

forceps (devices 42–47 in Attachment I). In addition, it was determined that rigid and nonrigid bronchoscope biopsy forceps and biliary sphincterotomes (devices 40, 41, and 55 in Attachment I) should also be considered critical devices rather than semicritical devices for the same reason as stated previously. These changes are reflected in a revised version of Attachment I included in this **Federal Register** notice.

B. Revisions to List I (Critical Reprocessed Single-Use Devices Previously Exempt From Premarket Notification Requirements That Will Now Require 510(k)s With Validation Data)

FDA recategorized nine device types from semicritical to critical. One of

these nine device types, nonelectric gastroenterology-urology biopsy forceps, was also considered high risk under the RPS. Therefore, nonelectric gastroenterology-urology biopsy forceps have been added to List I. Under MDUFMA, manufacturers of these biopsy forceps will be required to submit 510(k)s with validation data by (see **DATES**), which is 15 months following the publication of this revised list.

In addition, FDA is taking this opportunity to clarify the date by which manufacturers of the other devices in List I are required to submit 510(k)s with validation data. The correct date is July 30, 2004, which is 15 months following the initial publication of the

list (the April 30, 2003, **Federal Register** notice inadvertently identified two dates).

C. Revisions to List II (Reprocessed Single-Use Devices Subject to Premarket Notification Requirements That Will Now Require the Submission of Validation Data)

The only change to List II is to clarify the date by which 510(k) submissions are required by MDUFMA to be supplemented with validation data. The correct date is January 30, 2004, which is 9 months following the initial publication of the list (as noted previously, the April 30, 2003, **Federal Register** notice inadvertently identified two dates).

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 30, 2004, UNLESS OTHERWISE NOTED).

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for re-processed 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 (ENT) 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 instrument	KAB, KBG, KCI	NLB	Laryngeal, sinus, tracheal trocar
876.1075 ¹	Gastroenterology-urology biopsy instrument	FCL	NON	Nonelectric biopsy forceps
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 general use	DWO	NLK	Cardiovascular biopsy needle
878.4800	Manual surgical instrument for general use	GAA	NNC	Aspiration and injection needle
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

¹ 510(k)s with validation data to be submitted by September 27, 2004.