Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

4-8 December, 2017 I New Delhi

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Mr. Park, Se-il

- Division of
  High-Tech Medical Devices
- Assistant Director
- Executive Deputy Secretary General of AHWP

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An overview of regulations of medical devices and IVDs in South Korea

Park, Se-il

Ministry of Food and Drug Safety

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I. Medical Device Regulatory System

MINISTRY OF FOOD AND DRUG SAFETY

National Institute
of Food and Drug Safety Evalution

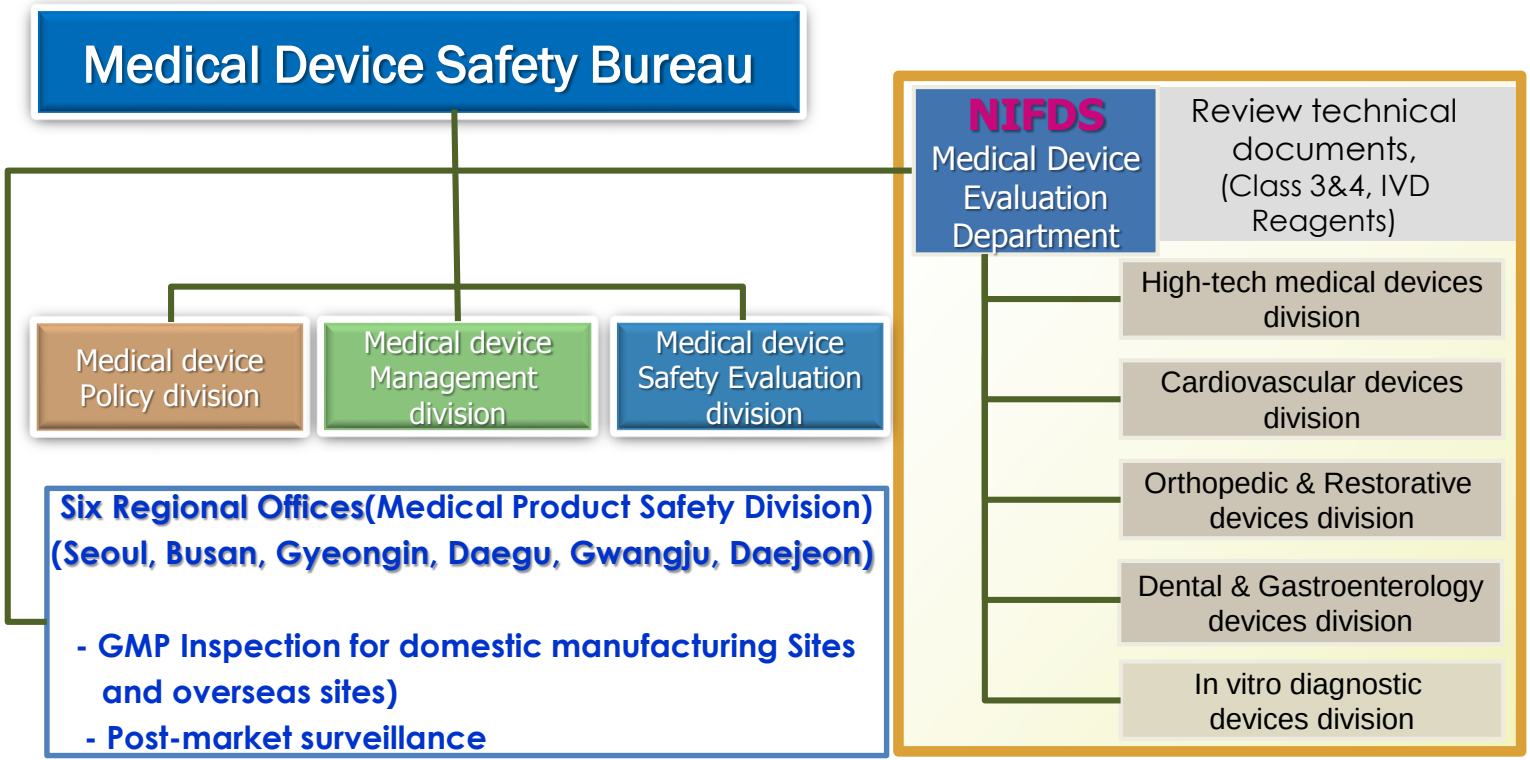
Introduction of Ministry of Food and Drug Safety

Responsibility

- MFDS is responsible for food and drug safety
  - Food and nutrition, agro-livestock, medicinal products(chemicals, biopharmaceuticals, herbal medicine), medical devices

Staffs : 1,797 ('17.05)

Organization of Medical Device Safety Bureau



Classification of Medical Devices

- Risk Based regulation : Classification of medical devices
  - ❖ 4 classes based on potential risk to human health and purpose of use Harmonized with GHTF/IMDRF rules
  - ❖ 2,225 items are designated by current Ministerial Notification

Class	Risk Levels & Purpose of Use	Device Examples	Numbers of classified devices
I	Little Risk	Forceps for medical use, Mechanical Stethoscope	**596**
II	Low Risk	Syringe, Infusion pump	**1,033**
III	Moderate Risk	Silk Suture, Contact Lens	**338**
IV	High Risk	Coronary stent,	**256**
I~IV			2
Total			**2,225**

II. Pre-Market Approval

MINISTRY OF FOOD AND DRUG SAFETY

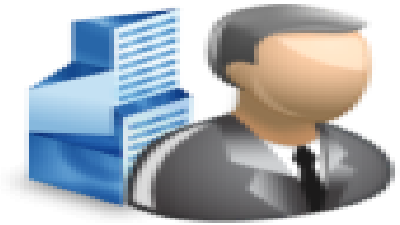
National Institute
of Food and Drug Safety Evalution

Certification of Class II Medical Devices

Application

TD Review Institution
(25 days)

Recognized SE* Devices	SE Devices	Modified Devices
▪Test Report of safety and performance * from labs designated by MFDS	▪Test Report of safety and performance, ▪ SE Check list	▪Test Report, ▪Comparison data (Origin & development process) , (Usage Status Overseas)

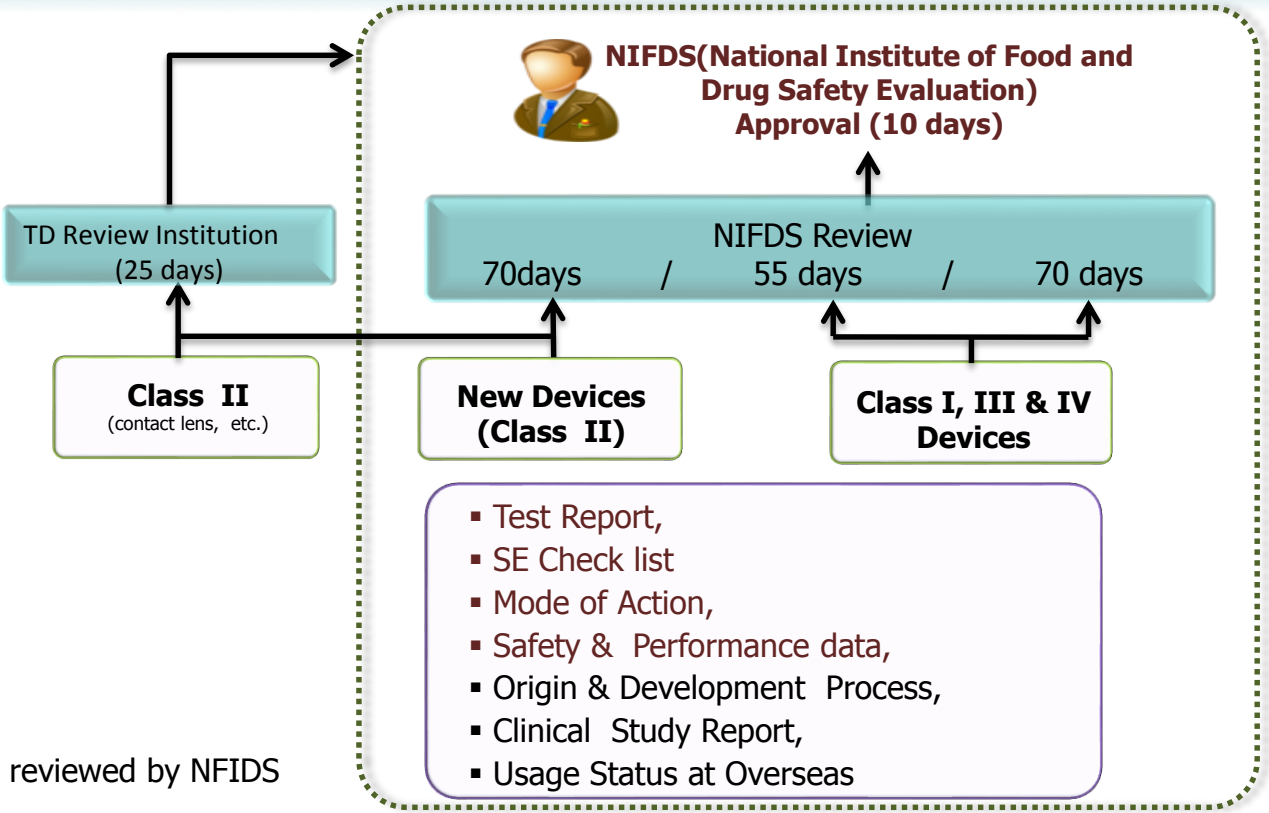


Medical Device Information & Technology Assistance Center

Certification (5 days)

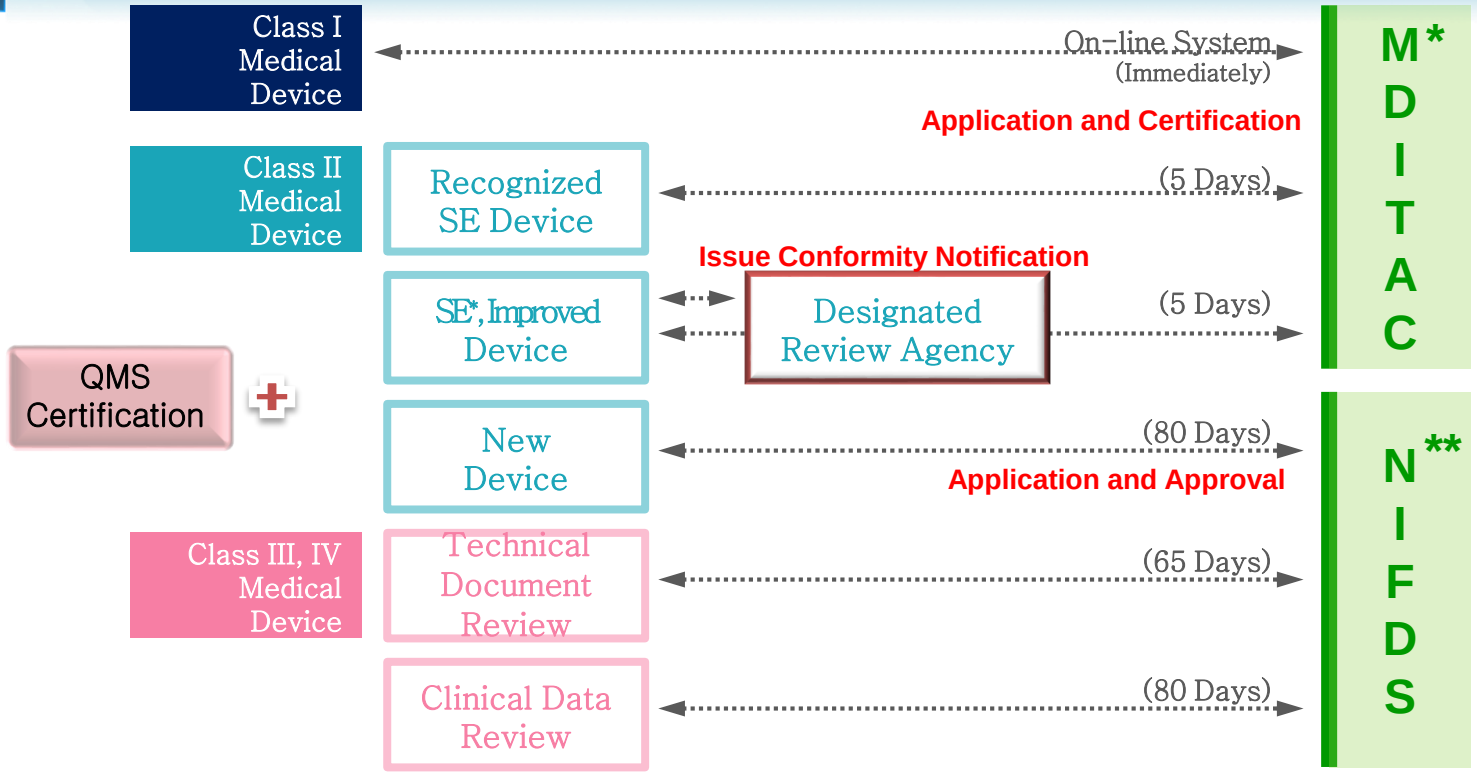
*** Substantially Equivalent : SE**

Certification of Class II, III, IV Medical Devices



※ All IVD reagents reviewed by NFIDS

Overview of Premarket Regulations



* Medical Device Information and Technology Assistance Center

** National Institute of Food and Drug Safety

Clinical Trial Approval Process

- **Who Must Apply?**
  - A person who intends to conduct clinical studies with medical devices
- **When to Apply?**
  - Prior to initiate studies

III. Test report Recognition

MINISTRY OF FOOD AND DRUG SAFETY

National Institute
of Food and Drug Safety Evalution

Recognition of Test Report

1. Test reports issued by the testing **laboratory designated by MFDS**

2. Test reports and certificate issued by the National Certification Body(NCB) under the IECEE CB-Scheme, which is run by **the International Electrotechnical Commission (IEC 60601-1, etc.)**

3. **Good Laboratory Practice(GLP) test report** issued by an authorized GLP laboratory under GLP of the Organization for the Economic Cooperation and Development(OECD)

4. Published journals in **Science Citation Index;**

5. Test report, which is issued by the director of the special agency and is deemed appropriate through examination of the content (including overview of testing facilities, major equipment, research personnel of the agency, investigator's experience, etc.) as tested at **domestic or foreign special agencies including colleges or research institutes, etc**.;

Recognition of Test Report

6. Test report (such as clinical trial results, etc.) submitted and evaluated as of the time of the license (approval) being obtained in the **country(OECD)** where the Medical Device was developed, which data shall demonstrate that such data was received or **approved by the government of such country or the notification authorities** to which license (approval) affairs are delegated by such government.

7. For performance and stability tests, the in-house company test report is recognized **if tested under ISO 13485 or equivalent**

8. **Test reports issued in accordance with the standard code recognized by** the medical devices field **KOLAS approved testing agency are recognized.**

9. Test report on biological safety of another product that is equivalent to the relevant product (**Same raw materials, equivalent human contact time/site**) is recognized

10. Foreign test report that complies **ISO 14155**(Clinical investigation of medical devices for human subjects – Good Clinical Practice)

Recognition of Test Report

- Data for Electrical and Mechanical Safety
- Data s for Radiation Safety
- Data for Electro Magnetic Compatibility Safety

(1, 2, 6, 8)

- Data Performance
- Data for Physics and Chemical Safety
- Data for Stability

(1, 5, 7)

- Data for Biological Safety

(1, 3, 9)

- Data for Clinical Safety

(1, 4, 6, 10)

Recent Amendments of the Regulation

Approval & GMP Process

Background

<Past> QMS Certification before distribution

Product Approval Application → product approval → Application for QMS conformity → Conformity → Distribution

Amended

QMS Certification before approval (Jan 29, 2016 ~)

Approval Application Includes QMS Conformity Assessment Application → Conformity → Distribution

Recent Amendments of the Regulation

Implementation Of International Standards

- Integrating 「Medical electrical equipment - Part1: General requirements for basic safety and essential performance (IEC 60601-1 ed 3.1)」(DEC, 2015)

  - Implementation date will be at Jan 1st, 2018

  - IEC 60601-1 ed 3.0 could be applied until the Implementation date

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Thank you