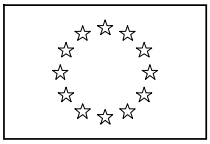

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.06.2000
COM(2000) 350 final

Proposal for a

COUNCIL DECISION

determining the Community position for a decision of the Joint Committee on amending certain Sectoral Annexes to the Agreement on Mutual Recognition between the European Community and the United States of America

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. Background

1. The Agreement on Mutual Recognition between the European Community (EC) and the United States of America (US) was approved by the Council by its Decision of 22 June 1998[1] and entered into force on 1 December 1998.

2. Article 21(1) of the Agreement foresees that the Sectoral Annexes can be amended by the Parties through the Joint Committee, set up under Article 14 of the Agreement. According to Article 3(3) of Council Decision 1999/78/EC, the position of the Community with regard to decisions to be taken by the Joint Committee within the framework of Article 21 of the Agreement, shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

3. Both the Community and the US have identified the need for amending certain Sectoral Annexes to the Agreement to reflect their current legislative and regulatory situation.

II Amendments to the Sectoral Annex for Telecommunications Equipment (TTE)

4. Directive 1999/5/EC on radio equipment and telecommunications terminal equipment[2] was adopted on 9 March 1999 and will repeal directive 1998/13/EC[3] as of 8 April 2000. The existing TTE Sectoral Annex makes a reference to directive 1998/13/EC and it must therefore be up-dated to take into account the new legal situation in the Community. More in detail, the amendments reflect the following:

   – Changed scope between directive 1998/13/EC and 1999/5/EC.

   – Changed conformity assessment procedures between the directives.

   – Changed relation to directive 1973/23/EEC on low voltage equipment and directive 1989/336/EEC on electromagnetic compatibility.

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1 Council Decision of 22 June 1998 on the conclusion of an Agreement on Mutual Recognition between the European Community and the United States of America (OJ L 31, .04.02.1999, p. 1).

2 Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 07.04.1999,p. 10).

3 Directive 98/13/EC of the European Parliament and the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition thereof (OJ L 74, 12.03.1998, p. 1).

III. Amendments to the Sectoral Annex for Electromagnetic Compatibility (EMC)

5. The US has proposed that the Federal Aviation Administration (FAA) be removed from the list of US designating Authorities indicated in Section IV. The reason being that the FAA does not have the legal authority to carry the responsibility of a designating authority. Therefore, for the US, the National Institute for Standards and Technology (NIST) and the Federal Communications Commission (FCC) exclusively shall serve as the only US authorities under Section IV to designate the conformity assessment bodies listed in Section V. This does not appear to cause problems for the good functioning of the MRA in this sector.

IV. Amendments to the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)

6. The US has noted that Article 1(3) of the Annex for GMPs states that the EC and US have agreed to reconsider the concepts of GMPs reproduced in that provision. Therefore, the US has proposed to clarify that, under the Agreement, the first paragraph of Article 1(3) has to be understood as the US definition and the second as the EC definition. Further, because equivalence is the cornerstone of the GMPs Annex, the US understands that the EC and the US shall maintain their respective requirements and shall carry out the inspections in accordance with their own requirements. In order to reflect this the US has proposed the following modification of Article 1(3) of the GMPs Annex (modifications compared to the existing text are underlined):

"3. 'Good Manufacturing Practices'

<u>In the United States</u>, GMPs mean the requirements found in the legislation, regulations and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

<u>In the EC</u>, GMPs are the part of quality assurance which ensures that products are consistently produced and controlled to a quality standard. GMPs include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorisation/product authorisation or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification).

Because equivalence is the cornerstone of this Annex, the Authorities of the Parties will maintain their respective requirements and will carry out the inspections against their own requirements."

V. Amendments to the Sectoral Annex for Medical Devices

7. The US wishes to revise Tables 1 and 2 of the Sectoral Annex for Medical Devices, which contain the lists of medical devices eligible for premarket assessment under the Agreement, in order to achieve consistency with US legislation currently in place.

8. The changes in Table 1 reflect the fact that only 25 categories of non-in vitro diagnostic class I devices need premarket notifications, as a result of the Food and Drug Administration Modernization ACT (FDAMA), which was enacted into law on 21 November 1997. The US proposes to add 6 categories to Table 1, while 44 categories should be removed (in vitro diagnostic devices are not covered by the Agreement). All 25 remaining categories are eligible for third party reviews and therefore premarket assessment under the Agreement.

9. The changes in Table 2 are also required as a result of the enactment of FDAMA. The United States considers that it is unable to accept reviews by accredited persons of premarket notifications for 4 categories of devices, because the FDAMA includes explicit language that prohibits use of third party bodies for the review of a class II medical device which is intended to be permanently implantable or life sustaining or life supporting.

10. For Table 2 the US also proposes to expand the scope of product coverage for class II medical devices eligible for third party pre-market assessment under the Agreement. The US proposes to add to Table 2 an additional 34 device categories that have become eligible for third party pre-market assessment under the FDAMA. 30 of the 34 additions are devices that the Community have previously expressed interest in including in the Agreement.

11. With these proposed changes, there will be a net decrease in the number of class I medical devices in Table 1 (from 63 to 25 categories), reflecting FDAMA regulatory simplification. The class I devices removed from Table 1 no longer require pre-market notification for marketing in the US. For Table 2, the addition of 34 categories of class II devices and the deletion of 4 ineligible categories will result in a net increase from 42 to 72 categories of class II devices. On balance, therefore, these changes would expand the scope of application of the MRA in this sector.

Proposal for a

COUNCIL DECISION

determining the Community position for a decision of the Joint Committee on amending certain Sectoral Annexes to the Agreement on Mutual Recognition between the European Community and the United States of America

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to the Council Decision of 22 June 1998 on the conclusion of an Agreement on Mutual Recognition between the European Community and the United States of America[4] and in particular Article 3(3) of that Decision,

Having regard to the proposal from the Commission[5],

Whereas both the Community and the United States of America have identified the need of amending certain Sectoral Annexes of the Mutual Recognition Agreement in order to reflect their current legislative and regulatory situation,

HAS DECIDED AS FOLLOWS:

Article 1

The position to be adopted by the European Community for a decision by the Joint Committee, set up under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, on amending the Sectoral Annexes on Telecommunications Equipment, Electromagnetic Compatibility, Pharmaceutical Good Manufacturing Practices (GMPs) and Medical Devices shall be based on the amendments specified in the annex to this Decision. Minor modifications to the amendments specified in the annex may be accepted without further decision by the Council.

[4] OJ L 31, .04.02.1999, p. 1

[5]

Article 2

The Council authorises the Commission to sign on behalf of the Community the decision of the Joint Committee that adopts the amendments mentioned in Article 1.

Article 3

The Decision of the Joint Committee shall be published in the Official Journal once it has been adopted.

Done at Brussels,

For the Council
The President

ANNEX

1. Amendments to the Sectoral Annex for Telecommunications Equipment

1. In Section I, under the EC, the whole text is replaced with the following:

   "Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity"

2. In Section III, paragraph 2(c) “Directive 98/13/EC” is deleted and replaced with "Directive 1999/5/EC".

3. In Section III, paragraph 2 the following subparagraphs are added:

   "(d) prescription of radio tests to be performed pursuant to annexes III and IV of Directive 1999/5/EC.

   (e) issuing of an opinion on a technical file pursuant to annex V of Directive 1999/5/EC."

4. In Appendix I, "ACTE Approval Committee for Terminal Equipment", "ADLNB Association of Designated Laboratories and Notified Bodies" and "CTR Common Technical Regulations" are deleted.

2. Amendments to the Sectoral Annex for Electromagnetic Compatibility (EMC)

1. In Section IV, under the “U.S.” column, “Federal Aviation Administration (FAA)” is deleted.

3. Amendments to the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)

Article 1, paragraph 3 is deleted in its entirety and is replace with the following text:

"3. 'Good Manufacturing Practices (GMPs)'

In the United States, GMPs means the requirements found in the legislation, regulations and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

In the EC, GMPs are the part of quality assurance which ensures that products are consistently produced and controlled to a quality standard. GMPs include, therefore, the system whereby the manufacturer receives the specifications of the products and/or process from the marketing authorisation/product authorisation or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification).

Because equivalence is the cornerstone of this Annex, the Authorities of the Parties will maintain their respective requirements and will carry out the inspections against their own requirements."

4. Amendments to the Sectoral Annex for Medical Devices

1. Table 1 is deleted in its entirety and is replaced with the following text:

TABLE 1

Class I products requiring premarket evaluations in the United States, included in scope of product coverage at beginning of transition period

DENTAL PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
872.4200	DENTAL HANDPIECES AND ACCESSORIES EBW - CONTROLLER, FOOT, 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
872.6250	DENTAL CHAIR AND ACCESSORIES KLC - CHAIR WITH A UNIT

872.6640	DENTAL OPERATIVE UNIT AND ACCESSORIES DYN - MOUTHPIECE, SALIVA EJECTOR EBR - UNIT, SUCTION OPERATORY EHZ - EVACUATOR, ORAL CAVITY EIA - UNIT, OPERATIVE DENTAL
872.6710	BOILING WATER STERILIZER ECG - STERILIZER, BOILING WATER

1.1. GASTROENTEROLOGY-UROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
876.5160	UROLOGICAL CLAMPS FOR MALES FHA - CLAMP, PENILE

GENERAL AND PLASTIC SURGERY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
878.4460	SURGEON'S GLOVES KGO - SURGEON'S GLOVES
880.5090	LIQUID BANDAGE KMF - BANDAGE, LIQUID

GENERAL HOSPITAL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
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 MMS - LUBRICANT, VAGINAL, PATIENT
880.6760	PROTECTIVE RESTRAINT BRT - RESTRAINT, PATIENT, CONDUCTIVE FMQ - RESTRAINT, PROTECTIVE

NEUROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
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

OBSTETRICS AND GYNECOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
884.2980	THERMOGRAPHIC SYSTEM LHQ - SYSTEM, TELETHERMOGRAPHIC (ADJUNCTIVE USE)
884.2982	LIQUID CRYSTAL TELETHERMOGRAPHIC SYSTEM LHM - SYSTEM, TELETHERMOGRAPHIC, LIQUID CRYSTAL KYA - SYSTEM, TELETHERMOGRAPHIC, LIQUID CRYSTAL, NONPOWERED (ADJUNCTIVE USE)

OPHTHALMOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
886.4070	POWERED CORNEAL BURR HQS - BURR, CORNEAL, AC-POWERED HOG - BURR, CORNEAL, BATTERY-POWERED HRG - ENGINE, TREPHINE, ACCESSORIES, AC-POWERED HRF - ENGINE, TREPHINE, ACCESSORIES, BATTERY-POWERED HLD - ENGINE, TREPHINE, ACCESSORIES, GAS-POWERED
886.4300	INTRAOCULAR LENS GUIDE KYB - LENS, GUIDE, INTRAOCULAR
886.4370	KERATOME HNO - KERATOME, AC-POWERED HMY - KERATOME, BATTERY-POWERED

ORTHOPEDIC PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
888.1500	GONIOMETER KQX - GONIOMETER, AC-POWERED

PHYSICAL MEDICINE PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
890.3850	MECHANICAL WHEELCHAIR LBE - STROLLER, ADAPTIVE IOR - WHEELCHAIR, MECHANICAL
890.5710	HOT OR COLD DISPOSABLE PACK IMD - PACK, HOT OR COLD, DISPOSABLE

RADIOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
892.1100	SCINTILLATION (GAMMA) CAMERA IYX - CAMERA, SCINTILLATION (GAMMA)
892.1110	POSITRON CAMERA IZC - CAMERA, POSITRON

2. Table 2 is deleted in its entirety and is replaced with the following text:

TABLE 2

Class II medical devices included in the scope of product coverage at beginning of transitional period

(US to develop guidance documents identifying US requirements and EC to identify standards needed to meet EV requirements)

ANESTHESIOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
868.5630	NEBULIZER CAF - NEBULIZER (DIRECT PATIENT INTERFACE)

CARDIOVASCULAR PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
870.1120	BLOOD PRESSURE CUFF DXQ - CUFF, BLOOD-PRESSURE
870.1130	NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM (except non-oscillometric) DXN - SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE
870.2300	CARDIAC MONITOR (INCLUDING CARDIOTACHOMETER AND RATE ALARM) DRT - MONITOR, CARDIAC (INCL. CARDIOTACHOMETER & RATE ALARM)
870.2330	ECHOCARDIOGRAPH DXK – ECHOCARDIOGRAPH
870.2340	ELECTROCARDIOGRAPH DPS – ELECTROCARDIOGRAPH

	MLC - MONITOR, ST SEGMENT (without alarm)
870.2350	ELECTROCARDIOGRAPH LEAD SWITCHING ADAPTOR DRW - ADAPTOR, LEAD SWITCHING, ELECTROCARDIOGRAPH
870.2360	ELECTROCARDIOGRAPH ELECTRODE DRX - ELECTRODE, ELECTROCARDIOGRAPH
870.2370	ELECTROCARDIOGRAPH SURFACE ELECTRODE TESTER KRC - TESTER, ELECTRODE, SURFACE, ELECTROCARDIOGRAPHIC
870.2880	ULTRASONIC TRANSDUCER JOP - TRANSDUCER, ULTRASONIC

DENTAL PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
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
872.3200	RESIN TOOTH BONDING AGENT KLE - AGENT, TOOTH BONDING, RESIN
872.3275	DENTAL CEMENT EMA - CEMENT, DENTAL EMB - ZINC OXIDE EUGENOL
872.3660	IMPRESSION MATERIAL ELW - MATERIAL, IMPRESSION
872.3690	TOOTH SHADE RESIN MATERIAL EBF - MATERIAL, TOOTH SHADE, RESIN
872.3710	BASE METAL ALLOY EJH - METAL, BASE

GASTROENTEROLOGY-UROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
876.1075	GASTROENTEROLOGY-UROLOGY BIOPSY INSTRUMENT KNW - INSTRUMENT, BIOPSY FCF - INSTRUMENT, BIOPSY, MECHANICAL, GASTROINTESTINAL FCK - INSTRUMENT, BIOPSY, SUCTION FCI - PUNCH, BIOPSY FCG - SET, BIOPSY NEEDLE AND NEEDLE, GASTRO-UROLOGY
#876.1500	ENDOSCOPE AND ACCESSORIES FEB - ACCESSORIES, CLEANING FOR ENDOSCOPE FER - ANOSCOPE, NON-POWERED FDP - APPARATUS, PNEUMOPERITONEUM, AUTOMATIC FDX - BRUSH, CYTOLOGY, FOR ENDOSCOPE
	FGS - CARRIER, SPONGE, ENDOSCOPIC FBN - CHOLEDOCHOSCOPE, FLEXIBLE OR RIGID FDF - COLONOSCOPE, GASTRO-UROLOGY FTJ - COLONOSCOPE, GENERAL AND PLASTIC SURGERY FFZ - CORD, ELECTRIC, FOR ENDOSCOPE FAJ - CYTOSCOPE, DIAGNOSTIC FBO - CYSTOURETHROSCOPE FDT - DUODEDOSCOPE, ESOPHAGO GASTRO KOG - ENDOSCOPE AND/OR ACCESSORIES GCP - ENDOSCOPE, AC-POWERED AND ACCESSORIES GCS - ENDOSCOPE, BATTERY-POWERED AND ACCESSORIES GCR - ENDOSCOPE, DIRECT VISION GDB - ENDOSCOPE, FIBER OPTIC GCQ - ENDOSCOPE, FLEXIBLE

	GCO - ENDOSCOPE, MIRROR GCN - ENDOSCOPE, PRISM GCM - ENDOSCOPE, RIGID FDA - ENTEROSCOPE GCL - ESOPHAGOSCOPE, GENERAL & PLASTIC SURGERY FDW - ESOPHAGOSCOPE, RIGID, GASTRO-UROLOGY FDS - GASTROSCOPE, GASTRO-UROLOGY GCK - GASTROSCOPE, GENERAL & PLASTIC SURGERY FFS - ILLUMINATOR, FIBEROPTIC, FOR ENDOSCOPE FCX - INSUFFLATOR, AUTOMATIC CARBON-DIOXIDE FOR ENDOSCOPE FHX - JELLY, LUBRICATING, FOR TRANSURETHRAL SURGICAL INSTRUMENT FTI - LAMP, ENDOSCOPE, INCANDESCENT GCI - LARYNGOSCOPE GCT - LIGHT SOURCE, ENDOSCOPIC, XENON ARC FCW - LIGHT SOURCE, FIBEROPTIC, ROUTINE FCQ - LIGHT SOURCE, INCONDESCENT, DIAGNOSTIC FCR - LIGHT SOURCE, PHOTOGRAPHIC, FIBEROPTIC GCH - MEDIASTINOSCOPE FBK - NEEDLE, ENDOSCOPIC FHP - NEEDLE, PNEUMOPERITONEUM, SIMPLE
	FHO - NEEDLE, PNEUMOPERITONEUM, SPRING LOADED FEC - OBTURATOR, FOR ENDOSCOPE FTK - PANCREATOSCOPE, BILIARY FAK - PANENDOSCOPE (GASTRODUODENOSCOPE) FAL - PANENDOSCOPE (URETHROSCOPE) GCG - PERITONEOSCOPE GCF - PROCTOSCOPE FEQ - PUMP, AIR, NON-MANUAL, FOR ENDOSCOPE FJL - RESECTOSCOPE

	FDC - RESECTOSCOPE, WORKING ELEMENT FCC - RETRIEVER, ENDOMAGNETIC FBI - RONGEUR, CYTOSCOPIC KDO - RONGEUR, CYSTOSCOPIC, HOT KGD - SCISSORS FOR CYTOSCOPE FDE - SET, LAPAROSCOPY FGA - SET, NEPHROSCOPE FED - SHEATH, FOR ENDOSCOPE FAM - SIGMOIDOSCOPE, FLEXIBLE FAN - SIGMOIDOSCOPE, RIGID, ELECTRICAL KDM - SIGMOIDOSCOPE, RIGID, NON-ELECTRICAL FDR - SPHYNCTEROSCOPE FET - TAPE, TELEVISION & VIDEO, CLOSED-CIRCUIT, USED DURING ENDOSCOPIC FBP - TELESCOPE, RIGID, ENDOSCOPIC GCW - TRANSFORMER, ENDOSCOPE FGB - URETEROSCOPE FGC - URETHROSCOPE
876.4500	MECHANICAL LITHOTRIPTER LQC - LITHOTRIPTER, BILIARY MECHANICAL FGK - TRIPSOR, STONE, BLADDER
876.5010	BILIARY CATHETER AND ACCESSORIES (biliary stone dislodger only) LQR - DISLODGER, STONE, BILIARY
876.5320	NONIMPLANTED ELECTRICAL CONTINENCE DEVICE KPI - STIMULATOR, ELECTRICAL FOR INCONTINENCE (NON-IMPLANTABLE)
876.5665	WATER PURIFICATION SYSTEM FOR HEMODIALYSIS FIP - SUBSYSTEM, WATER PURIFICATION

GENERAL HOSPITAL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
880.2910	CLINICAL ELECTRONIC THERMOMETER (except tympanic or pacifier) FLL - THERMOMETER, ELECTRONIC, CLINICAL
880.5400	NEONATAL INCUBATOR FMZ - INCUBATOR, NEONATAL
880.5410	NEONATAL TRANSPORT INCUBATOR FPL - INCUBATOR, NEONATAL TRANSPORT
880.5570	HYPODERMIC SINGLE LUMEN NEEDLE MMK - CONTAINER, SHARPS FMI - NEEDLE, HYPODERMIC, SINGLE LUMEN (except anti-stick and self-destruct)
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 MEA - PUMP, INFUSION, PCA (except for combination products regulated under the InterCenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, or the InterCenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.)
880.5860	PISTON SYRINGE FMF - SYRINGE, PISTON
880.6880	STEAM STERILIZER (greater than 2 cubic feet) FLE – STERILIZER, STEAM

NEUROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
882.1240	ECHOENCEPHALOGRAPH GXW - ECHOENCEPHALOGRAPH
882.1320	CUTANEOUS ELECTRODE GXY - ELECTRODE, CUTANEOUS
882.1400	ELECTROENCEPHALOGRAPH GWQ - ELECTROENCEPHALOGRAPH
882.1480	NEUROLOGICAL ENDOSCOPE GWG - ENDOSCOPE, NEUROLOGICAL
882.5890	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR FOR PAIN RELIEF GZJ - STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF

OBSTETRICS AND GYNECOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
884.1690	HYSTEROSCOPE AND ACCESSORIES HIH - HYSTEROSCOPE (AND ACCESSORIES)
884.1720	GYNECOLOGIC LAPAROSCOPE AND ACCESSORIES HET - LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)
884.2225	OBSTETRIC-GYNECOLOGIC ULTRASONIC IMAGER HEN - CALIPER, FETAL HEAD, ULTRASONIC HHX - HOLOGRAPH, FETAL ACOUSTICAL HEM - IMAGER, ULTRASONIC OBSTETRIC-GYNECOLOGIC HHJ - LOCATOR, INTRACORPOREAL DEVICE, ULTRASONIC

#884.2660	FETAL ULTRASONIC MONITOR AND ACCESSORIES HEP - MONITOR, BLOOD-FLOW, ULTRASONIC HEL - MONITOR, HEART RATE, FETAL, ULTRASONIC HEK - MONITOR, HEART SOUND, FETAL, ULTRASONIC HEI - MONITOR, HEART-VALVE MOVEMENT, FETAL, ULTRASONIC HEJ - MONITOR, HEMIC SOUND, ULTRASONIC HEQ - MONITOR, PRESSURE, ARTERIAL, FETAL, ULTRASONIC KNG - MONITOR, ULTRASONIC, FETAL
884.2960	OBSTETRIC ULTRASONIC TRANSDUCER AND ACCESSORIES HGL - TRANSDUCER, ULTRASONIC, OBSTETRIC
884.5300	CONDOM HIS - CONDOM

OPHTHALMOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
886.1570	OPHTHALMOSCOPE HLI - OPHTHALMOSCOPE, AC-POWERED HLJ - OPHTHALMOSCOPE, BATTERY-POWERED
886.1780	RETINOSCOPE HKL - RETINOSCOPE, AC-POWERED
886.1850	AC-POWERED SLIT-LAMP BIOMICROSCOPE HJO - BIOMICROSCOPE, SLIT-LAMP, AC-POWERED

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
886.4670	PHACOFRAGMENTATION SYSTEM HQC - UNIT, PHACOFRAGMENTATION

ORTHOPEDIC PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
888.1100	ARTHROSCOPE HRX - ARTHROSCOPE AND ACCESSORIES

RADIOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
#884.2660	FETAL ULTRASONIC MONITOR AND ACCESSORIES LXE - DOPPLER, FETAL ULTRASOUND MAA - MONITOR, FETAL DOPPLER ULTRASOUND
892.1000	MAGNETIC RESONANCE DIAGNOSTIC DEVICE MOS - COIL, MAGNETIC RESONANCE, SPECIALTY LNH - SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING LNI - SYSTEM, NUCLEAR MAGNETIC RESONANCE SPECTROSCOPIC

892.1200	EMISSION COMPUTED TOMOGRAPHY SYSTEM KPS - SYSTEM, TOMOGRAPHY, COMPUTED, EMISSION
892.1310	NUCLEAR TOMOGRAPHY SYSTEM JWM - SYSTEM, TOMOGRAPHY, COMPUTED, EMISSION
892.1360	RADIONUCLIDE DOSE CALIBRATOR KPT - CALIBRATOR, DOSE, RADIONUCLIDE
892.1540	NONFETAL ULTRASONIC MONITOR JAF - MONITOR, ULTRASONIC, NONFETAL
892.1550	ULTRASONIC PULSED DOPPLER IMAGING SYSTEM IYN - SYSTEM, IMAGING, PULSED DOPPLER, ULTRASONIC
892.1560	ULTRASONIC PULSED ECHO IMAGING SYSTEM IYO - SYSTEM, IMAGING, PULSED ECHO, ULTRASONIC
892.1570	DIAGNOSTIC ULTRASONIC TRANSDUCER ITX - TRANSDUCER, ULTRASONIC, DIAGNOSTIC
892.1600	ANGIOGRAPHIC X-RAY SYSTEM IZI - SYSTEM, X-RAY, ANGIOGRAPHIC
892.1610	DIAGNOSTIC X-RAY BEAM LIMITING DEVICE IZS - APERTURE, RADIOGRAPHIC IZW - COLLIMATOR, AUTOMATIC, RADIOGRAPHIC IZX - COLLIMATOR, MANUAL, RADIOGRAPHIC IZT - CONE, RADIOGRAPHIC KPW - DEVICE, BEAM LIMITING, X-RAY, DIAGNOSTIC
892.1620	CINE OR SPOT FLUOROGRAPHIC X-RAY CAMERA IZJ - CAMERA, X-RAY, FLUOROGRAPHIC, CINE OR SPOT
892.1630	ELECTROSTATIC X-RAY IMAGING SYSTEM IXK - SYSTEM, IMAGING, X-RAY, ELECTROSTATIC
892.1650	IMAGE-INTENSIFIED FLUOROSCOPIC X-RAY SYSTEM (except solid state) JAA - SYSTEM, X-RAY, FLUOROSCOPIC, IMAGE-INTENSIFIED

892.1670	SPOT FILM DEVICE IXL - DEVICE, SPOT-FILM
892.1680	STATIONARY X-RAY SYSTEM KPR - SYSTEM, X-RAY, STATIONARY
892.1720	MOBILE X-RAY SYSTEM IZL - SYSTEM, X-RAY, MOBILE
892.1740	TOMOGRAPHIC X-RAY SYSTEM IZF - SYSTEM, X-RAY, TOMOGRAPHIC
892.1750	COMPUTED TOMOGRAPHY X-RAY SYSTEM JAK - SYSTEM, X-RAY, TOMOGRAPHY, COMPUTED
892.1820	PNEUMOENCEPHALOGRAPHIC CHAIR HBK - CHAIR, PNEUMOENCEPHALOGRAPHIC
892.1850	RADIOGRAPHIC FILM CASSETTE IXA - CASSETTE, RADIOGRAPHIC FILM
892.1860	RADIOGRAPHIC FILM/CASSETTE CHANGER KPX - CHANGER, RADIOGRAPHIC FILM/CASSETTE
892.1870	RADIOGRAPHIC FILM/CASSETTE CHANGER PROGRAMMER IZP - PROGRAMMER, CHANGER, FILM/CASSETTE, RADIOGRAPHIC
892.1900	AUTOMATIC RADIOGRAPHIC FILM PROCESSOR EGT - CONTROLLER, TEMPERATURE, RADIOGRAPHIC EGW - DRYER, FILM, RADIOGRAPHIC IXX - PROCESSOR, CINE FILM IXW - PROCESSOR, RADIOGRAPHIC-FILM, AUTOMATIC EGY - PROCESSOR, RADIOGRAPHIC-FILM, AUTOMATIC, DENTAL

GENERAL AND PLASTIC SURGERY PANEL

SECTION	REGULATION NAME PRODUCT CODE - DEVICE NAME

#876.1500	ENDOSCOPE AND ACCESSORIES GCJ - LAPAROSCOPE, GENERAL AND PLASTIC SURGERY
878.4400	ELECTROSURGICAL CUTTING AND COAGULATION DEVICE AND ACCESSORIES HAM - APPARATUS, ELECTROSURGICAL GEI - DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES JOS - ELECTRODE, ELECTROSURGICAL JOT - ELECTRODE, GEL, ELECTROSURGICAL DWG - ELECTROSURGICAL DEVICE BWA - UNIT, ELECTROSURGICAL AND COAGULATION, WITH ACCESSORIES
878.4580	SURGICAL LAMP HBI - ILLUMINATOR, FIBEROPTIC, SURGICAL FIELD FTF - ILLUMINATOR, NON-REMOTE 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
878.4780	POWERED SUCTION PUMP JCX - APPARATUS, SUCTION, WARD USE, PORTABLE, AC-POWERED BTA - PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)