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Section 301 of MDUFMA amended Section 502 of the Federal Food, Drug and Cosmetic Act (FDCA) to require a device to bear the name of the manufacturer. This guidance document includes definitions, explains how the provision applies to SUDs, how to know whether a manufacturer’s mark is prominent and conspicuous, and when a reprocessor should place its mark on a device. It also includes a flow chart to help reprocessors decide whether to place their mark on the device, use a detachable label or use an attachment.
This guidance document describes the types of validation the FDA recommends to be submitted under 510(k) of the FDCA. It also provides guidance on submission and review procedures for validation. The FDA also offers definitions, a question-and-answer section on the MDUFMA 510(k) requirements, an overview of validation data and information on the reprocessing procedure, such as cleaning, packaging and sterilization.

The Federal Register announced that the FDA was amending classification regulations for reprocessed SUDs whose exemption from 510(k) had been terminated. It provides background, definitions, explains critical and semicritical devices, and outlines how the final rulemaking amends specific regulations.

The FDA announced its withdrawal of the direct final rule on classification regulations for reprocessed SUDs, citing adverse event comments.

This law amends the FDCA to improve regulations for devices. The regulation, which states that Congress finds prompt approval is critical, includes definitions, the authority to assess and use device fees, amendments regarding the regulations of devices, such as inspections, penalties and labeling, additional amendments for SUDS in Section 302 and information about premarket notification.

The FDA answers questions regarding the background of MDUFMA, user fees (including charts), user fee billing issues, third-party inspections, reprocessed SUDs and postmarket surveillance.
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This summary outlines the Medical Device User Fee and Modernization Act of 2002
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This legislation, which is Title II of the FDA Amendments Act of 2007, reauthorized
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This summary documents the open meeting during which the FDA stated its recognition
of the subject’s complexity. The meeting was held to hear what various parties affected
by SUDs think about the issue. Speakers raised concerns about SUDs and discussed
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of Medical Devices Currently Labeled, or Otherwise Intended, for Only One Use
This provides background on SUDs and outlines the requirements reprocessed SUDs
are subject to in the FDCA and the Code of Federal Regulations.
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Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but
Oversight Warranted, June 2000 GAO report

The Government Accountability Office (GAO) reviewed SUD reprocessing and
outlines its findings about various issues related to reprocessed SUDs, such as cost
savings, different types of devices, the frequency of reprocessing, possibility of safely
reprocessing, difficulties with the policy and requirements for reprocessors.

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Statement by David Feigal, then CDRH director, before the Senate Committee on
Health, Education, Labor and Pensions, June 27, 2000

Feigal discusses the FDA’s reexamination of its SUDs policy, its efforts and available
tools to ensure protection of public health. The statement provides background, the
scope of reuse, agency involvement in reuse (research, reports of patient injuries and
outreach), the FDA’s current policy, the agency’s proposed strategy regarding enforce-
ment priorities and the steps that were planned, such as final guidance documents, col-
laboration and phased-in enforcement.

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Reuse of Single-Use Devices, Medical Device Reporting, 1999

This article provides some background on the reprocessing of SUDs and discusses
how the increasing use of SUDs heightened concerns about patient safety and equi-
table regulations. It provides examples of the FDA’s list of frequently reprocessed
SUDs and addresses the FDA’s current policy and proposed strategy.

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Statement by Daniel Schultz, CDRH director, before the House Committee on
Government Reform, Sept. 26, 2006

Schultz told the committee that the FDA has many tools to ensure safe and effective
reprocessed SUDs. He discussed the regulations regarding SUD devices that have been
cleared for reprocessing, the changes under MDUFMA (such as the creation of the
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(510(k)) submissions, compliance activities, postmarket surveillance and ongoing FDA
activities.

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FDA Letter to Hospitals, Enforcement of FDA Requirements on Reprocessing of
Single-Use Devices, April 23, 2001

This letter announced the requirement that hospitals that reprocess SUDs must meet
the same requirements as the original product manufacturer. It summarizes the require-
ments and provides a timetable of enforcement. The letter also outlines the regulatory
enforcement actions the FDA is authorized to take for violations.
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This letter told hospitals of the FDA’s extension of its deadline for enforcement of postmarket requirements — medical device reporting, tracking, corrections and recalls, QS and labeling — for hospitals to Aug. 14, 2002. The document outlines the phased-in enforcement of requirements. It also provides examples of completed registration and device listing forms, where to obtain forms and how to complete and submit registration and listing forms.

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Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and Staff, July 2001
This guidance document clarifies the August 2000 document “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.” It includes questions to ask a potential reprocessor. The guidance also covers requirements for reporting an adverse event with a reprocessed SUD, QS and SUD compliance, sterilization and the list of SUDs known to be reprocessed.

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Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions; Final Guidance for Industry and Staff, July 2003
This document answers questions regarding registration and listing.

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Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, August 2000
This document provides guidance about responsibilities for SUD reprocessors. It includes a background of the use of and regulatory framework surrounding reprocessed SUDs. The guidance document summarizes the FDA’s priorities for enforcing premarket submission requirements regarding registration and listing, MDR, device tracking, corrections and removals, QS regulations, labeling and premarket requirements. It also includes comments the agency received after releasing its proposed strategy.

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Reusing Medical Devices Ensuring Safety The Second Time Around, FDA Consumer magazine, September-October 2000
This article covers the FDA’s concerns, the MDR system, the CDRH research program that explored the safety of reprocessed SUDs and the August 2000 guidance document on enforcement priorities. It also discusses whether the FDA’s approach for enforcement of regulatory requirements is appropriate.
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Guidance Document for Washers and Washer-Disinfectors Intended for Processing
Reusable Medical Devices, June 1998
This document is intended to clarify the regulatory status of washers and washer-
disinfectors for use in processing reusable devices. It discusses when 510(k) submissions
are required, which articles are exempt from 510(k) and addresses confusion about
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Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices
Intended by the Original Equipment Manufacturer for Single Use, April 2001
Hospitals that reprocess SUDs are subject to reporting requirements in 21 CFR Part
803 for adverse events involving SUDs. This guidance document describes MDR
requirements and provides guidance on the mandatory MedWatch form.

Section 29  .................................................................................................................. 411
Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and
Hospitals; Final Guidance for Industry and FDA, July 2001
Manufacturers engaged in reprocessing devices are subject to regulatory requirements.
This guidance document defines label and labeling and includes a question-and-answer
section on labeling requirements.

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Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities: FDA
Reviewer Guidance, April 1996
This guidance document, which says it will be updated because it was written before
the Good Guidance practices, includes recommendations regarding the content of
reuse instructions. It also covers premarket notification submissions, reprocessing
steps, labeling, documentation of validation and a checklist for reprocessing instruction.