Korean Jurisdictional Update

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I Special Act for Innovative Devices
Scope of 『Special Act for Innovative Devices』

- 3D-printed Medical Devices
- Devices with AI & Big Data Technology
- Genetic Testing Devices (NGS)
- Medical Devices with AR-VR Technology

Rapid pace of technological innovation

『Special Act for Innovative Devices』
Development of the draft & Proposed enactment in Dec, 2017
Main Features of the Special Act

- Expedited Review Process
  - Packaged support system
    - Pre-consultation
    - Guiding the approval pathway in the right direction
    - Special Task Force (TF) for innovative device review/approval process
  - Modular review process*: review of the submissions by each module
    * 1) Design & development of products
    * 2) Safety and performance
    * 3) Clinical trials
    * 4) Technical docs & clinical data

- Customized Safety Management System
  - Post-market Clinical Data Collection for innovative devices with reduction of pre-market data collection
  - Implementation of the negative list administration mode for modification of approval
  - Establishment of QMS Principles for software

- Technical Support for Market Entry
  - Technical support for clinical trials
  - Capacity building for regulatory & technological expertise
  - Promotion of international cooperative activities
In Vitro Diagnostic Device Act
Background of 『In Vitro Diagnostic Device (IVD) Act』

- **Medical Device Act (MDA)**
  - **Non-IVDs**
  - **IVDs**

- **Medical Device Act**
  - **Non-IVDs**
  - **IVDs**

- **IVD Act**
  - Customized management principles to reflect unique characteristics of IVDs

- No direct contact with the human body
  - Only for diagnosing diseases

『IVD Act』
Development of the draft & Proposed enactment in Dec, 2017
Main Features of 『IVD Act』

- Improved Clinical Trial Regulations for IVDs
  - Clinical trial approval, if approved by IRBs
  - Allowing clinical trials in non-designated facilities
  - Establishment of the IVD-specific GCP standards for IVD products

- Clinical Lab Accreditation Program & Approval System for IVDs
  - Allowing the use of advanced genetic testing equipment for research after receiving clinical lab accreditation
  - Simplifying approval process by combining IVD reagents, equipment and software as one system for approval (since Aug, 2016)

- Simultaneous Review System for IVD Companion Diagnostic Devices (CDx)
  - Allowing simultaneous approval for IVD CDx and drugs that are used with the device

Legal Foundation reflecting unique characteristics of IVDs for Flexible Review & Approval System
Implementation of UDI System
Overview of UDI System in Korea

- **Manufacturer**
- **Wholesale**
- **Retail**
- **Medical institutions**

**Product info** (UDI-DI related info)

**MD Information Integration System** (UDI SYSTEM, DB)

**system link**

**provided**

- **Ministry of Food and Drug Safety (MFDS)**
- **MD handlers**
- **Public**
- **Medical institutions**
- **Relevant government agencies**

**Health insurance management system**

**Customs clearance system for MD**
Establishment of MD Information Integration Center (under MFDS)

- MDITAC* assigned to manage the UDI system
  - Analysis, process and provision of the collected data, based on UDI
    *MDITAC: Medical Device Information Technology Assistance Center, an MFDS-affiliated public organization
- Development of related guidelines and reference literatures
- Help desk service on the UDI System

Future Directions of UDI System

Requirements for UDI placement & UDI registration

Class 4  Class 3  Class 2  All Classes
New Guidelines
New Guidelines on 3D-printed Devices

3D-printed Devices

Orthopedic Implants

Dental Implants

Personalized Products (QMS Inspection)

Biodegradable Scaffold for Skin Regeneration

Biodegradable Scaffold for Revascularization

Oct, 2017

- Guideline on Review & Approval for 3D-printed Personalized Orthopedic Implantable Devices

Oct, 2017

- Guideline on Review & Approval for 3D-printed Personalized Dental Implantable Devices

Dec, 2017

- Guideline on 3D-printed Personalized Devices to be Prepared for QMS Inspection

Dec, 2017

- Guideline on 3D-printed Biodegradable Scaffold for Skin Regeneration

Dec, 2017

- Guideline on 3D-printed Biodegradable Scaffold for Revascularization
New Guidelines on Innovative Medical Devices

- **Rehabilitation Robots**
- **Big data**
- **AI**
- **NGS**

**Guideline on Review & Approval for Rehabilitation Robots**

**Guideline on Review & Approval for Big Data & AI-applied Medical Devices**

**Guideline on Clinical Evaluation of Validity for Artificial Intelligence (AI) Medical Devices**

**Guideline on Cancers, Genetic Disorders and Congenital Anomaly Test on Fetus as per Testing Types of NGS Clinical Laboratories**
Thank you for your attention