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**

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## 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<br>878.4820 | I | GEY, HRG | 1 | C | Y |
| 129 | Ortho | External Fixation Frame | 888.3040<br>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<br>870.1390 | II | GCJ, DRC | 3 | C | N |
| 225 | Surgery | Surgical Cutting Accessories | 878.4800<br>874.4420 | I | GDZ, GDX, GES, KBQ, KAS | 2 | C | Y |
| 226 | Surgery | Electrosurgical Electrodes/Handles/Pencils | 876.4300<br>878.4400 | II | HAM, GEI, FAS | 2 | C | N |
| 227 | Surgery | Scissor Tips | 878.4800<br>884.4520<br>874.4420 | I | LRW, HDK, HDJ, JZB, KBD | 2 | C | Y |
| 228 | Surgery | Laser Fiber Delivery Systems | 878.4810<br>874.4500<br>886.4390<br>884.4550<br>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