Regulatory pathways for Innovative Medical Devices (An innovative medical device pathway)

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Ministry of Food and Drug Safety

Contents

1. Digital Health Industry

Digital Health Industry

[Global Market] ('20) 152 billion USD → ('27) 508 billion USD (expected)

[Korea Market] ('23) 4.15 billion USD → ('27) 5.6 billion USD (expected)

- The Fields of R&D: mental health, cardiovascular disease, diabetes, oncology, health management, and wellness app. etc

2. Innovation in Korean Regulatory Management System

1. Establishment of New Category Regarding 'Software'

- **11 new middle categories**
  - ✓ Ophthalmology, orthopedics. dentistry, otolaryngology, rehabilitation medicine, radiology, etc.
- **90 new subcategories, including 'cardiovascular image, treatment planning software'**
  - ✓ Reflection of artificial intelligence, virtual/augmented reality, information and communication technology, etc.

2. Establishment and Implementation of Digital Product Approval Guidelines

3. Establishment of Digital Health Devices Division (Feb. 2022)

Approved Products(1)

Artificial intelligence and big data for diagnosis

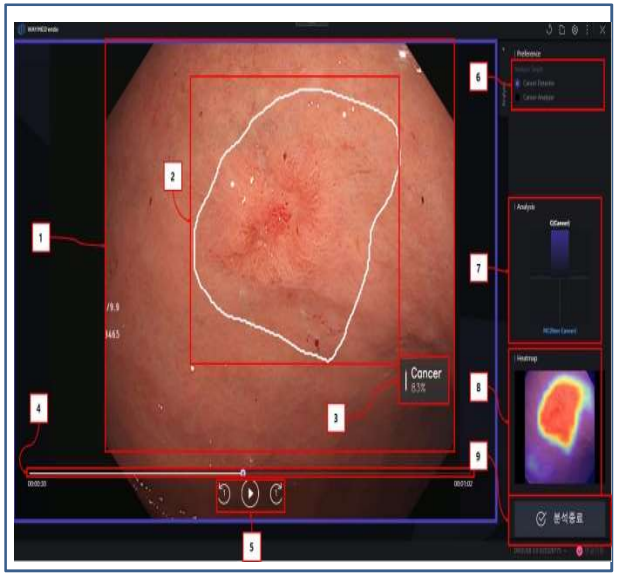
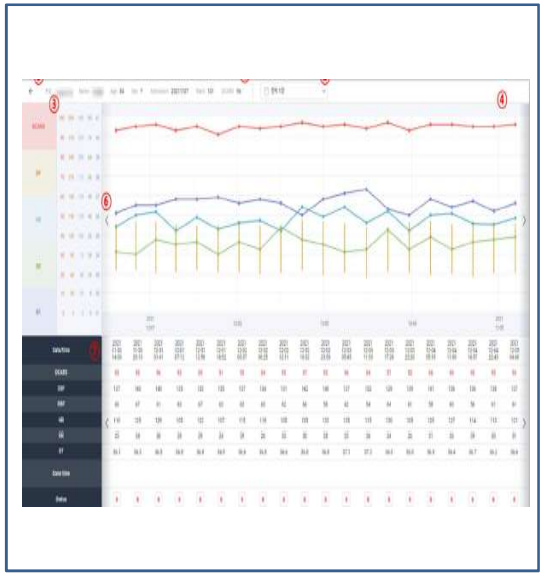


Image of gastric cancer



Vital sign, analysis software

IVD software

Approved Products(2)

Medical robot, Treatment plan software

Using cutting-edge digital technologies such as robots and AR/VR

Robotic surgery

Dental image,
treatment planning software

4. Designation of Innovative Medical Devices

Legal Basis

- **ACT ON NURTURING MEDICAL DEVICES INDUSTRY AND SUPPORTING INNOVATIVE MEDICAL DEVICES. Enforcement (May 1, 2020)**

Definition

Medical devices which have improved or are expected to improve the safety and effectiveness compared to existing medical devices or therapy;

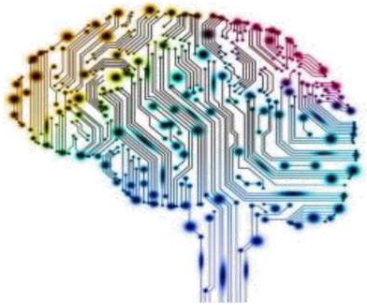
- by applying advanced technology such as information and communications technology (ICT), biotechnology (BT) and robotic technology or
- by improving the methodology for use among approved devices.

Incentive

- Priority review over other medical devices applications

1-1 Background of the Act

Innovative Technologies



- AI, Robotics and 3D printing tech applied Medical Devices
- Separate regulatory system for IVDDs

Safe Regulatory System

- Flexible regulatory system
  - Pre-market review criteria for medical devices with advanced and innovative technologies
  - Support in development and market authorization for IVDDs

Quick Market Access

- Fast Introduction of innovative devices in Global Market
  - Comprehensive Support for SMEs and R&D investments
  - Access to the new treatments by helping product realization and facilitating marketing authorization

1-2 Act on Innovative Medical Devices

1. Certifying and Supporting Innovative Device Manufacturers

- **(Pre-certification Program)** application procedure and the requirements, **valid in 3 years**, rules for certification withdrawals
- **(Supporting the manufacturers)** **preferential government-initiated R&D**, **tax** exemption, a special exception for **constructing research facilities**

2. Designation and Supporting Innovative Device Groups

- **(Innovative devices groups)** valid in 3 years for the **recognized groups** for breakthrough improvement of the therapy and treatment for rare or intractable diseases
- **(Designating Innovative devices)** **designate innovative devices** that are applicable to the recognized group
- **(Supporting approval of Innovative devices)** **exempt business license, modular review process* and priority review**

  * 4 phases : design & development, Safety & performance, Clinical trials and Technical docs & clinical data
- **(Post-market surveillance)** **less than 5-year period of follow up surveillance** required when needed a follow up for its clinical efficacy and adverse events observation

3. Special Exception for Innovative Software Devices

- **(Pre-certification program)** **exemption of some submission requirements** for the **pre-certified software manufacturers** by appraising the organization and personnel
- **(Modification approval)** **amendment approvals required for major changes** and **report for other changes**
- **(Clinical trial)** clinical trials for innovative software medical devices with **IRB approvals**
- **(GMP/QMS)** Good Management Practice established for software medial devices

4. Support for the Technology

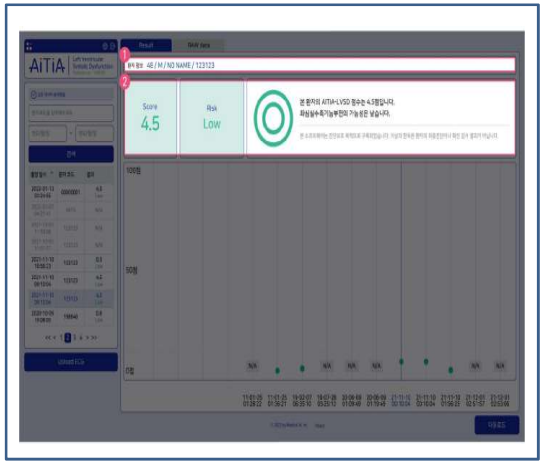
- **(R&D)** R&D initiatives, necessary information sharing, establishing basis for rewarding outstanding developers
- **(Clinical investigations)** support for clinical researches and clinical trials for conducting such investigations by MFDS and MOHW
- **(Safe regulatory framework)** support for studies and tests to acquire its safety and effectiveness, and manufacturing & quality management system

Innovative Medical Devices

Application of artificial intelligence, robot technology, etc.: 49 products designated(as of Nov 1, 2023)

Artificial intelligence fundus image reading solution

- Software that analyzes retinal images to locate abnormal areas and assist in diagnostic decision-making, based on a pre-trained artificial intelligence model for abnormality detection



Electrocardiograph Analysis Software

- A software that utilizes a 12-lead electrocardiogram to provide scores and risk assessment for the potential of Left Ventricular Systolic Dysfunction(LVSD)

Innovative Medical Devices

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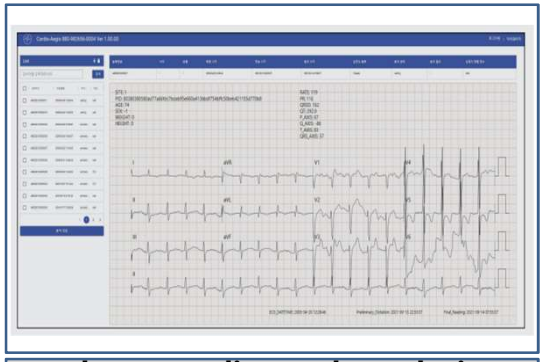

Electrocardiograph analysis software

Electrocardiograph analysis software

- Software as Medical Device that receives, stores and analyzes signals from an electrocardiogram(ECG) to predict the ECG results and assess the possibility of cardiac arrest within 24 hours

Cardiovascular risk assessment software

Cardiovascular risk assessment software

- Software as medical device that predicts cardiovascular disease risk like heart attack, stroke and etc., based on a simple eye examination using retina AI marker

3. Ongoing / Future Plan

1. Establishment of Customized Innovative Regulatory System

- Stimulation of clinical trials using digital technology
- Innovation of approval system for digital medical products, etc.

2. Regulatory Support on Digital Medical Product R&D through Regulatory Science

- Development of related guidelines, and support of human resource development, etc.
- Strengthening international cooperation activities

3. Implementation of AI-based Administrative Management System

- Operation of smart medical device vigilance system
- Designation of agency for specialized digital medical product evaluation

Thank you for your attention!

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