

regulation of a drug product under the act. Mr. Kokes was provided 30 days to file objections and request a hearing. Mr. Kokes did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

## II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Edwin Kokes has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Edwin Kokes is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)(see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Kokes, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kokes, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Kokes during his period of debarment.

Any application by Mr. Kokes for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N-0539 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2003.

### Steven K. Galson,

*Deputy Director, Center for Drug Evaluation and Research.*

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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 announcing the availability of a list (List I) of critical reprocessed single-use devices (SUDs) whose exemption from premarket submission 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)); and a list (List II) of reprocessed SUDs that are currently subject to 510(k) requirements for which FDA has determined that validation data, as specified under MDUFMA, is necessary in a 510(k). FDA is requiring submission of these data to ensure that these reprocessed SUDs are substantially equivalent to predicate devices in accordance with MDUFMA.

**DATES:** These actions are effective April 30, 2003. Manufacturers of SUDs identified in List I whose exemption is being terminated must submit 510(k)s for these devices by July 30, 2004, or their devices may no longer be marketed. Manufacturers who already have clearance letters for SUDs identified in List II must submit validation data for these devices by January 30, 2004, or marketing of these devices must cease.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (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 on Lists I and II 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 (Pub. L. 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 are currently subject to cleared 510(k)s also will need to submit the validation data specified by the agency.

In the near future, FDA will publish a guidance document providing more specific information about the types of validation data that should be submitted in premarket notification submissions for the reprocessed SUDs listed in this notice.

### A. Definitions

Under section 302(b) 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 in

the industry.<sup>1</sup> These categories of devices are defined as follows:

(1) A *critical reprocessed SUD* is intended to contact normally sterile tissue or body spaces during use.

(2) A *semicritical reprocessed SUD* is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(3) A *noncritical reprocessed SUD* is intended to make topical contact and not penetrate intact skin.

#### 1. Requirements for Critical Reprocessed SUDs

MDUFMA requires FDA to review the critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require premarket notification to ensure their substantial equivalence to predicate devices. By April 26, 2003, FDA must identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification will be terminated. List I in this **Federal Register** notice implements this MDUFMA requirement.

In accordance with MDUFMA, manufacturers of the devices identified in List I must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87 (21 CFR 807.87), within 15 months of publication of this notice or no longer market their device.

#### 2. Requirements for Semicritical Reprocessed SUDs

MDUFMA also requires FDA to review the semicritical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require premarket notification to ensure their substantial equivalence to predicate devices. FDA must identify these devices in a notice published in the **Federal Register** by April 26, 2004. Manufacturers of devices identified at that time will be required to submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance in addition to all the other required elements of a 510(k) identified in § 807.87, within 15 months of publication of that notice or no longer market their device.

#### 3. Requirements for Noncritical Reprocessed SUDs

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

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

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

1. For devices identified in List II that have not yet been cleared through the 510(k) process, manufacturers must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87, upon publication of this notice in order to market these devices. FDA will soon publish guidance to help submitters understand what types of validation data should be included in these 510(k)s.

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

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

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

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

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

In addition to the previous criterion, FDA used one other criterion to identify those reprocessed SUDs that will be subject to the new requirements established by MDUFMA. The agency has included in these lists all reprocessed SUDs intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). These are generally devices intended for use in neurosurgery ophthalmology. This criterion was included in FDA's evaluation because insufficient scientific information exists at this time to establish standard methods to eliminate CJD infectious agents.

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

<sup>1</sup> Spaulding, E.H., "The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections," P.S. Brachman and T.C. Eickoff (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 1971:254-274.

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

definitions reflect the Spaulding<sup>3</sup> 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.

<sup>3</sup> 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, 1971:254–274.

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA <sup>1</sup>

[Manufacturers who already have 510(k) clearance for these devices must submit validation data by January 26, 2004. Any new 510(k) will require validation data upon publication of this list.]

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 (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.
876.4300 .....	Endoscopic electro-surgical unit and accessories.	FAS	NLW	Active urological electro-surgical electrode.
876.4300 .....	Endoscopic unit accessories .....	FEH	NLV	Flexible suction coagulator electrode.
876.4300 .....	Endoscopic electro-surgical unit and accessories.	KGE	NLU	Electric biopsy forceps.
876.4300 .....	Endoscopic electro-surgical unit and accessories.	FDI	NLT	Flexible snare.
876.4300 .....	Endoscopic electro-surgical unit and accessories.	KNS	NLR	Endoscopic (with or without accessories) Electro-surgical 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 and accessories uni-directional 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, burrs, trephines and accessories.
882.4305 .....	Powered compound cranial drills, burrs, trephines . . .	HBF	NLP	(Powered, compound) drills, burrs, trephines and accessories.
882.4310 .....	Powered simple cranial drills, burrs, trephines.	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 needle .....	MQE	NNB	Assisted reproduction needle.
886.4370 .....	Keratome .....	HMY, HNO	NKY	Keratome blade.
886.4670 .....	Phaco-fragmentation system .....	HQC	NKX	Phacoemulsification needle.

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA <sup>1</sup>—Continued

[Manufacturers who already have 510(k) clearance for these devices must submit validation data by January 26, 2004. Any new 510(k) will require validation data upon publication of this list.]

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
892.5730 .....	Radionuclide brachytherapy source.	IWF	NMP	Isotope needle.

<sup>1</sup> Hemodialyzers have been excluded from this list because the reuse of hemodialyzers is addressed in "Guidance for Hemodialyzer Reuse Labeling" (final draft issued on October 6, 1995).

III. Comments

You may submit written or electronic comments on these lists to the Dockets Management Branch (see ADDRESSES). You may submit a single copy of an

electronic comment to <http://www.fda.gov/dockets/ecomments>. You should submit two copies of any mailed comments but individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk <sup>1,2,3,3*</sup>	Critical/semi-critical/non-critical	Premarket exempt
1 .....	Cardio .....	Cardiopulmonary Bypass Marker ..	Unclassified		MAB	1	C	N
2 .....	Cardio .....	Percutaneous & Operative Transluminal Coronary Angioplasty Catheter (PCTA).	post amend-ment	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
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
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 Otolaryngology, Including Laryngology & General Use In Otolaryngology.	874.4490	II	LMS	1	S	N
38 .....	ENT .....	Microsurgical Argon Fiber Optic Laser Cable, For Use In Otolaryngology.	874.4490	II	LXR	1	S	N

## ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk <sup>1,2,3,3*</sup>	Critical/semi-critical/non-critical	Premarket exempt
39 ....	ENT .....	Microsurgical Carbon-Dioxide Fiber Optic Laser Cable.	874.4500	II	EWG	1 S	N	
40 ....	ENT .....	Bronchoscope Biopsy Forceps (Non-Rigid).	874.4680	II	BWH	3 S	N	
41 ....	ENT .....	Bronchoscope Biopsy Forceps (Rigid).	874.4680	II	JEK	1 S	N	
42 ....	Gastro/Urol- ogy.	Biopsy Forceps Cover .....	876.1075	I	FFF	1 S	Y	
43 ....	Gastro/Urol- ogy.	Biopsy Instrument .....	876.1075	II	KNW	3 S	N	
44 ....	Gastro/Urol- ogy.	Biopsy Needle Set .....	876.1075	II	FCG	3 S	N	
45 ....	Gastro/Urol- ogy.	Biopsy Punch .....	876.1075	II	FCI	2 S	N	
46 ....	Gastro/Urol- ogy.	Mechanical Biopsy Instrument .....	876.1075	II	FCF	2 S	N	
47 ....	Gastro/Urol- ogy.	Non-Electric Biopsy Forceps .....	876.1075	I	FCL	3 S	Y	
48 ....	Gastro/Urol- ogy.	Cytology Brush For Endoscope ....	876.1500	II	FDX	2 S	N	
49 ....	Gastro/Urol- ogy.	Endoscope Accessories .....	876.1500	II	KOG	2 S	N	
50 ....	Gastro/Urol- ogy.	Extraction Balloons/Baskets .....	876.1500	II	KOG	2 S	N	
51 ....	Gastro/Urol- ogy.	Endoscopic Needle .....	876.1500	II	FBK	3 C	N	
52 ....	Gastro/Urol- ogy.	Simple Pneumoperitoneum Needle	876.1500	II	FHP	3 C	N	
53 ....	Gastro/Urol- ogy.	Spring Loaded Pneumoperitoneum Needle.	876.1500	II	FHO	3 C	N	
54 ....	Gastro/Urol- ogy.	Active Electrosurgical Electrode ....	876.4300	II	FAS	3 S	N	
55 ....	Gastro/Urol- ogy.	Biliary Sphincterotomes .....	876.5010, 876.1500	II	FGE	3 S	N	
56 ....	Gastro/Urol- ogy.	Electric Biopsy Forceps .....	876.4300	II	KGE	3 S	N	
57 ....	Gastro/Urol- ogy.	Electrosurgical Endoscopic Unit (With Or Without Accessories).	876.4300	II	KNS	3 S	N	
58 ....	Gastro/Urol- ogy.	Flexible Snare .....	876.4300	II	FDI	3 S	N	
59 ....	Gastro/Urol- ogy.	Flexible Suction Coagulator Elec- trode.	876.4300	II	FEH	3 S	N	
60 ....	Gastro/Urol- ogy.	Flexible Stone Dislodger .....	876.4680	II	FGO	3 S	Y	
61 ....	Gastro/Urol- ogy.	Metal Stone Dislodger .....	876.4680	II	FFL	3 S	Y	
62 ....	Gastro/Urol- ogy.	Needle Holder .....	876.4730	I	FHQ	1 C	Y	
63 ....	Gastro/Urol- ogy.	Non-Electrical Snare .....	876.4730	I	FGX	1 S	Y	
64 ....	Gastro/Urol- ogy.	Urological Catheter .....	876.5130	II	KOD	2 S	N	
65 ....	Gastro/Urol- ogy.	Single Needle Dialysis Set .....	876.5540	II	LBW, FIE	3 C	N	
66 ....	Gastro/Urol- ogy.	Hemodialysis Blood Circuit Acces- sories.	876.5820	II	KOC	2 S	N	
67 ....	Gastro/Urol- ogy.	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 .....	Implanted, Programmable Infusion Pump.	Post-amend- ment	III	LKK	3 C	N	
70 ....	General .....	Needle Destruction Device .....	Post-amend- ment	III	MTV	1 N	N	
71 ....	General .....	Non-Powered Flotation Therapy Mattress.	880.5150	I	IKY	2 N	Y	
72 ....	General .....	Non AC-Powered Patient Lift .....	880.5510	I	FSA	2 N	Y	
73 ....	General .....	Alternating Pressure Air Flotation Mattress.	880.5550	II	FNM	1 N	Y	

## ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk 1,2,3,3*	Critical/semi-critical/non-critical	Premarket exempt
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, KYK	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, Trepines & Accessories (Manual).	882.4300	II	HBS	3*	C	N
84 ....	Neuro	Drills, Burrs, Trepines & Accessories (Compound, Powered).	882.4305	II	HBF	3*	C	N
85 ....	Neuro	Drills, Burrs, Trepines & 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
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 needle .....	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	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
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

## ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk 1,2,3,3*	Critical/semi-critical/non-critical	Premarket exempt
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	I	GEY, HRG	1	C	Y
129 ..	Ortho .....	External Fixation Frame .....	888.3040 888.3030	II	JEC KTV KTT NHN	2	N	N
130 ..	Physical .....	Non-Heating Lamp for Adjunctive Use Inpatient Therapy.	Unclassified			1	N	N
131 ..	Physical .....	Electrode Cable, .....	890.1175	II	IKD	1	N	Y
132 ..	Physical .....	External Limb Component, Hip Joint.	890.3420	I	ISL	2	N	Y
133 ..	Physical .....	External Limb Component, Knee Joint.	890.3420	I	ISY	2	N	Y
134 ..	Physical .....	External Limb Component, Mechanical Wrist.	890.3420	I	ISZ	2	N	Y
135 ..	Physical .....	External Limb Component, Shoulder Joint.	890.3420	I	IQQ	2	N	Y
136 ..	Plastic .....	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
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 & Coagulation Device & 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

## ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk 1,2,3,3*	Critical/semi-critical/non-critical	Premarket exempt
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
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
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

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk 1,2,3,3*	Critical/semi-critical/non-critical	Premarket exempt
227 ..	Surgery .....	Scissor Tips .....	878.4800, 884.4520, 874.4420	I	LRW, HDK, HDJ, JZB, KBD GEX	2	C	Y
228 ..	Surgery .....	Laser Fiber Delivery Systems .....	878.4810 874.4500 886.4390 884.4550 886.4690	II	EWG LLW HQF HHR HQB	1	C	N

1 = low risk according to RPS  
 2 = moderate risk according to RPS  
 3 = high risk according to RPS  
 3\* = high risk due to neurological use

Dated: April 23, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-10413 Filed 4-23-03; 5:03 pm]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Inspector General**

**Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures**

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice.

**SUMMARY:** The OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing certain contractual joint venture arrangements.

**FOR FURTHER INFORMATION CONTACT:** Vicki Robinson or Joel Schaer, Office of Counsel to the Inspector General, (202) 619-0335.

**SUPPLEMENTARY INFORMATION:**

**Special Advisory Bulletin: Contractual Joint Ventures (April 2003)**

*Introduction*

This Special Advisory Bulletin addresses certain complex contractual arrangements for the provision of items and services previously identified as suspect in our 1989 Special Fraud Alert on Joint Venture Arrangements.<sup>1</sup> While

<sup>1</sup> The 1989 Special Fraud Alert was reprinted in the **Federal Register** in 1994. See 59 FR 65372 (December 19, 1994). The Special Fraud Alert is

much of the discussion in the 1989 Special Fraud Alert focused on investor referrals to newly formed entities, we observed that:

[t]he Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called "joint ventures." *A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services, or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services.* (Emphasis added.)

Notwithstanding that caution, the Office of Inspector General (OIG) is concerned that contractual joint venture arrangements are proliferating.<sup>2</sup>

*A. Questionable Contractual Arrangements*

The federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), prohibits knowingly and willfully soliciting, receiving, offering, or paying anything of value to induce referrals of items or services payable by a federal health care program. Kickbacks

also available on our Web page at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

<sup>2</sup> The kinds of contractual arrangements addressed in this Special Advisory Bulletin are sometimes referred to as "joint ventures" or "contractual joint ventures" or may be referenced by other terminology. For purposes of the analysis set forth in this Bulletin, a "joint venture" is any common enterprise with mutual economic benefit. The application of this Bulletin is not limited to "joint ventures" that meet technical qualifications under applicable state or common law.

are harmful because they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair competition by freezing out competitors unwilling to pay kickbacks. Both parties to an impermissible kickback transaction may be liable. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to 5 years, or both. The OIG may also initiate administrative proceedings to exclude persons from the federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.

This Special Advisory Bulletin focuses on questionable contractual arrangements where a health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

Some examples of potentially problematic contractual arrangements include the following: