



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 22 2010

Dear Endoscope Manufacturer:

Subject: Possible misbranding of reusable devices labeled for reprocessing by the STERIS System 1 processor

This letter requests your immediate attention regarding reusable medical devices with labeling that references the STERIS System 1 processor (SS1).

Background

In a notice dated December 3, 2009, FDA informed healthcare facilities that STERIS Corporation has significantly modified the SS1 and that FDA has not approved or cleared this modified product. Thus, FDA has not determined that the SS1 is safe or effective for its labeled claims, including claims that it sterilizes medical devices.

Use of a device that is promoted or labeled to sterilize or disinfect a medical device, but that does not properly perform these functions, poses risks to patients and users. Improperly disinfected or sterilized instruments may transmit pathogens to patients and healthcare staff, or expose them to hazardous chemicals. Improper sterilization or disinfection may also adversely affect the quality and function of reprocessed instruments.

The FDA notice also advised healthcare facilities to transition as soon as practicable to a legally-marketed alternative to the SS1 for their sterilization and disinfection needs. Facilities without an acceptable alternative to the SS1 were advised to promptly assess their patient-care needs and sterilization and disinfection requirements and take steps to obtain legally-marketed substitutes for the SS1.

What This Means to You

If your devices are labeled for use with the SS1, then they are misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act because they fail to bear adequate directions for use. Under FDA regulations, directions for use are inadequate if they omit or incorrectly specify preparation for use.¹

If your devices are labeled for use with the SS1, you should revise your labeling to correct these violations as soon as possible by removing all statements indicating that

¹ See 21 CFR 801.5(g).

your devices may be reprocessed with the SS1 and by specifying only legally-marketed reprocessing devices. FDA anticipates that you should be able to do this within one year. As explained below, questions about labeling revisions and any associated PMA or 510(k) submissions can be directed to Bob Gatling or Candace McManus.

Reusable medical devices must be labeled with adequate instructions for their reprocessing and these instructions should be validated.² Labeling includes labels as well as other written, printed, or graphic matter on a device or its containers or wrappers, or material accompanying a device, such as instructions for use and information shipped with the product or posted on the internet.

You may be required to provide to FDA a list of reusable devices that you produce that have been validated for reprocessing by a method other than the SS1 and identify the method that has been validated.³

FDA recommends that you take the following additional actions:

1. Review immediately all labeling for your reusable medical devices, including online information, for references to the SS1. These materials should be revised as outlined above in order to comply with applicable labeling requirements.
2. Consider immediately adding to your product packaging a notice stating, "The STERIS System 1 (SS1) is not a legally marketed device" and that your labeling will be revised to identify reprocessing methods using legally-marketed devices.
3. Take immediate action to validate at least one reprocessing method using legally-marketed devices if the SS1 is the only method described for reprocessing your device. Following validation, your labeling should be revised as indicated above, in order to comply with applicable labeling requirements.
4. Determine if your labeling changes require a PMA or 510(k) submission.
 - a. Relabeling a product approved in a PMA may require the submission of a PMA supplement.⁴

² See section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(f)(1); 21 CFR 801.5(g); Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf>.

³ This letter refers to previously-approved collections of information found in FDA regulations. These collections of information 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 collections of information under 21 CFR part 820 have been approved under OMB Control Number 0910-0073, the collections of information under 21 CFR part 807 subpart E have been approved under OMB Control Number 0910-0120, the collections of information under 21 CFR part 814 have been approved under OMB Control Number 0910-0231, and the collections of information under 21 CFR part 801 have been approved under OMB Control Number 0910-0485.

⁴ See 21 CFR 814.39; Guidance for Industry and FDA Staff: Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision, available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm>.

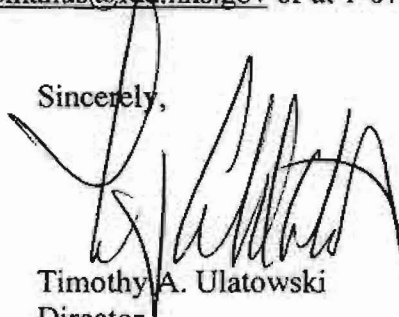
- b. Relabeling a reusable device cleared in a 510(k) premarket notification may require the submission of a new 510(k).⁵

Please contact Bob Gatling, Director, Program Operations Staff, Office of Device Evaluation, at 301-796-6560, with any questions related to PMA or 510(k) requirements.

You should also ensure that labeling instructions and validations of reprocessing methods for devices subject to PMAs and 510(k)s, and for any devices that claim to be exempt from 510(k) requirements, comply with the requirements of the Quality System regulation, 21 CFR part 820.

Question beyond those addressed to Bob Gatling can be directed to Candace McManus, Dr PH, at candace.mcmanus@fda.hhs.gov or at 1-877-260-3731.

Sincerely,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

⁵ See 21 CFR 807.81(a)(3); Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1), available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm>.