510(k) when using the draft STED format as described in the final guidance document.

(Comment 12) One comment inquires about incentives for manufacturers to participate in the pilot program. Related comments ask that FDA reconsider the devices eligible for the pilot program.

FDA is committed to ensuring that the FDA review process will not be unduly hindered if persons choose to follow the draft STED format. However, FDA cannot assure shorter review timeframes if the draft STED format is used. FDA believes that medical device companies with vision, leadership, a desire to influence the accelerating global harmonization effort, and the goal of ultimately reducing their regulatory burden, will participate in the pilot program. FDA has increased the list of eligible devices to provide more flexibility and believes the pilot program will help achieve an international uniformity of submissions.

(Comment 13) One comment asks that the pilot program focus only on 510(k)s, PMAs, and PMA supplements that are for high risk devices.

FDA has exempted from premarket evaluation virtually all the low risk devices that were subject to premarket requirements. Therefore, the candidates for the pilot program are of a moderate to high degree of risk. PMA supplements are not candidates for the pilot program.

(Comment 14) One comment asks that the same measures of success or failure of the pilot program be identified for all countries conducting the pilot and that FDA clearly define the criteria and analysis methods that will be used.

FDA agrees that measures of success and analytical methods should be clearly defined prior to initiation of the pilot. It is important to determine whether the core of a premarket submission can be based on the draft STED format. Both FDA and SG1 will track and assess whether: (1) There are significant impediments to filing and review of documents, (2) the STED harmonized format has utility for evaluating different regulatory classes of devices having different complexities, and (3) use of the STED harmonized format results in improved regulatory review times. FDA will post a report summarizing the results of its analysis of the pilot on its Web site.

(Comment 15) One comment notes that statutory and/or regulatory changes may be needed to fully implement the draft STED document concept of harmonized premarket submissions in the member countries.

Each of the five GHTF member countries has determined that the pilot program can proceed without the need for statutory or regulatory changes if current country-specific requirements are met. It remains to be determined how a STED document would be implemented if it becomes an alternative means of submission.

(Comment 16) One comment asks that FDA remove endosseous dental implants from the list of candidate devices for the pilot program. The comment notes that applying the harmonized process to these implants will not provide the agency with the necessary information on their safety and effectiveness.

FDA does not concur with the comment. The FDA draft guidance for the pilot premarket review program and the draft STED document both describe the need for applicants to consider country-specific information, including guidance documents, when preparing their premarket submissions for review. A premarket submission for an endosseous dental implant based on the draft STED format should consider all relevant available guidance documents.

III. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a way to apply GHTF recommendations as related to premarket submission to FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

IV. Electronic Access

You may obtain a copy of ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff,'' via fax machine by calling the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH home page is updated on a regular basis and includes: Civil money penalty guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), assistance for small manufacturers, information on video conferencing, electronic submissions, mammography devices, and other device-related information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16108 Filed 6–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0161]

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is adding nonelectric biopsy forceps (classified in 21 CFR 876.1075, *Gastroenterology-urology biopsy instrument*) to the list of critical reprocessed single-use devices (SUDs) whose exemption from premarket notification requirements is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), is necessary in a premarket notification (510(k)). FDA is requiring submission of these data to ensure that reprocessed single-use nonelectric biopsy forceps are substantially equivalent to predicate devices, in accordance with MDUFMA.

DATES: These actions are effective June 26, 2003. Manufacturers of reprocessed

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 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

[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. Eickof (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, IL 1971:254–274.

[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*.

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 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 (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.

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA[1] (MANUFACTURERS WHO ALREADY HAVE 510(K) CLEARANCE FOR THESE DEVICES MUST SUBMIT VALIDATION DATA BY JANUARY 30, 2004. ANY NEW 510(K) SUBMITTED AFTER PUBLICATION OF THE APRIL 30 LIST WILL REQUIRE VALIDATION DATA.)

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
Unclassified	Oocyte aspiration needles	MHK	NMO	Oocyte aspiration needles
Unclassified	Percutaneous transluminal angioplasty catheter	LIT	NMM	Transluminal peripheral angioplasty catheter
Unclassified	Ultrasonic surgical instrument	LFL	NLQ	Ultrasonic scalpel
868.5150	Anesthesia conduction needle	BSP	NNH	Anesthetic conduction needle (with or without introducer)
868.5150	Anesthesia conduction needle	MIA	NMR	Short term spinal needle
868.5730	Tracheal tube	BTR	NMA	Tracheal tube (with or without connector)
868.5905	Noncontinuous ventilator (IPPB)	BZD	NMC	Noncontinuous ventilator (respirator) mask
870.1200	Diagnostic intravascular catheter	DQO	NLI	Angiography catheter
870.1220	Electrode recording catheter	DRF	NLH	Electrode recording catheter
870.1220	Electrode recording catheter	MTD	NLG	Intracardiac mapping catheter
870.1230	Fiberoptic oximeter catheter	DQE	NMB	Fiberoptic oximeter catheter
870.1280	Steerable catheter	DRA	NKS	Steerable catheter
870.1290	Steerable catheter control system	DXX	NKR	Steerable catheter control system
870.1330	Catheter guide wire	DQX	NKQ	Catheter guide wire
870.1390	Trocar	DRC	NMK	Cardiovascular trocar
870.1650	Angiographic injector and syringe	DXT	NKT	Angiographic injector and syringe
870.1670	Syringe actuator for injector	DQF	NKW	Injector for actuator syringe
870.2700	Oximeter	MUD	NMD	Tissue saturation oximeter
870.2700	Oximeter	DQA	NLF	Oximeter
870.3535	Intra-aortic balloon and control system	DSP	NKO	Intra-aortic balloon and control system
870.4450	Vascular clamp	DXC	NMF	Vascular clamp
870.4885	External vein stripper	DWQ	NLJ	External vein stripper
872.5470	Orthodontic plastic bracket	DYW	NLC	Orthodontic plastic bracket
874.4680	Bronchoscope (flexible or rigid) and accessories	BWH	NLE	Bronchoscope (nonrigid) biopsy forceps
876.1075	Gastro-urology biopsy instrument	FCG	NMX	G-U biopsy needle and needle set
876.1075	Gastroenterology-urology biopsy instrument	KNW	NLS	Biopsy instrument
876.1500	Endoscope and accessories	FBK, FHP	NMY	Endoscopic needle
876.1500	Endoscope and accessories	MPA	NKZ	Endoilluminator
876.1500	Endoscope and accessories	GCJ	NLM	General and plastic surgery laparoscope
876.1500	Endoscope and accessories	FHO	NLX	Spring-loaded Pneumoperitoneum Needle

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA[1] (MANUFACTURERS WHO ALREADY HAVE 510(K) CLEARANCE FOR THESE DEVICES MUST SUBMIT VALIDATION DATA BY JANUARY 30, 2004. ANY NEW 510(K) SUBMITTED AFTER PUBLICATION OF THE APRIL 30 LIST WILL REQUIRE VALIDATION DATA.)—Continued

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for re-processed device	Product code name for reprocessed device
876.4300	Endoscopic electrosurgical unit and accessories	FAS	NLW	Active urological electrosurgical electrode
876.4300	Endoscopic electrosurgical unit and accessories	FEH	NLV	Flexible suction coagulator electrode
876.4300	Endoscopic electrosurgical unit and accessories	KGE	NLU	Electric biopsy forceps
876.4300	Endoscopic electrosurgical unit and accessories	FDI	NLT	Flexible snare
876.4300	Endoscopic electrosurgical unit and accessories	KNS	NLR	Endoscopic (with or without accessories) Electrosurgical unit
876.5010	Biliary catheter and accessories	FGE	NML	Biliary catheter
876.5540	Blood access device and accessories	LBW	NNF	Single needle dialysis set (co-axial flow)
876.5540	Blood access device and accessories	FIE	NNE	Fistula needle
876.5820	Hemodialysis systems and accessories	FIF	NNG	Single needle dialysis set with unidirectional pump
878.4300	Implantable clip	FZP	NMJ	Implantable clip
878.4750	Implantable staple	GDW	NLL	Implantable staple
880.5570	Hypodermic single lumen needle	FMI	NKK	Hypodermic single lumen needle
880.5860	Piston syringe	FMF	NKN	Piston syringe
882.4300	Manual cranial drills, burrs, trephines, and accessories	HBG	NLO	(Manual) drills, burrs, trephines, and accessories
882.4305	Powered compound cranial drills, burrs, trephines, and accessories	HBF	NLP	(Powered, compound) drills, burrs, trephines, and accessories
882.4310	Powered simple cranial drills, burrs, trephines, and accessories	HBE	NLN	(Simple, powered) drills, burrs, trephines, and accessories
884.1720	Gynecologic laparoscope and accessories	HET	NMH	Gynecologic laparoscope (and accessories)
884.6100	Assisted reproduction needles	MQE	NNB	Assisted reproduction needles
886.4370	Keratome	HMY, HNO	NKY	Keratome blade
886.4670	Phacofragmentation system	HQC	NKX	Phacoemulsification needle
892.5730	Radionuclide brachytherapy source	IWF	NMP	Isotope needle

[1] Hemodialyzers have been excluded from this list because the reuse of hemodialyzers is addressed in FDA's ''Guidance for Hemodialyzer Reuse Labeling'' (final draft issued on October 6, 1995).

IV. Comments

You may submit written or electronic comments on this notice to the Division of Dockets Management (see **ADDRESSES**). You may submit a single copy of an electronic comment to *http://www.fda.gov/dockets/ecomments*. You should submit two paper copies of any mailed comments but individuals may submit one paper copy. You should identify your comment with the docket number found in brackets in the heading of this document. You may see any comments FDA receives in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
1	Cardio	Cardiopulmonary Bypass Marker	unclassified		MAB	1	C	N[1]
2	Cardio	Percutaneous & Operative Transluminal Coronary Angioplasty Catheter (PTCA)	post-amendment	III	LOX	3	C	N
3	Cardio	Percutaneous Ablation Electrode	post-amendment	III	LPB	3	C	N
4	Cardio	Peripheral Transluminal Angioplasty (PTA) Catheter	unclassified		LIT	3	C	N
5	Cardio	Blood-Pressure Cuff	870.1120	II	DXQ	1	N	N
6	Cardio	Angiography Catheter	870.1200	II	DQO	3	C	N
7	Cardio	Electrode Recording Catheter	870.1220	II	DRF	3	C	N
8	Cardio	High-Density Array Catheter	870.1220	II	MTD	3	C	N
9	Cardio	Fiberoptic Oximeter Catheter	870.1230	II	DQE	3	C	N
10	Cardio	Steerable Catheter	870.1280	II	DRA	3	C	N
11	Cardio	Steerable Catheter Control System	870.1290	II	DXX	3	C	N
12	Cardio	Guide Wire	870.1330	II	DQX	3	C	N
13	Cardio	Angiographic Needle	870.1390	II	DRC	3	C	N
14	Cardio	Trocar	870.1390	II	DRC	3	C	N
15	Cardio	Syringes	870.1650	II	DXT	3	C	N
16	Cardio	Injector Type Syringe Actuator	870.1670	II	DQF	3	C	N
17	Cardio	Oximeter	870.2700	II	DQA	3	N	N
18	Cardio	Tissue Saturation Oximeter	870.2700	II	MUD	3	C	N
19	Cardio	Intra-Aortic Balloon System	870.3535	III	DSP	3	C	N
20	Cardio	Vascular Clamp	870.4450	II	DXC	3	C	N
21	Cardio	Device, Stabilizer, Heart	870.4500	I	MWS	2	C	Y[2]
22	Cardio	External Vein Stripper	870.4885	II	DWQ	3	C	N
23	Cardio	Compressible Limb Sleeve	870.5800	II	JOW	1	N	N
24	Dental	Bur	872.3240	I	EJL	1	C	Y
25	Dental	Diamond Coated Bur	872.3240	I	EJL	3	C	Y
26	Dental	Diamond Instrument	872.4535	I	DZP	3	C	Y
27	Dental	AC-Powered Bone Saw	872.4120	II	DZH	2	C	N
28	Dental	Manual Bone Drill and Wire Driver	872.4120	II	DZJ	2	C	N
29	Dental	Powered Bone Drill	872.4120	II	DZI	2	C	N
30	Dental	Intraoral Drill	872.4130	I	DZA	1	C	Y
31	Dental	Injection needle	872.4730	I	DZM	3	C	Y
32	Dental	Metal Orthodontic Bracket	872.5410	I	EJF	3	S	Y

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
33	Dental	Plastic Orthodontic Bracket	872.5470	II	DYW	3	S	N
34	ENT	Bur	874.4140	I	EQJ	1	C	Y
35	ENT	Diamond Coated Bur	874.4140	I	EQJ	3	C	Y
36	ENT	Microdebrider	874.4140	I	EQJ	3	C	Y
37	ENT	Microsurgical Argon Fiber Optic Laser Cable, for Uses Other Than Otology, Including Laryngology and General Use in Otolaryngology	874.4490	II	LMS	1	S	N
38	ENT	Microsurgical Argon Fiber Optic Laser Cable for Use in Otology	874.4490	II	LXR	1	S	N
39	ENT	Microsurgical Carbon-Dioxide Fiber Optic Laser Cable	874.4500	II	EWG	1	S	N
40 †	ENT	Bronchoscope Biopsy Forceps (Nonrigid)	874.4680	II	BWH	3	C	N
41 †	ENT	Bronchoscope Biopsy Forceps (Rigid)	874.4680	II	JEK	1	C	N
42 †	Gastro/Urology	Biopsy Forceps Cover	876.1075	I	FFF	1	C	Y
43 †	Gastro/Urology	Biopsy Instrument	876.1075	II	KNW	3	C	N
44 †	Gastro/Urology	Biopsy Needle Set	876.1075	II	FCG	3	C	N
45 †	Gastro/Urology	Biopsy Punch	876.1075	II	FCI	2	C	N
46 †	Gastro/Urology	Mechanical Biopsy Instrument	876.1075	II	FCF	2	C	N
47 †	Gastro/Urology	Nonelectric Biopsy Forceps	876.1075	I	FCL	3	C	Y
48	Gastro/Urology	Cytology Brush for Endoscope	876.1500	II	FDX	2	S	N
49	Gastro/Urology	Endoscope accessories	876.1500	II	KOG	2	S	N
50	Gastro/Urology	Extraction Balloons/Baskets	876.1500	II	KOG	2	S	N
51	Gastro/Urology	Endoscopic needle	876.1500	II	FBK	3	C	N
52	Gastro/Urology	Simple Pneumoperitoneum Needle	876.1500	II	FHP	3	C	N
53	Gastro/Urology	Spring Loaded Pneumoperitoneum Needle	876.1500	II	FHO	3	C	N
54	Gastro/Urology	Active Electrosurgical Electrode	876.4300	II	FAS	3	S	N
55 †	Gastro/Urology	Biliary Sphincterotomes	876.5010, 876.1500	II	FGE	3	C	N
56	Gastro/Urology	Electric Biopsy Forceps	876.4300	II	KGE	3	C	N
57	Gastro/Urology	Electrosurgical Endoscopic Unit (With or Without Accessories)	876.4300	II	KNS	3	S	N
58	Gastro/Urology	Flexible Snare	876.4300	II	FDI	3	S	N
59	Gastro/Urology	Flexible Suction Coagulator Electrode	876.4300	II	FEH	3	S	N

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
60	Gastro/Urology	Flexible Stone Dislodger	876.4680	II	FGO	3	S	Y
61	Gastro/Urology	Metal Stone Dislodger	876.4680	II	FFL	3	S	Y
62	Gastro/Urology	Needle Holder	876.4730	I	FHQ	1	C	Y
63	Gastro/Urology	Nonelectrical Snare	876.4730	I	FGX	1	S	Y
64	Gastro/Urology	Urological Catheter	876.5130	II	KOD	2	S	N
65	Gastro/Urology	Single Needle Dialysis Set	876.5540	II	LBW, FIE	3	C	N
66	Gastro/Urology	Hemodialysis Blood Circuit Accessories	876.5820	II	KOC	2	S	N
67	Gastro/Urology	Single Needle Dialysis Set	876.5820	II	FIF	3	C	N
68	GE/U	Hemorrhoidal Ligator	876.4400	II	FHN	2	C	N
69	General Hospital	Implanted, Programmable Infusion Pump	post-amendment	III	LKK	3	C	N
70	General Hospital	Needle Destruction Device	post-amendment	III	MTV	1	N	N
71	General Hospital	Nonpowered Flotation Therapy Mattress	880.5150	I	IKY	2	N	Y
72	General Hospital	Non-AC-Powered Patient Lift	880.5510	I	FSA	2	N	Y
73	General Hospital	Alternating Pressure Air Flotation Mattress	880.5550	II	FNM	1	N	Y
74	General Hospital	Temperature Regulated Water Mattress	880.5560	I	FOH	2	N	Y
75	General Hospital	Hypodermic Single Lumen Needle	880.5570	II	FMI	3	C	N
76	General Hospital	Piston Syringe	880.5860	II	FMF	3	C	N
77	General Hospital	Mattress Cover (Medical Purposes)	880.6190	I	FMW	2	N	Y
78	General Hospital	Disposable Medical Scissors	880.6820	I	JOK	1	N	Y
79	General Hospital	Irrigating Syringe	880.6960	I	KYZ, KYY	1	C	Y
80	Infection Control	Surgical Gowns	878.4040	II	FYA	1	C	N
81	Lab	Blood Lancet	878.4800	I	FMK	1	C	Y
82	Neuro	Clip Forming/Cutting Instrument,	882.4190	I	HBS	3*	C	Y
83	Neuro	Drills, Burrs, Trephines, and Accessories (Manual)	882.4300	II	HBG	3*	C	N
84	Neuro	Drills, Burrs, Trephines, and Accessories (Compound, Powered)	882.4305	II	HBF	3*	C	N
85	Neuro	Drills, Burrs, Trephines, and Accessories (Simple, Powered)	882.4310	II	HBE	3*	C	N
86	OB/GYN	Oocyte Aspiration Needle	Unclassified	II	MHK	3	C	N
87	OB/GYN	Laparoscope Accessories	884.1720	I	HET	2	C	Y

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
88	OB/GYN	Laparoscope Accessories	884.1720	II	HET	3	C	N
89	OB/GYN	Laparoscopic Dissectors	884.1720	I	HET	2	C	Y
90	OB/GYN	Laparoscopic Graspers	884.1720	I	HET	2	C	Y
91	OB/GYN	Laparoscopic Scissors	884.1720	I	HET	2	C	Y
92	OB/GYN	Insufflator Accessories (Tubing, Verres Needle, Kits)	884.1730	II	HIF	3	C	Y
93	OB/GYN	Laparoscopic Insufflator	884.1730	II	HIF	2	N	N
94	OB/GYN	Endoscopic Electrocautery and Accessories	884.4100	II	HIM	2	N	N
95	OB/GYN	Gynecologic Electrocautery (and Accessories)	884.4120	II	HGI	2	N	N
96	OB/GYN	Endoscopic Bipolar Coagulator-Cutter (and Accessories)	884.4150	II	HIN	2	N	N
97	OB/GYN	Culdoscopic Coagulator (and Accessories)	884.4160	II	HFI	2	N	N
98	OB/GYN	Endoscopic Unipolar Coagulator-Cutter (and Accessories)	884.4160	II	KNF	2	N	N
99	OB/GYN	Hysteroscopic Coagulator (and Accessories)	884.4160	II	HFH	2	N	N
100	OB/GYN	Unipolar Laparoscopic Coagulator (and Accessories)	884.4160	II	HFG	2	N	N
101	OB/GYN	Episiotomy Scissors	884.4520	I	HDK	1	C	Y
102	OB/GYN	Umbilical Scissors	884.4520	I	HDJ	1	C	Y
103	OB/GYN	Biopsy Forceps	884.4530	I	HFB	3	C	Y
104	OB/GYN	Assisted Reproduction Needles	884.6100	II	MQE	3	C	N
105	Ophthalmic	Endoilluminator	876.1500	II	MPA	3*	C	N
106	Ophthalmic	Surgical Drapes	878.4370	II	KKX	2	C	N
107	Ophthalmic	Ophthalmic Knife	886.4350	I	HNN	3	C	Y
108	Ophthalmic	Keratome Blade	886.4370	I not exempt	HMY, HNO	3	C	N
109	Ophthalmic	Phacoemulsification Needle	886.4670	II	HQC	3	C	N
110	Ophthalmic	Phacoemulsification/ Phacofragmentation Fluidic	886.4670	II	MUS	2	C	N
111	Ophthalmic	Phacofragmentation Unit	886.4670	II	HQC	1	N	N
112	Ortho	Saw Blades	878.4820	I	GFA, DWH, GEY, GET	1	C	Y
113	Ortho	Surgical Drills	878.4820	I	GEY, GET	1	C	Y
114	Ortho	Arthroscope accessories	888.1100	II	HRX	2	C	Y

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
115	Ortho	Bone Tap	888.4540	I	HWX	1	C	Y
116	Ortho	Burr	888.4540	I	HTT	1	C	Y
117	Ortho	Carpal Tunnel Blade	888.4540	I	LXH	2	C	Y
118	Ortho	Countersink	888.4540	I	HWW	1	C	Y
119	Ortho	Drill Bit	888.4540	I	HTW	1	C	Y
120	Ortho	Knife	888.4540	I	HTS	1	C	Y
121	Ortho	Manual Surgical Instrument	888.4540	I	LXH	1	C	Y
122	Ortho	Needle Holder	888.4540	I	HXK	1	C	Y
123	Ortho	Reamer	888.4540	I	HTO	1	C	Y
124	Ortho	Rongeur	888.4540	I	HTX	1	C	Y
125	Ortho	Scissors	888.4540	I	HRR	1	C	Y
126	Ortho	Staple Driver	888.4540	I	HXJ	1	C	Y
127	Ortho	Trephine	888.4540	I	HWK	1	C	Y
128	Ortho	Flexible Reamers/Drills	886.4070 878.4820	I	GEY, HRG	1	C	Y
129	Ortho	External Fixation Frame	888.3040 888.3030	II	JEC, KTW, KTT	2	N	N
130	Physical Medicine	Non-Heating Lamp for Adjunctive Use Inpatient Therapy	unclassified		NHN	1	N	N
131	Physical Medicine	Electrode Cable	890.1175	II	IKD	1	N	Y
132	Physical Medicine	External Limb Component, Hip Joint	890.3420	I	ISL	2	N	Y
133	Physical Medicine	External Limb Component, Knee Joint	890.3420	I	ISY	2	N	Y
134	Physical Medicine	External Limb Component, Mechanical Wrist	890.3420	I	ISZ	2	N	Y
135	Physical Medicine	External Limb Component, Shoulder Joint	890.3420	I	IQQ	2	N	Y
136	Plastic Surgery	Stapler	878.4800	I	GAG, GEF, FHM, HBT	2	C	Y
137	Radiology	Isotope Needle	892.5730	II	IWF	3	C	N
138	Resp	Endotracheal Tube Changer	unclassified	III	LNZ	3	C	N
139	Resp	Anesthesia conduction needle	868.5150	II	BSP	3	C	N
140	Resp	Short term spinal needle	868.5150	II	MIA	3	C	N
141	Resp	Respiratory Therapy and Anesthesia Breathing Circuits	868.5240	I	CAI	2	S	Y
142	Resp	Oral and Nasal Catheters	868.5350	I	BZB	1	C	Y
143	Resp	Gas Masks	868.5550	I	BSJ	1	S	Y
144	Resp	Breathing Mouthpiece	868.5620	I	BYP	1	N	Y

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
145	Resp	Tracheal Tube	868.5730	II	BTR	3	C	N
146	Resp	Airway Connector	868.5810	I	BZA	2	S	Y
147	Resp	CPAP Mask	868.5905	II	BZD	3	S	N
148	Resp	Emergency Manual Resuscitator	868.5915	II	BTM	2	S	N
149	Resp	Tracheobronchial Suction Catheter	868.6810	I	BSY	3	S	Y
150	Surgery	AC-Powered Orthopedic Instrument and Accessories	unclassified		HWE	2	C	N
151	Surgery	Breast Implant Mammary Sizer	unclassified		MRD	1	C	N
152	Surgery	Ultrasonic Surgical Instrument	unclassified		LFL	3	C	N
153	Surgery	Trocar	874.4420	I	KAB, KBG, KCI	3	C	Y
154	Surgery	Endoscopic Blades	876.1500	II	GCP, GCR	2	C	N
155	Surgery	Endoscopic Guidewires	876.1500	II	GCP, GCR	1	C	N
156	Surgery	Inflatable External Extremity Splint	878.3900	I	FZF	1	N	Y
157	Surgery	Noninflatable External Extremity Splint	878.3910	I	FYH	1	N	Y
158	Surgery	Catheter Needle	878.4200	I	GCB	3	C	Y
159	Surgery	Implantable Clip	878.4300	II	FZP	3	C	N
160	Surgery	Electrosurgical and Coagulation Unit With Accessories	878.4400	II	BWA	2	C	N
161	Surgery	Electrosurgical Apparatus	878.4400	II	HAM	2	C	N
162	Surgery	Electrosurgical Cutting and Coagulation Device and Accessories	878.4400	II	GEI	2	C	N
163	Surgery	Electrosurgical Device	878.4400	II	DWG	2	C	N
164	Surgery	Electrosurgical Electrode	878.4400	II	JOS	2	C	N
165	Surgery	Implantable Staple, Clamp, Clip for Suturing Apparatus	878.4750	II	GDW	3	C	N
166	Surgery	Percutaneous Biopsy Device	878.4800	I	MJG	3	C	Y
167	Surgery	Gastro-Urology Needle	878.4800	I	FHR	3	C	Y
168	Surgery	Aspiration and Injection Needle	878.4800	I	GAA	3	C	Y
169	Surgery	Biopsy Brush	878.4800	I	GEE	1	C	Y
170	Surgery	Blood Lancet	878.4800	I	FMK	1	C	Y
171	Surgery	Bone Hook	878.4800	I	KIK	1	C	Y
172	Surgery	Cardiovascular Biopsy Needle	878.4800	I	DWO	3	C	Y
173	Surgery	Clamp	878.4800	I	GDJ	1	C	Y
174	Surgery	Clamp	878.4800	I	HXD	1	C	Y

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
175	Surgery	Curette	878.4800	I	HTF	1	C	Y
176	Surgery	Disposable Surgical Instrument	878.4800	I	KDC	1	C	Y
177	Surgery	Disposable Vein Stripper	878.4800	I	GAJ	1	C	Y
178	Surgery	Dissector	878.4800	I	GDI	1	C	Y
179	Surgery	Forceps	878.4800	I	GEN	2	C	Y
180	Surgery	Forceps	878.4800	I	HTD	2	C	Y
181	Surgery	Gouge	878.4800	I	GDH	1	C	Y
182	Surgery	Hemostatic Clip Applier	878.4800	I	HBT	2	C	Y
183	Surgery	Hook	878.4800	I	GDG	1	C	Y
184	Surgery	Manual Instrument	878.4800	I	MDM, MDW	1	C	Y
185	Surgery	Manual Retractor	878.4800	I	GZW	1	C	Y
186	Surgery	Manual Saw and Accessories	878.4800	I	GDR, HAC	1	C	Y
187	Surgery	Manual Saw and Accessories	878.4800	I	HAC	1	C	Y
188	Surgery	Manual Surgical Chisel	878.4800	I	FZO	1	C	Y
189	Surgery	Mastoid Chisel	878.4800	I	JYD	1	C	Y
190	Surgery	Orthopedic Cutting Instrument	878.4800	I	HTZ	1	C	Y
191	Surgery	Orthopedic Spatula	878.4800	I	HXR	1	C	Y
192	Surgery	Osteotome	878.4800	I	HWM	1	C	Y
193	Surgery	Rasp	878.4800	I	GAC	1	C	Y
194	Surgery	Rasp	878.4800	I	HTR	1	C	Y
195	Surgery	Retractor	878.4800	I	GAD	1	C	Y
196	Surgery	Retractor	878.4800	I	HXM	1	C	Y
197	Surgery	Saw	878.4800	I	HSO	1	C	Y
198	Surgery	Scalpel Blade	878.4800	I	GES	1	C	Y
199	Surgery	Scalpel Handle	878.4800	I	GDZ	1	C	Y
200	Surgery	Scissors	878.4800	I	LRW	1	C	Y
201	Surgery	Snare	878.4800	I	GAE	1	C	Y
202	Surgery	Spatula	878.4800	I	GAF	1	C	Y
203	Surgery	Staple Applier	878.4800	I	GEF	2	C	Y
204	Surgery	Stapler	878.4800	I	GAG	2	C	Y
205	Surgery	Stomach and Intestinal Suturing Apparatus	878.4800	I	FHM	2	C	Y
206	Surgery	Surgical Curette	878.4800	I	FZS	1	C	Y
207	Surgery	Surgical Cutter	878.4800	I	FZT	1	C	Y
208	Surgery	Surgical Knife	878.4800	I	EMF	1	S	Y
209	Surgery	Laser Powered Instrument	878.4810	II	GEX	2	C	N

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

	Medical specialty	Device type	21 CFR section	Class	Product code	Risk*	Critical/semi-critical/noncritical	Premarket exempt
210	Surgery	Ac-Powered Motor	878.4820	I	GEY	2	C	Y
211	Surgery	Bit	878.4820	I	GFG	1	C	Y
212	Surgery	Bur	878.4820	I	GFF, GEY	1	C	Y
213	Surgery	Cardiovascular Surgical Saw Blade	878.4820	I	DWH	1	C	Y
214	Surgery	Chisel (Osteotome)	878.4820	I	KDG	1	C	Y
215	Surgery	Dermatome	878.4820	I	GFD	1	C	Y
216	Surgery	Electrically Powered Saw	878.4820	I	DWI	2	C	Y
217	Surgery	Pneumatic Powered Motor	878.4820	I	GET	2	C	Y
218	Surgery	Pneumatically Powered Saw	878.4820	I	KFK	2	C	Y
219	Surgery	Powered Saw and Accessories	878.4820	I	HAB	2	C	Y
220	Surgery	Saw Blade	878.4820	I	GFA	1	C	Y
221	Surgery	Nonpneumatic Tourniquet	878.5900	I	GAX	1	N	Y
222	Surgery	Pneumatic Tourniquet	878.5910	I	KCY	1	N	Y
223	Surgery	Endoscopic Staplers	888.4540	I	HXJ	2	C	Y
224	Surgery	Trocar	876.1500 870.1390	II	GCJ, DRC	3	C	N
225	Surgery	Surgical Cutting Accessories	878.4800 874.4420	I	GDZ, GDX, GES, KBQ, KAS	2	C	Y
226	Surgery	Electrosurgical Electrodes/Handles/Pencils	876.4300 878.4400	II	HAM, GEI, FAS	2	C	N
227	Surgery	Scissor Tips	878.4800 884.4520 874.4420	I	LRW, HDK, HDJ, JZB, KBD	2	C	Y
228	Surgery	Laser Fiber Delivery Systems	878.4810 874.4500 886.4390 884.4550 886.4690	II	GEX, EWG, LLW, HQF, HHR, HQB	1	C	N

[1] N means no.
[2] Y means yes.
† Indicates a change since last publication.

Dated: June 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0236]

Draft ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis'' dated June 2003. The draft guidance document provides recommendations for testing donors of blood and blood components for syphilis, and for recommended actions based on those test results. The