

the industry.<sup>1</sup> 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.

#### 1. 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 must identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification will be terminated. List I in this **Federal Register** notice implements this MDUFMA requirement.

In accordance with MDUFMA, manufacturers of the devices identified in List I 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 § 807.87 (21 CFR 807.87), within 15 months of publication of this notice or no longer market their device.

#### 2. Requirements for Semicritical Reprocessed SUDs

MDUFMA also requires FDA to review the semicritical 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. FDA must identify these devices in a notice published in the **Federal Register** by April 26, 2004. Manufacturers of devices identified at that time will be required to 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 § 807.87, within 15 months of publication of that notice or no longer market their device.

#### 3. Requirements for Noncritical Reprocessed SUDs

MDUFMA does not require FDA to take any action under this section for noncritical SUDs that are exempt from premarket submission requirements.

#### C. Reprocessed SUDs Already Subject to Premarket Notification Requirements

MDUFMA also requires FDA to review the types of reprocessed SUDs already subject to premarket notification requirements and to identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. FDA must publish a list of these devices in the **Federal Register** by April 26, 2003, and update the list as necessary. List II of this **Federal Register** notice implements this MDUFMA requirement. The devices on List II may be critical, semicritical, or noncritical reprocessed SUDs.

1. For devices identified in List II that have not yet been cleared through the 510(k) process, manufacturers 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 § 807.87, upon publication of this notice in order to market these devices. FDA will soon publish guidance to help submitters understand what types of validation data should be included in these 510(k)s.

2. For devices identified in List II that already have been cleared through the 510(k) process, manufacturers must submit validation data regarding cleaning, sterilization, and functional performance within nine months of publication of this notice or marketing must cease. FDA will soon publish guidance to explain how a 510(k) holder may submit the additional data now being required to support an earlier clearance.

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

FDA used a number of criteria to determine which device types should be included in the lists required by MDUFMA. As part of its consideration, FDA relied upon the Review Prioritization Scheme (RPS) it described in the February 2000 draft guidance document entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme."<sup>2</sup> In the RPS guidance, FDA set forth factors that could be used to evaluate risk associated

with reprocessed SUDs. This approach assigned an overall risk to each SUD based on: (1) The risk of infection and (2) the risk of inadequate performance following reprocessing. Based on these risk factors, three categories of risk (high, moderate, and low) were developed. The designation of "high risk" was assigned to those devices that posed the greatest risk of infection and inadequate performance after reprocessing. In response to several comments about potential subjectivity of the RPS, FDA did not use the RPS approach when the agency finalized its enforcement priorities for reprocessed SUDs on August 14, 2000.

FDA has determined, however, that the RPS is an appropriate risk-based tool for developing the lists required by MDUFMA because the RPS identifies the devices that are likely to raise the most concerns about both infection transmission and inadequate performance following reprocessing. In formulating these lists, the agency also had the benefit of comments from stakeholders and an internal centerwide committee to evaluate the results of the RPS and ensure its consistency. In addition, there was a final review of all the devices on these lists by the Director of the Office of Device Evaluation. In this context, the agency believes these steps have adequately addressed concerns about the subjectivity of the RPS.

In addition to the previous criterion, FDA used one other criterion to identify those reprocessed SUDs that will be subject to the new requirements established by MDUFMA. The agency has included in these lists all 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 ophthalmology. This criterion was included in FDA's evaluation because insufficient scientific information exists at this time to establish standard methods to eliminate CJD infectious agents.

Therefore, in order to develop the two lists required by MDUFMA, FDA used the following process. First, the agency identified the types of SUDs that are being reprocessed. FDA did this by searching the 510(k) database for any 510(k)s that had been submitted for reprocessed SUDs and by asking original equipment manufacturers and reproducers to provide information about types of devices that were being reprocessed. Second, FDA determined whether these devices are "critical," "semi-critical," or "non-critical". (These

<sup>1</sup> 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, 1971:254-274.

<sup>2</sup> This draft guidance document is available on the CDRH Web site at <http://www.fda.gov/cdrh/reuse/1156.pdf>.