

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 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 electrosurgical unit and accessories.	FAS	NLW	Active urological electrosurgical electrode.
876.4300	Endoscopic unit 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 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	Phacofragmentation system	HQC	NKX	Phacoemulsification needle.