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APPENDIX E TO SUBPART A OF PART 26—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM

1. Documentation

—Definition of a crisis/emergency and under what circumstances an alert is required
—Standard Operating Procedures (SOP's)
—Mechanism of health hazards evaluation and classification
—Language of communication and transmission of information

2. Crisis Management System

—Crisis analysis and communication mechanisms
—Establishment of contact points
—Reporting mechanisms

3. Enforcement Procedures

—Followup mechanisms
—Corrective action procedures

4. Quality Assurance System

—Pharmacovigilance programme
—Surveillance/monitoring of implementation of corrective action

5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44–171–418 8400, Fax 418–8416.

B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM–600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301–827–6190, fax: 301–594-1944.
Human Drugs: Director, Office of Compliance, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, phone: 301–796–3100, fax: 301–847–8747.
Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV–200), MPN II, 7500 Standish Pl., Rockville, MD 20855–2773, phone: 301–827–6644, fax: 301–594–1807.

[63 FR 60141, Nov. 6, 1998, as amended at 69 FR 48775, Aug. 11, 2004; 74 FR 13112, Mar. 26, 2009]

Subpart B—Specific Sector Provisions for Medical Devices

§ 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

§ 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

§ 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(b) Additional products and procedures may be made subject to this subpart by agreement of the parties.

§ 26.34 Regulatory authorities.

The regulatory authorities shall have the responsibility of implementing the provisions of this subpart, including the designation and monitoring of conformity assessment bodies (CAB's). Regulatory authorities will be specified in appendix C of this subpart. Each party will promptly notify the other party in writing of any change in the regulatory authority for a country.

§ 26.35 Length and purpose of transition period.

There will be a 3-year transition period immediately following the date described in § 26.80(a). During the transition period, the parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of conformity assessment bodies (CAB's) of the other party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this subpart.

§ 26.36 Listing of CAB's.

Each party shall designate conformity assessment bodies (CAB's) to participate in confidence building activities by transmitting to the other party a list of CAB's which meet the criteria for technical competence and independence, as identified in appendix A of this subpart. The list shall be accompanied by supporting evidence. Designated CAB's will be listed in appendix D of this subpart for participation in the confidence building activities once confirmed by the importing party. Nonconfirmation would have to be justified based on documented evidence.

§ 26.37 Confidence building activities.

(a) At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building program calculated to provide sufficient evidence of the capabilities of the designated conformity assessment bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties.

(b) The joint confidence building program should include the following actions and activities:

(1) Seminars designed to inform the parties and CAB's about each party's regulatory system, procedures, and requirements;

(2) Workshops designed to provide the parties with information regarding requirements and procedures for the designation and surveillance of CAB's;

(3) Exchange of information about reports prepared during the transition period;

(4) Joint training exercises; and

(5) Observed inspections.

(c) During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

(d) Both parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the parties allow.

(e) Both the parties will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the parties through the Joint Sectoral Committee.

§ 26.38 Other transition period activities.

(a) During the transition period, the parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

(b) The parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the parties of the importing country) or suspension of the distribution of the product.

§ 26.39 Equivalence assessment.

(a) In the final 6 months of the transition period, the parties shall proceed to a joint assessment of the equivalence of the conformity assessment bodies (CAB's) that participated in the confidence building activities. CAB's will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CAB's may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this subpart and with regard to any type of product covered by this subpart. The parties shall develop a list contained in appendix E of this subpart of CAB's determined to be equivalent, which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

(b) The parties shall allow CAB's not listed for participation in this subpart, or listed for participation only as to certain types of evaluations, to apply for participation in this subpart once the necessary measures have been taken or sufficient experience has been gained, in accordance with § 26.46.

(c) Decisions concerning the equivalence of CAB's must be agreed to by both parties.

§ 26.40 Start of the operational period.

(a) The operational period will start at the end of the transition period after the parties have developed the list of conformity assessment bodies (CAB's) found to be equivalent. The provisions of §§ 26.40, 26.41, 26.42, 26.43, 26.44, 26.45, and 26.46 will apply only with regard to listed CAB's and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

(b) The operational period will apply to quality system evaluation reports and product evaluation reports generated by CAB's listed in accordance with this subpart for the evaluations performed in the respective territories of the parties, except if the parties agree otherwise.

§ 26.41 Exchange and endorsement of quality system evaluation reports.

(a) Listed European Community (EC) conformity assessment bodies (CAB's) will provide FDA with reports of quality system evaluations, as follows:

(1) For preapproval quality system evaluations, EC CAB's will provide full reports; and

(2) For surveillance quality system evaluations, EC CAB's will provide abbreviated reports.

(b) Listed U.S. CAB's will provide to the EC Notified Body of the manufacturer's choice:

(1) Full reports of initial quality system evaluations;

(2) Abbreviated reports of quality systems surveillance audits.

(c) If the abbreviated reports do not provide sufficient information, the importing party may request additional clarification from the CAB.

(d) Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in

postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing party may request clarification from the exporting party which may lead to a request for reinspection. The parties will endeavor to respond to requests for clarification in a timely manner. Where divergence is not clarified in this process, the importing party may carry out the quality system evaluation.

§ 26.42 Exchange and endorsement of product evaluation reports.

(a) European Community (EC) conformity assessment bodies (CAB's) listed for this purpose will, subject to the specifications and limitations on the list, provide to FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

(b) U.S. CAB's will, subject to the specifications and limitations on the list, provide to the EC Notified Body of the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

§ 26.43 Transmission of quality system evaluation reports.

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing 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).

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
	Product Code—Device Name
Anesthesiology Panel (21 CFR part 868)	
868.1910	Esophageal Stethoscope
	BZW—Stethoscope, Esophageal
868.5620	Breathing Mouthpiece
	BYP—Mouthpiece, Breathing
868.5640	Medicinal Nonventilatory Nebulizer (Atomizer)
	CCQ—Nebulizer, Medicinal, Nonventilatory (Atomizer)
868.5675	Rebreathing Device
	BYW—Device, Rebreathing
868.5700	Nonpowered Oxygen Tent
	FOG—Hood, Oxygen, Infant
	BYL—Tent, Oxygen
868.6810	Tracheobronchial Suction Catheter
	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
	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
872.6640	Dental Operative Unit and Accessories

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
	EIA—Unit, Operative Dental
Ear, Nose, and Throat Panel (21 CFR Part 874)	
874.1070	Short Increment Sensitivity Index (SISI) Adapter
	ETR—Adapter, Short Increment Sensitivity Index (SISI)
874.1500	Gustometer
	ETM—Gustometer
874.1800	Air or Water Caloric Stimulator
	KHH—Stimulator, Caloric-Air
	ETP—Stimulator, Caloric-Water
874.1925	Toynbee Diagnostic Tube
	ETK—Tube, Toynbee Diagnostic
874.3300	Hearing Aid
	LRB—Face Plate Hearing-Aid
	ESD—Hearing-aid, Air-Conduction
874.4100	Epistaxis Balloon
	EMX—Balloon, Epistaxis
874.5300	ENT Examination and Treatment Unit
	ETF—Unit, Examining/Treatment, ENT
874.5550	Powered Nasal Irrigator
	KMA—Irrigator, Powered Nasal
874.5840	Antistammering Device
	KTH—Device, Anti-Stammering
Gastroenterology—Urology Panel (21 CFR Part 876)	
876.5160	Urological Clamp for Males
	FHA—Clamp, Penile
876.5210	Enema Kit
	FCE—Kit, Enema, (for Cleaning Purpose)
876.5250	Urine Collector and Accessories
	FAQ—Bag, Urine Collection, Leg, for External Use
General Hospital Panel (21 CFR Part 880)	
880.5270	Neonatal Eye Pad
	FOK—Pad, Neonatal Eye
880.5420	Pressure Infusor for an I.V. Bag
	KZD—Infusor, Pressure, for I.V. Bags
880.5680	Pediatric Position Holder
	FRP—Holder, Infant Position
880.6250	Patient Examination Glove
	LZB—Finger Cot
	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

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
	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
	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

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
	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
		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

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
		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
		MLZ—Vitrectomy, Instrument Cutter
OP	886.4670	Phacofragmentation System
		HQC—Unit, Phacofragmentation
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)

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
		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

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
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
	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.	

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
	870.1100	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 flow-meter	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 on-line blood gas monitor	2
	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

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
	872.3060	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
	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
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

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
	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
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

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
	886.3100	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
	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
	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

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
	892.5300	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]

APPENDICES 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 at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* 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