party may perform an inspection on its own.

### § 26.44 Transmission of product evaluation reports.

Transmission of product evaluation reports will take place according to the importing party's specified procedures.

### § 26.45 Monitoring continued equivalence.

Monitoring activities will be carried out in accordance with § 26.69.

### § 26.46 Listing of additional CAB's.

(a) During the operational period, additional conformity assessment bodies (CAB's) will be considered for equivalence using the procedures and criteria described in §§ 26.36, 26.37, and 26.39, taking into account the level of confidence gained in the overall regulatory system of the other party.

(b) Once a designating authority considers that such CAB's, having undergone the procedures of §§ 26.36, 26.37, and 26.39, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of § 26.66(a) and (b).

(c) Following such annual designations, the procedures for confirmation of CAB's under § 26.66(c) and (d) shall apply.

### § 26.47 Role and composition of the Joint Sectoral Committee.

(a) The Joint Sectoral Committee for this subpart is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who will each have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment of the equivalence of conformity assessment bodies (CAB's);

(2) Developing and maintaining the list of equivalent CAB's, including any limitation in terms of their scope of activities and communicating the list to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

### § 26.48 Harmonization.

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

### § 26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix A of this subpart.

### § 26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which

could necessitate additional controls or suspension of the distribution of the product.

## APPENDIX A TO SUBPART B OF PART 26—RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

1. For the European Community (EC) the following legislation applies to §26.42(a) of this subpart:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices
OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 4
Annex 5

b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169,12.7.1993, p.1. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 3
Annex 4
Annex 5
Annex 6

2. For the United States, the following legislation applies to §26.32(a):

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at ''http://www.fda.gov''.]

a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*

b. The Public Health Service Act, 42 U.S.C. 201 *et seq.*

c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.

d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789–14796 (April 3, 1996).

e. Draft Guidance Document on Accredited Persons Program, 63 FR 28392 (May 22, 1998).

f. Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA), 63 FR 36240 (July 2, 1998).

g. Guidance Document on Use of Standards, 63 FR 9561 (February 25, 1998).

## APPENDIX B TO SUBPART B OF PART 26—SCOPE OF PRODUCT COVERAGE

1. Initial Coverage of the Transition Period

Upon entry into force of this subpart as described in §26.80 (it is understood that the date of entry into force will not occur prior to June 1, 1998, unless the parties decide otherwise), products qualifying for the transitional arrangements under this subpart include:

a. All Class I products requiring premarket evaluations in the United States—see Table 1.

b. Those Class II products listed in Table 2.

2. During the Transition Period

The parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

a. Those for which review may be based primarily on written guidance which the parties will use their best efforts to prepare expeditiously; and

b. Those for which review may be based primarily on international standards, in order for the parties to gain the requisite experience.

The corresponding additional product lists will be phased in on an annual basis. The parties may consult with industry and other interested parties in determining which products will be added.

3. Commencement of the Operational Period

a. At the commencement of the operational period, product coverage shall extend to all Class I/II products covered during the transition period.

b. FDA will expand the program to categories of Class II devices as is consistent with the results of the pilot, and with FDA's ability to write guidance documents if the device pilot for the third party review of medical devices is successful. The MRA will cover to the maximum extent feasible all Class II devices listed in Table 3 for which FDA-accredited third party review is available in the United States.

4. Unless explicitly included by joint decision of the parties, this part does not cover any U.S. Class II-tier 3 or any Class III product under either system.

[The lists of medical devices included in these tables are subject to change as a result of the Food and Drug Administration Modernization Act of 1997.]

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]

| 21 CFR Section No. | Regulation Name<br>Product Code—Device Name |
|---|---|
| *Anesthesiology Panel (21 CFR Part 868)* | |
| 868.1910 | Esophageal Stethoscope<br>BZW—Stethoscope, Esophageal |
| 868.5620 | Breathing Mouthpiece<br>BYP—Mouthpiece, Breathing |
| 868.5640 | Medicinal Nonventilatory Nebulizer (Atomizer)<br>CCQ—Nebulizer, Medicinal, Nonventilatory (Atomizer) |
| 868.5675 | Rebreathing Device<br>BYW—Device, Rebreathing |
| 868.5700 | Nonpowered Oxygen Tent<br>FOG—Hood, Oxygen, Infant<br>BYL—Tent, Oxygen |
| 868.6810 | Tracheobronchial Suction Catheter<br>BSY—Catheters, Suction, Tracheobronchial |
| *Cardiovascular Panel* | |
| (None) | |
| *Dental Panel (21 CFR Part 872)* | |
| 872.3400 | Karaya and Sodium Borate With or Without Acacia Denture Adhesive<br>KOM—Adhesive, Denture, Acacia and Karaya With Sodium Borate |
| 872.3700 | Dental Mercury (U.S.P.)<br>ELY—Mercury |
| 872.4200 | Dental Handpiece and Accessories<br>EBW—Controller, Food, Handpiece and Cord<br>EFB—Handpiece, Air-Powered, Dental<br>EFA—Handpiece, Belt and/or Gear Driven, Dental<br>EGS—Handpiece, Contra- and Right-Angle Attachment, Dental<br>EKX—Handpiece, Direct Drive, AC-Powered<br>EKY—Handpiece, Water-Powered |
| 872.6640 | Dental Operative Unit and Accessories<br>EIA—Unit, Operative Dental |
| *Ear, Nose, and Throat Panel (21 CFR Part 874)* | |
| 874.1070 | Short Increment Sensitivity Index (SISI) Adapter<br>ETR—Adapter, Short Increment Sensitivity Index (SISI) |
| 874.1500 | Gustometer<br>ETM—Gustometer |
| 874.1800 | Air or Water Caloric Stimulator<br>KHH—Stimulator, Caloric-Air<br>ETP—Stimulator, Caloric-Water |
| 874.1925 | Toynbee Diagnostic Tube<br>ETK—Tube, Toynbee Diagnostic |
| 874.3300 | Hearing Aid<br>LRB—Face Plate Hearing-Aid<br>ESD—Hearing-aid, Air-Conduction |
| 874.4100 | Epistaxis Balloon<br>EMX—Balloon, Epistaxis |
| 874.5300 | ENT Examination and Treatment Unit<br>ETF—Unit, Examining/Treatment, ENT |
| 874.5550 | Powered Nasal Irrigator<br>KMA—Irrigator, Powered Nasal |
| 874.5840 | Antistammering Device<br>KTH—Device, Anti-Stammering |
| *Gastroenterology—Urology Panel (21 CFR Part 876)* | |
| 876.5160 | Urological Clamp for Males<br>FHA—Clamp, Penile |
| 876.5210 | Enema Kit<br>FCE—Kit, Enema, (for Cleaning Purpose) |
| 876.5250 | Urine Collector and Accessories<br>FAQ—Bag, Urine Collection, Leg, for External Use |
| *General Hospital Panel (21 CFR Part 880)* | |
| 880.5270 | Neonatal Eye Pad<br>FOK—Pad, Neonatal Eye |
| 880.5420 | Pressure Infusor for an I.V. Bag<br>KZD—Infusor, Pressure, for I.V. Bags |
| 880.5680 | Pediatric Position Holder<br>FRP—Holder, Infant Position |
| 880.6250 | Patient Examination Glove<br>LZB—Finger Cot |

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

| 21 CFR Section No. | Regulation Name |
|---|---|
| | Product Code—Device Name |
| | FMC—Glove, Patient Examination |
| | LYY—Glove, Patient Examination, Latex |
| | LZA—Glove, Patient Examination, Poly |
| | LZC—Glove, Patient Examination, Speciality |
| | LYZ—Glove, Patient Examination, Vinyl |
| 880.6375 | Patient Lubricant |
| | KMJ—Lubricant, Patient |
| 880.6760 | Protective Restraint |
| | BRT—Restraint, Patient, Conductive |
| | FMQ—Restraint, Protective |
| *Neurology Panel (21 CFR Part 882)* | |
| 882.1030 | Ataxiagraph |
| | GWW—Ataxiagraph |
| 882.1420 | Electroencephalogram (EEG) Signal Spectrum Analyzer |
| | GWS—Analyzer, Spectrum, Electroencephalogram Signal |
| 882.4060 | Ventricular Cannula |
| | HCD—Cannula, Ventricular |
| 882.4545 | Shunt System Implantation Instrument |
| | GYK—Instrument, Shunt System Implantation |
| 882.4650 | Neurosurgical Suture Needle |
| | HAS—Needle, Neurosurgical Suture |
| 882.4750 | Skull Punch |
| | GXJ—Punch, Skull |
| *Obstetrics and Gynecology Panel* | |
| (None) | |
| *Ophthalmology Panel (21 CFR Part 886)* | |
| 886.1780 | Retinoscope |
| | HKM—Retinoscope, Battery-Powered |
| 886.1940 | Tonometer Sterilizer |
| | HKZ—Sterilizer, Tonometer |
| 886.4070 | Powered Corneal Burr |
| | HQS—Burr, Corneal, AC-Powered |
| | HOG—Burr, Corneal, Battery-Powered |
| | HRG—Engine, Trephine, Accessories, AC-Powered |
| | HFR—Engine, Trephine, Accessories, Battery-Powered |
| | HLD—Engine, Trephine, Accessories, Gas-Powered |
| 886.4370 | Keratome |
| | HNO—Keratome, AC-Powered |
| | HMY—Keratome, Battery-Powered |
| 886.5850 | Sunglasses (Nonprescription) |
| | HQY—Sunglasses (Nonprescription Including Photosensitive) |
| *Orthopedic Panel (21 CFR Part 888)* | |
| 888.1500 | Goniometer |
| | KQX—Goniometer, AC-Powered |
| 888.4150 | Calipers for Clinical Use |
| | KTZ—Caliper |
| *Physical Medicine Panel (21 CFR Part 890)* | |
| 890.3850 | Mechanical Wheelchair |
| | LBE—Stroller, Adaptive |
| | IOR—Wheelchair, Mechanical |
| 890.5180 | Manual Patient Rotation Bed |
| | INY—Bed, Patient Rotation, Manual |
| 890.5710 | Hot or Cold Disposable Pack |
| | IMD—Pack, Hot or Cold, Disposable |
| *Radiology Panel (21 CFR Part 892)* | |
| 892.1100 | Scintillation (Gamma) Camera |
| | IYX—Camera, Scintillation (Gamma) |
| 892.1110 | Positron Camera |
| | IZC—Camera, Positron |
| 892.1300 | Nuclear Rectilinear Scanner |
| | IYW—Scanner, Rectilinear, Nuclear |
| 892.1320 | Nuclear Uptake Probe |
| | IZD—Probe, Uptake, Nuclear |
| 892.1330 | Nuclear Whole Body Scanner |
| | JAM—Scanner, Whole Body, Nuclear |
| 892.1410 | Nuclear Electrocardiograph Synchronizer |
| | IVY—Synchronizer, Electrocardiograph, Nuclear |
| 892.1890 | Radiographic Film Illuminator |
| | IXC—Illuminator, Radiographic-Film |

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

| 21 CFR Section No. | Regulation Name |
|---|---|
| | Product Code—Device Name |
| | JAG—Illuminator, Radiographic-Film, Explosion-Proof |
| 892.1910 | Radiographic Grid |
| | IXJ—Grid, Radiographic |
| 892.1960 | Radiographic Intensifying Screen |
| | EAM—Screen, Intensifying, Radiographic |
| 892.1970 | Radiographic ECG/Respirator Synchronizer |
| | IXO—Synchronizer, ECG/Respirator, Radiographic |
| 892.5650 | Manual Radionuclide Applicator System |
| | IWG—System, Applicator, Radionuclide, Manual |
| *General and Plastic Surgery Panel (21 CFR Part 878)* | |
| 878.4200 | Introduction/Drainage Catheter and Accessories |
| | KGZ—Accessories, Catheter |
| | GCE—Adaptor, Catheter |
| | FGY—Cannula, Injection |
| | GBA—Catheter, Balloon Type |
| | GBZ—Catheter, Cholangiography |
| | GBQ—Catheter, Continuous Irrigation |
| | GBY—Catheter, Eustachian, General & Plastic Surgery |
| | JCY—Catheter, Infusion |
| | GBX—Catheter, Irrigation |
| | GBP—Catheter, Multiple Lumen |
| | GBO—Catheter, Nephrostomy, General & Plastic Surgery |
| | GBN—Catheter, Pediatric, General & Plastic Surgery |
| | GBW—Catheter, Peritoneal |
| | GBS—Catheter, Ventricular, General & Plastic Surgery |
| | GCD—Connector, Catheter |
| | GCC—Dilator, Catheter |
| | GCB—Needle, Catheter |
| 878.4320 | Removable Skin Clip |
| | FZQ—Clip, Removable (Skin) |
| 878.4460 | Surgeon's Gloves |
| | KGO—Surgeon's Gloves |
| 878.4680 | Nonpowered, Single Patient, Portable Suction Apparatus |
| | GCY—Apparatus, Suction, Single Patient Use, Portable, Nonpowered |
| 878.4760 | Removable Skin Staple |
| | GDT—Staple, Removable (Skin) |
| 878.4820 | AC–Powered, Battery-Powered, and Pneumatically Powered Surgical Instrument Motors and Accessories/Attachments |
| | GFG—Bit, Surgical |
| | GFA—Blade, Saw, General & Plastic Surgery |
| | DWH—Blade, Saw, Surgical, Cardiovascular |
| | BRZ—Board, Arm (With Cover) |
| | GFE—Brush, Dermabrasion |
| | GFF—Bur, Surgical, General & Plastic Surgery |
| | KDG—Chisel (Osteotome) |
| | GFD—Dermatome |
| | GFC—Driver, Surgical, Pin |
| | GFB—Head, Surgical, Hammer |
| | GEY—Motor, Surgical Instrument, AC-Powered |
| | GET—Motor, Surgical Instrument, Pneumatic Powered |
| | DWI—Saw, Electrically Powered |
| | KFK—Saw, Pneumatically Powered |
| | HAB—Saw, Powered, and Accessories |
| 878.4960 | Air or AC-Powered Operating Table and Air or AC-Powered Operating Chair & Accessories |
| | GBB—Chair, Surgical, AC-Powered |
| | FQO—Table, Operating-Room, AC-Powered |
| | GDC—Table, Operating-Room, Electrical |
| | FWW—Table, Operating-Room, Pneumatic |
| | JEA—Table, Surgical with Orthopedic Accessories, AC-Powered |
| 880.5090 | Liquid Bandage |
| | KMF—Bandage, Liquid |

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

TABLE 2.—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]

| Panel | 21 CFR Section No. | Regulation Name |
|---|---|---|
| | | Product Code—Device Name |
| RA | 892.1000 | Magnetic Resonance Diagnostic Device<br>MOS—COIL, Magnetic Resonance, Specialty<br>LNH—System, Nuclear Magnetic Resonance Imaging<br>LNI—System, Nuclear Magnetic Resonance Spectroscopic |
| Diagnostic Ultrasound: | | |
| RA | 892.1540 | Nonfetal Ultrasonic Monitor<br>JAF—Monitor, Ultrasonic, Nonfetal |
| RA | 892.1550 | Ultrasonic Pulsed Doppler Imaging System<br>IYN—System, Imaging, Pulsed Doppler, Ultrasonic |
| RA | 892.1560 | Ultrasonic Pulsed Echo Imaging System<br>IYO—System, Imaging, Pulsed Echo, Ultrasonic |
| RA | 892.1570 | Diagnostic Ultrasonic Transducer<br>ITX—Transducer, Ultrasonic, Diagnostic |
| Diagnostic X-Ray Imaging Devices (except mammographic x-ray systems): | | |
| RA | 892.1600 | Angiographic X-Ray System<br>IZI—System, X-Ray, Angiographic |
| RA | 892.1650 | Image-Intensified Fluoroscopic X-Ray System<br>MQB—Solid State X-Ray Imager (Flat Panel/Digital Imager)<br>JAA—System, X-Ray, Fluoroscopic, Image-Intensified |
| RA | 892.1680 | Stationary X-Ray System<br>KPR—System, X-Ray, Stationary |
| RA | 892.1720 | Mobile X-Ray System<br>IZL—System, X-Ray, Mobile |
| RA | 892.1740 | Tomographic X-Ray System<br>IZF—System, X-Ray, Tomographic |
| RA | 892.1750 | Computed Tomography X-Ray System<br>JAK—System, X-Ray, Tomography, Computed |
| ECG-Related Devices: | | |
| CV | 870.2340 | Electrocardiograph<br>DPS—Electrocardiograph<br>MLC—Monitor, ST Segment |
| CV | 870.2350 | Electrocardiograph Lead Switching Adaptor<br>DRW—Adaptor, Lead Switching, Electrocardiograph |
| CV | 870.2360 | Electrocardiograph Electrode<br>DRX—Electrode, Electrocardiograph |
| CV | 870.2370 | Electrocardiograph Surface Electrode Tester<br>KRC—Tester, Electrode, Surface, Electrocardiographic |
| NE | 882.1400 | Electroencephalograph<br>GWQ—Electroencephalograph |
| HO | 880.5725 | Infusion Pump (external only)<br>MRZ—Accessories, Pump, Infusion<br>FRN—Pump, Infusion<br>LZF—Pump, Infusion, Analytical Sampling<br>MEB—Pump, Infusion, Elastomeric<br>LZH—Pump, Infusion, Enteral<br>MHD—Pump, Infusion, Gallstone Dissolution<br>LZG—Pump, Infusion, Insulin<br>MEA—Pump, Infusion, PCA |
| Ophthalmic Instruments: | | |
| OP | 886.1570 | Ophthalmoscope<br>HLI—Ophthalmoscope, AC-Powered<br>HLJ—Ophthalmoscope, Battery-Powered |
| OP | 886.1780 | Retinoscope<br>HKL—Retinoscope, AC-Powered |
| OP | 886.1850 | AC-Powered Slit-Lamp Biomicroscope<br>HJO—Biomicroscope, Slit-Lamp, AC-Powered |
| OP | 886.4150 | Vitreous Aspiration and Cutting Instrument<br>MMC—Dilator, Expansive Iris (Accessory)<br>HQE—Instrument, Vitreous Aspiration and Cutting, AC-Powered<br>HKP—Instrument, Vitreous Aspiration and Cutting, Battery-Powered<br>MLZ—Vitrectomy, Instrument Cutter |
| OP | 886.4670 | Phacofragmentation System<br>HQC—Unit, Phacofragmentation |

TABLE 2.—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]—Continued

| Panel | 21 CFR Section No. | Regulation Name |
|---|---|---|
| | | Product Code—Device Name |
| SU | 878.4580 | Surgical Lamp |
| | | HBI—Illuminator, Fiberoptic, Surgical Field |
| | | FTF—Illuminator, Nonremote |
| | | FTG—Illuminator, Remote |
| | | HJE—Lamp, Fluorescein, AC-Powered |
| | | FQP—Lamp, Operating-Room |
| | | FTD—Lamp, Surgical |
| | | GBC—Lamp, Surgical, Incandescent |
| | | FTA—Light, Surgical, Accessories |
| | | FSZ—Light, Surgical, Carrier |
| | | FSY—Light, Surgical, Ceiling Mounted |
| | | FSX—Light, Surgical, Connector |
| | | FSW—Light, Surgical, Endoscopic |
| | | FST—Light, Surgical, Fiberoptic |
| | | FSS—Light, Surgical, Floor Standing |
| | | FSQ—Light, Surgical, Instrument |
| NE | 882.5890 | Transcutaneous Electrical Nerve Stimulator for Pain Relief |
| | | GZJ—Stimulator, Nerve, Transcutaneous, For Pain Relief |
| | | Noninvasive Blood Pressure Measurement Devices: |
| CV | 870.1120 | Blood Pressure Cuff |
| | | DXQ—Cuff, Blood-Pressure |
| CV | 870.1130 | Noninvasive Blood Pressure Measurement System (except nonoscillometric) |
| | | DXN—System, Measurement, Blood-Pressure, Noninvasive |
| HO | 880.6880 | Steam Sterilizer (greater than 2 cubic feet) |
| | | FLE—Sterilizer, Steam |
| Clinical Thermometers: | | |
| HO | 880.2910 | Clinical Electronic Thermometer (except tympanic or pacifier) |
| | | FLL—Thermometer, Electronic, Clinical |
| AN | 868.5630 | Nebulizer |
| | | CAF—Nebulizer (Direct Patient Interface) |
| Hypodermic Needles and Syringes (except antistick and self-destruct): | | |
| HO | 880.5570 | Hypodermic Single Lumen Needle |
| | | MMK—Container, Sharpes |
| | | FMI—Needle, Hypodermic, Single Lumen |
| | | MHC—Port, Intraosseous, Implanted |
| HO | 880.5860 | Piston Syringe |
| | | FMF—Syringe, Piston |
| Selected Dental Materials: | | |
| DE | 872.3060 | Gold-Based Alloys and Precious Metal Alloys for Clinical Use |
| | | EJT—Alloy, Gold Based, For Clinical Use |
| | | EJS—Alloy, Precious Metal, For Clinical Use |
| DE | 872.3200 | Resin Tooth Bonding Agent |
| | | KLE—Agent, Tooth Bonding, Resin |
| DE | 872.3275 | Dental Cement |
| | | EMA—Cement, Dental |
| | | EMB—Zinc Oxide Eugenol |
| DE | 872.3660 | Impression Material |
| | | ELW—Material, Impression |
| DE | 872.3690 | Tooth Shade Resin Material |
| | | EBF—Material, Tooth Shade, Resin |
| DE | 872.3710 | Base Metal Alloy |
| | | EJH—Metal, Base |
| Latex Condoms: | | |
| OB | 884.5300 | Condom |
| | | HIS—Condom |

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| *Anesthesiology Panel* | | | |
| Anesthesia Devices | 868.5160 | Gas machine for anesthesia or analgesia | 2 |
| | 868.5270 | Breathing system heater | 2 |
| | 868.5440 | Portable oxygen generator | 2 |
| | 868.5450 | Respiratory gas humidifier | 2 |
| | 868.5630 | Nebulizer | 2 |
| | 868.5710 | Electrically powered oxygen tent | 2 |
| | 868.5880 | Anesthetic vaporizer | 2 |
| Gas Analyser | 868.1040 | Powered Algesimeter | 2 |
| | 868.1075 | Argon gas analyzer | 2 |
| | 868.1400 | Carbon dioxide gas analyzer | 2 |
| | 868.1430 | Carbon monoxide gas analyzer | 2 |
| | 868.1500 | Enflurane gas analyzer | 2 |
| | 868.1620 | Halothane gas analyzer | 2 |
| | 868.1640 | Helium gas analyzer | 2 |
| | 868.1670 | Neon gas analyzer | 2 |
| | 868.1690 | Nitrogen gas analyzer | 2 |
| | 868.1700 | Nitrous oxide gas analyzer | 2 |
| | 868.1720 | Oxygen gas analyzer | 2 |
| | 868.1730 | Oxygen uptake computer | 2 |
| Peripheral Nerve Stimulators | 868.2775 | Electrical peripheral nerve stimulator | 2 |
| Respiratory Monitoring | 868.1750 | Pressure plethysmograph | 2 |
| | 868.1760 | Volume plethysmograph | 2 |
| | 868.1780 | Inspiratory airway pressure meter | 2 |
| | 868.1800 | Rhinoanemometer | 2 |
| | 868.1840 | Diagnostic spirometer | 2 |
| | 868.1850 | Monitoring spirometer | 2 |
| | 868.1860 | Peak-flow meter for spirometry | 2 |
| | 868.1880 | Pulmonary-function data calculator | 2 |
| | 868.1890 | Predictive pulmonary-function value calculator | 2 |
| | 868.1900 | Diagnostic pulmonary-function interpretation calculator | 2 |
| | 868.2025 | Ultrasonic air embolism monitor | 2 |
| | 868.2375 | Breathing frequency monitor (except apnea detectors) | 2 |
| | 868.2480 | Cutaneous carbon dioxide ($PcCO_2$) monitor | 2 |
| | 868.2500 | Cutaneous oxygen monitor (for an infant not under gas anesthesia) | 2 |
| | 868.2550 | Pneumotachomometer | 2 |
| | 868.2600 | Airway pressure monitor | 2 |
| | 868.5665 | Powered percussor | 2 |
| | 868.5690 | Incentive spirometer | 2 |
| Ventilator | 868.5905 | Noncontinuous ventilator (IPPB) | 2 |
| | 868.5925 | Powered emergency ventilator | 2 |
| | 868.5935 | External negative pressure ventilator | 2 |
| | 868.5895 | Continuous ventilator | 2 |
| | 868.5955 | Intermittent mandatory ventilation attachment | 2 |
| | 868.6250 | Portable air compressor | 2 |
| *Cardiovascular Panel* | | | |
| Cardiovascular Diagnostic | 870.1425 | Programmable diagnostic computer | 2 |
| | 870.1450 | Densitometer | 2 |
| | 870.2310 | Apex cardiograph (vibrocardiograph) | 2 |
| | 870.2320 | Ballistocardiograph | 2 |
| | 870.2340 | Electrocardiograph | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 870.2350 | Electrocardiograph lead switching adaptor | 1 |
| | 870.2360 | Electrocardiograph electrode | 2 |
| | 870.2370 | Electrocardiograph surface electrode tester | 2 |
| | 870.2400 | Vectorcardiograph | 1 |
| | 870.2450 | Medical cathode-ray tube display | 1 |
| | 870.2675 | Oscillometer | 2 |
| | 870.2840 | Apex cardiographic transducer | 2 |
| | 870.2860 | Heart sound transducer | 2 |
| Cardiovascular Monitoring | | Valve, pressure relief, cardiopulmonary bypass | |
| | 870.1100 | Blood pressure alarm | 2 |
| | 870.1110 | Blood pressure computer | 2 |
| | 870.1120 | Blood pressure cuff | 2 |
| | 870.1130 | Noninvasive blood pressure measurement system | 2 |
| | 870.1140 | Venous blood pressure manometer | 2 |
| | 870.1220 | Electrode recording catheter or electrode recording probe | 2 |
| | 870.1270 | Intracavitary phonocatheter system | 2 |
| | 870.1875 | Stethoscope (electronic) | 2 |
| | 870.2050 | Biopotential amplifier and signal conditioner | 2 |
| | 870.2060 | Transducer signal amplifier and conditioner | 2 |
| | 870.2100 | Cardiovascular blood flowmeter | 2 |
| | 870.2120 | Extravascular blood flow probe | 2 |
| | 870.2300 | Cardiac monitor (including cardiotachometer and rate alarm) | 2 |
| | 870.2700 | Oximeter | 2 |
| | 870.2710 | Ear oximeter | 2 |
| | 870.2750 | Impedance phlebograph | 2 |
| | 870.2770 | Impedance plethysmograph | 2 |
| | 870.2780 | Hydraulic, pneumatic, or photoelectric plethysmographs | 2 |
| | 870.2850 | Extravascular blood pressure transducer | 2 |
| | 870.2870 | Catheter tip pressure transducer | 2 |
| | 870.2880 | Ultrasonic transducer | 2 |
| | 870.2890 | Vessel occlusion transducer | 2 |
| | 870.2900 | Patient transducer and electrode cable (including connector) | 2 |
| | 870.2910 | Radiofrequency physiological signal transmitter and receiver | 2 |
| | 870.2920 | Telephone electrocardiograph transmitter and receiver | 2 |
| | 870.4205 | Cardiopulmonary bypass bubble detector | 2 |
| | 870.4220 | Cardiopulmonary bypass heart-lung machine console | 2 |
| | 870.4240 | Cardiovascular bypass heat exchanger | 2 |
| | 870.4250 | Cardiopulmonary bypass temperature controller | 2 |
| | 870.4300 | Cardiopulmonary bypass gas control unit | 2 |
| | 870.4310 | Cardiopulmonary bypass coronary pressure gauge | 2 |
| | 870.4330 | Cardiopulmonary bypass online blood gas monitor | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 870.4340 | Cardiopulmonary bypass level sensing monitor and/or control | 2 |
| | 870.4370 | Roller-type cardiopulmonary bypass blood pump | 2 |
| | 870.4380 | Cardiopulmonary bypass pump speed control | 2 |
| | 870.4410 | Cardiopulmonary bypass in-line blood gas sensor | 2 |
| Cardiovascular Therapeutic | 870.5050 | Patient care suction apparatus | 2 |
| | 870.5900 | Thermal regulation system | 2 |
| Defibrillator | 870.5300 | DC-defibrillator (including paddles) | 2 |
| | 870.5325 | Defibrillator tester | 2 |
| Echocardiograph | 870.2330 | Echocardiograph | 2 |
| Pacemaker & Accessories | 870.1750 | External programmable pacemaker pulse generator | 2 |
| | 870.3630 | Pacemaker generator function analyzer | 2 |
| | 870.3640 | Indirect pacemaker generator function analyzer | 2 |
| | 870.3720 | Pacemaker electrode function tester | 2 |
| Miscellaneous | 870.1800 | Withdrawal-infusion pump | 2 |
| | 870.2800 | Medical magnetic tape recorder | 2 |
| | None | Batteries, rechargeable, class II devices | |
| *Dental Panel* | | | |
| Dental Equipment | 872.1720 | Pulp tester | 2 |
| | 872.1740 | Caries detection device | 2 |
| | 872.4120 | Bone cutting instrument and accessories | 2 |
| | 872.4465 | Gas-powered jet injector | 2 |
| | 872.4475 | Spring-powered jet injector | 2 |
| | 872.4600 | Intraoral ligature and wire lock | 2 |
| | 872.4840 | Rotary scaler | 2 |
| | 872.4850 | Ultrasonic scaler | 2 |
| | 872.4920 | Dental electrosurgical unit and accessories | 2 |
| | 872.6070 | Ultraviolet activator for polymerization | 2 |
| | 872.6350 | Ultraviolet detector | 2 |
| Dental Material | 872.3050 | Amalgam alloy | 2 |
| | 872.3060 | Gold-based alloys and precious metal alloys for clinical use | 2 |
| | 872.3200 | Resin tooth bonding agent | 2 |
| | 872.3250 | Calcium hydroxide cavity liner | 2 |
| | 872.3260 | Cavity varnish | 2 |
| | 872.3275 | Dental cement (other than zinc oxide-eugenol) | 2 |
| | 872.3300 | Hydrophilic resin coating for dentures | 2 |
| | 872.3310 | Coating material for resin fillings | 2 |
| | 872.3590 | Preformed plastic denture tooth | 2 |
| | 872.3660 | Impression material | 2 |
| | 872.3690 | Tooth shade resin material | 2 |
| | 872.3710 | Base metal alloy | 2 |
| | 872.3750 | Bracket adhesive resin and tooth conditioner | 2 |
| | 872.3760 | Denture relining, repairing, or rebasing resin | 2 |
| | 872.3765 | Pit and fissure sealant and conditioner | 2 |
| | 872.3770 | Temporary crown and bridge resin | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 872.3820 | Root canal filling resin (other than chloroform use) | 2 |
| | 872.3920 | Porcelain tooth | 2 |
| Dental X-ray | 872.1800 | Extraoral source x-ray system | 2 |
| | 872.1810 | Intraoral source x-ray system | 2 |
| Dental Implants | 872.4880 | Intraosseous fixation screw or wire | 2 |
| | 872.3890 | Endodontic stabilizing splint | 2 |
| Orthodontic | 872.5470 | Orthodontic plastic bracket | 2 |
| *Ear/Nose/Throat Panel* | | | |
| Diagnostic Equipment | 874.1050 | Audiometer | 2 |
| | 874.1090 | Auditory impedance tester | 2 |
| | 874.1120 | Electronic noise generator for audiometric testing | 2 |
| | 874.1325 | Electroglottograph | 2 |
| | 874.1820 | Surgical nerve stimulator/locator | 2 |
| Hearing Aids | 874.3300 | Hearing aid (for bone-conduction) | 2 |
| | 874.3310 | Hearing aid calibrator and analysis system | 2 |
| | 874.3320 | Group hearing aid or group auditory trainer | 2 |
| | 874.3330 | Master hearing aid | 2 |
| Surgical Equipment | 874.4250 | Ear, nose, and throat electric or pneumatic surgical drill | 1 |
| | 874.4490 | Argon laser for otology, rhinology, and laryngology | 2 |
| | 874.4500 | Ear, nose, and throat microsurgical carbon dioxide laser | 2 |
| *Gastroenterology/Urology Panel* | | | |
| Endoscope (including angioscopes, laparscopes, ophthalmic endoscopes) | 876.1500 | Endoscope and accessories | 2 |
| | 876.4300 | Endoscopic electrosurgical unit and accessories | 2 |
| Gastroenterology | 876.1725 | Gastrointestinal motility monitoring system | 1 |
| Hemodialysis | 876.5600 | Sorbent regenerated dialysate delivery system for hemodialysis | 2 |
| | 876.5630 | Peritoneal dialysis system and accessories | 2 |
| | 876.5665 | Water purification system for hemodialysis | 2 |
| | 876.5820 | Hemodialysis system and accessories | 2 |
| | 876.5830 | Hemodialyzer with disposable insert (kiil-type) | 2 |
| Lithotriptor | 876.4500 | Mechanical lithotriptor | 2 |
| Urology Equipment | 876.1620 | Urodynamics measurement system | 2 |
| | 876.5320 | Nonimplanted electrical continence device | 2 |
| | 876.5880 | Isolated kidney perfusion and transport system and accessories | 2 |
| *General Hospital Panel* | | | |
| Infusion Pumps and Systems | 880.2420 | Electronic monitor for gravity flow infusion systems | 2 |
| | 880.2460 | Electrically powered spinal fluid pressure monitor | 2 |
| | 880.5430 | Nonelectrically powered fluid injector | 2 |
| | 880.5725 | Infusion pump | 2 |
| Neonatal Incubators | 880.5400 | Neonatal incubator | 2 |
| | 880.5410 | Neonatal transport incubator | 2 |
| | 880.5700 | Neonatal phototherapy unit | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| Piston Syringes | 880.5570 | Hypodermic single lumen needle | 1 |
| | 880.5860 | Piston syringe (except antistick) | 1 |
| | 880.6920 | Syringe needle introducer | 2 |
| Miscellaneous | 880.2910 | Clinical electronic thermometer | 2 |
| | 880.2920 | Clinical mercury thermometer | 2 |
| | 880.5100 | AC-powered adjustable hospital bed | 1 |
| | 880.5500 | AC-powered patient lift | 2 |
| | 880.6880 | Steam sterilizer (greater than 2 cubic feet) | 2 |
| *Neurology Panel* | | | |
| | 882.1020 | Rigidity analyzer | 2 |
| | 882.1610 | Alpha monitor | 2 |
| Neuro-Diagnostic | 882.1320 | Cutaneous electrode | 2 |
| | 882.1340 | Nasopharyngeal electrode | 2 |
| | 882.1350 | Needle electrode | 2 |
| | 882.1400 | Electroencephalograph | 2 |
| | 882.1460 | Nystagmograph | 2 |
| | 882.1480 | Neurological endoscope | 2 |
| | 882.1540 | Galvanic skin response measurement device | 2 |
| | 882.1550 | Nerve conduction velocity measurement device | 2 |
| | 882.1560 | Skin potential measurement device | 2 |
| | 882.1570 | Powered direct-contact temperature measurement device | 2 |
| | 882.1620 | Intracranial pressure monitoring device | 2 |
| | 882.1835 | Physiological signal amplifier | 2 |
| | 882.1845 | Physiological signal conditioner | 2 |
| | 882.1855 | Electroencephalogram (EEG) telemetry system | 2 |
| | 882.5050 | Biofeedback device | 2 |
| Echoencephalography | 882.1240 | Echoencephalograph | 2 |
| RPG | 882.4400 | Radiofrequency lesion generator | 2 |
| Neuro Surgery | none | Electrode, spinal epidural | 2 |
| | 882.4305 | Powered compound cranial drills, burrs, trephines, and their accessories | 2 |
| | 882.4310 | Powered simple cranial drills burrs, trephines, and their accessories | 2 |
| | 882.4360 | Electric cranial drill motor | 2 |
| | 882.4370 | Pneumatic cranial drill motor | 2 |
| | 882.4560 | Stereotaxic instrument | 2 |
| | 882.4725 | Radiofrequency lesion probe | 2 |
| | 882.4845 | Powered rongeur | 2 |
| | 882.5500 | Lesion temperature monitor | 2 |
| Stimulators | 882.1870 | Evoked response electrical stimulator | 2 |
| | 882.1880 | Evoked response mechanical stimulator | 2 |
| | 882.1890 | Evoked response photic stimulator | 2 |
| | 882.1900 | Evoked response auditory stimulator | 2 |
| | 882.1950 | Tremor transducer | 2 |
| | 882.5890 | Transcutaneous electrical nerve stimulator for pain relief | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| *Obstetrics/Gynecology Panel* | | | |
| Fetal Monitoring | 884.1660 | Transcervical endoscope (amnioscope) and accessories | 2 |
| | 884.1690 | Hysteroscope and accessories (for performance standards) | 2 |
| | 884.2225 | Obstetric-gynecologic ultrasonic imager | 2 |
| | 884.2600 | Fetal cardiac monitor | 2 |
| | 884.2640 | Fetal phonocardiographic monitor and accessories | 2 |
| | 884.2660 | Fetal ultrasonic monitor and accessories | 2 |
| | 884.2675 | Fetal scalp circular (spiral) electrode and applicator | 1 |
| | 884.2700 | Intrauterine pressure monitor and accessories | 2 |
| | 884.2720 | External uterine contraction monitor and accessories | 2 |
| | 884.2740 | Perinatal monitoring system and accessories | 2 |
| | 884.2960 | Obstetric ultrasonic transducer and accessories | 2 |
| Gynecological Surgery Equipment | 884.1720 | Gynecologic laparoscope and accessories | 2 |
| | 884.4160 | Unipolar endoscopic coagulator-cutter and accessories | 2 |
| | 884.4550 | Gynecologic surgical laser | 2 |
| | 884.4120 | Gynecologic electrocautery and accessories | 2 |
| | 884.5300 | Condom | 2 |
| Ophthalmic Implants | 886.3320 | Eye sphere implant | 2 |
| Contact Lens | 886.1385 | Polymethylmethacrylate (PMMA) diagnostic contact lens | 2 |
| | 886.5916 | Rigid gas permeable contact lens (daily wear only) | 2 |
| Diagnostic Equipment | 886.1120 | Opthalmic camera | 1 |
| | 886.1220 | Corneal electrode | 1 |
| | 886.1250 | Euthyscope (AC-powered) | 1 |
| | 886.1360 | Visual field laser instrument | 1 |
| | 886.1510 | Eye movement monitor | 1 |
| | 886.1570 | Ophthalmoscope | 1 |
| | 886.1630 | AC-powered photostimulator | 1 |
| | 886.1640 | Ophthalmic preamplifier | 1 |
| | 886.1670 | Ophthalmic isotope uptake probe | 2 |
| | 886.1780 | Retinoscope (AC-powered device) | 1 |
| | 886.1850 | AC-powered slit lamp biomicroscope | 1 |
| | 886.1930 | Tonometer and accessories | 2 |
| | 886.1945 | Transilluminator (AC-powered device) | 1 |
| | 886.3130 | Ophthalmic conformer | 2 |
| (Diagnostic/Surgery Equipment) | 886.4670 | Phacofragmentation system | 2 |
| Ophthalmic Implants | 886.3340 | Extraocular orbital implant | 2 |
| | 886.3800 | Scleral shell | 2 |
| Surgical Equipment | 880.5725 | Infusion pump (performance standards) | 2 |
| | 886.3100 | Ophthalmic tantalum clip | 2 |
| | 886.3300 | Absorbable implant (scleral buckling method) | 2 |
| | 886.4100 | Radiofrequency electrosurgical cautery apparatus | 2 |
| | 886.4115 | Thermal cautery unit | 2 |
| | 886.4150 | Vitreous aspiration and cutting instrument | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 886.4170 | Cryophthalmic unit | 2 |
| | 886.4250 | Ophthalmic electrolysis unit (AC-powered device) | 1 |
| | 886.4335 | Operating headlamp (AC-powered device) | 1 |
| | 886.4390 | Ophthalmic laser | 2 |
| | 886.4392 | Nd:YAG laser for posterior capsulotomy | 2 |
| | 886.4400 | Electronic metal locator | 1 |
| | 886.4440 | AC-powered magnet | 1 |
| | 886.4610 | Ocular pressure applicator | 2 |
| | 886.4690 | Ophthalmic photocoagulator | 2 |
| | 886.4790 | Ophthalmic sponge | 2 |
| | 886.5100 | Ophthalmic beta radiation source | 2 |
| | none | Ophthalmoscopes, replacement batteries, hand-held | 1 |
| *Orthopedic Panel* | | | |
| Implants | 888.3010 | Bone fixation cerclage | 2 |
| | 888.3020 | Intramedullary fixation rod | 2 |
| | 888.3030 | Single/multiple component metallic bone fixation appliances and accessories | 2 |
| | 888.3040 | Smooth or threaded metallic bone fixation fastener | 2 |
| | 888.3050 | Spinal interlaminal fixation orthosis | 2 |
| | 888.3060 | Spinal intervertebral body fixation orthosis | 2 |
| Surgical Equipment | 888.1240 | AC-powered dynamometer | 2 |
| | 888.4580 | Sonic surgical instrument and accessories/attachments | 2 |
| | none | Accessories, fixation, spinal interlaminal | 2 |
| | none | Accessories, fixation, spinal intervertebral body | 2 |
| | none | Monitor, pressure, intracompartmental | 1 |
| | none | Orthosis, fixation, spinal intervertebral fusion | 2 |
| | none | Orthosis, spinal pedicle fixation | |
| | none | System, cement removal extraction | 1 |
| *Physical Medicine Panel* | | | |
| Diagnostic Equipment or (Therapy) Therapeutic Equipment | 890.1225 | Chronaximeter | 2 |
| | 890.1375 | Diagnostic electromyograph | 2 |
| | 890.1385 | Diagnostic electromyograph needle electrode | 2 |
| | 890.1450 | Powered reflex hammer | 2 |
| | 890.1850 | Diagnostic muscle stimulator | 2 |
| or (Therapy) | 890.5850 | Powered muscle stimulator | 2 |
| Therapeutic Equipment | 890.5100 | Immersion hydrobath | 2 |
| | 890.5110 | Paraffin bath | 2 |
| | 890.5500 | Infrared lamp | 2 |
| | 890.5720 | Water circulating hot or cold pack | 2 |
| | 890.5740 | Powered heating pad | 2 |
| *Radiology Panel* | | | |
| MRI | 892.1000 | Magnetic resonance diagnostic device | 2 |
| Ultrasound Diagnostic | 884.2660 | Fetal ultrasonic monitor and accessories | 2 |
| | 892.1540 | Nonfetal ultrasonic monitor | |
| | 892.1560 | Ultrasonic pulsed echo imaging system | 2 |
| | 892.1570 | Diagnostic ultrasonic transducer | 2 |

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

| Product Family | 21 CFR Section No | Device Name | Tier |
|---|---|---|---|
| | 892.1550 | Ultrasonic pulsed doppler imaging system | |
| Angiographic | 892.1600 | Angiographic x-ray system | 2 |
| Diagnostic X-Ray | 892.1610 | Diagnostic x-ray beam-limiting device | 2 |
| | 892.1620 | Cine or spot fluorographic x-ray camera | 2 |
| | 892.1630 | Electrostatic x-ray imaging system | 2 |
| | 892.1650 | Image-intensified fluoroscopic x-ray system | 2 |
| | 892.1670 | Spot film device | 2 |
| | 892.1680 | Stationary x-ray system | 2 |
| | 892.1710 | Mammographic x-ray system | 2 |
| | 892.1720 | Mobile x-ray system | 2 |
| | 892.1740 | Tomographic x-ray system | 1 |
| | 892.1820 | Pneumoencephalographic chair | 2 |
| | 892.1850 | Radiographic film cassette | 1 |
| | 892.1860 | Radiographic film/cassette changer | 1 |
| | 892.1870 | Radiographic film/cassette changer programmer | 2 |
| | 892.1900 | Automatic radiographic film processor | 2 |
| | 892.1980 | Radiologic table | 1 |
| CT Scanner | 892.1750 | Computed tomography x-ray system | 2 |
| Radiation Therapy | 892.5050 | Medical charged-particle radiation therapy system | 2 |
| | 892.5300 | Medical neutron radiation therapy system | 2 |
| | 892.5700 | Remote controlled radionuclide applicator system | 2 |
| | 892.5710 | Radiation therapy beam-shaping block | 2 |
| | 892.5730 | Radionuclide brachytherapy source | 2 |
| | 892.5750 | Radionuclide radiation therapy system | 2 |
| | 892.5770 | Powered radiation therapy patient support assembly | 2 |
| | 892.5840 | Radiation therapy simulation system | 2 |
| | 892.5930 | Therapeutic x-ray tube housing assembly | 1 |
| Nuclear Medicine | 892.1170 | Bone densitometer | 2 |
| | 892.1200 | Emission computed tomography system | 2 |
| | 892.1310 | Nuclear tomography system | 1 |
| | 892.1390 | Radionuclide rebreathing system | 2 |
| General/Plastic Surgery Panel | | | |
| Surgical Lamps | 878.4630 | Ultraviolet lamp for dermatologic disorders | 2 |
| | 890.5500 | Infrared lamp | 2 |
| | 878.4580 | Surgical lamp | 2 |
| Electrosurgical Cutting Equipment | 878.4810 | Laser surgical instrument for use in general and plastic surgery and in dermatology | 2 |
| | 878.4400 | Electrosurgical cutting and coagulation device and accessories | 2 |
| Miscellaneous | 878.4780 | Powered suction pump | 2 |

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

APPENDIXES C–F TO SUBPART B OF PART 26 [RESERVED]

## Subpart C—``Framework'' Provisions

### § 26.60 Definitions.

(a) The following terms and definitions shall apply to this subpart only:

(1) *Designating Authority* means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this part.

(2) *Designation* means the identification by a designating authority of a conformity assessment body to perform conformity assessment procedures under this part.

(3) *Regulatory Authority* means a government agency or entity that exercises a legal right to control the use or sale of products within a party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

(b) Other terms concerning conformity assessment used in this part shall have the meaning given elsewhere in this part or in the definitions contained in ''Guide 2: Standardization and Related Activities—General Vocabulary of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)'' (ISO/IEC Guide 2) (1996 edition), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the International Organization for Standardization, 1, rue de Varembé, Case postale 56, CH–1211 Genève 20, Switzerland, or on the Internet at ''http://www.iso.ch'' or may be examined at the Food and Drug Administration's Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD 20857, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. In the event of an inconsistency between the ISO/IEC Guide 2 and definitions in this part, the definitions in this part shall prevail.

### § 26.61 Purpose of this part.

This part specifies the conditions by which each party will accept or recognize results of conformity assessment procedures, produced by the other party's conformity assessment bodies (CAB's) or authorities, in assessing conformity to the importing party's requirements, as specified on a sector-specific basis in subparts A and B of this part, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the parties with regard to conformity assessment for all products covered under this part. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the party alleging its market access has been denied may, within 90 days of such consultation, invoke its right to terminate the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, in accordance with § 26.80.

### § 26.62 General obligations.

(a) The United States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other party's conformity assessment bodies (CAB's) and/or authorities.

(b) The European Community (EC) and its Member States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the EC and its Member States, produced by the other party's CAB's and/or authorities.

(c) Where sectoral transition arrangements have been specified in subparts A and B of this part, the obligations in paragraphs (a) and (b) of this section will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure