Federal Register* on June 6, 1997, reclassifying 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 final rule in the *Federal Register* on June 19, 1997, reclassifying infant radiant warmers from class III to class II.

Proposed Reclassification Actions

- Published a notice of panel recommendation in the *Federal Register* on November 13, 1996, to reclassify suction lipoplasty systems for aesthetic body contouring from class III to class II.

- Published a proposed rule in the *Federal Register* on June 11, 1997, to reclassify tweezer-type epilators intended to remove hair from class III to class I and exempting this device from the requirement of premarket notification.

- Published a proposed rule in the *Federal Register* on September 4, 1997, to reclassify instrumentation used for in vitro fertilization and related assisted reproduction procedures from class III to class II and to reclassify assisted reproduction microscopes and microscopic accessories from class III to class I and exempting them from the requirement of premarket notification.

Other Reclassification Activities

- Published a proposed rule in the *Federal Register* on June 18, 1997, retaining the following three preamendments class III devices in class III: the lung water monitor, powered vaginal muscle stimulator for therapeutic use, and stair-climbing wheelchair.

- Published a notice denying a request for a change in classification of the ostomy pouch and accessories in the *Federal Register* on July 10, 1997.

Guidance for Industry and Reviewers

In FY 97, ODE published 22 final guidance documents and 11 draft guidance documents for comment. One of these, the Convenience Kits Interim Regulatory Guidance issued on May 20, 1997, informs device firms that they can distribute kits composed of certain devices without 510(k) clearance if the separate components can be legally marketed and there are no changes in each component's intended use, and they have not been affected by any additional processing. See Appendix C for a complete listing of all FY 97 ODE guidance documents.

Advisory Panel Activities

CDRH's Medical Devices Advisory Committee consists of 16 panels divided according to medical device speciality. Each panel meets from one to five times per year, depending on its work load. Panel members provide 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.

In FY 97, ODE held 26 panel meetings. Each panel met at least once. There were 18 formal training sessions held for new panel members (special government employees known as SGEs). The two-hour training for SGEs covers the laws and regulations with respect to medical devices, organizational structure of

the agency, ODE's operations, the roles and responsibilities of panel members, the elements of a panel meeting, and conflicts of interest. ODE's Panel Coordinator conducts the training, with the Center's Committee Management Officer covering the topic of conflict of interest and related matters.

Monthly meetings with the Executive Secretaries provide them with guidance on agency policies and assume consistent implementation of these policies across ODE. These meetings also provide a setting where the Executive Secretaries can share their panel experiences with each other.

To further ensure consistent application of policy across the Office, the ODE Office Director and Panel Coordinator meet with the respective division director, Executive Secretary, and other appropriate division staff (i.e., medical officer, lead reviewer, branch chief, etc.) approximately 4-6 weeks prior to each scheduled panel meeting. At this meeting, the Office Director is briefed on the agenda for the scheduled panel meeting, the application to be considered, questions to be posed to the panel, and any other pertinent issues regarding the scheduled panel meeting.

Announcements of panel meetings are publicized in several ways: voice information via the FDA Advisory Committee Information Line (1-800-741-8138), printed information in the *Consumer Quarterly Report, the Federal Register*, and on the Internet. The panel meetings are open to the public and time is provided for public comment. Persons who wish to present their views generally contact the Executive Secretary and request time to speak in advance. A brief summary of the proceedings from panel meetings can be accessed via Internet (*http://www.fda.gov/cdrh/panelmtg.html*).

ODE continuously recruits highly-qualified experts to serve as consultants and panel members. Potential candidates are asked to provide detailed information concerning financial holdings, employment, and research grants and contracts to identify any potential conflict of interest. Every effort is made to ensure appropriate balance of membership. Female and minority representation on the panels are encouraged; currently females make up 45% of our membership and minorities 33%. 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 35 cases concerning the integrity of data submitted to the agency in premarket applications and handled 30 instances related to questions arising under the standards of conduct for employees. Under Application Integrity Programs (AIP), restrictions on the agency's substantive review of submissions from three firms were removed during FY 97 after the successful implementation of a corrective action plan by these firms.

Freedom of Information Requests

ODE staff received 1,440 FOI requests during FY 97, a decrease from 1,794 last fiscal year. During FY 97, the number of FOI requests closed was 2,376 compared to 2,140 in FY 96. The total number of FOI requests pending in ODE is 430, a significant decrease from 1,229 in FY 96.

Congressional Inquiries

Congressional interest in ODE programs continued to be strong during FY 97. ODE staff responded to 18 Congressional letters. Most inquiries related to excimer lasers, brain stimulators, and breast implants. Congressional hearings held during FY 97 dealt with FDA's budget, reform legislation, and home test kits to detect drugs of abuse.

Publications

During FY 97, ODE cleared 4 abstracts and 3 manuscripts authored by ODE staff for publication in professional and scientific journals, and 12 presentations delivered by ODE staff at professional, scientific and trade association meetings.

ODE Vendor Days

In FY 97, ODE, in coordination with the regulated industry, continued to sponsor "Vendor Days" - informational exchange seminars with device manufacturers. On October 9 and 11, 1996, a Vendor Day with manufacturers of Ultrasound Devices was held and one on June 12 and 13, 1997, with manufacturers of Sterilization and Packaging & Sharps Injury Prevention Devices. These 4-hour seminars included an open session for device viewing and demonstrations. These were the sixth and seventh Vendor Days, respectively, since the Vendor Day program began in 1994.

Site Visits

In FY 97, ODE continued its "Site Visit" program which was developed to enhance reviewer knowledge of how specific regulated devices are designed, manufactured, and tested. In FY 97, 13 firms were visited by a total of over 65 employees. The sites visited included manufacturers of breast implants, gastro-intestinal, lens care products, heart valves, ear, nose, throat, infection control, and other devices, IV catheters, optic accessories, and condoms.

In-House Training

The CDRH Staff College sponsored seminars, lectures, and grand rounds for ODE employees throughout the year. Supervisors continued to participate in monthly meetings to discuss current management issues, and all employees attended all-hands meetings to learn about new policies and procedures.

Programs

In FY 97, ODE created the ODE Intern Program which is designed to allow 4-5 college students to work in a practical work environment, gain entry level professional "real work" experience and work alongside some of the Agency's top healthcare authorities. The student is primarily responsible for assisting a senior reviewer in reviewing a variety of medical device submissions.

ODE along with a sister office, the Office of Health Industry Programs, instituted the DSMA/ODE Exchange Program, an internal program that allows scientific reviewers from the Office of Device Evaluation and the Office of Health Industry Programs to exchange places for a period of 60-90 days. Each participant is expected to learn about the operations and integral workings of the other Office.

In addition, ODE participates in the President's Worker Trainee Program. This program provides an opportunity for welfare recipients to learn and develop various skills while employed in the Federal workforce.

Computer Tracking Systems

ODE tracking system changes and additions accomplished with the Office of Systems and Management (OSM) included the following: completed the programming and testing of the PMA and Division Tracking system modules to capture data on the reviews of real-time PMA supplements; completed the tracking system to monitor the document process for Humanitarian Device Exemptions; started the modification of the ODE tracking system for year 2000 compliance issues; designed/programmed the IDE Pre-Original tracking system; completed the programming and testing of the PMA receipt-cohort reports; revised the programming of all IDE and 510(k) receipt-cohort reports; programmed three new IDE performance reports; removed the logic in the 510(k) tracking system for GMP checks; modified the IDE database to capture intended use for approved IDEs; produced letters and mailing labels for letters to 510(k) and PMA applicants; and programmed the index listings of 510(k) data to accompany the CDs of predicate 510(k) submissions which were made available to third-party reviewers.

Electronic Submissions

ODE reviewers continued to receive electronic submissions in FY 97 and the program is expanding. In FY 96 ODE received 3 510(k)s, 1 IDE, 1 PMA, and 18 PMA supplements from a total of 6 manufacturers. In FY 97, ODE received 10 510(k)s, 12 IDEs, 4 IDE amendments, 17 IDE supplements, 20 PMA supplements and 2 PMA amendments from a total of 12 manufacturers. Instructions for submitting electronic submissions can be found on the FDA home page at the address *www.fda.gov/cdrh/elecsub.html*.

Video Conferencing

During FY 97, ODE continued video conferencing interactions with industry through use of the Picture Tel and Intel Proshare systems. Increased use of video conferencing should occur in FY98 due to increased experience with this medium and a reduced travel budget.

ODE on the World Wide Web

ODE continued to develop its home page on the World Wide Web. In FY 97, ODE posted 14 draft guidance documents, and 14 final guidance documents. In addition, information on Premarket Approval Applications (PMAs) and Premarket Notifications (510(k)s) can be found on the **Programs in CDRH** page at *www.fda.gov/cdrh/programs.html*. Anyone can search the Releasable 510(k) and PMA databases, download 510(k) or PMA reports, obtain the monthly 510(k) and PMA listings, and read about the "Real-Time" program for PMA supplements. ODE will continue to use and expand this vehicle to distribute information. Information that can be found on the CDRH Home Page includes:

- ODE's Guidances
- Monthly 510(k) Clearance, PMA and HDE Approval Lists
- PMA, HDE, and 510(k) Summaries of Safety and Effectiveness Data
- 510(k) Substantial Equivalence Letters with the Indications for Use Enclosure
- ODE's Panel Meetings

Office Automation

The major accomplishment in this area was the conversion of the ODE PCs to Windows 95 and Microsoft Office. Through the tremendous efforts of the CDRH computer center, OSM, the ODE computer staff, ODE employees and contractor personnel, ODE moved to an integrated suite of software. ODE upgraded its base of equipment to run Windows 95 and moved the Office one step closer to a windows-based electronic mail system. Pending further testing and necessary equipment upgrades, ODE could move totally to Office 97 in FY 98. With the equipment upgrades, ODE will be in a better position to process electronic submissions on a wider scale.

MAJOR PROGRAM INITIATIVES
Fiscal Year 1997

CDRH Reengineering Efforts

The Center's reengineering efforts were initiated in FY 97 as a redirection strategy to improve efficiency without compromising our public health responsibilies. Existing budget constraints and future resource reductions were contributing factors as well. CDRH employees provided valuable input into the reengineering process through small group meetings with senior managers. Twelve teams were formed to generate ideas and develop pilots in the following areas: Recall Process; GMP Inspection Process; Standards Development Process; Regulations Development Process; Medical Device Reporting; Hazard/Benefit Evaluation Process; Pre-market Approval Process; Information Dissemination Process; 510(k) Process; Product Development Protocol (PDP) Process; Pre-Amendment PMA 515(b) Acceptance Process; and Administrative Process.

Reengineering projects of major interest to ODE include: revision of 510(k) procedures; new IDE/PMA procedures; risk based premarket, postmarket and GMP inspections; increased use of standards; down classification/exemption of some devices; preamendments devices; regulations writing; PDP; and streamlining MDR processes.

Reegineering is an ongoing process. Pilots will be used to test proposed changes and to improve existing processes. Successful ideas will become part of office procedures.

Canada and U.S. Medical Device Partnering Program

In FY97, branches from two ODE divisions, DRAERD and DGRD, participated with their Canadian counterparts in discussions of scientific and review issues and procedures. Review teams shared their perspectives on key new devices, guidance documents, etc. One parallel review was completed for a cochlear implant device after the manufacturer provided releases for specific device data to be shared. This partnering initiative is seen as an important step in harmonizing the scientific reviews of medical devices in North America.

Investigational Device Exemptions - Treatment IDEs

In the *Federal Register* of September 18, 1997 (62 FR 48940), FDA established procedures to allow for the treatment use of investigational devices. These procedures are intended to facilitate the availability of promising new therapeutic and diagnostic devices to desperately ill patients as early in the device development process as possible, i.e., before general marketing begins, and to obtain additional data on the device's safety and effectiveness. These procedures apply to patients with serious or immediately life-threatening diseases or conditions for which no comparable or satisfactory alternative device, drug, or therapy exists.

Under the final rule, treatment use of an investigational device will be considered when:

1. the device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;

2. there is no comparable or satisfactory alternative device available to treat or diagnose the disease or condition in the intended patient population;

3. the device is under investigation in a controlled clinical trial for the same use under an approved IDE, or all clinical trials have been completed; and,

4. the sponsor of the controlled clinical trial is pursuing marketing approval/clearance of the investigational device with due diligence.

When considering submitting a Treatment IDE, the sponsor should consult with the appropriate review division in order to determine if the device/indication would meet the criteria for approval. Requests for treatment use may be submitted as a supplement to the existing IDE and should include, among other things, an explanation of the rationale for the use of the device; the criteria for patient selection; a description of clinical procedures, laboratory tests, or other measures to be used to monitor the effects of the device and to minimize risk; written procedures for monitoring the treatment use; information that is relevant to the safety and effectiveness of the device for the intended treatment use; and a written protocol describing the treatment use.

In order to protect the rights, safety, and welfare of human subjects involved in the clinical trial, while at the same time facilitating the development of beneficial device therapies, FDA included certain safeguards in the Treatment IDE process. Some of these measures were already in place as part of the IDE regulation, while other safeguards were specifically designed for treatment use. Safeguards for this process include: the distribution of the device through qualified experts; maintenance of adequate manufacturing facilities; the submission of reports pursuant to 21 CFR 812.150; and compliance with the regulations governing informed consent and institutional review boards.

The Treatment IDE regulation becomes effective on January 16, 1998. For further guidance on Treatment IDEs, please see the *Federal Register* of September 18, 1997, (61 FR 48940) or contact the IDE Staff at (301) 594-1190.

STATISTICAL TABLES
Fiscal Year 1997

[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 93 - FY 97

Type of Submission	Number Received				
	FY 93	FY 94	FY 95	FY 96	FY 97
Premarket Approval (PMAs)					
Original Applications[a]	40	43	39	44	70
Amendments[a]	665	704	812	883	839
Supplements	395	372	499	415	409
Amendments to Supplements	782	788	838	823	819
Reports for Orig. Applications	442	407	487	435	435
Reports for Supplements	17	12	8	24	2
Master Files	71	130	92	65	130
PMA Subtotal	2,412	2,456	2,775	2,689	2,704
Investigational Device Exemptions (IDEs)					
Original Appplications	241	171	214	253	297
Amendments	320	254	210	219	223
Supplements	3,668	3,020	3,171	3,189	3,776
IDE Subtotal	4,229	3,445	3,595	3,661	4,296
Premarket Notification (510(k)s)					
Original Notifications	6,288	6,434	6,056	5,297	5,049
Supplements	3,940	4,571	4,552	3,246	2,785
Amendments	N/A	3,057	5,012	5,343	4,433
510(k) Subtotal	10,228	14,062	15,620	13,886	12,267
PMA/IDE/510(k) Total	16,869	19,963	21,990	20,236	19,267

a/ As of FY 97, data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form and content to PMAs but are exempt from the effectiveness requirements of PMAs. An approved HDE authorizes marketing of the humanitarian use device for a period of 18 months from the date of approval and this approval may be renewed.

Table 2. Original PMAs*
FY 93 - FY 97

Action	FY 93	FY 94	FY 95	FY 96	FY 97
Number Received	40	43	39	44	70
PMA Actions					
Filing Decisions					
Filed (%)	33(62)	38(60)	33(60)	45(73)	58(78)
Not Filed (%)	16(30)	25(40)	22(40)	17(27)	16(22)
Others(%)	4 (8)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	53	63	55	62	74
Review Activities					
Major Deficiencies	21	30	29	32	38
Minor Deficiencies	10	4	7	5	5
Other[a]	171	191	111	97	138
Review Activity Subtotal	202	225	147	134	181
Approval Decisions					
Approvals(%)	24(35)	26(39)	27(57)	43(57)	48(72)
Approvable(%)	23(34)	22(33)	16(34)	27(35)	14(21)
Not Approvable(%)	21(31)	18(27)	4 (9)	6 (8)	5 (7)
Denials	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Approval Decision Subtotal	68	66	47	76	67
Total PMA Actions	323	354	249	272	322
Average Review Time (Days:Months) for Approvals[b]					
FDA	328:10.8	374:12.3	276: 9.1	289: 9.5	207: 6.9
Non-FDA	109: 3.6	78: 2.6	81: 2.7	55: 1.8	40: 1.3
Total	437:14.4	452:14.9	357:11.7	343:11.3	247: 8.2
Average Elapsed Time (Days:Months) for Approvals[c]					
FDA	547:18.0	649:21.3	606:19.9	572:18.8	375:12.5
Non-FDA	252: 8.3	174: 5.7	167: 5.5	214: 7.0	122: 4.1
Total	799:26.3	823:27.1	773:25.4	786:25.9	497:16.6
Number under Review at End of Period[d]					
Active[e]	94	67	69	57	44
(Active and overdue)	(45)	(22)	(26)	(17)	(0)
On hold[f]	56	72	56	39	41
Total	150	139	125	96	85

*/ As of FY 97, data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form and content to PMAs but are exempt from the effectiveness requirements of PMAs. An approved HDE authorizes marketing of the humanitarian use device for a period of 18 months from the date of approval and this approval may be renewed.

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.

(Continued on next page.)

Table 2. Original PMAs
FY 93 - FY 97

(Continued from previous page.)

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.

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 93 - FY 97

Action	FY 93	FY 94	FY 95	FY 96	FY 97
Number Received	395	372	499	415	409
PMA Supplement Actions					
Panel Track Filing Decisions [a]					
Filed(%)	1 (10)	3(60)	4(0.8)	8 (89)	15(94)
Not Filed(%)	6 (90)	2(40)	1(0.2)	1 (11)	1 (6)
Other(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	7	5	5	9	16
Review Activities [a]					
Major Deficiencies	5	1	3	9	3
Minor Deficiencies	0	0	1	1	1
Other [b]	251	219	147	141	128
Review Activities Subtotal	256	220	151	151	132
Approval Decisions					
Panel track approvals(%) [c]	2 (1)	3 (1)	3 (1)	0 (0)	4 (1)
Nonpanel track approvals(%)	352(62)	382(65)	432(73)	462(85)	397(76)
Approvable(%)	91(16)	95(16)	78(13)	33 (6)	49 (9)
Not approvable(%)	124(21)	104(18)	75(13)	48 (9)	76(14)
Approval Decision Subtotal	569	584	588	543	526
Total PMA Supplement Actions	832	809	744	703	674
Average Review Time (Days:Months) for Approvals [d]					
FDA	168:5.5	253:8.3	179:5.9	146:4.8	100:3.3
Non-FDA	35:1.2	42:1.4	49:1.6	36:1.2	12:0.4
Total	203:6.7	295:9.7	228:7.5	182:6.0	112:3.7
Average Elapsed Time (Days:Months) for Approvals [e]					
FDA	213: 7.0	301: 9.9	209: 6.9	167: 5.5	120:4.0
Non-FDA	56: 1.8	70 : 2.3	66: 2.2	49: 1.6	23:0.8
Total	269 :8.8	371:12.2	275: 9.0	216: 7.1	143:4.8
Number under Review at End of Period [f]					
Active [g]	346	243	226	162	110
(Active and overdue)	(173)	(110)	(49)	(17)	(0)
On hold [h]	119	133	151	74	80
Total	465	376	377	236	190

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.

(Continued on next page.)

Table 3. PMA Supplements
FY 93 - FY 97

(Continued from previous page.)

d/ 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

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 93 - FY 97

Action	FY 93	FY 94	FY 95	FY 96	FY 97
Number Received	241	171	214	253	297
Number of Decisions					
Approved	60	47	109	171	172
Not approved	166	109	81	63	79
Other[a]	22	18	20	26	21
Total	248	174	210	260	272
Percent (%) of Approvals made during first review cycle[b]	27	30	57[d]	73	69
Average FDA Review Time (days)	28	29	29	28	29
Percent (%) of Decisions made within 30 Days	97	95	92[e]	99	100
Number under Review at End of Period[c]	14	11	15	8	32
Number Overdue at End of Period	3	0	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 93 - FY 97

Action	FY 93	FY 94	FY 95	FY 96	FY 97
Amendments Received[a]	320	254	210	219	223
Decisions on Amendments					
Approved(%)	93(29)	109(43)	106(50)	98(45)	101(46)
Not approved (%)	131(40)	68(27)	38(18)	29(13)	25(11)
Other (%)[b]	100(31)	77(30)	69(32)	91(42)	94(43)
Total	324	256	213	218	220
Average FDA Review Time (days)	25	24	22	18	18
Percent (%) of Decisions made within 30 Days	96	97	92[e]	98	100
Average Approval Time (days) for IDEs with Amendments					
FDA time	83	83	70	53	61
Non-FDA time	129	159	162	78	84
Total time[c]	212	242	232	131	145
Number of Amendments per Approved IDE	2.2	2.3	1.8	1.4	1.8
Amendments under Review at End of Period[d]	16	11	8	9	12
Amendments Overdue at End of Period	2	0	0	0	0

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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 93 - FY 97

Action	FY 93	FY 94	FY 95	FY 96	FY 97
Number Received	3,668	3,020	3,171	3,189	3,776
Number of Decisions	3,814	3,070	3,181	3,121	3,777
Average FDA Review Time (days)	24	23	22	21	21
Percent (%) of Decisions made within 30 Days	97	98	98	99	100
Number under Review at End of Period[a]	213	160	149	148	216
Number Overdue at End of Period	8	1	0	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
FY 93 - FY 97

Action	FY 93	FY 94	FY 95	FY 96	FY 97
Number Originals Received	6,288	6,434	6,056	5,297	5,049
Number of Decisions					
Substantially equivalent	4,007	5,498	5,594	4,501	4,405
Not substantially equivalent	135	135	101	64	57
Other[a]	931	1502	2,253	998	693
Total	5,073	7,135	7,948	5,563	5,155
Percent(%) not substantially Equivalent[b]	3.3	2.4	1.8	1.4	1.3
Average Review Time (days)					
FDA time[c]	162	184	137	110	97
Total time[d]	195	216	178	145	130
Median Review Time (days)					
FDA time[c]	144	134	91	85	81
Total time[d]	164	155	102	88	85
Percent (%) of Decisions made within 90 Days, based on					
FDA time[e]	46	45	62	80	95
Total time[d]	20	27	36	50	58
Number under Review at End of Period[f]					
Active[g]	3,822	2,414	1,486	1,408	1,287
(Active and overdue)	(1,894)	(460)	(9)	0	0
On hold[h]	1,335	1,960	964	821	865
Total	5,157	4,374	2,450	2,229	2,152

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 87 - FY 97

Type of Submission	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997
Orig. PMAs[a]	81	96	84	79	75	65	40	43	39	44	70
PMA Supp.[a]	700	727	810	660	593	606	395	372	499	415	409
Orig. IDEs	218	268	241	252	213	229	241	171	214	253	297
IDE Amend.	265	316	271	288	283	297	320	254	210	219	223
IDE Supp.	2,836	3,391	3,038	3,043	3,647	3,644	3,668	3,020	3,171	3,189	3,776
510(k)s	5,265	5,536	7,022	5,831	5,770	6,509	6,288	6,434	6,056	5,297	5,049
Total	9,365	10,334	11,466	10,153	10,581	11,350	10,952	10,293	10,189	9,417	9,824

a/ As of FY 97, data includes a special category of PMAs. Humanitarian Devices Exemption (HDE) applications are similar in both form and content to PMAs but are exempt from the effectiveness requirements of PMAs. An approved HDE authorizes marketing of the humanitarian use device for a period of 18 months from the date of approval and this approval may be renewed.

Table 9. Major Submissions Completed FY 87 - FY 97

Type of Submission	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997
Orig. PMAs	46	46	56	47	27	12	24	26	27	43	48
PMA Supp.	565	652	519	700	479	394	354	385	434	462	401
Orig. IDEs	224	260	245	248	220	215	248	174	210	260	272
IDE Amend.	253	327	280	270	287	297	324	256	213	218	220
IDE Supp.	2,784	3,405	3,023	2,968	3,705	3,469	3,814	3,070	3,181	3,121	3,777
510(k)s	4,992	5,513	6,136	6,197	5,367	4,862	5,073	7,135	7,948	5,563	5,155
Total	8,864	10,203	10,259	10,430	10,085	9,249	9,837	11,045	12,013	9,667	9,873

APPENDIX A. MAJOR ODE PROGRAMS
Fiscal Year 1997

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.

Product Development Protocols (PDPs)

The 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act allowed for two product pathways for a class III device: the PMA or, with prior FDA permission, the notice of completion of a PDP. The PDP process is based upon early consultation between the sponosor and the FDA leading to a device development and testing plan acceptable to both parties. It minimizes the risk that the sponsor will unknowingly pursue -- with the associated waste of capital and other resources -- the development of a device that FDA will not approve. The PDP plan incorporates four discrete stages of FDA review during the device design process: a PDP Summary Outline; FDA/Advisory Panel review of the full PDP; consideration and, where appropriate, pre-approval of design modifications and protocol revisions made during execution of the PDP; and action on the sponsors Notice of Completion. FDA review of the PDP summary may take up to 30 days; the review of the full PDP may take up to 120 days; and FDA must declare the PDP "completed" or "not completed" within ninety days of receiving the Notice. If the FDA finds that the Notice -- together with other information previously submitted -- shows that the requirements of the PDP, including Quality System Regulation Inspection (or GMP inspection in the case of sponsors without an established satisfactory inspection history), have been met, the Agency will declare the PDP complete and publish the Notice in the *Federal Register*.

Humanitarian Device Exemptions (HDEs)

An HDE application is essentially the same as a PMA in both form and content 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.

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.

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 Notifications (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 information to substantiate 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 found to be substantially equivalent. In FY 97, if the device was found to be "not substantially equivalent," the 510(k) submitter could submit a petition for reclassification of the device from class III to class I or II, submit a PMA to market the device, or follow the IDE regulations 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 the submitter receives clearance from FDA.

APPENDIX B. SIGNIFICANT MEDICAL DEVICE BREAKTHROUGHS
Fiscal Year 1997

The following devices were approved via PMAs, PMA Supplements, and HDEs or cleared via 510(k)s during FY97. 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/HDE

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

- Prostar® Percutaneous Vascular Surgical (PVS) System by Perclose, Inc. (P960043, April 30, 1997)
- NeuroCybernetic Prosthesis (NCP®) System by Cyberonics, Inc. (P970003, July 16, 1997)
- Medtronic® Activa™ Tremor Control System by Medtronic, Inc. (P960009, July 31, 1997)
- NeuroControl FREEHAND System® by NeuroControl Corp. (P950035, August 15, 1997)

Division of Clinical Laboratory Devices (DCLD)

- Dr. Brown's Home Drug Testing System by Personal Health & Hygiene, Inc. (P950040, January 21, 1997)
- IMx Tacrolimus II Assay by Abbott Laboratories (P970007, August 26, 1997)

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

- Needle Ease 2501 Sharps Needle Destruction Device for Home Use by Millenium Medical Supply, Inc. (P960044, March 6, 1997)
- GenESA System Closed-Loop Infusion System by Gensia, Inc. (P940001, September 12, 1997)
- NiC 1800 Sharps Needle Destruction Device for use in Health Care Setting by NIC Limited (P970036, September 26, 1997)

Division of General and Restorative Devices (DGRD)

- Dermagraft-TC™ by Advanced Tissue Sciences (P960007, March 18, 1997)
- Hyalgan® by FIDIA Pharmaceutical Corp. (P950027, May 28, 1997)
- SYNVISC® Hylan G-F 20 by Biomatrix, Inc. (P940015, August 8, 1997)

Division of Ophthalmic Devices (DOD)

- VISX Excimer Laser System Models "B" and "C" (PRK for astigmatism) by VISX, Inc. (P930016/S3, April 24, 1997)
- AMO® Array® Multifocal Ultraviolet-Absorbing Silicone Intraocular Lens Model SA40N by Allergan Medical, Inc. (P960028, September 5, 1997)
- SILIKON 1000 Silicone Oil by Richard James, Inc. (P950008, September 25, 1997)

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

- UroLume™ Endourethral Wallstent Prosthesis by American Medical Systems, Inc. (P920023/S1, April 11, 1997)
- Urologic Targis System by Urologix (P970008, August 23, 1997)
- Fetal Bladder Stent by Cook, Inc. (H960001, September 14, 1997)
- Sacral Nerve Stimulator by Medtronic, Inc. (P970004, September 29, 1997)

Devices Cleared via 510(k)

DCLD

- ProTime™ Microcoagulation System by International Technidyne Corp. (K961835, March 12, 1997)
- IgA and IgG Anti-Gliadin Antibody Test Kits by Immco Diagnostics, Inc. (K964341 and K963444, May 30, 1997)
- LEADCARE™ In Office Test System by ESA, Inc. (K971640, September 9, 1997)

DDIGD

- F.A.S.T.1™ Intraosseous Infusion System by Pyng Medical Corp. (K970380, April 25, 1997)

DGRD

- Bipolar Shoulder Prosthesis by Biomet, Inc. (K960363, February 18, 1997)
- Townley Bone Screws for Transfacetpedicular Screw Fixation System by Sofamor Danek USA, Inc. (K953076, February 28, 1997)
- Epilaser™ Normal Mode Ruby Laser by Spectrum Medical Technologies (K963947, March 5, 1997)
- Venisect Laser Lancet™ by Venisect, Inc. (K955653, April 11, 1997)
- Centauri Er:YAG Laser System by Premier Laser Systems (K932683, K933841, May 5, 1997) for treating tooth decay.

DRAERD

- STARRT Falloposcopy System by Conceptus, Inc. (K962587, January 31, 1997)
- Transonic HD01-Series Hemodialysis Monitors (R%,QA,CO,QB,QB2) by Transonic Systems, Inc. (K960817, February 11, 1997)
- Flexiflo Flocator Small Bowel Feeding System by Ross Products (K950017, March 14, 1997)
- Diffusion-Weighted MR Imaging/Magnetom Vision (Magnetic Resonance [MR] Diagnostic Device Accessory) by Siemens Medical Systems (K971055, June 20, 1997)
- Fly Through (TM) (3D CT/MR Reconstruction Software) by Siemens Medical Systems, Inc. (K971717, September 3, 1997)
- Seager Electroejaculator by National Rehabilitation Hospital (K962379, September 18, 1997)
- Asahi AM-R Series Dialyzers by Asahi Medical, Co., LTD. (K970650, September 30, 1997)

APPENDIX C. ODE GUIDANCE DOCUMENTS
Fiscal Year 1997

All ODE guidance documents are available from the Division of Small Manufacturers Assistance (DSMA, HFZ-220). To contact DSMA, call 800-638-2041 or 301-443-6579; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.

ODE guidance documents available on the CDRH Web Site are indicated by an asterisk (*). In the future, all ODE guidance documents will be available on the CDRH Web Site.

Office of Device Evaluation (ODE)

- Deciding When to Submit a New 510(k) for a Change to an Existing Device (January 10, 1997)*
- Convenience Kits Interim Regulatory Guidance (May 20, 1997)*

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

- Electrocardiograph (ECG) Electrode - Version 1.0 (February 11, 1997)
- Electrocardiograph (ECG) Lead Switching Adapter - Version 1.0 (February 11, 1997)
- Electrocardiograph (ECG) Surface Electrode Tester - Version 1.0 (February 11, 1997)
- Non-Invasive Blood Pressure (NIBP) Monitor Guidance (March 10, 1997)*

Division of Clinical Laboratory Devices (DCLD)

- Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)(November 6, 1996)*
- Review Criteria for Assessment of Rheumatoid Factor (RF) In Vitro Diagnostic Devices Using Enzyme-Linked Immunosassay (EIA) Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry (February 21, 1997)*
- Points to Consider for Hematology Quality Control Materials (September 30, 1997)*

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

- Preparation of Premarket Notifications [510(k)'s] for Dental Alloys (March 3, 1997)*

Division of General and Restorative Devices (DGRD)

- Reviewers Guidance Checklist for Orthopedic External Fixation Devices including Smooth or Threaded Pins (February 21, 1997)
- Reviewers Guidance Checklist for Intramedullary Rods (February 21, 1997)

Division of Ophthalmic Devices (DOD)

- Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers - Draft Document (October 10, 1996)*
- Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products (May 1, 1997)*
- Multifocal Intraocular Lens IDE Studies and PMAs Gudiance Document (updated May 29, 1997)
- Third Party Review Guidance for Phacofragmentation Systems (January 31, 1997)
- Third Party Review Guidance for Vitreous Aspiration and Cutting Instruments (January 31, 1997)

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

- Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscopy Sheaths with Protective Barrier Claims (October 21, 1997)*
- Guidance for the Content of Premarket Notification for Water Purification Components and Systems for Hemodialysis (May 30, 1997)*
- CDRH Interim Regulatory Policy for External Penile Rigidity Devices (September 10, 1997)*
- Guidance for Magnetic Resonance Diagnostic Devices - Criteria for Significant Risk Investigations (September 29, 1997)
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (April 11, 1997)*

Draft Guidance Documents Published on the CDRH Web Site for Comment Purposes Only

The following draft guidance documents were published during the fiscal year. All of these guidance documents appear on the internet for review and comment purposes only, and they are not for use until a final version is published.

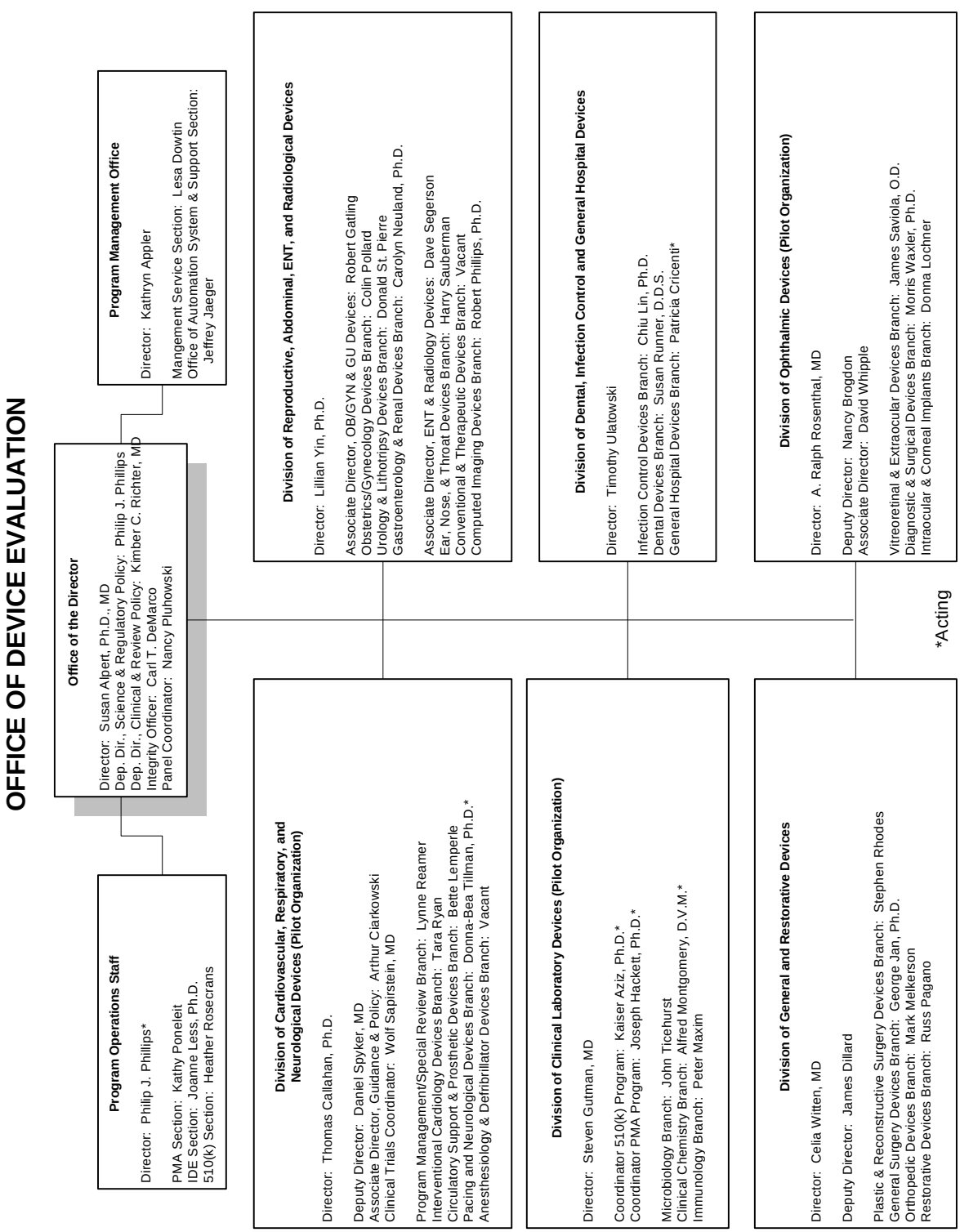
- Guidance for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters (February 26, 1997)
- Guidance for the Submission of Research and Marketing Applications for Permanent Pacing Leads - Version 2.1 (March 24, 1997)
- Medical Device Labeling - Suggested Format and Content - Version 4.4 (April 25, 1997)
- Dear Sponsor Letter Concerning the Revocation of 21 CFR Part 813 - IOL IDE Regulation (May 20, 1997)
- Guidance for the Submission of 510(k)s for Solid States X-ray Imaging Devices (June 4, 1997)
- Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH: Submission Guidance for a PMA (June 14, 1997)
- In-vivo Devices for the Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE (June 16, 1997)
- Discussion Points for Expansion of the Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers - Draft Document (September 5, 1997)

- Draft Points to Consider for Home Drugs of Abuse Test Kits (September 16, 1997)
- Guidance for Off-the-Shelf Software Use in Medical Devices (June 4, 1997)
- Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products (July 28, 1997)

APPENDIX D. PMA APPROVALS FOR FISCAL YEAR 1997

02-Oct-96	P920031	Behring DIagnostics, Inc.	EMIT 2000 Cyclosporine Specific Assay
11-Oct-96	P950037	Biotronik, Inc.	DROMOS DR/DR-A and DROMOS SR/SR-B Cardiac Pacing System
29-Oct-96	P950019	United States Surgical Corp.	Ray Threaded Fusion Cage (TFC)™
07-Nov-96	P920011	Telectronics Pacing Systems, Inc.	Maxim PFS Model 033-301
12-Nov-96	P960004	Sulzer Intermedics, Inc.	Thinline Endocardial Pacing Leads
15-Nov-96	P960019	Laser Vision Centers, Inc.	Laservision/VISX Excimer Laser
26-Nov-96	P940040	Roche Molecular Systems, Inc.	Amplicor™ Mycobacterium Tuberculosis Test
16-Dec-96	P960022	Bausch & Lomb, Inc.	Soflens 66™
21-Jan-97	P950040	Personal Health & Hygiene, Inc.	Dr. Brown's Home Drug Testing System
31-Jan-97	P960024	Ciba vision Corp.	Unizyme™ Enzymatic Cleaner
07-Feb-97	P930022	Medtronic, Inc.	Medtronic® Activa™ Tremor Control System
11-Feb-97	P960001	Depuy International Ltd.	Depuy Bone Cement
13-Feb-97	P940014	Angelini Pharmaceuticals	2-In-1 Drop
06-Mar-97	P960044	Millenium Medical Supply, Inc.	Needle Ease 2501 Sharps Needle Destruction Device for Home Use
10-Mar-97	P950029	ELA Medical	Chorus RM Model 7034 DDDR Pacemaker
18-Mar-97	P960007	Advanced Tissue Sciences	Dermagraft-TC™
21-Mar-97	P940002	Sulzer Medical	Natural-Knee® and Natural Knee® II with CSTI™
07-Apr-97	P950043	Medispec, Ltd.	Econolith™ Lithotripter
17-Apr-97	P960039	Biocompatibles, Inc.	Soft-55 EW Aphakic, Vifilcon A
30-Apr-97	P960043	Perclose Inc.	Prostar® Percutaneous Vascular Surgical (PVS) System
28-May-97	P950027	FIDIA Pharmaceutical Corp.	Hyalgan®
13-Jun-97	P960047	Osteonics Corp.	Osteonics Constrained Acetabular Insert
19-Jun-97	P960054	Johnson and Johnson GMBH	S-Rom Poly-Dial Constrained Liner
19-Jun-97	P960053	Avanta Orthopaedics	Total Trapezio Metacarpal Prosthesis
20-Jun-97	P960013	Pacesetter, Inc.	Tendril DX Model 1388T & 1388K Endocardial Pacing Lead
23-Jun-97	P960031	Xytronix Inc.	Periogard Periodontal Tissue Monitor
26-Jun-97	P960058	Advanced Bionics	Clarion Multi-Strategy Cochlear Implant
27-Jun-97	P960010	Medtronic Interventional Vascular	Medtronic Wiktor Prime Coronary Stent Delivery System
03-Jul-97	P940024	Telectronics	Guardian® ATP II Implantable Cardioverter/ Defibrillator
16-Jul-97	P970003	Cyberonics, Inc.	NeuroCybernetic Prosthesis (NCP®) System
18-Jul-97	P960040	Guidant, Inc.	Ventak AV AICD™ System
21-Jul-97	P970019	Healthtronics, Inc.	Healthtronics Lithotron Lithotripsy System
31-Jul-97	P960009	Medtronic, Inc.	Medtronic® Activa™ Tremor Control System
08-Aug-97	P940015	Biomatrix, Inc.	SYNVISC® Hylan G-F 20
15-Aug-97	P950035	NeuroControl Corp.	NeuroControl FREEHAND System®
23-Aug-97	P970008	Urologix	Urologic Targis System
26-Aug-97	P970007	Abbott Laboratories	IMx Tacrolimus II Assay
05-Sep-97	P960028	Allergan Medical, Inc.	AMO® Array® Multifocal Ultraviolet-Absorbing Silicone IOL
12-Sep-97	P940001	Gensia, Inc.	GenESA System Closed-Loop Infusion System
14-Sep-97	H960001	Cook, Inc.	Fetal Bladder Stent
19-Sep-97	P940016	B. Braun of America	H.E.L.P. System
25-Sep-97	P950008	Richard James, Inc.	SILIKON 1000 Silicone Oil
26-Sep-97	P970036	NIC Limited	NiC 1800 Sharps Needle Destruction Device
29-Sep-97	P970004	Medtronic, Inc.	Medtronic Sacral Nerve Stimulation (SNS) System
30-Sep-97	H970001	Rocket Medical, Inc.	Fetal Bladder Stent - hde
30-Sep-97	P970002	Alliance	Monostrut Cardiac Valve Prosthesis
30-Sep-97	P950005	Cordis Webster	Webster Diagnostic/Ablation Deflectable Tip Catheter
30-Sep-97	P910068	Vitrophage, Inc.	Vitreon®

APPENDIX E. ODE ORGANIZATIONAL CHART



APPENDIX F. ODE STAFF ROSTER
Fiscal Year 1997

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Waldron, Sandy
Wedlock, Chuck
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Gonzalez, Augustin
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Trinh, Hung
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Turtil, Steven
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Watson, Tony
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Wolf, Beverly
Yen, Dwight

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Calogero, Don
Chen, Tzeng
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Drum, Bruce
Eydelman, Malvina
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Felton, Eleanor
Gelles, Muriel
Greer, W. Anthony
Gomez-Novoa, Carmelina
Gouge, Susan
Hoang, Quynh
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Lepri, Bernard
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Romanell, Jake
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Warburton, Karen
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Williams, Ann Marie

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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
Mallis, Elias
Malshet, Vasant
McCool, Barbara
McGee, Leah
Miller, Linda
Miller, Pat
Monahan, Jack
Neuland, Carolyn
Nimmagadda, Rao
Nutter, Cathy
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Pagano, Russell
Pak, Yung
Perez, Rod
Phillips, Bob
Pollard, Colin
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Relacion, Cheryl
Rubendall, Rita
Sacks, William
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
Wolanski, Nicole
Yin, Lillian
Zaremba, Loren
Zaudtke, Peter