Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Frequently Asked Questions (FAQs) on the Status of Reprocessed Single Use Devices (SUDs) that receive a Not Substantially Equivalent (NSE) Letter

This guidance represents the Food and Drug Administration's (FDA'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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

1. What is a Not Substantially Equivalent letter and what does it mean if it pertains to a reprocessed SUD?

In general, firms submit premarket information to FDA for the purpose of obtaining marketing approval or clearance of their devices prior to commercial distribution. A premarket approval application (PMA) is usually required for entirely new types of devices, while a premarket notification submission (510(k)) may be submitted to demonstrate that a device is "substantially equivalent" to a legally marketed device (a "predicate" device) that did not require a PMA.

If FDA agrees that a device for which a 510(k) has been submitted is substantially equivalent to a legally marketed device, FDA issues a Substantially Equivalent (SE) letter. A "Not Substantially Equivalent" (NSE) letter is issued when FDA, based on the information submitted, determines that the device is not substantially equivalent to the already legally marketed device. Like any other 510(k) applicant, a SUD reprocessor who submits a 510(k) and receives an NSE letter may not legally market the device subject to that 510(k) because it has not been cleared for commercial distribution by FDA.

Some firms who previously received SE letters for certain reprocessed SUDs were required, by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), to submit additional cleaning, sterility, and functionality validation data (supplemental data) for FDA to review in order to determine if these reprocessed devices could continue to be legally marketed. If these firms either failed to submit the required supplemental data or FDA determined, based on the supplemental data submitted, that the reprocessed devices were not substantially equivalent to legally marketed predicate devices, the firms received NSE letters from FDA. If a firm submitted supplemental data to FDA but later withdrew its 510(k)s as described in section 302(b) of MDUFMA, it received a letter acknowledging the withdrawal from FDA.

Upon receipt of a NSE letter or a letter acknowledging withdrawal, the device subject to the letter may no longer be legally marketed. The reprocessor may notify its customers that it can no longer reprocess that device at this time. However, a reprocessor may submit a new 510(k) that includes the validation data required under MDUFMA and may be able to resume marketing if and when FDA determines that the information in the new 510(k) is adequate to establish substantial equivalence and issues a SE letter.

2. Will FDA require reprocessors to recall a distributed device that is the subject of a NSE letter or a letter acknowledging withdrawal?

Not necessarily. FDA intends to contact each affected reprocessor to determine their plans for retrieval or withdrawal of distributed product. In accordance with 21 CFR Part 7 and section 518(e) of the Federal Food, Drug, and Cosmetic Act (the Act), FDA will evaluate, on a case by case basis, whether the device that is the subject of the NSE or withdrawal letter should be recalled.

3. Should a customer continue to use in-stock, reprocessed SUDs once the reprocessor can no longer distribute as a result of a NSE letter or a letter acknowledging withdrawal?

Upon receipt of a NSE letter or a letter acknowledging withdrawal, the device subject to the letter may no longer be legally marketed. Customers may wish to contact the reprocessor to learn about any plans for retrieval or withdrawal of in-stock devices. If the device warrants a recall, the recall strategy will specify the level to which the recall will extend, as described in 21 CFR Part 7 or section 518(e) of the Act.

4. Is there an FDA site that lists information about which reprocessed SUDs are no longer eligible for commercial distribution?

Reprocessors who received 510(k) clearances prior to the requirement under the law to submit supplemental data, have those 510(k)s posted on FDA's searchable 510(k) database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Most SUD reprocessors who were required to submit supplemental data under MDUFMA, did submit. If FDA determined, based on a review of the supplemental data, that a device is Not Substantially Equivalent or if the SUD reprocessor requested withdrawal of the 510(k) and

supplemental data submission, the original 510(k) Substantial Equivalence determination was removed from the FDA's 510(k) database. In addition, a list of the devices that can no longer be legally marketed is provided separately on FDA's reuse website at http://www.fda.gov/cdrh/reuse/.

5. What other information can I learn from the FDA's website about the status of reprocessed SUDs that were subject to supplemental data requirements?

In addition to identifying reprocessed devices that can no longer be legally marketed, the site also lists those reprocessed devices for which FDA reviewed supplemental data submissions and determined that these devices remain substantially equivalent to legally marketed predicate devices. MDUFMA did not require the submission of supplemental data for all reprocessed SUDs, however, so these lists will not provide a complete accounting of all reprocessed SUDs. For additional information on the reprocessed devices for which supplemental data were required by MDUFMA, see List I and II published in the Federal Register on June 26, 2003 (http://www.fda.gov/OHRMS/DOCKETS/98fr/03-16109.html, 68 FR 38071.

6. If I have additional questions, who can I contact?

FDA recommends that you first contact the SUD reprocessor for information about the device in question. You may also contact the 510(k) Staff within the Office of Device Evaluation, CDRH at (301) 594-1190 or the Office of Compliance, CDRH at (240) 276-0100.

Contains Nonbinding Recommendations

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

Document issued on: May 1, 2006

The draft of this document was issued on October 11, 2005.

The information collection provisions in this guidance have been approved under OMB control number 0910-0577. This approval expires 5/31/2018. See additional PRA statement in Section IX of this guidance.

For questions regarding this document contact Casper Uldriks at the Center for Devices and Radiological Health (CDRH) at 240-276-0106, or at casper.uldriks@fda.hhs.gov.

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

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Contains Nonbinding Recommendations

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

I. Introduction

On October 26, 2002, section 301 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) amended section 502 of the Federal Food, Drug, and Cosmetic Act (the Act) to require a device, or an attachment to the device, to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. An important revision was made to section 502(u) of the Act by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109-43), which became law on August 1, 2005.

MDUFSA amended section 502(u) by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Section 502(u) no longer sets forth requirements for original equipment manufacturers (OEMs), unless those manufacturers also reprocess single-use devices. Under the amended provision, if the original device or an attachment to it does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer, the manufacturer who reprocesses the SUD may identify itself using a detachable label on the device's

packaging. The detachable label is intended to be affixed to the medical record of a patient by the user of the reprocessed SUD.

MDUFSA also requires that FDA issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not "prominent and conspicuous" under section 502(u) of the Act. On October 11, 2005, FDA issued draft guidance describing these circumstances. In addition, because section 502(u) requires that a reprocessed SUD or its attachment prominently and conspicuously bear the name of the reprocessor, except as described above, the document also provided guidance for reprocessors to determine whether their names, abbreviations, or symbols placed on the reprocessed SUDs are prominent and conspicuous.

MDFSA requires that FDA issue this guidance not later than 180 days after the date of enactment (August, 1, 2005). Therefore, the agency requested that interested persons submit their comments on the draft guidance within 30 days of its issuance. As discussed below, FDA received comments on the draft, all of which were considered in finalizing the guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

II. Consultation with Stakeholders

FDA received comments from stakeholders, all of which were considered in developing this guidance. Each stakeholder who responded provided comments on the effective date for implementing the reprocessor labeling requirement. MDUFSA identifies two effective dates for compliance with section 502(u) of the Act.

The first effective date is August 1, 2006, which is 12 months after the date of enactment on August 1, 2005. This date applies to those reprocessed SUDs for which the OEM first marked the original device in a prominent and conspicuous manner before August 1, 2006.

This date also applies to devices that are not marked or do not include an attachment with the OEM's name, as well as to devices which are marked or do include an attachment, but do not prominently and conspicuously bear the name of the OEM. Under section 502(u), the reprocessor may use a detachable label on such devices. Therefore, for all devices that are reprocessed and introduced or delivered for introduction into interstate commerce after August 1, 2006, the reprocessor must either mark the device, place its mark on an attachment, or where applicable, it may instead place its mark on a detachable label.

The second effective date relates to compliance in those situations where the OEM first marks its device after August 1, 2006. Two comments questioned this second effective date. The draft guidance provided that once the OEM marks the device, the reprocessor must mark the device, use an attachment, or where applicable, a detachable label. The comments argued that if the OEM marked its device after August 1, 2006, the reprocessor of the SUD should still have 12 months from the date on which the OEM first marked the device in which to mark the reprocessed device.

The statutory language in MDUFSA regarding the effective dates states that section 502(u) shall be effective with respect to reprocessed SUDs "12 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005, or the date on which the original device first bears the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, whichever is later." (emphasis added). The statutory language does not provide for an additional 12 month period for the reprocessor to mark the device where the OEM first marks its product after August 1, 2006. The statutory language is clear that when an OEM prominently and conspicuously marks its device for the first time after August 1, 2006, the reprocessor -- who must have already identified itself through a detachable label as of August 1, 2006 if it did not mark the device or use an attachment -- does not get an additional 12 months in which to put its mark on the device itself.

The statutory language that requires the reprocessor's mark on "the date on which" the OEM first marks the device will give health care providers necessary information so they can report device related adverse events accurately and promptly to FDA. Mistakes in reporting and failures to make reports due to the inability to identify the correct manufacturer of a reprocessed single-use device undermine the agency's postmarket surveillance program. Moreover, FDA believes that procedures for implementing compliant labeling specifications, among other manufacturing requirements, should already be established and implemented under a reprocessor's Quality Systems (QS) program, as required by 21 CFR Part 820.

In addition to the above comments on the effective date, one comment questioned whether the statute requires that the detachable label be placed in the patient record. The statutory language clearly indicates that a detachable label is intended to be affixed to the medical record of the patient under section 502(u)(2), as amended.

One commenter requested that FDA include guidance on whether the mark of the manufacturer of the original device should be required to be obliterated by the reprocessor when placing its mark on the SUD. This comment also requested an exemption from device

marking be permitted for comparative study purposes and that such studies not be considered to pose a significant risk under the Investigational Device Exemptions regulation (21 CFR 812). These issues fall outside the scope of this guidance and, therefore, are not addressed in this guidance.

The agency carefully considered all of the above comments. As discussed above, however, the information published in the draft guidance remains unchanged in this final guidance.

III. Definitions

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

Attachment: An article secured to a device in such a way that it cannot be removed inadvertently.

Detachable label: A removable label on the device packaging that identifies the manufacturer who reprocessed the SUD and is intended to be affixed to the patient record.

Mark: A name, generally recognized abbreviation of such name, or a unique and generally recognized symbol that identifies a particular manufacturer.

Prominent and conspicuous: A manner of marking a device, as required by section 502(u) of the Act, such that the manufacturer's mark is apparent to the user under ordinary conditions of use.

Reprocessor: A manufacturer who subjects a previously used SUD to additional processing and manufacturing for the purpose of an additional single use on a patient.

Single-Use Device: A device that is intended for one use, or on a single patient during a single procedure.

IV. Who Does this Guidance Cover?

This guidance applies to all manufacturers who reprocess single-use devices; therefore, it also applies to OEMs who reprocess SUDs.

V. How Do I Know Whether the Mark of a Manufacturer is Prominent and Conspicuous?

A. We recommend considering the following factors when deciding whether a manufacturer's mark is prominent and conspicuous:

1. Available space on the device itself
2. Contrast

3. Meaning
4. Font or Graphic Readability

B. You may use the following information and examples to help you decide whether a manufacturer's mark is prominent and conspicuous based on the above:

1. **Available space**: Is there enough space for the manufacturer's mark so that it can be recognized under ordinary conditions of use, such as in an operating room, emergency room, or ambulance?

   For example:

   The area of space the size of the side of a common ink pen would likely be adequate to display the mark of the manufacturer.

   The area of space the size of the head of a common thumbtack would likely not be adequate to display the mark of the manufacturer.

2. **Contrast:** We recommend that the difference between the color of the manufacturer's mark and the color of the background should make the manufacturer's name or mark apparent to the user under ordinary conditions of use.

   For example:

   A manufacturer's name using a dark color against a light background creates a contrast that should make the identification apparent.

   A manufacturer's name using a light color against a background that is different but not very much darker in color will make it less likely that the identification will be apparent under ordinary conditions of use.

   3. Font or Graphic Readability: Is the style of the text easy to read and large enough to see during ordinary conditions of use? The actual print and size of the name should be sufficiently clear to enable it to be read under ordinary conditions of use.

   For example:

   Newspapers, magazines, business letters, or mass media advertisements use a size and style of type that users can read easily.

   Office pens usually bear the mark of the manufacturer or vendor. The name on the pen is large enough so the user can read it while using the pen.

A script that is so ornate or elaborate that the name cannot be easily read will likely make the essential information less readable.

4. Meaning: Will the user understand the manufacturer's mark that appears on the product?
Assuming that the manufacturer has considered available space, contrast, and readability, FDA believes the full name of the manufacturer will be understandable during ordinary conditions of use. When a manufacturer uses an abbreviation of the name, or a symbol, instead of the full name, the manufacturer should use an abbreviation that is closely related to the full name or a unique and recognizable symbol that is associated with the manufacturer.

For example:

When a product bears a manufacturer's name, such as "American Business Company, Inc.," or "XYZ, Inc.," the user should be able to identify the manufacturer.

When a product manufactured by the Long Reprocessing Corporation is identified with the word "Long," the agency believes that the manufacturer will be identifiable under ordinary conditions of use.

When a product bears a unique mark that is generally recognized and associated with the manufacturer, such as an emblem or hood ornament on a car, the user should be able to identify the manufacturer under ordinary conditions of use.

A mark that is generic or not easily identified with a particular manufacturer, such as a hollow circle, will probably not help a user identify the manufacturer.
Note: We also recommend that you consider this factor in determining whether an abbreviation or symbol is "generally recognized" under section 502(u) of the Act.

VI. When is this New Labeling Requirement Effective?

The requirement that a reprocessed SUD, or an attachment to the SUD, must bear the reprocessor's mark is effective on one of the following dates, whichever is later:

1. August 1, 2006, which is 12 months after the law was enacted on August 1, 2005

   E.g., if the original device or an attachment to it bears the OEM's mark prominently and conspicuously on July 1, 2006, then the reprocessed SUD or its attachment must prominently and conspicuously bear the mark of the reprocessor no later than August 1, 2006.

OR

2. The date, after August 1, 2006, on which the original device or an attachment to it first bears the OEM's mark prominently and conspicuously. If the original device or an attachment to it did not prominently and conspicuously bear the OEM's mark prior to August 1, 2006, but does so at any later date, then the reprocessed SUD or its attachment must prominently and conspicuously bear the mark of the reprocessor before the reprocessed device may be legally marketed.

   For example, if the original device first prominently and conspicuously bears the OEM's mark on September 1, 2006, at that point in time a reprocessor must prominently and conspicuously use its own mark on the reprocessed device or its attachment before marketing.

After August 1, 2006, even if the original device or an attachment to it does not bear the OEM's mark (the OEM's mark is absent or is not prominent and conspicuous), the reprocessed SUD must identify the reprocessor. Under this circumstance, the reprocessor may identify itself through use of a detachable label on the packaging of the SUD, as described below.

VII. When Should a Reprocessor Place its Mark on a Device, Use a Detachable Label, or Use an Attachment?

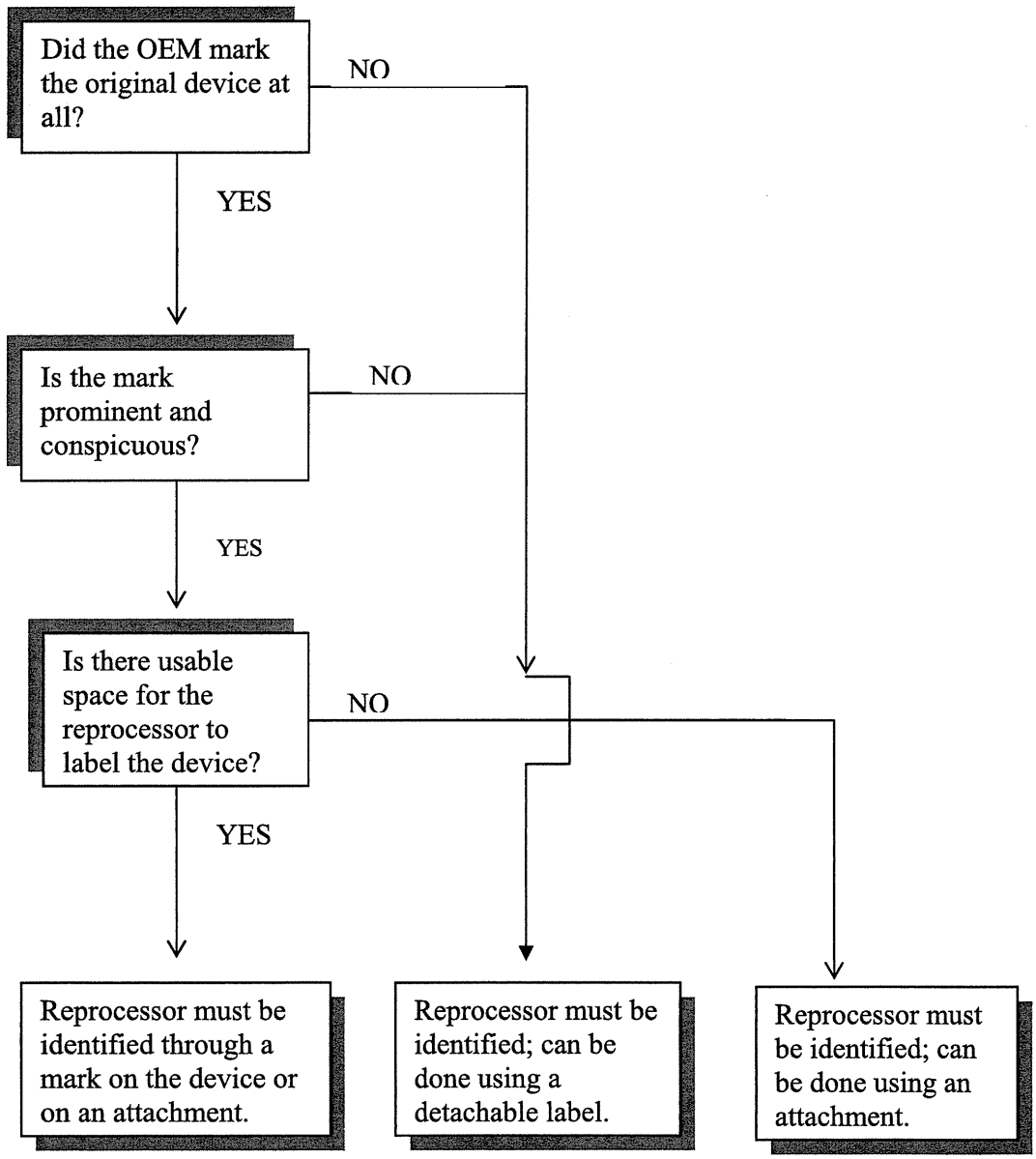
According to section 502(u) of the Act, a reprocessed SUD, or an attachment to it, must prominently and conspicuously bear the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of the name, or a unique and generally recognized symbol identifying such manufacturer. The only exception to this requirement is when the original device, or an attachment to it, does not prominently and conspicuously identify the name of the original equipment manufacturer, a generally recognized abbreviation of the name, or a unique and generally recognized symbol identifying such manufacturer. Under this circumstance, the reprocessor may use a detachable label on the packaging to identify the manufacturer of the reprocessed device.

As stated in MDUFSA, the detachable label is intended to be affixed to the medical record of a patient. FDA therefore recommends that this label contain a statement directing a practitioner to remove the detachable label and affix it to the patient's medical record when the reprocessed SUD is used.

If the original equipment manufacturer has marked the device in such a way that there is little or no usable space for a reprocessor to prominently and conspicuously mark the device, the reprocessor may satisfy the labeling requirement of section 502(u) through the use of an attachment to the device.

The following flow chart should help you decide whether you should place your mark on the device, use a detachable label, or use an attachment.

REPROCESSOR'S DECISION FLOW CHART
DO I PLACE MY MARK ON THE DEVICE, USE A DETACHABLE LABEL, OR USE AN ATTACHMENT?*



***Section 502(u) of the Federal Food, Drug, and Cosmetic Act, as amended.**

VIII. Can a Reprocessor Obtain a Waiver from this Labeling Requirement?

No. Section 502(u) does not provide for a waiver from the labeling requirement.

IX. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 0.1 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0577, expires 05/31/2018.

Guidance for Industry and FDA Staff

Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices

Document issued on: September 25, 2006

This guidance supersedes the document issued under this title on June 1, 2004

For questions regarding this document contact Ginette Y. Michaud, MD at 240-276-3700 or by electronic mail ginette.michaud@fda.hhs.gov.

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

Office of Device Evaluation

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I. Introduction

Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250, amended the Federal Food, Drug, and Cosmetic Act (the Act) by adding new section 510(o), which provided new regulatory requirements for reprocessed single-use devices (SUDs). According to this new provision, in order to ensure that reprocessed SUDs are substantially equivalent (SE) to predicate devices, premarket notification submissions (510(k)s) for certain reprocessed SUDs identified by FDA must include validation data. These validation data include cleaning, sterilization data, and functional performance data demonstrating that each SUD will remain SE to a predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the 510(k). The predicate device may be the Original Equipment Manufacturer's (OEM's) device, (i.e. the same device as originally manufactured), or any device of that type.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from the 510(k) requirements of the Act. Under MDUFMA, some previously 510(k)-exempt reprocessed SUDs are no longer exempt. Manufacturers of these FDA-identified (see below) reprocessed SUDs need to submit 510(k)s that include validation data. In addition, reprocessors of certain