Regulation system and perspective of SaMD

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Regulatory Authorities in Japan

MHLW
(Ministry of Health, Labour and Welfare)

- Final Authorization of applications
- Publishing Guidelines
- Supervising PMDA Activities

PMDA
(Pharmaceuticals and Medical Devices Agency)

- Scientific Review
- Consultation on Clinical Trials etc.

Legal structure for medical device regulations

Act	Pharmaceutical and Medical Device Act (**PMD Act**), 1960
Cabinet Order	Cabinet Order on PMD Act, 1961
Ministerial Ordinance	Ministerial Ordinance on PMD Act, 1961 GCP/GLP for medical device, 2005 Good Vigilance Practice (GVP) Quality Management System (QMS) etc.
Ministerial Notification	Essential Principles Certification criteria for class II/III devices Classification of medical devices List of orphan designation etc.
Notification	Information on application procedures Guidelines for clinical evaluation etc.

What is the definition of MD in Japan ?

The definition of Medical Devices in PMD Act

Medical devices are machinery or apparatus, etc. **intended for** use in the diagnosis, treatment or prevention of disease in humans or animals or **intended to** affect the structure or functions of the human or animal body, which are specified by Cabinet Order

~PMD Act Article 2.4

Intended use	Diagnosis, treatment or prevention of disease or Affect the structure or functions
Condition	Specified by Cabinet Order

Classification of non-IVD Medical Devices

As of July, 2021

GHTF Classification		Classification in Japan			
Class	Risk level	Class	# of JMDN**	Category	Pre-market regulation
A	**Low** Surgical retractors/ tongues depressors	Ⅰ	**1,214**	General MDs	Self declaration***
B	**Low to Moderate** Hypodermic needles/ suction equipment	Ⅱ	**2,003**	Controlled MDs + Designated Controlled MDs	Third party Certification (Review by RCB*) (**Designated** Controlled MDs and **Designated** Specially Controlled MDs)
C	**Moderate to High** Lung ventilator/ bone fixation plate	Ⅲ	**812**	Specially Controlled MDs + Designated Specially Controlled MDs	**Ministerial Approval (Review by PMDA) (Controlled MDs and Specially Controlled MDs)**
D	**High** Heart valves / implantable defibrillator	Ⅳ	**372**		

*RCB: Registered Certification Bodies

***MD software classified as Class I is **NOT** subjected to restrictions on the PMD-Act

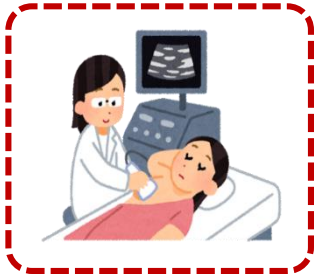
**JMDN: Japanese Medical Device Nomenclature

What is Software as a Medical Device (SaMD) ?

Previous legislation

program which
Determines performance
of medical device

install



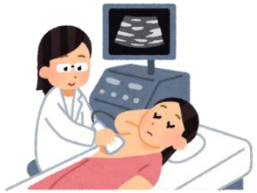
Medical device
（tangible object including software）

Current legislation

program which
determines performance
of medical device

Medical device（software only）

install



Q: Is this software regarded as medical device?
→“Guideline of determining whether software is classified as a medical device” (PSEHB/MDED Notification No.0331-1, PSEHB/CND Notification No. 0331-15, dated March 31, 2021)

DX(Digital Transformation) Action Strategies in Healthcare for SaMD (Software as a Medical Device) “DASH for SaMD”

1. Early grasp of research seeds and publication of the review policy

a.Grasp research seeds in the early stage of development

b. Organize and Publish the review policy based on characteristics of SaMD

2. Unification of the consulting contact point

a. Unify consultation service

b. Publish consultation case examples as many as possible

3. Review system based on characteristics of SaMD

a.Carry out efficient review based on characteristics of SaMD

b. Utilize the Post-Approval Change Management Protocol (PACMP/IDATEN) scheme

c. Consider establishing the innovative SaMD designation system

4. Enhanced structure for early realization

a. Establish new office which specialized in reviewing SaMD in PMDA and MHLW

b. Establish an expert examination committee for SaMD in the Pharmaceutical Affairs and Food Sanitation Council

c. Establish a collaborative forum among regulator, academia and industry

d. Enrich published database of approval cases

Thank you for your attention !

https://www.pmda.go.jp/english/index.html