

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE THE SUBMISSION OF VALIDATION DATA¹ (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.)—Continued

21 CFR section	Classification name	Product code for non-reprocessed device	Product code for reprocessed device	Product code name for reprocessed device
876.4300	Endoscopic electrosurgical unit and accessories	FAS	NLW	Active urological electrosurgical electrode
876.4300	Endoscopic electrosurgical unit and 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 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, trephines, and accessories
882.4305	Powered compound cranial drills, burrs, trephines, and accessories	HBF	NLP	(Powered, compound) drills, burrs, trephines, and accessories
882.4310	Powered simple cranial drills, burrs, trephines, and accessories	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 needles	MQE	NNB	Assisted reproduction needles
886.4370	Keratome	HMY, HNO	NKY	Keratome blade
886.4670	Phacofragmentation system	HQC	NKX	Phacoemulsification needle
892.5730	Radionuclide brachytherapy source	IWF	NMP	Isotope needle

¹ Hemodialyzers have been excluded from this list because the reuse of hemodialyzers is addressed in FDA's "Guidance for Hemodialyzer Reuse Labeling" (final draft issued on October 6, 1995).

IV. Comments

You may submit written or electronic comments on this notice to the Division of Dockets Management (see ADDRESSES). You may submit a single

copy of an electronic comment to <http://www.fda.gov/dockets/ecomments>. You should submit two paper copies of any mailed comments but individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.