OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1999

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

Acknowledgements

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ODE Program Operations Staff
ODE Review Divisions
ODE Program Management Office
OSM Division of Planning, Analysis and Finance
OSM Division of Information Technology Management

Carl T. DeMarco, Project Director
Cathy Hobbs, Editor and Production Specialist

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PREFACE

ODE staff are to be commended for another outstanding year! Under the leadership of Dr. Susan Alpert, all ODE employees continued to demonstrate a commitment to improve upon past successes. Everyone in ODE should feel a true sense of accomplishment.

Performance highlights for FY 99:

- approved 45 PMAs, 10 as expedited reviews, 8 as modular reviews, and 6 as humanitarian device exemptions;
- reviewed 17 of the 45 approved PMAs in 180 FDA days or less and 31 in less than 1 year;
- continued to reduce review times for PMAs and PMA Supplements;
- approved 437 PMA Supplements of which 133 were reviewed in real time;
- approved 3 PDP protocols, one as a panel track;
- approved or cleared 63 significant medical device breakthroughs (43 PMAs and 20 510(k)s);
- achieved, for a fourth consecutive year, a zero backlog in the 510(k) program at the end of the fiscal year;
- continued to reduce the FDA and total average review and median review times for 510(k)s;
- provided pre-IDE guidance to sponsors on 201 applications;
- approved 68% of IDEs in the first review cycle;
- reviewed 100% of all IDEs (originals, amendments, and supplements) within 30 days; with an average review time of 28 days; and
- issued 36, final and draft, guidance documents.

With a dedicated and highly trained workforce, ODE remains committed to meeting the public health challenges of the future.

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HIGHLIGHTS
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
Fiscal Year 1999

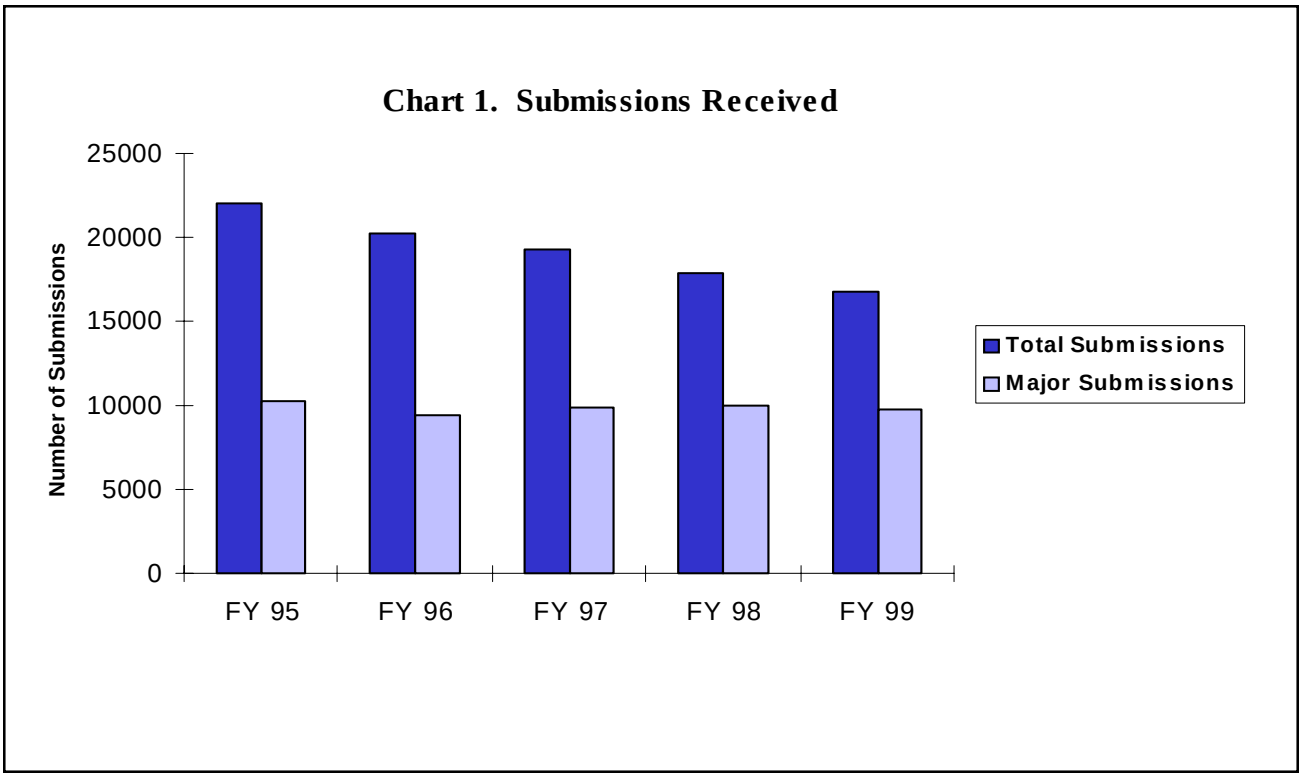
(October 1, 1998 - September 30, 1999)

The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is responsible for protecting the rights, safety and welfare of patients participating in clinical studies of significant risk medical device research and for evaluating the safety and effectiveness of medical devices as they enter the U.S. market place. (See Appendix A for further information on ODE's major program responsibilities.)

ODE's Major Program Initiatives (Investigational Device Exemption Regulation Modification, Humanitarian Device Regulation Modification, and Clinical Laboratory Improvement Amendments of 1988) are discussed in the next section of this report. Following are the highlights of ODE's review activities and performance for Fiscal Year 1999 (FY 99). 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 21 to 38.

Workload/Resources

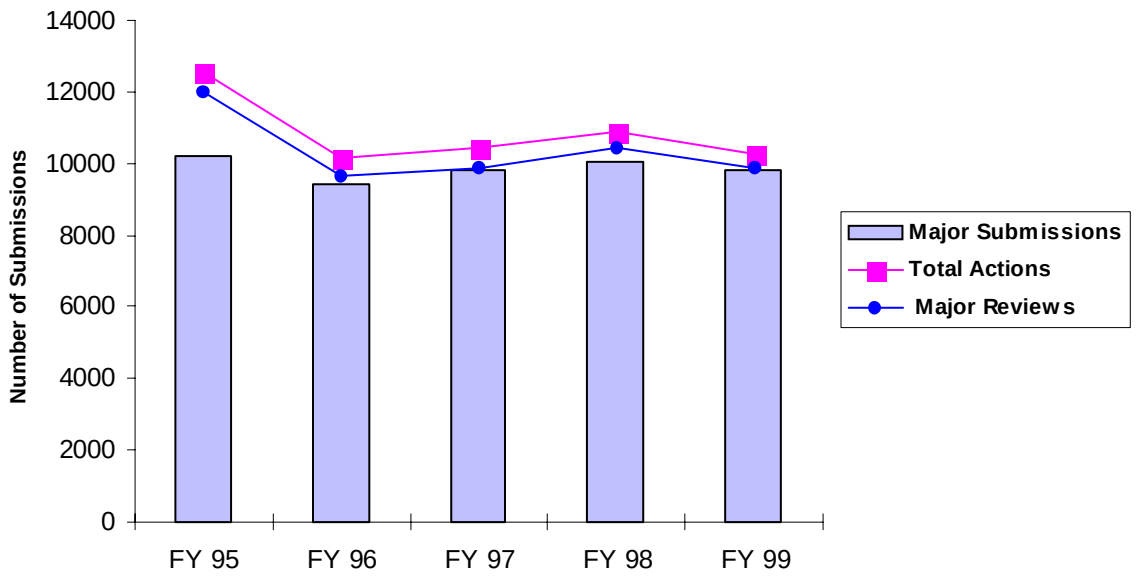
- During FY 99, ODE received a total of 16,812 submissions, compared to 17,861 in FY 98; 9,792 were major submissions compared to 10,016 last fiscal year.



• On the decision side, ODE completed the processing of 9,872 major submissions, compared to 10,455 major submissions in FY 98.

• ODE ended the fiscal year with 330 employees. During the year, ODE lost 17 full-time employees (8 scientific reviewers, 4 medical officers and 5 clericals) through resignation or retirement and added 21 new employees (9 scientific reviewers, 2 medical officers, 1 computer specialist,

Chart 2. Major Submissions, Reviews, and Total Actions



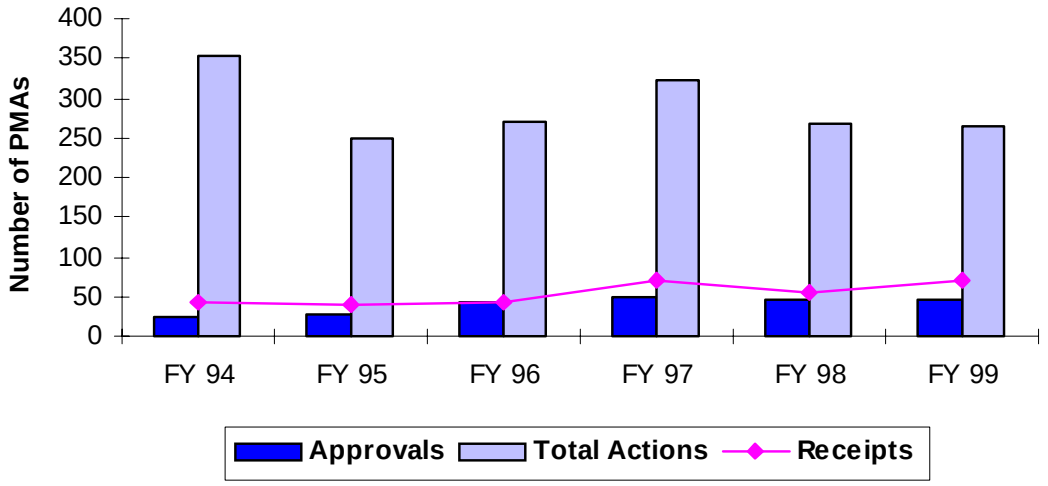
and 9 clericals). Thirteen of the new hires were women — 62% (1 African American female, 5%) and 2 were African American males (summer hires).

Premarket Approval Applications (PMAs)

• ODE received 72 complete original PMAs, 17 more than the number received in FY 98, and 251 modular submissions representing 57 PMA shells.

• The total number of PMAs in inventory (active and on hold) at the end of this fiscal year increased from 70 in FY 98 to 87, after six years of continued reduction. The number of active PMAs under review increased at the end of FY 99 to 49 compared to 29 last year, and those on hold decreased from 41 in FY 98 to 38 in FY 99. For the third consecutive year, there were no active and overdue PMAs at the end of the fiscal year.

Chart 3. Annual Receipts & Actions for PMA Decision Cohorts



• The total number of PMA actions decreased from 269 to 266 actions. These actions included 72 filing decisions, 141 review determinations, and 53 approval decisions.

Chart 4. Average Review Time for PMA Decision Cohort Approvals

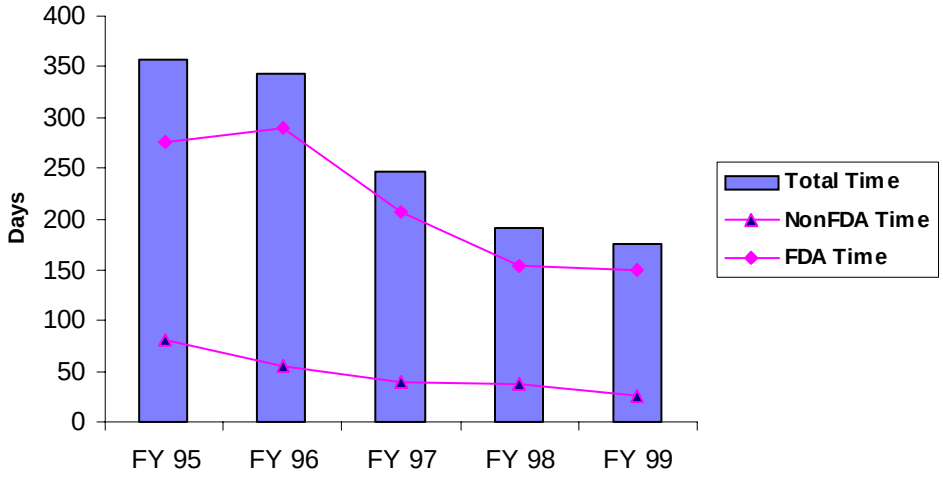
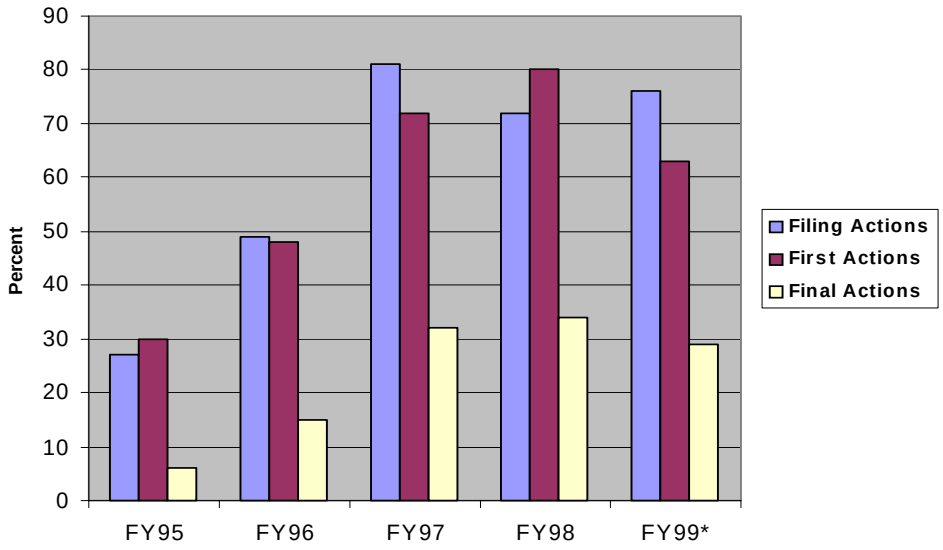


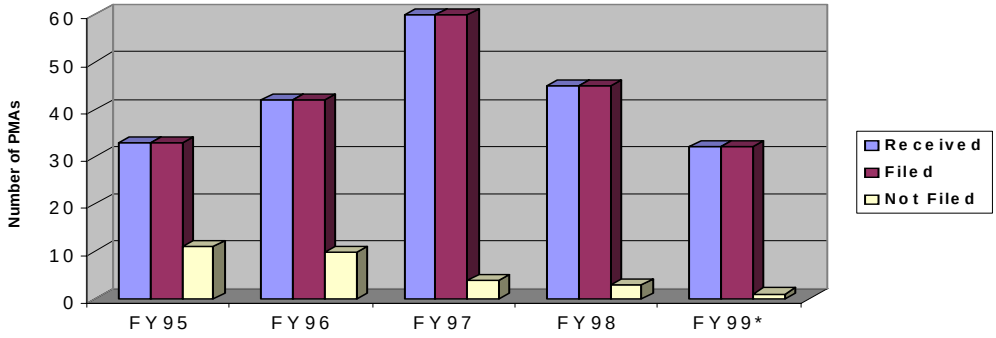
Chart 5. Percentage of PMA Receipt Cohort Actions Within Timeframes



*First six months.
Percent of receipt cohort "Filing" Actions within 45 days.
Percent of receipt cohort "First" Actions within 180 days (HDEs within 75 days) including withdrawals, conversions, etc.
Percent of receipt cohort "Final" Actions within 180 days (HDEs within 75 days) including withdrawals, conversions, etc.

• The 53 original PMA decisions were comprised of 45 approved PMAs, 7 approvable PMAs, and 1 nonapprovable PMA. Ten of the 45 approvals were expedited PMAs, and 6 were HDEs. See Appendix C for a complete list of PMA approvals.

Chart 6. Original Receipt Cohort PMAs Received & Filed



*First six months.

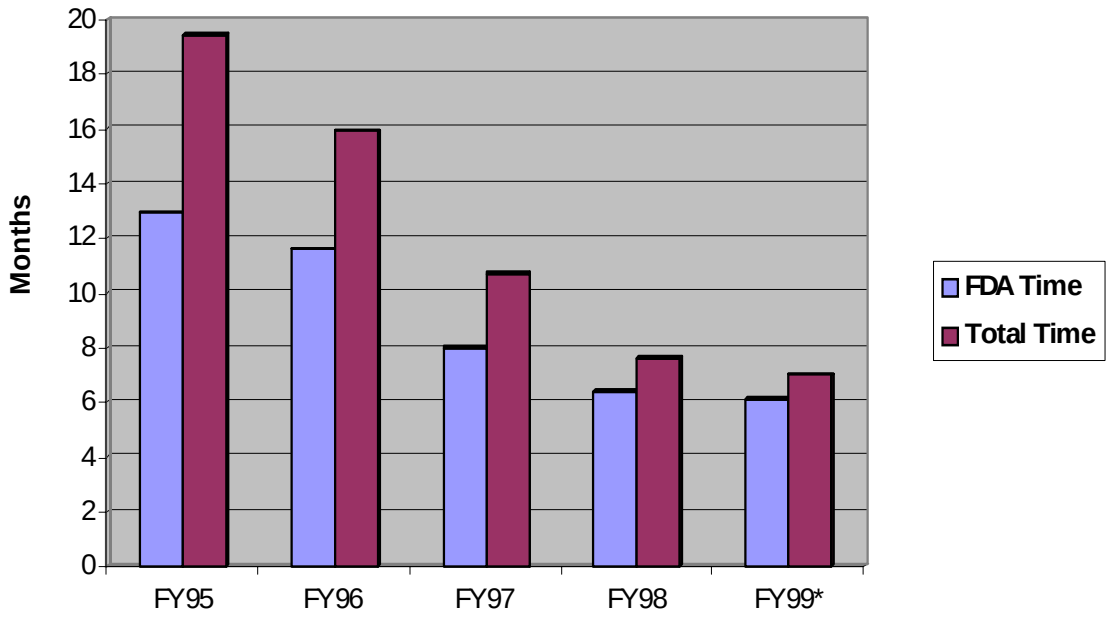
• Average FDA review time for original PMAs reaching final action decreased from 154 days in FY 98 to 149 days in FY 99. The non-FDA component of review time decreased from 37 days in FY 98 to 26 days this fiscal year. The total average review time decreased to 5.8 months, which represents the fifth consecutive year in which this review time has decreased. Furthermore, 17 PMAs were reviewed in 180 days or less, and 31 were completed within 1 year.

• In FY 99, the total average elapsed time for PMA decision cohort performance remained the same as last year at 12.5 months.

• For the first 6 months of FY 99 for PMA receipt cohort perfomance, the first action and final action data are as follows. The FDA time from filing to first decision average FDA days (median FDA days) decreased from 131(141) in FY 98 to 129(120) days in FY 99. The average FDA (total) elapsed time to an approval or denial decreased from 202(228) in FY 98 to 192(211) days in FY 99. The median FDA (total) elapsed time to an approval or denial increased from 179(180) in FY 98 to 191(231) days in FY 99.

• The number of PMA supplements received increased from last year's 513 to 556. There were 615 PMA supplement actions up from last year's 608 total actions. These actions included 17 panel track filing decisions, 72 scientific review decisions, and 437 approval decisions.

Chart 7. Receipt Cohort PMA Average Elapsed Time from Filing to Final Action



*First six months.

• For PMA supplements reaching final action, the average elapsed FDA review time dropped from 109 days in FY 98 to 92 days, and the total average elapsed time decreased from 153 days to 118 days.

• Just as in FY 97, there were no PMA supplements active and overdue at the end of this fiscal year. The number of active supplements increased slightly to 158 in FY 99 from 139 in FY 98, and the number of supplements on hold increased from 57 to 70.

• For the first 6 months of FY 99 for PMA supplements receipt cohort performance, the first action and final action as follows. The FDA time from filing to first decision average FDA days (median FDA days) decreased from 83(68) in FY 98 to 72(56) days in FY 99. The average FDA (total) elapsed time to an approval or denial decreased from 89(109) in FY 98 to 62(73) days in FY 99. The median FDA (total) elapsed time to an approval or denial decreased from 46(63) in FY 98 to 30(36) days in FY 99.

Real-Time Review of PMA Supplements

• A total of 135 requests were received and processed for real time PMA supplements in FY 99 which represents 24% of all supplements received. Of those submissions, 133 were approved. Most applicants chose telephone conferencing versus a face-to-face meeting or a video conference. The majority of these applications were reviewed in DCRND (43%) followed by DGRD (24%), DOD (15%),

Chart 8. Annual Receipts & Actions for PMA Supplement Decision Cohorts

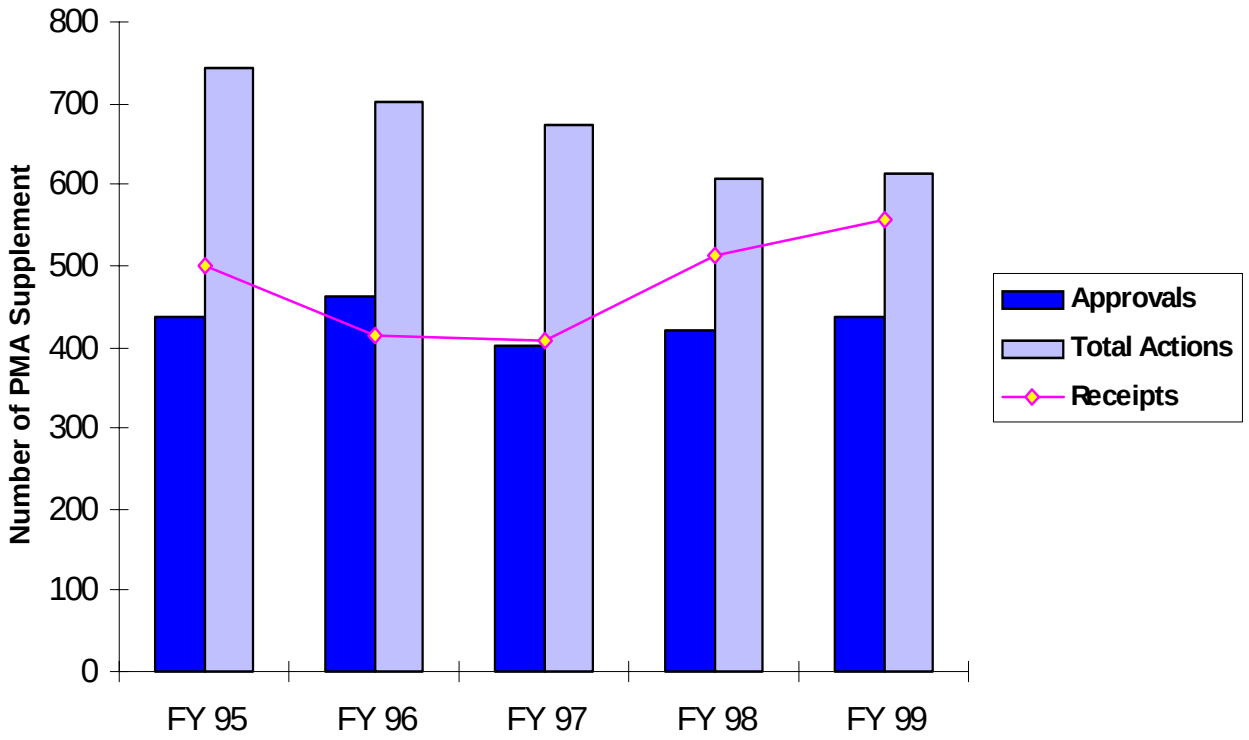
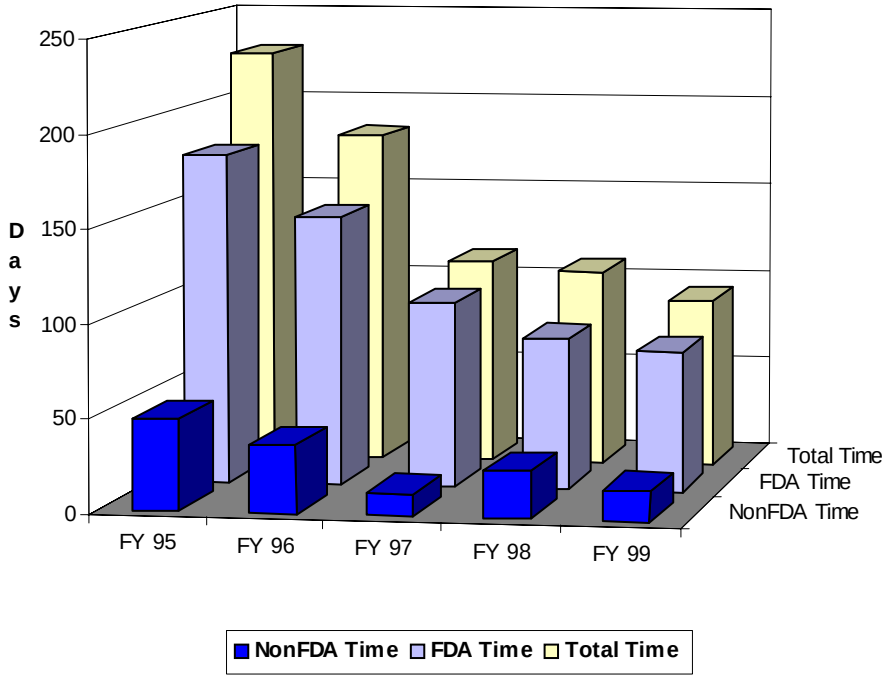


Chart 9. Average Review Time for PMA Supplement Decision Cohort Approvals



and DRAERD (11%) with seven percent among both DCLD and DDIGD. Overall, average review time from "meeting" to issuance of a decision letter (approvable, not approvable or approval order) was 20 days and 32 days from receipt to approval.

Product Development Protocols (PDPs)

• Three PDPs have been approved in FY 99, and reports are being received on their progress for the clinical study. Two original Notices of Completion were declared complete. In addition, one "Panel-Track" supplement, and 3 routine PDP supplements to the Notices of Completion were approved. Note that a PDP that has been declared complete is considered to have an approved PMA. ODE continues to encourage the use of the PDP process and will work with the interested applicants to fully evaluate their PMA options.

Modular PMA Review

• ODE received a total of 57 PMA shells and 251 modules. A total of 68 modules were found to be acceptable while 32 received deficiency letters. A number of modules were closed out during FY 99 because they were under review or on hold at the time the PMA was received. Applicants with

modular submissions that were under review or deficient when the PMA was received continued to receive feedback under the PMA for those modules. Review times for modular PMAs were approximately half that for traditional PMAs. However, this is based on a small number of submissions achieving PMA approval since modular review was implemented. A tracking system with modular PMA query capability became available during FY 99.

Investigational Device Exemptions (IDEs)

- During FY 99, ODE reviewed 201 pre-IDEs. Based on these reviews, guidance for the pre-original IDE submissions were provided through meetings with the sponsors, letters, or by fax, phone, and other.

- ODE received 304 original IDEs, a decrease from the 322 received in FY 98. There were 305 decisions made on original IDEs, a decrease from 325 last year.

- Ninety-nine percent of all original IDE decisions were issued within 30 days in FY 99. The average review time was 28 days.

- Of the IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle decreased slightly from 71% in FY 98 to 68% during FY 99.

- During this fiscal year, 275 IDE amendments were received. Decisions were made on 268 amendments: 97 approvals (36%); 42 disapprovals (16%); and 129 other administrative actions (48%). 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 from 90 days in FY 98. This average approval time consisted of 57 days for FDA time, up from 55 days last year, and 88 days for non-FDA time, up from 35 days in FY 98.

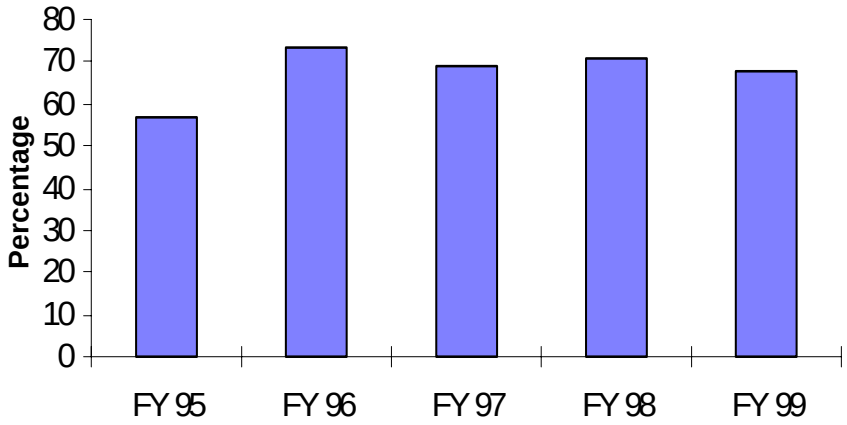
- ODE received 4,127 IDE supplements during FY 99. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe was 100 percent in FY 99. The average review time for IDE supplements decreased slightly to 20 days.

Premarket Notifications (510(k)s)

- ODE received 4,458 original 510(k)s, 1,872 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 2,962 amendments (additional information received while the 510(k) is under review, the receipt of which does not affect the review clock).

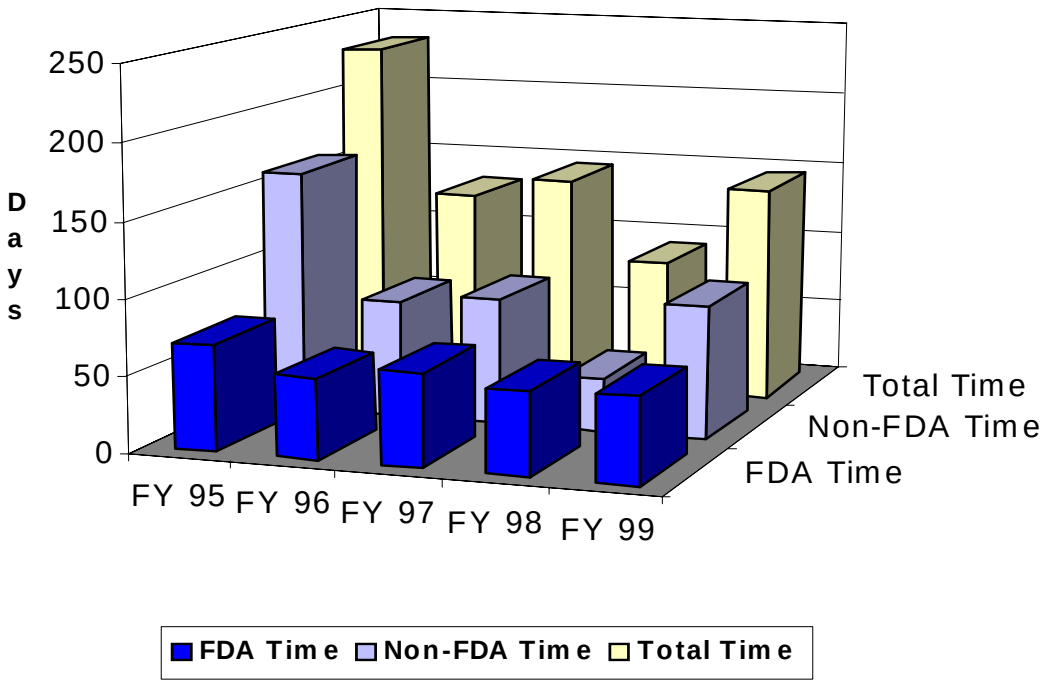
- The total average review time declined from 114 days in FY 98 to 102 days in FY 99, and the average FDA review time was 80 days, down from 89 days in FY 98. The median review time, i.e., the time it took to review 50% of the 510(k)s, has been falling from a high of 164 days in FY 93 to a current low of 76 days in FY 99.

Chart 10. Percentage of Original IDEs Approved on First Review Cycle*



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

Chart 11. Average Approval Time for IDEs with Amendments



- There were 1,404 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year, which is a decease of 140 from the 1,544 in FY 98's end-of-year inventory. The number on hold decreased from 487 at the end of FY 98 to 461. Most important, for the fourth consecutive fiscal year there were no 510(k)s active and overdue at the end of the reporting period.

- For the first 9 months of FY 99 for receipt cohort performance, the FDA time from receipt to final decision decreased to 66 days compared to 70 days for the first 9 months in FY 98.

- For the first 9 months of FY 99 for receipt cohort performance, the total time from receipt to final decision decreased to 77 days compared to 82 days for the first 9 months in FY 98.

Third-Party Review of 510(k)s

On November 21, 1998—as a follow-up to a two-year pilot—the Center began accepting 510(k)s reviewed by third-party organizations under the Accredited Persons provisions of FDAMA. More third parties are qualified to conduct reviews than in the pilot (see list of Accredited Persons at http://www.fda.gov/cdrh/modact/accredit.html), and we increased the number of eligible moderate risk devices by more than three-fold (see eligible device list at http://www.fda.gov/cdrh/dsma/3258.html). In October 1998, the Center published a final guidance document for the program (http://www.fda.gov/cdrh/modact/3pguide.html), and conducted a 2 and 1/2 day training program for third-party reviewers.

Chart 12. Average 510(k) Review Time for Decision Cohorts

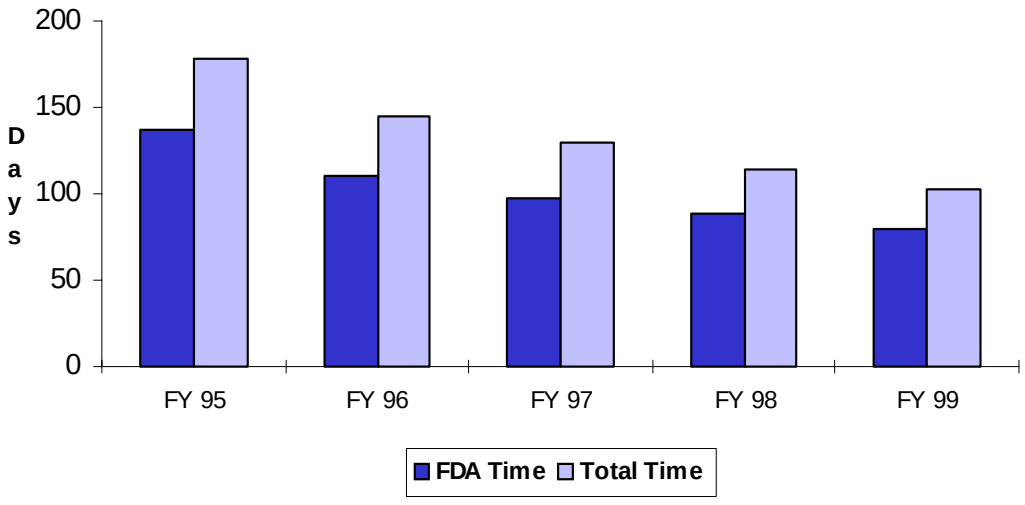
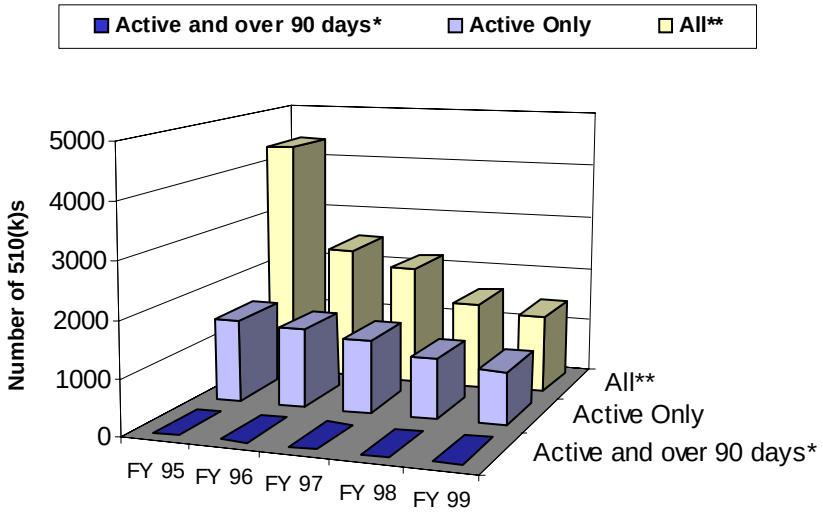


Chart 13. Pending 510(k) Decision Cohorts



*In the current review cycle, include those over 90 days.
**Under review and on hold.

During FY 99, ODE received 32 510(k)s with a third-party review. This was nearly an 80 percent increase over the 18 such submissions received in FY 98 under the pilot program, but was a small percentage of the more than 1,200 510(k)s that were eligible for third-party review. ODE issued substantial equivalence decisions on 29 "third party" 510(k)s in FY 99. The average total elapsed time from ODE's receipt to ODE's issuance of a final decision was 15 days, and 100 percent of the final decisions were issued within 30 days of ODE's receipt. The average total elapsed time from the third party's receipt to ODE's final decision was 57 days, as compared to the average total elapsed time of 105 days for ODE's final decisions on comparable 510(k)s that did not have a third-party review.

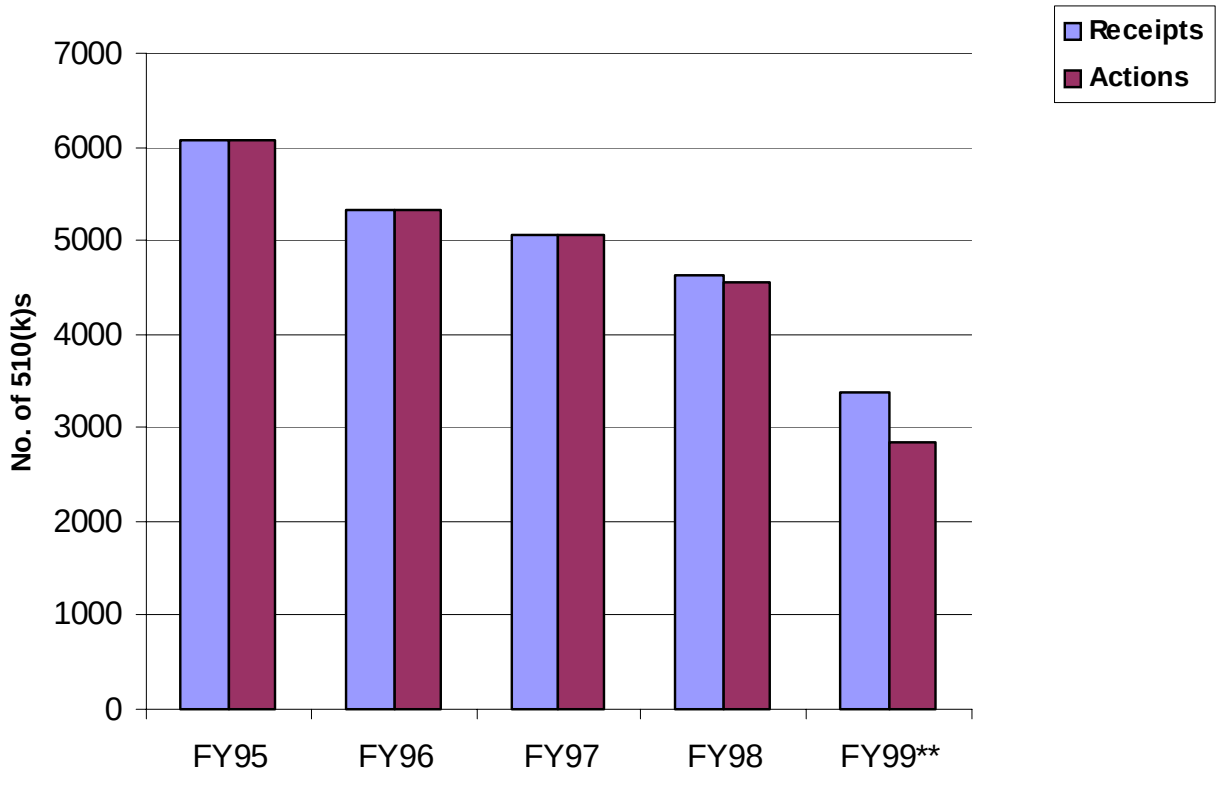
Special 510(k)s

From October 1, 1998 to September 30, 1999 ODE received 396 Special 510(k)s. Three hundred sixty-one have received final decisions with the average FDA review time of 24 days and the average total time of 29 days. Three hundred twenty-six were found substantially equivalent and the remaining 35 had other decisions such as withdrawn or deleted.

Abbreviated 510(k)s

During the same timeframe ODE received 85 Abbreviated 510(k)s. Seventy-five received final decisions (65 substantially equivalent and 9 other decisions, including 1 NSE) with a FDA average review time of 80 days and total time of 99 days. None of the Abbreviated 510(k)s went over 90 days.

Chart 14. Receipts & Actions for 510(k) Receipt Cohorts*



*Cut Off Date of 9/30/99 for all receipt cohorts.
**For the first nine months of FY 99.

Significant Jurisdictional Issues Involving Devices in FY 99

Title 21 of the Code of Federal Regulations Part 3 - Product Jurisdiction describes the procedure the Agency uses to assign Center jurisdiction over medical products whose jurisdiction is not clear or is in dispute. Requests for Designations (RFDs) over such products are made in writing to the Office of the Chief Mediator and Ombudsman. These formal submissions contain the material describing the requester's product and/or products and their proposal regarding which Center should be given lead designation over their product and which FDA regulatory authority, i.e. biological, device or drug, should apply.

In FY99, CDRH participated in the reviews of 18 RFD's received by the FDA's Ombudsman's Office, in addition to completing 4 RFDs received in FY98. Out of the 18 new RFDs assigned to CDRH (a single RFD, not counted in this 18, was received by the Ombudsman's Office which involved CDER & CBER only) for consideration, four were withdrawn before reviews could be completed, and one was not due for completion until FY00. Of the RFD's whose reviews were completed, 13 of the 18 received in FY99 and the four remaining from FY98, DDIGD was assigned to review six, DGRD assigned three, one was jointly reviewed by both DDIGD & DGRD, DCLD was assigned three, DCRND was assigned two, and DRAERD was assigned two to review.

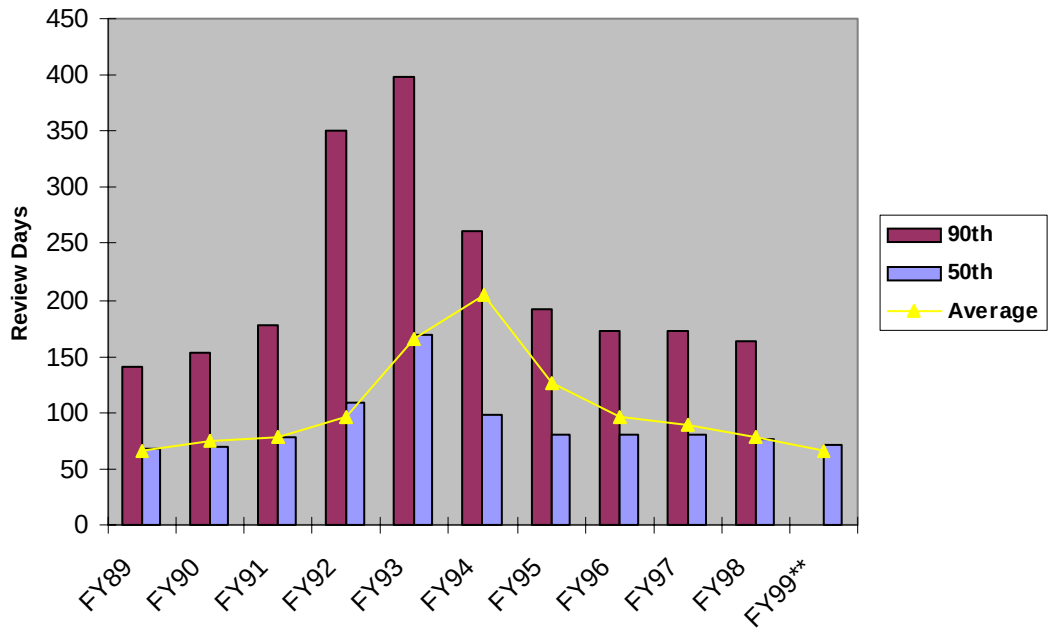
Significant Medical Device Breakthroughs

During FY 99, ODE approved 43 PMAs and cleared 20 510(k)s that represent significant medical device breakthroughs. See Appendix B for a complete list.

Classification Actions

- Published a final rule in the Federal Register on November 5, 1998, classifying the Apgar Timer, Lice Removal Kit, and Infusion Stand into class I exempt.

Chart 15. FDA Days from Receipt to Final Action for 510(k) Receipt Cohorts*



*Cut Off Date as of 9/30/99 for all receipt cohorts.
**For the first nine months of FY99. 90th percentile data not available for FY99.

- Published a final rule in the Federal Register on November 5, 1998, classifying the Sulfide Detection Device into class II.

- Published a final rule in the Federal Register on March 8, 1999, classifying the Nasal Dilator, the Intranasal Splint, and the Bone Particle Collector into class I exempt.

- Published a proposed rule in the Federal Register on June 10, 1999, to classify Female Condoms into class III.

- Published a final rule in the Federal Register on September 23, 1999, classifying the Electrogastrography System into class II.

Automatic Evaluation of Class III Designation

- Issued a classification order on August 20, 1999, for an Electrogastrography (EGG) System for the 3CPM EGG Machine by 3CPM Co., Inc.

Proposed Reclassification Actions

- Published a proposed rule in the Federal Register on November 6, 1998, to reclassify Liquid Chemical Sterilants into class II and General Purpose Disinfectants into class I exempt.

- Published a proposed rule in the Federal Register on February 8, 1999, to reclassify the Extracoporeal Shock Wave Lithotripter from class III to class II.

- Published a proposed rule in the Federal Register on March 15, 1999, to reclassify 38 Preamendments Class III Devices into Class II.

- Published a proposed rule in the Federal Register on May 10, 1999, to require PMAs or reclassify Glans Sheath Devices.

- Published a proposed rule in the Federal Register on July 30, 1999, to reclassify Surgeon's and Patient Examination Gloves as class II medical devices.

- Published a proposed rule in the Federal Register on August 9, 1999, to reclassify Cardiopulmonary Bypass Accessory Equipment, Goniometer Devices, and Electrode Cable Devices from class I into class II exempt.

Final Reclassification Actions

- Published a final rule in the Federal Register on October 26, 1998, reclassifying the Tweezer-Type Epilator from class III to class I exempt.

Other Reclassification Activities

- Issued a reclassification order on September 9, 1999, for the Nonabsorbable Expanded Polytetrafluroethylene Surgical Suture.

Final 515(b) Calls for PMAs

- Published a final rule in the Federal Register on April 14, 1999, to call for PMAs for three Class III Preamendments Physical Medicine Devices (microwave diathermy for all other uses, ultrasonic diathermy for all other uses, and ultrasound and muscle stimulator for all other uses).

- Published a final rule in the Federal Register on April 14, 1999, to call for PMAs for three Class III Preamendments Devices (suction anti-choke device, tongs anti-choke device, and implanted neuromuscular stimulator).

- Published a final rule in the Federal Register on August 19, 1999, to call for PMAs for the Silicone Inflatable Breast Prosthesis.

Guidance for Industry and Reviewers

In FY 99, ODE published 29 final guidance documents. ODE also published 7 draft guidance documents for comment. See Appendix D for a complete listing of all FY 99 ODE guidance documents.

Advisory Panel Activities

CDRH's Medical Devices Advisory Committee (MDAC) consists of 18 panels divided according to medical device specialty. Two new panels were added to the MDAC in FY 99 - Dispute Resolution Panel and the Molecular and Clinical Genetics Panel. ODE held a Go-Away (training) on September 29, 1999 for all ODE Executive Secretaries and managers.

New to our panels in FY 99 was participation by patient representatives. Patient representatives usually have a history of the disease for which a new diagnosis or treatment is being considered by the panel. MDAC had patient representatives serve on panels discussing glucose monitors and temporomandibular joint devices.

Each panel meets from one to five times per year, depending on its workload. Panel members provided advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification and reclassification of devices, the review of premarket approval applications, Product Development Protocols (PDPs) and 510(k)s, and the content of guidance documents designed to improve the interaction between the Agency and sponsors of medical devices.

In FY 99, ODE held 24 panel meetings. There were 17 formal training sessions held for new panel members (special government employees known as SGEs). The two-hour training for SGEs covered 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 conflict of interest.

Announcements of panel meetings were 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 were open to the public and time was provided for public comment. Persons who wished to present their views generally contacted the Executive Secretary and requested time to speak in advance. A brief summary of the proceedings from panel meetings can also be accessed via Internet (http://www.fda.gov/cdrh/panelmtg.html).

ODE continuously recruits highly qualified experts to serve as consultants and panel members. During FY 99, the MDAC recruitment brochure was revised to include the two new panels. The recruitment brochure was made available on the internet at http://www.fda.gov/cdrh/ode/advbrochure01.html. Potential candidates were asked to provide detailed information concerning financial holdings, employment, and research

grants and contracts to identify any potential conflict of interest. Every effort was made to ensure appropriate balance of membership. Female and minority representations were encouraged; currently females make up 45% of panel membership and minorities almost 27%. 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 38 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), no new firms were placed on the AIP list nor were any firms removed during FY 99.

ODE handled 17 instances related to questions arising under the standards of conduct for employees. During FY 99, as in years past, the ODE staff received several unsolicited gifts from the regulated industry. Both the offering of gifts and their acceptance is, in general, prohibited under applicable laws and regulations (see Standards of Ethical Conduct for Employees of the Executive Branch on the internet at http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_99.pdf).

Also during FY 99, several medical device manufacturers made charitable contributions in the name of individual ODE and Center staff members. The singling out of particular individuals for this type of recognition is not appropriate and should not be done.

Freedom of Information Requests

ODE staff received 1,355 FOI requests during FY 99, a decrease from 1,681 last fiscal year. During FY 99, the number of FOI requests closed was 834 compared to 1,696 in FY 98. The total number of FOI requests pending in ODE at the end of FY 99 is 771.

Congressional Inquiries

Congressional interest in ODE programs continued to be strong in FY 99. ODE staff responded to inquiries and participated in briefings on such topics as digital mammography, breast implants, tampons and dioxins, latex, genetic testing, reuse, and excimer lasers. ODE also participated in Congressional hearings held during FY 99 dealing with FDA's budget, FDAMA, Year 2000 (Y2K) issues, and genetic testing.

Publications

During FY 99, ODE cleared 14 abstracts or presentations and 10 manuscripts authored by ODE staff for publication in professional and scientific journals and delivered by ODE staff at professional, scientific and trade association meetings. See Appendix E for a bibliography of publications.

ODE Vendor Day

In FY 99, ODE, in conjunction with the regulatory industry, sponsored one Vendor Day - an informative exhibit and exchange seminar with device manufacturers.

Site Visits

In FY 99, ODE continued its Site Visit Program that was developed to enhance reviewer knowledge of how specific medical devices are designed, manufactured, and tested. In FY 99, the program continued to include not only visits to medical device manufacturing firms but also hospitals for the observation of certain devices in use. As a result, 14 firms and/or hospitals were visited to learn about heart valves, hearing aides, contact lenses, defibrillators, pacemakers, stents, dialysis systems, and many others.

In-House Training

ODE employees attended many courses, lectures, and grand rounds sponsored by the CDRH Staff College. Supervisors continued to participate in monthly meetings to discuss current management issues, and all employees attended all-hands meetings to learn about new FDAMA policies and procedures.

ODE sponsored three in-house training courses for employees and managers: The Indispensable Assistant; How to Become a Better Communicator; and Coaching and Teambuilding Skills for Managers.

Mentoring Program

ODE continued to improve and enhance its mentoring program. The program is designed to orient new employees to their job responsibilities and their workplace. The program matches new employees with a mentor who is expected to provide technical, informational and career guidance to the employee in an effort to ensure appropriate employee development. The ODE Program Management Office has served as an informal mentoring agent for minorities to facilitate their assimilation into the workforce.

Other Employee Programs

In FY 99, ODE continued and expanded the ODE Intern Program. The program allows 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. Special attention is given to minority candidates. ODE continued to expand the program to include American and foreign professionals. In FY 99, individuals from Canada and Japan participated in the program.

ODE, along with a sister organization, the Office of Health Industry Programs, continued the DSMA/ODE Exchange Program, an internal program that allows scientific reviewers from each Office 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.

ODE continued to participate in the President's Worker Trainee Program. This program provided an opportunity for welfare recipients to learn and develop various skills while employed in the Federal workforce.

ODE established the ODE Employee Exchange Program. The primary purpose of the program is to allow staff members the opportunity to work in other Offices and Centers within FDA to keep abreast of current advances and practices in sister organizations, as well as changes in legislation, regulations, scientific and legislative literature in other medical fields.

Minority Recruitment

In FY 99, ODE participated in several recruitment and job fairs in an effort to promote the hiring of minorities within the Office and the Center:

* Mexican American Engineering Society (MAES) Annual Conference
* League of Latin American Citizens (LULAC) Annual Conference
* Blacks in Government (BIG) National Training Conference
* University of Toledo - College of Engineering Career Expo

Computer Tracking Systems

ODE tracking system changes included premarket database enhancements, revised query programs, and a new database to support modular reviews. In addition, revisions were made in the 510(k), third party and product databases to support third party reviews. All CLIA data files maintained by the Centers for Disease Control were processed and the CLIA tracking system development continued.

Office Automation

ODE enhanced its computing capability with the installation of 235 new desktop computers. These computers replaced non-Y2K compliant computers and run the Windows NT operating system. In addition, ODE acquired Acrobat Exchange 4.0 to work with electronic submissions using pdf files. Personal computer limitations will no longer prevent ODE from accepting electronic submissions.

To further assist the ODE staff, ODE acquired additional laptop computers to enable ODE employees to work away from the office and to maintain contact by email. To complement the laptops for in-house presentations, each division received an LCD projector for use at panel meetings or office meetings. ODE also bought extra overhead and slide projectors for each division to provide easy access to this equipment for in-house use and for use by industry at ODE meetings. ODE purchased medical dictionary software to simplify the spell checking process and updated OCR software and scanners to afford ODE reviewers the benefit of paper to Microsoft Word conversions.

ODE utilizes the Microsoft Office 97 software suite with Outlook as the email program. The ability to pass documents within CDRH through network connections and outside CDRH through Outlook has greatly facilitated the acceptance and transfer of documents used in the review process.

Electronic Submissions

ODE reviewers continued to receive electronic submissions in FY 99 for the PMA, IDE and 510(k) programs. However, the number of submissions received in FY 99 declined from 64 to 47 and the number of sponsors/manufacturers dropped from 15 to 12. ODE reviewers received parts of submissions in electronic format but those submissions are not recorded as electronic submissions. Prior contact with an ODE division is requested before developing and sending an electronic submission. Instructions for submitting electronic submissions can be found on the FDA home page at the address www.fda.gov/cdrh/elecsub.html.

Video Conferencing

The ODE use of video conferencing to interact with the regulated industry decreased from 9 video conferences in FY 98 to one video conference in FY 99. The sole videoconference was held with a device manufacturer for the purpose of continuing an ongoing scientific review of IDE data in support of a modular PMA. Internally, six videoconferences were held between ODE and other government agencies. CDRH has the ability to conduct Room and Desktop Video Conferences with outside parties that have H.320 compliant systems, a standard for video conferencing over ISDN lines and other narrow-band transmission media.

World Wide Web Activity

ODE continued to provide information on the web that can be downloaded and searched through the CDRH home page at www.fda.gov/cdrh. Information on Premarket Approval Applications (PMAs) and Premarket Notifications (510(k)s) can be found on the "Program Areas" of the CDRH home page. Anyone can search the Releasable 510(k) and PMA databases, download 510(k) or PMA files, obtain the monthly PMA, HDE and 510(k) listings and Summaries of Safety and Effectiveness Data, and read about the "Real-Time" program for PMA supplements. A database of guidance documents is available at the address www.fda.gov/cdrh/ggpmain.html. The database is searchable by words in the document title, office, division, or any combination of these elements. Also, information on ODE's panel meeting schedules and summaries can be found on the internet at www.fda.gov/cdrh/panelmtg.html. ODE will continue to use this vehicle to distribute information in a timely manner.

MAJOR PROGRAM INITIATIVES
Fiscal Year 1999

IDE Regulation Modification – FDAMA Implementation

On November 23, 1998, a final rule was published to modify the investigational device exemptions (IDE) regulation to reflect amendments to the Federal Food, Drug, and Cosmetic Act (the act) by the FDA Modernization Act of 1997 (FDAMA). Under the new regulation, sponsors of an IDE may modify the device and/or clinical protocol, without approval of a new application or supplemental application, if the modifications meet certain statutory criteria and if notice is provided to FDA within 5 days of making the change. The final regulation also defines the credible information to be used by sponsors to determine if the statutory criteria are met.

HDE Regulation Modification

On November 3, 1998, a final rule was published to modify the regulations governing humanitarian devices to reflect the amendments to the act by FDAMA. The new rule contains provisions, such as:

- Reducing the review timeframe for HDEs from 180 days to 75 days;
- No longer requiring applicants to request extensions of approval of the HDE every 18 months;
- Permitting physicians to use an humanitarian use device prior to obtaining IRB approval in an emergency situation if the physician determines that the wait will cause the patient serious harm or death; and
- Allowing FDA to withdraw or suspend approval of an HDE under certain conditions following notice and opportunity for an informal hearing.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

During FY 99, manufacturers who wished to commercially market test or test systems must obtain clearance or approval from the Food and Drug Administration (FDA) and CLIA complexity categorization from the Centers for Disease Control and Prevention (CDC). Based on a request from Congress, Health Care Financing Administration (HCFA), CDC, and FDA reevaluated which agency should be responsible for the CLIA categorization function. The responsibility for the categorization of commercially marketed tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) will be transferred from the CDC to the FDA. This will allow manufacturers to submit premarket applications for products and requests for complexity categorization to one agency. CDRH will assume the CLIA functions on January 31, 2000. Staff in the Division of Clinical Laboratory Devices (DCLD) began training on the CLIA process. DCLD will determine complexity categorizations as they evaluate premarket submissions for clinical laboratory devices. Waived products, devices exempt from premarket notification and devices under premarket review by CBER also will be processed by DCLD. The following resources are available to obtain CLIA information: website http://www.fda.gov/cdrh/clia, phone number (301) 827-0496 and email CLIA@CDRH.FDA.GOV.

STATISTICAL TABLES
Fiscal Year 1999

[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 95 - FY 99

Type of Submission	Number Received				
	FY 95	FY 96	FY 97	FY 98	FY 99
Premarket Approval (PMAs) [a]					
Original Applications	39	44	70	55	72
Amendments	812	883	839	742	822
Supplements	499	415	409	513	556
Amendments to Supplements	838	823	819	863	927
Reports for Orig. Applications	487	435	435	431	412
Reports for Supplements	8	24	2	0	0
Master Files	92	65	130	94	25
PMA Subtotal	2,775	2,689	2,704	2,698	2,814
Investigational Device Exemptions (IDEs)					
Original Applications	214	253	297	322	304
Amendments	210	219	223	226	275
Supplements	3,171	3,189	3,776	4,277	4,127
IDE Subtotal	3,595	3,661	4,296	4,825	4,706
Premarket Notification (510(k)s)					
Original Notifications	6,056	5,297	5,049	4,623	4,458
Supplements	4,552	3,246	2,785	2,023	1,872
Amendments	5,012	5,343	4,433	3,692	2,962
510(k) Subtotal	15,620	13,886	12,267	10,338	9,292
PMA/IDE/510(k) Total	21,990	20,236	19,267	17,861	16,812

a/ As of FY 97, PMA 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.

Table 2. Original PMA Decision Cohort Performance*
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Number Received	39	44	70	55	72
PMA Actions					
Filing Decisions					
Filed (%)	33 (60)	45 (73)	58 (78)	51(84)	65(90)
Not Filed (%)	22 (40)	17 (27)	16 (22)	10(16)	7(10)
Others(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	55	62	74	61	72
Scientific Review Decisions					
Major Deficiencies	29	32	38	28	32
Minor Deficiencies	7	5	5	10	4
Other[a]	111	97	138	105	105
Scientific Review Decisions Subtotal	147	134	181	143	141
Approval Decisions					
Approvals(%)	27 (57)	43 (57)	48 (72)	46(71)	45(85)
Approvable(%)	16(34)	27 (35)	14 (21)	7(11)	7(13)
Not Approvable(%)	4 (9)	6 (8)	5 (7)	12(18)	1 (2)
Denials	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Approval Decision Subtotal	47	76	67	65	53
Total PMA Actions	249	272	322	269	266
Average Review Time (Days:Months) for Approvals[b]					
FDA	276 : 9.1	289 : 9.5	207 : 6..9	154: 5.1	149: 4.9
Non-FDA	81 : 2.7	55 : 1.8	40 : 1.3	37: 1.2	26: 0.9
Total	357 : 11.7	343 : 11.3	247 : 8.2	191: 6.4	175: 5.8
Average Elapsed Time (Days:Months) for Approvals[c]					
FDA	606 : 19.9	572 : 18.8	375 : 12.5	265 : 8.8	280: 9.2
Non-FDA	167 : 5.5	214 : 7.0	122 : 4.1	108 : 3.6	100: 3.3
Total	773 : 25.4	786 : 25.9	497 : 16.6	373 : 12.4	380: 12.5
Number under Review at End of Period[d]					
Active[e]	69	57	44	29	49
(Active and overdue)	(26)	(17)	(0)	(0)	(0)
On hold[f]	56	39	41	41	38
Total	125	96	85	70	87

*/ As of FY 97, PMA 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.

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.

(Continued on next page.)

Table 2. Original PMA Decision Cohort Performance*
FY 95 - FY 99

(Continued from previous page.)

b/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (*21 CFR Part 814*). Under this regulation, the review clock is *reset* upon 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.

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. Original PMA Receipt Cohort Performance*
FY 95 – FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Original PMAs Received					
PMAs	21	37	46	32	24
Expedited PMAs	12	5	10	6	3
HDEs[a]	0	0	4	7	5
Total	33	42	60	45	32
Filing Decisions[b]					
Filed	33	42	60	45	32
Not Filed	11	10	4	3	1
Number (%) of Filing/Not Filing Decisions within 45 Days	14(27)	26(49)	55(81)	35(72)	25(76)
Average Days/Cycle	113	67	38	44	40
Final Actions[c]					
Approvals	24	29	48	28	14
Denials	0	0	0	0	0
Other[d]	9	11	8	4	1
Total	33	40	56	32	15
Filing to First Action Excluding withdrawals, conversions, etc. [e]					
Number Received and Filed	24	30	52	41	31
Number of First Actions	24	30	52	40	31
Average FDA Days	227	178	145	131	129
Median FDA Days	218	180	171	141	120
Number (%) of First Actions within 180 Days[f]	8(33)	18(60)	38(73)	33(80)	20(64)
Filing to First Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	33	42	60	45	32
Number of First Actions	33	41	60	44	32
Average FDA Days	242	200	145	128	127
Median FDA Days	218	183	171	140	119
Number (%) of First Actions within 180 Days[f]	10(31)	20(48)	43(72)	36(80)	20(63)

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Table 3. Original PMA Receipt Cohort Performance*
FY 95 – FY 99

(Continued from previous page.)

	FY 95	FY 96	FY 97	FY 98	FY 99
Filing to Final Actions Excluding withdrawals, conversions, etc.[h]					
Number Received and Filed	24	30	52	41	31
Number of Final Actions	22	29	48	28	14
Average FDA (Total) Review Days	390(516)	358(476)	255(332)	202(228)	192(211)
Median FDA (Total) Review Days	365(449)	326(399)	200(256)	179(180)	191(231)
Number (%) of Final Actions within 180 FDA Days[f]	2(8)	6(21)	19(40)	15(54)	5(36)
Number (%) of Final Actions within 180 Total Days[f]	2(8)	4(14)	16(33)	10(36)	4(29)
Filing to Final Action Including withdrawals, conversions, etc.[i]					
Number Received and Filed	33	42	60	45	32
Number of Final Actions	33	40	58	32	15
Average FDA (Total) Review Days	393(590)	353(482)	242(324)	195(232)	184(212)
Median FDA (Total) Review Days	364(534)	310(408)	182(256)	177(180)	180(228)
Number (%) of Final Actions within 180 FDA Days[f]	3(9)	8(20)	23(41)	16(50)	5(33)
Number (%) of Final Actions within 180 Total Days[f]	2(6)	6(15)	18(32)	11(34)	4(27)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[c]	1.7	1.9	1.7	1.5	1.5
Percentile FDA (Total) Days from Filing to First Action[e,g]					
25th	158(150)	165(156)	104(102)	90(96)	70(67)
50th (Median)	218(218)	182(179)	170(170)	140(141)	119(120)
75th	312(292)	231(193)	179(179)	167(167)	182(183)
90th	371(371)	316(241)	196(199)	181(181)	220(220)
Percentile FDA (Total) Days from Filing to Final Action[i]					
25th	312(382)	232(265)	144(163)	164(144)	142(142)
50th (Median)	364(534)	310(408)	182(256)	177(180)	185(228)
75th	470(798)	425(765)	369(435)	234(288)	251(261)
90th	550(946)	710(900)	429(667)	332(406)	263(288)

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Table 3. Original PMA Receipt Cohort Performance*
FY 95 - FY 99

(Continued from previous page.)

Percentile FDA (Total) Days from Filing to Final Action[h]					
25th	312(342)	233(272)	151(163)	146(149)	152(177)
50th (Median)	365(449)	326(399)	200(256)	178(180)	191(239)
75th	474(682)	419(752)	386(483)	234(278)	251(261)
90th	550(946)	712(961)	440(680)	336(406)	263(288)
Number pending as of 9/30/99					
Active	0	2	1	3	8
Active and Overdue	0	0	0	0	0
On hold[j]	0	0	3	10	9
Total	0	2	4	13	17
Summary of PMA Receipt Cohort					
Approved	24	29	48	28	14
Denied	0	0	0	0	0
Withdrawn	9	10	7	4	1
Other	0	1	1	0	0
Under Review	0	2	1	3	8
On Hold[j]	0	0	3	10	9
Total	33	42	60	45	32

*/ For each fiscal year, September 30, 1999 was used as the cutoff date. The FY 99 cohort represents only receipts through March 31, 1999 (first six months of the fiscal year). 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.

a/ As of FY 97, PMA data includes Humanitarian Devices Exemption (HDE) applications. HDEs 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. The time frame for review is 75 days after receipt of an HDE that is accepted for filing versus the 180 days after receipt of a PMA to take action on the application.

b/ The filing decision represents the count of applications with a filing date within the fiscal year as of the cutoff date. For example, a PMA that is considered complete at the time of submission would have a received date equal to the filed date. However, if the agency refuses to file the PMA, it is considered incomplete and the filed date becomes the date of the amendment that makes the submission complete for filing. Therefore, it is possible that the submission may be received in one fiscal year but not be considered a filed PMA until a subsequent fiscal year. For the purpose of receipt cohort reporting, PMAs are considered "received" based on the filing date rather than the receipt date.

c/ The final action analyses include actions as of the cutoff date for PMAs received within the fiscal year.

d/ Includes only actions that resulted in withdrawal, conversion, and other final actions not resulting in approval or denial.

e/ The first action analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure excludes PMAs with a final action of withdrawal, conversion, or other final actions.

f/ The proportion of HDEs is based on a 75 day review period.

g/ The first action analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure include PMAs with any final action including approval, denial, withdrawal, conversion, or other final actions.

h/ The final actions analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure excludes PMAs with a final action of withdrawal, conversion, or other final action not resulting in approval or denial.

i/ The final actions analyses include actions as of the cutoff date for PMAs that were filed within the fiscal year. This measure includes PMAs with any final action including approval, denial, withdrawal, conversion, or other final actions.

j/ "On hold" describes the FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 4. PMA Supplement Decision Cohort Performance*
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Number Received	499	415	409	513	556
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed(%)	4 (0.8)	8 (89)	15 (94)	7 (78)	17(89)
Not Filed(%)	1 (0.2)	1 (11)	1 (6)	2 (22)	2 (11)
Other(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	5	9	16	9	19
Scientific Review Decisions					
Major Deficiencies	3	9	3	4	12
Minor Deficiencies	1	1	1	2	0
Other[b]	147	141	128	62	60
Scientific Review Decisions Subtotal	151	151	132	68	72
Approval Decisions					
Panel track approvals(%)[c]	3 (1)	0 (0)	4 (1)	5 (1)	11 (2)
Nonpanel track approvals(%)	432 (73)	462 (85)	397 (76)	416(78)	426 (81)
Approvable(%)	78 (13)	33 (6)	49 (9)	47 (9)	25 (5)
Not approvable(%)	75 (13)	48 (9)	76 (14)	63(12)	62 (12)
Approval Decision Subtotal	588	543	526	531	524
Total PMA Supplement Actions	744	703	674	608	615
Average Review Time (Days:Months) for Approvals[d]					
FDA	179 : 5.9	146 : 4.8	100 : 3.3	82 : 2.7	76: 2.5
Non-FDA	49 : 1.6	36 : 1.2	12 : 0.4	25 : 0.8	16: 0.5
Total	228 : 7.5	182 : 6.0	112 : 3.7	107 : 3.6	92: 3.0
Average Elapsed Time (Days:Months) for Approvals[e]					
FDA	209 : 6.9	167 : 5.5	120 : 4.0	109 : 3.6	92: 3.0
Non-FDA	66 : 2.2	49 : 1.6	23 : 0.8	43 : 1.4	26: 0.9
Total	275 : 9.0	216 : 7.1	143 : 4.8	153 : 5.1	118: 3.9
Number under Review at End of Period[f]					
Active[g]	226	162	110	139	158
(Active and overdue)	(49)	(17)	(0)	(0)	(0)
On hold[h]	151	74	80	57	70
Total	377	236	190	196	228

*/ As of FY 97, PMA 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.

a/ Filing and not filing decisions are for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

(Continued from previous page.)

Table 4. PMA Supplement Decision Cohort Performance*
FY 95 - FY 99

(Continued from previous page.)

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 are subject to the full administrative procedures normally associated with original PMAs, i.e., panel review, preparation of a summary of safety and effectiveness.

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 5. PMA Supplement Receipt Cohort Performance*
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
PMA Supplements Received					
PMA Supplements	490	410	402	510	253
Expedited PMA Supplements	1	3	3	1	2
HDEs[a]	0	0	0	0	4
Total	491	413	405	511	259
Filing Decisions[b]					
Filed	1(100)	4(100)	10(91)	16(94)	13(93)
Not Filed	0(0)	0(0)	1(9)	1(6)	1(7)
Number (%) of Filing/Not Filing Decisions within 45 Days	1(100)	3(75)	9(82)	14(82)	11(79)
Average Days/Cycle	36	45	39	42	38
PMA Supplement Final Actions[c]					
Approvals	445	379	365	413	208
Denials	0	0	0	0	0
Other[d]	45	34	32	73	34
Filing to First Action Excluding withdrawals, conversions, etc.[e]					
Number Received and Filed	446	379	373	471	259
Number of First Actions	446	377	373	435	231
Average	129	121	88	83	72
Median	115	126	67	68	56
Number (%) of First Actions within 180 Days[f]	328(73)	295(78)	333(89)	389(83)	209(81)
Filing to First Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	491	413	405	511	267
Number of First Actions	491	411	405	474	231
Average	130	121	91	72	73
Median	114	126	70	85	56
Number (%) of First Actions within 180 Days[f]	361(74)	322(78)	357(88)	425(83)	216(81)

(Continued on next page.)

Table 5. PMA Supplement Receipt Cohort Performance*
FY 95 - FY 99

(Continued from previous page.)

	FY 95	FY 96	FY 97	FY 98	FY 99
Filing to Final Action Excluding withdrawals, conversions, etc.[h]					
Number Received and Filed	445	379	373	471	259
Number of Final Actions	446	379	365	450	232
Average	142(178)	148(185)	103(124)	89(109)	62(73)
Median	120(143)	132(150)	69(84)	46(63)	30(36)
Number (%) of Final Actions within 180 FDA Days[f]	310(70)	259(69)	304(83)	374(83)	212(91)
Number (%) of Final Actions within 180 Total Days[f]	262(59)	236(63)	286(78)	352(78)	209(90)
Filing to Final Action Including withdrawals, conversions, etc.[i]					
Number Received and Filed	491	413	405	511	267
Number of Final Actions	490	413	397	487	239
Average	142(195)	147(202)	107(141)	89(47)	64(31)
Median	119(153)	132(156)	73(94)	115(65)	74(36)
Number (%) of Final Actions within 180 FDA Days[f]	343(70)	284(69)	324(82)	408(84)	218(91)
Number (%) of Final Actions within 180 Total Days[f]	280(57)	249(60)	290(75)	371(76)	213(89)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[c]	1.1	1.2	1.1	1	1.1
Percentile FDA (Total) Days from Filing to First Action[e,g]					
25th	60(60)	57(59)	29(29)	23(24)	22(22)
50th (Median)	114(115)	126(126)	70(67)	72(68)	56(56)
75th	183(183)	179(179)	155(148)	175(175)	174(172)
90th	239(235)	196(196)	181(181)	194(197)	—(—)
Percentile FDA (Total) Days from Filing to Final Action[i]					
25th	60(71)	57(76)	29(36)	23(24)	22(22)
50th (Median)	114(153)	126(156)	70(94)	72(65)	56(36)
75th	183(250)	179(225)	155(181)	175(179)	174(115)
90th	239(372)	196(446)	181(347)	194(274)	—(182)

(Continued on next page.)

Table 5. PMA Supplement Receipt Cohort Performance*
FY 95 - FY 99

(Continued from previous page.)

	FY 95	FY 96	FY 97	FY 98	FY 99
Percentile FDA (Total) Days from Filing to Final Action[h]					
25th	61(69)	64(76)	32(35)	22(24)	18(22)
50th (Median)	120(143)	132(150)	69(82)	46(63)	30(36)
75th	192(235)	187(210)	158(177)	171(177)	91(112)
90th	266(343)	303(373)	206(287)	197(267)	176(180)
Number under review as of 9/30/99					
Active	1	0	3	9	6
Active and Overdue	0	0	0	0	0
On hold[j]	0	0	5	16	22
Total	1	0	8	25	28
Summary of PMA Supplement Receipt Cohort					
Approved	445	379	365	413	205
Denied	0	0	0	0	0
Withdrawn	38	28	25	23	7
Other	7	6	7	50	27
Under Review	1	0	3	9	6
On Hold[j]	0	0	5	16	22
Total	491	413	405	511	267

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*/ For each fiscal year, September 30, 1999 was used as the cutoff date. The FY 99 cohort represents only receipts through March 31, 1999 (first six months of the fiscal year). 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 as 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.

a/ As of FY 97, PMA supplement data includes Humanitarian Devices Exemption (HDE) applications. HDEs are similar in both form and content to PMA supplements but are exempt from the effectiveness requirements of PMA supplements. An approved HDE authorizes marketing of the humanitarian use device. The time frame for review is 75 days after receipt of an HDE that is accepted for filing versus the 180 days after receipt of a PMA supplement to take action on the application.

b/ Filing and not filing decisions are for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

c/ The final action analyses include actions as of the cutoff date for PMA supplements received within the fiscal year.

d/ Includes only actions that resulted in withdrawal, conversion, and other final actions not resulting in approval or denial.

e/ The first action analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final actions.

f/ The proportion of HDEs is based on a 75 day review period.

g/ The first action analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final actions.

h/ The final actions analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final action not resulting in approval or denial.

i/ The final actions analyses include actions as of the cutoff date for PMA supplements that were filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final actions.

j/ "On hold" describes the FDA processing of applications officially suspended pending receipt of additional information from the applicant.

Table 6. Original IDEs
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Number Received	214	253	297	322	304
Number of Decisions					
Approved	109	171	172	201	176
Not approved	81	63	79	82	82
Other[a]	20	26	21	42	47
Total	210	260	272	325	305
Percent (%) of Approvals made during first review cycle[b]	57[d]	73	69	71	68
Average FDA Review Time (days)	29	28	29	27	27
Percent (%) of Decisions made within 30 Days	92[e]	99	100	100	99
Number under Review at End of Period[c]	15	8	32	29	28
Number Overdue at End of Period	0	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 7. IDE Amendments
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Amendments Received[a]	210	219	223	226	275
Decisions on Amendments					
Approved(%)	106 (50)	98 (45)	101 (46)	94 (42)	97 (36)
Not approved (%)	38 (18)	29 (13)	25 (11)	36 (16)	42 (16)
Other (%)[b]	69 (32)	91 (42)	94 (43)	95 (42)	129 (48)
Total	213	218	220	225	268
Average FDA Review Time (days)	22	18	18	19	18
Percent (%) of Decisions made within 30 Days	92[e]	98	100	100	100
Average Approval Time (days) for IDEs with Amendments					
FDA time	70	53	61	55	57
Non-FDA time	162	78	84	35	88
Total time[c]	232	131	145	90	145
Number of Amendments per Approved IDE	1.8	1.4	1.8	1.4	1.6
Amendments under Review at End of Period[d]	8	9	12	13	19
Amendments Overdue at End of Period	0	0	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 premarket 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 8. IDE Supplements
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Number Received	3,171	3,189	3,776	4,277	4,127
Number of Decisions	3,181	3,121	3,777	4,209	4,224
Average FDA Review Time (days)	22	21	21	21	20
Percent (%) of Decisions made within 30 Days	98	99	100	100	100
Number under Review at End of Period[a]	149	148	216	284	187
Number Overdue at End of Period	0	0	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 9. 510(k) Decision Cohort Performance
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Number Originals Received	6,056	5,297	5,049	4,623	4,458
Number of Decisions					
Substantially equivalent	5,594	4,501	4,405	3,824	3,652
Not substantially equivalent	101	64	57	65	66
Other[a]	2,253	998	693	1,340	875
Total	7,948	5,563	5,155	5,229	4,593
Percent(%) not substantially Equivalent[b]	1.8	1.4	1.3	1.7	1.8
Average Review Time (days)					
FDA time[c]	137	110	97	89	80
Total time[d]	178	145	130	114	102
Median Review Time (days)					
FDA time[c]	91	85	81	81	71
Total time[d]	102	88	85	83	76
Percent (%) of Decisions made within 90 Days, based on					
FDA time[e]	62	80	95	97	99
Total time[d]	36	50	58	59	66
Number under Review at End of Period[f]					
Active[g]	1,486	1,408	1,287	1,057	943
(Active and overdue)	(9)	0	0	0	0
On hold[h]	964	821	865	487	461
Total	2,450	2,229	2,152	1,544	1,404

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 10. 510(k) Receipt Cohort Performance*
FY 95 - FY 99

	FY 95	FY 96	FY 97	FY 98	FY 99
Number of 510(k)s Received[a]					
Traditional	6078	5318	5059	4527	3050
Special	0	0	0	80	268
Abbreviated	0	0	0	21	70
Total Receipts	6078	5318	5059	4628	3388
Actions on 510(k)s					
Substantially Equivalent	4796	4302	4146	3544	2367
Not Substantially Equivalent (%)[b]	86(1.8)	57(1.3)	53(1.3)	63(1.8)	39(1.6)
Other[c]	1196	959	856	950	443
Total Actions	6078	5318	5055	4557	2849
Average Cumulative Days for 510(k) Decisions Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	97	93	90	81	67
Total Time from Receipt to Final Decision[e]	125	120	115	99	76
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	96	91	89	79	66
Total Time from Receipt to Final Decision[e]	146	150	134	109	77
Number of Decisions (%) within 90 Days, Based on:					
FDA Days from Receipt to First Action	4934(81)	4998(94)	4968(98)	4609(100)	3376(100)
FDA Cumulative Days from Receipt to Final Decision	3645(60)	3472(65)	3558(70)	3518(76)	2425(72)
Total Cumulative Days from Receipt to Final Decision[e]	2967(49)	2901(55)	3025(60)	3025(65)	2238(66)
Average Number of FDA Cycles from Receipt to Final Action	1.6	1.5	1.5	1.4	1.3
Percentile FDA (Total) Days from Receipt to Final Action					
25th	42(50)	51(59)	51(57)	47(51)	42(45)
50th (Median)	80(92)	80(88)	80(86)	76(83)	72(77)
75th	124(194)	115(188)	106(175)	90(149)	112(152)
90th	192(322)	173(332)	172(312)	163(256)	N/A(N/A)
Number under review as of 9/30/99					
Active	0	0	1	14	221
Active and Overdue	0	0	0	0	0
On hold	0	0	3	57	318
Total	0	0	4	71	539

(Continued on next page.)

Table 10. 510(k) Receipt Cohort Performance*
FY 95 - FY 99

(Continued from previous page.)

Summary of 510(k) Receipt Cohort					
Substantially Equivalent	4796	4302	4146	3544	2367
Not Substantially Equivalent	86	57	53	63	39
Other	1196	959	856	950	443
Under Review	0	0	1	14	221
On Hold	0	0	3	57	318
TOTAL	6078	5318	5059	4628	3388

* For each fiscal year, September 30, 1999 was used as the cutoff date. The FY99 cohort represents only receipts through June 30, 1999 (first nine months of the fiscal year).

a/ IncludesThird Party 510(k)s: FY97 = 14; FY98 = 18; FY99 = 21.

b/ Based on “substantially equivalent” and “not substantially equivalent” decisions only.

c/ 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.

d/ 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.

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

Table 11. Major Submissions Received FY 89 - FY 99

Type of Submission	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Orig. PMAs[a]	84	79	75	65	40	43	39	44	70	55	72
PMA Supp.[a]	810	660	593	606	395	372	499	415	409	513	556
Orig. IDEs	241	252	213	229	241	171	214	253	297	322	304
IDE Amend.	271	288	283	297	320	254	210	219	223	226	275
IDE Supp.	3,038	3,043	3,647	3,644	3,668	3,020	3,171	3,189	3,776	4,277	4,127
510(k)s	7,022	5,831	5,770	6,509	6,288	6,434	6,056	5,297	5,049	4,623	4,458
Total	11,466	10,153	10,581	11,350	10,952	10,293	10,189	9,417	9,824	10,016	9,792

a/ As of FY 97, PMA 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.

Table 12. Major Submissions Completed FY 89 - FY 99

Type of Submission	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Orig. PMAs [a]	56	47	27	12	24	26	27	43	48	46	45
PMA Supp. [a]	519	700	479	394	354	385	435	462	401	421	437
Orig. IDEs	245	248	220	215	248	174	210	260	272	325	305
IDE Amend.	280	270	287	297	324	256	213	218	220	225	268
IDE Supp.	3,023	2,968	3,705	3,469	3,814	3,070	3,181	3,121	3,777	4,209	4,224
510(k)s	6,136	6,197	5,367	4,862	5,073	7,135	7,948	5,563	5,155	5,229	4,593
Total	10,259	10,430	10,085	9,249	9,837	11,045	12,014	9,667	9,873	10,455	9,872

a/ As of FY 97, PMA 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.

APPENDIX A. MAJOR ODE PROGRAMS

Fiscal Year 1999

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 sponsor 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.

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).

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. Some PMA supplements can be as complex as an original application. Although the statutory timeframe is 180 days for PMA Supplements, FDA is committed to reviewing these in shorter timeframes and has reduced review timeframes through the use of real-time supplement process, 30-day notices, and expedited reviews.

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 originally 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. 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 1999

The following devices were approved via PMAs, PMA Supplements, and HDEs or cleared via 510(k)s or classified via the Automatic Evaluation of Class III Designation process during FY99. 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 action.

Devices Approved via PMA/HDE

Division of Cardiovascular, Respiratory and Neurological Devices (DCRND)

Chilli® Cooled Ablation System by Cardiac Pathways Corp. (February 2, 1999)

Eclipse TMR Holmium Laser System by Eclipse Medical Technologies, Inc. (February 11, 1999)

AngioJet® Rheolytic™ Thrombectomy System (AngioJet® Drive Unit, AngioJet® Pump Set, and AngioJet® Rheolytic™ Thrombectomy LF140 Catheter) by Possis, Inc. (March 12, 1999)

Cardiodioseal Septal Occlusion System by Nitinol Medical Technologies, Inc. (September 8, 1999)

Diva Platform Implantable Pulse Generators and ProVit III Application Software (Version 3.3.2) by Vitatron, Inc. (September 27, 1999)

ANCURE™ Tube System, ANCURE™ Bifurcated System, ANCURE™ Iliac Balloon Catheter by Guidant Corporation (September 28, 1999)

AneuRx™ Stent Graft System by Medtronic AVE (September 28, 1999)

Cardioseal Septal Occlusion System by Nitinol Medical Technologies, Inc. (September 28, 1999)

Shelhigh No-React Porcine Pulmonic Valve by Shelhigh, Inc. (September 30, 1999)

Division of Clinical Laboratory Devices (DCLD)

Ciba Corning ACS Prostate Specific Antigen (PSA) Immunoassay by Chiron Corp. (December 8, 1998)

PathVysion™ HER-2 DNA Probe Kit by Vysis, Inc. (December 11, 1998)

Access® Alpha-fetoprotein (AFP) Reagents on the Access® Immunoassay Analyzer by Beckman Coulter, Inc. (February 8, 1999)

Digene Human Papillomavirus (HPV) Test Using Hybrid Capture II Technology by Digene, Inc. (March 17, 1999)

PRO-Trac II™ Tacrolimus ELISA Kit by DioSorin, Inc. (April 27, 1999)

Hepatitis C Check/Express by Home Access Health Corp. (April 28, 1999)

Continuous Glucose Monitoring System by MiniMed, Inc. (June 15, 1999)

Tandem-MP Free (Non-Complexed) Prostate Specific Antigen (PSA) Immunoenzymetric Assay by Beckman Coulter, Inc. (June 16, 1999)

Tandem-MP PSA Immunoenzymetric Assay by Beckman Coulter, Inc. (June 16, 1999)

Autocyte PREP System by AutoCyte, Inc. (June 17, 1999)

Bayer Immuno 1 System PSA Assay by Beckman Coulter, Inc. (June 25, 1999)

Tandem-MP PSA Immunoenzymetric Assay by Beckman Coulter, Inc. (August 3, 1999)

Biotrin Parvovirus B19 IgG Enzyme Immunoassay by Biotrin International, LTD (August 6, 1999)

Biotrin Parvovirus B19 IgM Enzyme Immunoassay by Biotrin International LTD (August 6, 1999)

AIA-Pack PA by Tosoh Medics, Inc. (September 10, 1999)

GEN-PROBE® AMPLIFIED™ Mycobacterium Direct (MTD) Test by Gen-PROBE, Inc. (September 30, 1999)

Division of General and Restorative Devices (DGRD)

Lumbar I/F Cage® with VSP® Spine System by DePuy AcroMed, Inc. (February 2, 1999)

INTER FIX™ Threaded Fusion Device by Sofamor Danek USA (May 14, 1999)

SpinalPak® Fusion Stimulator by Biolectron, Inc. (September 24, 1999)

Division of Ophthalmic Devices (DOD)

VISX's Star S2 Excimer Laser for PRK for Hyperopia (+1 to +4D) by VISX (November 2, 1998)

LADARVision® Excimer Laser (Scanning) System for PRK for Myopia by Autonomous Technologies Corp. (November 2, 1998)

UV-Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic by Starr Surgical Co. (November 4, 1998)

Nidek EC-5000 Excimer Laser (Scanning) for PRK for Myopia by Nidek Technologies, Inc. (December 17, 1998)

Intacs™ Intrastromal Corneal Ring Segments for Myopia by KeraVision, Inc. (April 9, 1999)

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

VOCARE® Bladder System by Neurocontrol Corp. (December 28, 1998)

VOCARE® Bladder System by Neurocontrol Corp. (February 19, 1999)

PROSORBA Immunoadsorption Column by Cypress Biosciences (March 15, 1999)

Urolume Endoprosthesis by American Medical Systems, Inc. (March 29, 1999)

Medtronic Interstim Continence Control System by Medtronic, Inc. (April 15, 1999)

T-Scan 2000 by TransScan Medical Inc. (April 16, 1999)

UVAR XTS Photopheresis System by Therakos , Inc. (Johnson & Johnson) (August 5, 1999)

Durasphere™ Injectable Bulking Agent by Advanced UroScience, Inc. (September 13, 1999)

Artificial Bowel Sphincter Prosthesis by American Medical Systems, Inc. (September 20, 1999)

FemSoft® Urethral Insert by Rochester Medical Corp. (September 30, 1999)

510(k) Clearances or Automatic Evaluation of Class III Designation Devices (AE)

DCRND

Mercator Atrial High Density Array Catheter by Cardiac Pathways Corp. (January 27, 1999)

Constellation Multiple Electrode Pacing and Recording System by Boston Scientific Corporation (March 11, 1999)

CH 2000 Cardiac Diagnostic System for T-wave Alternans by Cambridge Heart (April 12, 1999)

Ensite 3000 System by Endocardial Solutions, Inc. (April 21, 1999)

Tracer O-T-W Mapping Device by Cardima, Inc. (May 11, 1999)

ZOLL M Series Rectilinear Low Energy Biphaxic External Defibrillator and Cardioverter by Zoll Medical Corporation (September 3, 1999)

DCLD

QuickScreen at Home Drug Test by Phamatech, Inc. (October 16, 1998)

PreVue™ Borrelia Burgdorferi Antibody Detection Assay (Lyme Disease) by Chembio Diagnostic Systems, Inc. (February 12, 1999)

Touch Tear IgE Microassay Kit by Touch Scientific, Inc. (August 9, 1999)

Binax NOW Streptococcus Pneumoniae Urinary Antigen Test by Binax, Inc. (August 27, 1999)

Nuclisens Cytomegalovirus (CMV) PP67 by Organon Teknika Corp. (September 15, 1999)

DGRD

Centauri Laser for Hard Tissue Use in Pediatric Populations by Premier Laser Systems, Inc. (October 9, 1998)

INTER-OP METASUL Acetabular System by Sulzer Orthopedics, Inc. (August 3, 1999)

Delite Dental Erbium Laser by Continuum Biomedical, Inc. (September 8, 1999)

DOD

Adventure Tints, Color Enhanced Tinted Soft Contact Lens by Adventure in Colors, Inc. (May 10, 1999)

Colorsoft Color Enhanced Tinted Soft Contact Lens by Colorsoft Laborites Corp. (June 3, 1999)

Softchrome Tints Transparent Tinted Soft Contact Lens by Softchrome, Inc. (August 27, 1999)

DRAERD

Celsior Cold Flush, Storage and Transport Solution by Sangstat Medical Corp. (August 5, 1999)

The 3CPM EGG Machine by 3CPM Co., Inc. (August 20, 1999) (AE)

Thermoflex System by Argomed, Inc. (August 26, 1999)

APPENDIX C. ORIGINAL PMA/PDP/HDE APPROVALS FOR FISCAL YEAR 1999

02-Oct-98	P960006	Guidant Corp.	SWEET TIP® Rx Models 4143, 4144, 4145, 4243, 4244, and 4245 Steroid-Eluting, Positive-Fixation, Porous Tip, Pacing Leads
05-Oct-98	P960014	Global Therapeutics, Inc.	Magellan-C Percutaneous Transluminal Coronary Angioplasty Catheter
09-Oct-98	P980016	Medtronic, Inc.	Medtronic® Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960 (GEM™ DR) Application Software, Medtronic® Model 6940 CapSureFix® Lead and Model 9466 Patient Magnet
27-Oct-98	P980023	Biotronik, Inc.	Phylax Implantable Cardioverter Defibrillator (ICD) System
02-Nov-99	D970012	American Medical Systems	AMS 700 Series Inflatable Penile Prosthesis
02-Nov-98	P970043	Autonomous Technologies	LADARVision® Excimer Laser System for PRK Myopia
11-Dec-98	P980024	Vysis, Inc.	PathVysion™ HER-2 DNA Probe Kit
17-Dec-98	P970053	Nidek Technologies, Inc.	Nidek EC-5000 Excimer Laser System for PRK Myopia
23-Dec-98	P970010	Norian Corp.	Norian® SRS® Cement
28-Dec-98	H980005	Neurocontrol Corp.	VOCARE® Bladder System
29-Jan-99	P980035	Medtronic, Inc.	Medtronic.Kappa™ 700/600 Series Pacemakers
02-Feb-99	P960025	DePuy AcroMed Corp.	Lumbar I/F Cage® with VSP® Spine System
02-Feb-99	P980003	Cardiac Pathways Inc.	Chilli® Cooled Ablation System
05-Feb-99	P980006	Bausch & Lomb	PureVision™ (balafilcon A) Visibility Tinted Contact Lens for Extended Wear
08-Feb-99	P980041	Beckman Coulter, Inc.	Access® AFP Reagents on the Access® Immunoassay Analyzer
11-Feb-99	P970029	Eclipse Surgical Tech.	Eclipse TMR Holmium Laser System
19-Feb-99	H980008	Neurocontrol Corp.	VOCARE® Bladder System
12-Mar-99	P980037	Possis, Inc.	AngioJet® Rheolytic™ Thrombectomy System (AngioJet® Drive Unit, AngioJet® Pump Set, and AngioJet® Rheolytic™ Thrombectomy LF140 Catheter)
09-Apr-99	P980031	KeraVision, Inc.	Intacs™ Intrastromal Corneal Ring Segments for Myopia
16-Apr-99	P970033	TransScan Medical, Inc.	T-Scan 2000
27-Apr-99	P970025	American Standards Co.	PRO-Trac II™ Tacrolimus ELISA Kit
28-Apr-99	P980046	Home Access Health Corp.	Hepatitis C Check/Express Kit
04-May-99	P960016	Daig Corp.	Daig Livewire TC™ Steerable Electrophysiology Catheter
14-May-99	P970015	Sofamor Danek, Inc.	INTER FIX™ Threaded Fusion Device
03-Jun-99	D970003	Guidant Corp.	PULSAR™/PULSAR Max™ Pulse Generators
15-Jun-99	P980022	MiniMed, Inc.	Continuous Glucose Monitoring System
17-Jun-99	P970018	AutoCyte, Inc.	AutoCyte PREP™ System
02-Jul-99	P980052	TMJ Concepts	Patient-Fitted Total Temporomandibular Joint Reconstruction Prosthesis System
02-Jul-99	P960033	Staar Surgical Co.	STAARVISC™ Sodium Hyaluronate Viscoelastic
06-Aug-99	P970054	Biotrin International LTD	Biotrim Parvovirus B19 IgG Enzyme Immunoassay
06-Aug-99	P970055	Biotrin International LTD	Biotrim Parvovirus B19 IgM Enzyme Immunoassay
08-Sep-99	H990004	Nitinol Medical Tech.	Cardioseal Septal Occlusion System
13-Sep-99	P980053	Advanced UroScience, Inc.	Durasphere™ Injectable Bulking Agent
15-Sep-99	P980049	ELA Medical, Inc.	Defender™ II Model 9201 Implantable Cardiovertor Defibrillater

20-Sep-99	H990003	American Medical Systems	Artificial Bowel Sphincter Prosthesis
27-Sep-99	P990001	Vitatron, Inc.	Diva Platform Implantable Pulse Generators and ProVit III Application Software (Version 3.3.2)
27-Sep-99	P990008	Cook, Inc.	Cook® MBC PTCA Balloon Dilatation Catheter
28-Sept-99	P980043	Medtronic Cardiac Surgery	Medtronic Hancock® II Bioprosthetic Heart Valve
28-Sep-99	P980017	Guidant Corp.	ANCURE™ Tube System, ANCURE™ Bifurcated System, ANCURE™ Iliac Balloon Catheter
28-Sep-99	P990020	Medtronic AVE	AneuRx™ Stent Graft System
28-Sep-99	H990005	Nitinol Medical Technologies	Cardioseal Septal Occlusion System
28-Sep-99	P970056	Bausch & Lomb Surgical	KERACOR® 116 Ophthalmic Excimer Laser System for PRK Myopia
30-Sep-99	P990004	Ethicon, Inc.	Surgifoam Absorbable Gelatin Sponge, U.S.P.
30-Sep-99	P990002	Rochester Medical Corp.	FemSoft® Urethral Insert
30-Sep-99	H980007	Shelhigh, Inc.	Shelhigh No-React Procine Pulmonic Valve Conduit

APPENDIX D. ODE GUIDANCE DOCUMENTS
Fiscal Year 1999

ODE guidance documents are available from the Division of Small Manufacturers Assistance (DSMA, HFZ-220). To contact DSMA, call 800-638-2041 or 301-443-6597; fax 301-443-8818; Email dsma@cdrh.fda.gov; or write to DSMA (HFZ-220, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307.

Many also are available through the CDRH Facts-0n-Demand (a faxback service at 800-899-0381 or 301-837-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/) which provide easy access to the latest information and operating policies and procedures.

Office of Device Evaluation

Frequently Asked Questions on the New 510(k) Paradigm (October 22, 1998)

Guidance for Industry General/Specific Intended Use (November 4, 1998) (FDAMA)

Pre-IDE Program: Issues and Answers (D-99-1) (March 25, 1999)

Division of Cardiovascular, Respiratory and Neurological Devices

Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm) (November 5, 1998)

Diagnostic ECG Guidance (including Non-Alarming ST Segment Measurement) (November 5, 1998)

Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1 (November 11, 1998)

Recommended Clinical Study Design for Ventricular Tachycardia Ablation (May 7, 1999)

Off-the-Shelf Software Use in Medical Devices (September 9, 1999)

Division of Clinical Laboratory Devices

Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used by the Consumer (December 30, 1998)

Points to Consider on Assayed and Unassayed Quality Control Material (February 3, 1999)

Industry Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators (February 22, 1999)

In Vitro Diagnostic Fibrin Monomer Paracoagulation Test (April 27, 1999)

Document for Special Controls Erythropoitin Assay Premarket Notifications [510(k)s] (April 28, 1999)

Labeling for Laboratory Tests (June 24, 1999)

Division of Dental, Infection Control, and General Hospital Devices

Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products (January 14, 1999)

Division of General and Restorative Devices

Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 2, 1999)

Guidance for the Submission of a Premarket Notification for a Dermabrasion Device (March 2, 1999)

Guidance for Spinal System 510(k)s (May 7, 1999)

Guidance Document for Powered Muscle Stimulator 510(k)s (June 9, 1999)

Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater (July 31, 1999) (updated August 30, 1999)

Division of Ophthalmic Devices

Aqueous Shunts – 510(k) Submissions (November 16, 1998)

Guidance on 510(k) Submissions for Keratoprotheses (March 21, 1999)

Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (November 14, 1998)

Harmonic Imaging with/without Contrast – Premarket Notification Requirements (November 16, 1998)

Submission of Premarket Notifications for Radionuclide Dose Calibrators (November 20, 1998)

Content of Premarket Notifications for Intracorporeal Lithotripters (November 30, 1998)

Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography (December 3, 1998)

Submission of 510(k) Premarket Notifications of Home Uterine Activity Monitors (May 12, 1999)

Submission of 510(k)s for Solid State X-ray Imaging Devices (August 6, 1999)

Draft Guidance Documents Distributed on the Internet for Comment Purposes Only:

Submission of 510(k) Premarket Notifications of Home Uterine Activity Monitors (May 12, 1999)

Electro-optical Sensors for the In Vivo Detection of Cervical Cancer and Its Precursors: Submission Guidance for an IDE/PMA (May 12, 1999)

Intraocular Lens Guidance (draft) (released to web July 16, 1999)

Accountability Analysis for Clinical Studies for Ophthalmic Devices (draft) (FR Notice of Availability August 4, 1999)

Neurological Embolization Devices (August 13, 1999)

Dura Substance Devices (August 13, 1999)

Preclinical and Clinical Data and Labeling for Breast Prostheses (August 16, 1999)

APPENDIX E. ODE PUBLICATIONS
Fiscal Year 1999

The following is a bibliography of articles and abstracts prepared by the ODE staff and published or presented during FY99.

Journal, Newsletter Articles and Book Chapter

Baker, K.H., Chaput, M.P., Clavet, C.R., Varney, G.W., To T.M., and Lytle, C.D. Evaluation of Endoscope Sheaths as Viral Barriers. *Laryngoscope* 109(4):636-639, April 1999.

Carey, C.C. and Ruggera, P.S. In-Vitro Assessment of the Effects of Cellular Phones on Implantable Cardioverter Defibrillatory (ICD) Function. *Proceedings, 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Science*, IEEE EMB Press, Hong Kong, November 1998.

Fugate, K.J. FDA Study Finds Test Kits Effective in Spotting Birth Defects. *Public Health Reports* 113(5):382, Sept.-Oct. 1998.

Gutman, S. The Role of Food and Drug Administration Regulation of In Vitro Diagnostic Devices—Applications to Genetics Testing. *Clinical Chemistry* 45(5):746-749, May 1999.

Harvey, B.E. and Richter, K.C. Letter to the Editor. *Clinical Perspectives in Gastroenterology*, 2(5):246, Sept.-Oct. 1999.

Ho, C. and Ocuin, E. Considerations Regarding Real Time Off-Site Monitoring. *Biomedical Sciences Instrumentation*, 35:153-158, 1999.

Lytle, C.D. and Baker, K.H. Ability of a Viral Penetration Test (ASTM F1671-95) to Detect Small Holes. *JTEVA* (Journal of Testing and Evaluation), 27(3):231-233, May 3, 1999.

Phillips, P.J. and Less, J.R. The Development of a New 510(k) Program. *Medical Devices and Diagnostic Industry*, 21(6):151-159, June 1999.

Rechen, E., Barth, D.J., Marlowe, D., and Kroger, L. FDA Use of International Standards in the Premarket Review Process. *Biomedical Instrumentation & Technology*, 32(5):518-526, 1998.

Robison, W.G., Jr., Jacot, J.L., Katz, M.L., and Glover, J.P. Relative Role of Oxidative Stress in Diabetic Retinopathy Evaluated Using a Vitamin E Deficiency Model. *Invest. Ophthalmol Vis. Sci.*, 39(4):S466, 1999.

Abstracts and Presentations

Arshinoff, S.A., Calogero, D., Eydelman, M., Bilotta, R., Hadi, H., and Senft, S.H. Post Operative Intraocular Pressure, Endothelial Cell Counts, and Pachymetry After Viscoelastic Use in Cataract Surgery. Poster Exhibition, Am. Acad. Of Ophthalmology, New Orleans, LA, November 1998.

Baker, K.H. and McCullagh, L. High Level Disinfection of ENT Endoscopes. A Workshop for Nurses at the National Meeting of the Society of Otolaryngology/Head and Neck Surgery, New Orleans, LA, September 1999.

Carey, C.C. Trends in Defibrillator Technology, A Model for the Improved Method: Ensuring a 90-Day Review Clock for 510(k)s. AAMI 33rd Annual Meeting and Exposition, Philadelphia, PA, June 1998.

Carey, C.C. FDA Regulations and Their Impact on Widespread Use of AEDs. International Society of Computerized Electrocardiology (ISCE) 23rd Annual Conference, Keystone, CO, April 1998.

Carey, C.C., Kramer, M.D. and Callahan, T.J. Streamlining the Regulatory Review Process for Arrhythmia Detectors and Alarm: A Case Study. FDA/Sigma Xi Science Forum, Washington, DC, December 1998.

Carey, C.C. and Milne, K. A Regulatory Perspective on the Use of Databases for Arrhythmia Detection Algorithm Testing. AAMI 33rd Annual Meeting and Exposition, Philadelphia, PA, June 1998.

Durfor, C. Medical Devices Containing Cellular and Cellular-Derived Products: When to Consider Traditional or New Scientific Approaches in Biocompatibility Testing. Surfaces in Biomaterials '99, Scottsdale, AZ, August-September 1999.

Harvey, B.E. The Role of the FDA in the Premarket Evaluation of Medical Devices: Three Dimensional (3D) Reconstruction of Spiral CT/MR Digital Data Sets (a.k.a. "Virtual Colonoscopy"). First International Symposium Virtual Colonoscopy, Boston, MA, October 1998.

Heaton, T. and Phillips, R. FDA Concerns with Low-Energy Brachytherapy Sources. CIRMST Meeting at the National Institute of Standards and Technology, Germantown, MD, October 1998.

Ho, C.S.C. and Ocuin, E. Considerations Regarding Real Time Off-Site Monitoring. 36th Annual Rocky Mountain Bioengineering Symposium, Copper Mt., CO, April 1999.

Robison, W.G., Jr., Jacot, J.L., Katz, M.L., and Glover, J.L. The Vitamin E Deficiency Model for Evaluating the Role of Oxidative Stress in Diabetic Retinopathy. Assoc. for Ocular Pharmacology and Therapeutics, 4th Annual Meeting, Irvine, CA, January 1999.

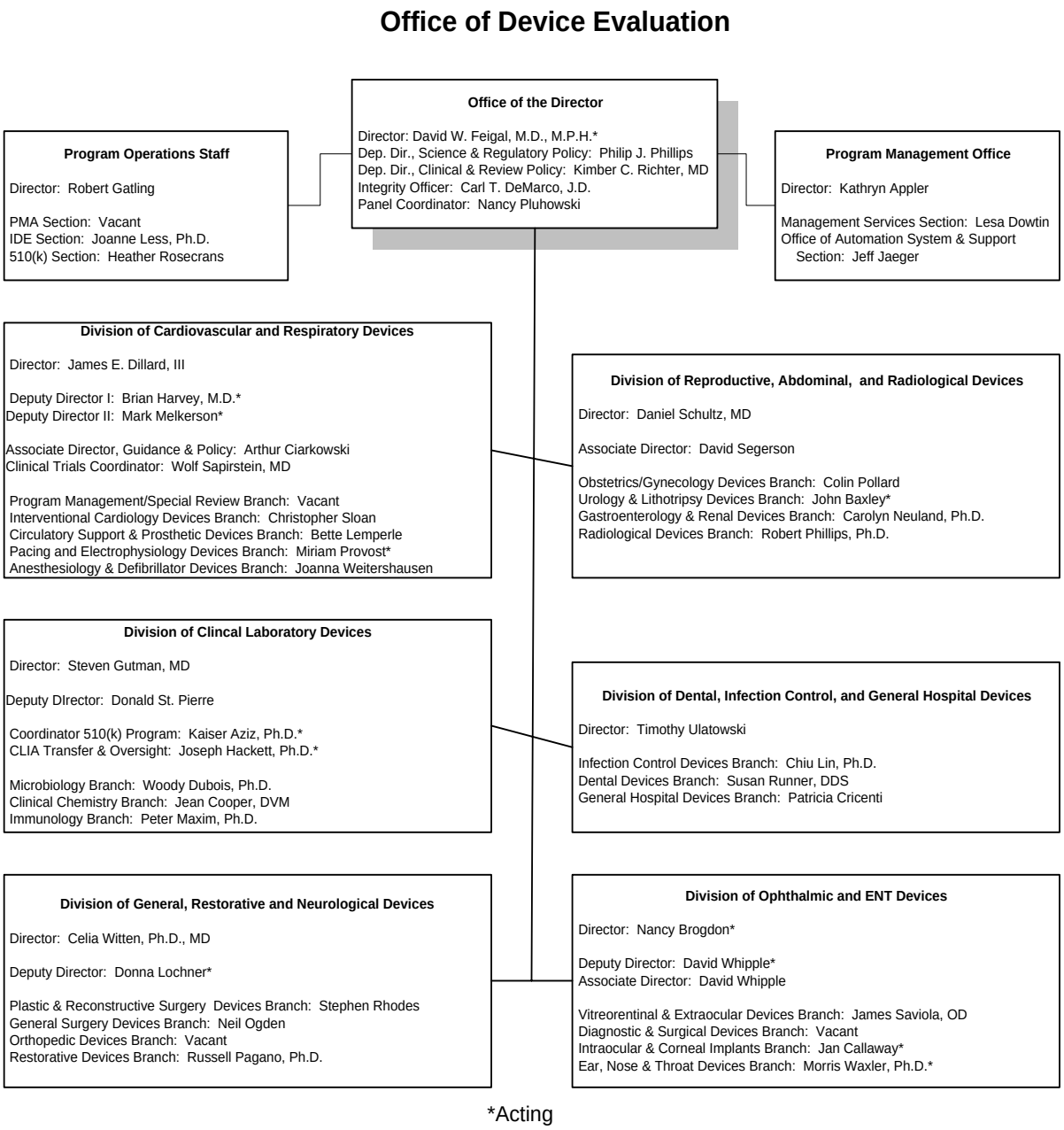
Robison, W.G., Jr., Jacot, J.L., Katz. M.L., and Glover, J.P. Relative Role of Oxidative Stress in Diabetic Retinopathy Evaluated Using a Vitamin E Deficiency Model. Assoc. for Research in Vision and Ophthalmology Meeting, Ft. Lauderdale, FL, September 1999.

Ruggera, P.S., Carey, C.C., and Bassen, H.I. A Standard Test Method for Evaluating In Vitro Implantable Cardioverter Defibrillator and Cellular Phone Interactions. FDA/Sigma Xi Science Forum, Washington, DC, December 1998.

Senft, S.H., Arshinoff, S.A., Calogero, D., Eydelman, M., Hadi, H., and Bilotta, R. Problems Associated with Viscoelastic Use in Cataract Surgery. Symposium on Cataract, IOL and Refractive Surgery, Seattle, WA, April 1999.

APPENDIX F. ODE ORGANIZATIONAL CHART

(As of May 17, 2000)



*Acting

The organizational chart above represents an ODE reorganization that occurred after the close of FY 99. The former organization structure, as it existed in FY 99, is represented in all other sections of the annual report.

APPENDIX G. ODE STAFF ROSTER
Fiscal Year 1999

Office of the Director

Acker, Rita
Alpert, Susan
DeMarco, Carl
Gibbs, Danielle
Gornick, MaryAnn
Hobbs, Cathy
Phillips, Philip
Pluhowski, Nancy
Richter, Kimber

Program Management Office

Appler, Kathryn
Broughton, Shirley
Cancino, Isella
Clingerman, Angie
Dowtin, Lesa
Jaeger, Jeff
Koviack, Bob
Robins, Lisa
Trammell, Dan
Wedlock, Chuck
Wilson, Robin

Program Operations Staff

Berk, Gene
Fisher, Lisa
Gatling, Robert
Jackson, Barbara
Less, Joanne
Lyons, Linda
Melling, Doreen
Melvin, Marsha
Morris, Janine
Parker, Mervin
Perticone, Diane
Poneleit, Kathy
Rechen, Eric
Rosecrans, Heather
Shulman, Marjorie
Stuart, Brandi

Division of Clinical Laboratory Devices

Aziz, Kaiser
Bautista, Josephine
Benson, Carol
Bernhardt, Pat
Blagmon, Djuana
Brindza, Larry
Bucher, Betty
Callaghan, Jim
Calvin, Veronica
Chace, Nina
Chenault, Michelle
Chesler, Ruth
Cooper, Jean
Dada, Valerie
Danishesky, Avis
Diggs, Denise
Dubois, Woody
Fourcroy, Jean
Fugate, Kearby
Gaffey, Claudia
Gaines, Kessia
Gonzalez, Augustin
Gutman, Steve
Hackett, Joe
Hanna, Nancy
Hansen, Sharon
Hawthorne, Ann
Heyliger, Marian
Jones, Doris
King, Lisa

Lappalainen, Sharon
Lyle, Dave
MacArthy, Philip
Magruder, Louise
Maxim, Peter
McClain-Bennett, Joan
Michaud, Ginette
Moore, Deborah
Moore, Nancy
Peacock, Albert
Pinkos, Arlene
Poole, Freddie
Rahda, Edappallath
Rao, Prasad
Reeves, Pat
Robinowitz, Max
Rogers, Liz
Selepak, Sally
Shively, Roxanne
Simms, Tom
Sliva, Clara
St. Pierre, Don
Stuart, Michelle
Summers, Peter
Ticehurst, John
Vadlamudi, Kris
Weeks, Susan
Wei, Tena
Whitaker, Kathleen
Wilbon, Tanya
Wood, Geretta
Wright, Kathy

Division of Cardiovascular, Respiratory and Neurological Devices

Abel, Dorothy
Allis, Steven
Astor, Brad
Bazaral, Mike
Berman, Mike
Brown, Michele
Buckley, Donna
Callahan, Tom
Carey, Carole
Chandeysson, Paul
Cheng, Jim
Ciarkowski, Art
Costello, Ann
Danielson, Judy
Donelson, Jan
Foreman, Christy
Fleischer, Dina
Frankenfield, Shannon
Gabriel, Lynette
Galgon, Rick
Gantt, Doyle
Gibbons, Gwen
Glass, John
Gomez-nova, Carmelina
Goode, Jennifer
Ho, Charles
Huynh, Ann
Hwang, Shang
Jones, Edwena
Kaiser, Suzanne
Karanian, John
Kennell, Lisa
Kichula, Christina
Kramer, Mark
Kroen, Marian
Kurtzman, Steve
Lacy, Frank
Lacy, Fred
Lee, James
Lemperle, Bette
Letzing, Bill
Madoo, Lark
Mazzaferro, Bob
Moyal, Al
Moynahan, Megan
Nguyen, Thinh
Ocuin, Esther
Oktay, Semih
O'Neill, Carroll
Parkhurst, John
Peters, Kimberly
Portnoy, Stuart
Price, Veronica
Puglisi, Mike
Roy, Joydeb

Ryan, Tara
Sapirstein, Wolf
Shanker, Rhona
Shein, Mitch
Sloan, Chris
Smallwood, Senora
Spyker, Dan
Stuhlmuller, John
Subramanian, Ramiah
Terry, Doris
Tillman, Donna-Bea
Truesdale, Curtis
Turtil, Steven
Usher, Will
Wang, Emil
Weitershausen, Joanna
Wentz, Catherine
Yakubik, Janet
Zimmerman, Barbara
Zuckerman, Bram

Division of Dental, Infection Control, and General Hospital Devices

Barrett, Sue
Betz, Robert
Blackwell, Angela
Blount, Sharon
Bolden, Brenda
Browne, Myra
Burdick, William
Cricenti, Pat
Cunningham, Terrell
Dorsey, Regina
Fox, Pat
Fuller, Janie
Hibbard, Viola
Hoard, Renita
Levchuck, John
Lin, Chiu
Marshall, Felicidad
Mayhall, Elaine
Nakayama, Von
Naveau, Irene
O'Connell, Linh
O'Lone, Martha
Robinson, Mary Jo
Runner, Susan
Samuels-Reid, Joy
Scott, Pam
Shipps, Gerald
Shire, Sandra
Smith, Gwen
Soprey, Pandu
Sturniolo, Mike
Trinh, Hung
Ulatowski, Tim

Division of General and Restorative Devices

Allen, Peter
Allen, Samie
Anderson, Jodi
Arepelli, Sam
Basu, Sankar
Berkowitz, David
Berne, Bernie
Bourke, Tracey
Bowsher, Kristen
Courtney, Mike
Dawisha, Sahar
DeLuca, Bob
Demian, Hany
Dillard, Jim
Durfor, Charles
Einberg, Elmar
Eudy, Mike
Felten, Richard
Fogarty, Pauline
Foy, Keith
Gantt, Gail
Glass, Jerilyn
Goode, John
Hinckley, Steve
Horbowyj, Roxi
Hudson, Peter
Jan, George
Kaiser, Aric
Keith, Erin
Kim, Sam
Krause, David

Lee, Kevin
Mattamal, George
Melkerson, Mark
Mishra, Nirmal
Munzner, Bob
Ogden, Neil
Pagano, Russell
Pak, Yung
Phi, Khai
Phillips, Mary Ellen
Rhodes, Holly
Rhodes, Stephen
Schroeder, Marie
Scudiero, Jan
Sloan, Nadine
Stevens, Ted
Sung, Pei
Torres-Cabassa, Angel
Tudor, Natalie
Vinson, Priscilla
Warfield, Diana
Watson, Tony
Weiblinger, Rick
Williams, Berry
Williams, Paul
Witten, Celia
Wolf, Beverly
Yahiro, Martin
Yen, Dwight

Division of Ophthalmic Devices

Alexander, Kesia
Baker, Karen
Beers, Everette
Berman, Sheryl
Boulware, Ashley
Brogdon, Nancy
Brown, Daniel
Burns, Adrienne
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Linda
Copeland, Karen
Cygnarowicz, Teresa
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Felton, Eleanor
Glover, Joel
Gouge, Susan
Hoang, Quynh
Jaffe, Sidney
Jones, Susanna
Kaufman, Daryl
Krawczyk, Claudine
Lepri, Bernard
Leslie, Sharmeka
Lochner, Donna
Malshet, Vasant
McCarthy, Denis
Montgomery, Al
Moore, Shirley
Nicholas, Marsha
Romanell, Jake
Rorer, Eva
Rosenthal, Ralph
Sauberman, Harry
Saviola, James
Selfon, Eric
Sharpe, Skip
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Thornton, Sara
Warburton, Karen
Warren, Jim
Waxler, Morris
Whipple, David

Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices

Abt, Mary
Allen, Cheryl
Arnaudo, Joe
Baxley, John
Byrd, Laura
Chen, John

Cooper, Jeff
Cornelius, Mary Jo
Czerska, Ewa
Dart, Linda
Daws-Kopp, Kathryn
Doyle, Bob
Eba, Felissa
Fredericksen, Jane
Gammell, Paul
Gonzalez, Gema
Harvey, Brian
Harvey, Elisa
Herrera, Hector
Jevtich, Milorad
Kammula, Raju
Kang, Andrew
Kuchinski, Mike
Mallis, Elias
McCool, Barbara
McGee, Leah
Miller, Linda
Miller, Pat
Mitchell, Diane
Monahan, Jack
Neuland, Carolyn
Nimmagadda, Rao
Nutter, Cathy
Olvey, Kathleen
Perez, Rod
Phillips, Bob
Pollard, Colin
Price, Veronica
Provost, Miriam
Relacion, Cheryl
Rubendall, Rita
Sacks, William
Sauls, Mattie
Schielke, Mary
Schultz, Dan
Segerson, Dave
Seiler, Jim
St. Pierre, Don
Virmani, Mridulika
Williams, Dick
Wolanski, Nicole
Yin, Lillian
Zaremba, Loren
Zaudtke, Peter