

AORN Guidance Statement: Reuse of Single-Use Devices

Introduction

Today's economic environment has compelled health care organizations to explore methods to reduce health care costs. One prospective approach to controlling rising costs is to reprocess single-use medical devices. Reprocessing is rigorously regulated by the US Food and Drug Administration (FDA). AORN, the Association of periOperative Registered Nurses, recognizes the need for each health care facility to provide safe, cost-effective, quality care to patients and realizes that many facilities in today's marketplace are reprocessing and reusing devices labeled for single use. These devices are reprocessed either within the facility or by an external third party contracted to provide the reprocessing service.

Background

As surgery evolved and increased in complexity, the number of single-use devices utilized during surgery increased and continues to rise. In response to this trend, the practice of reprocessing and reusing single-use medical devices began during the 1970s.¹ As technology led to a wide variety of materials used in device manufacture and devices became more complex, concern for patient safety, informed consent, and ethical practice intensified. In the late 1990s, the FDA determined that increased regulation of reprocessing was needed to promote safe practice and protect the public's safety. Although original equipment manufacturers have been regulated for many years, the FDA determined that they, along with third-party reprocessors and hospital reprocessors, should be regulated uniformly according to the Food, Drug, and Cosmetic Act. The FDA sought the expertise of manufacturers, reprocessors, hospitals, users, and other interested parties in developing a regulatory document, and in August 2000, it published its rule governing the reprocessing/reusing of devices labeled for single-use only. The document is applicable to both hospitals and third-party reprocessors.

Reprocessing of single-use devices (SUDs) is additionally addressed in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which establishes new statutory requirements for SUDs, including labeling to identify the devices as reprocessed, submission of validation data for many reprocessed SUDs, and submission of premarket

notification (510[k]) with validation data for some SUDs that previously were exempt from 510(k) submission requirements. Firms and hospitals that are reprocessing are considered by the FDA as manufacturers and therefore must comply with statutory and regulatory requirements.² In addition, the FDA has published an approved list of single-use devices that are acceptable for reprocessing and a list of items that may not be reprocessed. In essence, the regulations regard reprocessors in the same way as original equipment manufacturers.^{3,4}

Guidance Statement

Reprocessing single-use medical devices is chosen by some health care facilities as a cost containment effort and to reduce the amount of waste generated. It is the role and responsibility of each health care facility to determine whether and to what extent it will engage in such practice. As licensed professionals, perioperative nurses must demonstrate accountability to the nursing profession, to other members of the health care team, and to the public they serve.⁵ AORN, the professional organization of and for perioperative nurses, believes certain basic tenets must underpin any reprocessing program. The foremost concern is for the patient's safety. Therefore,

- ◆ if a device cannot be cleaned, it cannot be reprocessed and reused;
- ◆ if sterility of a post-processed device cannot be demonstrated, the device cannot be reprocessed and reused;
- ◆ if the integrity and functionality of a reprocessed SUD cannot be demonstrated and documented as safe for patient care and/or equal to the original device specifications, the device cannot be reprocessed and reused; and
- ◆ if anything is opened it needs to be decontaminated before reprocessing.

Per requirements of the MDUFMA regulation, the FDA has published a list of reprocessed SUDs that have 510(k) approval/clearance; whose manufacturers have provided supplemental data on functionality, cleaning, and sterility; and which now are on the published list of devices that are acceptable for reprocessing.²

Although some operational savings may be realized by reusing certain devices, any cost-benefit analysis would necessarily include labor costs;

program costs, including quality system requirements such as sterility and post-processing device testing (see section on quality system requirements); documentation costs; and the potential cost of device failure. Using the results of a thorough cost-benefit analysis, each provider facility must make an informed choice as to whether it wishes to invest the necessary resources to develop a safe reprocessing system within the facility. Use of an external reprocessor presents a different, but related, set of factors for consideration. When a decision is made in favor of using an external reprocessing company, it is the user facility's responsibility to assess the quality of services provided under the contractual arrangement.⁶ The user facility should review the processes used by the contracted agent and determine whether correct procedures are being followed.⁷ Regardless of whether an internal reprocessing program is developed or an external reprocessing company is selected, the user facility should be aware that the FDA views any reprocessor as a manufacturer and, as such, subject to federal regulations.^{3,8,9}

Federal Regulatory Requirements

In August 2000, the FDA issued guidance on the practice of reprocessing and reusing medical devices intended to be used only once. The FDA's goal in issuing this regulation was to ensure a reprocessing and reuse regulatory program that is based on good science and protects the public health. At the same time, the FDA intended to ensure equitable regulatory requirements for all parties engaged in reprocessing. In the guidance document,¹⁰ the FDA indicates that hospitals and third parties that reprocess SUDs are subject to the same regulations as the original equipment manufacturers. The MDUFMA also addressed reprocessing of SUDs by amending the federal Food, Drug and Cosmetic Act (the Act) and establishing new statutory requirements applicable to reprocessed SUDs, including requirements for

- ◆ quality system regulations,
- ◆ medical device reporting,
- ◆ registration and listing,
- ◆ labeling,
- ◆ premarket approval and premarket notification,
- ◆ medical device corrections and removals, and
- ◆ medical device tracking.²

Quality System Regulation

All manufacturers, including hospital and third-party reproducers, are subject to the FDA Good Manufacturing Practices (GMP) requirements. These requirements are presented in the quality system regulation that governs the methods, facilities, and controls used for designing, manufacturing, packaging, labeling, storing, installing, and servicing medical devices.³ Quality system refers to the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. For device manufacturers, including reproducers, this system is required in addition to any quality improvement program that may be in place as required by other regulatory bodies. The quality system regulation addresses the areas shown in Table 1.¹¹

Medical Device Reporting (MDR)

Under MEDWATCH, the FDA's medical device reporting program resulting from the Safe Medical Devices Act of 1990 (Public Law 101-629),¹² both manufacturers and users are required to report deaths or serious injuries to the FDA if it can be reasonably determined that a medical device may have caused or contributed to the incident. Manufacturers also must report certain device malfunctions.¹³ Because the FDA considers reproducers to be manufacturers when they reprocess an SUD,⁹ hospital reproducers have dual reporting responsibility. They are subject to manufacturer's reporting requirements (21 CFR, Part 803 Subpart E)¹⁴ as well as those for the device user facility (21 CFR, Part 803, Subparts A and C).^{15,16} Although user facilities must report only deaths or serious injury, manufacturers' reporting requirements are more extensive and require additional supplemental information. Manufacturers (reproducers) also must report any event that requires the manufacturer (reproducer) to take immediate remedial action. The Jan 26, 2000, issue of the *Federal Register* contains the most recent MDR requirements. Hospitals that reprocess SUDs are subject to both user facility reporting and the more comprehensive manufacturer reporting requirements.¹⁷

Registration and Listing

All persons or entities owning or operating establishments that manufacture, prepare, or process devices must register with the FDA. The FDA uses

Table 1

QUALITY SYSTEM REGULATION ¹	
Area Addressed	Code of Federal Regulations
Management responsibility	21 CFR, Part 820.20, 22, 25
Design controls	21 CFR, Part 820.30
Document controls	21 CFR, Part 820.40
Purchasing controls	21 CFR, Part 820.50
Product identification and traceability	21 CFR, Part 820.60, 65
Production and process validation	21 CFR, Part 820.70, 72, 75
Acceptance activities such as inspections, tests, or other verification activities	21 CFR, Part 820.80, 86
Nonconforming product control	21 CFR, Part 820.90
Corrective and preventive action	21 CFR, Part 820.100
Labeling and packaging controls	21 CFR, Part 820.120, 130
Handling, storage, distribution, and installation controls	21 CFR, Part 820.120, 140, 150, 160
Records including device master record, device history record, quality system record, and complaint files controls	21 CFR, Part 820.180, 181, 184, 186, 198
Servicing controls	21 CFR, Part 820.200
Use of statistical techniques to establish, control, and verify the acceptability of process capability and product characteristics	21 CFR, Part 820.250

1. "Quality system regulation," *CFR 21 Part 820, US Food and Drug Administration*, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820> (accessed 3 Oct 2005).

this information to identify and locate establishments that it is required to inspect. When registering, the following information must be provided:

- ◆ name and address,
- ◆ business names used,
- ◆ business name of owner or operator, and
- ◆ establishment type.

When registering for the first time, a specific FDA form is required. An additional registration form must be submitted annually thereafter. In addition to registering with the FDA, each reprocessing entity must provide a list of the devices it intends to reprocess. A separate listing form must be submitted for each device to be reprocessed. Devices are listed by category. The following information is required:

- ◆ FDA classification name,
- ◆ FDA product code,
- ◆ brand name, and
- ◆ common or usual name.

Additional information about registration and listing is available in the *Code of Federal Regulations* (21 CFR, Part 807).¹⁸ The necessary forms can be obtained from the Office of Compliance, Center for Devices and Radiologic Health (HFZ-307), US Food and Drug Administration, 2094 Gaither Road, Rockville, MD 20850. The Center for Devices and Radiologic Health (CDRH) offers an additional document, *CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a, and 2892*. This document can be obtained from the

Division of Small Manufacturers Assistance (DMSA) at telephone number 800-638-2041 or 301-638-2041; e-mail DMSA@CDRH.fda.gov.

Labeling

The FDA directions for labeling can be found in 21 CFR, Part 801.¹⁹ The term *labeling* includes package inserts as well as the information printed on the actual label of the package. Labeling requirements include the name and location of the manufacturer (reprocessor) and adequate direction for the device's intended use. If the manufacturer (reprocessor) knows of uses other than the intended use of the device, FDA requires the manufacturer (reprocessor) to provide adequate labeling for alternate uses of the device as are known. In addition, MDUFMA added new labeling requirement for reprocessed SUDs (Section 502[v] of the Act). Beginning after January 26, 2004, reprocessed SUDs that are introduced into interstate commerce must prominently and conspicuously bear the statement "Reprocessed device for single use. Reprocessed by [insert the name of the manufacturer that reprocessed the device]."² For additional information about labeling requirements, obtain a copy of the FDA guidance document *Labeling Regulatory Requirements for Medical Devices* from <http://www.fda.gov/cdrh/dsma/470.pdf> or contact the Division of Small Manufacturers Assistance (DSMA) by phone at 800-638-2041 or 301-638-2041; e-mail DMSA@CDRH.fda.gov.

Premarket Approval and Premarket Notification

After registering with the FDA and submitting a list of devices to be manufactured (reprocessed) and distributed for use, the registered entity must meet premarket submission requirements for each listed device. Certain devices may be exempt from the premarket submission requirement. If exempt, the device need only be listed with the FDA. Additional information about exemptions can be found in 21 CFR, Part 807.75.²⁰ The FDA has defined a phase-in period for premarket submissions to accommodate entities that are presently engaged in reprocessing. Following the phase-in period, a premarket submission must be submitted for any new device to be manufactured (reprocessed) at least 90 days before beginning distribution of the device.

There are two types of premarket submissions: a premarket notification, or 510(k), and a premarket approval (PMA) application. The type of submission required is based on the device classification, as defined in 21 CFR, Part 814.²¹ Unless specifically exempted, a premarket notification (510[k]) is required for all Class I and Class II devices. A premarket notification (510[k]) submission must contain enough information for the FDA to determine whether the particular device is "substantially equivalent" to another device that has been previously judged to be safe and effective and has been cleared for marketing/reprocessing. The predicate device selected must have the same intended use as the device for which the 510(k) is submitted. The predicate device may be the original SUD of the original equipment manufacturer (OEM) provided that the 510(k) compares the unique characteristics of the submitted device to those of the predicate device so the FDA can determine equivalency with respect to safety and effectiveness. The following information is required for a premarket notification (510[k]) submission:

- ◆ device trade name, proprietary name, usual name, or classification name;
- ◆ entity registration number;
- ◆ device classification;
- ◆ action taken to determine device performance standards;
- ◆ proposed labels, labeling, and advertisements to describe the device, its intended use, and the directions for its use, including photos and/or engineering drawings if appropriate;
- ◆ appropriate data to show that the registered entity has considered the consequences and effects any changes or modifications in the device might have on the safety and effectiveness of the device;
- ◆ 510(k) summary or 510(k) statement as defined in 21 CFR, Part 807.92, 93;²²
- ◆ financial disclosure statement;⁹
- ◆ statement certifying truth, accuracy, and completeness of material submitted; and
- ◆ any other information requested by the FDA.

For specific guidance on preparing 510(k) submissions, consult *Regulatory Requirements for Medical Devices*, available at <http://www.fda.gov/cdrh/manual/510kprt1.html>, or contact the Division of Small Manufacturers Assistance. Locate other relevant guidelines at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGPSearch.CFM>.

All Class III devices require a PMA. A PMA application must include valid scientific evidence demonstrating the safety and effectiveness of the original and/or reprocessed device. Each PMA application should evaluate the unique characteristics of the submitted device. Clinical data (eg, results of clinical trials) may be required. Some clinical trials require FDA approval of an investigational device exemption (IDE) application for the device(s) to be studied. For additional information, consult the following sources:

- ◆ 21 CFR, Part 814.20;²¹
- ◆ 21 CFR, Part 812;²²
- ◆ *Device Advice: Premarket Approval (PMA)*, available at <http://www.fda.gov/cdrh/devadvice/pma> (accessed 3 Oct 2005);
- ◆ *Guidance for Institutional Review Boards and Clinical Investigators, "Significant risk and nonsignificant risk medical device studies,"* available at <http://www.fda.gov/oc/ohrt/irbs/devices.html> (accessed 3 Oct 2005); and
- ◆ *Device Advice: Clinical Trials and Investigational Device Exemption (IDE)*, available at <http://www.fda.gov/cdrh/devadvice/ide/application.shtml> (accessed 3 Oct 2005).

The FDA also requires a satisfactory inspection of the manufacturing (reprocessing) facilities before approving a PMA application. The application should include a comprehensive manufacturing (reprocessing) section that clearly identifies all manufacturing (reprocessing) controls. Under MDUFMA, some SUDs that previously were exempt from 510(k) submission requirements under Sections 510(l) or (m) of the Act are no longer exempt and are required under Section 510(o)(2) of the Act to submit 510(k) notifications that include validation data. Validation data also was required for some reprocessed SUDs that already had been cleared under 510(k). Under Section 510(o) of the Act, reprocessors that either did not submit validation data for those reprocessed SUDs within specified time frames or received "not substantially equivalent letters" from the FDA can no longer legally market those reprocessed devices. Finally, under Section 515(c)(2) of the Act, reprocessors of Class III SUDs are required to submit premarket reports instead of premarket approval applications.²

Medical Device Corrections and Removals

Device correction and/or removal from the point of use must be promptly reported to the FDA when the

correction or removal is initiated by the manufacturer (reprocessor) to reduce a health risk to the user or to correct a violation of the Food, Drug, and Cosmetic Act. For example, if a facility reprocessed an SUD that resulted in a patient's adverse reaction and the hospital chose to remove the remainder of the lot of those reprocessed SUDs from circulation to decrease the possibility of other patients having adverse reactions, that action would be a removal and the facility would be required to report the removal to the FDA. Corrections are defined as

*the repair, modification, adjustment, relabeling, destruction, or inspection of a device without its physical removal from its point of use.*²³

Removal is defined as

*the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.*²³

Distributed devices withdrawn from the marketplace due to a minor violation of the Food, Drug, and Cosmetic Act or as a matter of stock rotation need not be reported. Stock recoveries need not be reported, nor should devices removed for routine servicing. The term *stock recoveries* refers to devices that have been prepared for use, but have not left the physical premises and jurisdiction of the manufacturer (reprocessor)—eg, devices that have not left the reprocessing area. However, each correction and/or removal must be documented regardless of whether it is reported to the FDA.

When a report must be filed with the FDA, the report must be filed within 10 days of the correction/removal action. The report should include the following information:

- ◆ registration number of the entity manufacturing/reprocessing the device;
- ◆ date of the report;
- ◆ sequence number of the report from that entity;
- ◆ name, address, and telephone number of the reporting entity;
- ◆ name, title, address, and telephone number of individual responsible for the correction/removal action;
- ◆ brand name, classification name, and common name of the device and its intended use;
- ◆ marketing status of the device;
- ◆ model, catalog, and code number of the device and the manufacturer's (reprocessor's) lot, serial, or other identification number for the device;

- ◆ description of event leading to correction/removal action;
- ◆ any injuries resulting from device use;
- ◆ total number of devices manufactured (reprocessed) subject to the correction/removal action;
- ◆ date of manufacture/distribution/reprocessing and expected shelf life of the device;
- ◆ name, address, telephone number of all to whom the device has been distributed and the number of devices distributed to each; and
- ◆ copies of all communication regarding the correction/removal action and the names and address of all recipients of the communication.

For additional information about correction and removal requirements, consult 21 CFR, Part 806.

Medical Device Tracking

Medical device tracking is intended to ensure that manufacturers (reprocessors) of certain devices can locate those devices should corrective action and/or notification about such devices become necessary. Original equipment manufacturers are subject to the medical device tracking regulation only when the FDA issues a tracking order for a device manufactured by the OEM. Reprocessors are subject to the medical device tracking regulation only when the FDA issues an order for the specific device(s) being reprocessed. For additional information on device tracking, including the types of devices currently subject to tracking orders, consult *Guidance on Medical Device Tracking*, available at <http://www.fda.gov/cerh/modact/tracking/pdf> or from the Center for Devices and Radiologic Health (CDRH) at 301-827-0111. Request document number 169.

Definitions

Class I medical device: A medical device for which general controls provide reasonable assurance of the safety and effectiveness of the device or, if there is insufficient evidence to reasonably ensure safety and effectiveness, the device is not life-supporting or life-sustaining, its use is not substantially important in preventing impairment of human health, and/or its use “does not present a potential unreasonable risk of illness or injury.”²³

Class II medical device: A medical device for which general controls alone do not provide reason-

able assurance of device safety and effectiveness but for which there is sufficient information to establish special controls (eg, performance standards, guidelines, patient registries, postmarket surveillance) to provide that assurance.²³

Class III medical device: A medical device for which neither general controls nor special controls provide reasonable assurance of device safety and effectiveness and the device is life-supporting or life sustaining or its use “is of substantial importance in preventing impairment of human health” or “presents a potential risk of illness or injury.”²³

Opened-but-unused device: A device whose sterility is compromised before being introduced onto the sterile field and which is not contaminated with blood and/or other potentially infectious materials (OPIM) external to the sterile field.²⁴

Reprocessing: Includes all operations to render a contaminated reusable or single-use device patient ready. Single-use devices to be reprocessed may be either used or unused. Reprocessing steps include cleaning, decontamination, and sterilization/disinfection.⁹

Resterilization: The repeated application of a process intended to remove or destroy all viable forms of microbial life, including bacterial spores.⁹ Because sterility is not an absolute, the accepted sterility assurance level (SAL) is usually defined as 10⁻⁶.

Reuse: The repeated or multiple uses of any medical device whether marketed as reusable or single-use. Repeated/multiple use may be on the same patient or on different patients with applicable reprocessing of the device between uses.²⁵

Single-use device (SUD): A device intended by the manufacturer to be used on one patient during one procedure. The device is not intended for reprocessing and/or use on another patient or on the same patient at another time. Device labeling may or may not identify the device as single-use or disposable, but manufacturer instructions for reprocessing are absent.⁹

Third-party reprocessor: A business establishment, separate from the user facility and the device manufacturer, one of whose primary businesses is to reprocess single-use/disposable medical devices.

NOTES

1. “Reuse of single-use devices,” *AORN Journal* 73 (May 2001) 957-966.

2. “Medical Device User Fee and Modernization Act (MDUFMA) of 2002,” PL 107-250, 107th Congress, <http://www.fda.gov/cdrh/mdufma> (accessed 3 Oct 2005).

3. "Guidance for industry and for FDA staff: Enforcement priorities for single-use devices reprocessed by third parties and hospitals," (Aug 14, 2000) US Food and Drug Administration, <http://www.fda.gov/cdrh/reuse/1168.html> (accessed 3 Oct 2005).

4. "Medical devices; reprocessed single-use devices; termination of exemptions from premarket notification; requirement for submission of validation data," US Food and Drug Administration, <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-16109.html> (accessed 3 Oct 2005).

5. "AORN explications for perioperative nursing," in *Standards, Recommended Practices, and Guidelines* (Denver: AORN, Inc, 2005) 86-115.

6. Joint Commission on Accreditation of Healthcare Organizations, "Standard LD.3.50: Services provided by consultation, contractual agreements, or other agreements are provided safely and effectively," in *Comprehensive Accreditation Manual for Hospitals* (Oakbrook Terrace, Ill: Joint Commission on Accreditation of Healthcare Organizations, 2005) LD 13.

7. "Letter re: Reusable medical devices rented or leased from third parties," US Food and Drug Administration, <http://www.fda.gov/cdrh/comp/rentleasethird.html> (accessed 23 Aug 2005).

8. "Quality system regulation, Definitions," CFR 21, Part 820.3, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=820.3> (accessed 3 Oct 2005).

9. "Letter to American College of Healthcare Executives: Reuse of single-use or disposable medical devices," US Food and Drug Administration, <http://www.fda.gov/cdrh/comp/policymayaply.html> (accessed 3 Oct 2005).

10. Center for Devices and Radiological Health, US Food and Drug Administration, US Department of Health and Human Services, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Washington, DC: US Government Printing Office, Aug 14, 2000).

11. "Quality system regulation," CFR 21, Part 820, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820> (accessed 3 Oct 2005).

12. "Safe Medical Devices Act of 1990," Public Law 101-629, <http://thomas.loc.gov/cgi-bin/query/C?c101:.:temp/~c101exlXhd> (accessed 23 Aug 2005).

13. "Medical device reporting: General provisions," CFR 21, Part 803.1, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=803.1> (accessed 3 Oct 2005).

14. "Manufacturer reporting requirements," CFR 21, Part 803, Subpart E, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803> (accessed 23 Aug 2005).

15. "Medical device reporting: General provisions," CFR 21, Part 803, Subpart A, US Food and Drug Adminis-

tration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803> (accessed 23 Aug 2005).

16. "User facility reporting requirements," CFR 21, Part 803, Subpart C, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803> (accessed 23 Aug 2005).

17. US Department of Health and Human Services, "Medical device reporting: Manufacturer reporting, importer reporting, user facility reporting, distributor reporting," *Federal Register* 65 (Jan 26, 2000) 4112-4121.

18. "Establishment regulation and device listing for manufacturers and initial importers of devices," CFR 21, Part 807, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=807> (accessed 23 Aug 2005).

19. "Labeling," CFR 21, Part 801, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=801> (accessed 23 Aug 2005).

20. "Exemption from premarket notification," CFR 21, Part 807.65, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=807.65> (accessed 23 Aug 2005).

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22. "Investigational device exemptions," CFR 21, Part 812, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812> (accessed 3 Oct 2005).

23. "Medical devices: Reports of corrections and removals, definitions," CFR 21, Part 806.2, US Food and Drug Administration, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm> (accessed 3 Oct 2005).

24. "Guidance for industry and for FDA staff: Enforcement priorities for single-use devices reprocessed by third parties and hospitals," US Food and Drug Administration, http://www.fda.gov/cdrh/reuse/1168.html#_Toc492780057 (accessed 2 Feb 2006).

25. Center for Devices and Radiological Health, US Food and Drug Administration, US Department of Health and Human Services, "FDA's proposed strategy on reuse of single-use devices, docket no 99N-4491," *Federal Register* 64 (Nov 3, 1999) 59782-59783.

RESOURCES

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