



MFDS Regulatory Considerations on Medical Device Cybersecurity

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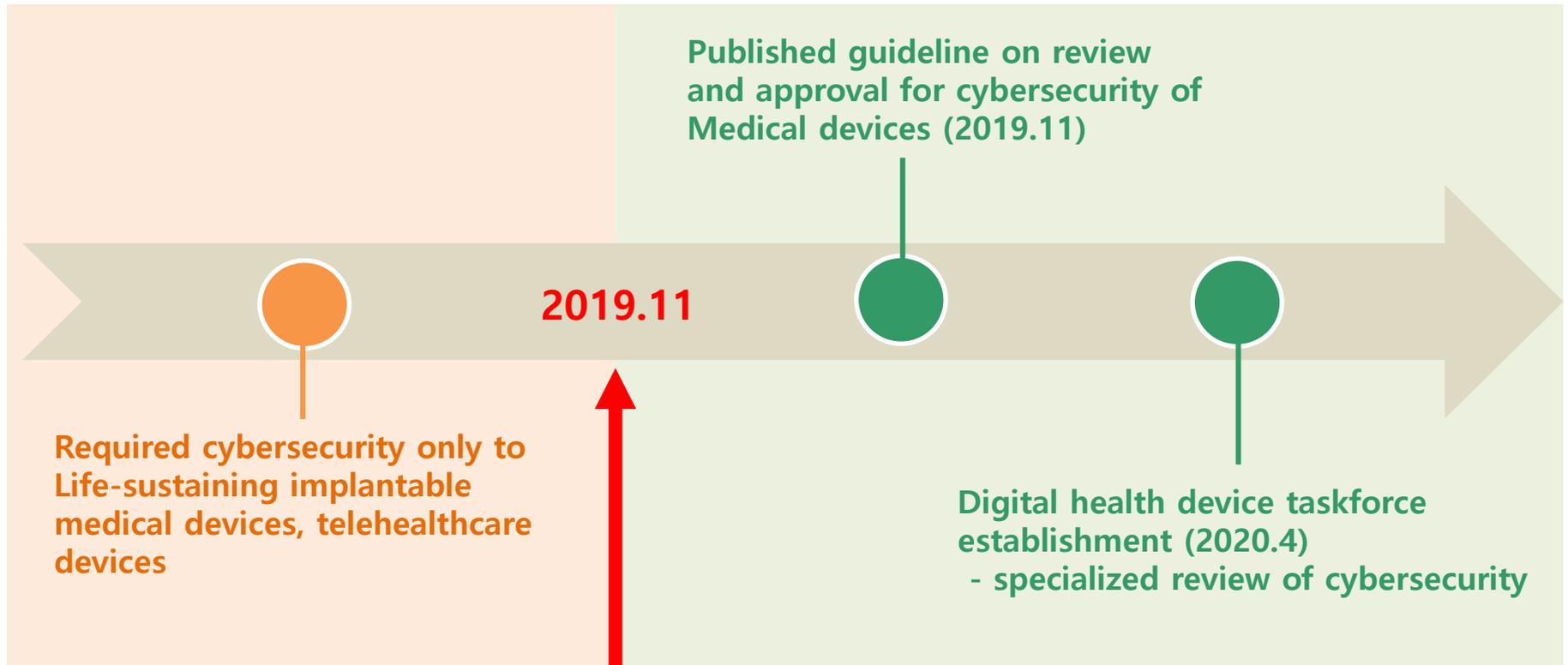
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Ministry of Food and
Drug Safety



✓ Application of Cybersecurity



Required cybersecurity to all wired/wireless communication applied medical devices

Considerations of review - Scope

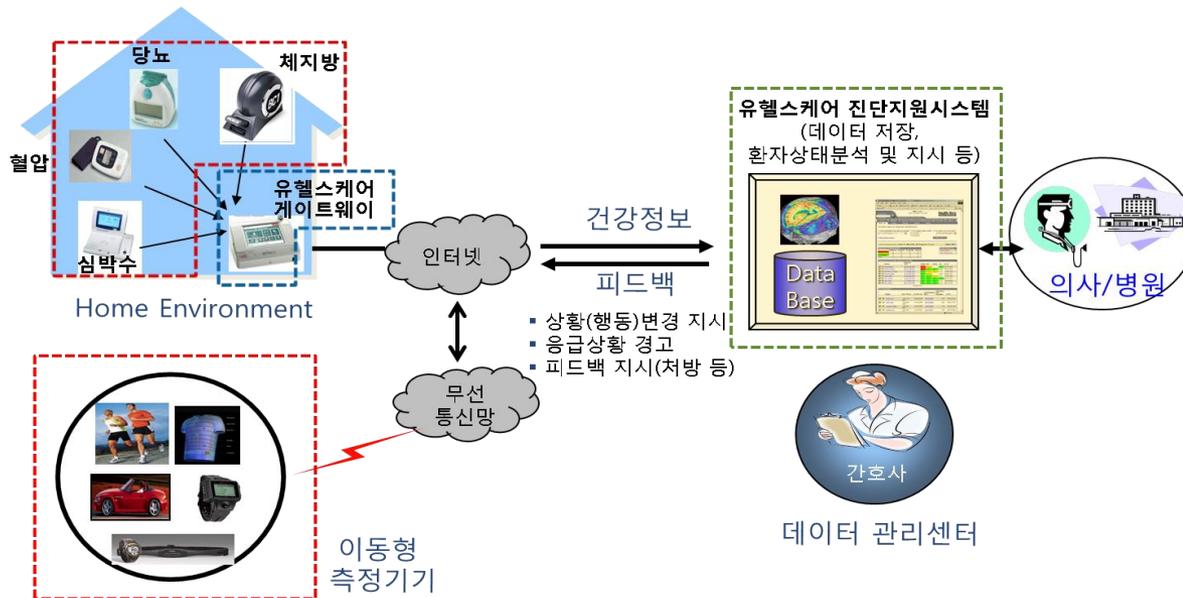
Medical devices capable of wired/wireless communication

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Medical devices that monitor patient biometric information using communications

Examples

Telehealthcare device, picture archiving and communication system, patient monitoring device, bio-signal measurement device, etc.



Considerations of review - Scope

Medical devices capable of wired/wireless communication

2 Medical devices controlled with communications

Examples

Implantable cardiac pacemakers, implantable insulin injectors, surgical robots etc.



Considerations of review - Scope

Medical devices capable of wired/wireless communication

3 Medical devices that use communications for maintenance

Examples

Laser surgery device, ultrasonic diagnostic imaging equipment and most of the electronic medical devices with wired and wireless communication.



Considerations of review - Principles

Application of cybersecurity **through risk management process** of medical device manufacturing quality management system.



Considerations of review - Principles

Manufacturer requires compliance with the three principles of **confidentiality, integrity and availability** in order to ensure cyber security of medical devices.



Ability to keep personal medical information from **being disclosed to unauthorized person or from being used for unauthorized purposes.**



Ability to prevent personal medical information from **being transformed or destroyed in an unauthorized method.**



Personal medical information must be provided immediately to authorized users and should be in a required form at a required place.

Considerations of review - Requirements

< Checklist for Essential Principles of Cybersecurity Medical Devices >

1) Cybersecurity Safety Level : Major Moderate Minor

2) Communication Technology : Bluetooth Low Energy, 3G, LTE, Wi-Fi

Sending and receiving personal health records such as biometric information of patient

3) Communication Purpose : Device Control

Maintenance such as Firmware or Software Updates

4) Use of public networks : Y

Essential Principles of Cybersecurity	Requirement Application	Verification method of conformity	Reference Standards	Document number
1. Identification and Security				
1.1 Access control and Certification It shall be possible to give access authority depending on user's role based on identification and authentication and make the user access only authorized data.	Applied	Software V&V document	'IEC 62304' 'Guidance on Smart Healthcare Cybersecurity' 'Handbook for IoT security testing methods and criteria'	Software Validation Report (SW-V-1194)
1.2 No multiple access The Same user shall not have multiple access.	Applied	Software V&V document	(Same as above)	(Same as above)

Considerations of review - Requirements

- Submission requirements : Checklist, Risk management, software validation&verification

1. Medical device cybersecurity essential principles checklist

- **Material to confirm cybersecurity requirement compliance**
- **Fill out the requirement checklist form** depending on product's characteristics

2. Cybersecurity risk management document

- **Management of cybersecurity related risks** throughout the product life cycle
- **Product purpose and feature based cybersecurity related risk analysis**

3. Software verification and validation document

- **Verification of the risk control measures**
- **Must include verification procedures, test results of the risk control measures**

Roles and Responsibilities of Regulators



Strengthening cybersecurity through legal regulation

- ✓ Mandatory regulation of cybersecurity to medical devices (2019.11)
- ✓ Amendment of cybersecurity guidance for global harmonization (2021.10)



Improving industry understanding of cybersecurity and its regulations

- ✓ Published cybersecurity related Frequently Asked Questions(FAQ) for medical device pre-market approval (2021.5)
- ✓ Provided seminar of medical device cybersecurity requirements for industry (2021.5~, every month)

Thank you