

# **Concurrent FDA 510 k and CE/MDD Assessment process**

Sim Sang-Woo

Institute for Testing and Certification(ITC)  
ASIA

- 1. Requirement of Regulation**
- 2. FDA Assessment process**
- 3. CE/MDD Assessment process**
- 4. FDA and CE/MDD QSR Requirement**
- 5. Post-Market Surveillance Requirement**

# Requirement of Regulation

# Considered Requirement of Regulation

- Development new product
- Considered Requirement of Regulation when it start
- Failed If can not satisfied the regulation requirement.
- Risk to bankrupts cause of waste money.
- Need to agenda to meet the regulation as marketing strategy when it start

# Both of major market has different system

- Most of company want into US and EU market.
- Unfortunately both have different way of system
- Risk to patient is measurement of classification.
- Slightly different to consider a classification.
- Evaluated the product which has guidance as their classification.

# **FDA Assessment Process**

# FDA Classes

- Class I
  - Class II
  - Class III
- 
- Decide to Intended use

# FDA Classes

[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

**Search Classification Database** [Help](#) | [Download Files](#) | [More About Classification](#)

<b>Device</b>	<input type="text"/>	<b>Product Code</b>	<input type="text"/>
<b>Review Panel</b>	<input type="text" value="v"/>	<b>Submission Type</b>	<input type="text" value="v"/>
<b>Regulation Number</b>	<input type="text"/>	<b>Third Party Eligible</b>	<input type="text" value="v"/>
<b>Sort By</b>	<input type="text" value="Device Name (A-Z)"/>	<b>Device Class</b>	<input type="text" value="v"/>

For full-text search, select *Go To Simple Search* button

**Records per Report Page**

# FDA classification

## Class I: General controls

### General controls

- Registration (FY 2009 Fee: \$ 1,851)
- Listing
- Require a 21 CFR 820 or QSR
- Labeling according to 21 CFR 801 or 809
- 510(K) submission (premarket notification)

# FDA Classification

## **Class II: General controls and special controls**

### **Special controls**

- Require an additional labeling
- Request to standard and Guidance.
- Premarket surveillance

# FDA Classification

**Class III: General controls and premarket approval**

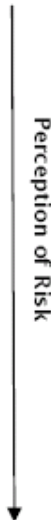
**Premarket approval (PMA)**

-Review the document which is considered safe and effective

# FDA classification and guideline

Class	Controls to Demonstrate Safety & Effectiveness	510(k)?	Prior Notifications/Certifications	FDA Response Time to 510(k)	Notes & Comments
I	General	Most exempt	None	N/A	Quality system must meet requirements of QSR, but many in this class exempt from design control aspects (Section 820.30)  Compliance with QSR is self-imposed, but may be subject to FDA inspection
	<ul style="list-style-type: none"> <li>• Manufacturer establishment registration (\$1,706 per year)</li> <li>• Listing of devices</li> <li>• Compliance with quality system requirements [Title 21 of the U.S. Code of Federal Regulations (CFR), Part 820 (21 CFR 820 or QSR)]</li> <li>• Labeling in accordance with 21 CFR 801 or 809</li> <li>• Submission of premarket notification, a 510(k)</li> </ul>				
II	General and special	Yes	At least 90 days before intended introduction of device to the U.S. market	Within 90 days if approved as received	510(k) submission discount available to both U.S. and non-U.S. companies  FDA reviewers work with the submitter to avoid delays
	General (see above) Special <ul style="list-style-type: none"> <li>• Additional labeling requirements</li> <li>• Conform with mandatory or voluntary standards or FDA</li> </ul>	\$3,404 (\$1,702 for "small businesses")		If clarification required, 90 days begins again	

Lower



# FDA classification and guideline

Class	Controls to Demonstrate Safety & Effectiveness	510(k)?	Prior Notifications/Certifications	FDA Response Time to 510(k)	Notes & Comments
	guidance documents • Requirement to conduct specified postmarket surveillance activities				
III	General and premarket approval (PMA) General (see Class I) PMA • Detailed scientific review process (carried out by FDA) of data submitted by the manufacturer	Yes \$185,000 (\$46,250 for "small businesses") Fee waived for first PMA submitted by a company (if turnover less than \$30 million)	Detailed submission including provision of clinical data to demonstrate safety and effectiveness Planned clinical studies need to be carried out in compliance with FDA-approved protocol	180 working days from receipt if approved as received 320 days if additional information required	FDA may inspect manufacturer's facility for compliance with the QSR prior to approval Marketing not approved until acceptable response to any observed nonconformities has been lodged with FDA

Higher

# Exemption of requirements of Class I product

- Many Class I (75%) exempted the 510(k)
- Class I product which is exempted 510k is easy to into US
- No certificate and surveillance audit
- Example of exempted 510(k) and GMP

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm>

## Class II and 510(k)

- Aim of 510(k) is approved substantially equivalent with Predicate
- No special guidance to submit a 510(k)
- Request to 510k:
  - Details of product
  - Substantially equivalent with Predicate

# 510(k) data

- Preparation time of 510(k)
- **Require a data:** Specification of product, Comparison with Predicate devices, bench test, Animal and clinical data.
- **Submission fee:** \$ 3,693 (FY2009), "small businesses fee: \$ 1,847"
- **FDA review date :** 90 working day

# Class III : Pre-market approval (PMA)

- Most of Class III should be performed the pre-market approval (PMA).
- **Require a data:** Specification of product. IDE and clinical data.
- **Submission fee:** \$200,725 (FY2009), "small businesses." \$50,181
- **FDA review:** 180 days. Additional request: 320days

# FDA Classification

- Classified as its intended use
- Basic model.
- Low risk
- Low classification

# **CE/MDD Assessment process**

# CE/MDD Class

- Classified by Rule
- FDA has product cord.
- Classification of CE/MDD

**Class I:** Lowest risk

**Class IIa:** Intermediate risk

**Class IIb:** Higher intermediate risk

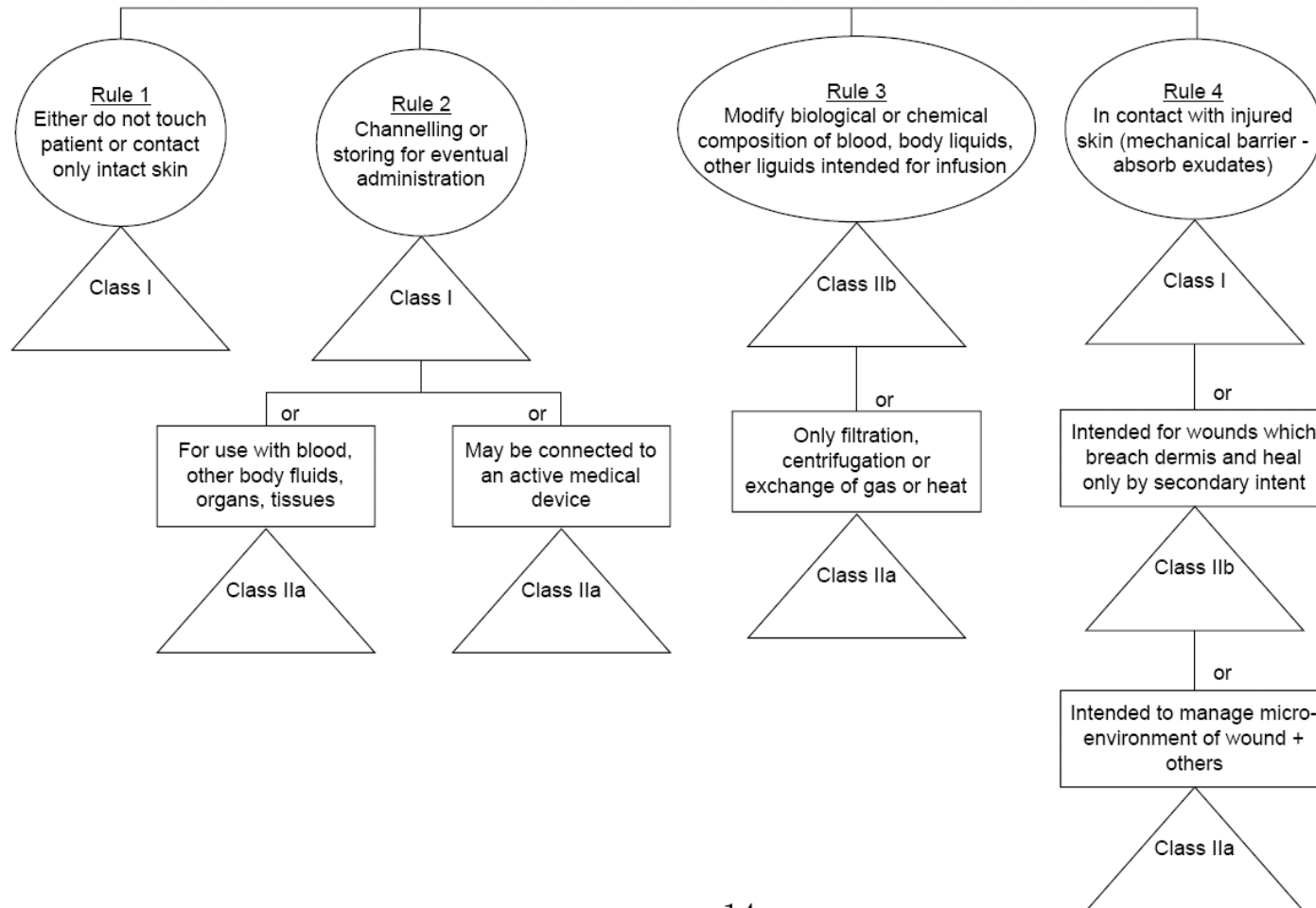
**Class III:** Highest risk

# Rules system

- **Time(Contact time with patient)**
  - Transient ( Under 60min)
  - Short term ( Over 60min and less than 30day)
  - Long term ( Over 30days)
- **Invasiveness**
- **Active devices**

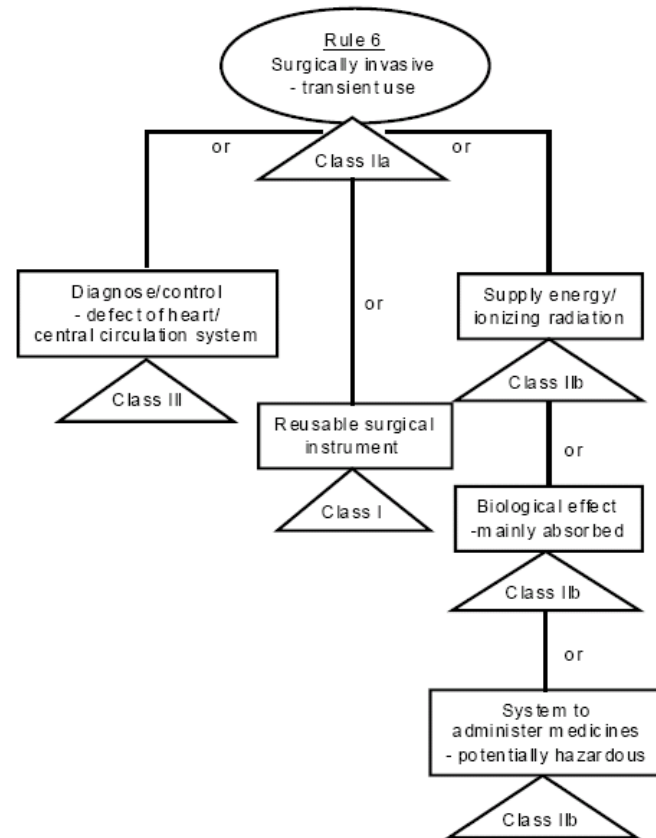
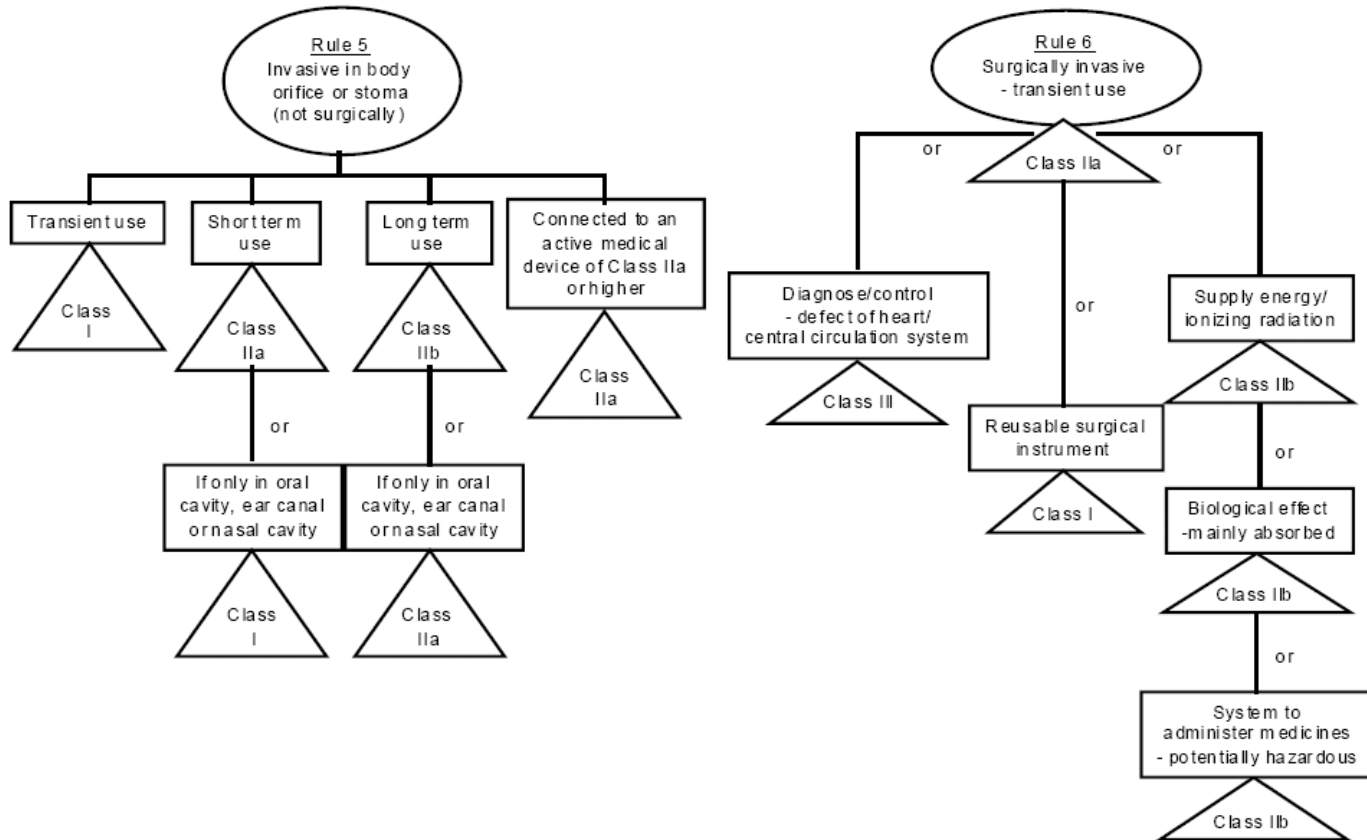
# Classification Rules

## NON INVASIVE DEVICES



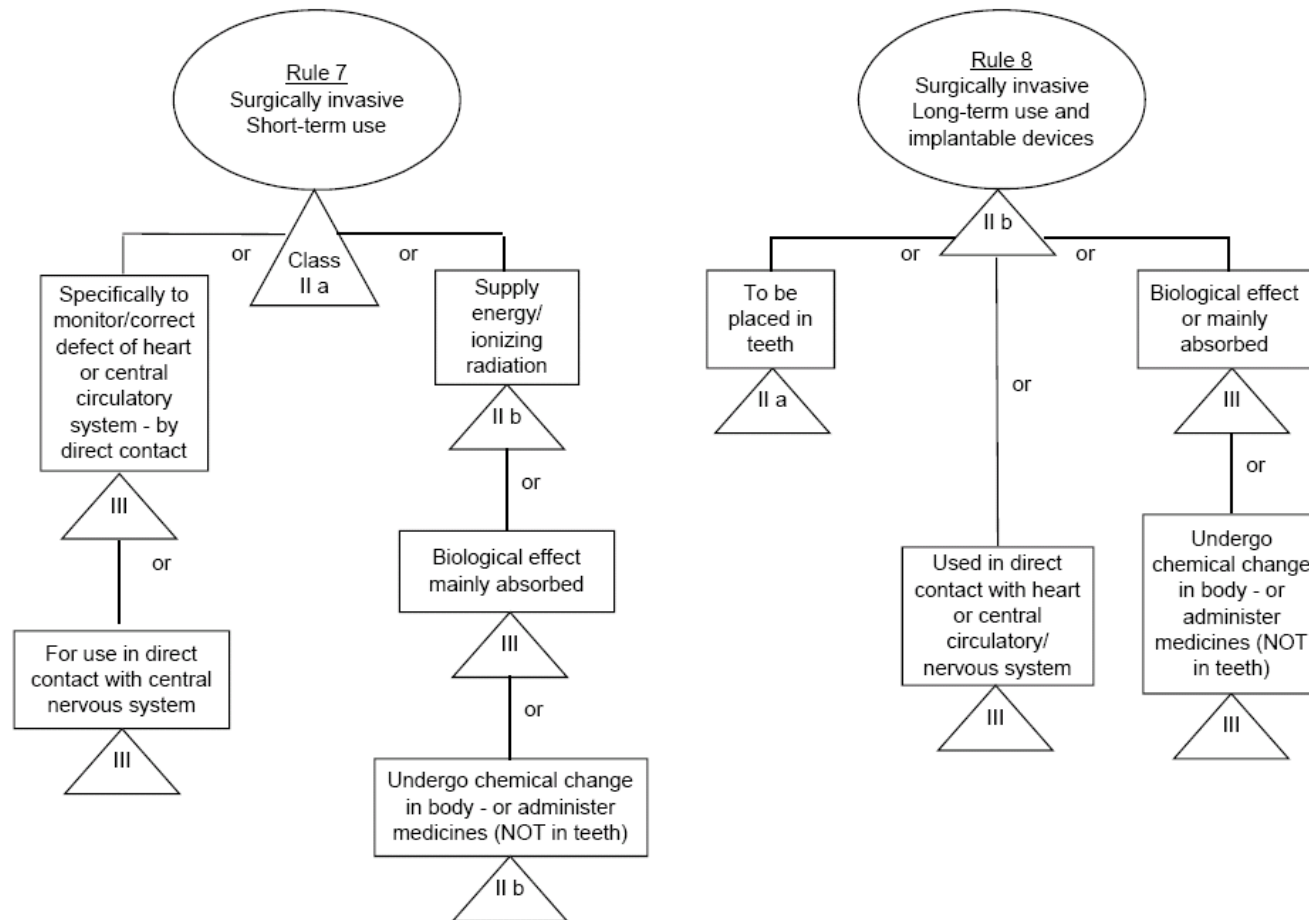
# Classification Rules

## INVASIVE DEVICES

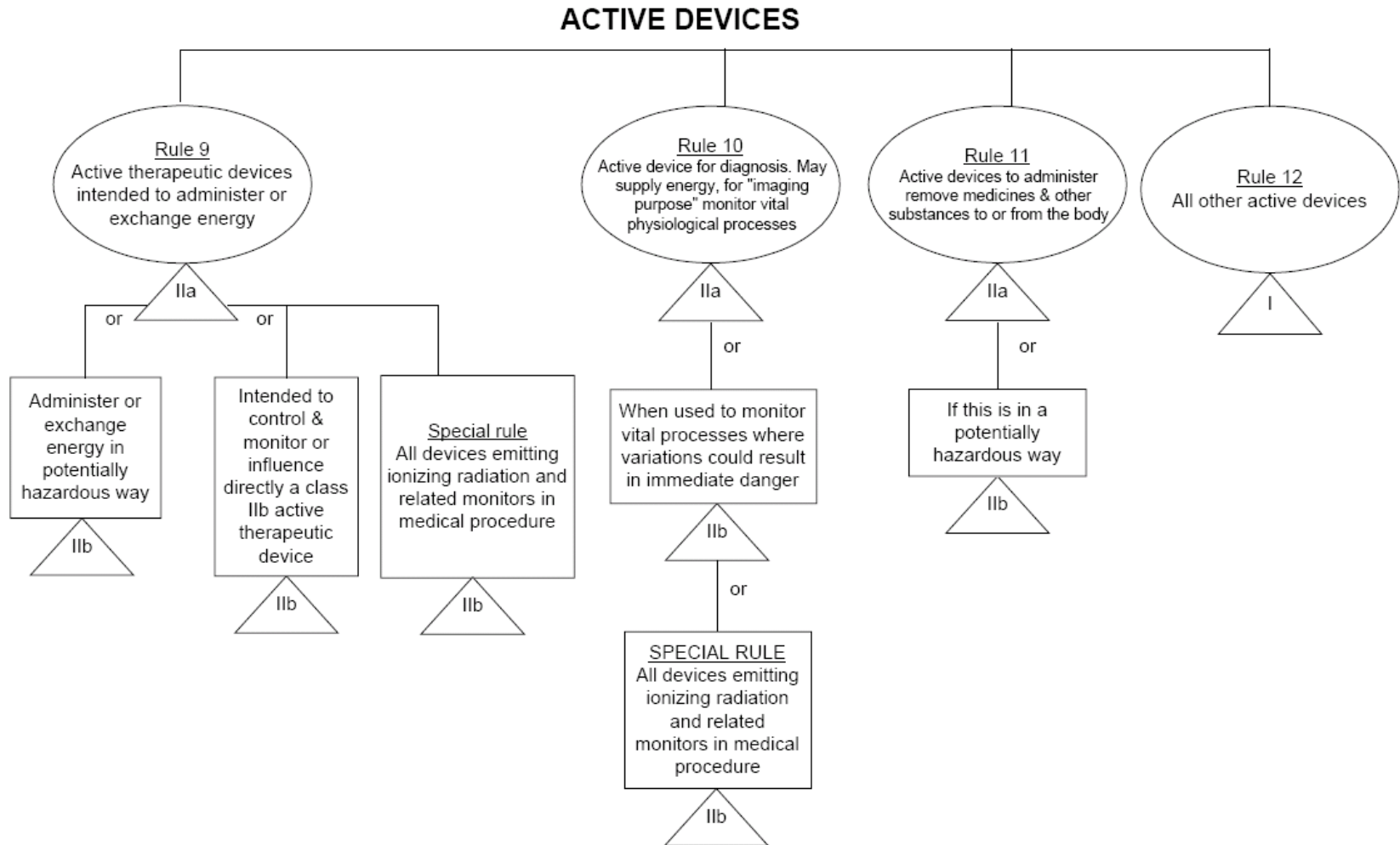


# Classification Rules

## INVASIVE DEVICES

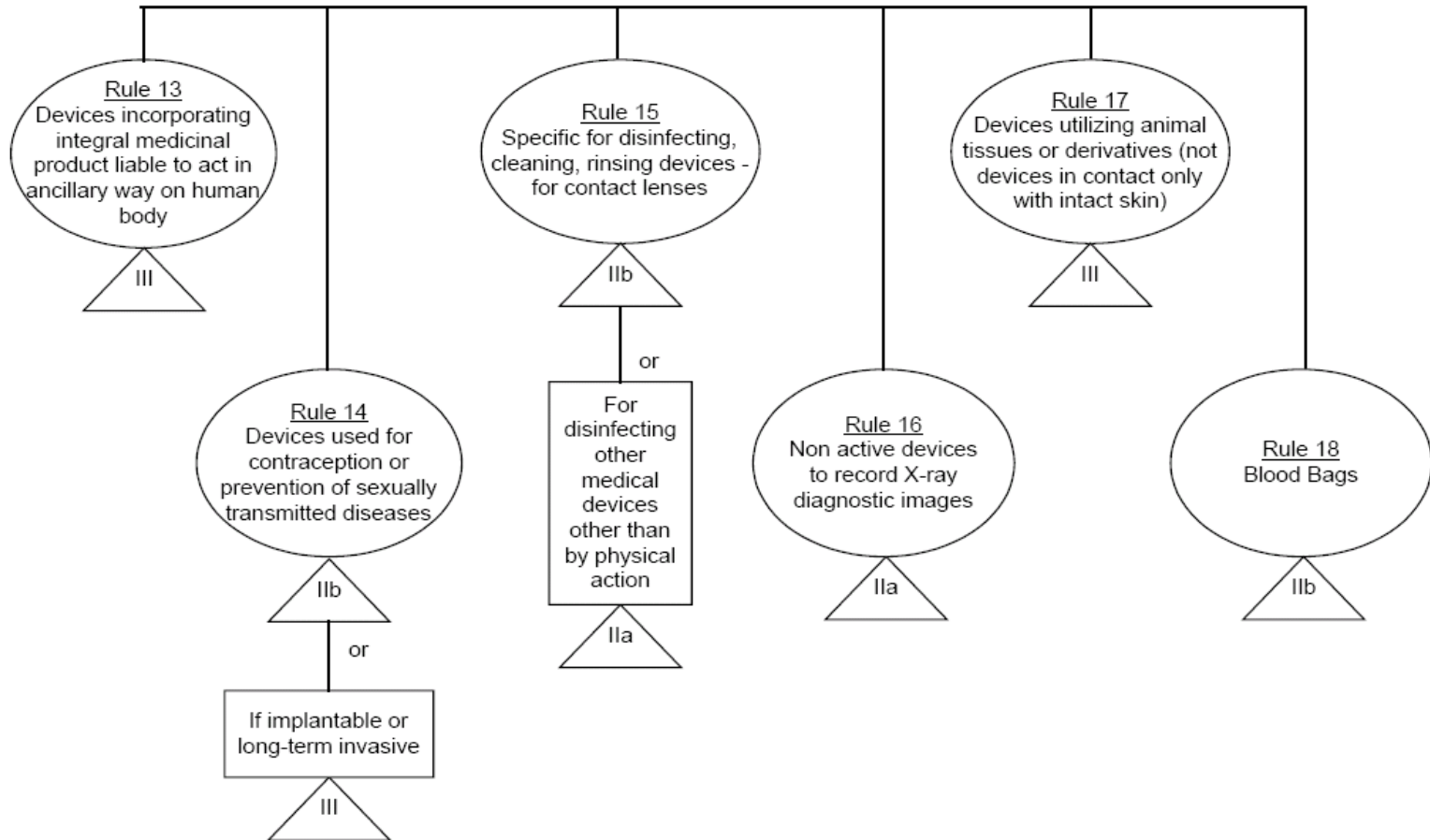


# Classification Rules



# Classification Rules

## SPECIAL RULES



# Notified Body(NB)

- Accredited by CE members
- Review and corticated in medical device  
Class I Sterile, Class I measurement, Class IIa,  
Class IIb, Class III
- When CE marking, NB number(4number)  
should be labeled in CE marking

# Conformity assessment matrix

	Device Classification							
MDD Annex	Class I	Class I S/M*	Class IIa		Class IIb		Class III	
II plus Sec 4							✓ or	
II minus Sec 4			✓ or		✓ or			
III						✓ +		✓ +
IV		✓ or		✓ or		✓ or		✓ or
V		✓ or		✓ or		✓ or		✓
VI		✓		✓		✓		
VII	✓	+ ✓		+ ✓				

\* Sterile or Measuring

# Certificate by conformity assessment

- **EC Design-Examination Certificate** (Annex II section 4)
- **EC Type Examination Certificate** (Annex III)
- **Full Quality Assurance System Approval Certificate** (Annex II section 3)
- **EC Verification Certificate** (Annex IV)
- **Production Quality Assurance System Approval Certificate** (Annex V)
- **Product Quality Assurance System Approval Certificate** (Annex VI)

# **FDA and CE/MDD QSR Requirement**

# Laws or Standards?

FDA	CE/MDD
<p>Title 21 of the Code of Federal Regulations, Part 820 (21 CFR 820),</p> <p><b>Quality System Regulation (QSR)</b> or current Good Manufacturing Practice (cGMP) requirements.</p>	<p>(93/42/EEC).</p> <p>EN ISO 13485:2003, "Medical devices — Quality management systems — Requirements for regulatory purposes."</p>

# Sections & Subsections

- QSR: 15 Section
- ISO 13485: 8 Section, Major part 7(Design and development, Production, Services)
- Requirement of regulation would be optional or not, according to classification of medical device

# QSR & ISO 13485 Sections

United States: 21 CFR 820	Europe: EN ISO 13485
A General Provisions	1 Scope
B Quality System Requirements	2 Normative References
C Design Controls	3 Terms and Definitions
D Document Controls	4 Quality Management System
E Purchasing Controls	5 Management responsibility
F Identification and Traceability	6 Resource Management
G Production and Process Controls	7 Product Realization
H Acceptance Activities	8 Measurement, Analysis and Improvement
I Nonconforming Product	
J Corrective and Preventive Action	
K Labeling and Packaging Control	
L Handling, Storage, Distribution and Installation	
M Records	
N Servicing	
O Statistical Techniques	

# QSR (21 CFR 820) ISO13485:2003

	QSR (21 CFR 820)	ISO 13485:2003
Overall approach	Procedure-based, includes 36 requirements for documenting specific procedures	Process-based, follows ISO 9001:2000, includes 17 requirements for documenting specific procedures
Management reviews	Must ensure that the QS satisfies the 21 CFR 820 requirements, together with the manufacturer's quality policy and objectives	Includes specific requirements for management review input and output
Human resources	All personnel must be trained to adequately perform their assigned responsibilities	Company required to determine necessary competence for personnel performing work affecting product quality (including training necessary to achieve this competence level) and effectiveness of the training must be evaluated
Specific quality records	Manufacturers must establish and maintain device master record (DMR), device history record (DHR), design history file (DHF)	Requirements for similar files as in the QSR, but different terminology is used
Design transfer	Specific requirement for procedure documenting transfer from development to production	No specific requirement

# QSR (21 CFR 820) ISO13485:2003

	QSR (21 CFR 820)	ISO 13485:2003
Product distribution	Records of finished device shipments must be maintained for all devices	Records of finished device shipments required only for active implantable devices. Extent of traceability of other devices up to the manufacturer
Customer requirements	No specific requirement to meet anything other than regulatory requirements	Customer requirements to be met as well as regulatory requirements
Risk management	Does not specifically mention risk management; however, effective risk analysis is expected by FDA as part of the design process	The output from a risk management process must be one of the design inputs
Complaints	Includes specific requirements related to the recording and investigation of complaints; refers also to regulations on Medical Device Reporting (21 CFR 803) and Reports of Corrections and Removals (21 CFR 806)	Includes specific requirement for authorization if a complaint is not followed by corrective and/or preventive action
Labeling	Includes full set of labeling requirements	No specific labeling requirements; covered under process control
Packaging design and construction	Includes specific requirements for packaging design and construction	No specific requirements for packaging design and construction; covered under design control and process control

# Design and Development

FDA	CE/MDD
<p>Class I exempted.</p> <ul style="list-style-type: none"><li>-Software and automatic process</li><li>-Tracheobronchial suction catheters</li><li>-Surgical glove</li><li>-Monitoring device. (ex. Cure and inspection or secure to patient)</li><li>-Manual radionuclide applicator systems</li><li>-Radiological device</li></ul>	<p>Class I exempted.</p> <p>Options in class IIa, IIb, III, But, Must be included MDD Annex III EC-type examination certificate and MDD Annex IV EC verification</p>

# Fulfilled with organization and regulation

- Organization where is place on FDA and CE market should be established the QS.
- Should be decided to add the appropriate QS through a gap analysis, If organization has expanded a market
- It means one of QS included ISO 13485 and QSR

# Management responsibility

- Require a "quality objective" in QSR과 ISO 13485.
- QSR is required only quality objective
- ISO 13485 is required the quality objective which is measurable method such as quality policy appropriatly.

# Differences

- Slightly differences has between QSR and ISO 13485.
- Different point of view
- For example, FDA audtor more consider in process validation than ISO 13485 auditor but opposite to risk management.

# **Post-Market Surveillance Requirement**

# post-market requirements

- Manufacturer should be performed in post-production
  - Activities that appropriated management according to use of mis-treated medical device.
  - Included the prevention action.

# Definition

FDA	EU
<p><b>MDR (Medical Device Report):</b> reporting of a qualifying adverse incident to the US Food and Drug Administration.</p> <p><b>Recall:</b> Used to describe any "removal or "correction" of devices that do not meet regulatory requirements.</p> <p><b>Correction:</b> Modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.</p> <p><b>Removal:</b> The physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.</p> <p><b>Advisory notice:</b> Communication to customers advising of the need for post-market action.</p>	<p><b>Medical Devices Vigilance System:</b> The system that applies in Europe to both adverse event reporting and post-market corrective action.</p> <p><b>Vigilance report:</b> A report to a European Competent Authority providing details of an adverse incident.</p> <p><b>FSCA (Field Safety Corrective Action):</b> Any post-market activity that concerns devices that have already been sold, in order to reduce a risk of death or serious deterioration in the state of health.</p> <p><b>FSN (Field Safety Notice):</b> Communication to customers in relation to a Field Safety Corrective Action.</p>

# FDA Requirement

- 21 CFR Part 7:  
Recalls
- 21 CFR Part 803:  
Medical Device Reporting
- 21 CFR Part 806: Medical Devices;  
Reports of Corrections and Removals

# MDRs (Medical Device Report)

- Demanded the report when it happened as death or is serious and damages by product which is into US market
- Submit a Form FDA 3500A
- Refer to <http://www.fda.gov/cdrh/devadvice/351.html>

# Recalls

- From market management activity after incidence the medical device of the United States Recall is simply not only physical recall of the product in the market also regulation and the re-label ring, includes prosecuting attorney or a disuse.
- **FDA Recall Classification**

Class I

Class II

Class III

# Recalls

- Major of Recall
- Warning in public
- Vaidation
- Medical Device Recalls and Corrections and Removals  
<http://www.fda.gov/cdrh/devadvice/51.html>

# EU requirement

- Post-market surveillance
- Vigilance system
- MEDDEV 2.12-1 (rev. 5, updated in April 2007)

# EU requirement

- List of vigilance contact points within the National/Competent Authorities

[http://ec.europa.eu/enterprise/medical\\_devices/ca/ca\\_vig.htm](http://ec.europa.eu/enterprise/medical_devices/ca/ca_vig.htm)

# Thank you

[www.asiaitc.com](http://www.asiaitc.com)

[itc0432@hanmail.net](mailto:itc0432@hanmail.net)

[itc0432@asiaitc.com](mailto:itc0432@asiaitc.com)