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CLASS III DEVICES

Classification Panel	Pre - Amendments CLASS III		TRANSITIONAL	TOTAL
	No Final 515(b)	Final 515(b)	Class III	
Clinical Chemistry/ Clinical Toxicology	0	0	1	1
Hematology/Pathology	6	0	1	7
Immunology/Microbiology	2	0	4	6
Anesthesiology	8	0	0	8
Cardiovascular	25	1	1	27
Dental	12	0	1	13
Ear, Nose and Throat	5	0	1	6
Gastroenterology/GU	11	0	0	11
General and Plastic Surgery	5	1	4	10
General Hospital/ Personal Use	2	0	0	2
Neurological	8	3	0	11
OB/GYN	15	3	2	20
Ophthalmic	2	0	9	11
Orthopedic	23	0	2	25
Physical Medicine	7	0	0	7
Radiology	0	0	0	0
TOTAL	131	8	26	165

Revised March 11, 1992

Transitional Class III Devices
(Approved PMA Required)

Clinical Chemistry and Clinical Toxicology Devices

Human chorionic gonadotropin (HCG) test system intended for any uses other than early detection of pregnancy (21 CFR 862.1155)

Hematology and Pathology Devices

Cervical smear processing devices

Immunology and Microbiology Devices

Carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer (21 CFR 866.6010)

Biological derived in vitro diagnostic substances for the identification or analysis of alpha-fetoprotein (AFP), tumor-associated antigen (TAA) or tumor-associated polypeptide antigen (TPA) as an aid in the detection and management of cancer

Gonococcal antibody test (GAT) (21 CFR 866.3290)

Oxidase screening test for gonorrhea (21 CFR 866.2420)

Cardiovascular Devices

Vascular grafts of animal (including human) origin

Dental Devices

Triphosphate granules for dental bone repair (21 CFR 872.3930)

Ear, Nose and Throat Devices

Injectable polytetrafluoroethylene (Teflon)

General and Plastic Surgery Devices

Absorbable powder for lubricating a surgeon's glove (21 CFR 878.4480)

Absorbable hemostatic agent and dressing (21 CFR 878.4490)

Injectable silicone

Absorbable and nonabsorbable surgical sutures except for

21 CFR 878.4830	Absorbable surgical gut suture
21 CFR 878.5010	Nonabsorbable polypropylene suture
21 CFR 878.5000	Nonabsorbable poly (ethylene terephthalate) surgical suture
21 CFR 878.5020	Nonabsorbable polyamide (nylon) surgical suture
21 CFR 878.	Natural nonabsorbable silk suture
21 CFR 878.4493	Absorbable poly (glycolide/L-lactide) surgical suture
21 CFR 878	Stainless steel surgical suture

Obstetrical and Gynecological Devices

Hysteroscopy fluid
Self-Aspirated Cervical Cytological Collection Device

Ophthalmic Devices

Intraocular lens (21 CFR 886.3600)
Intraocular fluid (21 CFR 886.4275)
Soft (hydrophilic) contact lens (21 CFR 886.5925)
Soft (hydrophilic) contact lens solution (21 CFR 886.5928)
Rigid gas permeable contact lens (21 CFR 886.5916)
Rigid gas permeable contact lens solution (21 CFR 886.5918)
Contact lens heat disinfection unit (21 CFR 886.5933)
Gases used within the eye to place pressure on a detached retina (21 CFR 866.4270)
Intraocular pressure measuring device (21 CFR 886.4280)
if subject to IND or NDA

Orthopedic Devices

Bone heterogrphs (21 CFR 888.3015)
Polymethylmethacrylate (PMMA) bone cement (21 CFR 888.3027)

HIGH PRIORITY PRE-AMENDMENTS CLASS III DEVICES
FOR PREMARKET APPROVAL

Device	Panel	21 CFR	Reclass. Petition	Reclassified		FR Notice Date		Effective Date	Comment
				Class	Date	Proposed	Final		
Implanted Cerebellar Stimulator	NE	882.5820	No	-	-	9-6-83	6-28-84	9-26-84	Rec.- 0
Implanted Diaphragmatic/Phrenic Nerve Stimulator	NE	882.5830	No	-	-	8-16-85	4-8-86	7-7-86	Rec.- 1 App.- 1
Replacement Heart Valve	CV	870.3925	No	-	-	2-12-86	5-13-87	12-9-87	Rec.- 5 App.- 4
Implantable Pacemaker Pulse Generator	CV	870.3610							Priority Lowered
Pacemaker Programmer	CV	870.3700							Priority Lowered
Contraceptive Tubal Occlusion Device and Introducer	OB/ GYN	884.5380	No	-	-	10-7-85	10-1-87	12-31-87	Rec.- 2 App.-
Contraceptive Intrauterine Device (IUD) and Introducer	OB/ GYN	884.5360	No	-	-	8-19-85	5-5-86	8-4-86	Rec.- 0
Transabdominal Amnioscope (Fetoscope) and Accessories	OB/ GYN	884.1600	No	-	-	3-3-86	10-31-86	1-29-87	Rec.- 0
Implanted Intracerebral/Subcortical Stimulator for Pain Relief	NE	882.5840	No	-	-	7-25-85	12-1-88	3-1-89	Rec.- 2

HIGH PRIORITY PRE-AMENDMENTS CLASS III DEVICES
FOR PREMARKET APPROVAL

Device	Panel	'21 CFR'	Reclass. Petition	Reclassified		FR Notice Date		Effective Date	Comment
				Class	Date	Proposed	Final		
Automated Differential Cell Counter	Hemo/Path	864.5220	Yes	* II	8-7-90	11-20-85	-	-	Reclassified
Automated Heparin Analyzer	Hemo/Path	864.5680	Yes						
Automated Blood Cell Separator (CBER Review)	Hemo/Path	864.9245				2-19-88			
Infant Radiant Warmer	GH	880.5130	Yes			1-15-86			

High Priority Listing in Federal Register of January 6, 1989

Endosseous Implant	DE	872.3640	Yes			12-7-89			
Silicone Gel-Filled Breast Prosthesis	GPS	878.3540	No	-	-	5-17-90	4-10-91	7-9-91	Rec - 10 App -
Endolymphatic Shunt Tube with Valve	ENT	874.3850	Yes			5-4-90			

* ADCC Class II to flag or identify specimens containing abnormal blood cells; other uses remain in Class III; proposed section 515(b) rule withdrawn 7-16-91 (56 FR 32359)

Preamendments Class III Devices
(Final Section 515(b) Regulation in Effect)

<u>21CFR</u>	<u>Classification Name</u>	<u>Effective Date</u>
870.3925	Replacement heart valve	12/9/87
878.3540	Silicone gel-filled breast prosthesis	7/9/91
882.5820	Implanted cerebellar stimulator	9/26/84
882.5830	Implanted diaphragmatic/phrenic nerve stimulator	7/7/86
882-5840	Implanted intracerebral/subcortical stimulator for pain relief	3/1/89
884.1600	Transabdominal amnioscope (fetoscope) and accessories	1/29/87
884.5360	Contraceptive intrauterine device (IUD) and introducer	8/4/86
884.5380	Contraceptive tubal occlusion device and introducer	12/31/87

February 24, 1992

PREAMENDMENTS CLASS III DEVICES
(APPROVED PMA NOT PRESENTLY REQUIRED)

Clinical Chemistry / Clinical Toxicology Devices

None

Hematology and Pathology Devices

864.5220	Automated differential cell counter intended for uses other than to flag or identify specimens containing abnormal blood cells
864.5680	Automated heparin analyzer (pending reclassification petition)
864.7250	Erythropoietin Assay
864.7300	Fibrin monomer paracoagulation test
864.9205	Electromagnetic blood and plasma warming device
864.9245	Automated blood cell separator

Note: CBER regulates the automated blood cell separator

Immunology and Microbiology Devices

866.3305	Herpes simplex virus serological reagents
866.3510	Rubella virus serological reagents

Anesthesiology Devices

868.1120	Indwelling blood oxyhemoglobin concentration analyzer
868.1150	Indwelling blood carbon dioxide partial pressure (Pco ₂) analyzer
868.1170	Indwelling blood hydrogen ion concentration (pH) analyzer
868.1200	Indwelling blood oxygen partial pressure (Po ₂) analyzer
868.2450	Lung water monitor
868.2500	Cutaneous oxygen monitor
868.5400	Electroanesthesia apparatus
868.5610	Membrane lung for long-term pulmonary support

Cardiovascular Devices

870.1025	Arrhythmia detector and alarm
870.1350	Catheter balloon repair kit
870.1360	Trace microsphere
870.3300	Arterial embolization device
870.3375	Cardiovascular intravascular filter
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3535	Intra-aortic balloon and control system
870.3545	Ventricular bypass (assist) device
870.3600	External pacemaker pulse generator
870.3610	Implantable pacemaker pulse generator
870.3620	Pacemaker lead adaptor
870.3680	Cardiovascular permanent pacemaker electrode
870.3700	Pacemaker programmers
870.3710	Pacemaker repair or replacement material
870.3800	Annuloplasty ring
870.3850	Carotid sinus nerve stimulator
870.4230	Cardiopulmonary bypass defoamer
870.4260	Cardiopulmonary bypass arterial line blood filter
870.4320	Cardiopulmonary bypass pulsatile flow generator
870.4350	Cardiopulmonary bypass oxygenator
870.4360	Nonroller-type cardiopulmonary bypass blood pump
870.5200	External cardiac compressor
870.5225	External counter-pulsating device
870.5300	High energy DC-defibrillator (including paddles)
870.5550	External transcutaneous cardiac pacemaker (noninvasive)

Dental Devices

- 872.3400 Karaya and 12% or more sodium borate with or without acacia denture adhesive
- 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive
- 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive
- 872.3500 Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive
- 872.3540 OTC denture cushion or pad made of a material other than wax-impregnated cotton cloth or not intended to be discarded following one day's use
- 872.3560 OTC denture reliner
- 872.3570 OTC denture repair kit
- 872.3600 Partially fabricated denture kit
- 872.3640 Endosseous implant (pending reclassification petition)
- 872.3820 Root canal filling resin if chloroform is used as an ingredient in the device
- 872.6080 Airbrush
- 872.6730 Endodontic dry heat sterilizer

Ear Nose and Throat Devices

- 874.3400 Tinnitus masker
- 874.3850 Endolymphatic shunt tube with valve (pending reclassification petition)
- 874.3930 Tympanostomy tube with semipermeable membrane
- 874.5350 Suction antichoke device
- 874.5370 Tongs antichoke device

Gastroenterology - Urology Devices

- 876.3350 Penile inflatable implant
- 876.3630 Penile rigidity implant
- 876.3750 Testicular prosthesis

- 876.4480 Electrohydraulic lithotripter
- 876.5220 Colonic irrigation system for uses other than colon cleansing when medically indicated such as before radiological or endoscopic examinations
- 876.5270 Implanted electrical urinary continence device
- 876.5280 Implanted mechanical/hydraulic urinary continence device
- 876.5540 Implanted blood access device and accessories
- 876.5860 High permeability hemodialysis system
- 876.5870 Sorbent hemoperfusion system
- 876.5955 Peritoneo-venous shunt

General and Plastic Surgery Devices

- 878.3530 Silicone inflatable breast prosthesis
- 878.3610 Esophageal prosthesis
- 878.3720 Tracheal prosthesis
- 878.5360 Tweezer-type epilator
- 878.5650 Topical oxygen chamber for extremities

General Hospital and Personal Use Devices

- 880.5130 Infant radiant warmer (pending reclassification petition)
- 880.5760 Chemical cold pack snakebite kit

Neurological Devices

- 882.1790 Ocular plethysmograph
- 882.1825 Rheoencephalograph
- 882.5150 Intravascular occluding catheter
- 882.5800 Cranial electrotherapy stimulator
- 882.5850 Implanted spinal cord stimulator for bladder evacuation
- 882.5860 Implanted neuromuscular stimulator
- 882.5940 Electroconvulsive therapy device (proposed rule in 9/5/90 FR to reclassify when performance standard in effect)
- 882.5950 Artificial embolization device

Obstetrical and Gynecological Devices

884.1060	Endometrial aspirator
884.1100	Endometrial brush
884.1185	Endometrial washer
884.2050	Obstetric data analyzer
884.2620	Fetal electroencephalographic monitor
884.2685	Fetal scalp clip electrode and applicator
884.2980	Telethermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses
884.2982	A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses
884.4100	Endoscopic electrocautery and accessories
884.4150	Bipolar endoscopic coagulator-cutter and accessories
884.4250	Expandable cervical dilator
884.4270	Vibratory cervical dilators
884.5050	Metreurynter-balloon abortion system
884.5225	Abdominal decompression chamber
884.5940	Powered vaginal muscle stimulator for therapeutic use

Ophthalmic Devices

886.3400	Keratoprosthesis
886.3920	Eye valve implant

Orthopedic Devices

888.3120	Ankle joint metal/polymer non-constrained cemented prosthesis
888.3150	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis
888.3180	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis
888.3200	Finger joint metal/metal constrained uncemented prosthesis

888.3210 Finger joint metal/metal constrained cemented prosthesis

888.3220 Finger joint metal/polymer constrained cemented prosthesis

888.3300 Hip joint metal constrained cemented or uncemented prosthesis

888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis

888.3320 Hip joint metal/metal semiconstrained, with a cemented acetabular component, prosthesis

888.3330 Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis

888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis

888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis

888.3410 Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis

888.3480 Knee joint femorotibial metallic constrained cemented prosthesis

888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis

888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis

888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis

888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis

888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis

888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis

888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis

888.3790 Wrist joint metal constrained cemented prosthesis

Physical Medicine Devices

- 890.3610 Rigid pneumatic structure orthosis
- 890.3890 Stair-climbing wheelchair
- 890.5275 Microwave diathermy for use other than in applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies
- 890.5290 Shortwave diathermy for uses other than in generating deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment malignancies
- 890.5300 Ultrasonic diathermy for uses other than in generating deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment malignancies
- 890.5525 Iontophoresis device intended for introducing ions of soluble salts or other drugs into the body for medical purposes other than inducing sweating for use in the diagnosis of cystic fibrosis or for other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug
- 890.5860 Ultrasound and muscle stimulator for use other than applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms and joint contractures, but not for the treatment of malignancies.

Radiology Devices

None