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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