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Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

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MEDICAL DEVICE RECALLS

Examination of Selected Cases

GAO/PEMD-90-6

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Program Evaluation and
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The Honorable Henry Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

As you requested, this report contains our additional descriptive analyses and profiles of two types of medical device recalls, based on the data we collected for our August 1989 report entitled Medical Device Recalls: An Overview and Analysis 1983-88 (GAO/PEMD-89-15BR). In that report, we provided information on the overall numbers and selected characteristics of all recalls that were initiated during the 1983-88 study period. Appendix I of this report contains further background information and a description of our study's objectives, scope, and methodology.

In appendices II and III, we have included the results of our further analyses of two types of recall: (1) those that involved medical devices approved for marketing by the Food and Drug Administration (FDA) through its premarket approval (PMA) process and recalled for some type of design problem (hereafter referred to as PMA-design recalls) and (2) those that FDA classified as the most serious according to health risk (class I).

Our medical device recall profiles include product and manufacturer identification, the nature of the problem for which the device was recalled, the health consequences of the device problem, and a description of the recall. (See appendices IV and V.)

Results in Brief

In our additional analyses and profile development, we found that there were 28 PMA-design and 48 class I recalls. Six recalls fell into both groups, and taken together, the two categories accounted for 70, or 4 percent, of the universe of recalls (1,635) initiated during fiscal years 1983 through 1988. Although they are a relatively small proportion of the total, these two types of recall are probably among the most important from a public health perspective. This is so because devices involved in PMA-design recalls were determined to be unlike any other devices currently on the market or were assigned by FDA to the highest risk category (class 3) and then passed through FDA's most stringent

review of evidence pertaining to their safety and effectiveness. And, class I recalls are reserved for those situations in which there is the greatest likelihood that the death of a patient or other serious adverse health consequence could occur because of a device problem.

The most frequent causes of PMA-design recalls were failure of the device to perform during use as reliably as expected and failure of the original process design to achieve its intended results. Design problems were also the most frequent reason for initiating class I recalls. There were no actual adverse health consequences associated with the majority of PMA-design recalls or with 42 percent of the class I recalls. However, about one third of the PMA-design recalls and over half the class I recalls were associated with at least one patient's injury or death. FDA's computerized recall data bases, which were the basis of this report, were not designed to store and aggregate all the available information about a particular recall. They do not include the total number of patient injuries and deaths associated with the product. Therefore, we could not determine whether the data entry indicating "at least one injury or death" was an accurate indicator of the overall adverse health consequences of these recalls.

There is no requirement that device manufacturers notify FDA of recalls, and we found that in many cases the agency was not aware of the recall until after it had started or even until it had been completed. FDA was notified of 42 percent of PMA-design recalls either after they had started or only after they had been completed. Similarly, the agency learned of many class I recalls (44 percent) after they had been initiated. In nearly half of the cases, FDA learned of both PMA-design and class I recalls from a source other than the manufacturer. The other sources included device users, competitors, and FDA inspections. FDA did not formally request that manufacturers initiate any of the recalls in this study; all were recorded as having been voluntarily initiated by manufacturers.

Additionally, we found that reports of device problems, as prescribed in the medical device reporting regulation, had not been filed on the devices involved in 64 percent of the PMA-design recalls or nearly half the class I recalls at the time of FDA's evaluation of the potential health hazard of the device problem and determination of the appropriate classification of the recall.

Issues for Future Study

The data contained in this report suggest the need for additional study in this area to focus on potential vulnerabilities in FDA's medical device premarketing approval and recall processes. The facts presented here lead to questions about the number of device recalls that remain unknown to FDA and about the timeliness of those recall actions taken by FDA and device manufacturers that originate in either biennial good manufacturing practices inspections or in the irregularly scheduled inspections conducted for other purposes. They also call into question the effectiveness of the medical device reporting (MDR) regulation as an "early warning" of medical device problems that may lead to recalls, given that nearly two thirds of PMA-design and almost half of the class I recalls did not have an MDR report associated with them when critical FDA decisions about the recall were being made.

It was beyond the scope of this study to review and assess the underlying structures, procedures, and overall operations of either the medical device premarket approval or recall system. Such an assessment would provide the broader context for viewing the recalls presented in this report and in our earlier briefing report.[1] However, the nature and content of the data bases that were the source for this analysis permit only a descriptive overview of recalls.

A more complete understanding of the structure and processes involved in the medical device recall system and of the implications of its operation in particular cases could be gained by selecting a sample of recalls and reviewing them in depth, making use of FDA's detailed case history files and additional data collected from device manufacturers and users. We will examine such a sample of recalls in a subsequent study. A careful sample selection process in such a study could provide insights into how the recall process operates for various types of devices and thus a basis for interpreting the descriptive overview developed in this report.

As you requested, we obtained informal, oral comments from FDA officials. Their comments were primarily technical, and we revised our draft to take account of them as appropriate. As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after the issue date. At that time, we will send copies to the secretary of Health and Human Services and the director of the Center for Devices and Radiological Health, and to other interested parties upon request.

[1]See U.S. General Accounting Office, Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR (Washington, D.C.: August 1989).

If you have any questions or would like additional information, please call me at (202) 275-1854 or Dr. Michael J. Wargo, Director of Program Evaluation in Physical Systems Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix VI.

Sincerely yours,

Eleanor Chelimsky
Assistant Comptroller General

Contents

Tables

Abbreviations

CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
GAO	General Accounting Office
MDR	Medical device reporting (regulation)
PMA	Premarket approval

Background, Objectives, Scope, and Methodology

Background

Each day thousands of individual medical devices are used in the diagnosis and treatment of illness and injury.[1] The Food and Drug Administration (FDA)—which is authorized to regulate medical devices during all phases of their development, testing, production, distribution, and use—recognizes more than 1,600 different types of medical devices. They represent an industry of more than $14 billion in sales annually.

Recent decades have seen massive changes in the variety and complexity of medical devices: greater dependence on technology for most aspects of medical diagnosis, therapy, and care of the ill; and a phenomenal rise in automation. Radical treatments now involve plastic, metallic and electronic implants. Health care professionals must now choose among medical devices, many of which lack product standardization, become rapidly obsolete, or malfunction in ways that defy detection until a patient has been injured thereby.

FDA uses two principal systems to assure the safety and effectiveness of medical devices. The first, premarketing review, is a system of checks, reviews, and approval requirements that are applied before a device is made available to the public.[2] The second, postmarketing surveillance, is a monitoring system designed to provide an "early warning" of problems associated with the devices after they are in general use.[3] We examined the implementation of one element of the postmarketing surveillance system, the medical device reporting (MDR) regulation, in a previous report.[4] The MDR regulation, which went into effect on December

[1]The term "medical device" is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act of 1938 (as amended by the Medical Device Amendments of 1976) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is recognized in the official National Formulary or the U.S. Pharmacopeia or any supplement to them; that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or intended to affect the structure or any function of the human body or bodies of other animals; and that does not achieve any of its principal intended purposes through chemical action within or on the body and does not depend upon being metabolized in order to achieve any of its principal intended purposes. The effect of the 1976 amendments was to enlarge the 1938 definition to include devices intended for use in diagnosis of conditions other than diseases (such as pregnancy), in vitro diagnostic products, and specific products previously regulated as new drugs, including soft contact lenses, bone cements, and sutures.

[2]See U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14 (Washington, D.C.: August 1988) for a more detailed discussion of FDA's premarketing review system.

[3]See U.S. General Accounting Office, Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting, GAO/PEMD-87-1 (Washington, D.C.: December 1986) for a more detailed discussion of FDA's postmarketing surveillance activities.

[4]See U.S. General Accounting Office, Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989).

13, 1984, requires that a problem report be submitted to FDA whenever manufacturers or importers of medical devices become aware of information that reasonably suggests that one of their devices may have caused or contributed to serious injury or death, or that the device has malfunctioned and, if the malfunction recurs, is likely to cause or contribute to a serious injury or death.

Medical device recalls constitute a second element of the postmarketing surveillance system. If a product exhibits a problem after it has been made available for general use, or if empirical data on postmarketing use (including MDR reports) indicate that a problem's rate of occurrence exceeds an expected range, one of the remedial actions available to the device's manufacturer is to recall the product or remove it from the market.[5] FDA has no authority under the Federal Food, Drug, and Cosmetic Act, as amended, or any other laws it administers to order a manufacturer to recall a product without a court order, but the agency may request a recall. In practice, the overwhelming majority of recalls are voluntarily initiated by the manufacturer, with FDA oversight.[6]

At the request of the chairman of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, we conducted a review and analysis of those medical device recalls known to FDA that were initiated in fiscal years 1983 through 1988.[7] The results of this review are contained in our report entitled Medical Device Recalls: An Overview and Analysis 1983-88 (GAO/PEMD-89-15BR).

In response to this earlier report, the chairman requested that we provide the Subcommittee with a follow-up report containing additional information about two specific types of medical device recall: (1) recalls of devices approved for marketing through FDA's premarket approval (PMA) process but subsequently recalled because of design problems

[5]In addition to employing the term "recall" to refer to the removal of a device from the market or its return to the manufacturer for repair, FDA also uses the word to denote field repairs, hazard warnings, the correction of labeling or promotional materials that the agency considers to be in violation of the laws it administers, and other situations.

[6]See U.S. General Accounting Office, Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR (Washington, D.C.: August 1989), for a more detailed discussion of FDA's recall-related authority and further background information.

[7]Because there is no statutory or regulatory requirement that manufacturers report recalls to FDA, some corrective actions taken by manufacturers that would be classified as recalls by FDA may remain unknown to the agency, and consequently would not be included in the totals derived from FDA's records.

(hereafter referred to as PMA-design recalls) and (2) class I (the most serious) recalls.

These two subsets of all the possible types of recalls were selected by the Subcommittee because of the characteristics of the PMA-design recalls and the seriousness of the potential health consequences associated with class I recalls. The statutory requirement for "well controlled investigations" or other "valid scientific evidence" of a device's safety and effectiveness is an integral part of the premarket approval process.[8] It is therefore of special interest when a device with a premarket approval is recalled on account of a problem attributed to its design.[9] Class I recalls are of interest because they are the most serious in FDA's three-level classification of recalls, a system based on the potential health and safety risks posed by the device problem.[10]

During fiscal years 1983 through 1988, there were 28 recalls in the PMA-design category, and there were 48 class I recalls. Six of the 28 PMA-design recalls were judged by FDA to involve health risks serious enough to warrant classification as class I, so the two sets of recalls that are the subject of this report overlap to this extent. Together the two categories accounted for 70, or 4 percent, of the 1635 total recalls initiated from fiscal year 1983 through fiscal year 1988.

Objectives, Scope, and Methodology

For each PMA-design and class I recall, our principal objectives were

- to identify the recalled product and its manufacturer;
- to describe the nature of the problem for which the device was recalled;
- to identify the health consequences of the device problem; and
- to provide a description of the recall (its date, magnitude, and other characteristics).

We have also provided statistical summaries of the two categories of recalls and discussed some possible implications of their characteristics.

[8]Appendix II contains further discussion of the premarket approval process.

[9]Design is one of nine categories used by FDA analysts to classify the causes of device problems identified by manufacturers. See appendix II of this report and our earlier report entitled Medical Device Recalls: An Overview and Analysis 1983-88, pp. 22-23, for a detailed discussion of FDA's device-problem causal attribution system.

[10]See appendix III for a more detailed discussion of FDA's recall classification criteria.

The information on which this report is based was derived from the integration of two automated data bases maintained at the Center for Devices and Radiological Health (CDRH). They are called the "recall" and "problem" data bases and were set up to track recall processing at CDRH. These data also permit analysis of the causes of device problems; however, they are not the primary recall records. FDA officials stated that the complete history of each recall is contained only in archived paper and microfiche files maintained by CDRH. A systematic review of these files was beyond the scope of this study. We will examine a sample of the records in a subsequent study.

FDA provided us with a computer tape that contained information on recalls initiated during fiscal years 1983 through 1988. We did not independently verify the information contained on the data tape or evaluate the internal controls of the computer systems that produced the tape. We did, however, examine extreme entries, deleted some that were logically impossible, and corrected a number of other data-entry errors in consultation with FDA staff. For example, we found a number of cases in which important information about the recall (such as whether an injury or death had occurred) was missing from the tape. And, in some other cases, the stored data were contradictory or unclear. (For example, in one case, a narrative data field indicated that "numerous deaths" had been reported, but the data field for health consequences contained the code for "at least one patient injury.") When CDRH analysts were able to provide documentation of the data-entry errors, we corrected the information on the data tape.[11]

Our analysis was conducted during the months of June and July 1989, using the frequency and cross-tabulation procedures of the Statistical Analysis System, and was performed in accordance with generally accepted government auditing standards.

[11] The data tape that FDA provided to us contained records for 41 recalls that fell into the PMA-design category. However, as this report was being prepared for publication, CDRH staff discovered systematic errors in one of their data bases. Thirteen recalls were found not to have involved a premarket-approved device as the data base had indicated. Our correction of these errors reduced the PMA-design category to 28 recalls.

Descriptive Analysis of Medical Device Recalls of Premarket-Approved Devices 1983-88

The Premarket Approval Process

Premarket approval (PMA) of a device is required in order to market a medical device when the general controls authorized by the Federal Food, Drug, and Cosmetic Act, as amended, are insufficient to ensure safety and effectiveness, when information does not exist to establish a performance standard, and when the device supports life, prevents health impairment, or potentially presents an unreasonable risk of illness or injury.[1] Premarket-approved devices include complex drug-delivery systems, life-supporting prostheses, and sophisticated electronic devices for controlling, modifying, and performing essential physiological functions. PMA is granted on the basis of "well controlled investigations" or other "valid scientific evidence" that supports the device manufacturer's or importer's claim that its device is safe and effective.

In a related study, we reported that available statistics on original PMA applications and approvals showed that over the past seven years, PMA applications have ranged between 60 and 97 per year and approvals between 24 and 72 per year. A total of 323 applications were approved between 1976 and 1986. In addition, FDA received almost 2,400 PMA application "supplements" between 1980 and 1986, and roughly 1,900 (79 percent) of these were approved. Although PMA devices represent a relatively small proportion of the medical devices entering the marketplace, PMA devices have special importance because they have passed through what is intended to be FDA's most stringent review of evidence pertaining to the device's safety and effectiveness.[2] Thus, when one of these devices must be recalled for a problem attributed to its design, that recall may have important implications for the PMA process.

FDA's review of PMA applications has three major steps: (1) administrative review to determine whether the application includes all the required information and is otherwise suitable for filing, (2) scientific

[1]See U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14 (Washington, D.C.: August 1988), pp. 35-39, for a more detailed discussion of the premarket approval process.

[2]Since 1976, premarket notification as prescribed in section 510(k) of the amendments has been the predominant route to commercial distribution for medical devices. Section 510(k) of the amendments requires that device manufacturers (1) notify FDA at least ninety days before marketing a new device, (2) provide their preliminary judgment concerning the class that the device belongs in and the basis for that assessment, and (3) describe the actions they have taken to comply with the applicable performance standards (section 514) or premarket approval (section 515) provisions of the amendments. Section 510(k) does not explicitly require FDA to review the manufacturer's judgment concerning classification of the device. Nor does it require the manufacturer to refrain from marketing for more than 90 days if FDA has not made a determination. In our earlier study entitled Medical Devices: FDA's 510(k) Operations Could Be Improved, pp. 22-23, we reported that during the previous seven years there was an average of 5,000 510(k) or premarket notification applications annually, with an 85 percent approval rate.

and regulatory review by scientific and compliance personnel, and (3) review and recommendation by an advisory committee composed of experts from the medical and other relevant academic fields.

The administrative review is the "gatekeeper" that assures FDA of having a complete application before the device is put through the scientific and regulatory review of the manufacturer's claim that the device is safe and effective. For this latter step, the regulations set forth standards of scientific evidence that the agency must apply. The review may be based on controlled studies and investigations, objective trials without matched controls, documented case histories conducted by qualified experts, reports of significant experience (such as the results of research conducted in foreign countries), or any combination of these forms of evidence.

For devices that have been approved for marketing through this route and are later changed or made to deviate from the conditions described in the original approval, manufacturers must obtain FDA's approval of a "supplemental" premarket application describing the changes and showing that the changed device remains safe and effective. Supplements are required for, among other things, adding a new indication for use, using a new principle of operation, and adding a color additive that comes in contact with the body for a significant period of time.

In spite of the requirements of the premarketing notification and approval processes, it is impossible to identify and solve all of the potential problems that a device may experience once it is in general use, and some of the problems that occur while a device is in use lead to a decision to recall the product. Based on the experience of FDA's Center for Devices and Radiological Health (CDRH) analysts, FDA developed a nine-category scheme for the common causes of device problems that lead to recalls. These include: (1) design, (2) production control, (3) component control, (4) expiration dating and Radiation Control for Health and Safety Act violations, (5) change control, (6) training, (7) misbranding, (8) no premarket approval, and (9) other.[3] Most recalls are assigned to one of the classes by CDRH analysts after reviewing narrative statements, provided by the manufacturer, about the cause of the device problem.

[3]See Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR (Washington, D.C.: August 1989), pp. 22-23, for a detailed definition and discussion of other causal classes and examples of each.

In our earlier analysis of recalls, we found that a problem with product design was the most frequent overall cause of medical device recalls, accounting for 44 percent of the 1,635 recalls that occurred between fiscal years 1983 and 1988.[4] FDA further divided the "design" category as a cause of device problems into seven subcategories. These subcategories are shown in table II.1.[5]

[4]See Medical Device Recalls: An Overview and Analysis 1983-1988, pp. 23-24.

[5]FDA officials said that they do not regard all seven of the subcategories as referring to kinds of problems that might reasonably be expected to be prevented by the premarket approval process. They identified categories D1, D2, and D5 (labeled respectively "device design," "component design/selection," and "software design") as most relevant to the PMA process.

Table II.1: FDA's Classification of the Causes of Medical Device Design Problems

Code	Category	Definition	Examples
D1	Device design	The finished device does not perform as reliably as expected during use although it meets the approved original design specifications, is not adversely affected by the manufacturing process or use of a defective component or material, and is properly used according to its labeling	(1) Tubal occlusion clips repeatedly fell off the clip applicator into the patient due to poor design of the applicator head; (2) the physical location of a ventilator switch resulted in the ventilator being accidentally shut off; and (3) the coating on slides in a test kit peeled due to humidity
D2	Component design/selection	Components/materials selected designed for an application do not perform as reliably as expected although they meet the original or modified specification and are not adversely affected by the manufacturing process	(1) The plastic raw material used in a female luer lock did not have sufficient strength and cracked under use; (2) a preservative used in an in vitro diagnostic broke down when subjected to high temperature, diluting the diagnostic medium; and (3) a flexible rubber component used in a preset magnetic valve allowed the magnets to shift, resulting in preset condition change
D3	Packaging design/selection	The packaging does not properly serve its intended function although it is manufactured as designed and is not adversely affected by the manufacturing process	(1) Packaging for a sterile device could not be adequately sealed because of the adhesive composition; (2) a test kit was adversely affected during shipment due to freezing because it was not adequately protected against warehouse conditions; and (3) the outer wrapper of condoms allowed the lubricant to dry out
D4	Labeling design	Labeling does not contain information required by labeling regulations (21 CFR 801 & 21 CFR 809.10)	Labeling was unacceptable because it lacked name and address of manufacturer and other required information was missing
D5	Software design (device), including firmware	The software does not adequately perform its intended function although the program is written and prepared as designed	(1) Pacemaker programmer allowed pacemaker to be programmed into an incorrect configuration; (2) the algorithm did not accurately convert pressure signal to readings at low pressures
D6	Software design (manufacturing process)	The original process software does not adequately perform its intended function although the program is written, prepared, and implemented as designed	Lack of software validation led to labeling of contact lenses with incorrect expiration dates
D7	Process design	Implementation of the original process design does not achieve its intended results, adversely affecting the product or resulting in conditions that could have an adverse effect on health	(1) Lack of packaging controls to assure sealed device compromised sterility of a urethral catheter; (2) inadequate welding procedures, validation, and stress testing led to strut failures of heart valves

Source: CDRH, FDA, "Problem/Cause/Solution: Code Directory."

Descriptive Analysis

Between fiscal years 1983 and 1988, there was a total of 28 medical device recalls involving devices that had entered the market via FDA's PMA process and were subsequently recalled because of a design problem (PMA-design recalls). For example, a manufacturer obtained a PMA for a heart valve and later received information suggesting that something about the design of the valve might be causing it to fracture after it had been implanted. When the manufacturer recalled the valve, this constituted a PMA-design recall. These types of recall represent approximately 2 percent of all the device recalls that FDA learned of during those years. This appendix contains a summary of information about premarket-approved medical devices recalled because of design problems. Appendix IV presents a case-by-case profile of this information.

Fiscal year 1987 saw the largest number of PMA-design recalls, 8, which were 29 percent of the total number of such recalls during the years 1983-88. Table II.2 shows the complete distribution of PMA-design recalls over these fiscal years.

Table II.2: PMA-Design Recalls, Fiscal Years 1983-88

Fiscal year	No. of recalls	Percent
1983	4	14%
1984	2	7
1985	6	21
1986	5	18
1987	8	29
1988	3	11
Total	**28**	**100%**

Source: FDA recall data tape

The majority of PMA-design recalls (18, or 64 percent) were designated by FDA as class II (medium serious).[6] Of the remaining 10 recalls, 6 were class I (most serious) and 4 were class III (least serious), as indicated in table II.3.

[6]See appendix III for a detailed explanation of the three recall classes.

Table II.3: PMA-Design Recalls by Recall Class, Fiscal Years 1983-88

Recall class	No. of recalls	Percent[a]
I (most serious)	6	21%
II (medium serious)	18	64
III (least serious)	4	14
Total	**28**	**100%**

[a]Percentages do not total 100 because of rounding.

Source: FDA recall data tape.

Two of FDA's three device classes were represented among the PMA-design recalls.[7] As would be expected, because all class 3 (high-risk) devices require premarket approval, most PMA-design recalls (25, or 89 percent) were associated with class 3 devices. As indicated in table II.4, class 2 devices were associated with 3, or 11 percent, of the recalls.

Table II.4: PMA-Design Recalls by Device Class, Fiscal Years 1983-88

Device class	No. of recalls	Percent
2 (medium risk)	3	11%
3 (high risk)	25	89
Total	**28**	**100%**

Source: FDA recall data tape

Eight of the 19 medical specialties used by FDA in device classification were represented among PMA-design recalls.[8] Devices falling within the cardiovascular-specialty classification were the type of device most frequently involved in PMA-design recalls, with 11, or 39 percent. As table II.5 shows, devices falling within the ophthalmology specialty accounted for 6, or 21 percent; the anesthesiology and gastroenterology, urology specialties followed, with each accounting for 3, or 11 percent, of the recalls. No other medical specialty accounted for more than 7 percent of the PMA-design recalls.

[7]The 1976 Amendments created a three-tiered system in which devices would be classified and regulated by FDA according to their potential health risk, with class 1 devices presenting the least risk and class 3 devices the most. It is important to remember that the potential degree of health risk associated with recall classes is designated in a descending order from class I to class III, and the risk of device classes is designated in an ascending order from class 1 to class 3. Therefore, classes I and 1 have opposite meanings for recall and device classes. See Medical Device Recalls: An Overview and Analysis 1983-88, p. 15, for a more detailed explanation of the criteria for device classification and appendix III of this report for a discussion of recall classification.

[8]FDA's 19 medical specialties are anesthesiology; cardiovascular; chemistry; dental; ear, nose, and throat; gastroenterology and urology; general hospital; general and plastic surgery; hematology; immunology; microbiology; neurology; obstetrics and gynecology; ophthalmology; orthopedic; pathology; physical medicine; radiology; and toxicology.

Table II.5: PMA-Design Recalls by Medical Specialty, Fiscal Years 1983-88

Medical specialty	No. of recalls	Percent[a]
Cardiovascular	11	39%
Ophthalmology	6	21
Anesthesiology	3	11
Gastroenterology, urology	3	11
General and plastic surgery	2	7
Immunology	1	4
Neurology	1	4
Orthopedics	1	4
Total	**28**	**100%**

[a]Percentages do not total 100 because of rounding.

Source: FDA recall data tape

As indicated in table II.6, there were two subcategories of design problem that most often resulted in a PMA-design recall. In the first, some element of a device's design caused the finished device not to perform as reliably as intended. This type of design problem accounted for 8, or 29 percent, of the PMA-design recalls. In the second—which also accounted for 8, or 29 percent, of the PMA-design recalls—the implementation of the original process design did not achieve its intended results. In addition, faulty component design or selection was responsible for 6, or 21 percent, of the recalls. Finally, there were three PMA-design recalls in which a device's software did not perform its intended function adequately—even though the program was written, prepared, and implemented as designed.

Table II.6 PMA-Design Recalls by Specific Design Problem Categories, Fiscal Years 1983-88

Category	No. of recalls	Percent[a]
Device design	8	29%
Process design	8	29
Component design/ selection	6	21
Software design (device)	3	11
Packaging design/ selection	1	4
Labeling design	1	4
Software design (manufacturing)	1	4
Total	**28**	**100%**

[a]Percentages do not total 100 because of rounding.

Source: FDA recall data tape

As the data in table II.7 indicate, FDA was notified or became aware of PMA-design recalls prior to their initiation in 11 cases, or 58 percent of the time. In the remainder of the cases, FDA learned of the recalls after they had started or were already over.[9] In over half the cases (57 percent), FDA learned of the existence of the recall from the device manufacturer. (See table II.8.) However, in nearly one third of the cases, FDA discovered the recall or was informed that it would take place during one of its inspections of a manufacturer—for example, during one of its biennial good manufacturing practices or MDR inspections. In the remaining cases, FDA was notified of the recall by a device user or a competitor.[10]

Table II.7: When FDA Learned About PMA-Design Recalls, Fiscal Years 1983-88

When FDA learned about recall	No. of recalls[a]	Percent[b]
Before recall	11	58%
During recall	6	32
After recall	2	11
Total	**19**	**100%**

[a]Data were missing in 9, or 32 percent, of the 28 PMA-design recall cases.

[b]These percentages are based on the 19 recalls for which data were present. Percentages do not total 100 because of rounding.

Source: FDA recall data tape

Table II.8: How FDA Learned of PMA-Design Recalls, Fiscal Years 1983-88

How FDA learned of recall	No. of recalls[a]	Percent[b]
Notified by firm	12	57%
FDA inspection	16	29
Notified by user	2	10
Notified by competitor	1	5
Total	**21**	**100%**

[a]Data on how FDA learned of a recall were missing or listed as "N/A" in 7, or 25 percent, of the 28 PMA-design recall cases.

[b]These percentages are based on the 21 recalls in which the source of notification was indicated. Percentages do not total 100 because of rounding.

Source: FDA recall data tape

[9]Data on when FDA was notified or became aware of PMA-design recalls were missing in 9 cases. These percentages are based on the 19 cases for which data were present.

[10]Data on how FDA learned of a recall were missing or listed as "N/A" in 7, or 25 percent, of the 28 PMA-design recall cases. These percentages are based on the 21 recalls in which the source of notification was indicated.

Manufacturers are not required by statute to notify FDA about recalls, but the reporting requirements of the MDR regulation appear to require MDR reports on events that are serious enough to warrant any class I and at least some class II recalls.[11] MDR did not, however, appear to serve FDA as a very effective "early warning" of the device problems leading to PMA-design recalls. Sixty-four percent of the PMA-design recalls initiated during the years since the MDR regulation went into effect did not have an MDR report associated with them at the time that FDA evaluated the health hazard of the device problem prompting the recall. (See table II.9.)

Table II.9: PMA-Design Recalls With and Without MDR Reports, Fiscal Years 1985-88

No. of MDR reports	No. of recalls[a]	Percent
At least one	8	36%
None	14	64
Total	**22**	**100%**

[a]MDR report data were missing in 6, or 22 percent, of the 28 PMA-design recall cases.
Source: FDA recall data tape

The data in table II.10 show that there were no adverse health consequences associated with the majority (19, or 68 percent) of the PMA-design recalls. The four PMA-design recalls that were associated with the death of a patient all involved replacement heart valves. Five of the 28 recalls (18 percent) were associated with a patient injury.

Table II.10: Adverse Health Consequences Associated With PMA-Design Recalls, Fiscal Years 1983-88

Reported health consequence	No. of recalls	Percent
Patient death	4	14%
Patient injury	5	18
No deaths or injuries reported	19	68
Total	**28**	**100%**

Source: FDA recall data tape

[11]See our report entitled Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD 89-10 (Washington, D.C.: February 1989), pp. 14-15, for a detailed explanation of the reporting requirements.

Descriptive Analysis of Class I Medical Device Recalls

Introduction

FDA has established three regulatory classes of recalls: class I, class II, and class III.[1] Our focus in this appendix is the class I recall. The basis for a class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (as when, for example, an implantable cardiac pacemaker is recalled because its batteries are failing prematurely).

This class of recall is labeled "most serious," in contrast to the situation in class II where FDA has determined that the use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or that the probability of serious health consequences is remote, and in contrast to class III, where the use of, or exposure to, the product is not believed likely to cause adverse health consequences.

This appendix presents the relevant findings from our earlier report that were related to class I medical device recalls.[2] It also contains additional descriptive analysis of the class I recalls included in the case-by-case profiles presented in appendix V.

Descriptive Analysis

In our earlier study of medical device recalls, we determined that FDA learned of a total of 1,635 recalls from fiscal year 1983 through fiscal year 1988.[3] Of that total, 48 (or 3 percent) were class I recalls. Class I recalls occurred in eight of FDA's 19 medical practice specialties. As expected, we found that devices with highest risks for a patient injury (that is, class 3 devices) were more likely to be among the most serious recalls (that is, class I), while devices with the lowest risk (that is, class 1) were more likely to be included among the least serious class of recalls (that is, class III). However, nearly two-thirds of class I recalls (65 percent) were associated with medium-risk class 2 devices—that is,

[1] 21 CFR 7.3. See Federal Register, 43 (June 16, 1978), p. 26218.

[2] See U.S. General Accounting Office, Medical Device Recalls: An Overview and Analysis 1983-1988, GAO/PEMD-89-15BR (Washington, D.C.: August 1989), pp. 15-17.

[3] See Medical Device Recalls: An Overview and Analysis 1983-1988, p. 12.

those which require performance standards to ensure their safety and effectiveness.[4]

There was a positive relationship between the recall class and the existence of an MDR report—that is, the more serious the level of the recall, the more likely it was that an MDR report was associated with the device problem. Nonetheless, only 16, or 52 percent, of the class I recalls had a report associated with them at the time FDA evaluated the health hazard posed by the device problem which prompted the recall. Generally, devices that entered the market through the PMA process were more likely to be associated with a class I recall than with either of the two other classes of recall. In contrast, recalls of devices without PMAs were most often placed in class II. This tendency of PMA-device recalls to be placed in class I is not surprising, because some of the same factors that led to the requirement for premarket approval of a device would also be likely to cause its recall to be placed in class I. These factors include consideration of whether the device is either a life-supporting prosthesis or a complex, sophisticated electronic device used in controlling, modifying, or performing essential physiological functions.

A further analysis of the data indicated that the majority of these recalls (29, or 60 percent) occurred because of some type of design problem. (See table III.1.) Problems involving production controls—that is, the execution of the manufacturing plan or the actual implementation of equipment and procedures—accounted for 19 percent of these recalls. Problems with component controls—that is, the use of nonconforming or contaminated components in the manufacturing process—resulted in 5, or 10 percent, of the class I recalls.

[4]In a previous study, we reported that no performance standards had yet been developed under the procedures detailed in the 1976 Amendments and that the failure to develop such performance standards resulted in medium-risk devices under premarketing review being treated in the same manner as the relatively innocuous low-risk devices. We note that the development of such standards would not necessarily have prevented the devices from being recalled. See U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14 (Washington, D.C.: August 1988), pp. 32-34.

Table III.1: Causes of Problems Leading to Class I Medical Device Recalls, Fiscal Years 1983-88

Category	No. of recalls	Percent[a]
Design	29	60%
Production control	9	19
Component control	5	10
Change control	2	4
Employee error	1	2
No PMA	1	2
Other	1	2
Total	**48**	**100%**

[a]Percentages do not total 100 because of rounding.

Source: FDA recall data tape

As in the PMA-design recall situation, FDA became aware of the class I recalls before they were initiated in more than half the cases. (See table III.2.) The agency learned of 18, or 44 percent, of the class I recalls after they had started.[5] However, in contrast to the PMA-design recall situation, FDA learned about all of the class I recalls before they had been completed.

Table III.2: When FDA Learned About Class I Recalls, Fiscal Years 1983-88

When FDA learned about recall	No. of recalls[a]	Percent[b]
Before recall	23	56%
During recall	18	44
After recall	0	0
Total	**41**	**100%**

[a]Information on the timing of FDA s notification was missing in 7, or 15 percent, of the 48 class I recall cases.

[b]These percentages are based on the 41 cases for which the data were available.

Source: FDA recall data type

Because FDA's inspections of device manufacturers during the six years of our study period did not uncover any completed recalls serious enough to be placed in class I, it might be argued that few of these most serious recalls are likely to have remained unknown to FDA. There is, however, no statutory requirement that device manufacturers notify FDA of recalls, and some corrective actions by manufacturers serious enough to be labeled class I recalls did remain unknown to FDA until it learned of them during an inspection or was informed of them by a

[5]Information on the timing of FDA's notification was missing in 7, or 15 percent, of the 48 class I recall cases. These percentages are based on the 41 cases for which the data were available.

device user or one of the manufacturer's competitors. As shown in table III.3, FDA was notified of class I recalls by the manufacturer in 23, or 58 percent of the cases, which is similar to the percentage of PMA-design recalls where FDA was informed by the manufacturer. In 17, or 43 percent, of the cases, FDA learned of the recall from some other source. In 10 of these cases, or 25 percent of the class I recalls, FDA learned of the recall through an agency inspection.[6]

Table III.3: How FDA Learned About Class I Recalls, Fiscal Years 1983-88

How FDA learned about recall	No. of recalls[a]	Percent[b]
Notified by firm	23	58%
FDA inspection	10	25
Notified by user	6	15
Notified by competitor	1	3
Total	**40**	**100%**

[a]Information on the source of notification was missing or listed as "N/A" in 8, or 17 percent, of the 48 class I recalls.

[b]These percentages are based on the 40 cases for which the source of the recall notification was indicated. Percentages do not total 100 because of rounding.

Source: FDA recall data tape

The proportion of class I recalls that involved the occurrence of an adverse health consequence (that is, the injury or death of a patient) was greater than that for PMA-design recalls. (See table III.4.) This outcome was to be expected since PMA-design recalls are dispersed among all three recall classes, whereas only class I recalls are based on "a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." At least one death was associated with 17, or 35 percent, of the 48 class I recalls; 11, or 23 percent of these recalls, were associated with at least one injury. In the 20 cases that did not involve an injury or death, the potential for such adverse health consequences was nevertheless present in view of the fact that these cases were classified as class I recalls.

[6]The source was missing or listed as "N/A" in 8, or 17 percent, of the 48 class I recall cases. These percentages are based on the 40 class I recalls for which the source of the recall notification was indicated.

Table III.4: Adverse Health Consequences Associated With Class I Recalls, Fiscal Years 1983-88

Reported health consequence	No. of recalls	Percent
Patient injury	11	23%
Patient death	17	35
No deaths or injuries reported	20	42
Total	**48**	**100%**

Source: FDA recall data tape.

Profiles of Medical Device Recalls Involving Premarket Approved Devices Recalled Because of a Design Problem 1983-88

Case number: 1

Product Identification

Description:	Vena cava occluder
Device class:	2
Medical specialty:	Cardiovascular
Brand:	*
Use:	Occludes the vena cava, to prevent passage of thromboemboli
Manufacturer:	Concept, Inc., Clearwater, FL

Problem

Description:	Blocked venogram port prohibited entry of X-ray dye
Cause:	Incomplete drilling of handle during manufacture (D7)[a]
Health consequences:	No deaths or injuries reported

Recall Description

Date:	12/14/82
Recall class:	III
Quantity recalled (units):	147 units
Who notified FDA of recall?:	*
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	U0373

Case number: 2

Product Identification

Description:	Transcutaneous gas monitor
Device class:	2
Medical specialty:	Anesthesiology
Brand:	*
Use:	Monitors gases in newborns
Manufacturer:	Novametrix Medical Systems, Wallingford, CT

Problem

Description:	Electrodes overheat, causing burns to skin
Cause:	Corrosion of electrical contacts in thermistor circuitry (D2)
Health consequences:	Patient injury

Recall Description

Date:	11/15/82
Recall class:	II
Quantity recalled (units):	1,443 units
Who notified FDA of recall?:	User
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z0504

*Missing or not clearly indicated on the FDA recall data tape.

Case number: 3

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	*
Use:	Replaces natural or prosthetic heart valve
Manufacturer:	Shiley, Inc., Irvine, CA

Problem

Description:	Strut failure
Cause:	Inadequate welding, validation, and stress testing procedures (D7)
Health consequences:	Patient death

Recall Description

Date:	06/06/83
Recall class:	I
Quantity recalled (units):	5,770 valves
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	*
FDA control number:	U1523

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Case number: 4

Product Identification

Description	Test kit
Device class:	2
Medical specialty:	Immunology
Brand:	Quantitope AFP Test Kit
Use:	Used as a control
Manufacturer:	Kallestad Labs, Chaska, MN

Problem

Description:	Misbranded
Cause:	Product distributed with a label which said "FDA approved" (D4)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	07/07/83
Recall class:	III
Quantity recalled (units):	150 kits
Who notified FDA of recall?:	Firm
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	U1883

Case number: 5

Product Identification

Description:	Replacement aortic valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Bjork-Shiley Convexo-Concave 60-Degree Cardiac Valve Prosthesis
Use:	Replaces natural or prosthetic heart valve
Manufacturer:	Shiley, Inc., Irvine, CA

Problem

Description:	Strut failure
Cause:	Inadequate welding, validation, and stress testing procedures (D7)
Health consequences:	Patient death

Recall Description

Date:	07/06/83
Recall class:	I
Quantity recalled (units):	7,400 valves
Who notified FDA of recall?:	Firm
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	U2183

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Case number: 6

Product Identification

Description:	Absorbable mesh for surgical use
Device class:	3
Medical specialty:	General and plastic surgery
Brand:	Vicryl
Use:	Clamps blood vessels closed during surgery
Manufacturer:	Ethicon, Inc., Somerville, NJ

Problem

Description:	Possible non-sterility
Cause:	Product was stored in desiccant paper for a prolonged period before sterilization, resulting in loss of moisture (D7)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	11/07/83
Recall class:	II
Quantity recalled (units):	682
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z0174

Case number: 7

Product Identification

Description:	Implantable cardiac pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	*
Use:	Regulates cardiac rate and rhythm
Manufacturer:	Cordis Corp., Miami, FL

Problem

Description:	Early battery failure
Cause:	Pacemakers stressed by being subjected to temperatures above 115 degrees C. during gas analysis for moisture content; written quality control test inadequate and not validated (D7)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	10/04/84
Recall class:	II
Quantity recalled (units):	192 pacemakers
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z0595

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Case number: 8

Product Identification

Description:	External cardiac pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Cordis Brand Chronscor III
Use:	High-rate atrial pacing
Manufacturer:	Cordis Corp., Miami, FL

Problem

Description:	Switch intermittently shorts components, resulting in pacing rate 5 times the programmed rate
Cause:	Components selected and their arrangement were inadequate for the device's design (D1)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	06/11/85
Recall class:	II
Quantity recalled (units):	4 pacemakers
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z5755

Case number: 9

Product Identification

Description:	Microprocessor analyzer
Device class:	3
Medical specialty:	Anesthesiology
Brand:	Microprocessor Based Analyzer
Use:	Lead testing of implantable pacemaker
Manufacturer:	Seamed Corporation, Redmond, WA

Problem

Description:	Inaccurate test results if used when the batteries were low or depleting
Cause:	The low-battery warning scheme in the software did not provide sufficient warning of battery depletion (D5)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	05/07/85
Recall class:	II
Quantity recalled (units):	57 units
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z3605

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Case number: 10

Product Identification

Description:	Accessories to contact lenses
Device class:	3
Medical specialty:	Ophthalmology
Brand:	Aqua Pure, CVS, Brooks
Use:	Sterilization of contact lenses
Manufacturer:	Sadler Wells, Inc., Lackawanna, NY

Problem

Description:	Product was not packaged under aseptic conditions or in accordance with good manufacturing practices
Cause:	Firm was unaware that the product is a medical device and failed to obtain PMA or manufacture according to good manufacturing practices (D7)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	04/05/85
Recall class:	II
Quantity recalled (units):	1,500 cases
Who notified FDA of recall?:	Competitor
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z3485

Case number: 11

Product Identification

Description:	Plasma separator module
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	Fenwal PS-400 Plasma Separator Model
Use:	Separation of plasma
Manufacturer:	Travenol Labs, Inc., Savage, MD

Problem

Description:	Inaccurate scale readouts may result in patient fluid imbalance
Cause:	Voltage drop that may occur on the 5-volt DC supply to the scale circuitry, which is aggravated if the 5-volt regulator is at the low end of its tolerance specification (D1)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	05/09/85
Recall class:	II
Quantity recalled (units):	28
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z3615

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Case number: 12

Product Identification

Description:	Contact lens accessories (distilled water)
Device class:	3
Medical specialty:	Ophthalmology
Brand:	*
Use:	Maintenance of contact lenses
Manufacturer:	Albany Laboratories, Inc., Albany, NY

Problem

Description:	Product was contaminated with pseudomonas aeruginosa, an ophthalmic pathogen
Cause:	No PMA; product produced without good manufacturing practices (D7)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	08/20/85
Recall class:	II
Quantity recalled (units):	*
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z5215

Case number: 13

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Bjork-Shiley Cardiac Valve Prosthesis 600 (Mitral and Aortic)
Use:	Replaces natural or prosthetic heart valve
Manufacturer:	Shiley, Inc., Irvine, CA

Problem

Description:	Strut of the valves may fracture
Cause:	Firm developed larger valves, having had minimal failure with small valves; strut failures began shortly after (D1)
Health consequences:	Patient death

Recall Description

Date:	10/14/85
Recall class:	I
Quantity recalled (units):	2,752 valves
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z1536

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Case number: 14

Product Identification

Description:	Cardiac pulse generator
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Programmalith III
Use:	Regulates cardiac rate and rhythm
Manufacturer:	Pacesetter Systems, Inc., Sylmar, CA

Problem

Description:	Loss of function and telemetry capability due to temperature sensitivity of circuits
Cause:	Combination of resistance and amplifier gain in oscillator creates abnormal sensitivity to temperature
Health consequences:	Patient injury

Recall Description

Date:	09/04/85
Recall class:	I
Quantity recalled (units):	690 pacemakers
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z1246

Case number: 15

Product Identification

Description:	Patient monitor: arrythmia detector and alarm
Device class:	3
Medical specialty:	Cardiovascular
Brand:	H-P Adult Monitors, Models 78353B and 78354A
Use:	Measures various body parameters
Manufacturer:	Hewlett-Packard Co., Waltham, MA

Problem

Description:	Potential for all patient alarms to be indefinitely suspended
Cause:	Software error (D5)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	04/22/86
Recall class:	II
Quantity recalled (units):	4061
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z6296

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Case number: 16

Product Identification

Description:	Intraocular lens accessories (cannula)
Device class:	3
Medical specialty:	Ophthalmology
Brand:	Bailey Lens Shooter/Cannula
Use:	Facilitates the implantation of intraocular lenses
Manufacturer:	Pacific Device, Inc., San Diego, CA

Problem

Description:	Rust on the exterior, and the tip of the shaft could dislodge inside the eye
Cause:	The stainless steel selected for the cannula was not corrosion resistant (D2)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	01/21/86
Recall class:	II
Quantity recalled (units):	441
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z4106

Case number: 17

Product Identification

Description:	Intraocular lens
Device class:	3
Medical specialty:	Ophthalmology
Brand:	Surgidev Slyte 63 Anterior Chamber Intraocular Lens
Use:	Replaces lens of human eye
Manufacturer:	Surgidev Corp., Goleta, CA

Problem

Description:	High occurrence of postoperative hyphemia
Cause:	Design; could also be operative technique (D1)
Health consequences	Patient injury

Recall Description

Date:	03/12/86
Recall class:	II
Quantity recalled (units):	*
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z6016

==========

Case number: 18

Product Identification

Description:	Chromic surgical suture
Device class:	3
Medical specialty:	General and plastic surgery
Brand:	Soft Gut (Cat Gut) Suture
Use:	Used in closing wounds in humans and animals
Manufacturer:	Davis and Geck, American Cyanamid, Danbury, CT

Problem

Description:	Untying of knots caused wound separation
Cause:	Specific reason for knot insecurity not identified, probably a material selection problem (D2)
Health consequences:	Patient injury

Recall Description

Date:	08/13/86
Recall class:	II
Quantity recalled (units):	97 cartons
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	After recall
MDR report?:	Yes
FDA control number:	Z0077

Case number: 19

Product Identification

Description:	Implantable bone growth stimulator
Device class:	3
Medical specialty:	Orthopedics
Brand:	Ostrogen
Use:	Stimulates bone growth
Manufacturer:	BGS Medical Corp., Milwaukee, WI

Problem

Description:	The plastic trays in which the products are wrapped have high electrostatic potential and may cause stimulators to fail by stressing the integrated circuits
Cause:	Packaging of product caused electrical overstress; problem located in the wash and pack process (D7)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	08/14/86
Recall class:	II
Quantity recalled (units):	540 units
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	Yes
FDA control number:	Z0047

==========

Case number: 20

Product Identification

Description:	Prescription daily and extended wear contact lenses
Device class:	3
Medical specialty:	Ophthalmology
Brand:	CSI (Crofilcom) (A) Daily and Extended Wear
Use:	Correction of vision
Manufacturer:	Sola-Suntax Ophthalmics, Phoenix, AZ

Problem

Description:	Through a computer error, many lenses labeled with incorrect expiration dates
Cause:	Lack of software validation (D6)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	12/01/86
Recall class:	III
Quantity recalled (units):	3,000
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z1567

Case number: 21

Product Identification

Description:	Electronic memory cartridge for pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Intermedics Pacemaker Program Module, Electronic Memory
Use:	Obtains data from Intermedics programmable pulse generator
Manufacturer:	Intermedics, Inc., Freeport, TX

Problem

Description:	"High" lead impedance may be displayed, instead of the actual measured lead impedance
Cause:	Displayed a "high" lead impedance when used with Cosmos and Nova pulse generators, for lead impedances over 600 ohms (D5)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	09/25/86
Recall class:	III
Quantity recalled (units):	1,099 units
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z1307

Case number: 22

Product Identification

Description:	Automatic/implantable cardioverter defibrillator[b]
Device class:	3
Medical specialty:	Cardiovascular
Brand:	AICD Model AIDB or AID-BR
Use:	Tests ventricular tachycardia and fibrillation
Manufacturer:	Cardiac Pacemakers, St. Paul, MN

Problem

Description:	Electrical failure
Cause:	Failure in 50 ohm internal resistors manufactured with shorter and smaller diameter internal wire; may cause failure of internal fuse, totally disabling device (D2)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	02/02/87
Recall class:	II
Quantity recalled (units):	319
Who notified FDA of recall:	Firm
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z2307

Case number: 23

Product Identification

Description:	Ophthalmic saline solution
Device class:	3
Medical specialty:	Ophthalmology
Brand:	Alcon Saline Solution for Sensitive Eyes
Use:	Rinsing, storing, and disinfecting daily and extended wear contact lenses
Manufacturer:	Alcon Laboratories, Inc., Fort Worth, TX

Problem

Description:	Product contaminated with toluene and xylene
Cause:	Product contaminated due to absorption of solvent or exposure to vapors (D3)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	11/21/86
Recall class:	II
Quantity recalled (units):	219 bottles
Who notified FDA of recall?:	User
When FDA learned of recall:	Before recall
MDR report:	*
FDA control number:	Z2217

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Case number: 24

Product Identification

Description:	Unipolar and Bipolar programmable single chamber heart pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Teletronics 10 mm Optima-MPT Pacemaker
Use:	Regulates cardiac rate and rhythm
Manufacturer:	Teletronics, Inc., Lane Cove, NSW [Foreign]

Problem

Description:	Sudden no-output failure mode caused by "tin whiskers"
Cause:	Growth of "whiskers" from silver or tin-copper compounds used in the diode (D2)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	03/19/87
Recall class:	I
Quantity recalled (units):	3,727
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	Yes
FDA control number:	Z3457

Case number: 25

Product Identification

Description:	Kidney lithotripter electrode
Device class:	3
Medical specialty:	Gastroenterology, urology
Brand:	Dornier 700 and 900
Use	Provides ultrasonic shockwaves for fragmenting renal stones
Manufacturer:	Dornier Medizintechnik, Germering [Foreign]

Problem

Description:	Epoxy that holds locking mechanism to the electrode may fail, altering focus position
Cause:	Age or storage conditions of epoxy (D2)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	05/22/87
Recall class:	II
Quantity recalled (units):	673
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z4777

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Case number: 26

Product Identification

Description:	Neodynium YAG laser
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Optilase 1000 YAG Laser System
Use:	Used for laser delivery in peripheral vascular use
Manufacturer:	Trimedyne, Inc., Santa Ana, CA

Problem

Description:	Noncompliance with performance standard for laser products
Cause:	Laser discharged without requiring fiber to be in fiber optic part or pressure on foot switch; beam attenuator and safety interlock do not comply with requirements of standard (D1)
Health consequences:	No deaths or injuries reported

Recall Description

Date:	12/09/87
Recall class:	II
Quantity recalled (units):	18 units
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z1178

Case number: 27

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Edwards Duromedics Aortic Bileaflet Valve, Model 3160
Use:	Replaces natural or prosthetic heart valve
Manufacturer:	Hemex Scientific, Austin, TX

Problem

Description:	Defective valves due to leaflet escape
Cause:	Firm has been unable to determine why the valves are failing (D1)
Health consequences:	Patient death

Recall Description

Date:	06/13/88
Recall class:	I
Quantity recalled (units):	26,000
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	Yes
FDA control number:	Z4648

Case number: 28

Product Identification

Description:	Kidney lithotripter
Device class:	3
Medical specialty:	Gastroenterology, urology
Brand:	Dornier Kidney Lithotripter
Use:	Disintegrates kidney stones with shockwaves through a water medium
Manufacturer:	Dornier Medizintecknik GMBH, Germering [Foreign]

Problem

Description:	Patient burns
Cause:	Product design allows patient contact with cushion lamp for extended period of time (D1)
Health consequences:	Patient injury

Recall Description

Date:	06/17/88
Recall class:	II
Quantity recalled (units):	10
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z5258

[a]Cause codes in parentheses are explained in table 2.1.

[b]Some recalls were listed in the FDA data base as being of "defibrillators" and others as of "defibrillator batteries." Because some of the former also appear to concern battery problems and because there has been controversy over the accuracy of FDA's descriptions of recalls (see Biomedical Safety and Standards, 19:7 (April 1, 1989), pp. 50-51), we have listed all such recalls as being of "defibrillators." However, this should also be understood to cover cases in which only battery packs or other components were recalled.

Source: FDA recall data tape.

Profiles of Class I Medical Device Recalls 1983-88

Case number: 1

Product Identification

Description:	Bypass valve (hemodialysis machine)
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	*
Use:	Used in an artificial kidney machine for treatment of patients with renal failure
Premarketing approval?:	No
Manufacturer:	Extracorporeal, Inc., Pinella's Park, FL

Problem

Description:	Valve failed to go into bypass mode
Cause:	Residual magnetism in armature and yoke assembly of valve
Health consequences:	Patient injury

Recall Description

Recall date:	09/17/82
Quantity recalled (units):	3,215 valves
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	U0123

==========

Case number: 2

Product Identification

Description:	Carbon dioxide absorber
Device class:	2
Medical specialty:	Anesthesiology
Brand:	*
Use:	*
Premarketing approval?:	No
Manufacturer:	Ohmeda, Inc., Madison, WI

Problem

Description:	Exhalation port to breathing bag blocked and activation of oxygen flush valve prevented
Cause:	Disc occluded exhalation valve
Health consequences:	Patient death

Recall Description

Recall date:	04/08/83
Quantity recalled (units):	74,000 units
Who notified FDA of recall?:	*
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	U1443

*Missing or not clearly indicated on the FDA recall data tape

Case number: 3

Product Identification

Description:	Intraocular lens
Device class:	3
Medical specialty:	Ophthalmology
Brand:	*
Use:	Replaces lens of human eye
Premarketing approval?:	No
Manufacturer:	Intermedics Intraocular, Inc., Pasadena, CA

Problem

Description:	Nonsterility
Cause:	Product sterilized in a case for which sterilization process had not been validated
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	06/07/83
Quantity recalled (units):	980 lenses
Who notified FDA of recall?:	*
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	U1743

==========

Case number: 4

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Bjork-Shiley Convexo-Concave Heart Valve
Use:	Replaces natural or prosthetic heart valve
Premarketing approval?:	Yes
Manufacturer:	Shiley, Inc., Irvine, CA

Problem

Description:	Strut failure
Cause:	Inadequate welding, validation, and stress testing procedures
Health consequences:	Patient death

Recall Description

Recall date:	06/06/83
Quantity recalled (units):	5,770 valves
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	*
FDA control number:	U1523

Case number: 5

Product Identification

Description:	Anesthesia machine
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Foregger 710 and 705
Use:	Administers anesthetic agents to induce general anesthesia during surgery
Premarketing approval?:	*
Manufacturer:	Puritan Bennett, Kansas City, MO

Problem

Description:	Sticking spool valves, resulting in excessive or inadequate anesthesia delivery
Cause:	In switching from one mode to another, valve can become partially or fully stuck and not go into the specified mode
Health consequences:	Patient death

Recall Description

Recall date:	07/18/83
Quantity recalled (units):	733 units
Who notified FDA of recall?:	*
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	U2043

==========

Case number: 6

Product Identification

Description:	Catheter
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	*
Use:	Provides temporary vascular access for hemodialysis in acute renal failure
Premarketing approval?:	No
Manufacturer:	Cobe Labs, Lakewood, CO

Problem

Description:	Nonsterility
Cause:	Lot released for shipment without undergoing sterilization
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	06/24/83
Quantity recalled (units):	840 catheters
Who notified FDA of recall?:	Firm
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	U1813

Case number: 7

Product Identification

Description:	Replacement aortic valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Bjork-Shiley Convexo-Concave 60-Degree Cardiac Valve Prosthesis
Use:	Replaces natural or prosthetic heart valve
Premarketing approval?:	Yes
Manufacturer:	Shiley, Inc., Irvine, CA

Problem

Description:	Strut failure
Cause:	Inadequate welding, validation, and stress testing procedures
Health consequences:	Patient death

Recall Description

Date:	07/06/83
Recall class:	I
Quantity recalled (units):	7,400 valves
Who notified FDA of recall?:	Firm
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	U2183

==========

Case number: 8

Product Identification

Description:	Dialysis unit
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	*
Use:	Recirculation in kidneys for patients with kidney failure
Premarketing approval?:	No
Manufacturer:	Extracorporeal, Inc., Pinella's Park, FL

Problem

Description:	Possible miswiring of transformer circuit caused increase in dialysate temperature
Cause:	Wires transposed leading from transformer to circuit board
Health consequences:	Patient death

Recall Description

Recall date:	10/30/83
Quantity recalled (units):	96 units
Who notified FDA of recall?:	User
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z0434

Case number: 9

Product Identification

Description:	Pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Gamma Series lithium cupric sulfide cells
Use:	Regulates cardiac rate and rhythm
Premarketing approval?:	No
Manufacturer:	Cordis, Miami, FL

Problem

Description:	Batteries had shorter-than-predicted service life
Problem cause:	Use of unprotected feed-throughs in certain Codel lithium cupric sulfide cell lots resulted in dendritic growth, depleting battery due to current drain
Health consequences:	Patient injury

Recall Description

Recall date:	12/02/83
Quantity recalled (units):	10,878 pacemakers
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z0664

==========

Case number: 10

Product Identification

Description:	Pediatric crib with security top
Device class:	2
Medical specialty:	Physical medicine
Brand:	*
Use:	Holds pediatric patients
Premarketing approval?:	No
Manufacturer:	Midmark, Versailles, OH

Problem

Description:	Entrapment of patients
Cause:	Top incorrectly installed or secured
Health consequences:	Patient death

Recall Description

Recall date:	03/01/84
Quantity recalled (units):	1,000 cribs
Who notified FDA of recall?:	User
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z0584

Case number: 11

Product Identification

Description:	Q-fever-positive human serum, 0.5-ml vials
Device class:	2
Medical specialty:	Microbiology
Brand:	*
Use:	In vitro diagnosis of Q fever
Premarketing approval?:	No
Manufacturer:	Centers for Disease Control, Atlanta, GA

Problem

Description:	Product did not meet Centers for Disease Control quality standard
Cause:	Instability of reagent
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	01/18/84
Quantity recalled (units):	210 vials
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z0194

==========

Case number: 12

Product Identification

Description:	Pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	*
Use:	Regulates cardiac rate and rhythm
Premarketing approval?:	No
Manufacturer:	Cardiac Pacemakers, Inc., St. Paul, MN

Problem

Description:	Device could abruptly fail due to shorting of timing crystal
Cause:	Due to an improper case composition, dendrites may grow from the case of the crystal into the tuning fork, causing a short and resulting in sudden loss of output
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	01/30/84
Quantity recalled (units):	*
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z1024

Case number: 13

Product Identification

Description:	Pediatric crib
Device class:	2
Medical specialty:	General hospital
Brand:	*
Use:	Holds pediatric patients after surgery
Premarketing approval?:	No
Manufacturer:	Cambridge Scientific Industries, Cambridge, MD

Problem

Description:	Risk of entrapment if improperly assembled or secured
Cause:	Poor design of crib
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	06/07/84
Quantity recalled (units):	76 cribs
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z2744

==========

Case number: 14

Product Identification

Description:	Pediatric crib
Device class:	2
Medical specialty:	General hospital
Brand:	*
Use:	Holds pediatric patients after surgery or active pediatric patients
Premarketing approval?:	No
Manufacturer:	Hill-Rom Co., Batesville, IN

Problem

Description:	Entrapment of patients, which resulted in serious injuries and deaths
Cause:	Design of bed, including assembly instructions, allowed the entrapments
Health consequences:	Patient death

Recall Description

Recall date:	05/18/84
Quantity recalled (units):	213 cribs
Who notified FDA of recall?:	User
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z1944

Case number: 15

Product Identification

Description:	Apnea monitor
Device class:	2
Medical specialty:	Anesthesiology
Brand:	*
Use:	Ventilates and monitors infant breathing
Premarketing approval?:	No
Manufacturer:	Healthdyne, Home Care Products Division, Marietta, GA

Problem

Description:	Low respiration sensitivity alarm did not function as designed
Cause:	Static electricity caused damage to electrical components and circuitry
Health consequences:	Patient death

Recall Description

Recall date:	02/01/84
Quantity recalled (units):	7,000 units
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z3214

==========

Case number: 16

Product Identification

Description:	Anesthesia machine (T-handle)
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Foregger Model 705 and 710
Use:	Selects various vaporizer modes
Premarketing approval?:	No
Manufacturer:	Puritan-Bennett Corp., Overland Park, KS

Problem

Description:	Certain vaporizer turrets developed a loose "T" handle, resulting in inaccurate vaporization of liquid anesthesia agents
Cause:	Epoxy bond may fracture, permitting handle to wobble and resulting in an intermittent by-pass leak within the turret manifold
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	10/08/84
Quantity recalled (units):	73 units
Who notified FDA of recall?:	User
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z0445

Case number: 17

Product Identification

Description:	Silicone tubing
Device class:	2
Medical specialty:	Anesthesiology
Brand:	C V Fragmatome Aspiration Tubing
Use:	Used in anterior segment surgery and posterior vitrectomy
Premarketing approval?:	No
Manufacturer:	Cooper Vision, Inc., Irvine, CA

Problem

Description:	Stiff tubing that may prevent suction cut-off
Cause:	Vendor provided defective raw materials that did not meet the specifications, resulting in a defective finished product
Health consequences:	Patient injury

Recall Description

Recall date:	12/19/84
Quantity recalled (units):	674 units
Who notified FDA of recall?:	FDA Inspection
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z1545

==========

Case number: 18

Product Identification

Description:	Positive pressure volume ventilator
Device class:	2
Medical specialty:	Anesthesiology
Brand:	*
Use:	Regulates positive pressure breathing in both home and hospital use
Premarketing approval?:	No
Manufacturer:	Life Products, Inc., Boulder, CO

Problem

Description:	Erratic or stopped cycling, sticking power switch and alarm, etc.
Cause:	Circuitry problems and deficiencies; components did not perform reliably although they met original design specifications
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	06/20/84
Quantity recalled (units):	252 ventilators
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z3354

Case number: 19

Product Identification

Description:	Calibrated vaporizers
Device class:	2
Medical specialty:	Anesthesiology
Brand:	*
Use:	Used in gas-dispensing circuit of anesthesia machine, to vaporize anesthetic
Premarketing approval?:	No
Manufacturer:	Ohmeda, Madison, WI

Problem

Description:	Failure of thrust pin in the temperature compensation mechanism
Cause:	Thrust pin loosened due to shock, impact, or excessive vibration of the vaporizer
Health consequences:	Patient death

Recall Description

Recall date:	11/14/84
Quantity recalled (units):	Undetermined
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z0675

==========

Case number: 20

Product Identification

Description:	Oxygen flush valves
Device class:	2
Medical specialty:	Anesthesiology
Brand:	*
Use:	Component of anesthesia machine that flushes breathing circuits with oxygen
Premarketing approval?:	No
Manufacturer:	Puritan Bennett Corp., Overland, KS

Problem

Description:	E-clip used in valve distorts internal diaphragm, causing intermittent leak of oxygen
Cause:	Clip added to valve in 1982; after 1.5 years, clip began distorting diaphragm
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	09/19/84
Quantity recalled (units):	90 valves
Who notified FDA of recall?:	User
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z0335

Case number: 21

Product Identification

Description:	Apnea monitor/bradycardia detector
Device class:	2
Medical specialty:	General hospital
Brand:	*
Use:	Monitors respiration and heart rate in infants
Premarketing approval?:	No
Manufacturer:	Clinical Data, Inc., Boston, MA

Problem

Description:	Alarms may not sound if infant breathing or heart rate slows or stops
Cause:	Sensitivity to electrostatic discharge of integrated circuits (through metal set screws on knobs on detector panel)
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	02/08/85
Quantity recalled (units):	2,210 monitors
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z2585

==========

Case number: 22

Product Identification

Description:	Defibrillator[a]
Device class:	2
Medical specialty:	Cardiovascular
Brand:	*
Use:	Power source for cardiac defibrillators
Premarketing approval?:	No
Manufacturer:	General Electric Co., Battery Business, Gainesville, FL

Problem

Description:	Abnormally rapid loss of discharge capacity after charging and removal from charger
Cause:	Possible that cobalt was inadvertently incorporated into batteries during manufacture
Health consequences:	Patient injury

Recall Description

Recall date:	03/08/85
Quantity recalled (units):	3,453 batteries
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z2715

Case number: 23

Product Identification

Description:	Defibrillator[a]
Device class:	2
Medical specialty:	Cardiovascular
Brand:	*
Use:	Power source for Pioneer Pulsar 4 cardiac defibrillators
Premarketing approval?:	No
Manufacturer:	General Electric Co., Gainesville, FL

Problem

Description:	Batteries lost a substantial portion of their charge 1 hour to 4 days after disconnection from the battery charger
Cause:	Possible that cobalt was inadvertently incorporated into batteries during manufacture
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	02/28/85
Quantity recalled (units):	60 batteries
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z3475

==========

Case number: 24

Product Identification

Description:	Pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	*
Use:	Regulates cardiac rate and rhythm
Premarketing approval?:	No
Manufacturer:	Cordis, Miami, Fl

Problem

Description:	Potential for sudden loss of output
Cause:	Batteries give off dioxolane vapor (electrolyte); boards absorbed vapor and expanded, breaking unfilled open-plated holes
Health consequences:	Patient injury

Recall Description

Recall date:	04/19/85
Quantity recalled (units):	28,931 pacemakers
Who notified FDA of recall?:	Competitor
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z3415

Case number: 25

Product Identification

Description:	Defibrillator[a]
Device class:	2
Medical specialty:	Cardiovascular
Brand:	*
Use:	Power source for cardiac defibrillators
Premarketing approval?:	No
Manufacturer:	General Electric Co., Gainesville, FL

Problem

Description:	Batteries were contaminated with cobalt that could cause battery and defibrillator failure
Cause:	Cobalt was introduced unknowingly onto the negative plate during the plate impregnation process
Health consequences:	Patient injury

Recall Description

Recall date:	02/15/85
Quantity recalled (units):	8,200 batteries
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z3025

==========

Case number: 26

Product Identification

Description:	Hemodialysis delivery system and monitor
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	*
Use:	*
Premarketing approval?:	*
Manufacturer:	Drake Willock Division, CD Medical Co., Portland, OR

Problem

Description:	Sticking or nonfunctional bypass valves
Cause:	Use of stainless steel in valve that was susceptible to corrosion; during normal operation, valve's plunger and plunger guide surface are wetted by dialysate
Health consequences:	Patient injury

Recall Description

Recall date:	02/11/85
Quantity recalled (units):	12,300 units
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	*
FDA control number:	Z2545

Case number: 27

Product Identification

Description:	Defibrillator[a]
Device class:	3
Medical specialty:	Cardiovascular
Brand:	*
Use:	Power source for cardiac defibrillators
Premarketing approval?:	No
Manufacturer:	General Electric Co., Gainesville, FL

Problem

Description:	Batteries can lose part of their charge after disconnection from the battery charger
Cause:	Cobalt introduced unknowingly onto negative plate during the plate impregnation process in battery manufacture
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	06/24/85
Quantity recalled (units):	130 batteries
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z3055

==========

Case number: 28

Product Identification

Description:	Defibrillator[a]
Device class:	3
Medical specialty:	Cardiovascular
Brand:	*
Use:	Hospital's emergency room or operating room cardiac stimulator
Premarketing approval?:	Yes
Manufacturer:	General Electric Co., Battery Business, Gainesville, FL

Problem

Description:	Batteries fail at a high rate; abnormally rapid loss of discharge capacity after being charged
Cause:	Reportedly contaminated with cobalt, an unapproved material, during production
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	03/19/85
Quantity recalled (units):	152 batteries
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z2855

Case number: 29

Product Identification

Description:	Vaporizer
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Ohmeda (for halothane and ethranes)
Use:	Vaporizes anesthesia gas
Premarketing approval?:	Yes
Manufacturer:	Primary Medical Products, Los Angeles, CA

Problem

Description:	Misbranding: conversion for use with anesthetic agents other than those for which vaporizer was designed
Cause:	Device converted from one type of vaporizer to another without a 510(k) or PMA application
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	07/16/85
Quantity recalled (units):	23 units
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z1696

==========

Case number: 30

Product Identification

Description:	Defibrillator[a]
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Saft "ED" Electrodeposited Nickel-Cadmium Battery Cell
Use:	Alternate power source for defibrillators
Premarketing approval?:	No
Manufacturer:	Saft America, Inc., Valdosta, GA

Problem

Description:	Premature nickel-cadmium battery failures
Cause:	Short circuits due to nickel screen electrode edges protruding over electrode separator and masking contact with other electrodes
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	03/29/85
Quantity recalled (units):	3,145 batteries
Who notified FDA of recall?:	User
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z4655

Case number: 31

Product Identification

Description:	Dialysate delivery system
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	*
Use:	Patient dialysis
Premarketing approval?:	No
Manufacturer:	Drake Willock Division, C. D. Medical, Portland, OR

Problem

Description:	Problems with bypass mode, blood pump, concentrate rods, and flow rate indicator
Cause:	Gate B on the integrated circuit was not performing as expected, allowing the bypass valve to remain open during alarm conditions
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	04/30/85
Quantity recalled (units):	535 units
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	Yes
FDA control number:	Z4285

==========

Case number: 32

Product Identification

Description:	Portable positive pressure respirator
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Volume Ventilators Model LP-3, LP-42, LP-5
Use:	Ventilates patients who need complete or partial breathing assistance
Premarketing approval?:	No
Manufacturer:	Life Products, Inc., Boulder, CO

Problem

Description:	Motor and alarm malfunction, circuit defects, circuit boards fall out
Cause:	Numerous good manufacturing practices violations in handling of components, manufacturing procedures, and testing
Health consequences:	Patient death

Recall Description

Recall date:	10/07/85
Quantity recalled (units):	5,304 respirators
Who notified FDA of recall?:	FDA inspection
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z1966

Case number: 33

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Bjork-Shiley Cardiac Valve Prosthesis 600 (Mitral and Aortic)
Use:	Replaces natural or prosthetic heart valve
Premarketing approval?:	Yes
Manufacturer:	Shiley, Inc., Irvine, CA

Problem

Description:	Strut of the valves may fracture
Cause:	Firm developed larger valves, having had minimal failure with small valves; strut failures began shortly after
Health consequences:	Patient death

Recall Description

Date:	10/14/85
Recall class:	I
Quantity recalled (units):	2,752 valves
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z1536

==========

Case number: 34

Product Identification

Description:	Cardiac pulse generator
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Programmalith III
Use:	Regulates cardiac rate and rhythm
Premarketing approval?:	Yes
Manufacturer:	Pacesetter Systems, Inc., Sylmar, CA

Problem

Description:	Loss of function and telemetry due to temperature sensitivity of circuits
Cause:	Combination of resistance and amplifier gain in oscillator creates abnormal sensitivity to temperature
Health consequences:	Patient injury

Recall Description

Date:	09/04/85
Recall class:	I
Quantity recalled (units):	690 pacemakers
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z1246

Case number: 35

Product Identification

Description:	Infant ventilator
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Bear Cub Infant Ventilator Model BP 2001
Use:	Provides respiratory support to infants
Premarketing approval?:	No
Manufacturer:	Bear Medical Systems, Inc., Riverside, CA

Problem

Description:	Sudden increase in positive-end expiratory pressure caused by a component failure
Cause:	Failure of the variable orifice valve; can delay exhalation enough to cause an increase in positive-end expiratory pressure
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	07/17/85
Quantity recalled (units):	390 ventilators
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	No
FDA control number:	Z1306

==========

Case number: 36

Product Identification

Description:	Defibrillator[a]
Device class:	2
Medical specialty:	Cardiovascular
Brand:	General Electric (Batteries)
Use:	Power source for cardiac defibrillators
Premarketing approval?:	No
Manufacturer:	Battery Specialties, Cookville, TN

Problem

Description:	Abnormally rapid loss of discharge capacity after being charged and removed from charger
Cause:	A defect in the nickel-cadmium battery provided by General Electric may cause the battery to fail
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	11/18/85
Quantity recalled (units):	*
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z5805

Case number: 37

Product Identification

Description:	Sporicide-disinfectant for hemodialyzers
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	Renew-D Disinfectant
Use:	Disinfects reused hemodialysis equipment
Premarketing approval?:	No
Manufacturer:	Alcide Corporation, Norwalk, CT

Problem

Description:	Gram-negative organisms were found in dialyzer after use of the disinfectant; patients experienced pyrogen-like reactions and bacteremias
Cause:	The product as originally designed was not effective for its intended use
Health consequences:	Patient injury

Recall Description

Recall date:	06/09/86
Quantity recalled (units):	4,000 cases
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	Yes
FDA control number:	Z6066

==========

Case number: 38

Product Identification

Description:	Unipolar and Bipolar programmable single chamber heart pacemaker
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Teletronics 10 mm Optima-MPT Pacemaker
Use:	Regulates cardiac rate and rhythm
Premarketing approval?:	Yes
Manufacturer:	Teletronics, Inc., Lane Cove, NSW [Foreign]

Problem

Description:	Sudden no-output failure mode caused by "tin whiskers"
Cause:	Growth of "whiskers" from silver or tin-copper compounds used in the diode
Health consequences:	No deaths or injuries reported

Recall Description

Date:	03/19/87
Recall class:	I
Quantity recalled (units):	3,727
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	Yes
FDA control number:	Z3457

Case number: 39

Product Identification

Description:	Medical linear accelerator
Device class:	2
Medical specialty:	Radiology
Brand:	Therac-25 Linear Accelerator
Use:	Used in clinical (cancer) radiotherapy
Premarketing approval?:	No
Manufacturer:	Atomic Energy of Canada, Ltd., Ontario

Problem

Description:	Software defects could cause massive, fatal radiation overdoses
Cause:	Two software defects that may cause massive radiation
Health consequences:	Patient death

Recall Description

Recall date:	06/03/87
Quantity recalled (units):	5 accelerators
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z3827

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Case number: 40

Product Identification

Description:	Implantable pacing leads
Device class:	3
Medical specialty:	Cardiovascular
Brand:	"Lifeline" Bipolar, Coaxial Implantable Leads
Use:	Used with internal pacemakers for long-term pacing of the heart
Premarketing approval?:	No
Manufacturer:	Intermedics, Inc., Freeport, TX

Problem

Description:	Increased failure manifested by over- and under-sensing, loss, and failure to stimulate
Cause:	Polyurethane insulation for the inner coil developed a localized weakness which failed (cracked) and resulted in intermittent contact between the inner and outer coils
Health consequences:	Patient injury

Recall Description

Recall date:	07/20/87
Quantity recalled (units):	2,197 leads
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z5337

Case number: 41

Product Identification

Description:	Blood oxygenator with integral filter
Device class:	3
Medical specialty:	Cardiovascular
Brand:	CML-2 Membrane Oxygenator
Use:	Blood gas exchange during cardiac surgical procedures
Premarketing approval?:	No
Manufacturer:	Cobe Labs, Lakewood, CO

Problem

Description:	Outlet connector of venous reservoir could be loosened, allowing air and fluid leakage
Cause:	Leak appears to occur in outlet connector at screw threads
Health consequences:	Patient death

Recall Description

Recall date:	08/19/87
Quantity recalled (units):	*
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	Yes
FDA control number:	Z5867

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Case number: 42

Product Identification

Description:	Respirator, neonatal ventilator
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Healthdyne Model 105, Type 3 Infant Ventilator
Use:	Provides respiratory support to infants in hospital neonatal intensive care units
Premarketing approval?:	No
Manufacturer:	Healthdyne, Inc., Marietta, GA

Problem

Description:	Stopped functioning during use and had burnt odor; some developed internal fire
Cause:	Reversed positioning of a capacitor on the electronic version of pressure alarm
Health consequences:	No deaths or injuries reported

Recall Description

Recall date:	05/07/87
Quantity recalled (units):	65 respirators
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	Yes
FDA control number:	Z5877

Case number: 43

Product Identification

Description:	Pacemaker
Device class:	2
Medical specialty:	Cardiovascular
Brand:	CPI/Ultra Unipolar and Bipolar
Use:	Regulates cardiac rate and rhythm
Premarketing approval?:	Yes
Manufacturer:	Cardiac Pacemakers, St. Paul, MN

Problem

Description:	High pacing rate, no output, no sensing, loss of interrogation and telemetry capacity
Cause:	Gold migration through dielectric paste from one circuit pathway to another, causing short; defective vendor lot of dielectric paste
Health consequences:	Patient death

Recall Description

Recall date:	10/27/87
Quantity recalled (units):	1,911 pacemakers
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	Yes
FDA control number:	Z0528

Case number: 44

Product Identification

Description:	Sorbent regenerated dialysate delivery system for hemodialysis
Device class:	2
Medical specialty:	Gastroenterology, urology
Brand:	"Redy" 2000 and "Dialert"
Use:	Treatment of acute and chronic renal failure
Premarketing approval?:	No
Manufacturer:	Organon Teknika Corp., Oklahoma City, OK

Problem

Description:	May infuse unsate levels of potassium and/or calcium into dialysate
Cause:	Intermittent sensing by electrode sensor, sending incorrect voltage to infusate pump
Health consequences:	No deaths or injuries reported

Recall Description

Date:	02/29/88
Quantity recalled (units):	304 units
Who notified FDA of recall?:	Firm
When FDA learned of recall:	Before recall
MDR report?:	No
FDA control number:	Z3478

Case number: 45

Product Identification

Description:	Volume ventilator
Device class:	2
Medical specialty:	Anesthesiology
Brand:	"Bear 1" Adult Volume Ventilator
Use:	Delivers air or oxygen to patients in need of respiratory support
Premarketing approval?	No
Manufacturer:	Bear Medical Systems, Inc., Riverside, CA

Problem

Description:	Reports of fire that may be due to defective main solenoid
Cause:	Rubber in piston valve of the solenoid comes loose, resulting in metal-to-metal contact; sparks can ignite oxygen
Health consequences:	Patient death

Recall Description

Date:	03/23/88
Quantity recalled (units):	1,467
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	Yes
FDA control number:	Z4938

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Case number: 46

Product Identification

Description:	Respiratory monitor
Device class:	2
Medical specialty:	Anesthesiology
Brand:	Apnea Monitor 9200, Respiratory/Heart Rate Monitor
Use:	Monitors the heart rate and respiration of infants who run the risk of apnea
Premarketing approval?	No
Manufacturer:	Aquitron Medical, Inc., Minneapolis, MN

Problem

Description:	Monitor alarm may fail
Cause:	Audible alarm was found to have ten percent failure rate when tested at firm
Health consequences:	Patient injury

Recall Description

Date:	03/12/88
Quantity recalled (units):	4,963
Who notified FDA of recall?:	Firm
When FDA learned of recall:	During recall
MDR report?:	Yes
FDA control number:	Z3548

Case number: 47

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Edwards Duromedics Aortic Bileaflet Valve, Model 3160
Use:	Replaces natural or prosthetic heart valve
Premarketing approval?:	Yes
Manufacturer:	Hemex Scientific, Austin, TX

Problem

Description:	Defective valves due to leaflet escape
Cause:	Firm has been unable to determine why the valves are failing
Health consequences:	Patient death

Recall Description

Date:	06/13/88
Recall class:	I
Quantity recalled (units):	26,000
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	Yes
FDA control number:	Z4648

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Case number: 48

Product Identification

Description:	Replacement heart valve
Device class:	3
Medical specialty:	Cardiovascular
Brand:	Medtronic Hall D-16 Prosthetic Heart Valve
Use:	Replaces natural or prosthetic heart valve
Premarketing approval?:	No
Manufacturer:	Carbomedics, Inc., Austin, TX

Problem

Description:	Mechanical failure resulting from disk fracture
Cause:	Tension bending force when disc inserted in housing and impact on disc when it strikes housing seat top
Health consequences:	Patient death

Recall Description

Date:	07/19/88
Quantity recalled (units):	317 valves
Who notified FDA of recall?:	*
When FDA learned of recall:	*
MDR report?:	No
FDA control number:	Z5908

[a]Some recalls were listed in the FDA data base as being of "defibrillators" and others as of "defibrillator batteries." Because some of the former also appear to concern battery problems and because there has been controversy over the accuracy of FDA's descriptions of recalls (see Biomedical Safety and Standards, 19:7 (April 1, 1989) pp. 50-51), we have listed all such class I recalls as being of "defibrillators." However, this classification should be understood to cover only those cases in which battery packs or other components were recalled.

Source: FDA recall data tape.

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