

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	878.4820 888.3040 888.3030	II	JEC KTW 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