

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