Reprocessing Single-Use Medical Devices: Information for Health Care Facilities

This page provides information to help health care facilities understand the use of reprocessed medical devices originally labeled for single-use, and to clarify the level of FDA's regulatory oversight of these reprocessed single-use medical devices to remain as safe and effective as the original manufactured devices.

Introduction

The practice of reprocessing devices that are intended for single-use (known as single-use devices, SUDs) began in hospitals in the late 1970s. Since that time, this practice has become widespread as a mechanism to save costs for health care facilities and reduce medical waste. For example, use of reprocessed SUDs may reduce environmental impact by limiting the use of non-renewable resources and decreasing the amount of medical waste that requires treatment and disposal. The FDA ensures the safety and effectiveness of reprocessed SUDs by regulating device manufacturers, third party reprocessors, and hospitals that reprocess SUDs in the same manner as the original equipment manufacturer (OEM). In doing so, reprocessors of SUDs are held to the same regulatory requirements as the original manufacturer of the single use device.

As defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), single-use devices (SUDs) are those devices intended for one use, or on a single patient during a single procedure (FD&C Act 201(ll)(1)). An OEM may choose to label its device for single use because the device is not originally designed or intended to be reused (for example, the OEM did not conduct reprocessing/reuse testing as part of their original premarket evaluation), or the OEM has chosen not to market the device for reuse. However, the absence of reprocessing validation testing by the OEM does not mean the device is unable to be reprocessed. While not all SUDs are suitable for reprocessing and reuse, certain SUDs may be demonstrated safe and effective for reuse via reprocessing validation testing. To support the reprocessing and reuse of SUDs, third-party reprocessors, including health care facilities, must meet the FDA's regulatory requirements. While the following information provides a brief overview of some of these requirements, more detailed information regarding the statutory and regulatory requirements for reprocessed SUDs can be found under the Additional Resources links at the bottom of this page.

Overview of Statutory and Regulatory Requirements

Reprocessed SUDs should be capable of withstanding necessary cleaning, disinfection or sterilization, and continue to comply with all applicable FDA requirements after each instance of reprocessing, up to the maximum number of times that the devices are intended to be reprocessed. Most reprocessed SUDs are required to present reprocessing validation testing as part of premarket submissions to the FDA.

A) Class I or Class II Reprocessed SUDs

In accordance with section 510(o) of the FD&C Act, a reprocessor of a class I or class II single-use medical device must submit a premarket notification to the FDA that includes the following testing and validation data evaluated for a specified maximum number of times the device is reprocessed (unless the device is expressly exempted from section 510(o)) to demonstrate that the reprocessed SUD is substantially equivalent to (i.e., as safe and effective as) a predicate device:

- Cleaning,
- Disinfection,
- Sterilization (if required), and
- Functional performance of the device, including the rationale for the maximum number of times the device can be reprocessed.

For additional information about the content of premarket notifications for reprocessing Class I and II SUDs, please see Content of a 510(k) (/medical-devices/premarket-notification-510k/content-510k) and 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 (/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification).

B) Class III Reprocessed SUDs

In accordance with section 515(c)(2)(A) of the FD&C Act, a reprocessor of a class III single-use medical device must submit to the FDA a premarket report that includes:

- The device name, including both the trade or proprietary name and the common or usual name.
- The establishment registration number of the owner or operator submitting the report.

- Actions taken to comply with performance standards under section 514.
- Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use. Note: The proposed labeling must include the statement ‘‘Reprocessed device for single use. Reprocessed by [the person or establishment responsible for reprocessing]’’
- Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective.
- A description of the device’s components, ingredients, and properties.
- A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.
- Such samples of the device that may be reasonably required.
- A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.
- A statement that the applicant believes to the best of their knowledge that all data and information submitted are truthful and accurate and that no material fact has been omitted in the report.
- Any additional data and information that is determined necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.
- Validation data described in section 510(o)(1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report.

C) Labeling & Postmarket Requirements

In accordance with section 502(v) of the FD&C Act, reprocessed SUDs must be labeled with the statement “Reprocessed device for single use. Reprocessed by [the person or establishment responsible for reprocessing].” Reprocessed SUDs that lack this required labeling information are considered misbranded. Third party reprocessors and health care facilities that reprocess SUDs must also meet applicable device labeling requirements (21 CFR Part 801), including unique device identification (21 CFR Part 830).

Generally, third party reprocessors and health care facilities that reprocess SUDs must also meet the same postmarket requirements as the original equipment manufacturer (OEM),

including medical device reporting (21 CFR Part 803), corrections and removals (21 CFR Part 806), and quality systems (21 Part CFR 820). Information about these requirements is provided in Additional Resources below.

Questions

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.

Additional Resources

- Reprocessed Single-Use Devices Frequently Asked Questions | FDA (/medical-devices/reprocessing-single-use-medical-devices-information-health-care-facilities/reprocessed-single-use-devices-frequently-asked-questions)
- Overview of Device Regulation | FDA (/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation)
- Recalls, Corrections and Removals (Devices) | FDA (/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices)
- Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250 | FDA (/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-and-modernization-act-2002-mdufma-pl-107-250)
- Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data (September 29, 2005, 70 FR 56911) (https://www.govinfo.gov/content/pkg/FR-2005-09-29/pdf/05-19510.pdf)
- CPG Sec. 300.500 Reprocessing of Single Use Devices 2005 |FDA (/regulatory-information/search-fda-guidance-documents/cpg-sec-300500-reprocessing-single-use-devices)
- Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors - Three Additional Questions: Guidance for Industry, FDA Staff, Third-Party and Hospital Reprocessors 2003 | FDA (/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital-0)
- Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Final Guidance for Industry and FDA Staff 2001 | FDA (/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital)

- Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA | FDA (/regulatory-information/search-fda-guidance-documents/labeling-recommendations-single-use-devices-reprocessed-third-parties-and-hospitals)
- Single-Use Devices | Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC (https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/reuse-single-use-devices.html?CDC_AAref_Val=https://www.cdc.gov/infectioncontrol/guidelines/disinfection/reuse-of-devices.html)
- 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 | FDA (/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification)
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff | FDA (/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling)