

Guidance Document For Washers And Washer-Disinfectors Intended For Processing Reusable Medical Devices (Text Only)

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Center for Devices and Radiological Health

Infection Control Devices Branch
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Chiu Lin, Ph.D. Chief, Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, HFZ-480, Office of Device Evaluation, 9200 Corporate Blvd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Chiu Lin, Ph.D. at 240-276-3700.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov (<mailto:CDRH-Guidance@fda.hhs.gov>) to receive a copy of the guidance. Please use the document number (004) to identify the guidance you are requesting.

CDRH GUIDANCE DOCUMENT FOR WASHERS AND WASHER-DISINFECTORS INTENDED FOR PROCESSING REUSABLE MEDICAL DEVICES

Purpose:

The purpose of this document is to clarify the regulatory status of the washers and washer-disinfectors intended for use in processing reusable medical devices. This document provides guidance to the regulated industry on when a premarket notification [510(k)] submission is required.

Background:

Washers and washer-disinfectors that are intended for use in processing reusable medical devices are considered devices pursuant to Sec. 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Food and Drug Administration (FDA) believes there is a need to clarify when 510(k) submissions are required for washers and washer-disinfectors intended for use in processing reusable medical devices. The specific intended use of the washer and washer-disinfectors will determine whether a 510(k) submission is needed for the device.

Washers and washer-disinfectors intended to process only "general purpose" articles, such as laboratory glassware, pipettes, bottles and containers, although considered as medical devices, are treated as "general purpose" articles exempt from registration under 21 CFR 807.65(c), and therefore exempt from 510(k) requirements. Washers and washer-disinfectors labeled only to wash and sanitize body waste receptacles, such as bedpans, are classified in 21 CFR 880.6800 and are exempt from the 510(k) requirements of the Act (subject to the Limitations on Exemptions found in 21 CFR 880.9). In addition, washers, washer-disinfectors, and disinfectors intended solely for the reprocessing of flexible endoscopes are considered accessories to endoscopes and have been reviewed and classified as Class II Endoscopes and accessories.

Washers and washer-disinfectors intended for the cleaning and disinfection of other reusable medical devices, such as stainless steel devices, surgical instruments, including devices with lumens, respiratory therapy equipment, and other medical devices, were legally marketed medical devices prior to the enactment of the Medical Device Amendments of 1976. FDA has not initiated classification procedures to formally classify this category of devices and are thus "unclassified." While the Agency has reviewed and cleared premarket notifications for these devices for use in the processing of reusable medical devices, we recognize that there is confusion within the regulated industry on whether 510(k) submissions are needed for these devices. This guidance document addresses primarily these unclassified washers and washer-disinfectors.

Public Health Implications:

FDA has considered two important public health implications in the regulation of washers and washer-disinfectors intended for use in processing reusable medical devices: (1) when the washer-disinfectors is used as the terminal process and (2) the impact on the effectiveness of a terminal sterilization process when the washer is used during an intermediate cleaning step. FDA recognized the interdependency of cleaning and the effectiveness of a terminal process and began to ask reusable device manufacturers to validate the recommended processing steps for their devices. Since the cleaning and disinfection of reusable medical devices in a washer-disinfectors may be a terminal process (the final treatment prior to the reusable medical device's use on a patient), it is critical that these washers-disinfectors be effective. If they are ineffective, then devices that are processed in them may have an increased potential for the transmission of diseases and multi-drug resistant microorganisms. Furthermore, published reports in the literature indicate that sterilization processes require the proper cleaning of reusable medical devices. Cleaning failures negatively impact the effectiveness of these processes.

CDRH Regulatory Guidance for Washers and Washer-Disinfectors Intended for use in Processing Reusable Medical Devices

Washers and washer-disinfectors intended for use in processing reusable medical devices, e.g., stainless steel surgical instruments and respiratory therapy equipment, are considered medical devices within the meaning of Section 201(h) of the Act. Currently, no classification regulation describing the preamendment washers and washer-disinfectors exists, however, unclassified medical devices are subject to 510(k) requirements of the Act.

The agency intends to obtain a recommendation on the classification of the preamendments, unclassified washers and washer-disinfectors at a future meeting of the General Hospital and Personal Use Devices Advisory Panel. While these unclassified washers and washer-disinfectors intended for use in processing reusable medical devices undergo formal classification procedures, manufacturers should continue to submit premarket notifications.

Washers and washer-disinfectors that are intended to process "general purpose" articles, and thus exempt from 510(k) requirements under 21 CFR 807.65(c), become subject to premarket notification requirements of the Act if the intended use of the devices are modified to include the processing of reusable medical devices. Washers and washer-disinfectors intended only to wash and sanitize body waste receptacles, such as bedpans, are exempt from 510(k) requirements under 21 CFR 880.6800, subject to the Limitation on Exemptions. Washers, washer-disinfectors, and disinfectors intended solely for the processing of flexible endoscopes are considered as accessories to endoscopes and are classified as Class II devices under 21 CFR 876.1500. These devices are subject to the premarket notification requirements of the Act.

A regulatory guidance for cleaning accessories to washers and washer-disinfectors, such as enzymatic cleaners, detergents, and lubricants was issued May 3, 1995. This guidance is available through the Division of Small Manufacturers Assistance, at the address below.

Implementation:

Since we recognize the confusion within the regulated industry regarding when 510(k) submissions are necessary for the unclassified washers and washer-disinfectors intended for use in processing reusable medical devices, FDA will allow manufacturers of these devices up to 12 months, from the date of issuance of this guidance, to come into compliance with the premarket notification requirements of the Act. During the 12-month grace period, FDA will exercise discretion in the enforcement of the provisions of the announced guidance and will work with the device manufacturers to insure compliance. Manufacturers are expected to promptly submit an appropriate premarket notification(s), register, list, and comply with all other provisions of the Act.

It is recommended that the manufacturers review the "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in a Health Care Facilities", dated August, 1993 for the types of performance testing that should be provided in a 510(k) submission. FDA will develop an interim guidance for washers and washer-disinfectors intended for processing reusable medical devices or will recognize published international and national voluntary standards for these washers and washer-disinfectors. (A copy of the guidance can be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at [its Internet address \(/MedicalDevices/DeviceRegulationandGuidance/default.htm\)](#)).

If there are any questions concerning this guidance, please contact the Chief, Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation at (301) 443-8913.

**More in [Guidance Documents \(Medical Devices and Radiation-Emitting Products\)](#)
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)**

Cross-Center Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)