OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1998

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

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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
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Table of Contents

PREFACE

Congratulations to the ODE staff are in order for another outstanding year in ODE! FY 98 statistics demonstrate that the ODE staff's hard work produced timely and quality reviews and continued improvement overall.

FY 98 was the best year in a decade for PMAs. ODE reviewers improved the average review time by 25% from PMA receipt to approval in FY 98.

The total median review time for 510(k)s was 83 days! Also, more than 99% had 90-day FDA cycles.

ODE approved 71% of original IDEs in the first review cycle. This demonstrated the extent of interaction staff had with industry.

Other performance highlights included:

- approved 46 PMAs, 7 under expedited review, and 4 as humanitarian device exemptions;
- reviewed 18 of the 46 approved PMAs in 180 days or less and 37 in less than 1 year;
- continued to reduce review times for PMAs and PMA Supplements;
- approved 421 PMA Supplements of which 139 were reviewed in real time;
- approved 4 PDP protocols;
- approved or cleared 50 significant medical device breakthroughs (29 PMAs and 21 510(k)s);
- continued, for a third year, a zero backlog in the 510(k) program;
- continued to reduce the FDA and total average review and median review times for 510(k)s;
- provided pre-IDE guidance to companies on 143 applications;
- approved 71% of IDEs in the first review cycle;
- reviewed 100% of all IDEs (originals, amendments, and supplements) within 30 days; the average review time was 27 days; and
- issued 47 guidance documents, 10 of which were the result of the FDA Modernization Act of 1997.

The premarket programs' successes are indeed noteworthy, and this is a direct result of teamwork within CDRH. Staff in ODE, OC, OSB, OST and OHIP participated in product reviews, and, without the support of OSM and CDRH management, this work could not be completed and reported.

My personal thanks to all who contributed to another terrific year!

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

HIGHLIGHTS
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
Fiscal Year 1998

(October 1, 1997 - September 30, 1998)

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

ODE's Major Program Initiatives (FDA Modernization Act of 1997, CDRH Reengineering Update, Investigational Device Exemptions, New 510(k) Paradigm, Evaluation of Automatic Class III Designation, and Modular PMA Review) are discussed in the next section of this report. Following are the highlights of ODE's review activities and performance for Fiscal Year 1998 (FY 98). 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 37.

Cohort Reporting

Starting with this FY 98 Annual Report, both receipt and decision cohort statistics are included in the annual report. A *receipt cohort* is a group of submissions received by the Center over a specified time frame (usually a fiscal year), while a *decision cohort* is a group of submissions upon which a decision was made within a specified time frame. For example, the percentage of the submissions received during a fiscal year and completed within a specified number of days is a receipt cohort statistic (e.g. 65% of the 3,424 510(k)s received in the first nine months of FY 98 were completed within 90 total cumulative days), while the percentage of submissions closed out with a final decision during a fiscal year that were completed within an applicable regulatory time frame is a decision cohort statistic (e.g. 59% of the 5,229 decisions completed in FY 98 were done within 90 total cumulative days).

Statistics derived from decision and receipt cohort data will differ because the population of submissions that make up each cohort is not the same. The FY 98 receipt cohort, for example, consists of submissions received during FY 98, not all of which are completed in this fiscal year. The FY 98 decision cohort contains products received in previous fiscal years. Receipt cohort statistics will be revised and reported in subsequent annual reports.

Workload/Resources

- During FY 98, ODE received a total of 17,861 submissions, compared to 19,267 in FY 97; 10,016 were major submissions compared to 9,824 last fiscal year.

- On the decision side, ODE completed the processing of 10,455 major submissions, compared to 9,873 major submissions in FY 97.

- ODE ended the year with 340 employees. In order to meet resource changes, the Office targeted an attrition rate of @2.5% in FY 98. During the year, ODE lost 22 full-time employees (14 scientific reviewers, 2 medical officers and 6 clericals) through resignation or retirement and added 11 new employees (5 scientific reviewers, 3 medical officers and 3 clericals) (3% attrition). Three of the new hires (27%) were African-American (2 females and 1 male) and 8 were women (73%).

Chart 1. Submissions Received

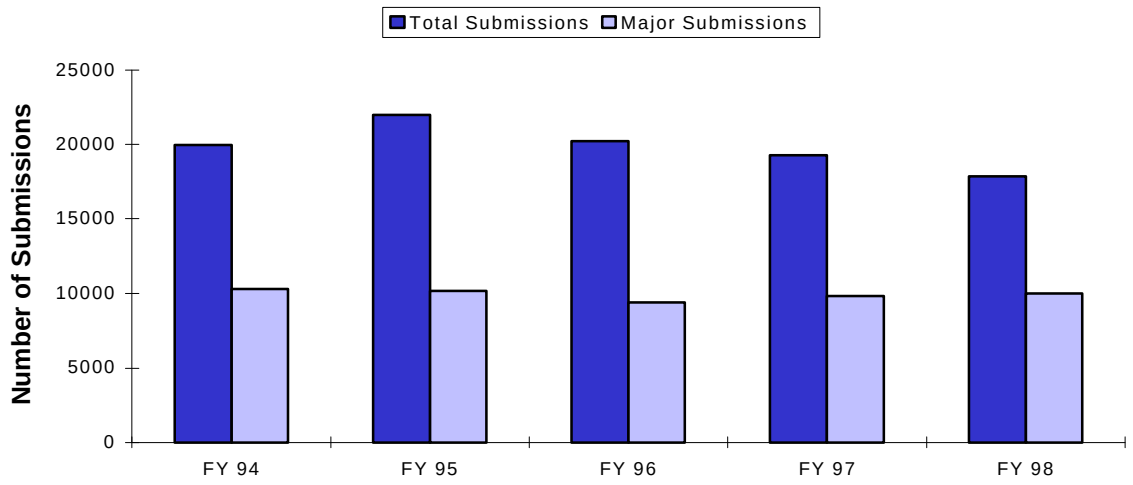
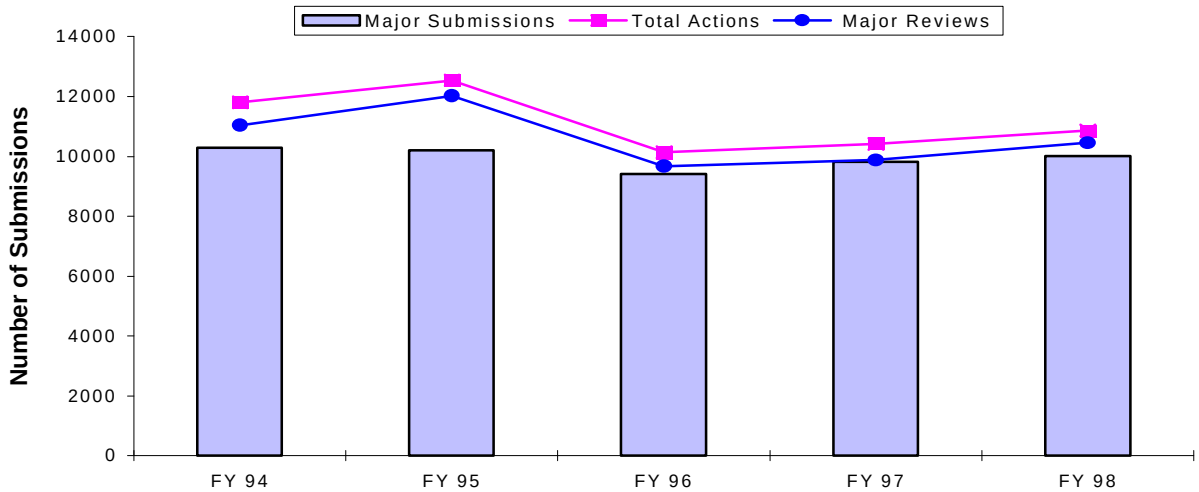


Chart 2. Major Submissions, Reviews, and Total Actions



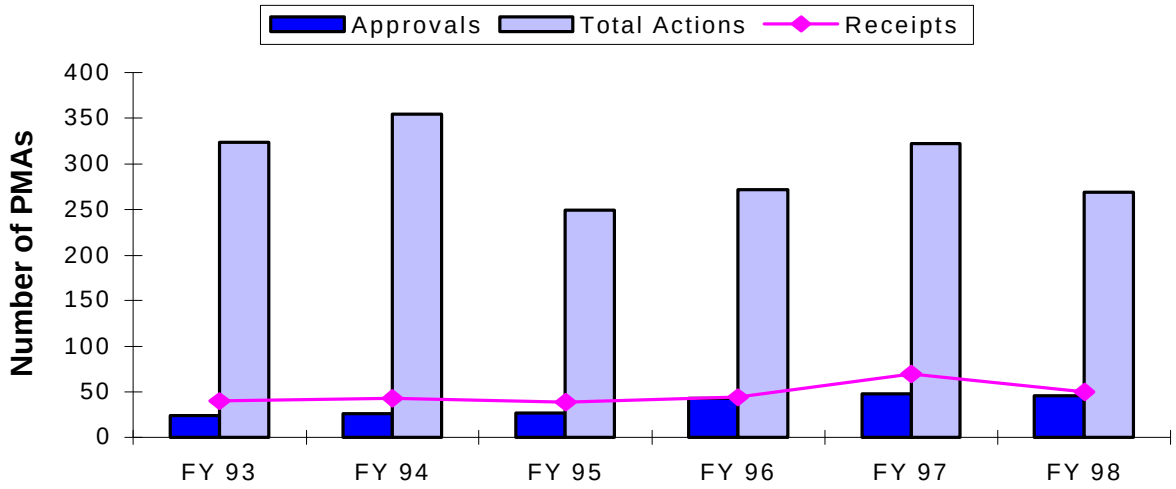
Premarket Approval Applications (PMAs)

- ODE received 55 complete original PMAs, 15 less than the number received in FY 97, and 49 modular submissions.

- The total number of PMAs in inventory (active and on hold) at the end of this fiscal year dropped for the sixth year in a row, from 85 last year to 70. The number of active PMAs under review decreased at the end of FY 98 to 29 compared to 44 last year, and those on hold remained the same at 41. For the second consecutive year, there were no active and overdue PMAs at the end of the fiscal year.

- The total number of PMA actions decreased from 322 to 269 actions. These actions included 61 filing decisions, 143 review determinations, and 65 approval decisions.

Chart 3. Annual PMA Receipts & Actions



- The 65 original PMA decisions were comprised of 46 approved PMAs, 7 approvable PMAs, and 12 nonapprovable PMAs. Seven of the 46 approvals were expedited PMAs, and 4 were HDEs. See Appendix C for a complete list of PMA approvals.

- Average FDA review time for original PMAs reaching final action decreased from 207 days in FY 97 to 154 days in FY 98. The non-FDA component of review time decreased from 40 days in FY 97 to 37 days this fiscal year. The total average review time decreased to 6.4 months, which represents the fourth consecutive year in which this review time has decreased. Furthermore, 18 PMAs were reviewed in 180 days or less, and 37 were completed within 1 year.

- The total average elapsed time for PMAs continued its downward trend from a high of 823 days (27.1 months) in FY 94 to its current low of 373 days (12.4 months) in FY 98.

Chart 4. Average Review Time for PMA Approvals

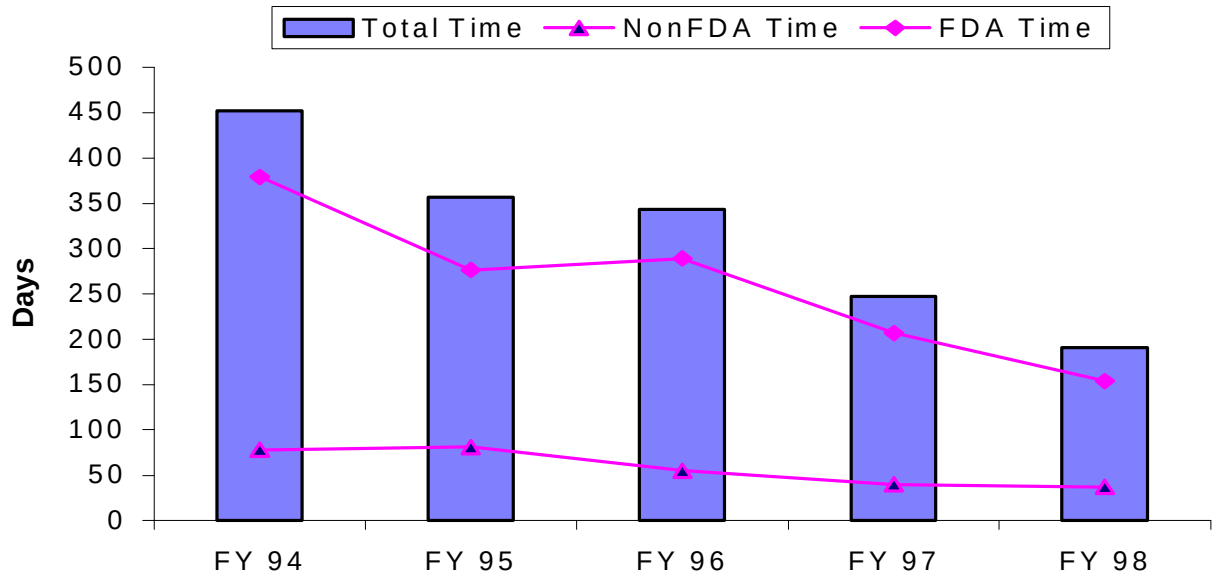
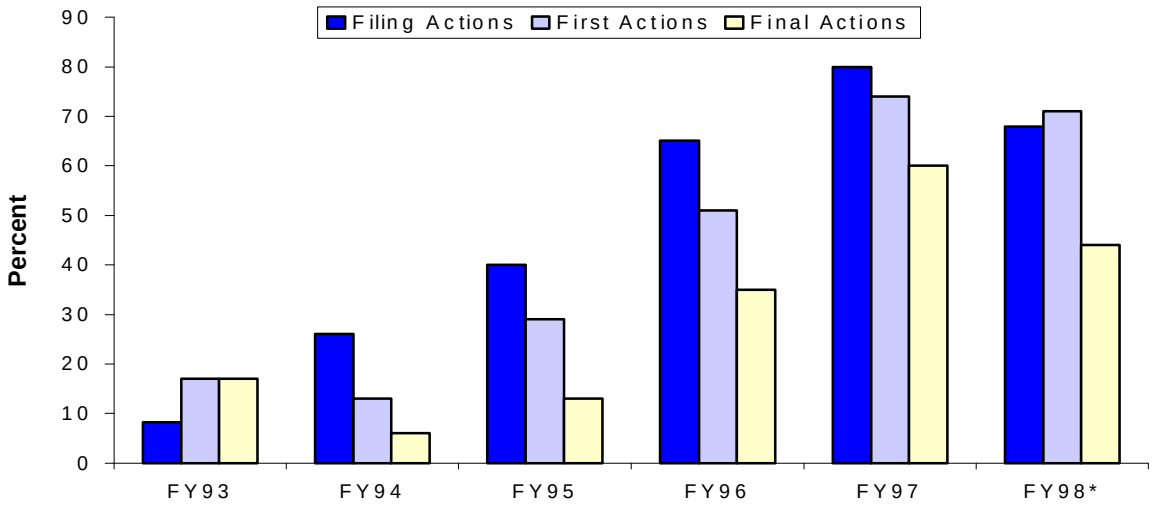
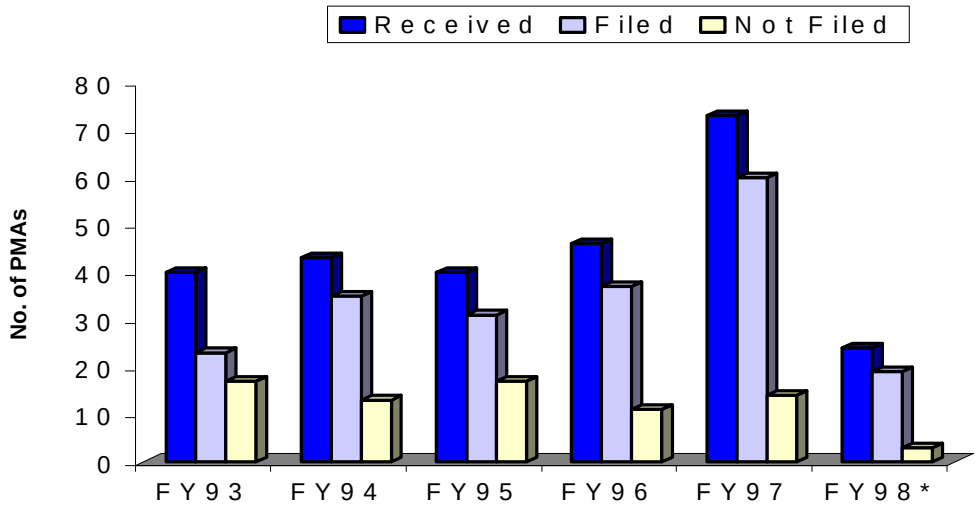


Chart 5. Percentage of PMA Receipt Cohort Actions Within Timeframes



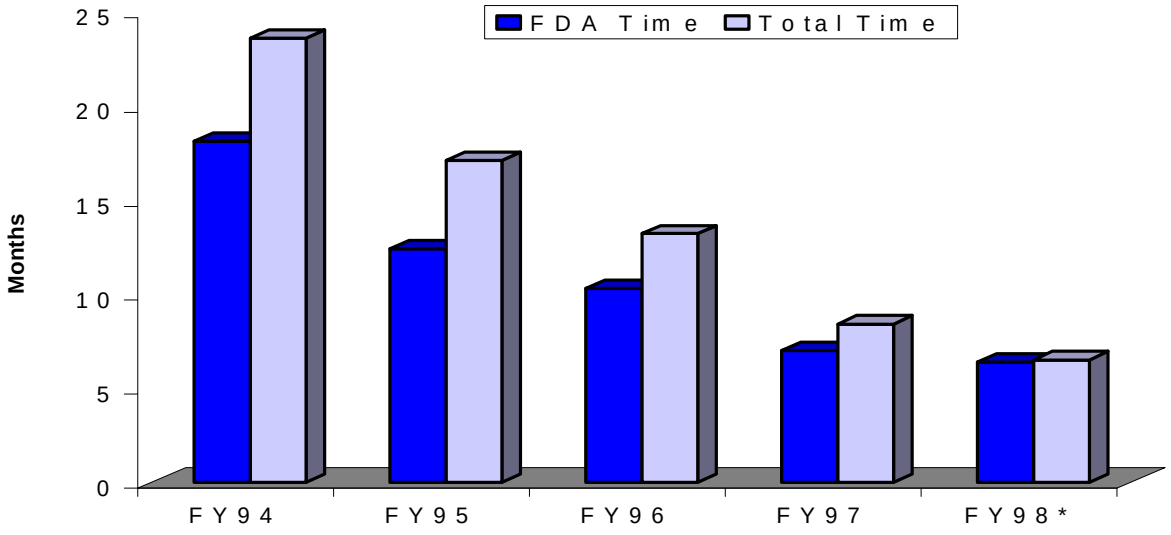
*First six months
Percent of receipt cohort "Filing" Actions within 45 days.
Percent of receipt cohort "First" Actions within 180 days (HDEs within 75 days) including withdrawals, conversions, etc.
Percent of receipt cohort "Final" Actions within 180 days (HDEs within 75 days) including, withdrawals,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

Chart 6. Original Receipt Cohort PMAs Received and Filed



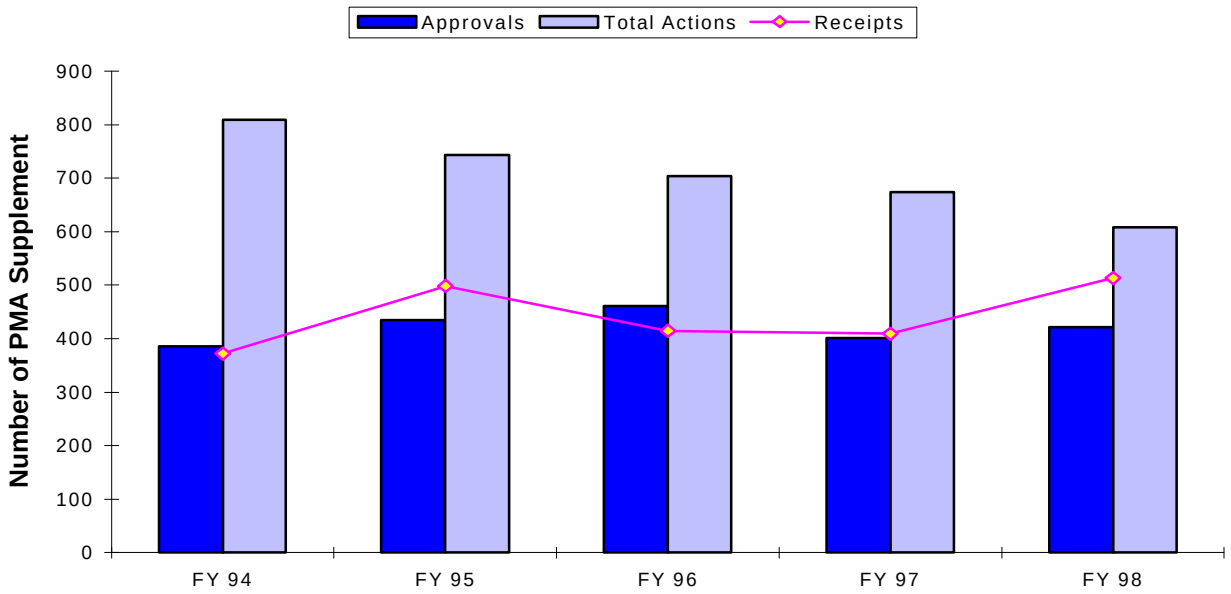
* First six months.

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



* First six months.

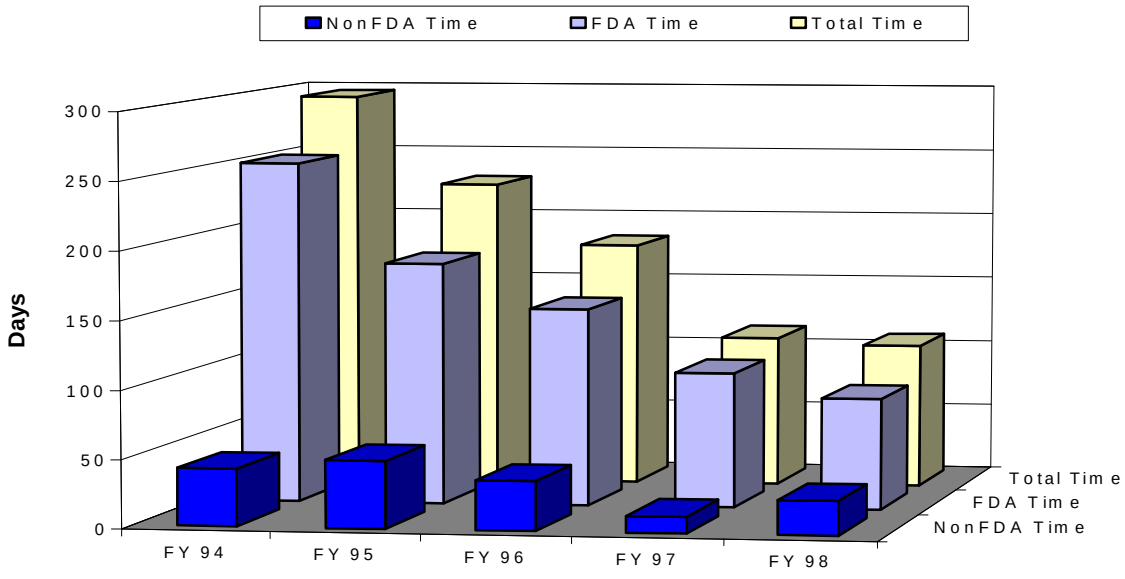
Chart 8. Annual PMA Supplement Receipts and Actions



- The number of PMA supplements received increased slightly from last year's 409 to 513. There were 608 PMA supplement actions down from last year's 674 total actions. These actions included 7 panel track filing decisions, 68 review determinations, and 531 approval decisions.

- For PMA supplements the average review time dropped from 112 days in FY 97 to 107 days, and the total average elapsed time rose slightly from 143 days to 153 days. There were 139 PMA Supplements completed in "real time" for FY 98.

Chart 9. Average Review Time for PMA Supplements



- 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 139 from 110 for FY 97, and the number of supplements on hold decreased from 80 to 57.

Real-Time Review of PMA Supplements

- A total of 139 requests were received and processed for real time PMA supplements in FY 98 which represents 27% of all supplements received. Of those submissions, 126 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 (46%) followed by DRAERD (24%), DGRD (21%) and DOD (6%) with fewer in 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)

- In FY 98, ODE received 11 inquiries from companies interested in the PDP process. These cut across 5 of our 6 review divisions. Four PDPs have been approved, and reports are being received on their progress. ODE continues to work with the remaining companies on their PDPs or other product review options.

Modular PMA Review

- ODE received a total of 25 PMA shells, found 6 modules to be acceptable, and issued 7 deficiency letters on shells or modules.

Investigational Device Exemptions (IDEs)

- During FY 98, ODE reviewed 143 pre-IDEs. Based on these reviews, guidance for the original IDE submissions were provided through meetings with the sponsors, letters, or by fax, phone, and other.

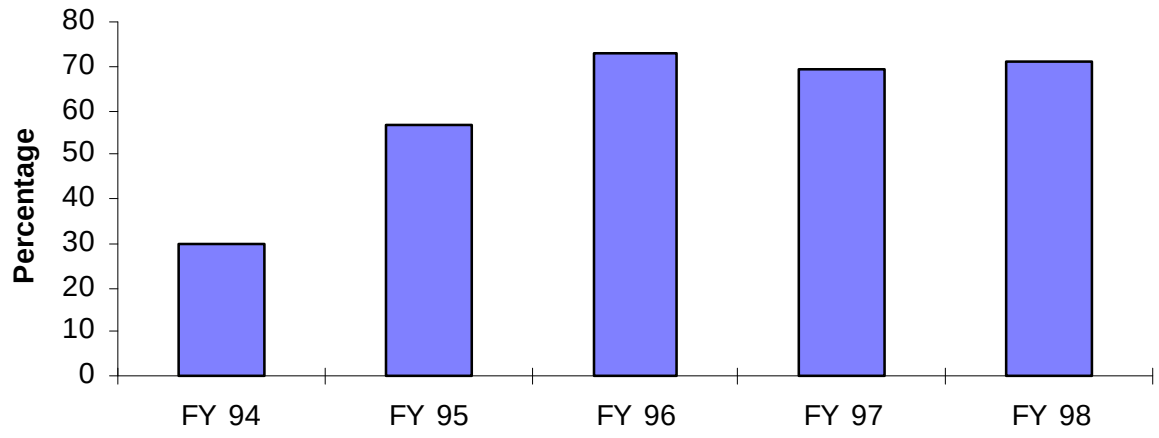
- ODE received 322 original IDEs, an increase from the 297 received in FY 97. There were 325 decisions made on original IDEs, an increase from 272 last year.

- One hundred percent of all original IDE decisions were issued within 30 days in FY 98. The average review time was 27 days.

- Of the IDEs which were complete enough to support substantive review, the percentage of IDEs approved on the first review cycle increased slightly from 69% in FY 97 to 71% during FY 98.

- During this fiscal year, 226 IDE amendments were received. Decisions were made on 225 amendments: 94 approvals (42%); 36 disapprovals (16%); and 95 other administrative actions (42%). One hundred percent of these decisions were made within 30 days.

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

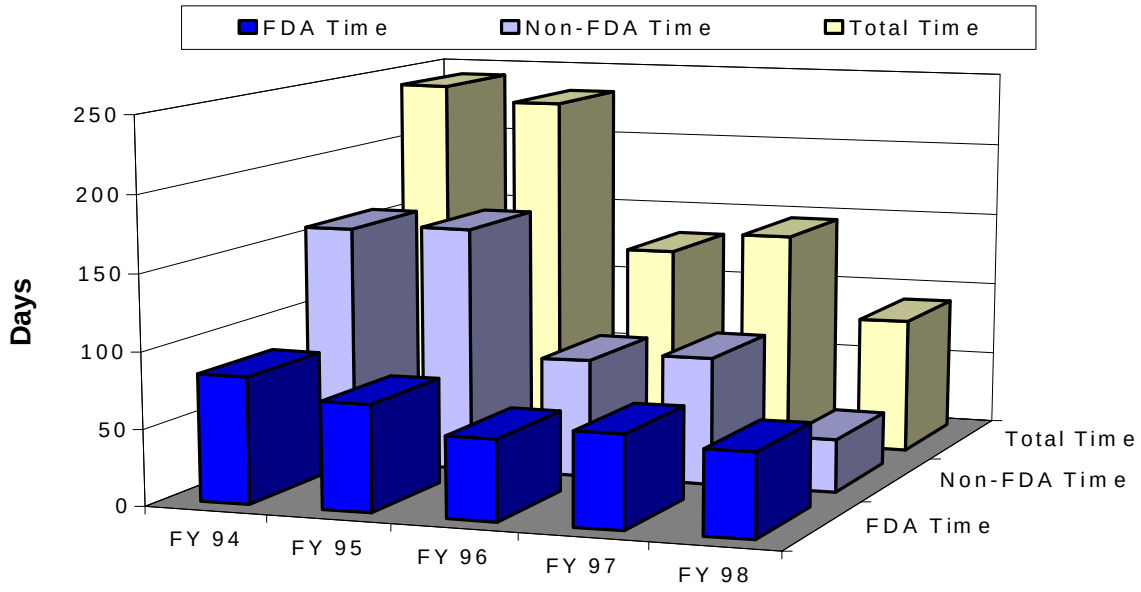


* Base on those IDEs complete enough to permit substantial review.

- It took an average total time of 90 days to approve original IDEs with amendments, down from 145 days in FY 97. This average approval time consisted of 55 days for FDA time, down from 61 days last year, and 35 days for non-FDA time, down from 84 days in FY 97.

- ODE received 4,277 IDE supplements during FY 98. 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 98. The average review time for IDE supplements remained constant at 21 days.

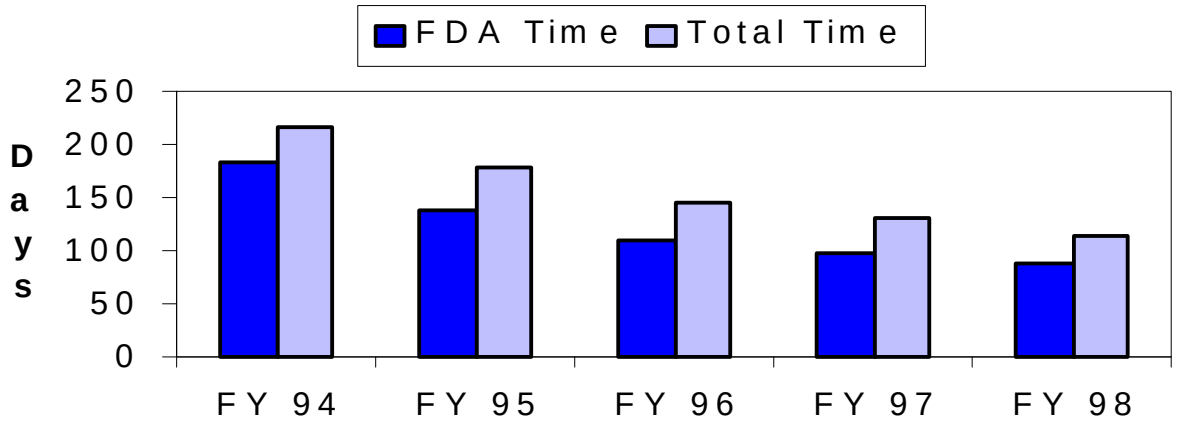
Chart 11. Average Approval Time for IDEs and Amendments



Premarket Notifications (510(k)s)

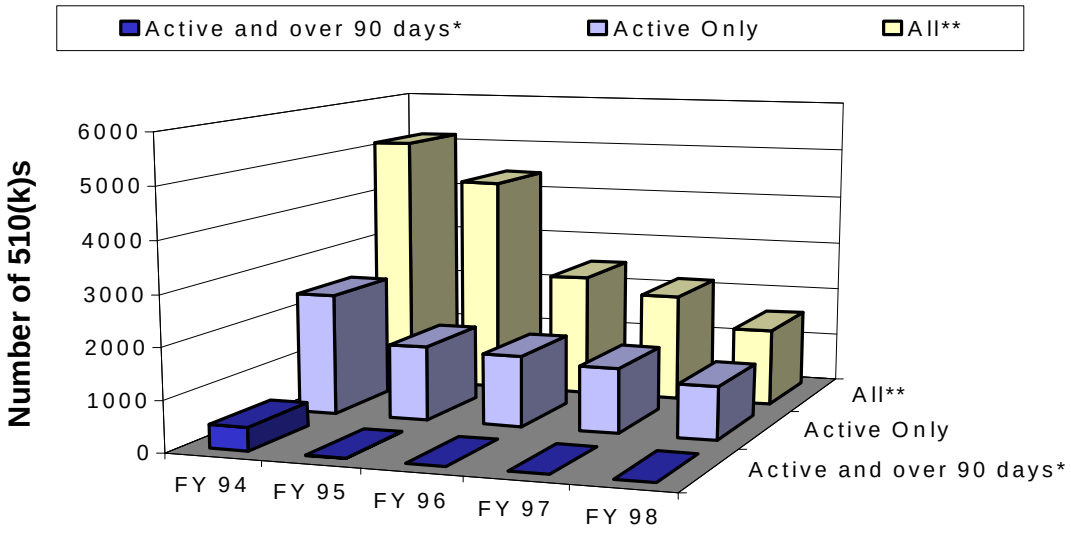
- ODE received 4,623 original 510(k)s, 2,023 510(k) supplements (responses to hold letters, the receipt of which restart the 90-day review clock), and 3,692 amendments (additional information received while the 510(k) is under review, the receipt of which does not affect the review clock).

Chart 12. Average 510(k) Review Time



- The total average review time declined from 130 days in FY 97 to 114 days in FY 98, and the average FDA review time was 89 days, down from 97 days in FY 97. 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 83 days in FY 98.

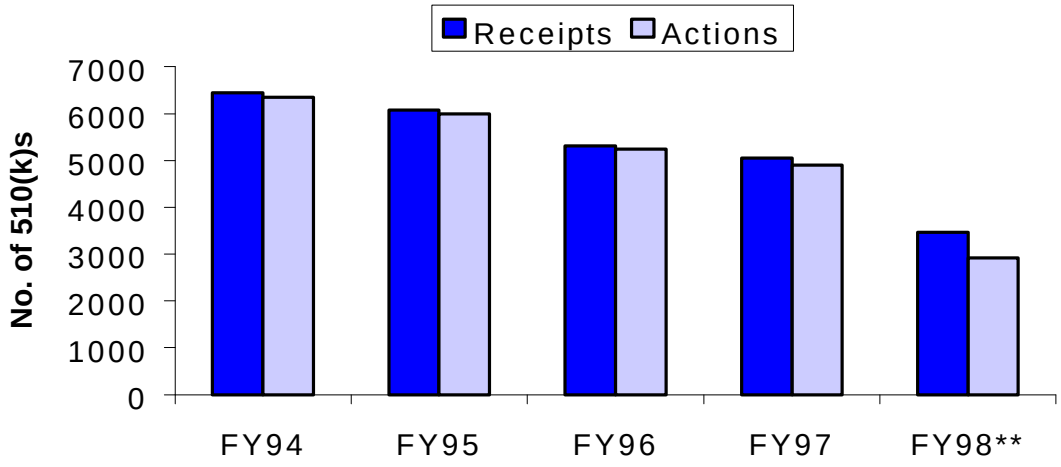
Chart 13. Pending 510(k)s



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

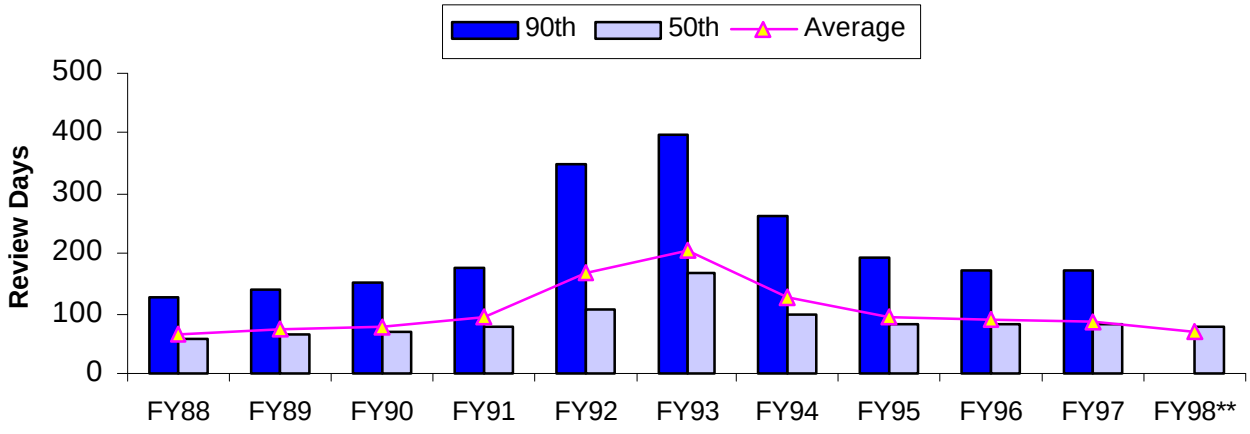
- There were 1,544 510(k)s in inventory (those under active review or on hold) at the end of this fiscal year, which is a decease from the 2,152 in FY 97's end-of-year inventory. The number on hold decreased from 865 at the end of FY 97 to 487. Most important, for the third consecutive fiscal year there were no 510(k)s active and overdue at the end of the reporting period.

Chart 14. 510(k) Receipt Cohort, Receipts and Actions*



* Cutoff Date of 9/30/98 for all receipt cohorts.
** For the first nine months of FY 99.

Chart 15. Receipt Cohort, FDA Days from Receipt to Final Action*



* Cutoff Date as of 9/30/98 for all receipt cohorts.
** For the first nine months of FY98. 90th percentile data not available for FY98.

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

On July 31, 1998, the Center completed the second year of a voluntary pilot program to test the feasibility of using third-party review groups to improve the efficiency of the Center's review of 510(k)s for selected low and moderate risk devices. During the 2-year period of August 1996 to July 1998, ODE received 31 510(k)s that had been reviewed by third parties participating in the pilot. ODE had issued final decisions for 30 of these 31 submissions as of the end of FY 98, and 1 submission was on hold for additional information. ODE's final decision matched the third party's recommendation for 97% (29 of 30) of the decisions, and was issued without the need for additional information for 55% (17 of 31) of the submissions. The cumulative FDA time from ODE's receipt of a third-party review to the issuance of a substantial equivalence decision averaged 19 days (median = 14 days), and was 30 days or less for 90% of the submissions. The total elapsed time from the date of a third party's receipt of a 510(k) to the date of FDA's final decision averaged 78 days (median = 54 days), which compares favorably with the total elapsed time for FDA's review of comparable 510(k)s submitted directly to the agency.

On November 21, 1998, the third party pilot came to an end and will be replaced by the Accredited Persons program established by the FDA Modernization Act of 1997. The Center took steps during FY 98 to implement this program. On May 22, 1998, FDA published a *Federal Register* notice establishing accreditation criteria for Accredited Persons, as required by law. FDA also announced the availability of a May 20, 1998 draft guidance document entitled Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997. On May 20, 1998, CDRH made available a list of devices that will be eligible for Accredited Person review. CDRH began accepting accreditation applications on July 20, 1998 and had received 15 such applications by the end of FY 98. In October 1998, CDRH made available an initial list of Accredited Persons and conducted a 2 and 1/2 day training program for these organizations.

Significant Jurisdictional Issues Involving Devices in FY 98

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. A Request for Designation (RFD) over such a product is made in writing by the manufacturer to the FDA's Office of the Chief Mediator and Ombudsman. This formal submission contains the material describing the requester's product and/or products and a proposal regarding which Center should be given lead designation over their product and which authority (Biological, Device or Drug) should apply.

In FY 98 CDRH participated in the reviews of 24 new RFDs received by the FDA's Ombudsman's Office, in addition to completing 6 RFDs received in FY 97. Out of the 24 new RFDs assigned to CDRH for consideration, DDIGD was assigned to review 11 (eleven), DGRD assigned 7 (seven), DCRND assigned 3 (three), DRAERD assigned 2 (two) and DCLD assigned 1 (one) to review.

The Office of the Chief Mediator and Ombudsman assigned lead Center designation to the 30 RFDs (24 new ones received in FY 98 and the six remaining from FY 97) worked on during FY 98 as follows:

- 10 were assigned with CDRH as lead Center.
- 1 was returned to the submitter for lack of adequate information. This was the first RFD, which the Office of the Chief Mediator and Ombudsman refused to file for lack of adequate information.
- 4 were pending final designation by the Ombudsman's Office.
- 15 were assigned to CDER or CBER as lead Center.

Significant Medical Device Breakthroughs

During FY 98, ODE approved 29 PMAs and cleared 21 510(k)s that represent significant medical device breakthroughs. See Appendix B for a complete list.

Final Reclassification Actions

- Published a final rule in the *Federal Register* on November 21, 1997, classifying Analyte Specific Reagents from class III to class II and I.
- Published a final rule in the *Federal Register* on December 17, 1997, reclassifying Tumor Associated Antigen Immunological Test Kit from class III to class II.
- Published a final rule in the *Federal Register* on February 17, 1998, reclassifying Suction Lipoplasty from class III to class II.
- Published a final rule in the *Federal Register* on June 3, 1998, reclassifying Immunohistochemical Reagents and Test Kits from class III to class II and I.
- Published a final rule in the *Federal Register* on July 27, 1998, reclassifying Pedicle Screw Spinal Systems from class III to class II.
- Published a final rule in the *Federal Register* on July 29, 1998, reclassifying Vitamin D Test Systems from class III to class II.
- Published a final rule in the *Federal Register* on September 10, 1998, reclassifying In Vitro Fertilization and Assisted Reproduction Devices (10 devices) from class III, 9 to class II and 1 to class I.

Evaluation of Automatic Class III Designation Cleared

- Dynamic Orthotic Cranioplasty - DOC™ Band identified as a class III generic type of neurology device under 21 CFR 882.5970 on May 29, 1998.
- Diamond Probe®/Perio 2000 System identified as a class III generic type of dental device under 21 CFR 872.1870 on July 17, 1998.

Proposed Reclassification Actions

- Published a proposed rule in the *Federal Register* on December 16, 1997, to reclassify Penile Rigidity Implants from class III to class II.
- Published a proposed rule in the *Federal Register* on March 5, 1998, reclassifying OTC Test Sample Collection Systems for Drugs of Abuse Testing from class III to class I and exempting them from the requirement of premarket notification.

Guidance for Industry and Reviewers

In FY 98, ODE published 33 final guidance documents, 10 of which were the result of the FDA Modernization Act of 1997. ODE also published 14 draft guidance documents for comment. See Appendix D for a complete listing of all FY 98 ODE guidance documents.

Advisory Panel Activities

CDRH's Medical Devices Advisory Committee consists of 16 panels divided according to medical device specialty. Each panel meets from one to five times per year, depending on its work load. Panel members provide advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification of devices into one of three regulatory categories, the review of premarket approval applications, and the content of guidelines or guidance documents designed to improve the interaction between the Agency and sponsors of medical devices.

A new guidance document titled *Guidance on Amended Procedures for Advisory Panel Meetings* was issued on March 20, 1998 to provide standard operating procedures to be followed by CDRH, CBER, FDA personnel and interested persons outside FDA in carrying out Section 513(b)(6) of the FD&C Act as amended by Section 205 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). These procedures are specific to panel meetings where a specific submission is being considered by the panel. This guidance as well as other CDRH FDAMA guidance documents can be found on the internet at: http://www.fda.gov/cdrh/modact/modguid.html.

Training for Panel Chairs was held on October 23, 1997. CDRH reengineering initiatives and other medical device program issues were discussed.

In FY 98, ODE held 32 panel meetings. There were 21 formal training sessions held for new panel members (special government employees known as SGEs). The two-hour training for SGEs covers the laws and regulations with respect to medical devices, organizational structure of the agency, ODE's operations, the roles and responsibilities of panel members, the elements of a panel meeting, and conflict of interest.

ODE's Panel Coordinator holds monthly meetings with the Executive Secretaries and provides guidance on agency policies and the consistent implementation of these policies across ODE. To further ensure consistent application of policy across the Office, the ODE Office Director and Panel Coordinator meet with the respective division director, Executive Secretary, and other appropriate division staff (i.e., medical officer, lead reviewer, branch chief, etc.) approximately 4-6 weeks prior to a scheduled panel meeting. At this meeting, the Office Director is briefed on the agenda for the scheduled panel meeting, the clinical aspects of the data in the sponsor's application, questions to be posed to the panel, and any other pertinent issues regarding the scheduled panel meeting.

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

ODE continuously recruits highly qualified experts to serve as consultants and panel members. Potential candidates are asked to provide detailed information concerning financial holdings, employment, and research grants and contracts to identify any potential conflict of interest. Every effort is made to ensure appropriate balance of membership. Female and minority representations are encouraged; currently females make up 41% of panel membership and minorities almost 29%. 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 30 cases concerning the integrity of data submitted to the agency in premarket applications. Under the Application Integrity Program (AIP), restrictions on the agency's substantive review of submissions from one firm was removed during FY 98 after the successful implementation of a corrective action plan by this firm.

ODE handled 12 instances related to questions arising under the standards of conduct for employees. During this fiscal year, 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. Manufacturers, their representatives, and consultants are strongly urged not to send gifts to the staff. Further information on gifts and other matters related to ethical conduct can be found in the *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.

Freedom of Information Requests

ODE staff received 1,681 FOI requests during FY 98, an increase from 1,440 last fiscal year. During FY 98, the number of FOI requests closed was 1,696 compared to 2,376 in FY 97. The total number of FOI requests pending in ODE is 672.

Congressional Inquiries

Congressional interest in ODE programs continued to be strong during FY 98. ODE staff responded to 12 Congressional letters. Most inquiries related to excimer lasers, brain stimulators, and breast implants. Congressional hearings held during FY 98 dealt with FDA's budget, Dr. Jane Henney's confirmation, Year 2000 (Y2K) issues and drug testing policy.

Publications

During FY 98, ODE cleared 5 abstracts and 9 manuscripts authored by ODE staff for publication in professional and scientific journals, and 12 presentations delivered by ODE staff at professional, scientific and trade association meetings. See Appendix E for a bibliography of publications.

ODE Vendor Days

In FY 98, ODE, in coordination with the regulated industry, continued to sponsor Vendor Days – informative exchange seminars with device manufacturers.

- October 8, 1997 - Orthopedic Implants Workshop Vendor Day.

- November 18, 1997 - "New Technology" devices. This particular Vendor Day featured small firms with various types of new devices from all product areas. Some of the featured devices included the ICR, Intratromal Corneal Ring, NCP System for Epilepsy, Diasensor 1000 Noninvasive Blood Glucose Monitor and many others.

Site Visits

In FY 98, 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 98, the program was expanded from visits only to medical device manufacturing firms to include hospitals for the observation of certain devices in use.

As a result, 10 firms and/or hospitals were visited to learn about endoscopic control systems, dental lasers, surgical gowns and drapes, MRI, image-directed medical robotics device, heart valves, stents and PTCA catheters.

In-House Training

ODE employees attended many courses, lecturers, and grand rounds sponsored by the CDRH Staff College. Additionally, ODE held the Design Control Validation for Medical Devices Course on September 21-22, 1998.

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 Intern Programs

In FY 98, ODE 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. This fiscal year, ODE expanded the program to include foreign and domestic professionals which allowed individuals from Canada and Korea to also participate in the program.

Computer Tracking Systems

ODE tracking system changes included premarket database enhancements, revised query programs, and reports to support reengineering and FDAMA initiatives. Specific accomplishments included:

- 510(k) Paradigm modifications, including modifications to Internet FOI 510(k) files
- Tracking of requests for Evaluation of Automatic Class III Designation (De Novo requests)
- PMA modifications for Day 100 Meetings, 30-Day Notifications
- 135-Day Supplements, and status letter tracking
- Pre-IDE and Pre-PMA Meeting Tracking

- Humanitarian Device Exemptions Revisions
- ODE Division Level Tracking revisions to support changed requirements
- Receipt/Decision cohort summary reports definition and programming (FDAMA/Reengineering)
- Initial PMA Modular Review System requirements analysis
- Conformance Standards Database development and implementation
- Year 2000 compliance for all premarket applications

Electronic Submissions

ODE reviewers continued to receive electronic submissions in FY 98; however, the number of submissions received in FY 98 was one less than the number received in FY 97. To accommodate electronic submissions, ODE upgraded approximately one-third of its personal computers to overcome the limitations preventing some reviewers from processing electronic submissions. Instructions for submitting electronic submissions can be found on the FDA home page at the address www.fda.gov/cdrh/elecsub.html.

Type of Electronic Submission	FY96	FY97	FY98
PMA Original	1	0	4
PMA Supplement	18	20	16
PMA Amendment	0	2	4
PMA Reports	0	0	2
PMA Modular	0	0	1
IDE Original	1	12	7
IDE Supplement	0	17	15
IDE Amendment	0	4	2
510(k)	3	10	13
Totals	23	65	64
Sponsors/Manufacturers	6	12	15

Video Conferencing

ODE expanded the use of the PictureTel videoconferencing system to interact with industry. In FY 97, two videoconferences were held. In FY 98, nine video conferences were held that covered the following issues: real-time review of a PMA supplement application, real-time review of an amendment to a PMA supplement, a pre-submission meeting, a Product Development Protocol presentation, a meeting to discuss devices and proposed protocols for two pre-IDE submissions, and a discussion with industry concerning FDA expectations.

World Wide Web Activity

As a result of the collaboration between ODE, the Office of Health and Industry Programs and the Office of Systems and Management under the Good Guidance Practices program, new and revised guidance documents have been expeditiously made available on the web. In addition, older guidance documents

were made available from copies on the DSMA Facts-on-Demand system or by scanning documents into electronic format. Information on Premarket Approval Applications (PMAs) and Premarket Notifications (510(k)s) can be found on the **Programs in CDRH** page at www.fda.gov/cdrh/programs.html. Anyone can search the Releasable 510(k) and PMA databases, download 510(k) or PMA files, obtain the monthly PMA listings, and read about the "Real-Time" program for PMA supplements. ODE will continue to use this vehicle to distribute information.

Information that can be found on the CDRH Home Page includes:

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

Office Automation

ODE purchased new personal computers to upgrade approximately one-third of its installed base of computers. This computer purchase coincided with the major conversion of its desktop office software from Microsoft Office 95 to Office 97/Outlook. Prior to the conversion, ODE conducted a pilot test of the new electronic mail system (Microsoft Outlook). This test proved to be successful and the full-scale conversion to Microsoft Office 97/Outlook began in September 1998. All of ODE's PCs should be converted by the end of December 1998. The new software allowed ODE to more easily accept and utilize Microsoft Word documents through the electronic mail system. This upgrade proved very helpful for international standards collaboration and for the back-and-forth dialog between ODE and the regulated industry.

MAJOR PROGRAM INITIATIVES
Fiscal Year 1998

FDA Modernization Act of 1997

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997, known as FDAMA. This legislation has affected many FDA program areas.

ODE staff has been actively involved in developing new regulations, guidance documents, policies and procedures to implement the provisions of FDAMA along with continuing work on the CDRH reengineering effort.

Extensive information on FDAMA and our implementation efforts can be found on the internet under FDA Modernization Act of 1997, CDRH Stakeholder Information at http://www.fda.gov/cdrh/modact/modern.html.

CDRH Reengineering Update

Reengineering efforts in the Center were initiated in FY 97 to optimize the public health impact of CDRH resources and increase efficiency of our work. Budget constraints and resource reductions made these efforts particularly necessary. Ten teams were established initially. Several of these teams completed their work in FY 98 and additional teams were established.

Teams with particular impact on ODE include the 510(k) team, the PMA team, the PDP team, the 515(b) team and the Standards team. All these teams generated ideas that have been piloted successfully and have become part of ODE standard procedures.

Newer teams include the Radiation Health team, the Postmarket team, the Bioresearch Monitoring team and the Registration and Listing team. Significant work is also continuing on Information Dissemination and on two new GMP inspection methods (QSIT and HACCP).

Reengineering efforts in CDRH can be found on the internet at http://www.fda.gov/cdrh/reengine.html.

Investigational Device Exemptions (IDE)

On January 20, 1998, the “Guidance on IDE Policies and Procedures” was issued. This comprehensive document, which is intended for both ODE Staff and the regulated industry, provides guidance on all aspects of the IDE Program. Chapter I addresses general issues pertinent to the review of IDE applications and updates the previous guidance “Clarifications of IDE Policies and Procedures” (dated September 13, 1991). Chapter II discusses several new regulations that affect the IDE program, including changes to the Medicare program establishing criteria and procedures for extending coverage to certain investigational devices, waiver of informed consent for emergency research, and disqualification of clinical investigators. Chapter III addresses mechanisms for early/expanded access to unapproved devices, including the provisions of the FDA Modernization Act of 1997. These mechanisms include

emergency use of unapproved medical devices, individual patient access to investigational devices intended for serious diseases, treatment use of investigational devices, and continued access to investigational devices.

The New 510(k) Paradigm

Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications went into effect on March 20, 1998. The Paradigm was a result of the CDRH organization transformation initiative by the 510(k) Process Reengineering Team. While the New Paradigm maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the Act, it also presents the "Special 510(k): Device Modification" option, which utilizes certain aspects of the Quality System Regulation, and the "Abbreviated 510(k)" option, which relies on the use of guidance documents, special controls, and recognized standards to facilitate 510(k) review. From March 20, 1998 to September 30, 1998 ODE received 78 Special 510(k)s. Sixty-six have received final decisions with the average FDA review time of 21 days and the average total time of 22 days. Sixty-one were found substantially equivalent and the remaining five had other decisions such as withdrawn or deleted. None of the closed out Special 510(k)s went over 30 days. During the same timeframe ODE received 21 Abbreviated 510(k)s. Seven have received final decisions (6 substantially equivalent and 1 other decision) with a FDA average review time of 62 days and total time of 62 days. None of the Abbreviated 510(k)s went over 90 days.

Evaluation of Automatic Class III Designation

Under new Section 513(f)(2) of the FD&C Act, devices that have been found not substantially equivalent due to lack of a predicate may be placed in class I if the general controls described in the Act are sufficient to provide reasonable assurance of safety and effectiveness. If general controls are not adequate, a device will be placed in class II if there is sufficient information to establish special controls which, together with the general controls, provide such assurance. Special controls may include performance standards, postmarket surveillance, patient registries, and development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)). Devices placed into class II are subject to these controls. The Agency will need to reach a conclusion that the reasonable assurance of safety and effectiveness standard is met by the information in the 510(k) and the accompanying request for Evaluation of Automatic Class III Designation as a basis for placing the product in either class I or II. A product will be classified as class III if general controls are not adequate to provide reasonable assurance of safety and effectiveness and there is not sufficient information to establish special controls that would provide such assurance. While the process is new, its implementation is based on using the types of information and data ordinarily submitted in 510(k)s and/or reclassification petitions.

Modular PMA Review

Currently, a premarket approval application (PMA) includes various types of product design, bench and animal testing (preclinical), clinical data and manufacturing information. Some of this information is reviewed more than once, first when submitted as a report to an IDE and again, much later in the process, when submitted in the PMA. In addition, the reviewer responsible for the IDE may not be the person reviewing the same information in the PMA. As part of PMA Reengineering, CDRH is seeking to remodel PMA review to increase efficiency and effectiveness.

CDRH has implemented a modular approach to the submission of PMAs. This process requires that the applicant submit and receive agreement from the review division for its shell outline which describes what data and information will be submitted in each module. The essence of a modular concept for data development, submission, review, and closure is to break the contents of a PMA into well-delineated modules. Each module is then submitted as soon as the applicant has performed the testing and analyses, even during the IDE process, thus compiling a complete PMA over time. This should allow more rapid closure of the PMA because much of the review work will have already been done. Since the inception of this program in January of 1998, CDRH has received a total of 25 shell outlines and 84 modules. CDRH has issued 7 modular deficiency letters and 6 modular acceptance letters.

STATISTICAL TABLES
Fiscal Year 1998

[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 94 - FY 98

Type of Submission	Number Received				
	FY 94	FY 95	FY 96	FY 97	FY 98
Premarket Approval (PMAs) [a]					
Original Applications	43	39	44	70	55
Amendments	704	812	883	839	742
Supplements	372	499	415	409	513
Amendments to Supplements	788	838	823	819	863
Reports for Orig. Applications	407	487	435	435	431
Reports for Supplements	12	8	24	2	0
Master Files	130	92	65	130	94
PMA Subtotal	2,456	2,775	2,689	2,704	2,698
Investigational Device Exemptions (IDEs)					
Original Applications	171	214	253	297	322
Amendments	254	210	219	223	226
Supplements	3,020	3,171	3,189	3,776	4,277
IDE Subtotal	3,445	3,595	3,661	4,296	4,825
Premarket Notification (510(k)s)					
Original Notifications	6,434	6,056	5,297	5,049	4,623
Supplements	4,571	4,552	3,246	2,785	2,023
Amendments	3,057	5,012	5,343	4,433	3,692
510(k) Subtotal	14,062	15,620	13,886	12,267	10,338
PMA/IDE/510(k) Total	19,963	21,990	20,236	19,267	17,861

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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Number Received	43	39	44	70	55
PMA Actions					
Filing Decisions					
Filed (%)	38 (60)	33 (60)	45 (73)	58 (78)	51(84)
Not Filed (%)	25 (40)	22 (40)	17 (27)	16 (22)	10(16)
Others(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	63	55	62	74	61
Review Activities					
Major Deficiencies	30	29	32	38	28
Minor Deficiencies	4	7	5	5	10
Other[a]	191	111	97	138	105
Review Activity Subtotal	225	147	134	181	143
Approval Decisions					
Approvals(%)	26 (39)	27 (57)	43 (57)	48 (72)	46(71)
Approvable(%)	22 (33)	16(34)	27 (35)	14 (21)	7(11)
Not Approvable(%)	18 (27)	4 (9)	6 (8)	5 (7)	12(18)
Denials	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Approval Decision Subtotal	66	47	76	67	65
Total PMA Actions	354	249	272	322	269
Average Review Time (Days:Months)					
for Approvals[b]					
FDA	374 : 12.3	276 : 9.1	289 : 9.5	207 : 6..9	154:5.1
Non-FDA	78 : 2.6	81 : 2.7	55 : 1.8	40 : 1.3	37:1.2
Total	452 : 14.9	357 : 11.7	343 : 11.3	247 : 8.2	191:6.4
Average Elapsed Time (Days:Months)					
for Approvals[c]					
FDA	649 : 21.3	606 : 19.9	572 : 18.8	375 : 12.5	265 : 8.8
Non-FDA	174 : 5.7	167 : 5.5	214 : 7.0	122 : 4.1	108 : 3.6
Total	823 : 27.1	773 : 25.4	786 : 25.9	497 : 16.6	373 : 12.4
Number under Review at End of Period[d]					
Active[e]	67	69	57	44	29
(Active and overdue)	(22)	(26)	(17)	(0)	(0)
On hold[f]	72	56	39	41	41
Total	139	125	96	85	70

*/ 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 94 - FY 98

(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 94 – FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Original PMAs Received					
PMAs	41	29	41	56	18
Expedited PMAs	2	11	5	13	3
HDEs[a]	0	0	0	4	3
Total	43	40	46	73	24
Filing Decisions[b]					
Filed	36	31	37	60	19
Not Filed	13	17	11	14	3
Number (%) of Filing/Not Filing Decisions within 45 Days	13(26)	21(40)	31(65)	60(80)	15(68)
Average Days/Cycle	90	78	51	37	54
Final Actions[c]					
Approvals	29	22	24	38	9
Denials	0	0	0	0	0
Other[d]	13	14	16	15	3
Filing to First Action Excluding withdrawals, conversions, etc. [e]					
Number Received and Filed	26	19	28	51	17
Number of First Actions	26	19	28	51	16
Average FDA Days	334	230	187	143	143
Median FDA Days	249	219	180	170	157
Number (%) of First Actions within 180 Days[f]	3(12)	5(26)	16(57)	38(75)	11(69)
Filing to First Action Including withdrawals, conversions, etc[g]					
Number Received and Filed	31	24	35	57	18
Number of First Actions	31	24	35	57	17
Average FDA Days	311	228	193	143	145
Median FDA Days	245	218	180	170	161
Number (%) of First Actions within 180 Days[f]	4(13)	7(29)	18(51)	42(74)	12(71)

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Table 3. Original PMA Receipt Cohort Performance*
FY 94 – FY 98

(Continued from previous page.)

	FY 94	FY 95	FY 96	FY 97	FY 98
Filing to Final Actions Excluding withdrawals, conversions, etc.[h]					
Number Received and Filed	26	19	24	38	9
Number of Final Actions	29	22	24	38	9
Average FDA (Total) Review Days	584(709)	399(467)	301(380)	214(253)	191(194)
Median FDA (Total) Review Days	615(627)	387(417)	286(343)	178(184)	192(192)
Number (%) of Final Actions within 180 FDA Days[f]	2(8)	2(11)	6(25)	19(50)	2(22)
Number (%) of Final Actions within 180 Total Days [f]	1(4)	2(11)	4(17)	16(42)	1(11)
Filing to Final Action Including withdrawals, conversions, etc. [i]					
Number Received and Filed	31	24	31	43	9
Number of Final Actions	42	36	40	53	12
Average FDA (Total) Review Days	543(691)	372(515)	311(395)	210(252)	191(194)
Median FDA (Total) Review Days	575(623)	365(486)	291(354)	178(179)	192(192)
Number (%) of Final Actions within 180 FDA Days[f]	5(16)	8(33)	17(55)	31(72)	5(56)
Number (%) of Final Actions within 180 Total Days[f]	2(6)	3(13)	11(35)	26(60)	4(44)
Average Number of FDA Cycles from Receipt to Final Action Including withdrawals, conversions, etc.[c]	1.8	1.8	1.6	1.4	1.3
Percentile FDA (Total) Days from Filing to First Action[g]					
25th	207	168	165	110	108
50th (Median)	245	218	180	170	161
75th	491	264	217	179	177
90th	623	364	259	189	225
Percentile FDA (Total) Days from Filing to Final Action[i]					
25th	274(413)	256(373)	180(221)	135(140)	165(177)
50th (Median)	575(623)	365(486)	291(354)	178(179)	192(192)
75th	711(1054)	467(693)	352(468)	278(347)	206(206)
90th	807(1165)	550(832)	433(779)	416(520)	281(287)

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Table 3. Original PMA Receipt Cohort Performance*
FY 94 - FY 98

(Continued from previous page.)

Number under review as of 9/30/98					
Active	0	0	2	7	5
Active and Overdue	0	0	0	0	0
On hold[j]	1	4	4	13	7
Total	1	4	6	20	12

Summary of PMA Receipt Cohort					
Approved	29	22	24	38	9
Denied	0	0	0	0	0
Withdrawn	12	13	10	8	2
Other	1	1	6	7	1
Under Review	0	0	2	7	5
On Hold[j]	1	4	4	13	7
Total	43	40	46	73	24

*/ For each fiscal year, September 30, 1998 was used as the cutoff date. The FY 98 cohort represents only receipts through March 31, 1998 (first six months of the fiscal year).

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 analysis includes all filing or not filing decisions made as of the cutoff date for the PMAs received in each fiscal year. The number filed in each fiscal year, includes all filing actions for that fiscal year, regardless of the year in which the PMA was actually received.

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 received and filed within the fiscal year. This measure excludes PMAs with a final action of withdrawal, conversion, or other final action.

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 received and filed within the fiscal year. This measure include PMAs with any final action including approval, denial, withdrawal, conversion, or other final action.

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

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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Number Received	372	499	415	409	513
PMA Supplement Actions					
Panel Track Filing Decisions[a]					
Filed(%)	3 (60)	4 (0.8)	8 (89)	15 (94)	7 (78)
Not Filed(%)	2 (40)	1 (0.2)	1 (11)	1 (6)	2 (22)
Other(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	5	5	9	16	9
Review Activities					
Major Deficiencies	1	3	9	3	4
Minor Deficiencies	0	1	1	1	2
Other[b]	219	147	141	128	62
Review Activities Subtotal	220	151	151	132	68
Approval Decisions					
Panel track approvals(%)[c]	3 (1)	3 (1)	0 (0)	4 (1)	5 (1)
Nonpanel track approvals(%)	382 (65)	432 (73)	462 (85)	397 (76)	416(78)
Approvable(%)	95 (16)	78 (13)	33 (6)	49 (9)	47 (9)
Not approvable(%)	104 (18)	75 (13)	48 (9)	76 (14)	63(12)
Approval Decision Subtotal	584	588	543	526	531
Total PMA Supplement Actions	809	744	703	674	608
Average Review Time (Days:Months)					
for Approvals[d]					
FDA	253 : 8.3	179 : 5.9	146 : 4.8	100 : 3.3	82 : 2.7
Non-FDA	42 : 1.4	49 : 1.6	36 : 1.2	12 : 0.4	25 : 0.8
Total	295 : 9.7	228 : 7.5	182 : 6.0	112 : 3.7	107 : 3.6
Average Elapsed Time (Days:Months)					
for Approvals[e]					
FDA	301 : 9.9	209 : 6.9	167 : 5.5	120 : 4.0	109 : 3.6
Non-FDA	70 : 2.3	66 : 2.2	49 : 1.6	23 : 0.8	43 : 1.4
Total	371 : 12.2	275 : 9.0	216 : 7.1	143 : 4.8	153 : 5.1
Number under Review at End of Period[f]					
Active[g]	243	226	162	110	139
(Active and overdue)	(110)	(49)	(17)	(0)	(0)
On hold[h]	133	151	74	80	57
Total	376	377	236	190	196

*/ 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 94 - FY 98

(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 require the full administrative procedures normally associated with original PMAs, i.e., panel review, preparation of a summary of safety and effectiveness, and publication of a *Federal Register* notice.

d/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to the 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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
PMA Supplements Received					
PMA Supplements	373	492	410	407	217
Expedited PMA Supplements	0	1	3	3	3
HDEs[a]	0	0	0	0	0
Total	373	493	413	410	220
Filing Decisions[b]					
Filed	1	1	4	6	4
Not Filed	0	0	0	1	1
Number (%) of Filing/Not Filing Decisions within 45 Days	1(100)	1(100)	3(75)	5(71)	4(80)
Average Days/Cycle	45	36	45	45	49
PMA Supplement Final Actions[c]					
Approvals	316	446	377	361	171
Denials	0	0	0	0	0
Other[d]	55	44	31	31	20
Filing to First Action Excluding withdrawals, conversions, etc.[e]					
Number Received and Filed	313	447	380	373	202
Number of First Actions	313	447	378	373	195
Average	147	129	124	88	90
Median	128	115	127	67	75
Number (%) of First Actions within 180 Days[f]	209(67)	328(73)	296(78)	333(89)	173(86)
Filing to First Action Including withdrawals, conversions, etc.[g]					
Number Received and Filed	368	491	413	405	219
Number of First Actions	367	491	411	405	211
Average	155	130	121	91	90
Median	132	114	126	70	84
Number (%) of First Actions within 180 Days[f]	237(64)	361(74)	322(78)	357(88)	187(89)

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Table 5. PMA Supplement Receipt Cohort Performance*
FY 94 - FY 98

(Continued from previous page.)

	FY 94	FY 95	FY 96	FY 97	FY 98
Filing to Final Action Excluding withdrawals, conversions, etc.[h]					
Number Received and Filed	311	445	377	359	176
Number of Final Actions	316	446	377	362	176
Average	186(228)	142(178)	146(181)	97(116)	86(96)
Median	167(183)	120(143)	132(150)	67(76)	56(65)
Number (%) of Final Actions within 180 FDA Days[f]	177(57)	311(70)	259(69)	306(85)	150(85)
Number (%) of Final Actions within 180 Total Days[f]	158(51)	263(59)	236(63)	288(80)	144(82)
Filing to Final Action Including withdrawals, conversions, etc.[i]					
Number Received and Filed	366	488	408	387	190
Number of Final Actions	371	490	408	392	190
Average	192(262)	142(191)	145(192)	100(129)	86(97)
Median	168(193)	119(152)	131(151)	69(91)	59(66)
Number (%) of Final Actions within 180 FDA Days[f]	204(56)	343(70)	283(69)	326(84)	163(86)
Number (%) of Final Actions within 180 Total Days[f]	176(48)	281(58)	249(61)	300(78)	153(81)
Average Number of FDA Cycles from Receipt to Final Action Includling withdrawals, conversions, etc.[c]	1.2	1.1	1.2	1.1	1
Percentile FDA (Total) Days from Filing to First Action[g]					
25th	54	60	57	29	25
50th (Median)	132	114	126	70	84
75th	205	183	179	155	174
90th	322	239	196	181	183
Percentile Total FDA Days from Filing to Final Action[i]					
25th	61(70)	62(71)	63(74)	30(35)	23(25)
50th (Median)	168(193)	119(152)	131(151)	69(91)	59(66)
75th	250(352)	192(250)	186(222)	161(180)	170(175)
90th	388(606)	267(367)	295(407)	204(325)	186(206)

(Continued on next page.)

Table 5. PMA Supplement Receipt Cohort Performance*
FY 94 - FY 98

(Continued from previous page.)

	FY 94	FY 95	FY 96	FY 97	FY 98
Number under review as of 9/30/98					
Active	0	0	2	7	8
Active and Overdue	0	0	0	0	0
On hold[j]	2	3	3	11	21
Total	2	3	5	18	29
Summary of PMA Supplement Receipt Cohort					
Approved	316	446	377	361	171
Denied	0	0	0	0	0
Withdrawn	45	37	25	23	6
Other	10	7	6	8	14
Under Review	0	0	2	7	8
On Hold[j]	2	3	3	11	21
Total	373	493	413	410	220

*/ For each fiscal year, September 30, 1998 was used as the cutoff date. The FY 98 cohort represents only receipts through March 31, 1998 (first six months of the fiscal year).

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 received and filed within the fiscal year. This measure excludes PMA supplements with a final action of withdrawal, conversion, or other final action.

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 received and filed within the fiscal year. This measure includes PMA supplements with any final action including approval, denial, withdrawal, conversion, or other final action.

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

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

Table 6. Original IDEs
FY 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Number Received	171	214	253	297	322
Number of Decisions					
Approved	47	109	171	172	201
Not approved	109	81	63	79	82
Other[a]	18	20	26	21	42
Total	174	210	260	272	325
Percent (%) of Approvals made during first review cycle[b]	30	57[d]	73	69	71
Average FDA Review Time (days)	29	29	28	29	27
Percent (%) of Decisions made within 30 Days	95	92[e]	99	100	100
Number under Review at End of Period[c]	11	15	8	32	29
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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Amendments Received[a]	254	210	219	223	226
Decisions on Amendments					
Approved(%)	109 (43)	106 (50)	98 (45)	101 (46)	94 (42)
Not approved (%)	68 (27)	38 (18)	29 (13)	25 (11)	36 (16)
Other (%)[b]	77 (30)	69 (32)	91 (42)	94 (43)	95 (42)
Total	256	213	218	220	225
Average FDA Review Time (days)	24	22	18	18	19
Percent (%) of Decisions made within 30 Days	97	92[e]	98	100	100
Average Approval Time (days) for IDEs with Amendments					
FDA time	83	70	53	61	55
Non-FDA time	159	162	78	84	35
Total time[c]	242	232	131	145	90
Number of Amendments per Approved IDE	2.3	1.8	1.4	1.8	1.4
Amendments under Review at End of Period[d]	11	8	9	12	13
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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Number Received	3,020	3,171	3,189	3,776	4,277
Number of Decisions	3,070	3,181	3,121	3,777	4,209
Average FDA Review Time (days)	23	22	21	21	21
Percent (%) of Decisions made within 30 Days	98	98	99	100	100
Number under Review at End of Period[a]	160	149	148	216	284
Number Overdue at End of Period	1	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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Number Originals Received	6,434	6,056	5,297	5,049	4,623
Number of Decisions					
Substantially equivalent	5,498	5,594	4,501	4,405	3,824
Not substantially equivalent	135	101	64	57	65
Other[a]	1,502	2,253	998	693	1,340
Total	7,135	7,948	5,563	5,155	5,229
Percent(%) not substantially					
Equivalent[b]	2.4	1.8	1.4	1.3	1.7
Average Review Time (days)					
FDA time[c]	184	137	110	97	89
Total time[d]	216	178	145	130	114
Median Review Time (days)					
FDA time[c]	134	91	85	81	81
Total time[d]	155	102	88	85	83
Percent (%) of Decisions made within 90 Days, based on					
FDA time[e]	45	62	80	95	97
Total time[d]	27	36	50	58	59
Number under Review at End of Period[f]					
Active[g]	2,414	1,486	1,408	1,287	1,057
(Active and overdue)	(460)	(9)	0	0	0
On hold[h]	1,960	964	821	865	487
Total	4,374	2,450	2,229	2,152	1,544

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 94 - FY 98

	FY 94	FY 95	FY 96	FY 97	FY 98
Number of 510(k)s Received[a]					
Traditional	6452	6078	5317	5059	3424
Special	0	0	0	0	32
Abbreviated	0	0	0	0	8
Total Receipts	6452	6078	5317	5059	3464
Actions on 510(k)s					
Substantially Equivalent	4831	4796	4298	4104	2318
Not Substantially Equivalent (%)[b]	101(2)	86(1.8)	58(1.3)	51(1.2)	37(1.6)
Other[c]	1520	1195	948	801	566
Total Actions	6351	5991	5246	4905	2921
Average Cumulative Days for 510(k) Decisions Excludes Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	132	97	93	89	75
Total Time from Receipt to Final Decision[e]	163	125	120	111	86
All Decisions Including Withdrawals and Deletes					
FDA Time from Receipt to Final Decision[d]	127	96	91	87	70
Total Time from Receipt to Final Decision[e]	200	146	149	125	82
Number of Decisions (%) within 90 Days, Based on:					
FDA Days from Receipt to First Action	4414(68)	4934(81)	4997(94)	4960(98)	3447(100)
FDA Cumulative Days from Receipt to Final Decision	2944(46)	3645(60)	3465(65)	3535(70)	2482(72)
Total Cumulative Days from Receipt to Final Decision[e]	2073(32)	2967(49)	2900(55)	3020(60)	2252(65)
Average Number of FDA Cycles from Receipt to Final Action	1.7	1.6	1.5	1.5	1.3
Percentile FDA (Total) Days from Receipt to Final Action					
25th	54(75)	42(50)	51(59)	51(57)	48(51)
50th (Median)	98(151)	80(92)	80(88)	80(86)	78(83)
75th	168(307)	124(194)	115(188)	109(175)	109(156)
90th	262(449)	192(322)	173(332)	174(312)	N/A(N/A)
Number under review as of 9/30/98					
Active	0	0	0	26	237
Active and Overdue	0	0	0	0	0
On hold	0	1	13	77	305
Total	0	1	13	103	542

(Continued on next page.)

Table 10. 510(k) Receipt Cohort Performance*
FY 94 - FY 98

(Continued from previous page.)

Summary of 510(k) Receipt Cohort					
Substantially Equivalent	4831	4796	4298	4104	2318
Not Substantially Equivalent	101	86	58	51	37
Other	1520	1195	948	801	566
Under Review	0	0	0	26	237
On Hold	0	1	13	77	305
TOTAL	6452	6078	5317	5059	3464

* For each fiscal year, September 30, 1998 was used as the cutoff date. The FY98 cohort represents only receipts through June 30, 1998 (first nine months of the fiscal year).

a/ IncludesThird Party 510(k)s: FY97 = 15; FY98 = 15.

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 88 - FY 98

Type of Submission	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998
Orig. PMAs[a]	96	84	79	75	65	40	43	39	44	70	55
PMA Supp.[a]	727	810	660	593	606	395	372	499	415	409	513
Orig. IDEs	268	241	252	213	229	241	171	214	253	297	322
IDE Amend.	316	271	288	283	297	320	254	210	219	223	226
IDE Supp.	3,391	3,038	3,043	3,647	3,644	3,668	3,020	3,171	3,189	3,776	4,277
510(k)s	5,536	7,022	5,831	5,770	6,509	6,288	6,434	6,056	5,297	5,049	4,623
Total	10,334	11,466	10,153	10,581	11,350	10,952	10,293	10,189	9,417	9,824	10,016

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 88 - FY 98

Type of Submission	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998
Orig. PMAs [a]	46	56	47	27	12	24	26	27	43	48	46
PMA Supp. [a]	652	519	700	479	394	354	385	435	462	401	421
Orig. IDEs	260	245	248	220	215	248	174	210	260	272	325
IDE Amend.	327	280	270	287	297	324	256	213	218	220	225
IDE Supp.	3,405	3,023	2,968	3,705	3,469	3,814	3,070	3,181	3,121	3,777	4,209
510(k)s	5,513	6,136	6,197	5,367	4,862	5,073	7,135	7,948	5,563	5,155	5,229
Total	10,203	10,259	10,430	10,085	9,249	9,837	11,045	12,014	9,667	9,873	10,455

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 1998

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 and publish the Notice in the *Federal Register*.

Humanitarian Device Exemptions (HDEs)

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

PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made; for example, changes to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the PMA regulation, changes that affect the safety or effectiveness of the device require FDA premarket approval. FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology. PMA supplements can be as complex as an original application. 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 1998

The following devices were approved via PMAs, PMA Supplements, and HDEs or cleared via 510(k)s during FY98. They represent significant medical breakthroughs because they are first-of-a kind, e.g. they use a new technology or energy source, or, they provide a major diagnostic or therapeutic advancement, such as reducing hospital stays, replacing the need for surgical intervention, reducing the time needed for a diagnostic determination, etc. The information for each device includes the trade name and/or classification name, firm, PMA/510(k) number and date of approval.

Devices Approved via PMA/HDE

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

ACS MULTI-LINK™ Coronary Stent System by Guidant Corp. (P970020, October 2, 1997)

Toronto SPV® Valve by St. Jude Medical, Inc. (P970030, November 24, 1997)

Medtronic FREESTYLE® Aortic Root Bioprosthesis by Medtronic, Inc. (P970031, November 26, 1997)

Spectranetics 12 Fr. Laser Sheath Kit by Spectranetics Corp. (P960042, December 9, 1997)

AVE Micro Stent® II Over-the-wire Coronary Stent System by Arterial Vascular Engineering, Inc. (P970035, December 23, 1997)

Perma-Flow Coronary Bypass Graft Model 2C10 by Possis Medical, Inc. (H970005, April 30, 1998)

Thoratec® Ventricular Assist Device (VAD) System by Thoratec Laboratories Corp. (P870072/S5, May 21, 1998)

SciMed® Radius™ Coronary Stent with Delivery System by SciMed Life Systems, Inc. (P970061, July 16, 1998)

NIR ON™ Ranger™ w/SOX™ NIR ON™ Ranger™ Premounted Stent Systems by Boston Scientific Corp. (P980001, August 11, 1998)

The Heart Laser™ CO2 TMR System by PLC Medical Systems, Inc. (P950015, August 20, 1998)

Possis Perma-Seal® Dialysis Access Graft, Model 2C20 by Possis Medical, Inc. (P980017, September 25, 1998)

Novacor® LVAS by Baxter Healthcare Corp. (P980012, September 29, 1998)

HeartMate® VE LVAS by Thermo Cardiosystems, Inc. (P920014/S7, September 29, 1998)

Division of Clinical Laboratory Devices (DCLD)

Oncor INFORM HER-2/neu Gene Detection System by Oncor, Inc. (P940004, December 30, 1997)

TANDEM® free PSA test by Hybritech, Inc. (P970038, March 10, 1998)

AutoDelfia human alpha-fetoprotein (AFP) Test Kit by WALLAC OY (P970037, March 31, 1998)

SalEst™ System by Biex, Inc. (P970032, April 29, 1998)

AutoPap Primary Screener System by NeoPath, Inc. (P950009/S002, May 5, 1998)

Fetal Fibronectin EIK by Adeza Biomedical (P920048/S002, August 14, 1998)

Hercep Test Immunohistochemistry System by DAKO Corp. (P980018, September 25, 1998)

Division of General and Restorative Devices (DGRD)

Apligraf by Organogenesis, Inc. (P950032, May 22, 1998)

DermaBond by Closure Medical Corp. (P960052, August 26, 1998)

Semi-Constrained PIP Finger Joint Prosthesis by Avanta Orthopaedics, Inc. (H980002, September 28, 1998)

Division of Ophthalmic Devices (DOD)

VISX Excimer Laser System Models "B" and "C" for PRK for High Myopia (0 to -12D) with and without astigmatism (up to -4D) by VISX (P930016/S5, January 29, 1998)

Kremer Excimer Laser System for LASIK by Photomed, Inc. (P970005, July 30, 1998)

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

URO-STIM Bladder Stimulator by Wm. Kaplan, M.D. (H970003, December 16, 1997)

Sahara Clinical Bone Sonometer by Hologic, Inc. (P970017, March 12, 1998)

Excorim® Immunoadsorption System by Cobe BCT, Inc. (H970004, April 6, 1998)

M1000 Imagechecker (Image Analysis System) by R2 Technology, Inc. (P970058, June 26, 1998)

Devices Cleared via 510(k)

DCLD

Platelet Function Analyzer (PFA-100) System by Dade International (K970505, November 17, 1997)

Premier Platinum Heliobacter pylori antigens HPSA Enzyme I in human stool by Meridan Diagnostics, Inc. (K980076, May 12, 1998)

Accu-Chek Voice Mate by Boehringer Mannheim Corp. (K982079, August 28, 1998)

HemaPrompt Over-the-Counter Fecal Occult blood test by Aerscher Diagnostics (K981661, September 15, 1998)

DDIGD

Bridge Sentry Administration Set, Infusion Pump by Bridge Medical, Inc. (K973593, August 25, 1998)

DGRD

Hakin Programmable Valve System by Johnson & Johnson Professionals, Inc. (K974739, July 1, 1998)

DRAERD

FemAssist Urinary Occlusion Device by Insight Medical (K963858, October 21, 1997)

Restore by NEBL , Inc. (K971359, November 14, 1997)

Sterling Diagnostic Imaging Direct Radiography by Sterling Diagnostic Imaging, Inc. (K973206, December 4, 1997)

The Uromed Patch by Uromed, Corporation (K974600, March 31, 1998)

Vocal Cord Medialization System (Vocom Implant) by Smith & Nephew ENT (K974311, March 4, 1998)

Wallstent Enteral Endoprosthesis by Schneider (USA) Inc. (K980113, April 3, 1998)

Neotonus Model 1000 Muscle Simulator System by Neotonus, Inc. (K973096, June 12, 1998

Multiple Use Labeling of Specific Hemodialyzers:

> Cahp High Performance Cellulose Diacetate [Low Flux] by Baxter Healthcare Corp. (K970654, November 12, 1997)

CA Cellulose Acetate Hollow Fiber Dialyzer [Low Flux] (CA-90) by Baxter Healthcare Corp. (K970661, November 12, 1997)

CA Cellulose Acetate Hollow Fiber Dialyzer (CA-170/CA-210) [High Flux] by Baxter Healthcare Corp. (K970653, March 11, 1998)

Fresenius Polysulfone Hemodialyzers, Both Low and High Flux by Fresenius Medical Care North America (K970700, September 15, 1998)

Fresenius' 95 C/1.5 Citric Acid Heat (95°) Processing of Polysulfone Hemodialyzers by Fresenius Medical Care North America (K974090, August 27, 1998)

Altra Flux 200 Hemodialyzer [High Flux] by Althin Medical, Inc. (K970679, July 23, 1998)

Altra Nova 200 Hemodialyzer [High Flux] by Althin Medical, Inc. (K970681, July 23, 1998)

Clirans T-Series Hollow Fiber Dialyzers by Terumo Medical Corporation (K970708, December 19, 1997)

APPENDIX C. ORIGINAL PMA/HDE APPROVALS FOR FISCAL YEAR 1998

02-Oct-97	P970020	Guidant Corp.	ACS MULTI-LINK™ Coronary Stent System
24-Nov-97	P970030	St. Jude Medical, Inc.	Toronto SPV® Valve
26-Nov-97	P970031	Medtronic Cardiac Surgery	Medtronic FREESTYLE® Aortic Root Bioprosthesis
09-Dec-97	P960042	Spectranetics Corp.	Spectranetics 12 Fr. Laser Sheath Kit
12-Dec-97	P970021	Gynecare, Inc.	ThermaChoice Uterine Balloon Therapy (UBT) System
16-Dec-97	H970003	William Kaplan, M.D.	URO-STIM Bladder Stimulator
22-Dec-97	P960036	Mentor Corp.	MemoryLens UV-Absorbing Hydrophilic Posterior Chamber IOL Model U940A
23-Dec-97	P970035	Arterial Vascular Engineering, Inc.	AVE Micro Stent® II Over-the-Wire Coronary Stent System & AVE GFX
30-Dec-97	P940004	Oncor, Inc.	Oncor®Amplitect™ HER/NEU (ERBB2)
29-Jan-98	P960030	Pacesetter, Inc.	Passive Plus DX® Endocardial Steroid Eluting Pacing Lead
30-Jan-98	P970012	Medtronic, Inc.	Medtronic Kappa 400 Series Pacemakers
20-Feb-98	P970052	Cardiovascular Dynamics, Inc.	FACT, ARC, LYNX and Guardian™ Balloon Coronary Dilatation Catheters
10-Mar-98	P970038	Hybritech, Inc.	Tandem®Free PSA Immuno-radiometric Assay
12-Mar-98	P970017	Hologic, Inc.	Sahara Clinical Bone Sonometer
31-Mar-98	P970037	Wallac OY	AutoDelfia HAFP Test Kit
03-Apr-98	P950031	LOBOB Laboratories	LOBOB Contact Lens Cleansing Solution
06-Apr-98	H970004	Cobe BCT, Inc.	EXCORIM Immunoadsorption System
28-Apr-98	P940026	LOBOB Laboratories	LOBOB C/D/S Solution for RGP Contact Lenses
29-Apr-98	P970032	Biex, Inc.	SalEst™System
30-Apr-98	P940025	LOBOB Laboratories	LOBOB W/RW Drop for RGP Contact Lenses
30-Apr-98	H970005	Possis Medical, Inc.	Perma-Flow Coronary Bypass Graft Model 2C10
22-May-98	P950032	Organogenesis, Inc.	Apligraf (Graftskin)
27-May-98	P960057	Gliatech, Inc.	ADCON-L Adhesion Barrier Gel
29-May-98	P970026	Myriad Ultrasound Systems, Ltd.	SoundScan
29-May-98	P970044	Dornier Medical Systems, Inc.	Dornier Urowave Microwave Thermotherapy System
24-Jun-98	P970062	BMT, Inc.	Genestone 190 Lithotripter
25-Jun-98	P970051	Cochlear Corp.	Nucleus 24 Cochlear Implant System
26-Jun-98	P970040	Lunar Corp.	Achilles & Ultrasonometer
26-Jun-98	P970058	R2 Technology, Inc.	M1000 ImageChecker
16-Jul-98	P960011	Bio-Technology General Corp.	BioLon 1% Sodium Hyaluronate Viscoelastic Surgical Aid Fluid
16-Jul-98	P960018	Healthcare Products Plus, Inc.	Needlyzer – the Needle Destroyer Model ND2
16-Jul-98	P970061	SciMed Life Systems, Inc.	SciMed® Radius™ Coronary Stent with Delivery System
30-Jul-98	P970005	Photomed, Inc.	Kremer Excimer Laser System for LASIK
06-Aug-98	P980015	Biomedical Disposal, Inc.	Sharpx Needle Destruction Unit
11-Aug-98	P980001	Boston Scientific Corp.	NIR ON™ Ranger™ Premounted Stent Systems
12-Aug-98	P960034	Pharmacia & Upjohn Co.	CeeOn Heparin Surface Modified Ultraviolet-Absorbing PMMA Posterior Chamber Intraocular Lens
19-Aug-98	P970024	Angeion Corp.	Angeion® Sentinel™ Implantable Cardioverter Defibrillator
20-Aug-98	P950015	PLC Medical Systems, Inc.	The Heart Laser™ CO2 TMR System
26-Aug-98	P960052	Closure Medical Corp.	DermaBond
25-Sep-98	P970034	Ophthalmic Innovations International, Inc.	Ultraviolet-Absorbing PMMA Posterior Chamber IOLs
25-Sep-98	P980017	Possis Medical, Inc.	Perma-Seal® Dialysis Access Graft Model 2C20
25-Sep-98	P980018	DAKO Corp.	DAKO Hercep Test
25-Sep-98	P980025	Logicon RDA	Logicon Caries Detector
28-Sep-98	H980002	Avanta Orthopaedics, Inc.	Proximal Interphalangeal (PIP) Finger Joint
29-Sep-98	P980009	Schneider (USA) Inc.	Magic WALLSTENT® Endoprothesis
29-Sep-98	P980012	Baxter Healthcare Corp.	Novacor® LVAS

APPENDIX D. ODE GUIDANCE DOCUMENTS
Fiscal Year 1998

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

Note: Guidance documents followed by "(FDAMA)" were issued as part of the CDRH implementation of the Food and Drug Administration Modernization Act of 1997.

Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages (October 10, 1997)

IDE Policies and Procedures (January 20, 1998) (FDAMA)

Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies (February 19, 1998) (FDAMA)

Early Collaboration Meetings Under the FDA Modernization Act (February 19, 1998) (FDAMA)

30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes (February 19, 1998) (FDAMA)

Determination of Intended Use for 510(k) Devices (February 19, 1998) (FDAMA)

Procedures for Class II Device Exemptions from Premarket Notification (February 19, 1998) (FDAMA)

New Section 513(f)(2) – Evaluation of Automatic Class III Designation (February 19, 1998) (FDAMA)

Guidance on the Recognition and Use of Consensus Standards (February 19, 1998) (FDAMA)

Bioresearch Monitoring Agreement for PMAs and PDPs (February 23, 1998)

Guidance on Amended Procedures for Advisory Panel Meetings (March 20, 1998) (FDAMA)

PMA/510(k) Expedited Review (March 20, 1998) (FDAMA)

The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalent in Premarket Notifications (March 20, 1998)

Division of Cardiovascular, Respiratory, and Neurological Devices

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 28, 1998)

Guidance for Off-the-Shelf Software Use in Medical Devices, Draft Guidance, (June 20, 1997) Notice of Availability in FR, August 17, 1998

Division of Clinical Laboratory Devices

Guidance for Submission of Immunohistochemistry Applications to the FDA (June 3, 1998)

Division of Dental, Infection Control, and General Hospital Devices

Guidance Document for Washers and Washer-Disinfectants Intended for Processing Reusable Medical Devices (June 2, 1998)

Dental Impression Materials Premarket Notification (August 17, 1998)

OTC Denture Cushions, Pads, Reliners, Repair Kits and Partially Fabricated Denture Kits (August 18, 1998)

Dental Cements Premarket Notification (August 18, 1998)

Division of General and Restorative Devices

Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses (April 28, 1998)

Guidance Document for Surgical Lamp 510(k)s (July 13, 1998)

Division of Ophthalmic Devices (DOD)

Intraocular Lens (IOL) Guidance Document (draft) issued October 10, 1997 and updated April 17, 1998

Retinoscope Guidance (July 8, 1998)

Slit Lamp Guidance (July 8, 1998)

Ophthalmoscope Guidance (July 8, 1998)

Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear (August 11, 1998)

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

Tympanostomy Tubes Submission Guidance for a 510(k) Premarket Notification (January 14, 1998)

Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents (February 5, 1998)

Uniform Contraceptive Labeling: Guidance to Industry Level 2 Guidance (July 23, 1998)

Latex Condoms for Men - Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions Level 2 Guidance (July 23, 1998)

Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers (August 7, 1998)

Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems (August 7, 1998)

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

Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants and High Level Disinfectants (December 18, 1997)

Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products (February 13, 1998)

Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator (BGS) Devices (March 18, 1998)

Guidance on the Content and Format of Premarket Notification 510(k) Submissions of Washers and Washer-Disinfectors (June 2, 1998)

Guidance for Industry In-Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic Chloride Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic Creatinine Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic Glucose Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic Potassium Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic Sodium Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic Urea Nitrogen Test System (July 6, 1998)

Guidance for Industry In-Vitro Diagnostic C-Reactive Protein Immunological Test System (July 20, 1998)

Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures (Guidance for Industry, FDA Reviewer/Staff and Compliance) (July 24, 1998)

Guidance for Industry In-Vitro Diagnostic Calibrators (July 29, 1998)

APPENDIX E. ODE PUBLICATIONS
Fiscal Year 1998

The following is a bibliography of articles and abstracts prepared by the ODE staff and published or presented during FY98.

Journal, Newsletter Articles and Book Chapter

Arepalli, S.R., Jones, E.P., Howcroft, T.K., Carlo, I., Wang, C-R., Lindahl, K.F., Singer, D.S., and Rudikoff, S. Characterization of Two Class I Genes from the H2-M Region: Evidence for a New Subfamily. *Immunogenetics*, 47:264-271, 1998.

Deane, J.S., Hall, A.B., Thompson, J.R., and Rosenthal, A.R. Prevalence of Lenticular Abnormalities in a Population-Based Study: Oxford Clinical Cataract Grading in the Melton Eye Study. *Ophthalmic Epidemio*l, 4:195-206, 1997.

Demian, H.W. and McDermott, K. Regulatory Perspective on Characterization and Testing of Orthopedic Bone Cements. *Biomaterials*, 19:1607-1618, 1998.

Gutman, S., Richter, K., and Alpert, S. Update on FDA Regulation of In Vitro Diagnostic Devices. *JAMA*, 280(2):190-192, 1998.

Hall, A.B., Thompson, J.R., Deane, J.S., and Rosenthal, A.R. LOCSIII Versus the Oxford Clinical Cataract Classification and Grading System for the Assessment of Nuclear, Cortical and Posterior Subcapsular Cataract. *Ophthalmic Epidemiol*, 4:179-194, 1997.

Kessler, L. and Richter, K. Technology Assessment of Medical Devices at the Center for Devices and Radiological Health. *Am. J. of Managed Care*, 4:SP129-SP138, 1998.

Phillips, R. Medical Radiation Standards. *In* Handbook of Health Physics and Radiological Health, Third Edition, 1998.

Provost, M.C. FDA Regulation of Water Purification Systems for Hemodialysis. *AAMI Dialysis Monograph Series*, 1998.

Thompson, J.R., Deane, J.S., Hall, A.B., and Rosenthal, A.R. Associations between Lens Features Assessed in the Oxford Clinical Cataract Classification and Grading System. *Ophthalmic Epidemiol*, 4:207-212, 1997.

Abstracts

Chadwick, D., Chenault, V.M., Carter, E.R., and Herman, E. Cardiovascular and Hemodynamic Parameters in an Animal Model of Diabetes: Psammomys Obesus (Sand Rat). FDA/Sigma Xi Science Forum, NIH, Bethesda, MD, December 8-9, 1997.

Chenault, V.M., Ediger, M.N., Durkin, A.J., Waynant, R.W., and Ansaris, R.R. Spectroscopic Detection of Ocular Pathologies in a Nutritionally Induced Animal Model of Diabetes. FDA/Sigma Xi Science Forum, NIH, Bethesda, MD, December 8-9, 1997.

Harvey, B.E., and Alpert, S. Regulatory Policy and Computer Assisted Imaging Technologies: "Virtual Endoscopy" 1998 FDA Update. Medicine Meets Virtual Reality, San Diego, CA, January 28-31, 1998.

Kues, H.A., D'Anna, S.A., Osiander, R., Green, W.R., and Monahan, J.C. Absence of Ocular Effects in the Rabbit and Non-Human Primate from Single or Repeated 60 GHz CW Exposure at 10 mW/cm2. Bioelectromagnetic Society Annual Meeting, Tampa, FL, June 7-11, 1998.

Vadlamudi, S., Turkeltaub, P., Fugate, K., Kaczmarek, R., and Noah, C. Correlation Studies of In-Vitro IgE to the Skin Test Reaction: the Third NHANES Survey and a CRADA Study. FDA/Sigma Xi Science Forum, NIH, Bethesda, MD, December 8-9, 1997.

APPENDIX F. ODE ORGANIZATIONAL CHART

(As of 5/99)

Office of Device Evaluation

Office of the Director

Director: Susan Alpert, Ph.D., MD
Dep. Dir., Science & Regulatory Policy: Philip J. Phillips
Dep. Dir., Clinical & Review Policy: Kimber C. Richter, MD
Integrity Officer: Carl T. DeMarco, J.D.
Panel Coordinator: Nancy Pluhowski

Program Operations Staff

Director: Robert Gatling

PMA Section: Kathy Poneleit
IDE Section: Joanne Less, Ph.D.
510(k) Section: Heather Rosecrans

Program Management Office

Director: Kathryn Appler

Management Services Section: Lesa Dowtin
Office of Automation System & Support Section: Jeff Jaeger

Division of Cardiovascular, Respiratory, and Neurological Devices

Director: Thomas Callahan, Ph.D.

Deputy Director: Vacant
Associate Director, Guidance & Policy: Arthur Ciarkowski
Clinical Trials Coordinator: Wolf Sapirstein, MD

Program Management/Special Review Branch: Vacant
Interventional Cardiology Devices Branch: Chris Sloan
Circulatory Support & Prosthetic Devices Branch: Bette Lemperle
Pacing and Neurological Devices Branch: Donna-Bea Tillman, Ph.D.
Anesthesiology & Defibrillator Devices Branch: Vacant

Division of Reproductive, Abdominal, ENT, and Radiological Devices

Director: Daniel Schultz, MD*

Associate Director, OB/GYN & G/U Devices: Vacant
Obstetrics/Gynecology Devices Branch: Colin Pollard
Urology & Lithotripsy Devices Branch: Donald St. Pierre
Gastroenterology & Renal Devices Branch: Carolyn Neuland, Ph.D.

Associate Director, ENT & Radiological Devices: Dave Segerson
Conventional & Therapeutic Radiation Devices Branch: Vacant
Computed Imaging Devices Branch: Robert Phillips, Ph.D.

Division of Clincal Laboratory Devices (Pilot Organization)

Director: Steven Gutman, MD

Coordinator 510(k) Program: Kaiser Aziz, Ph.D.*
Coordinator PMA Program: Joseph Hackett, Ph.D.*

Microbiology Branch: Woody Dubois, Ph.D.
Clinical Chemistry Branch: Jean Cooper, DVM
Immunology Branch: Peter Maxim, Ph.D.

Division of Dental, Infection Control, and General Hostpital Devices

Director: Timothy Ulatowski

Infection Control Devices Branch: Chiu Lin, Ph.D.
Dental Devices Branch: Susan Runner, DDS
General Hospital Devices Branch: Patricia Cricenti

Division of General and Restorative Devices

Director: Celia Witten, Ph.D., MD

Deputy Director: James Dillard

Plastic & Reconstructive Surgery Devices Branch: Stephen Rhodes
General Surgery Devices Branch: Neil Ogden
Orthopedic Devices Branch: Mark Melkerson
Restorative Devices Branch: Russell Pagano, Ph.D.

Division of Ophthalmic Devices

Director: A. Ralph Rosenthal, MD

Deputy Director: Nancy Brogdon
Associate Director: David Whipple

Vitreorentinal & Extraocular Devices Branch: James Saviola, OD
Diagnostic & Surgical Devices Branch: Morris Waxler, Ph.D.
Intraocular & Corneal Implants Branch: Donna Lochner
Ear, Nose & Throat Devices Branch: Harry Sauberman

*Acting

APPENDIX G. ODE STAFF ROSTER

Fiscal Year 1998

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Spyker, Dan
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Tillman, Donna-Bea
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Wang, Emil
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Fox, Pat
Fuller, Janie
Hibbard, Viola
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Mayhall, Elaine
Mills, George
Nakayama, Von
Naveau, Irene
O'Connell, Linh
O'Lone, Martha
Robinson, Mary Jo
Runner, Susan
Samuels-Reid, Joy
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Smith, Gwen
Soprey, Pandu
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DeLuca, Bob
Demian, Hany
Dillard, Jim
Durfor, Charles
Einberg, Elmar
Eudy, Mike
Felten, Richard
Fogarty, Pauline
Foy, Keith
Gantt, Gail
Glass, Jerilyn
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Hinckley, Steve
Horbowyj, Roxi
Hudson, Peter
Jan, George
Kaiser, Aric
Keith, Erin
Kim, Sam
Krause, David
Lee, Kevin
Mattamal, George
McDermott, Ken
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Mishra, Nirmal
Morris, Janine
Munzner, Bob
Nairn, Beth
Nashman, Jodi
Nightengale, Stephen
Niver, Samie
Ogden, Neil
Pagano, Russell
Panitch, Orlee
Phillips, Mary Ellen
Rhodes, Holly
Rhodes, Stephen
Schroeder, Marie
Scudiero, Jan
Sloan, Nadine
Sternchak, Dick
Stevens, Ted
Sung, Pei

Torres-Cabassa, Angel
Townsend, Barbara
Tudor, Natalie
Vinson, Priscilla
Watson, Tony
Weiblinger, Rick
Williams, Berry
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Wolf, Beverly
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Burns, Adrienne
Callaway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Linda
Drum, Bruce
Eydelman, Malvina
Falls, Deborah
Felton, Eleanor
Gelles, Muriel
Gomez-Novoa, Carmelina
Gouge, Susan
Greer, W. Anthony
Hoang, Quynh
Jones, Susanna
Kaufman, Daryl
Krawczyk, Claudine
Lepri, Bernard
Leslie, Sharmeka
Lochner, Donna
McCarthy, Denis
Moore, Shirley
Nicholas, Marsha
Romanell, Jake
Rosenthal, Ralph
Saviola. James
Shih, Ming-Chuen
Smith, Myra
Storer, Patricia
Thornton, Sara
Usher, Wil
Warburton, Karen
Waxler, Morris
Whipple, David
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Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices

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Baxley, John
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Chen, John
Cooper, Jeff
Cornelius, Mary Jo
Cygnarowicz, Teresa
Dart, Linda
Daws-Kopp, Kathryn
Doyle, Bob
Eba, Felissa
Fredericksen, Jane
Gammell, Paul
Gonzalez, Gema
Harvey, Brian
Harvey, Elisa
*Henter, Thomas
Herrera, Hector
Jaffee, Sydney
Jasper, Susan
Jevtich, Milorad
Kammula, Raju
Kang, Andrew
*Kasnner, Julian
Kuchinski, Mike
Mallis, Elias
Malshet, Vasant
McCool, Barbara
McGee, Leah
Miller, Linda
Miller, Pat
Monahan, Jack

Neuland, Carolyn
Nimmagadda, Rao
Nutter, Cathy
Olvey, Kathleen
Pak, Yung
Perez, Rod
Phillips, Bob
Pollard, Colin
Provost, Miriam
Relacion, Cheryl
Rubendall, Rita
Sauberman, Harry
Sauls, Mattie
Schultz, Dan
Segerson, Dave
Seiler, Jim
Sharpe, Skip
Shuping, Ralph
Smith, Ernest
St. Pierre, Don
Tsai, Miin-Rong
Virmani, Mridulika
Warren, Jim
Williams, Dick
Williams, Eugene
Wolanski, Nicole
Yin, Lillian
Zaremba, Loren
Zaudtke, Peter

- Summer Student
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