Concurrent preparation for the conformity assessment of KFDA, CE and FDA

April, 2011

Table of contents

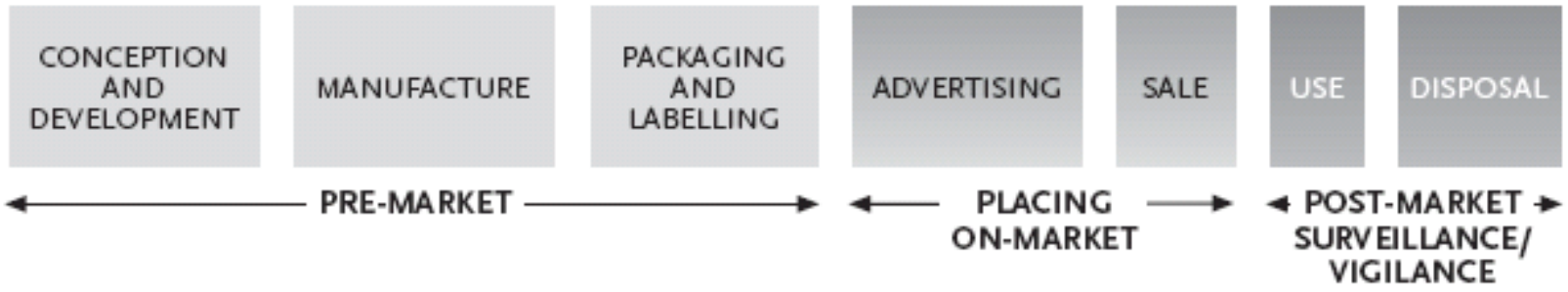
I. Medical device safety and governmental regulation

Participants in ensuring the safety of medical device

Interested parties of medical devices in Korea, EU and USA

Korea	EU	USA
Medical Device Act	Medical Device Directive	Federal Food Drug & Cosmetic Act
Manufacturer	Manufacturer	Manufacturer
Registered Importer	Authorised Representative	U.S. Agents
KFDA	Notified Body	FDA
Medical Device Technical Document Review Agency		Third Party

Common stages of government regulations



Common framework for medical device regulations

STAGE	PRE-MARKET	PLACING ON-MARKET	POST-MARKET
CONTROL/ MONITOR	**PRODUCT**	**SALE**	**AFTER-SALE/USE**
PERSON	**MANUFACTURER**	**VENDOR**	**VENDOR/USER**
Items or activities regulated	**Device attributes** • Safety and performance	**Establishment registration** • List products available or in use • Requires vendor to fulfill after-sale obligations	**Surveillance/vigilance** • After-sale obligations • Monitoring of device's clinical performance • Problem identification and alerts
	Manufacturing • Quality systems		
	Labelling • Accurate description of product • Instructions for use	**Advertising** • Prohibits misleading or fraudulent advertisement	

II. Comparison of conformity assessment procedure

1. Definition of Medical Device

Korea (Medical Device Act)

Chapter 1, Article 2

For the purpose of this Act, the term "medical device" means any instrument, machine, contrivance, material or similar article that is used on human beings or animals either alone or in combination with other devices and that falls under any of the following Items provided below. However, drugs or quasi-drugs under the Pharmaceutical Affairs Act or, among the disabled-assistive-devices under Article 65 of the Act for Welfare of the Disabled, artificial limbs and orthotics shall be excluded:

1. Articles used for the purpose of diagnosis, cure, alleviation, treatment, or prevention of illness;
2. Articles used for the purpose of diagnosis, cure or alleviation of or compensation for an injury or disability;
3. Articles used for the purpose of test, replacement, or modification of the structure or functions [of the body]; or
4. Articles used for the purpose of control of conception.

1. Definition of Medical Device

EU (Medical Device Directive – 93/42/EEC amended by 2007/47/EC)

Article 1

'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

1. Definition of Medical Device

USA (the Federal Food Drug & Cosmetic Act)

201(h)

A device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

2. Classification of Medical Device

Korea	EU	USA
KFDA Notification No. 2010-91	MDD Annex IX	21 CFR 862-892
Class 1 Class 2 Class 3 Class 4	Class I , Class I (sterile, measure)* Class IIa Class IIb Class III	Class I Class II Class III
- Classification of medical devices are already defined.	- Classify according to the classification Rule (Rule 1 ~ Rule 18)	- Classification of medical devices are already defined.

Example of classification

Compressible Limb Therapy System

Example of classification (Korea)

KFDA notification No. 2010-91
Regulation to the classification of medical devices

A17000
Cardiovascular devices

A17100.01
Compression system pump, sequential

[Class 2]

Example of classification (EU)

1. Time

- **Transient** - Normally intended for continuous use for less than 60 minutes.
- **Short term** - Normally intended for continuous use for not more than 30 days.
- **Long term** - Normally intended for continuous use for more than 30 days.

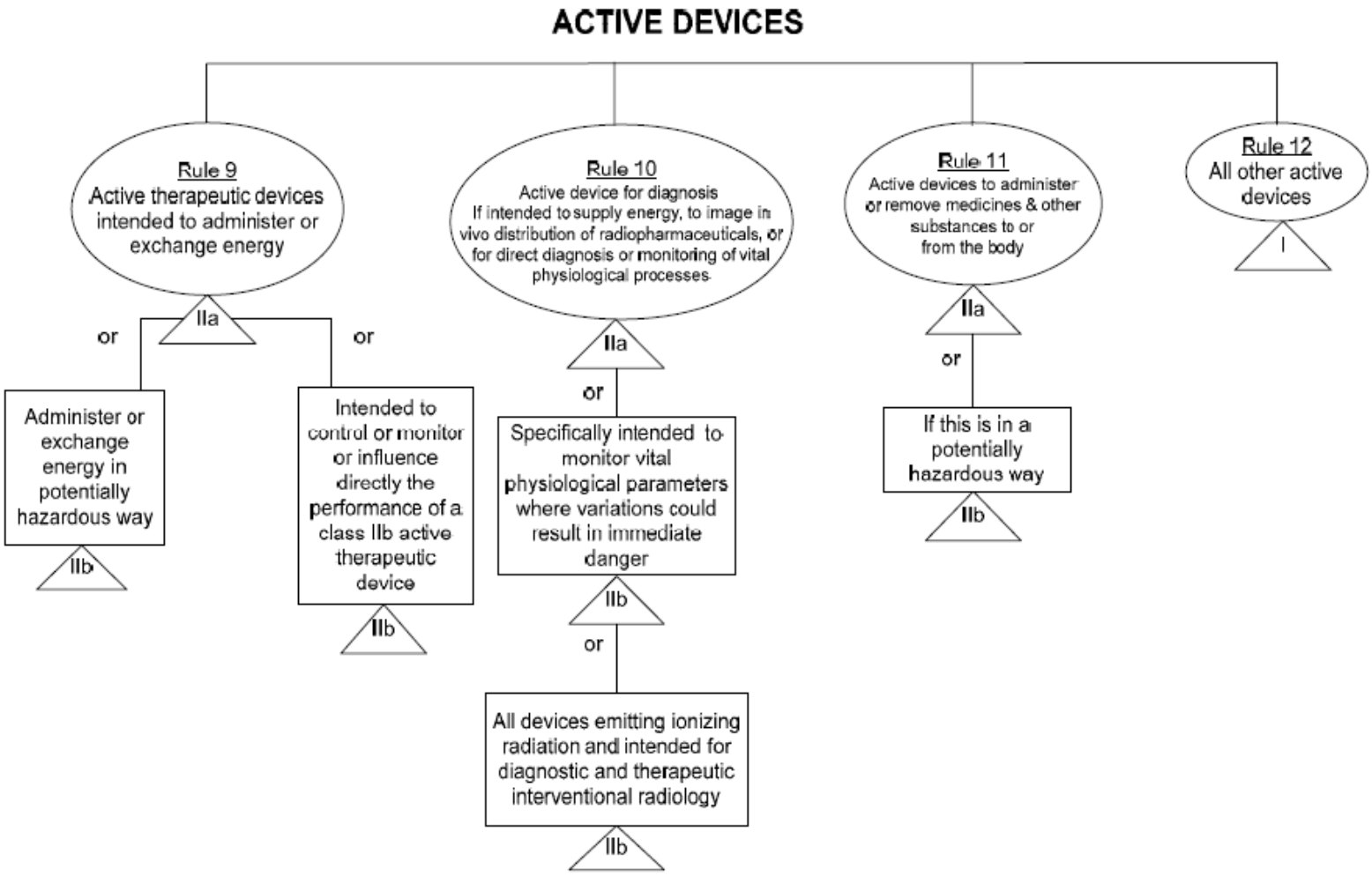
2. Invasiveness

3. Active devices

4. Devices with a measuring function

SUBJECTS
Non invasive devices – Rules 1, 2, 3, 4
Invasive devices – Rules 5, 6, 7, 8
Active devices – Rules 9, 10, 11, 12
Special rules – Rules 13, 14, 15, 16, 17, 18

Example of classification (EU)



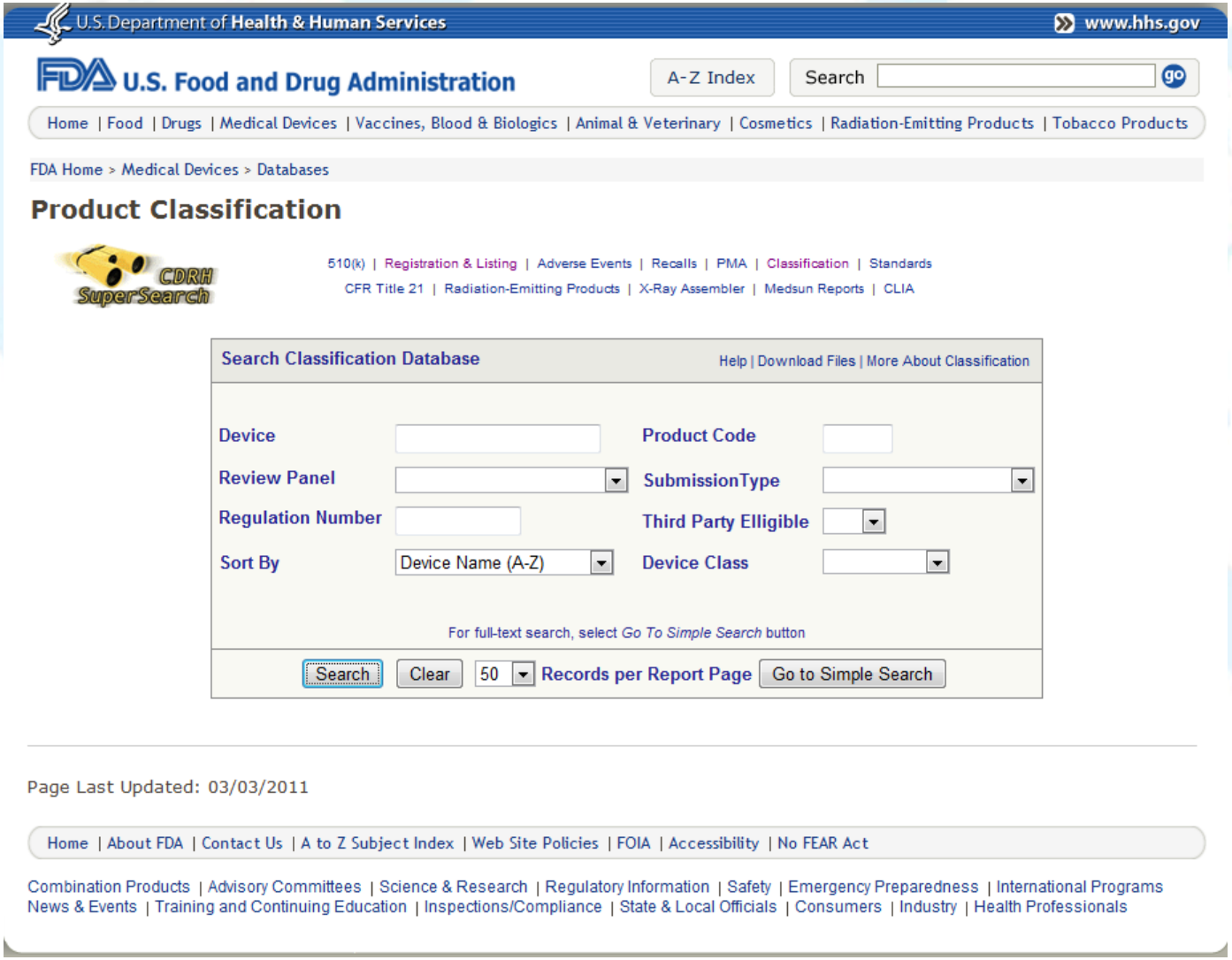
Example of classification (EU)

Class IIa

Rule 9 - Active therapeutic devices intended to administer or exchange energy

RULE 9	EXAMPLES
All active therapeutic devices intended to administer or exchange energy are in Class IIa	Electrical and/or magnetic and electromagnetic energy - Muscle stimulators - External bone growth stimulators - TENS devices - Eye electromagnets - Electrical acupuncture Thermal energy - Cryosurgery equipment. - Heat exchangers, except the types described below Mechanical energy - Powered dermatomes - Powered drills - Dental hand pieces. Light - Phototherapy for skin treatment and for neonatal care Sound - Hearing aids Ultrasound - Equipment for physiotherapy

Example of classification (USA)



Example of classification (USA)

Class 2

New Search | Back To Search Results

Device	Massager, Powered Inflatable Tube
Regulation Description	Powered inflatable tube massager.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	IRP
Submission Type	510(k)
Regulation Number	890.5650
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

- Eligible for *Accredited Persons Expansion Pilot Program*

Accredited Persons

- Intertek Testing Services
- Kema Quality B.v.
- Regulatory Technology Services, Llc
- Tuv Rheinland Of North America, Inc.
- Tuv Sud America Inc.
- Underwriters Laboratories, Inc.

3. Conformity assessment procedure (Korea)

Class of medical devices	Risk classification	Approval or Certification
Class 4	High risk	Product approval by KFDA Clinical data
Class 3	Medium risk	Product approval by KFDA
Class 2	Low risk	Product approval by KFDA
		Technical document review by Review Agency
Class 1	Extremely low risk	Product notification to KFDA

3. Conformity assessment procedure (EU)

Medical Device Directive 93/42/EEC amended by 2007/47/EC
Article 11, Conformity assessment procedures

CONFORMITY ASSESSMENT PROCEDURES	CLASSES					
ANNEXES	I	I Sterile	I measure	IIa	IIb	III
II (+ section 4)						√
II (- section 4)		√	√	√	√	
III					√	√
IV		√	√	√	√	√
V		√	√	√	√	√
VI		√	√	√	√	
VII	√	√	√	√		

3. Conformity assessment procedure (EU)

- **In case of Class IIa**

- **Select a conformity assessment procedure as follow;**

  1. Annex II (- Section 4)
  2. Annex IV + Annex VII
  3. Annex V + Annex VII
  4. Annex VI + Annex VII

- **Type of certificate**

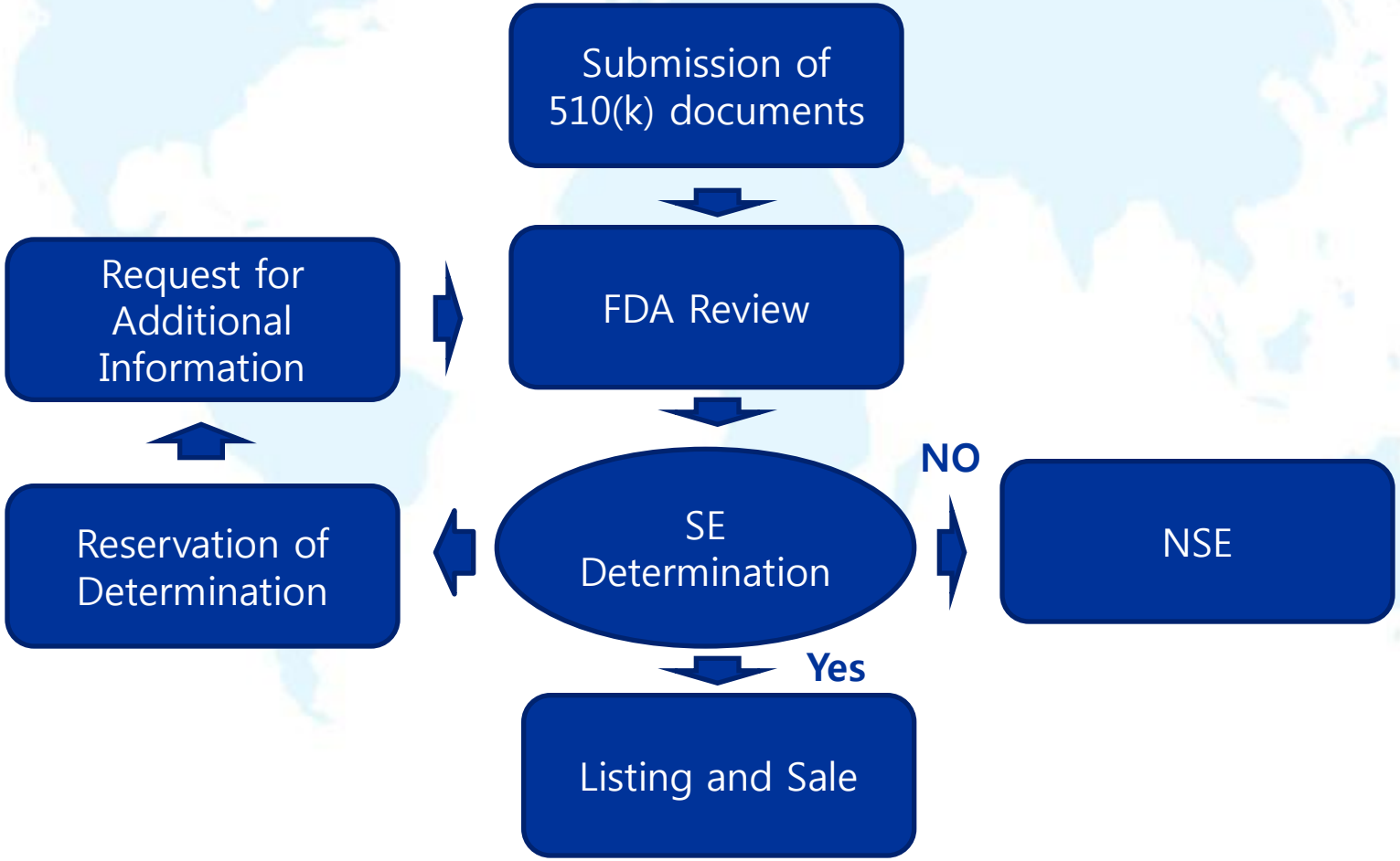
  - **Full Quality Assurance System Approval Certificate** (Annex II)
  - **EC Verification Certificate (**Annex IV)
  - **Production Quality Assurance System Approval Certificate** (Annex V)
  - **Product Quality Assurance System Approval Certificate** (Annex VI)

3. Conformity assessment procedure (USA)

Class of Medical Device	Assessment Procedure
Class I & Class II Exempt	No submission required.
Class I	510k or premarket notification
Class II	510k or premarket notification
Class III	Premarket Approval (PMA)

3. Conformity assessment procedure (USA)

510(k) Procedure



4. Applied standards

Korea	EU	USA
▪ Common Standards and Specifications for Electromechanical Safety of Medical Devices ▪ Common Standards and Specifications for Biological Safety of Medical Devices ▪ Common Standards and Specifications for Electromagnetic Safety of Medical Devices ▪ International standards(ISO, IEC)	▪ Harmonized Standard (EN) ▪ International standards(ISO, IEC etc.)	▪ International standards(ISO, IEC etc.) ▪ National standards and association standards (ANSI, ASTM etc.)

Example of applied standard (EU)

EN 60601-1:1990 and its amendments

Medical electrical equipment -- Part 1: General requirements for safety
IEC 60601-1:1988

EN 60601-1:2006

Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2005

EN 60601-1-2:2007

Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-2:2007 (Modified)

EN 60601-1-4:1996

Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
IEC 60601-1-4:1996

EN 60601-1-6:2007

Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-6:2006

EN ISO 14971:2007

Medical devices - Application of risk management to medical devices (ISO 14971:2007)

Example of applied standard (USA)

H Standard / Guidance Document Referenced (if applicable)

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- IEC 980 2003, Graphical symbols for use in the labeling of medical devices
- IEC1041 1998, Information supplied by the manufacturer with medical devices
- ISO 13485 2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14155-1 2003, Clinical investigation of medical devices for human subjects - Part 1 General requirements
- ISO 14971 2000/A1 2003, Medical devices - Application of risk management to medical devices
- IEC 60601-1 1990/A1 93/A295/A13 96, Medical electrical equipment - Part 1 General requirements for safety (IEC 60601-1 1988/A1 91/A2 95)
- IEC 60601-2-10 2000/A1 01, Medical electrical equipment - Part 2-10 Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-1-2 2001, Medical electrical equipment - Part 1 General requirements for safety - Collateral standard Electromagnetic compatibility - Requirements and tests

5. Technical File and submission documents

References

- **NB-MED/2.5.1/Rec5**
  Technical Documentation

- **510(k) Submission Process**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm

Technical File (EU)

1. General

- Content of technical documentation

2. Product Description

- a general description of the device(s)
- a description of the intended use and operation of the device(s)
- description of the methods of manufacture envisaged
- description of the accessories, adaptors and other devices or
- equipment and other interfaces which are intended by the
- manufacturer to be used in combination with the device(s)
- classification of the device under the relevant Directive

Technical File (EU)

3. Technical Requirements

- Identification of technical requirements
- Solutions adopted to fulfil the essential requirements
- Standards applied

4. Design

- the results of the risk analysis
- specification of materials, and manufacturing/special processing
- specifications, drawings and circuit diagrams for components,
- sub-assemblies and the complete product including packaging, where appropriate.
- the specifications of the checks, tests and trials that are intended to be carried out as part of routine production

Technical File (EU)

4. Design

- the performances and compatibilities intended by the Manufacturer
- labelling, including any instructions for use
- identification of ‘shelf-life’ reflected by any ‘use by’ date, or other ‘lifetime’ of the device(s)
- Results of Bench Testing
- Clinical data
- Documentation and reporting of Design Changes

Example of Technical file contents

- General description of the device
- Description of intended use
- Class of device, chosen classification rule and justification
- Description of accessories (if applicable)
- Description of incorporated pharmaceutical substances (if applicable)
- Description of utilized tissues of animal origin (if applicable)
- Planned production methods
- Description of checks during and at the end of production
- Responses to essential requirements
- List of applied standards

Example of Technical file contents

- Risk analysis
- Specification of materials
- Drawings and schematics
- Labelling
- Description of packaging
- Instructions for use
- Lifetime and/or shelf-life
- Sterilization validation (if applicable)
- Software validation (if applicable)
- Test reports (electrical / mechanical / biocompatibility etc.)
- Clinical data
- Project for EC declaration of conformity

Information requested in 510k (21 CFR 807.87)

- Submitter's name, address, phone/fax, contract person
- Device classification name, regulation number, device class.
- Common/usual name and trade/proprietary name and model number.
- Identification of marketed device to which equivalence is claimed.

Information requested in 510k (21 CFR 807.87)

- Copy of Medical device user Fee Cover sheet
- CDRH Premarket review submission cover sheet
- Indication for use statement
- Truthful and Accurate statement
- Labeling

Technical document request

- Picture, engineering drawings
- Performance Data(bench, animal, clinical)
- Sterilization, Software information
- Address information requested in specific guidance documents
- Standards Data Report (FDA form 3654)
- If 510(k) has clinical trial (FDA form 3674)

General Document List for 510(k)Submission

1. Medical Device User Fee Cover Sheet
2. CDRH PMA Cover sheet
3. 510(k) Cover Letter
4. Indication for Use
5. 510(k) Summary or Statement
6. Truthful and accurate statement
7. Safety and Effectiveness Statement
8. Label and Package
9. User Manual
10. Product Description
11. Substantial Equivalence Report
12. Clinical Data
13. Test Reports

When FDA requests additional information

- Incomplete application (reject application)
- Test reports are required to prove substantial equivalence
- Review Period: 90 days (working day)
- Additional information should be submitted within 30 days
- Deadline can be extended by written request (up to 6 months)

- Deadline cannot be extended via FAX or email

6. Quality system

Korea	EU	Japan
KFDA Notification No. 2010-93(Amended on December 27, 2010) **Standards for Manufacture, Import and Quality Management of Medical Device**	**EN ISO 13485: 2003**	**21 CFR Part 820** **Quality System Regulation (QS)/** **Good Manufacturing Practices (GMP)**
	Annex II Section 3 (Quality system) Section 5 (Surveillance)	
	Annex V Section 3 (Quality system) Section 4 (Surveillance)	
	Annex VI Section 3 (Quality system) Section 4 (Surveillance)	

III. Concurrent Preparation strategy

Effective Way?

Plan to reduce assessment time and cut costs

1. Use test reports at the same time
   - CB test report
   - GLP report
   - Accredited testing laboratory

2. Shorten preparation time of technical file by using existing technical file.

3. Establish quality management system which fulfill KFDA, EU and USA requirements.
   - ISO 13485: 2003 & QSR requirement

Thank you.

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