IMDRF International Medical Device Regulators Forum

Regulatory Updates

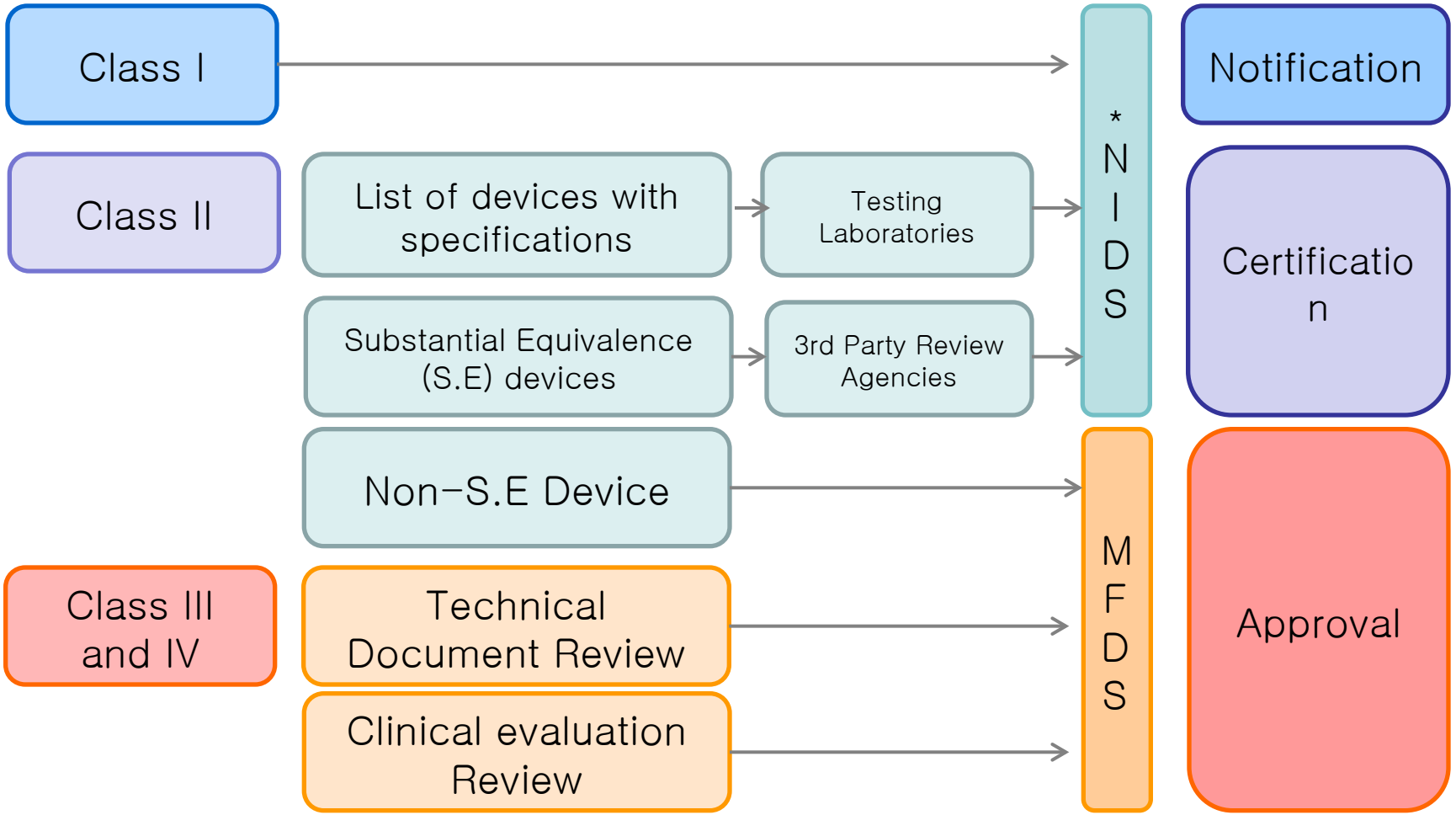
Ministry of Food and Drug Safety (MFDS)
Republic of Korea

September 2018

Safety Management System for Medical Devices

Overall Medical Device Regulations			Relevant Tasks	
Pre-Market	QMS Conformity		Conformity Assessment	Manufacturing Class 2 to 4 Importing Class 2 to 4
	Business License		Business License for Manufacturing and Importing Medical Devices	
	Item Approval Certification Notification	Notification (class 1)	Notifications of Item (immediately notified at the submission of application) ※ Exemption of QMS inspection	
		Certification-Approval (Class 2 to 4)	Approval for Clinical Investigation Plan (If needed)	
			Technical Documents Review	Class 2
				Class 3&4
			Certification	Class 2
			Approval	Class 3&4
Distribution	Selling-Renting-Repairing		Selling & Renting Business Notification Repairing Business Notification	
Post-Market	Post-Market Safety Management		Inspection of QMS Compliance	
			Recall	
			Adverse Event Reporting	
			Management of Labeling and Advertising	
			Tracking of High Risk Medical Devices	
			Administrative Disposition and Punishment (penalty, fine)	

Medical Device Approval System



* NIDS : National Institute of Medical Device Safety Information

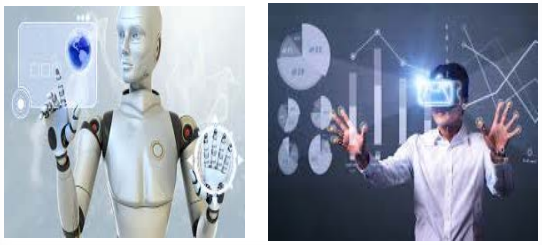
Regulatory and Policy UPDATES

1. Draft of Medical Device Industry Promotion and Innovative Medical Device Support Act
2. Revision of “Regulation on Medical Device Nomenclature & Classification”
3. Establishment of NIDS
4. Implementation of UDI system
5. Revision of Medical Device Regulations
6. Guideline publications

Draft of Medical Device Industry Promotion and Innovative Medical Device Support Act (Aug, 2018)

Special Law for Innovative Devices

Medical Device Industry Promotion Act



Integration

Draft of 『Medical Device Industry Promotion and Innovative Medical Device Support Act』

Regulation on Medical Device Nomenclature & Classification

- Amendments **: Nomenclature & classification for Innovative Medical Devices**
  - IVD software for prognosis or prediction to disease, except cancer, tumor [2]
  - IVD software for predisposition to disease, except cancer, tumor [2]
  - IVD software for predisposition to cancer, tumor[3]
  - IVD software for prognosis to cancer, tumor [3]
  - IVD software for predisposition to cancer, tumor [3]
  - Retinal diagnostic system [3]
  - Smart contact lens [3]

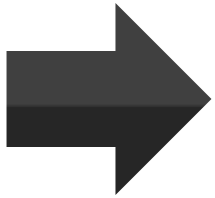
Establishment of NIDS (on June 14th, 2018)

Vision and Mission

- Support of medical device industrial development and safety management by providing comprehensive technical support and information regarding domestic and international medical device trend and clinical information.

* MDITAC has been promoted to NIDS

MDITAC
의료기기정보기술지원센터
Medical Device Information & Technology Assistance Center



NIDS
한국의료기기안전정보원
National Institute of Medical Device Safety Information

Preparation of UDI implementation

- Amendments to MDA (on December, 2016)
  - Mandatory requirement of having a unique device identifier on a medical device label

  * Effective date : July 2019 for class IV, July 2020 for class III, July 2021 for class II, July 2022 for class I

	Class 4 (high risk)	**Class 3** (serious risk)	**Class 2** (potential risk)	**Class 1** (lower risk)
Placing UDI	**July, 2019**	July, 2020	July, 2021	July, 2022

- Advance notice of MDA notification (from May to July, 2018)
  - Preparation of medical device supply record, reporting categories, methods, etc
- Publication of UDI-related Guidelines(on June, 2018)
  - Guideline for Obtaining Unique Device Identifiers
  - Guideline for Placing UDI Barcodes
  - Guideline for Submitting UDI Data to the Unique Device Identification Database

Promotion of ISO 13485: 2016 implementation

'18.12	Revision of regulation on medical device manufacturing and quality control standards for implementation of ISO 13485: 2016

* Will be implemented by Jan, 2020

Proposal of international standard of medical device using 3D printer

Dec, 2018	GMP guideline for each manufacturing process of personalized medical devices using 3D printing
2019~	Proposal of GMP-related International Standards (draft) for 3D printed medical devices

* Will be presenting about the status of guideline preparation at the ISO TC 210 meeting in November, 2018 in Seoul.

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New Guidelines on Innovative Medical Devices




Purpose

As there are increased numbers of VR and AR-based devices used in clinical environments, Korea MFDS has published this guideline to provide specific regulatory considerations for VR and AR-based devices and also give applicants a specific direction when making pre-market submissions

July, 2018	Pre-market Submission Guideline for VR and AR based medical devices

New Guidelines

July, 2018	Premarket Submission Guideline for Other Blood Typing (except for ABO, RhD) IVD Reagents
July, 2018	Guideline on the Format and Content of Safety Precautions
July, 2018	Premarket Submission Guideline for Tissue Stain IVD Reagents
May, 2018	Administrative Practices on Safety Information Management
April, 2018	Guideline on Medical Device Adverse Event Reporting

Thank you for your attentions!