

GAO

Report to the Committee on Oversight
and Government Reform, House of
Representatives

January 2008

**REPROCESSED
SINGLE-USE
MEDICAL DEVICES**

**FDA Oversight Has
Increased, and
Available Information
Does Not Indicate
That Use Presents an
Elevated Health Risk**





Highlights of [GAO-08-147](#), a report to the Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Within the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) is responsible for reviewing the safety and effectiveness of medical devices. The decision to label a device as single-use or reusable rests with the manufacturer. To market a reusable device, a manufacturer must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Alternatively, a single-use device (SUD) may be marketed without such data after demonstrating to FDA that the device is safe and effective if used once. Even though labeled for single-use, some SUDs are reprocessed for reuse with FDA clearance. This report addresses (1) the SUD reprocessing industry—the number of reprocessing establishments, the types of devices reprocessed, and the extent to which hospitals use reprocessed SUDs, (2) the steps FDA has taken to strengthen oversight of reprocessed SUDs, both on its own and in response to legislative requirements, and (3) the safety of reprocessed SUDs compared with other types of medical devices.

GAO reviewed FDA data on reprocessors, reprocessed SUDs, and device-related adverse events, as well as FDA documents and inspection reports, studies published in peer-reviewed journals, and relevant statutes and regulations. GAO interviewed FDA officials and officials from associations of manufacturers, reprocessors, and providers.

To view the full product, including the scope and methodology, click on [GAO-08-147](#). For more information, contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov.

REPROCESSED SINGLE-USE MEDICAL DEVICES

FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

What GAO Found

FDA has information on domestic reprocessing establishments, but it does not have data on the extent of actual production or on where the devices are being used. FDA officials identified 11 establishments that reported planning to market or actively marketing more than 100 types of reprocessed SUDs in the United States as of July 2007. Reprocessed SUDs ranged from devices used external to the body, such as blood pressure cuffs, to surgical devices used to repair joints. While many hospitals were believed to be reprocessing their own SUDs in 2000, FDA identified only one hospital in 2007 that was reprocessing SUDs. Reprocessed SUDs are being used in a variety of hospitals throughout the nation, including military hospitals. However, the Department of Veterans Affairs, which operates one of the nation's largest health care systems, prohibits their use entirely.

Since 2000, FDA has taken a number of steps—on its own and in response to legislation—to enhance its regulation of reprocessed SUDs both before they go to market (called premarket review) and afterwards (called postmarket oversight). In 2000, FDA published guidance that clarified its policies on the regulation of reprocessed SUDs. This guidance was directed at third-party entities and hospitals engaged in reprocessing SUDs for reuse. Following legislation passed in 2002, FDA imposed additional requirements for about 70 types of reprocessed devices and implemented new labeling requirements so that users would recognize those devices that had been reprocessed. In terms of postmarket review, FDA now inspects reprocessors and monitors reports of adverse events involving reprocessed SUDs. Seven of the 10 reprocessing establishments that FDA inspected in the last 3 years had problems requiring corrective actions. Regarding adverse event reporting, FDA modified its reporting forms in 2003 to enable FDA to better identify and analyze those adverse events involving reprocessed SUDs.

Neither existing FDA data nor studies performed by others are sufficient to draw definitive conclusions about the safety of reprocessed SUDs compared to similar original devices. While FDA has made changes to its data collection process regarding reprocessed SUD-related adverse events, the data are not suitable for a rigorous comparison of the safety of reprocessed SUDs compared to similar original SUDs. The other studies published since 2000 that GAO identified are likewise insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. FDA officials have concluded that the cost of conducting rigorous testing would not be an efficient use of resources, especially given that the available data, while limited, do not indicate that reprocessed SUDs present an elevated health risk. FDA has analyzed its data on reported adverse events related to reprocessed SUDs and has concluded that there are no patterns that point to these devices creating such risks. After reviewing FDA's processes for monitoring and investigating its adverse event data, we found no reason to question FDA's analysis. HHS provided language to clarify several sentences of a draft of this report which GAO generally incorporated.

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Abbreviations

AMDR	Association of Medical Device Reprocessors
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HHS	Department of Health and Human Services
MDR	Medical Device Reporting
MDUFMA	Medical Device User Fee and Modernization Act of 2002
MedSun	Medical Product Safety Network
SUD	single-use device

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United States Government Accountability Office
Washington, DC 20548

January 31, 2008

The Honorable Henry A. Waxman
Chairman
The Honorable Tom Davis
Ranking Member
Committee on Oversight and Government Reform
House of Representatives

The federal government, through the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS), takes the lead in ensuring that the thousands of types of medical devices sold for use in surgeries and other medical procedures are reasonably safe and effective and do not pose a threat to public health.¹ These devices range from bandages and surgical clamps to complicated devices such as heart pacemakers. Unless exempt, all devices are subject to FDA review—referred to as premarket review—before they may be legally marketed in the United States.

Using many types of devices, such as tongue depressors, a second time is not feasible, while others, such as stethoscopes, are specifically designed and sold to be used more than once. The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.

Some devices fall into another category—they are labeled and marketed by the original manufacturer as single-use devices (SUD), but with clearance from FDA are marketed after being reprocessed for reuse—that is, they are cleaned, sterilized, and performance-tested by one of numerous entities that are in business to reprocess them for reuse. These

¹Generally, a medical device includes items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease or other condition. 21 U.S.C. § 321(h). Throughout this report, the term *device* refers to a medical device that is not being regulated as a drug or a biological product.

reprocessed SUDs² can range from relatively simple items for external use, such as inflatable sleeves to improve blood circulation, to complex items placed inside the body, such as catheters inserted into the heart to monitor cardiac function.

For more than two decades, establishments such as hospitals and private companies have reprocessed various types of SUDs, citing lower purchasing and in-house sterilization costs and reduced medical waste. This development followed an increase in the number of devices labeled as single-use. Because these devices were intended to be discarded after one use, manufacturers did not develop appropriate cleaning, sterilization, and testing methods or provide instructions to health care providers about how to clean and sterilize them while still maintaining performance.

Concerns have been raised by the committee and others about the potential risks of infection from reprocessed SUDs or their failure to function properly. The original manufacturers of the SUDs, in particular, have objected to SUD reprocessing, saying that the reprocessed SUDs are inherently unsafe because these devices are not designed to facilitate cleaning and sterilization. Reprocessing firms, on the other hand, contend that reprocessed SUDs are indeed safe, citing a lack of data that show otherwise. In a June 2000 report on SUD reprocessing, we found that although there was little available evidence of harm from the use of reprocessed SUDs, FDA oversight of SUD reprocessing was inconsistent.³ Since that time, Congress has acted to strengthen oversight requirements. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) required that the labeling of all reprocessed SUDs specifically state that they are reprocessed SUDs as well as identify the reprocessor. The act also directed FDA to increase its oversight of these devices by identifying reprocessed SUDs that should not be marketed unless the reprocessing

²The term *reprocessed*, with respect to a SUD, means an original SUD that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. 21 U.S.C. § 321(I)(2).

³GAO, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted*, GAO/HEHS-00-123 (Washington, D.C.: June 20, 2000).

establishment first provided data demonstrating effective cleaning, sterilization, and functional performance.⁴

In light of action taken since our last report, you asked us to review how the reprocessing industry and FDA's oversight of reprocessed SUDs had changed since June 2000. Specifically, our report addresses the following three questions:

- What is known about the reprocessing industry—the number of reprocessing establishments, the types of devices they are reprocessing, and the extent to which hospitals are using reprocessed SUDs?
- What steps has FDA taken to strengthen oversight of reprocessed SUDs on its own initiative and to implement requirements set forth in MDUFMA?
- What is known about the extent to which the safety of reprocessed SUDs compares favorably or unfavorably with the safety of similar original SUDs?

To address these questions, we examined and evaluated available information on the SUD reprocessing industry in the United States and FDA's oversight of this industry. In conducting our work, we (1) reviewed available data on the types and characteristics of, FDA guidance and standards pertaining to, and FDA inspection reports on, SUD reprocessing establishments; (2) reviewed FDA-generated data and analyses on reported adverse events involving reprocessed SUDs; (3) interviewed FDA officials, representatives of the device reprocessing and manufacturing industry, including professional associations representing device manufacturing establishments⁵ and the Association of Medical Device Reprocessors (AMDR), which represents two firms that operate three

⁴Pub. L. No. 107-250, § 302, 116 Stat. 1588, 1616-20. For additional information on other provisions of MDUFMA, see GAO, *Food and Drug Administration: Methodologies for Identifying and Allocating Costs of Reviewing Medical Device Applications Are Consistent with Federal Cost Accounting Standards, and Staffing Levels for Reviews Have Generally Increased in Recent Years*, [GAO-07-882R](#) (Washington, D.C.: June 25, 2007).

⁵These associations included the Advanced Medical Technology Association and the Medical Device Manufacturers Association.

large reprocessing establishments in the United States,⁶ and officials representing provider associations and medical facilities of the Departments of Veterans Affairs and Defense; (4) reviewed relevant statutes, regulations, and *Federal Register* notices; and (5) conducted a literature search of peer-reviewed periodicals and reviewed other information to determine what is known about the safety of reprocessed SUDs.

In some cases, FDA data were not available or sufficiently reliable to allow us to develop detailed information or perform analyses. For example, we determined that FDA's data were not sufficiently reliable to determine the number of domestic establishments reprocessing SUDs prior to July 2007 or the number of foreign establishments reprocessing SUDs. As a result, we were unable to analyze trends in the number of reprocessing establishments or the types of devices they were reprocessing since 2000 and we were limited to reporting on domestic reprocessing establishments. Also, neither industry nor FDA representatives were able to provide comprehensive information on the size of the reprocessed SUDs market in the United States—in terms of volume and value—compared to the overall U.S. market for medical devices. See appendix I for additional information on our methodology and data limitations.

We conducted our work between November 2006 and January 2008 in accordance with generally accepted government auditing standards.

Results in Brief

FDA has information on domestic reprocessing establishments, but it does not have data on the extent of actual production or where the reprocessed SUDs are being used. According to FDA officials, as of July 2007, 11 establishments reported they were planning to market or actively marketing more than 100 types of reprocessed SUDs in the United States. The types of reprocessed SUDs ranged from compression sleeves used externally to maintain circulation during and after surgery to invasive devices used to lift and stabilize the heart during open-heart surgery. In terms of relative volume among the reprocessing establishments, 3 of the establishments account for about 90 percent of the SUD reprocessing business, according to AMDR. The extent of actual production of

⁶FDA defines a device establishment as a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3 (2007). Medical device manufacturers may have more than one establishment. FDA considers reprocessing of SUDs to be manufacturing.

reprocessed SUDs by the 11 establishments is largely unknown, however, because FDA does not gather these data and because many reprocessing establishments, for business reasons, treat their production numbers as proprietary information. When we last reported on the reprocessing industry in 2000, many hospitals were believed to be reprocessing their own SUDs, but FDA identified only one hospital that was reprocessing SUDs in July 2007. Our inquiries with representatives of private and federal hospitals indicated that reprocessed SUDs are being used across a wide spectrum of the nation's hospitals, including military hospitals. The Department of Veterans Affairs, one of the nation's largest health care providers, prohibits their use entirely however.

FDA has taken a number of steps to increase its oversight of reprocessed SUDs since 2000, both on its own initiative and in response to requirements established by MDUFMA in 2002. FDA has changed its approach to premarket review and postmarket surveillance:

- Premarket review. This aspect of oversight involves FDA's review of manufacturer submissions related to specifications, proposed labeling, and other information about a device to assess its safety and effectiveness before allowing it to be marketed. Shortly after our June 2000 report, FDA issued guidance clarifying its policies on the regulation of reprocessed SUDs, which was directed at hospitals and third-party reprocessing establishments. Also, in response to MDUFMA's requirements for increased oversight, FDA identified more than 70 types of reprocessed SUDs that would be subject to additional premarket submission requirements. For example, to obtain FDA clearance to market many types of reprocessed SUDs, such as scalpel blades and drill bits, reprocessing establishments must submit additional data to FDA on the processes used to clean, sterilize, and test the devices. Also in response to MDUFMA, FDA began reviewing the labeling accompanying reprocessed SUDs as well as the markings on the devices themselves for compliance with new requirements that they clearly indicated the device was reprocessed and identified the reprocessing establishment.
- Postmarket surveillance. This aspect of oversight involves inspecting establishments that reprocess SUDs and collecting and analyzing data about device-related adverse events that occur when a device is used, such as infections, injuries to patients or providers, or breakage. With the issuance of its August 2000 guidance, FDA intended to make clear its plans to subject hospitals and other third-party establishments that reprocess SUDs to FDA inspection for compliance with applicable regulatory requirements just like other establishments manufacturing medical devices. According to FDA, 10 of the 11 establishments it identified as

engaged in reprocessing in the United States in July 2007 were inspected during the period August 2004 through October 2007; the remaining establishment registered with FDA in 2006 as a reprocessing establishment and is scheduled for inspection in 2008. During inspections at 7 of the establishments, FDA identified compliance issues that required corrective action. For example, one inspection revealed that the establishment had reprocessed two models of a type of SUD before it had received FDA clearance to market those particular models of reprocessed SUDs. However, the establishment had stopped reprocessing these models of SUDs prior to FDA's inspection and FDA inspectors determined that the establishment had voluntarily taken the corrective actions that were required. With respect to adverse event data, FDA modified its forms in 2003 for reporting device-related adverse events to indicate whether a reprocessed SUD was involved. This change, required by MDUFMA, was designed to enable FDA to differentiate those adverse events involving reprocessed SUDs from those involving other devices. In addition, an FDA workgroup is studying whether refinements, such as additional instructions, could further improve the device-related adverse event reports involving reprocessed SUDs.

Neither existing FDA data nor studies performed by others are sufficient to draw definitive conclusions about the safety of reprocessed SUDs compared to similar original devices. While FDA has made changes to its data collection process regarding reprocessed SUD-related adverse events, the data are not suitable for a rigorous comparison of the safety of reprocessed SUDs compared to similar original SUDs. For such a comparison to be definitive, FDA would have to collect additional data that would identify the type of device and adverse event, the number of original and reprocessed SUDs of that type in use, the number of times each reprocessed SUD was used, and the rate of adverse events associated with the original devices. With regard to safety-related data outside of FDA, the limited number of peer-reviewed studies related to reprocessing published since 2000 was insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. FDA officials have concluded that the cost of conducting rigorous testing would not be an efficient use of resources, especially given that the available data, while limited, do not indicate that reprocessed SUDs present an elevated health risk. FDA has analyzed its data on reported adverse events related to reprocessed SUDs and has concluded that there are no patterns that point to these devices creating such risks. After reviewing FDA's processes for monitoring and investigating its adverse event data, we found no reason to question FDA's analysis.

In commenting on a draft of this report, HHS provided language to clarify several sentences which we generally incorporated. We also incorporated HHS's technical comments as appropriate.

Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), FDA is responsible for reviewing the safety and effectiveness of medical devices before they go to market (premarket review) and ensuring that they remain safe and effective afterwards (postmarket oversight). Manufacturers intending to sell medical devices in the United States, including reprocessed SUDs, must register with FDA and provide information listing the devices they intend to market.⁷ FDA considers establishments engaged in reprocessing (that is, any activity needed to render a used SUD ready for use on a subsequent patient) to be the manufacturers of those reprocessed SUDs.⁸ Establishments, including reprocessing establishments, are required to update their registrations annually and their device listings twice each year.

FDA's premarket review activities for devices—that is, for reusable devices, for originally manufactured SUDs, and for reprocessed SUDs—mainly involve analyzing information submitted by those establishments that plan to market devices, including clinical or engineering documents and proposed labeling and instructions for use. Devices encompass a wide range of complexity and potential risk, and higher-risk or innovative devices require a more rigorous level of premarket review than lower-risk devices. For example, many relatively simple, low-risk devices, such as scissors used for medical purposes, are exempt from premarket review requirements. For other devices, such as catheters, manufacturers are

⁷When establishments register with FDA, they indicate which of several FDA-regulated activities they plan to engage in, such as manufacturing, importing, relabeling and repackaging devices, or reprocessing SUDs. When establishments identify their devices—a process known as medical device listing—establishments indicate which devices are associated with each activity, in order to allow FDA to determine which devices are manufactured or imported and which are reprocessed, for example. By listing a device with FDA, an establishment does not necessarily mean it is commercially distributing that device. For example, some listed devices may not yet be available, but are being considered for the future or are awaiting premarket clearance, if required.

⁸FDA does not consider the activity of resterilizing unused devices to be reprocessing. The need to resterilize such “open but unused” devices may arise when a surgical procedure is cancelled after the devices had been removed from their sterile packaging, and a hospital may send these devices out to be resterilized and repackaged by an outside establishment.

required to submit documentation for FDA’s review and receive clearance before they may be marketed.

For all devices, FDA has assigned about 1,700 device types⁹ into one of three classes based on the level of risk posed and controls necessary to ensure their safety and effectiveness.¹⁰ Class I (low-risk) devices include such things as elastic bandages. Class II (medium-risk) devices include items like powered bone drills. Class III (high-risk) devices include those that support or sustain human life such as balloon angioplasty catheters. Most class I devices are exempt from premarket submission requirements set forth in Section 510(k) of the FDCA (premarket notification).¹¹ For most class II devices, manufacturers are required to submit a premarket notification report. The premarket notification report must provide evidence that the device is substantially equivalent to a device already on the market before FDA will allow it to be marketed.¹² For class III devices, manufacturers are required to submit an application for premarket

⁹Throughout this report we refer to *type of device* or *device type* to indicate a generic category of device. Each FDA-identified device type has a particular intended use (for example, a scalpel is intended to cut tissue) and may have more specialized “indications for use” (for example, a scalpel designed to make incisions on the cornea). Each device type may include a variety of models made by different manufacturers. Accessories used along with a particular device may have their own product code or be included in the same product code as the main device.

¹⁰Device classifications and exemptions from premarket review are codified in parts 862 through 892 of title 21 of the Code of Federal Regulations; in addition, FDA’s Web site provides searchable databases at www.fda.gov/cdrh/databases.html. Class I devices are those for which compliance with the *general controls*, such as basic manufacturing requirements specified in FDA’s quality system regulation, are sufficient to ensure safety and effectiveness. Class II devices are subject to both the general controls and *special controls*, such as postmarket surveillance, to ensure safety and effectiveness. Class III devices, in addition to going through premarket approval, which is the most rigorous premarket review, are subject to general controls and may be subject to special controls as well.

¹¹21 U.S.C. § 360(k).

¹²*Substantially equivalent* or *substantial equivalence* means the device has the same intended use as another legally marketed device and the same technical characteristics, or different technical characteristics that are found to be as safe and effective as the marketed device and do not raise different questions of safety or effectiveness. 21 U.S.C. § 360(c)(i). Most devices enter the market by demonstrating their substantial equivalence. New devices are automatically classified as class III devices and must go through premarket approval before they may be marketed. Manufacturers of new devices automatically classified into class III can petition FDA for reclassification. 21 U.S.C. § 360c(e).

approval, which must provide evidence, including clinical data, demonstrating that the device is safe and effective.¹³

FDA's postmarket surveillance activities mainly involve inspecting device establishments and collecting and analyzing reports about device safety. FDA inspects registered device establishments, including reprocessing establishments, to assess compliance with applicable quality control and adverse event reporting regulations, among others.¹⁴ In addition to inspecting device establishments, FDA's postmarket activities include collecting and analyzing reports of device-related adverse events to ensure that devices already on the market remain safe and effective. Manufacturers are required to report device-related deaths, serious injuries, and certain malfunctions to FDA. In addition, user facilities, such as hospitals and nursing homes, are required to report device-related deaths to FDA and to the device manufacturer, and to report serious injuries to the manufacturer or, if the manufacturer is unknown, to FDA. Both manufacturers and user facilities may also voluntarily report to FDA less-serious device-related events that are not likely to result in subsequent serious injuries if the malfunction were to recur.¹⁵ FDA maintains databases that include both mandatory and voluntary reports of device-related adverse events, which agency officials can search to conduct research on trends or emerging problems with device safety. FDA scientists review these reports, request follow-up investigations, and

¹³21 U.S.C. § 360e.

¹⁴FDA's quality system regulation specifies quality control processes that all device manufacturers, including reprocessing establishments, must follow to ensure that devices are safe and effective for their intended use and otherwise in compliance with the FDCA. See 21 C.F.R. pt. 820 (2007). FDA inspectors document instances where establishments are not in compliance with the regulation but generally do not indicate a specific corrective action. FDA also conducts premarket inspections of establishments. Premarket inspections are conducted prior to the introduction of devices into the U.S. market. Postmarket inspections occur after a device has already been marketed.

¹⁵User facilities must also submit to FDA an annual report of device-related deaths and serious injuries that they have filed each year. Manufacturers must submit a supplemental or follow-up report for an adverse event within 1 month after receiving information that is required to be reported but that was not included in the initial adverse event report because it was either not known or not available at the time. Manufacturers can request alternative summary reporting under 21 C.F.R. § 803.19(b). In addition, health care professionals, consumers, and others may also voluntarily report device-related product problems as well as device-related adverse events. See app. IV for additional information on specific device-related adverse event reporting requirements, including the time frames in which manufacturers and user facilities are required to submit reports.

determine whether further action is needed to ensure patient safety.¹⁶ Such action may include product recalls, public health advisories to notify health care providers and the public of potential device-related health and safety concerns, or requiring a manufacturer to change the instructions in its device labeling. FDA officials told us that the vast majority of reports involve a device malfunction that has the potential to cause a death or serious injury if the malfunction were to recur, even though there was no death or serious injury in the reported event.¹⁷

Varied Information Available on Reprocessed SUD Industry

FDA has information on domestic reprocessing establishments and the devices they are reprocessing or considering for reprocessing, but it does not have data on the extent of actual production or on where the devices are being used. Collectively, according to FDA, 11 establishments were actively reprocessing or planning to reprocess more than 100 different types of SUDs in the United States as of July 2007.¹⁸ (See app. II for a list of the types of SUDs that have been listed by reprocessing establishments.) While definitive information on the size of the reprocessed SUD market is not available, representatives of the reprocessing industry estimate that 3 of the 11 registered reprocessing establishments (2 of which are owned by the same firm) account for the vast majority of the total reprocessing business in the United States. Only one hospital was included among the

¹⁶FDA officials told us that, while the agency reviews all adverse event reports, it places the highest priority on reports involving pediatric deaths, multiple deaths or serious injuries from a single device, fires, burns, or highly unusual events such as radiation exposure, over- or underdosing of radiation, radiation being delivered to the wrong site, and severe allergic reactions (anaphylaxis).

¹⁷However, FDA officials told us that, taken as a whole, even less-serious reports can provide valuable information. The review of malfunction reports can lead to identification of significant problems with devices that have the potential for serious injuries or deaths. FDA conducts ongoing analyses to identify emerging trends in the type or volume of problems that could warrant further review, for example, if FDA receives similar reports of user-error associated with a particular device.

¹⁸FDA data indicated that more than 40 establishments were registered as reprocessing establishments as of March 2007, including 13 located outside the United States. However, upon our request, FDA officials determined that many of these establishments had registered as reprocessing establishments in error, and FDA officials identified 11 establishments in the United States that were engaged in reprocessing SUDs as of July 2007. As of October 2007, FDA officials were in the process of determining whether the 13 registered establishments located outside of the United States were actively engaged in reprocessing, and if so, whether they were marketing reprocessed SUDs in this country. The officials stated that the agency plans to issue assignments by March 2008 for the inspection of foreign establishments it identifies as actively reprocessing SUDs for the U.S. market but they did not specify a date by which the inspections would be completed.

11 active reprocessing establishments identified by FDA. Our inquiries with hospital representatives and federal agencies that administer hospitals, such as the Department of Veterans Affairs, indicated use of reprocessed SUDs among hospitals varies.

**Eleven Active
Reprocessing
Establishments
Collectively May Be
Reprocessing More than
100 Types of SUDs**

FDA identified 11 establishments actively reprocessing SUDs in the United States as of July 2007, 1 of which was a hospital. Seven establishments engaged exclusively in reprocessing or in reprocessing and one other activity, such as contract sterilizer. According to representatives of the reprocessing industry, 3 of these 7 account for about 90 percent of all SUD reprocessing. Four of the 11 reprocessing establishments registered with FDA to undertake three or more FDA-regulated activities including distribution or manufacturing. For example, 1 reprocessing establishment manufactures over 80 different types of medical devices but reprocesses only one type of SUD that it also manufactures. Four of the 11 establishments, including the hospital, have each listed only one type of reprocessed SUD.¹⁹

The more than 100 types of devices that reprocessing establishments reported actively reprocessing or planning to reprocess represent devices with a range of intended uses, some more invasive than others. For example, compression sleeves, which are used to provide intermittent compression to a patient's limbs to help prevent postoperative blood clots from forming, are intended to make contact with patients' skin only, not to enter the body. In contrast, surgical devices such as orthopedic drill bits or surgical saw blades are intended for use in internal parts of the body. Electrophysiology catheters are inserted into the heart to measure cardiac rhythm and have been reprocessed for over 20 years. While we found no reliable data on the volume of reprocessed SUDs by device type, representatives of 3 large reprocessing establishments have stated that noninvasive devices such as compression sleeves account for the greatest volume of their overall business, with surgical devices representing a much smaller share of their business.

¹⁹By listing a device with FDA, an establishment does not necessarily mean it is actively reprocessing and commercially distributing that device. For example, some listed devices may not yet be available, but are being considered for the future or are awaiting premarket clearance, if required. Therefore the listed devices we report represent both those SUDs that are currently available as reprocessed and those that were being considered for reprocessing.

Information on the Size of the Reprocessed SUD Market Is Not Available

Data on the exact size of the SUD reprocessing industry—in terms of the volume or value of reprocessed SUDs sold—and how it compares to the original SUD industry or the overall medical device industry are not available. FDA neither collects nor reports on the volume or value of reprocessed SUDs sold; the agency also does not maintain data on the volume or value of original SUDs or on all medical devices sold. Regarding private sector data sources, we found that data on the SUD reprocessing industry were either not available or were considered proprietary by industry sources. Similarly, representatives of trade associations that represent establishments that manufacture original SUDs and reusable devices could not provide data on the proportion of the overall medical device industry that consists of devices labeled for single-use and could be reprocessed.

Hospital Use of Reprocessed SUDs Varies

Two FDA studies indicate that hospital use of reprocessed SUDs varies. In 2002, FDA reported that about one-fourth of U.S. hospitals used at least one type of reprocessed SUD, with larger hospitals being more likely to do so.²⁰ To develop this estimate, FDA surveyed more than 5,000 hospitals.²¹ Nearly half of responding hospitals with more than 250 beds reported using reprocessed SUDs, compared with 12 percent of responding hospitals with fewer than 50 beds.²² This information was supplemented by a more recent study in 2005. In this study, which focused on hospitals' level of satisfaction with reprocessed SUDs, FDA received information from 102 representatives of hospitals across the nation. About 40 percent indicated they used a third party to reprocess SUDs. FDA followed up with

²⁰U.S. Food and Drug Administration, *Final Report: Survey on the Reuse and Reprocessing of Single-Use Devices (SUDs) in U.S. Hospitals* (Rockville, Md., 2002). Prepared for FDA by Eastern Research Group, Inc., Lexington, Mass., Contract 223-98-8002.

²¹The survey response rate was 79.4 percent, which included both complete and partial responses.

²²Most of the hospitals reported contracting with other establishments to perform the reprocessing, but the initial results of the survey indicated that about 13 percent of those that used reprocessed SUDs reported doing their own reprocessing. FDA informed us that, to enforce the requirement that hospitals that do their own reprocessing register with FDA and comply with appropriate quality control regulations, inspectors visited all of the hospitals that reported performing their own reprocessing and a statistical sample of about 200 of the approximately 900 hospitals that did not respond to the survey. According to FDA officials, the inspectors who visited these hospitals determined that most were not involved in reprocessing and had responded to the survey question in error. FDA officials told us that all of the hospitals that FDA's inspectors determined were reprocessing SUDs indicated that they planned to stop the practice after the FDA inspectors' visits.

focus groups to obtain more detailed information on the differing perspectives of various types of hospital personnel about the hospitals' use of reprocessed SUDs. In general, participating hospitals that reported using reprocessed SUDs indicated their facilities had specific policies regarding reprocessing, used a variety of types of reprocessed SUDs, and believed that reprocessing provides substantial cost savings.

In our discussions with representatives of reprocessing establishments and a managed care organization that runs several hospitals, we were told that hospitals or hospital systems generally set their own policies regarding whether to use reprocessed SUDs, which reprocessing establishment to use, and which reprocessed SUDs are acceptable to the hospitals' physicians and other clinical personnel. This holds true for some federal hospitals as well. The Department of Defense, for example, allows individual medical facilities the option of using SUDs that are reprocessed by establishments that are registered with FDA as reprocessors.²³ According to Department of Defense officials, as of October 2007

- 3 of the Navy's 22 medical centers and hospitals reported using reprocessed SUDs;
- 4 of the Army's 26 medical centers and hospitals reported using, or planning to use, reprocessed SUDs; and
- 1 of the Air Force's 17 medical centers and hospitals reported using reprocessed SUDs.

In contrast to the Department of Defense policy, the Department of Veterans Affairs has had an agencywide policy prohibiting the use of reprocessed SUDs in any of its medical centers since at least 1991. According to Department of Veterans Affairs officials, the agency could not determine whether reprocessed SUDs are safe or not. However, the agency does not allow the use of reprocessed SUDs because manufacturers did not design SUDs to be used more than once and, as a consequence, do not provide instructions on cleaning and sterilizing these devices. These officials told us that the department's policy has remained

²³Department of Defense medical facilities are not obligated to use reprocessed SUDs. Medical facilities that choose to use reprocessed SUDs must follow Department of Defense and service-level policy, which is based on current FDA guidance, and can not reprocess SUDs internally but must utilize a third-party reprocessor registered with FDA as a reprocessor.

largely unchanged, although the agency has reconsidered it at various times.

FDA Has Increased Its Oversight of SUD Reprocessing

FDA has taken actions, both on its own initiative and in response to legislation, to strengthen the agency's oversight of reprocessed SUDs. These actions include (1) requiring additional premarket data submissions for 72 types of reprocessed SUDs and (2) conducting postmarket activities such as inspections of reprocessing establishments to ensure compliance with regulatory requirements and other surveillance to assess whether reprocessing is associated with an increased public health risk.

FDA Identified More than 70 Types of SUDs That Require Additional Premarket Review

FDA's premarket oversight of reprocessed SUDs has increased, beginning with actions FDA took on its own initiative in 2000. In August of that year, FDA issued guidance that clarified its policies on the regulation of reprocessed SUDs. This guidance was directed at hospitals and third-party entities engaged in reprocessing SUDs for reuse. At the time, a sizeable minority of U.S. hospitals were thought to be reprocessing their own SUDs without FDA oversight.²⁴ FDA recognized that hospitals were not likely to be familiar with its regulations, so the guidance included time frames for these reprocessing establishments to comply.²⁵ According to FDA officials, the agency intended to subject each type of reprocessed SUD to the same level of premarket review as required of original SUDs. For example, if the SUD was exempt from premarket requirements before it was used for the first time, the reprocessed SUD would also be exempt.

MDUFMA, enacted in 2002, directed FDA to review the premarket submission requirements for reprocessed SUDs and identify those devices for which FDA would require additional validation data to document cleanliness, sterility, and performance following reprocessing. This meant that reprocessing establishments had to submit additional premarket

²⁴In our 2000 report, we referred to surveys in the late 1990s indicating that between 16 and 31 percent of hospitals reported using reprocessed SUDs, with at least one-third of those hospitals reporting contracting with independent reprocessing companies. [GAO/HEHS-00-123](#) at 8–9.

²⁵See U.S. Food and Drug Administration, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Rockville, Md., Aug. 14, 2000). Among other things, this guidance specified that hospitals and third-party establishments engaged in reprocessing must comply with registration and listing, quality system regulation, and applicable premarket requirements.

documentation for certain types of reprocessed SUDs to demonstrate that they remain safe and effective or substantially equivalent to another device already on the market. MDUFMA directed FDA to identify devices that fell into the following two categories and to determine whether additional information was needed to determine their continued marketability:

- The first category consisted of reprocessed SUDs that had been *exempt from* premarket notification at the time MDUFMA was enacted.²⁶ For these reprocessed SUDs, FDA was required to determine whether the devices' premarket notification exemptions should be terminated to provide reasonable assurance of their safety and effectiveness. Manufacturers of devices identified by FDA were required to provide premarket notification with validation data on cleaning, sterilization, and functional performance to ensure that the reprocessed SUDs remained safe and effective after the maximum number of reprocessing cycles.²⁷ FDA, in response, identified 20 types of reprocessed SUDs that met these criteria and revoked their premarket notification exemptions. Examples of types of reprocessed SUDs that had their exemptions terminated and that were required to submit the additional validation data included noncompression heart positioners (devices intended to move, lift, and stabilize the heart during open heart surgery), nonelectric biopsy forceps (devices used to remove a specimen of tissue for microscopic examination), and various surgical devices such as specialized needles and catheters.
- The second category consisted of reprocessed SUDs that were *already subject* to premarket notification at the time MDUFMA was enacted. FDA was required to determine whether additional documentation on cleaning, sterilization, and performance was necessary to ensure that the device remained safe and effective after the maximum number of reprocessing cycles. FDA, in response, identified 52 types of reprocessed SUDs that met those criteria and required that premarket submissions for them include such data. Examples of device types that were subject to the additional validation data requirement included electric biopsy forceps, surgical drills

²⁶This provision of MDUFMA applied only to *critical* and *semicritical reprocessed SUDs*. Critical reprocessed SUDs are intended to contact normally sterile tissue or body spaces during use, and semicritical reprocessed SUDs are intended to contact intact mucous membranes and not penetrate normally sterile areas of the body. 21 U.S.C. § 321(mm)(1), (2).

²⁷According to FDA officials, FDA does not set a limit on the number of times a device type may be reprocessed; the purpose of the validation data is to ensure that reprocessing establishments test, and document to FDA's satisfaction, that a SUD may be reprocessed for at least the number of times the establishment has designated.

and accessories, and oximeters (devices used to measure the level of oxygen in a patient’s blood).

Appendix III summarizes FDA’s methodology for identifying the 72 types of reprocessed SUDs for which the agency has required additional premarket data submissions in accordance with MDUFMA.²⁸

As part of its premarket review, FDA evaluates not only the devices themselves but the accompanying labeling and instructions for use. MDUFMA required that the labeling of all reprocessed SUDs state that the device had been reprocessed and the name of the establishment that reprocessed it. This provision took effect in January 2004 and applies to devices marketed after that date. MDUFMA and subsequent legislation also required that reprocessed SUDs or an attachment to such devices “prominently and conspicuously” bear the reprocessing establishment’s name, abbreviation, or symbol.²⁹ FDA issued guidance that first became effective on August 1, 2006, to help reprocessing establishments comply with this requirement.³⁰

FDA Actions for Postmarket Oversight of Reprocessed SUDs Have Taken Several Forms

FDA’s actions regarding its postmarket oversight of reprocessed SUDs have included (1) clarifying that SUD reprocessing establishments are subject to the same inspection requirements as other device manufacturing establishments and (2) updating reporting forms to better

²⁸In addition to directing FDA to identify those reprocessed SUDs that should require additional validation data to document cleanliness, sterility, and performance following reprocessing, for class III reprocessed SUDs, MDUFMA created a new requirement. Those manufacturers marketing class III reprocessed SUDs would have to submit a premarket report, which requires among other things a full description of the methods used in, and the facilities and controls used for, the reprocessing and packaging of the device. According to FDA, the agency had received one premarket report for a class III reprocessed SUD as of July 2007, but the applicant subsequently withdrew it.

²⁹Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, § 2(c), 119 Stat. 439, 441 (2005). When MDUFMA was enacted this requirement applied to all devices, but subsequently Public Law 109-43 limited it to reprocessed SUDs only. In cases where the original SUD is not marked directly with the manufacturer’s name, abbreviation, or symbol, the reprocessing establishment may provide a detachable identification label on the device’s package that is intended to be attached to the patient’s medical record.

³⁰U.S. Food and Drug Administration, *Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices* (Rockville, Md., May 1, 2006).

FDA Clarified Oversight
Policies and Plans for
Inspecting Reprocessing
Establishments

identify those device-related adverse event reports involving reprocessed SUDs.

With the issuance of its August 2000 guidance, FDA intended to make clear its plans to subject hospitals and other third-party establishments that reprocess SUDs to FDA inspection for compliance with applicable regulatory requirements just like other establishments manufacturing medical devices. For the 11 U.S. establishments actually reprocessing SUDs as of July 2007, FDA had inspected 10 at least once during the period August 2004 through October 2007. These included multiple inspections of the 3 reprocessing establishments that industry representatives estimate to account for about 90 percent of all U.S. SUD reprocessing. FDA had not inspected 1 of the 11 reprocessing establishments. This establishment was first registered as a reprocessing establishment in 2006, and FDA officials told us that the agency plans to inspect it in 2008.³¹

We reviewed FDA summaries and other documents related to inspections conducted from August 2004 through October 2007 for the 10 inspected reprocessing establishments. For 3 establishments, none of the inspections indicated that corrective actions were needed. That is, no objectionable conditions or practices were found during the inspection. For the remaining 7 reprocessing establishments, at least one FDA inspection for those establishments during this period found that corrective actions were needed. This means that the inspection identified objectionable conditions or practices through which the establishment failed to meet either regulatory or administrative requirements. In general, in cases like these, depending upon the severity of the objectionable conditions identified, FDA determined whether the establishments could take corrective actions voluntarily, or whether conditions warranted issuance of FDA warning letters or more severe enforcement actions such as product seizures or

³¹FDA instructs its district offices to select medical device establishments for inspection using the following priority order: (1) device manufacturers with a pending medical device premarket application for approval; (2) manufacturers of class III devices that have never been inspected; (3) follow-up inspections for previously conducted for-cause or compliance inspections; (4) manufacturers of high-risk devices identified by special assignment from FDA, such as manufacturers of devices with a higher frequency of recalls and adverse event reports or manufacturers of new devices that have not been manufactured and distributed for very long; and (5) SUD reprocessing establishments. See FDA guidance *Inspection of Medical Device Manufacturers* (June 15, 2006) (<http://www.fda.gov/cdrh/comp/guidance/7382.845.html>, downloaded Oct. 25, 2007).

injunctions.³² In the cases we reviewed that involved corrective actions, we found the following:

- For 6 establishments, FDA investigators determined that actions taken by the establishments were adequate to address the deficiencies identified during the establishment inspections. FDA considers these inspections to be resolved. For example, one inspection revealed that the establishment had reprocessed two models of SUDs before it received FDA approval to reprocess them. The firm stopped reprocessing these models of SUDs prior to FDA's inspection and FDA inspectors determined that the establishment had voluntarily taken the corrective actions that were required. In another instance, FDA investigators found that the establishment had not maintained complaint files appropriately. Specifically, the establishment received a complaint from one hospital that five blood pressure cuffs reprocessed by that establishment did not function properly. However, the establishment listed all five devices as a single complaint rather than documenting each nonfunctioning device separately as required. At the end of the inspection, the establishment agreed to make each device a separate complaint rather than group several devices under one complaint number.
- The inspection for 1 establishment was open and under investigation as of November 2007. For this establishment, FDA inspectors identified a number of objectionable conditions, including instances in which the establishment did not adequately investigate reported problems associated with reprocessed SUDs or submit reports of device problems to FDA within the required time. In September 2007, FDA conducted a meeting with officials representing the establishment to discuss the inspection findings in detail. The establishment subsequently provided a written response to FDA containing the actions it proposed to take in order to correct the deficiencies identified by FDA investigators. FDA officials told us that the agency will not consider the inspection deficiencies to be resolved until FDA investigators reinspect the establishment. As of November 2007, FDA had not scheduled a reinspection of this establishment.

FDA Has Taken Steps to Improve Adverse Event Reports Related to Use of Reprocessed SUDs

MDUFMA directed FDA to modify its forms for mandatory and voluntary reporting of incidents involving devices to indicate when device-related adverse event reports involved reprocessed SUDs. Since fall 2003, FDA has included a check box in its mandatory and voluntary adverse event

³²See app. II for additional information on the inspection results.

reporting forms to indicate whether the device associated with the adverse event was a reprocessed SUD.³³

In addition to the change already made, an FDA workgroup is investigating whether further refinements in the device-related adverse event reporting forms, such as additional instructions, could further improve the accuracy of the adverse event reports associated with reprocessed SUDs. FDA officials told us that, while the new labeling and marking requirements for reprocessed SUDs, as well as the updated reporting forms, may eventually enhance their ability to identify device-related adverse event reports involving reprocessed SUDs, as of July 2007, agency officials had not detected an appreciable change in the reports submitted involving reprocessed SUDs.

Available Data Lack Rigor for Definitive Comparisons but Do Not Indicate That Reprocessed SUDs Pose an Elevated Health Risk

While FDA has made changes to its data collection process regarding reprocessed SUD-related adverse events, the data are not suitable for a rigorous comparison of the safety of reprocessed SUDs relative to original SUDs of the same type on their initial use. Such a comparison would require collecting additional data such as the type of device and adverse event and the number of original and reprocessed SUDs of that type in use. The limited number of peer-reviewed studies related to reprocessing that we identified were insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. Despite the limitations of available data, FDA's analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk.

³³The number of adverse event reports associated with all devices increased substantially from 2000 to 2006. In 2000, FDA received about 77,000 reports of adverse events associated with all devices. By 2006, this number had increased more than fourfold to about 320,000 reports.

Rigorous Safety Comparisons Not Possible through Current or Planned Adverse Event Reporting

While FDA's database of device-related adverse events is designed to provide information about trends such as infection outbreaks or common user error caused by inadequate instructions, it is not comprehensive. That is, the system cannot generate sufficient data on device performance that would be required to compare the safety of reprocessed SUDs with either original SUDs on their initial use or to other devices in general.³⁴ Such a study, at a minimum, would require data that would identify the type of device and adverse event, the number of original and reprocessed SUDs of that type in use, the number of times each reprocessed SUD was used, and the rate of adverse events associated with the original devices. FDA officials, including the Director of the Center for Devices and Radiological Health, have described the effort that would be required and acknowledged the shortcomings of the current adverse event reporting system to generate comparative safety data. FDA officials indicated to us, however, that such studies would not be an efficient use of agency resources given the existing level of FDA oversight.

To supplement our review of the safety information developed and analyzed by FDA, we conducted a review of the scientific literature related to SUD reprocessing published in peer-reviewed journals since 2000. We identified six studies that addressed the safety of reprocessed SUDs. On examination, none of the six studies were comprehensive enough to support an overall conclusion about the relative safety of reprocessed SUDs compared to SUDs on their initial use. They were limited in that they tested relatively few devices, and the reprocessing establishments had not been inspected by FDA.

FDA Has Found No Causative Link between a Reprocessed SUD and Reported Patient Injury or Death

FDA has reviewed available adverse event reports associated with reprocessed SUDs and has not identified a causative link between the adverse event and the fact that the devices involved were reprocessed. In September 2006, the Director of FDA's Center for Devices and Radiological Health testified that based on available adverse event data, FDA had identified 434 reports submitted from October 2003 to July 2006 in which reprocessed SUDs were identified on the reporting form. With respect to these reports, FDA determined that the majority of the reports,

³⁴We have reported on the limitations of FDA's adverse event data. For example, in 2000, we reported that all adverse event reporting systems, such as FDA's, that rely on health care providers to take the initiative to make a report experience a high level of underreporting. See GAO, *Adverse Events: Surveillance Systems for Adverse Events and Medical Errors*, GAO/T-HEHS-00-61 (Washington, D.C.: Feb. 9, 2000).

including all 15 of the reports involving deaths, did not involve a reprocessed SUD. For example, FDA determined that many of the reported events involved reusable devices such as magnetic resonance imaging machines or SUDs on their initial use. Of the 434 reports, FDA further reviewed the 65 events that it found actually involved or were suspected to involve a reprocessed SUD and that the reprocessed SUD was one of several possible causal factors in the adverse event. In reviewing these 65 reports, FDA found that the types of adverse events reported to be associated with the use of reprocessed SUDs were the same types of events that are reported for new, nonreprocessed devices.

In 2005, FDA consulted hospitals participating in the agency's Medical Product Safety Network (MedSun) about their experiences, including adverse events or safety concerns, with reprocessing.³⁵ None of the representatives of MedSun hospitals who participated in the FDA focus groups reported being aware of any infections related to the use of reprocessed SUDs. However, hospital representatives noted that if an infection occurred, it would be very difficult to discern if a reprocessed SUD was the cause. Similarly, none of the hospital representatives expressed significant concerns about potential malfunctions with reprocessed SUDs, even though some of them indicated that malfunctions of reprocessed SUDs occurred on occasion (for example, surgical blades and other tools sometimes may not have been sharpened properly).³⁶ Overall, however, participating hospital representatives generally expressed confidence in reprocessed SUDs, with some participants stating that there were actually fewer performance problems with reprocessed SUDs than with new SUDs. According to FDA, all participants believed that reprocessing establishments are more stringently regulated by FDA than are the manufacturers of the original devices, and this provided them a sense of confidence in the reprocessing process.

After reviewing the available evidence—including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000,

³⁵MedSun was launched in 2002 to collect more-detailed adverse event reports about devices from a network of approximately 350 large hospitals that report through an Internet-based system. Participating MedSun hospitals voluntarily provide detailed information related to the design and use of devices. MedSun also encourages reporting of "close calls" so that preventative action can be taken before patients are injured.

³⁶One small hospital, for example, reported that it had discontinued the use of a reprocessed SUD after one broke during a procedure.

and the results of our and FDA's consultations with hospital representatives—we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat.

Agency Comments

In commenting on a draft of this report, HHS provided language to clarify several sentences which we generally incorporated. We also incorporated HHS's technical comments as appropriate. HHS's written comments appear in appendix V.

As arranged with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, appropriate congressional committees, and other interested parties. We will also make copies available to others on request. In addition, this report is available at no charge on the GAO Web site at <http://www.gao.gov>. If you or your staff have questions about this report, please contact me at (202) 512-7114 or williamsonr@gao.gov. GAO staff who made major contributions to this report are listed in appendix VI.



Randall B. Williamson
Acting Director, Health Care

Appendix I: Scope and Methodology

To address the report objectives, we (1) reviewed relevant laws, regulations, and agency guidance; (2) interviewed Food and Drug Administration (FDA) officials, representatives of professional associations of manufacturing establishments,¹ and the Association of Medical Device Reprocessors (AMDR); (3) interviewed officials from a provider association, private hospitals, and the Departments of Defense and of Veterans Affairs regarding their policies on the use of reprocessed single-use devices (SUD); and (4) reviewed FDA data, market research, and peer-reviewed studies. We conducted our work between November 2006 and January 2008 in accordance with generally accepted government auditing standards.

We consulted a variety of sources, including FDA officials who track industry trends, professional associations representing device manufacturers and reprocessing establishments, and hospitals. We found that neither industry nor FDA representatives were able to provide comprehensive information on the number and volume of devices manufactured for the United States, or on the subset of devices that are SUDs or reprocessed SUDs.

To determine the number of reprocessing establishments, we reviewed FDA data on the number of registered reprocessing establishments. FDA data indicated that more than 40 establishments were registered as reprocessing establishments as of March 2007, including 13 located outside the United States. After we determined that the FDA list did not match information provided by two FDA district offices, FDA officials determined that many of the establishments had registered as reprocessing establishments in error and subsequently identified 11 establishments in the United States that, as of July 2007, were engaged in reprocessing SUDs. We determined FDA's information on the number of establishments reprocessing SUDs in the United States as of July 2007 was sufficiently reliable for our purposes. However, given the errors in the FDA list of registered reprocessing establishments in 2007 and the lack of information on foreign establishments registered as reprocessors, we determined that FDA's data were not sufficiently reliable to determine the number of establishments reprocessing SUDs prior to July 2007 or the

¹These associations included the Advanced Medical Technology Association and the Medical Device Manufacturers Association.

number of foreign reprocessing establishments at any time.² As a result, we were unable to analyze trends in the number of reprocessing establishments or the types of devices being reprocessed since 2000, and we were limited to reporting on domestic reprocessing establishments.

Regarding the types of SUDs being reprocessed, our ability to provide precise information was limited because although FDA maintains databases of the types of devices the reprocessing establishments listed with FDA, it does not confirm that all listed devices are currently available. As a result, FDA's data may include types of SUDs that the reprocessing establishments no longer reprocess, types of SUDs they plan to reprocess, or types of SUDs they listed in error—in effect, overstating the types of SUDs the establishments are reprocessing or plan to reprocess.³ In addition, representatives of one reprocessing establishment identified one device type listed in the FDA database that the establishment never reprocessed, but only reesterilized and repackaged in unused form. While we were unable to determine their reliability, we used FDA's data listing the types of SUDs being reprocessed for the limited purpose of portraying the types of SUDs that the reprocessing establishments were reprocessing or planned to reprocess as of July 2007.

To determine available research published about the safety of reprocessed SUDs since we last reported on the topic in 2000, we reviewed FDA documents related to adverse events involving reprocessed SUDs and an FDA-sponsored survey of the experience of some hospitals related to SUDs, reviewed summaries of, and other documents related to, FDA inspections of reprocessing establishments conducted from August 2004 through October 2007, and conducted a literature search of studies (which we call articles) published in peer-reviewed journals from January 2000 through January 2007. We performed the literature review of peer-

²FDA officials were unable to determine whether the 13 establishments located outside of the United States that were registered as reprocessing establishments in 2007 were actively engaged in reprocessing, and if so, whether they were marketing reprocessed SUDs in this country. According to FDA officials, the agency is actively working to determine whether any of the 13 foreign establishments registered as reprocessors, plus an additional foreign establishment that FDA officials identified as potentially reprocessing SUDs, have imported reprocessed SUDs into the United States in the 6 months prior to October 2007. The officials stated that the agency plans to issue assignments by March 2008 for the inspection of all foreign establishments it identifies as actively reprocessing SUDs for the U.S. market but they did not specify a date by which the inspections would be completed.

³For example, an establishment might list a device for which it intends to obtain premarket clearance but does not yet have such clearance.

reviewed articles by searching the following databases: BIOSIS, EMBASE, Medline, ProQuest, and the Science Citation Index.⁴

Of the more than 30 articles located through the literature search, we identified a total of 6 articles that were published in peer-reviewed journals and that addressed the safety of reprocessed SUDs.⁵ These articles are listed below:

Colak, T.; Ersoz, G.; Akca, T.; Kanik, A.; Aydin, S. "Efficacy and Safety of Reuse of Disposable Laparoscopic Instruments in Laparoscopic Cholecystectomy: A Prospective Randomized Study." *Surgical Endoscopy* 18, no. 5 (2004): 727–731.

daSilva, M.; Ribeiro, A.; Pinto T. "Safety Evaluation of Single-Use Devices After Submission to Simulated Reutilization Cycles." *Journal of AOAC International* 88, no. 3 (2005): 823–829.

Fedel, M.; Tessarolo, F.; Ferrari, P.; et al. "Functional Properties and Performance of New and Reprocessed Coronary Angioplasty Balloon Catheters." *Journal of Biomedical Materials Research* 78, no. 2 (2006): 364–372.

Lipp, M.; Jaehnichen, G.; Golecki N.; et al. "Microbiological, Microstructure, and Material Science Examinations of Reprocessed Combitubes® After Multiple Reuse." *Anesthesia & Analgesia* 91 (2000): 693–397.

Roth, K.; Heeg, P.; Reichl, R. "Specific Hygiene Issues Relating to Reprocessing and Reuse of Single-Use Devices for Laparoscopic Surgery." *Surgical Endoscopy* 16, no. 7 (2002): 1091–1097.

⁴We performed our search using the following key words: SUD, single-use, single-use devices, one use, disposable equipment, medical device(s), equipment, reprocess, reuse, use again, safety, infection, malfunction, contaminate, contamination, or injury. We also examined other articles published in peer-reviewed journals identified during the course of our review.

⁵We did not review letters of opinion, news articles, commentary, association position statements, federal government publications such as FDA informational news articles or guidance documents, and previous GAO reports. We also excluded articles if the periodical was published outside of the United States; we could not confirm that the publication was peer reviewed; if the authors were known or thought to be associated with device trade associations, reprocessing establishments, or manufacturers; or if the study was directly sponsored by a manufacturer.

Wilson, S.; Everts, R.; Kirkland, K.; et al. "A Pseudo-Outbreak of *Aureobasidium* Species Lower Respiratory Tract Infections Caused by Reuse of Single-Use Stopcocks During Bronchoscopy." *Infection Control and Hospital Epidemiology* 21, no. 7 (2000): 470–472.

On examination, none of these studies were comprehensive enough to support an overall conclusion about the relative safety of reprocessed SUDs compared to SUDs on their initial use. Several limitations in the articles we identified through our literature review make it difficult to support an overall statement comparing the safety of reprocessed SUDs with the safety of other devices. These limitations include the following:

- Five of the six articles described studies that were conducted outside of the United States, so we could not determine whether the reprocessing methods and facilities would have met FDA's approval. The remaining article, while conducted in the United States, was published prior to MDUFMA's enactment in 2002 and subsequent FDA actions to implement new requirements.
- The articles reported on studies that tested few types of devices. Because each study used different types of devices, it is not possible to compare and aggregate their results to support general conclusions regarding the relative safety of reprocessed SUDs.

Appendix II: Reprocessing Establishments, Types of Reprocessed Devices Listed, and FDA Inspection Results

Establishment	Number of device types listed ^{a,b}	Examples of types of devices ^b	Years of Inspections conducted from August 2004 through October 2007		Inspection finding	Inspection finding status
A	20	Blood pressure cuff Cardiac stabilizer Laparoscopic instruments	2006	2005	Corrective action indicated Corrective action indicated	Open investigation Resolved
B	40	Curette External fixation device Electrophysiology catheter	2007	2005	Corrective action indicated No action indicated	Resolved
C	11	Tracheal tube stylet Protective restraint Bite block for endoscope	2006	2005	Corrective action indicated No action indicated	Resolved
D	43	Surgical saw blade Nonelectric biopsy forceps Orthopedic knife, burr	2007	2005	Corrective action indicated No action indicated	Resolved
E	11	Oxygen mask Oximeter Compression sleeve	2007	2005	No action indicated No action indicated No action indicated	
F	29	Oxygen mask Nonelectric biopsy forceps Arthroscopic accessories Pneumatic tourniquet	2006	2005	No action indicated No action indicated	
G	1	External fixation clamp	2007	2006	Corrective action indicated Corrective action indicated	Resolved Resolved
H	14	Orthopedic cutting instrument, bone tap Reamer, burr, drill bit	^c n.a.			
I	1	Disposable surgical instrument kit	2007	2006	No action indicated Corrective action indicated	Resolved
J	1	Disposable surgical instrument kit	2007	2006	Corrective action indicated Corrective action indicated	Resolved Resolved

**Appendix II: Reprocessing Establishments,
Types of Reprocessed Devices Listed, and
FDA Inspection Results**

Establishment	Number of device types listed^{a, b}	Examples of types of devices^b	Years of Inspections conducted from August 2004 through October 2007	Inspection finding	Inspection finding status
K	1	Compression sleeve	2004	No action indicated	

Source: GAO analysis of Food and Drug Administration (FDA) data.

Notes: n.a. = not applicable.

^aDevice types indicate all devices assigned to a distinct product code by FDA. Each device type may include a variety of actual instruments, manufacturers, and models. For example, some device types include the device itself, such as a powered saw, and its accessories.

^bThese data are provided for illustrative purposes to show the types of devices FDA data indicated that the 11 reprocessing establishments were reprocessing or planned to reprocess as of July 2007. Available data were limited because the FDA data on listed devices are not regularly verified and, as a result, the data may include types of SUDs that the reprocessing establishments no longer reprocess or plan to reprocess or that reprocessing establishments listed in error—in effect, overstating the types of SUDs establishments are reprocessing or plan to reprocess.

^cThe establishment first registered as a reprocessing establishment in 2006; as of July 2007 no inspections had been conducted but FDA officials reported plans to inspect the establishment in 2008.

Appendix III: FDA's Review of Premarket Requirements for Reprocessed SUDs Following MDUFMA

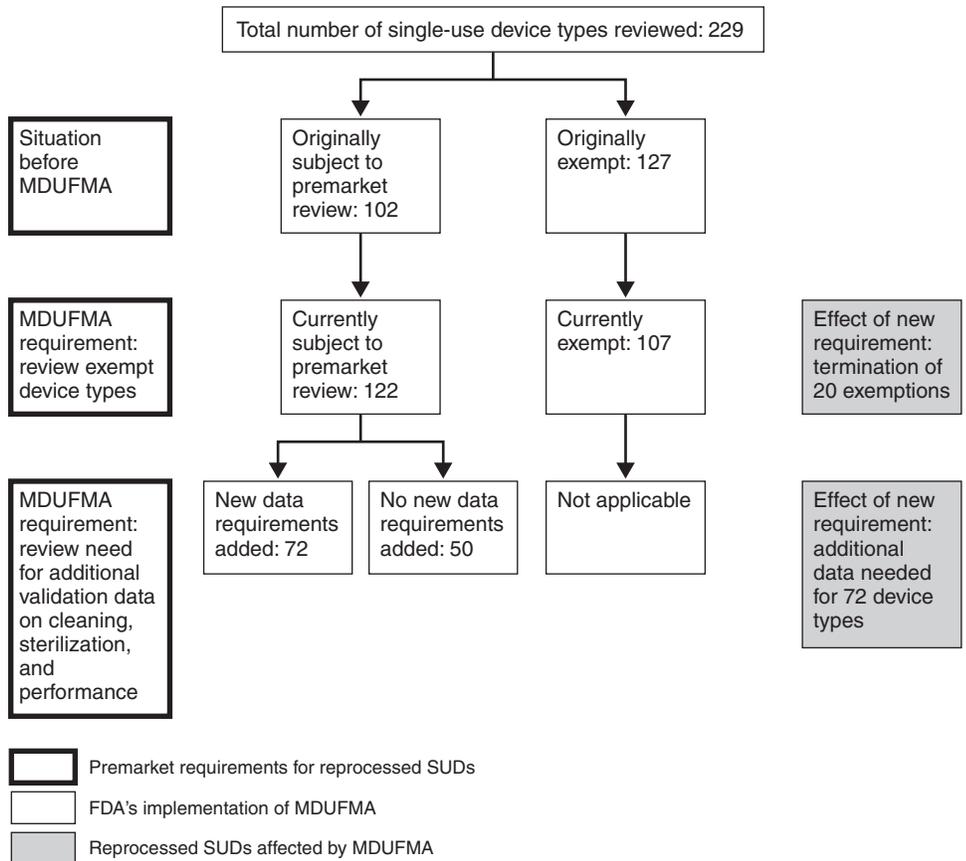
The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) required the Food and Drug Administration (FDA) to identify reprocessed single-use devices (SUD) that should be subject to additional premarket data submission requirements to ensure their safety and effectiveness. To identify these reprocessed SUDs, FDA analyzed the risks of infection or inadequate performance for 229 types of SUDs that the agency identified as either actually or potentially being reprocessed. For purposes of implementing MDUFMA, FDA took into account such factors as the physical characteristics of each type of SUD, including coatings that could be damaged by reprocessing, the type of contamination associated with the type of SUD's intended use, and the severity of potential injuries that could result if that type of SUD fails after reprocessing. FDA published the results of its review in a series of *Federal Register* Notices between April 2003 and September 2005.¹ These devices were either: (1) previously exempt from premarket notification and have had their exemptions revoked, and now also require validation data on cleaning, sterilization, and functional performance; or (2) already subject to premarket notification and now also require the additional validation data.

Reprocessing establishments that did not provide the required premarket notification and validation data by the deadlines established in these notices could no longer legally market those devices. Figure 1 summarizes the results of FDA's review in chart form.

¹70 Fed. Reg. 56911 (Sept. 29, 2005), 69 Fed. Reg. 19433 (Apr. 13, 2004), 68 Fed. Reg. 38071 (June 26, 2003), and 68 Fed. Reg. 23139 (Apr. 30, 2003).

Appendix III: FDA's Review of Premarket Requirements for Reprocessed SUDs Following MDUFMA

Figure 1: Overview of FDA's Implementation of MDUFMA's Premarket Review Requirements for Reprocessed SUDs, April 2003 through September 2005



Source: GAO.

As of May 30, 2007, FDA had received a total of 6 premarket notification submissions with additional validation data for 2 types of reprocessed SUDs that had their exemptions revoked following enactment of MDUFMA. Of these 6 submissions, 4 were cleared by FDA and 2 were pending as of May 30, 2007. FDA also received 88 submissions of premarket validation data for 16 types of reprocessed SUDs that had not been exempt at the time MDUFMA was enacted but that were subsequently required to submit additional validation data. Of these 88 submissions, 74 were cleared by FDA, 4 were found not substantially equivalent and therefore not marketable, and 10 were either withdrawn or pending as of May 30, 2007.

Appendix IV: Reporting Requirements for Device-Related Adverse Events

The Food and Drug Administration's (FDA) reporting framework for device-related adverse events includes both mandatory and voluntary components, depending on who is doing the reporting. Under FDA's Medical Device Reporting (MDR) regulation, device user facilities (including hospitals and other providers)¹ and manufacturers (including reprocessing establishments) must report deaths and serious injuries that a device has caused or may have contributed to. User facilities must report deaths to FDA and the manufacturer, and serious injuries to the manufacturer, if known, otherwise to FDA, whenever they become aware of information that reasonably suggests that a device has or may have caused or contributed to the death or serious injury of a patient. Manufacturers must report device-related deaths and serious injuries to FDA whenever they become aware of information that reasonably suggests that one of their devices has or may have contributed to the event. Manufacturers are also required to submit device malfunction reports to FDA whenever they become aware of information that reasonably suggests that one of their marketed devices has malfunctioned and that the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. See table 1 for a summary of MDR mandatory reporting requirements.

¹For purposes of device-related adverse event requirements, a device user facility is defined as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility that is not a physician's office. 21 C.F.R. § 803.3 (2007).

Appendix IV: Reporting Requirements for Device-Related Adverse Events

Table 1: Summary of MDR Mandatory Reporting Requirements for Device-Related Adverse Events

Reporter	What	To whom	When
User facility	Deaths	FDA and manufacturer	Within 10 work days from becoming aware of relevant information
	Serious injuries ^a	Manufacturer (FDA if manufacturer unknown)	Within 10 work days from becoming aware of relevant information
	Annual report of deaths and serious injuries ^a	FDA	January 1
Manufacturer ^b	Deaths and serious injuries ^a	FDA	30 calendar days from becoming aware of relevant information
	Malfunctions ^c	FDA	30 calendar days from becoming aware of relevant information
	Events that require immediate remedial action to prevent an unreasonable risk of substantial harm to the public health. ^d	FDA	Within 5 work days of becoming aware of relevant information

Source: FDA.

Notes: This table does not include the medical device reporting responsibilities of device importers.

^aFDA defines “serious injury” as an injury or illness that is life threatening; or results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. 21 C.F.R. § 803.3 (2007).

^bManufacturers are also required to submit supplemental and baseline reports. Supplemental reports include information that was not known or available when the original report was submitted. They must be filed within 1 month after the manufacturer becomes aware of new information. Baseline reports include information about the manufacturer and the device that is the subject of a reported adverse event. They are required when the manufacturer submits the adverse event report and must be updated annually.

^cMalfunctions must be reported if the device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

^dThese reports must also be submitted when FDA notifies the manufacturer in writing that 5-day reports involving subsequent events of the same nature associated with a particular type of device or similar devices are needed.

In addition to its mandatory reporting component, FDA also has a voluntary component for reporting device-related adverse events, known as FDA’s MedWatch program. Health care professionals can voluntarily report serious adverse events, product quality problems, or product use

errors that they suspect are associated with the devices they prescribe, dispense, or use. Consumers and others can also voluntarily report adverse events, product use errors, or quality problems, that they suspect are associated with the use of a device.

Appendix V: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

JAN 7 2008

Randall B. Williamson
Acting Director, Health Care
U.S. Government Accountability Office
Washington, D.C. 20548

Dear Mr. Williamson:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased and Available Information Does Not Indicate That Use Presents and Elevated health Risk (GAO 08-147).

The Department appreciates the opportunity to comment on this draft before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca Hernandez".

Vincent J. Ventimiglia
Assistant Secretary for Legislation

for

**General Comments of the Department of Health and Human Services (HHS) on the
Government Accountability Office's Draft Report Entitled, "Reprocessed Single-Use
Medical Devices: FDA Oversight Has Increased and Available Information Does Not
Indicate That Use Presents an Elevated Health Risk," (GAO-08-147)**

General Comments

Page 1

footnote one: revise as follows:

Generally, a medical device includes items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease or other condition. 21 U.S.C. § 321(h). Throughout this report, the term *device* refers to a medical device that is not being regulated as a drug or a biological product.

Page 5, 9th line from the bottom:

replace the sentence beginning with "Also, in response" with:

Also, in response to MDUFMA's requirements for increased oversight, FDA identified more than 70 types of reprocessed SUDs that would be subject to additional premarket submission requirements.

Page 7, first sentence under Background:

replace "ensuring that all devices are reasonably safe and effective" with:

reviewing the safety and effectiveness of nonexempt devices.

Page 9, footnote 14:

strike "and" in the last sentence and replace with:

but generally do not

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Matt Byer; Julian Klazkin; Suzanne Rubins; Stan Stenersen; and Jennifer Wiley made key contributions to this report.

Related GAO Products

Food and Drug Administration: Methodologies for Identifying and Allocating Costs of Reviewing Medical Device Applications Are Consistent with Federal Cost Accounting Standards, and Staffing Levels for Reviews Have Generally Increased in Recent Years. [GAO-07-882R](#). Washington, D.C.: June 25, 2007.

Food and Drug Administration: Limited Available Data Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications. [GAO-05-1042](#). Washington, D.C.: September 30, 2005.

Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted. [GAO/HEHS-00-123](#). Washington, D.C.: June 20, 2000.

Adverse Events: Surveillance Systems for Adverse Events and Medical Errors. [GAO/T-HEHS-00-61](#). Washington, D.C.: February 9, 2000.

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