

**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