

definitions reflect the Spaulding³ classification and are the same definitions FDA used earlier in developing its RPS.) FDA then applied the criteria described previously and "listed" any reprocessed SUD that was 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.

All devices identified in List I (previously exempt from 510(k)) have been determined to be critical reprocessed SUDs. In addition to being critical, they are either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with CJD. It should be noted that not all exempt devices that are critical have been listed. Critical reprocessed SUDs that are not listed in List I at this time may be reconsidered in subsequent updates of the list. The devices in List II (devices currently subject to 510(k) requirements that now will require the submission of validation data) are 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.

FDA has also provided a reference list in Attachment 1. To show how FDA evaluated the risk of a specific device,

Attachment 1 includes the entire group of devices FDA considered when identifying the reprocessed SUDs in Lists I and II, and shows how FDA applied the criteria that determined whether the device would be identified on either of these lists.

In the **Federal Register** of February 4, 2003 (68 FR 5643), FDA invited interested persons to provide information and share views on the implementation of MDUFMA. The agency received several comments that identified specific reprocessed SUDs to be included in Lists I and II. The agency considered these recommendations while finalizing this document. Although FDA's lists do not include all the reprocessed SUDs that were recommended, the agency believes that those devices that pose the greatest risk of infection transmission and inadequate performance have been identified. The agency recognizes, however, that these lists may need to be re-evaluated and updated over time. Therefore, FDA will consider comments from the public on additional devices that should be included in the lists at any time. The agency also notes that MDUFMA permits FDA to request validation data for a device type that is subject to 510(k) clearance but not yet

included in List II. If this were to occur, FDA would ensure that manufacturers were aware of this change in the 510(k) submission requirements for that type of device by promptly updating the list.

Finally, FDA received one comment that suggested the agency's prior determinations about risk associated with reprocessed SUDs precluded FDA from now requiring 510(k)s for devices that were previously exempt or additional data for devices that were already cleared. FDA believes that this comment ignores the existence of MDUFMA's requirements. It is true that FDA had initially developed a regulatory approach for reprocessed SUDs that sought to treat those devices and original devices in a similar manner and that FDA had not required additional data to be submitted for certain reprocessed SUDs under that approach. However, through MDUFMA Congress clearly stated its intent to have the agency re-examine its policy with respect to reprocessed SUDs and legislated additional controls for those devices. FDA is committed to fulfilling its responsibilities under MDUFMA. The development and publication of these lists is part of the agency's implementation of these new statutory provisions.

LIST I.—CRITICAL REPROCESSED SINGLE-USE DEVICES PREVIOUSLY EXEMPT FROM PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE 510(K)S WITH VALIDATION DATA

[To be submitted by July 26, 2004]

21 CFR section	Classification name	Product code for Non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
872.3240	Dental bur	Diamond Coated	NME	Dental diamond coated bur.
872.4535	Dental diamond instrument	DZP	NLD	Dental diamond instrument.
872.4730	Dental injection needle	DZM	NMW	Dental needle.
874.4140	Ear, nose, and throat bur	Microdebrider	NLY	ENT high speed microdebrider.
874.4140	Ear, nose, and throat bur	Diamond Coated	NLZ	ENT diamond coated bur.
874.4420	Ear, nose, throat manual surgical * * *	KAB, KBG, KCI	NLB	Laryngeal, Sinus, Tracheal trocar.
878.4200	Introduction/drainage catheter and accessories.	GCB	NMT	Catheter needle.
878.4800	Manual surgical instrument	MJG	NNA	Percutaneous biopsy device.
878.4800	Manual surgical instrument	FHR	NMU	Gastro-Urology needle.
878.4800	Manual surgical instrument for * * *	DWO	NLK	Cardiovascular biopsy needle.
878.4800	Manual surgical instrument for * * *	GAA	NNC	Aspiration and injection.
882.4190	Forming/cutting clip instrument	HBS	NMN	Forming/cutting clip instrument.
884.1730	Laparoscopic insufflator * * *	HIF	NMI	Laparoscopic insufflator and accessories.
884.4530	OB/GYN specialized manual instrument	HFB	NMG	Gynecological biopsy forceps.
886.4350	Manual ophthalmic surgical instrument	HNN	NLA	Ophthalmic knife.

³ 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.