

Guidance for Industry and for FDA Staff

Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.

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

**Division of Enforcement III
Office of Compliance**

Preface

Public Comment:

For 60 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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Guidance for Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals¹

A. Introduction

One of the principle components of FDA’s November 3, 1999 proposed strategy² on the reuse of single-use devices (SUDs) was the establishment of agency enforcement priorities concerning regulatory requirements for third parties and hospitals that engage in reprocessing devices labeled for single use (see Appendix A for FDA’s definitions of terms used in this document regarding reuse). FDA proposed to prioritize its enforcement activities based on the degree of risk posed by the reprocessing.

To accomplish this process, FDA proposed the following steps:

1. develop a list of commonly reused SUDs;
2. develop a list of factors to determine the degree of risks associated with reprocessing devices;
3. use that list of factors to divide the list of commonly reprocessed SUDs into three categories of risk – high, moderate, and low; and
4. develop priorities for enforcement of premarket regulatory requirements for third party and hospital reprocessors, based on the category of risk (high, moderate, and low).

We received many comments expressing concern that we were proposing to develop a new regulatory system for reprocessed SUDs that was outside of the current classification system under section 513 of the Federal Food, Drug, and Cosmetic Act (the Act) for class I,

¹ This document is intended to provide guidance. It represents the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alterative approach may be used if such approach satisfies the requirements of the applicable statue, regulations, or both.

² 64 FR 59782-59783, Nov. 3, 1999.

class II, and class III devices. We clarified at the December 14, 1999, FDA public meeting, and subsequently, that the categorization of devices by risk would be used only to set enforcement priorities; it would not entail a process outside of the current classification system.

Under the proposed strategy, devices would still be classified as class I, II, and III and still have premarket notification (510(k)) or premarket approval (PMA) requirements based on that classification. The proposed risk categorization scheme would only apply to our enforcement priorities, it would not relate to established premarket submission requirements.

For example, if we categorized a certain type of device as high risk under the risk categorization scheme, it would mean that we would set the enforcement of regulatory requirements for that device as the highest priority. It would not affect the classification of the device or the type of marketing submission that would be required for that device. If the generic type of that device were class III, we would generally require an approved PMA application before marketing. If the generic type of device were class II, we would require clearance of a 510(k) before marketing. A high risk categorization, therefore, would affect the timing of FDA's enforcement of these requirements rather than the requirements themselves.

We are issuing two companion draft guidances that would implement our proposed enforcement strategy:

1. One draft guidance is entitled “[Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme](#)” (“companion Risk Scheme guidance”). This draft guidance sets forth factors we would consider in categorizing a reprocessed device as high, moderate, or low risk, which we would use in setting our enforcement priorities for premarket requirements. An appendix to the companion Risk Scheme guidance lists commonly reprocessed SUDs, and lists what category of risk FDA believes a particular device falls within if reprocessed. If any device designated by the companion Risk Scheme guidance as moderate or high risk is currently exempt from premarket requirements, FDA will propose to amend its classification

regulations for those devices to require premarket submissions. This will be done on a product-by-product basis.

2. The other draft guidance document (herein) is entitled “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals” (“SUD Enforcement guidance”). This draft guidance sets forth our priorities for enforcing premarket requirements, based on the risk categorization of a device, as described in the companion Risk Scheme guidance.

In addition to premarket requirements (Sections 513 and 515 of the Act; 21 Code of Federal Regulations (CFR) Parts 807 and 814), third parties and hospitals that engage in manufacturing activities, including reprocessing of SUDs for reuse, may be subject to all other requirements of the Act including: registration and listing (Sections 510 of the Act; 21 CFR Part 807); submission of adverse event reports under the Medical Device Reporting (MDR) regulation (Section 519(a)(b) and (c) of the Act; 21 CFR Part 803); manufacturing requirements under the Quality System (QS) regulation (Section 520(f) of the Act; 21 CFR Part 820); Labeling (Section 502 of the Act; 21 CFR Part 801); Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821); and Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806).

These requirements, references to additional guidances that will help clarify these requirements, and FDA's enforcement priorities for these requirements are explained in more detail below.

B. Purpose

The purpose of this draft SUD Enforcement guidance is to describe FDA's enforcement priorities for third parties and hospitals that reprocess SUDs. The enforcement priorities for premarket requirements are based on the degree of risk associated with reprocessing SUDs as categorized by the risk scheme. A list of the types of SUDs that are subject to this guidance and their risk category

according to the draft risk categorization scheme is included in Appendix B. Although the list is not comprehensive, it represents FDA’s current understanding of the types of SUDs that are most often reused. FDA considers any reprocessed SUDs that are not on the list to be high risk.

C. Scope

This draft SUD enforcement guidance is applicable to third party and hospital reprocessors of these types of devices. This enforcement priorities set forth in this guidance do not apply to:

1. Permanently implantable pacemakers. The reuse of permanent pacemakers is addressed in [Compliance Policy Guide 7124.12](#) (issued on October 1, 1980 and revised in March 1995).
2. “Opened-but-unused” SUDs (as defined in Appendix A).
3. Health care facilities that are not hospitals³.

FDA is aware that hospitals may not be the only health care facilities that reprocess devices labeled for single use. At this time, the agency is limiting its focus to SUD reprocessing by third party and hospital reprocessors. In the near future, FDA intends to examine whether it should include other establishments that may reprocess SUDs.

D. Why is FDA phasing in the enforcement of regulatory requirements for SUD reprocessors?

FDA is planning to phase in the enforcement of regulatory requirements for third parties and hospitals that reprocess SUDs as described later in this document. With respect to premarket requirements, FDA intends to begin to enforce premarket notification and premarket application requirements within six (6) months of issuance of a final guidance if the reprocessed device is categorized as high risk, within twelve (12) months if the device is categorized as

³ For the purpose of this guidance, a hospital is defined as an acute health care facility.

moderate risk, and within eighteen (18) months if the device is categorized as low risk. Although FDA has not previously enforced premarket requirements for third party reprocessors, FDA currently enforces all other requirements applicable to manufacturers (such as registration, adverse event reporting, and quality system regulations) against third party reprocessors. The issuance of this draft or any final guidance will not change the continuing obligation of third party reprocessors to comply with those provisions of the Act. However, FDA would not enforce these requirements for hospitals until six (6) months from the issuance of a final guidance document.

FDA is establishing a phased-in approach for enforcement of regulatory requirements for third party and hospital reprocessors for a number of reasons. First, FDA believes that the health risk associated with reprocessing SUDs varies with the device and that the agency's regulatory activities should be implemented in accordance with the degree of risk involved. In addition, possible unintended and unpredictable consequences of the agency's immediate enforcement of all requirements (e.g., potential shortages in certain hospitals) support the need for a phased-in implementation period. Moreover, the agency is aware that establishments such as hospitals may be unfamiliar with FDA regulations and will need time to learn about the requirements and to develop programs to comply with these requirements. Finally, the agency's limited resources would not permit immediate enforcement of all regulatory requirements with respect to third party and hospital reprocessors. However, nothing in this guidance precludes FDA from taking immediate action against any particular product that is causing harm.

E. What are the Act's requirements that apply to third party and hospital reprocessors?

The requirements that apply to third party and hospital reprocessors are:

1. Registration and Listing (Section 510 of the Act; 21 CFR Part 807);

2. Medical Device Reporting (Sections 519(a)(b) and (c) of the Act; 21 CFR Part 803);
3. Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821);
4. Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806);
5. Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820);
6. Labeling (Section 502 of the Act; 21 CFR Part 801); and
7. Premarket Requirements (Sections 513 and 515 of the Act; 21 CFR Parts 807 and 814).

Each of these is described briefly below, with a citation to the corresponding section of the Act, FDA regulation in the CFR, and to other FDA guidances that are helpful in understanding a particular requirement. FDA is also including, in Appendix C, a list of additional guidances that may be helpful. FDA may issue additional guidances as needed.

1. Registration and Listing (Section 510 of the Act; 21 CFR Part 807):

Generally, owners and operators of establishments who process devices must register their establishment with FDA, and list each device. Establishments that are registering for the first time must use Form FDA-2891 (“Initial Registration of Device Establishment”). Copies of the form can be obtained from the Office of Compliance, Center for Devices and Radiological Health (HFZ-307), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850, or from Food and Drug Administration district offices.

The initial list of all SUDs that an establishment reprocesses must be reported on Form FD-2892 (“Medical Device Listing”). A separate Form FD-2892 must be submitted for each device or device class

added to the existing list. Copies of Form FD-2892 can be obtained from the address listed above.

Additional details regarding registration and listing are available in “CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA-2891, 2891a, and 2892”. A copy of this guidance can be obtained by contacting the Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041 or 301-443-6597; or from FDA’s web page at www.fda.gov/cdrh/dsma/rlman.html.

2. Medical Device Reporting (Sections 519 (a)(b) and (c) of the Act; 21 CFR Part 803):

Device user facilities and manufacturers must report certain adverse events to FDA. Manufacturer reporting requirements and duties are more extensive than device user facility requirements. Hospitals who engage in manufacturing activities, such as reprocessing, may be subject to manufacturer reporting requirements, as well as user facility reporting requirements. FDA realizes, therefore, that hospitals that reprocess may need additional guidance from the agency on how to submit manufacturer adverse event reports. Accordingly, FDA intends to provide additional guidance to hospital reproducers about applicable manufacturing adverse event requirements.

Further assistance in understanding medical device reporting (MDR) is available in a series of FDA publications. A detailed description of the MDR regulation is available in “Medical Device Reporting: An Overview.” A copy of this document can be obtained from FDA’s web page at www.fda.gov/cdrh/mdrovrw.pdf or from the National Technical Information Service, Springfield, VA 22161, by calling 703-487-4650.

3. Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821):

The purpose of medical device tracking is to ensure that manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution in the event corrective actions or notifications about the device are

necessary. Manufacturers are not subject to the Medical Device Tracking regulation unless and until FDA issues an order to the manufacturer. Likewise, reprocessors will not be subject to the Tracking regulation unless an FDA order has been issued for the specific device(s) being reprocessed. Additional information on device tracking, including the types of devices subject to tracking orders, is available in FDA's "Guidance on Medical Device Tracking." A copy of the guidance can be obtained from CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 169 when prompted for the document shelf number, or on the FDA web page at www.fda.gov/cdrh/modact/tracking.pdf.

4. Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806):

All device manufacturers must report to FDA, within a specified time, certain types of device corrections and removals. Records of all corrections and removals must also be maintained. Each device manufacturer must submit a written report to FDA of any correction or removal of a device initiated by the manufacturer if the correction or removal was initiated to reduce a risk to health posed by the device, or to remedy certain violations of the Act. The term "correction" is defined in 21 CFR 806.2(e) as "the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." The term "removal" is defined in 21 CFR 806.2(i) as the "removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection." For additional assistance, contact DSMA at the telephone numbers listed above.

5. Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820):

Current good manufacturing practice (CGMP) requirements are set forth in the Quality System regulation that governs the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices. These requirements include, among others, process

validation requirements (see 21 CFR 820.75). Additional information on the Quality System regulation is available in FDA’s “Guideline on General Principles of Process Validation”. A copy is available at www.fda.gov/cdrh/ode/425.pdf or call DSMA at the telephone numbers previously provided.

In addition to process validation and other quality system requirements, all class II, class III, and some class I devices must comply with design control requirements, including design validation requirements (21 CFR 820, Subpart C).

6. Labeling (Section 502 of the Act; 21 CFR Part 801):

FDA has general labeling requirements regarding the name and place of manufacture and the inclusion of adequate directions for use. FDA’s guidance “Labeling: Regulatory Requirements for Medical Devices” contains relevant information. A copy of this guidance is available at the FDA web site www.fda.gov/cdrh/dsma/470.pdf or call DSMA at the previously listed telephone numbers. FDA may issue further guidance on specific labeling for reprocessed devices.

7. Premarket Requirements (Sections 513 and 515 of the Act; 21 CFR Parts 807 and 814):

a. What type of premarket submission should I submit?

There are two types of premarket submission requirements - a premarket notification (or 510(k)) and a premarket application (PMA).

The type of submission you should submit generally depends on the classification of a device. The classification regulation for a medical device, as provided under 21 CFR Parts 862-892, establishes the class for each type of device and whether it is exempt from premarket requirements.

Unless the classification regulation specifically exempts a device, a premarket notification (510(k)) submission is required for class I and class II devices. Class III devices may require either a

premarket notification (510(k)) submission or a premarket approval (PMA) application, depending on the particular type of class III device. The classification regulation for each type of class III device indicates whether a premarket application is required. For your convenience, FDA has indicated on the list of categorized frequently reused SUDs, the type of marketing application that is generally required for each particular type of device. The risk categorization of high, moderate, or low for reused SUDs does NOT necessarily correspond to the type of submission that is required.

b. What do I have to demonstrate to get FDA marketing clearance of a 510(k)?

FDA must issue an order determining, on the basis of information in a 510(k) submission, that a device is as safe and effective as a legally marketed predicate device (i.e., "substantially equivalent" within the meaning of section 513(i) of the Act). The predicate device must have the same intended use as the device that is the subject of the 510(k) submission. The applicant assumes the burden to identify the legally marketed predicate device and to make sufficient comparisons between its device and the predicate device to establish that they are equivalent with respect to important safety and effectiveness factors. The criteria that FDA uses in deciding to grant marketing clearance for 510(k) submissions are more fully described in section 513(i) of the Act and 21 CFR 807.100.

For a reprocessed SUD, the legally marketed device for comparison is generally the SUD of the original device manufacturer (OEM).

c. What type of information do I need in my 510(k) submission to demonstrate substantial equivalence to a predicate device and receive marketing clearance?

You must submit a complete submission that includes all the information described in the 510(k) regulation, 21 CFR 807.87. General guidance on the information that needs to be submitted in 510(k) submissions is available in FDA guidance "Premarket

Notification 510(k): Regulatory Requirements for Medical Devices.” A copy of this guidance can be found at www.fda.gov/cdrh/manual/510kprt1.html or call DSMA at the telephone numbers previously listed. The information you provide in a submission must evaluate the unique characteristics of each type of device. You should search FDA’s web site, assemble all relevant guidance for specific devices or specific processes, complete the tests and gather information as recommended, and then compile complete submissions. The web site address to search for applicable FDA guidances is www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGP/Search.CFM. For additional assistance, contact DSMA at the telephone numbers previously provided.

d. What do I have to demonstrate to get FDA marketing approval for a PMA?

FDA’s basis for approval of a PMA is a finding that the device has a reasonable assurance of safety and effectiveness on the basis of valid scientific evidence. The threshold for approval of a PMA is different from that of a 510(k) submission. Unlike a device subject to a 510(k) marketing clearance, PMA approval is not contingent upon simply comparing your device with a legally marketed predicate device. The factors that FDA uses to grant marketing approval of PMAs are more fully described in section 515(d) and 21 CFR 814.44.

e. What type of information do I need in my PMA application to demonstrate that my device meets the criteria for marketing approval?

You must submit a complete application that includes all the information described in the PMA regulation, 21 CFR 814.20. FDA has general guidances on the information that needs to be submitted in PMA applications. Additional information on PMA requirements is available in FDA’s “Guidance for Preparation of PMA Manufacturing Information.” A copy can be obtained from www.fda.gov/cdrh/ode/448.pdf.

The information you provide in an application should evaluate the unique characteristics of each type of device. To assist you in submitting your PMA application for specific products, FDA has posted device-specific and process-specific guidances on its worldwide web site to supplement the general requirements noted above. You can search for applicable FDA guidances at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGP/Search.CFM or call DSMA at the telephone numbers previously provided.

A PMA application for a reprocessed SUD must include valid scientific evidence that demonstrates the safety and effectiveness of the reprocessed device. A reprocessor may need to include clinical data to establish safety and effectiveness.

In addition to the review of data in a PMA application, FDA requires a satisfactory inspection of the manufacturing facilities before a PMA application may be approved. As part of the PMA application, a comprehensive manufacturing section, which clearly identifies all appropriate manufacturing controls, must be submitted. Guidances about manufacturing information to include in premarket submissions is available in FDA's "Guidance in Quality System Regulation: Information for Various Premarket Reprocessors Submissions." A copy of this guidance can be obtained at <http://www.fda.gov/cdrh/comp/qsrpma.html> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1140 when prompted for the document shelf number. Reprocessors and hospitals that intend to reprocess devices that will require a PMA should be prepared for a pre-approval inspection. FDA intends to explore the possibility of collaborating with other federal and state agencies to ensure timely and appropriate inspections.

- f. What happens after a third party or hospital reprocessor submits a 510(k) submission or a PMA application that is administratively incomplete?*

FDA initially will review your 510(k) submission or PMA application to make a threshold determination as to whether it contains sufficient information to begin a substantive review. If the submission or application does not on its face, contain all the

information required under 21 CFR 807.87(for 510(k)s) or 21 CFR 814.20 (for PMAs), FDA will not review that application or submission any further and the file will be placed on hold (see 21 CFR 807. 87 and 814.42(e)). You may submit the additional information to complete the file, but FDA does not intend to exercise the enforcement discretion described in this document for reprocessed SUDs that are not the subject of complete applications or submissions. In other words, FDA may take immediate enforcement action for failure to comply with premarket requirements upon determining a 510(k) submission or PMA application is administratively incomplete.

In addition, the agency wants submitters to realize that a 510(k) submission or PMA application that is administratively complete may nevertheless be difficult to review if it is poorly organized or does not address device specific issues. In these situations, there are likely to be delays in premarket review.

- g. *Can I combine several different models and brands of the same type of device into one 510(k) submission or PMA application?*

Premarket (510(k)) submissions and PMA applications are device specific; FDA requires a 510(k) or a PMA for each device. Only closely related variations of the same type of device should be grouped in one submission or application. FDA advises reprocessors to examine device groupings that original device manufacturers have developed as examples of appropriate device groupings. Data and information in the submission or application must support the substantial equivalence (510(k)) or safety and effectiveness (PMA) of the entire group of devices in a marketing submission.

- h. *What if I need to conduct clinical studies as part of my 510(k) submission or PMA application?*

FDA regulations (21 CFR Parts 812, 50, and 56) describe the procedures for the conduct of clinical studies used to support marketing submissions. Clinical studies of devices categorized as high risk will most likely be considered significant risk devices, as defined in 21 CFR 812.3(m). Clinical studies of significant risk

devices need prior FDA approval of an investigational device exemption (IDE) application before the study may begin. In addition, most clinical studies need prior approval of the local institutional review board and informed consent from the patient. Additional information on IDE requirements is available in two FDA guidance documents: “Significant and Non-significant Risk Medical Device Studies” (accessible at <http://www.fda.gov/cdrh/d861.html>) and “IDE Policies and Procedures” (accessible at www.fda.gov/cdrh/ode/idepolicy.html). Copies of these guidances can also be obtained by calling DSMA at the telephone numbers previously provided.

F. Enforcement Priorities and Periods of Enforcement Discretion for FDA Requirements

As previously described in section E of this document, third party and hospital reprocessors can be subject to the Act’s premarket and other requirements. To date, FDA has not actively enforced premarket requirements against third party or hospital reprocessors, and has not actively enforced any non-premarket requirements against hospital reprocessors (e.g., registration, listing, MDR, tracking, corrections and removals, quality system, and labeling).

Below, we describe a phased-in approach to enforcement of those requirements for third party and hospital reprocessors that FDA has not previously enforced. Until this draft guidance is finalized, FDA does not intend to enforce premarket requirements for third party or hospital reprocessors, or any non-premarket requirements that may apply to hospital reprocessors. FDA intends to continue to enforce all non-premarket requirements against third-party reprocessors.

Any exercise of enforcement discretion, however, does not preclude the agency from taking enforcement action sooner than the time periods described below if the agency determines that any reprocessed medical device presents a significant risk to public health. Conversely, the agency may continue to exercise its discretion to not actively enforce FDA requirements for longer periods of time than

described below when there may be shortages of medically necessary devices or for other compelling reasons.

**1. ENFORCEMENT DISCRETION PERIOD FOR
PREMARKET REQUIREMENTS (Sections 513, and 515
of the Act; 21 CFR Parts 807 and 814):**

a. SUDs categorized as High Risk in the companion Risk Scheme guidance:

FDA intends to continue to exercise its discretion to not enforce premarket requirements for third party and hospital reproducers of devices that are considered high risk for one (1) year from the date of issuance of a final SUD enforcement guidance provided:

1. FDA receives a 510(k) submission or a PMA application within six (6) months of the issuance of the final SUD enforcement guidance;
2. The 510(k) submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review (see discussion under 7.f.); and
3. The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within six (6) months of the filing date.

Once this guidance is finalized, FDA intends to enforce these premarket requirements if the third party or hospital reproducer fails to satisfy any of the conditions described above.

b. SUDs categorized as Moderate Risk in the companion Risk Scheme guidance:

FDA intends to continue to exercise its discretion to not enforce premarket requirements for third party and hospital reproducers of devices that are considered moderate risk for eighteen (18) months

from the date of issuance of a final SUD enforcement guidance provided:

1. FDA receives a 510(k) submission or a PMA application within twelve (12) months of the issuance of the final SUD enforcement guidance;
 2. The 510(k) submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review (see discussion under 7.f.); and
 3. The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within six (6) months of the filing date.
- c. *SUDs categorized as Low Risk in the companion Risk Scheme guidance:*

Many devices in this category are exempt from premarket requirements. For third party and hospital reproprocessors of low risk devices that are not exempt from premarket requirements, FDA intends to continue to exercise its discretion to not enforce premarket requirements for these devices for two (2) years from the date of issuance of a final SUD Enforcement guidance provided:

1. FDA receives a 510(k) submission or a PMA application within eighteen (18) months of the issuance of the final SUD enforcement guidance;
2. The 510(k) submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review (see discussion under 7.f.); and
3. The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within two (2) years of the filing date.

FDA intends to reexamine low risk devices, however, to see if it is appropriate for FDA to promulgate regulations to exempt low risk devices that are reprocessed from any premarket requirements. These decisions will be made on a case-by case basis.

2. ENFORCEMENT DISCRETION PERIODS FOR REGISTRATION, LISTING, SUBMISSION OF ADVERSE EVENTS (MDR), QUALITY SYSTEMS, LABELINGS, TRACKING, AND CORRECTION AND REMOVAL REQUIREMENTS (Sections 502, 510, 513, 515, 519, and 520 of the Act; 21 CFR Parts 807, 803, 820, 801, 821, and 806)

a. Hospitals:

FDA intends to exercise its discretion to not enforce registration, listing, adverse event reporting (MDR), quality system, tracking (which are triggered only by a specific FDA Tracking order), and corrections and removal requirements for hospital reproducers for six (6) months from the date of issuance of a final SUD enforcement guidance. This discretionary period for adverse event (MDR) requirements only applies to manufacturer MDR reporting requirements; it does not include user facility MDR reporting requirements. FDA will continue to actively enforce MDR requirements for all device user facilities, including hospital reproducers.

b. Third Party Reprocessors:

FDA will continue its present practice of actively enforcing all non-premarket requirements for third party reproducers. The issuance of this draft or any final guidance does not change the obligation of third party reproducers to continue to comply with registration, listing, MDR, quality system, labeling, and medical device corrections and removals requirement.

Appendix A: Definitions of terms

For the purposes of this guidance, FDA has defined the following terms:

Hospital: a hospital is an acute health care facility.

Single-use device: a single-use device is a device that is intended to be used only on one patient during a single procedure. It is not intended to be reprocessed (cleaned and disinfected/sterilized) and used on another patient. The labeling identifies the device as disposable and does not include instructions for reprocessing. Some single-use devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.

Opened-but-unused: an opened-but-unused device is a single-use device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient.

Reuse: the repeated use or multiple use of any medical device including reusable and single-use medical devices, on the same patient or on different patients, with applicable reprocessing (cleaning and disinfection/sterilization) between uses.

Reprocessing: includes all operations performed to render a contaminated reusable or single-use device patient-ready. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

Resterilization: the repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility level.

Appendix B: List of frequently reprocessed SUDs and their risk category according to the risk categorization scheme from the companion Risk Scheme guidance (attachment 2)

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Cardiovascular	Angiography catheter	870.1200	N	510(k)	II	DQO	high
	blood pressure cuff	870.1120	N	510(k)	II	DXQ	low
	cardiac ablation catheter	unclassified	N	PMA	III	LPB	high
	cardiac guidewire	870.1330	N	510(k)	II	DQX	high
	compressible limb sleeve	870.5800	N	510(k)	II	JOW	low
	Electrophysiology recording catheter	870.1120	N	510(k)	II	DRF	high
	intra aortic balloon catheter	870.3535	N	510(k)	III	DSP	high
	needle	870.1390	N	510(k)	II	DRC	high
	percutaneous transluminal coronary angioplasty (PTCA) catheter	unclassified	N	PMA	III	LOX	high
	percutaneous transluminal angioplasty (PTA) catheter	unclassified	N	510(k)	II	LIT	high
	syringes	870.1670, 870.1650, unclassified	N	510(k)	II	DXT	high
	trocars	870.1390	N	510(k)	II	DRC	moderate
Respiratory	breathing mouthpiece	868.5620	Y	N/A	I	BYP	low
	endotracheal tubes	unclassified	N	PMA	III	LZN	high
	masks	868.5550	Y	N/A	I	BSJ	low
	oral and nasal catheters	868.5350	Y	N/A	I	BZB	low
	respiratory therapy and anesthesia breathing circuits	868.5240	Y	N/A	I	CAI	moderate
	tracheobronchial suction catheter	868.6810	N	510(k)	I	BSY	high

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Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Gastroenterology/ Urology	biliary sphincterotomes	876.4300	N	510(k)	II	KNS	high
	biopsy needles	876.1075	N	510(k)	II	FCG	high
	endoscopic guidewires	876.1500	N	510(k)	II	KOG	low
	endoscopic staplers	876.4400	N	510(k)	II	FHN	low
	extraction balloons/baskets	876.1500	N	510(k)	II	KOG	high
	non-electric biopsy forceps	876.1075	N	510(k)	II	FCL	high
	trocar	876.5090	N	510(k)	II	FBQ	low
	urethral catheters	876.5130	N	510(k)	II	KOD	moderate
Nephrology	hemodialysis blood tubing	876.5820	N	510(k)	II	KOC	moderate
OB-GYN	laparoscopic dissectors	884.1720	Y	N/A	I	HET	low
	laparoscopic graspers	884.1720	Y	N/A	I	HET	high
	laparoscopic scissors	8884.1720	Y	N/A	I	HET	high
	trocar	884.1720	N	510(k)	II	HET	low
Orthopedics	arthroscopy instruments	888.1100	N	510(k)	II	HRX	low
	carpal tunnel blade	888.4540	Y	N/A	I	LXH	moderate
	drill bits	878.4540	Y	N/A	I	HTW	low
	external fixation device	878.3900, 878.3910	Y	N/A	I	FZF, FYH	low
	flexible reamers/drills	886.4070 878.4820	Y	N/A	I	GEY, HRG	low
	saw blades	878.4820	Y	N/A	I	GFA, DWH, GEY, GET	low
	surgical drills	878.4820	Y	N/A	I	GEY, GET	low
Surgery	biopsy forceps	876.1075 876.4300 884.4530 874.4680 874.4680	N	510(k)	II	FCL KGE HFB BWH JKK	high
	biopsy needles	878.4800	Y	N/A	I	DWE	high
	burr	878.4820	Y	N/A	I	GFF, GEY	low

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Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
	electrosurgical electrodes/handles/pencils	876.4300 878.4800	N	510(k)	II	HAM, GEI, FAS, FEH, KNS	moderate
	endoscopes	876.1500	N	510(k)	II	many	high
	endoscopic blades	876.1500	N	510(k)	II	GCP, GCR	moderate
	endoscopic guidewires	876.1500	N	510(k)	II	GCP, GCR	low
	endoscopic staplers	888.4540	Y	N/A	I	HXJ	moderate
	fascia holders	878.4800	Y	N/A	I		moderate
	laproscope	884.1720 876.1500	N	510(k)	II	HET, GCJ	low
	laser fiber delivery systems	878.4810 874.4500 874.4770 874.4496 878.4810 886.4390 884.4550 886.4690	N	510(k)	II	GEX, EWG, LXR, LMS, LLW, HQF, HHR, HQB,	low
	scissor tips, removable inserts	878.4800 888.4540 884.4520 874.4420	Y	N/A	I	LRW, HHR, HDK, HDJ, JZB, KBD	moderate
	surgical cutting accessories	878.4800 874.4420	Y	N/A	I	GDZ, GDX, GES, KBQ, KAS	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	Y	N/A	I	KAB KBG KCI	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	N	510(k)	II	FBQ, FBM, GCJ, DRC	moderate

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Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Plastic Surgery	stapler	878.4800 882.4190	Y	N/A	I	GAG, GEF, FHM, HBT, HBS	moderate
Laboratory	glucometer lancets	878.4800	Y	N/A	I	FMK	low
Ophthalmic	keratome blade	886.4370	N	510(k)	I	HMY, HNO, MYD	high
	OR drapes	878.4370	N	510(k)	II	KKX	moderate
	phacoemulsification needle	886.4670	N	510(k)	II	MUS	high
Infection Control	OR gowns	878.4040	N	510(k)	II	FYA	low
	sharps containers	880.5570	N	510(k)	II	MTV, FMI	low
	syringes, piston	880.5860	N	510(k)	II	FMF	high
General Hospital	infusion pump, implanted	unclassified	N	PMA	III	MDY, LKK	high
	syringe, irrigating	880.6960	Y	N/A	I	KYZ, KYY	low
Dental	braces, plastic	872.5470	N	510(k)	II	DYW	high
	braces, metal	872.5410	Y	N/A	I	EJF	high
	burr	872.3240	Y	N/A	I	EJL	moderate

Appendix C: Additional guidances that may be helpful on the reuse issue

In addition to the guidances and resources referenced in the body of this document, the following is a partial list of other FDA guidances and material that may be helpful to third parties and hospitals that reprocess SUDs. Copies of the guidances can be obtained from the FDA web site at www.fda.gov/opacom/morechoices/industry/guidedc.htm. FDA also encourages you to explore our web site for information on reuse of medical devices. The web site address is www.fda.gov/cdrh/reuse.

[Overview of FDA Modernization Act of 1997, Medical Device Provisions, February 19, 1998](#)

[Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program, June 30, 1986](#)

[Premarket Approval \(PMA\) Manual, October 1, 1998](#)

[Guidance on IDE Policies and Procedures, January 20, 1998](#)

[Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, August 1996](#)

[Guidance on Premarket Notification \(510\(k\)\) Submissions for Sterilizers Intended for Use in Health Care Facilities, March 1993](#)

[“Medical Device Labeling: Suggested Format and Content” \(draft\) at www.fda.gov/cdrh/ode/labeling.pdf.](#)

FDA Labeling Requirements at www.fda.gov/cdrh/devadvice/33.html#contents.