

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 30, 2004. ANY NEW 510(K) SUBMITTED AFTER PUBLICATION OF THE APRIL 30 LIST WILL REQUIRE VALIDATION DATA.)

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for re-processed 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 ventilator (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	G CJ	NLM	General and plastic surgery laparoscope
876.1500	Endoscope and accessories	FHO	NLX	Spring-loaded Pneumoperitoneum Needle