

single-use biopsy forceps must submit 510(k)s for these devices by September 27, 2004, or their devices may no longer be marketed.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara A. Zimmerman, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Public Law 107-250) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, in order to ensure that reprocessed SUDs are substantially equivalent to predicate devices, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data. These required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

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 premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs will no longer be exempt from premarket notification requirements. Manufacturers of these identified devices will need to submit 510(k)s that include validation data to be specified by FDA. Reprocessors of certain SUDs that currently have cleared 510(k)s also will need to submit the validation data specified by the agency.

A. Definitions

Under section 302(d) of MDUFMA, a reprocessed SUD is defined as an “* * * original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an

additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.”

B. Reprocessed SUDs Exempt From Premarket Notification

Reprocessed SUDs are divided into three groups: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions set forth in MDUFMA, and all three reflect a classification scheme recognized by the industry.¹ These categories of devices are defined as follows:

1. A critical reprocessed SUD is intended to contact normally sterile tissue or body spaces during use.
2. A semicritical reprocessed SUD is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.
3. A noncritical reprocessed SUD is intended to make topical contact and not penetrate intact skin.

C. Requirements for Critical Reprocessed SUDs

MDUFMA requires FDA to review the critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require premarket notification to ensure their substantial equivalence to predicate devices. By April 26, 2003, FDA was required to identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification requirements will be terminated and for which FDA has determined that validation data, as specified under MDUFMA, is necessary in a 510(k). According to the new law, manufacturers of the devices whose exemption from premarket notification requirements is terminated must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in 21 CFR 807.87, within 15 months of publication of the list or no longer market their devices.

II. FDA's Implementation of New Section 510(o) of the Act

In the **Federal Register** of April 30, 2003 (68 FR 23139), FDA described the methodology and criteria it used to

¹ These are known in the industry as the Spaulding definitions, and are described in Spaulding, E. H., “The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections,” P. S. Brachman and T. C. Eickoff (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, IL 1971:254-274.

determine which previously exempt critical reprocessed SUDs are now subject to 510(k) submission requirements, including the submission of validation data. First, FDA described how it identified the types of SUDs being reprocessed and how the Spaulding definitions (see footnote 1) were used to categorize these devices as critical, semicritical, or noncritical. (This list, which was Attachment 1 to that **Federal Register** notice, is being reprinted as Attachment 1 to this notice.) Next, the agency described its use of the Risk Prioritization Scheme (RPS)² that it used to evaluate the risk (high, moderate, or low) associated with an SUD based on: (1) Risk of infection and (2) risk of inadequate performance following reprocessing. FDA identified its final risk criterion as those reprocessed SUDs intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). (These are generally devices intended for use in neurosurgery and ophthalmology.)

Using this methodology and criteria, the devices included in List I (“Critical Reprocessed Single-Use Devices Previously Exempt From Premarket Notification Requirements That Will Now Require 510(k)s With Validation Data”) of the April 30, 2003, **Federal Register** notice are those critical reprocessed SUDs that were either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with the causative agents of CJD.

III. Revisions to Attachment I, List I, and List II

A. Revisions to Attachment I (List of SUDs Known To Be Reprocessed or Considered for Reprocessing)

FDA has re-evaluated the list of reprocessed SUDs with regard to the critical and semicritical device designations. In doing so, the agency has determined that all gastroenterology-urology biopsy instruments should be considered critical devices rather than semicritical devices because these devices are intended to break the mucous membrane and come in contact with sterile tissue when taking a biopsy. This includes biopsy forceps covers, biopsy instruments, biopsy needle sets, biopsy punches, mechanical biopsy instruments, and nonelectric biopsy

² This scheme is described in the agency's February 2000 draft guidance document entitled “Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme.” The document is available on the Internet at <http://www.fda.gov/cdrh/reuse/1156.pdf>.