

## Food and Drug Administration, HHS

## § 26.50

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

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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.]

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

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

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TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD<sup>1</sup>—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
880.6760	KMJ—Lubricant, Patient Protective Restraint BRT—Restraint, Patient, Conductive FMQ—Restraint, Protective
<i>Neurology Panel (21 CFR Part 882)</i>	
882.1030	Ataxiagraph GWW—Ataxiagraph
882.1420	Electroencephalogram (EEG) Signal Spectrum Analyzer
882.4060	GWS—Analyzer, Spectrum, Electroencephalogram Signal Ventricular Cannula
882.4545	HCD—Cannula, Ventricular Shunt System Implantation Instrument
882.4650	GYK—Instrument, Shunt System Implantation
882.4750	Neurosurgical Suture Needle HAS—Needle, Neurosurgical Suture Skull Punch GXJ—Punch, Skull
<i>Obstetrics and Gynecology Panel (None)</i>	
<i>Ophthalmology Panel (21 CFR Part 886)</i>	
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 Photosensi- tive)
<i>Orthopedic Panel (21 CFR Part 888)</i>	
888.1500	Goniometer KQX—Goniometer, AC-Powered
888.4150	Calipers for Clinical Use KTZ—Caliper
<i>Physical Medicine Panel (21 CFR Part 890)</i>	
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
<i>Radiology Panel (21 CFR Part 892)</i>	
892.1100	Scintillation (Gamma) Camera IYX—Camera, Scintillation (Gamma) Positron Camera
892.1110	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<sup>1</sup>—Continued

21 CFR Section No.	Regulation Name Product Code—Device Name
892.1910	JAG—Illuminator, Radiographic-Film, Explosion-Proof Radiographic Grid
892.1960	IXJ—Grid, Radiographic Radiographic Intensifying Screen
892.1970	EAM—Screen, Intensifying, Radiographic Radiographic ECG/Respirator Synchronizer
892.5650	IXO—Synchronizer, ECG/Respirator, Radiographic Manual Radionuclide Applicator System
	IWG—System, Applicator, Radionuclide, Manual
<i>General and Plastic Surgery Panel (21 CFR Part 878)</i>	
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

<sup>1</sup>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)<sup>1</sup>

Panel	21 CFR Section No.	Regulation Name Product Code—Device Name
RA	892.1000	Magnetic Resonance Diagnostic Device MOS—COIL, Magnetic Resonance, Specialty LNH—System, Nuclear Magnetic Resonance Imaging LNI—System, Nuclear Magnetic Resonance Spectroscopic
Diagnostic Ultrasound:		
RA	892.1540	Nonfetal Ultrasonic Monitor JAF—Monitor, Ultrasonic, Nonfetal
RA	892.1550	Ultrasonic Pulsed Doppler Imaging System IYN—System, Imaging, Pulsed Doppler, Ultrasonic
RA	892.1560	Ultrasonic Pulsed Echo Imaging System IYO—System, Imaging, Pulsed Echo, Ultrasonic
RA	892.1570	Diagnostic Ultrasonic Transducer ITX—Transducer, Ultrasonic, Diagnostic
Diagnostic X-Ray Imaging Devices (except mammographic x-ray systems):		
RA	892.1600	Angiographic X-Ray System IZI—System, X-Ray, Angiographic
RA	892.1650	Image-Intensified Fluoroscopic X-Ray System MQB—Solid State X-Ray Imager (Flat Panel/Digital Imager) JAA—System, X-Ray, Fluoroscopic, Image-Intensified
RA	892.1680	Stationary X-Ray System KPR—System, X-Ray, Stationary
RA	892.1720	Mobile X-Ray System IZL—System, X-Ray, Mobile
RA	892.1740	Tomographic X-Ray System IZF—System, X-Ray, Tomographic
RA	892.1750	Computed Tomography X-Ray System JAK—System, X-Ray, Tomography, Computed
ECG-Related Devices:		
CV	870.2340	Electrocardiograph DPS—Electrocardiograph MLC—Monitor, ST Segment
CV	870.2350	Electrocardiograph Lead Switching Adaptor DRW—Adaptor, Lead Switching, Electrocardiograph
CV	870.2360	Electrocardiograph Electrode DRX—Electrode, Electrocardiograph
CV	870.2370	Electrocardiograph Surface Electrode Tester KRC—Tester, Electrode, Surface, Electrocardiographic
NE	882.1400	Electroencephalograph GWQ—Electroencephalograph
HO	880.5725	Infusion Pump (external only) MRZ—Accessories, Pump, Infusion FRN—Pump, Infusion LZF—Pump, Infusion, Analytical Sampling MEB—Pump, Infusion, Elastomeric LZH—Pump, Infusion, Enteral MHD—Pump, Infusion, Gallstone Dissolution LZG—Pump, Infusion, Insulin MEA—Pump, Infusion, PCA
Ophthalmic Instruments:		
OP	886.1570	Ophthalmoscope HLI—Ophthalmoscope, AC-Powered HLJ—Ophthalmoscope, Battery-Powered
OP	886.1780	Retinoscope HKL—Retinoscope, AC-Powered
OP	886.1850	AC-Powered Slit-Lamp Biomicroscope HJO—Biomicroscope, Slit-Lamp, AC-Powered
OP	886.4150	Vitreous Aspiration and Cutting Instrument MMC—Dilator, Expansive Iris (Accessory) HQE—Instrument, Vitreous Aspiration and Cutting, AC-Powered HKP—Instrument, Vitreous Aspiration and Cutting, Battery-Powered
OP	886.4670	MLZ—Vitreotomy, Instrument Cutter Phacofragmentation System 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)<sup>1</sup>—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				
CV	870.1120	Noninvasive Blood Pressure Measurement Devices:		
		Blood Pressure Cuff		
CV	870.1130	DXQ—Cuff, Blood-Pressure		
		Noninvasive Blood Pressure Measurement System (except nonoscillometric)		
HO	880.6880	DXN—System, Measurement, Blood-Pressure, Noninvasive		
		Steam Sterilizer (greater than 2 cubic feet)		
Clinical Thermometers:		FLE—Sterilizer, Steam		
HO	880.2910	Clinical Electronic Thermometer (except tympanic or pacifier)		
AN	868.5630	FLL—Thermometer, Electronic, Clinical		
		Nebulizer		
Hypodermic Needles and Syringes (except antistick and self-destruct):		CAF—Nebulizer (Direct Patient Interface)		
HO	880.5570	Hypodermic Single Lumen Needle		
		MMK—Container, Sharpes		
HO	880.5860	FMI—Needle, Hypodermic, Single Lumen		
		MHC—Port, Intraosseous, Implanted		
Selected Dental Materials:		Piston Syringe		
		FMF—Syringe, Piston		
		DE	872.3060	Gold-Based Alloys and Precious Metal Alloys for Clinical Use
				EJT—Alloy, Gold Based, For Clinical Use
		DE	872.3200	EJS—Alloy, Precious Metal, For Clinical Use
				Resin Tooth Bonding Agent
		DE	872.3275	KLE—Agent, Tooth Bonding, Resin
				Dental Cement
		DE	872.3660	EMA—Cement, Dental
				EMB—Zinc Oxide Eugenol
		DE	872.3690	Impression Material
				ELW—Material, Impression
DE	872.3710	Tooth Shade Resin Material		
		EBF—Material, Tooth Shade, Resin		
Latex Condoms:		Base Metal Alloy		
		EJH—Metal, Base		
OB	884.5300	Condom		
		HIS—Condom		

<sup>1</sup>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<sup>1</sup>

Product Family	21 CFR Section No	Device Name	Tier
<i>Anesthesiology Panel</i>			
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
Gas Analyser	868.5710	Electrically powered oxygen tent	2
	868.5880	Anesthetic vaporizer	2
	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
	868.2775	Electrical peripheral nerve stimulator	2
Peripheral Nerve Stimulators			
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 <sub>2</sub> ) monitor	2
	868.2500	Cutaneous oxygen monitor (for an infant not under gas anesthesia)	2
	868.2550	Pneumotachometer	2
868.2600	Airway pressure monitor	2	
868.5665	Powered percussor	2	
868.5690	Incentive spirometer	2	
868.5905	Noncontinuous ventilator (IPPB)	2	
Ventilator	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
<i>Cardiovascular Panel</i>			
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<sup>1</sup>—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 cardi tachometer 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 on-line blood gas monitor	2

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD<sup>1</sup>—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	
<i>Dental Panel</i>			
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
Dental Material	872.6350	Ultraviolet detector	2
	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<sup>1</sup>—Continued

Product Family	21 CFR Section No	Device Name	Tier
	872.3820	Root canal filling resin (other than chloroform use)	2
Dental X-ray	872.3920	Porcelain tooth	2
	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
	874.1050	Audiometer	2
Ear/Nose/Throat Panel Diagnostic Equipment	874.1090	Auditory impedance tester	2
	874.1120	Electronic noise generator for audiometric testing	2
	874.1325	Electroglottograph	2
Hearing Aids	874.1820	Surgical nerve stimulator/locator	2
	874.3300	Hearing aid (for bone-conduction)	2
	874.3310	Hearing aid calibrator and analysis system	2
Surgical Equipment	874.3320	Group hearing aid or group auditory trainer	2
	874.3330	Master hearing aid	2
	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	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 (kil-type)	2
Lithotripter	876.4500	Mechanical lithotripter	2
	876.1620	Urodynamics measurement system	2
Urology Equipment	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
Neonatal Incubators	880.5725	Infusion pump	2
	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<sup>1</sup>—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	
Miscellaneous	880.6920	Syringe needle introducer	2	
	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	
<i>Neurology Panel</i>				
Neuro-Diagnostic	882.1020	Rigidity analyzer	2	
	882.1610	Alpha monitor	2	
	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 RPG	882.1240	Echoencephalograph	2
		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<sup>1</sup>—Continued

Product Family	21 CFR Section No	Device Name	Tier	
<i>Obstetrics/Gynecology Panel</i> 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	
Ophthalmic Implants	884.5300	Condom	2	
	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	Ophthalmic 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	
886.4670	Phacofragmentation system	2		
(Diagnostic/Surgery Equipment)	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<sup>1</sup>—Continued

Product Family	21 CFR Section No	Device Name	Tier
	886.4170	Cryophthalmic unit	2
	886.4250	Ophthalmic electrolysis unit	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
<i>Orthopedic Panel</i>			
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 interlaminar fixation orthosis	2
	888.3060	Spinal intervertebral body fixation orthosis	2
<i>Surgical Equipment</i>	888.1240	AC-powered dynamometer	2
	888.4580	Sonic surgical instrument and accessories/attachments	2
	none	Accessories, fixation, spinal interlaminar	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	2
	none	System, cement removal extraction	1
<i>Physical Medicine Panel</i>			
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) Therapeutic Equipment	890.5850	Powered muscle stimulator	2
	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
<i>Radiology Panel</i>			
MRI	892.1000	Magnetic resonance diagnostic device	2
Ultrasound Diagnostic	884.2660	Fetal ultrasonic monitor and accessories	2
	892.1540	Nonfetal ultrasonic monitor	2
	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<sup>1</sup>—Continued

Product Family	21 CFR Section No	Device Name	Tier
	892.1550	Ultrasonic pulsed doppler imaging system	
Angiographic Diagnostic X-Ray	892.1600	Angiographic x-ray system	2
	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
CT Scanner	892.1980	Radiologic table	1
	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

<sup>1</sup>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>".

## § 26.60

[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 Varembe, 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.

## 21 CFR Ch. I (4–1–03 Edition)

#### § 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