CHAPTER 3

END OF TRANSITION PERIOD

Article 9

Equivalence Assessment

1. In the final six months of the transition period, the Parties shall proceed to a joint assessment of the equivalence of the CABs that participated in the confidence building activities. CABs will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CABs may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this Annex and with regard to any type of product covered by this Annex. The parties shall develop a list contained in Appendix 5 of CABs 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.

2. The Parties shall allow CABs not listed for participation in the MRA, or listed for participation only as to certain types of evaluations, to apply for participation in this MRA once the necessary measures have been taken or sufficient experience has been gained, in accordance with Article 16.

3. Decisions concerning the equivalence of CABs must be agreed to by both Parties.

CHAPTER 4

OPERATIONAL PERIOD

Article 10

Start of the operational period

1. The operational period will start at the end of the transition period after the Parties have developed the list of CABs found to be equivalent. The provisions of this Chapter will apply only with regard to listed CABs and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

2. The operational period will apply to quality system evaluation reports and product evaluation reports generated by CABs listed in accordance with this Annex for the evaluations performed in the respective territories of the Parties, except if the Parties agree otherwise.

Article 11

Exchange and endorsement of quality system evaluation reports

1. Listed EC CABs will provide FDA with reports of quality system evaluations, as follows:

   (a) For pre-approval quality system evaluations, EC CABs will provide full reports; and

   (b) For surveillance quality system evaluations, EC CABs will provide abbreviated reports.

2. Listed U.S. CABs will provide to the EC Notified Body of the manufacturer's choice:

   (a) Full reports of initial quality system evaluations;

   (b) Abbreviated reports of quality systems surveillance audits.

3. If the abbreviated reports do not provide sufficient information, the importing Party may request additional clarification from the CAB.

4. Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CABs 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 post-market 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 re-inspection. The Parties will endeavour 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.

Article 12

Exchange and endorsement of product evaluation reports

1. EC CABs listed for this purpose will, subject to the specifications and limitations on the list, provide to the FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

2. U.S. CABs 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.

3. Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CABs 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 re-evaluation. The parties will endeavour to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing Party.

Article 13

Transmission of quality system evaluation reports

Quality system evaluation reports covered by Article 11 concerning products covered by this Annex 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.

Article 14

Transmission of product evaluation reports

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

Article 15

Monitoring continued equivalence

Monitoring activities will be carried out in accordance with Article 10 of the Agreement.

Article 16

Listing of Additional CABs

1. During the operational period, additional CABs will be considered for equivalence using the procedures and criteria described in Articles 6, 7, and 9 of this Annex, taking into account the level of confidence gained in the overall regulatory system of the other Party.

2. Once a designating authority considers that such CABs, having undergone the procedures of Articles 6, 7, and 9 of this Annex, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of Article 7(a) and (b) of the Agreement.

3. Following such annual designations, the procedures for confirmation of CABs under Articles 7(c) and (d) of the Agreement shall apply.

CHAPTER 5

JOINT SECTORAL COMMITTEE

Article 17

Role and composition of the Joint Sectoral Committee

1. A Joint Sectoral Management Committee is set up to monitor the activities under both the transitional and operational phases of this Annex.

2. The Committee will be co-chaired by a representative of the FDA for the U.S. and a representative of the EC who will each have one vote. Decisions will be taken by unanimous consent.

3. The JSC's functions will include:

   (a) making a joint assessment of the equivalence of CABs;

   (b) developing and maintaining the list of equivalent CABs, including any limitation in terms of their scope of activities and communicating the list to all authorities and the Joint Committee;

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

(d) consideration of the issue of suspension.

CHAPTER 6

HARMONIZATION AND INFORMATION EXCHANGE

Article 18

Harmonization

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

Article 19

Regulatory cooperation

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.

The Parties shall notify each other in writing of any changes to Appendix 1.

Article 20

Alert system and exchange of post-market vigilance reports

1. 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 to be attached to this Sectoral Annex. 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.

2. 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 1

RELEVANT LEGISLATION, REGULATIONS AND PROCEDURES

1. For the European Community the following legislation applies to Article 2(1):

   (a) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. Conformity assessment procedures.
   *Annex II (with the exception of section 4)
   *Annex IV
   *Annex V

   (b) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Conformity assessment procedures.
   *Annex II (with the exception of section 4)
   *Annex III
   *Annex IV
   *Annex V
   *Annex VI

2. For the United States, the following legislation applies to Article 2(1):

   (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 C.F.R., in particular, Parts 800 to 1299.

   (d) Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program, 61 Fed. Reg. 14,789-14,796 (April 3, 1996).

APPENDIX 2

SCOPE OF PRODUCT COVERAGE

1. Initial Coverage of the Transition Period:

Upon entry into force of this Annex, ([1]) products qualifying for the transitional arrangements under this Agreement 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:

() It is understood that the date of entry into force will not occur prior to 1 June 1998, unless the Parties decide otherwise.

(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 the 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 U.S.

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

TABLE 1

CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS
IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE
AT BEGINNING OF TRANSITION PERIOD

ANESTHESIOLOGY PANEL (868)

Section No.	Regulation Name Product Code – Device Name
868.1910	ESOPHAGEAL STETHOSCOPE BZW – STETHOSCOPE, ESOPHAGEAL
868.5620	BREATHING MOUTHPIECE BYP – MOUTHPIECE, BREATHING

868.5640	MEDICINAL NONVENTILATORY NEBULIZER (ATOMIZER) CCQ – NEBULIZER, MEDICINAL, NON-VENTILATORY (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

Section No.	Regulation Name Product Code – Device Name

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(NONE)

DENTAL PANEL (872)

Section No.	Regulation Name Product Code – Device Name
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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 HANDPIECES 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 EIA – UNIT, OPERATIVE DENTAL

EAR, NOSE, AND THROAT PANEL (874)

Section No.	Regulation Name Product Code – Device Name
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	ANTI-STAMMERING DEVICE KTH – DEVICE, ANTI-STAMMERING

GASTROENTEROLOGY – UROLOGY PANEL (876)

Section No.	Regulation Name Product Code – Device Name
876.5160	UROLOGICAL CLAMPS 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 (880)

Section No.	Regulation Name Product Code – Device Name
880.5270	NEONATAL EYE PAD FOK – PAD, NEONATAL EYE

880.5420	PRESSURE INFUSER FOR 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 (882)

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
882.4650	NEUROSURGICAL SUTURE NEEDLE HAS – NEEDLE, NEUROSURGICAL SUTURE
882.4750	SKULL PUNCH GXJ – PUNCH, SKULL

OBSTETRICS AND GYNECOLOGY PANEL

Section No.	Regulation Name Product Code – Device Name

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(NONE)

OPHTHALMOLOGY PANEL (886)

Section No.	Regulation Name Product Code – Device Name

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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
886.4300	KERATONE HNO – KERATONE, AC-POWERED HMY – KERATONE, BATTERY-POWERED
886.5850	SUNGLASSES (NON-PRESCRIPTION) HQY – SUNGLASSES (NON-PRESCRIPTION INCLUDING PHOTOSENSITIVE)

ORTHOPEDIC PANEL (888)

Section No.	Regulation Name Product Code – Device Name

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888.1500	AC-POWERED GONIOMETER KQX – GONIOMETER, AC-POWERED
888.4150	CALLIPERS FOR CLINICAL USE KTZ – CALLIPER

PHYSICAL MEDICINE PANEL (890)

Section No.	Regulation Name Product Code – Device Name
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 (892)

Section No.	Regulation Name Product Code – Device Name
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 WAM – 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