Regulation of SaMD in Japan

PMDA
Office of SaMD

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Outline

1.Regulation of SaMD in Japan

2.How to review SaMD

Definition of Medical Devices in Japan

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

Article 2.4, PMD Act

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

Medical Devices Specified by Cabinet Order

○ Medical appliances
— (85 items： e.g. Medical disinfector, Respiration assisting apparatus, Physioclinic appliance, thermometer, Blood pressure or Pulse wave appliance, Electrosurgical, Medical Scissors , Injection needles, Syringe, Dental unit, Vision corrective lens, etc.)

○ Medical supplies
— (6 items： e.g. radiographic film , suture , Orthopedic Appliances, etc.)

○ Dental materials
— (9 items ：e.g. dental metal , dental crowns , etc.)

○ Sanitary goods
— (4 items ：e.g. Menstrual tampon , condom , contraceptive device , etc.)

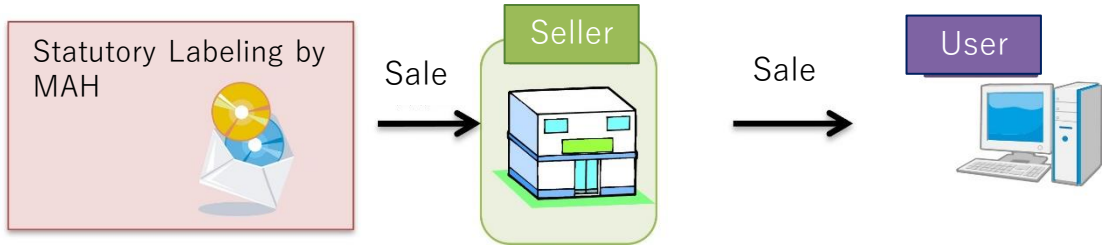
○ Program
○ Recording media on which programs are recorded
— (6 items ： e.g. Program for diagnosis of disease)

Software as a Medical Device (SaMD) has been regulated in PMD Act since 25th Nov. 2014

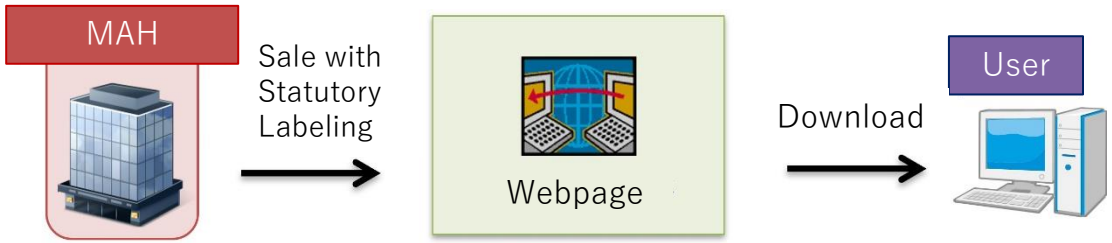
○ Medical Devices designated for animal— (12 items)

Provision of SaMD

1. Provision via storage media

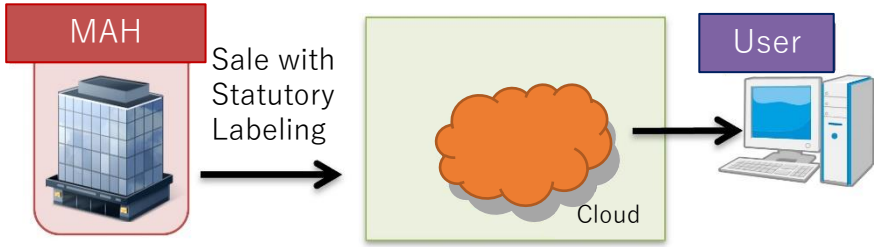


2. Provision via download sales



3. Provision through a telecommunication line

A user operates SaMD through a telecommunication line, and results, such as diagnostic data based on the data provided, are subsequently received by the user automatically.



Etc…

Approval, Certification, Self Declaration

GHTF Classification		Classification in Japan			
Class	Risk level	Class	# of JMDN**	Category	Pre-market regulation
A	**Low** Surgical retractors/ tongues depressors	I	1,225	General MDs	Self declaration***
B	**Low to Moderate** Hypodermic needles/ suction equipment	II	2,027	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	826	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	375		

*RCB: Registered Certification Bodies
**JMDN: Japanese Medical Device Nomenclature

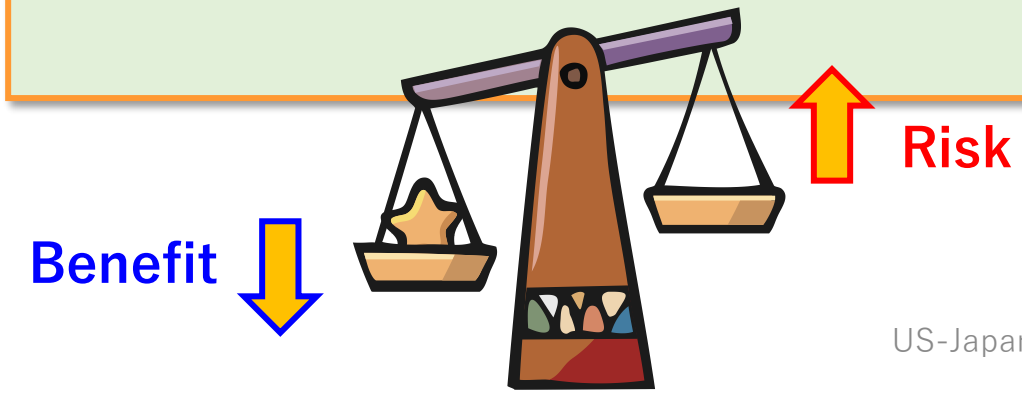
***MD software classified as Class I is **NOT** subjected to restrictions on the PMD-Act

Reasons of Approval Rejection

(a) The given device is judged that it does **NOT** have its own effectiveness and/or performance as to be concerned in the application.

(b) The given device is judged of **NO** value for medical use because its adverse effect(s) far exceed its effectiveness and/or performance.

PMD Act, Article 23-2-5 paragraph (2), item (iii), (a) & (b)



Review as Medical Device, Not just as Function

What is the medical utility of the product?

What RISKs are associated with the implementation of the product?

A function could be utilized in a various situation

→ Understanding of the function itself is not enough to determine the sufficiency of the evaluation.

It is important to understand how the product can be implemented into the current medical practice as a medical device.

e.g.

Relationship to current practice

- Combination with current practice
- Substitute for current practice
- Replace current practice
- Add new scheme/mean

etc…

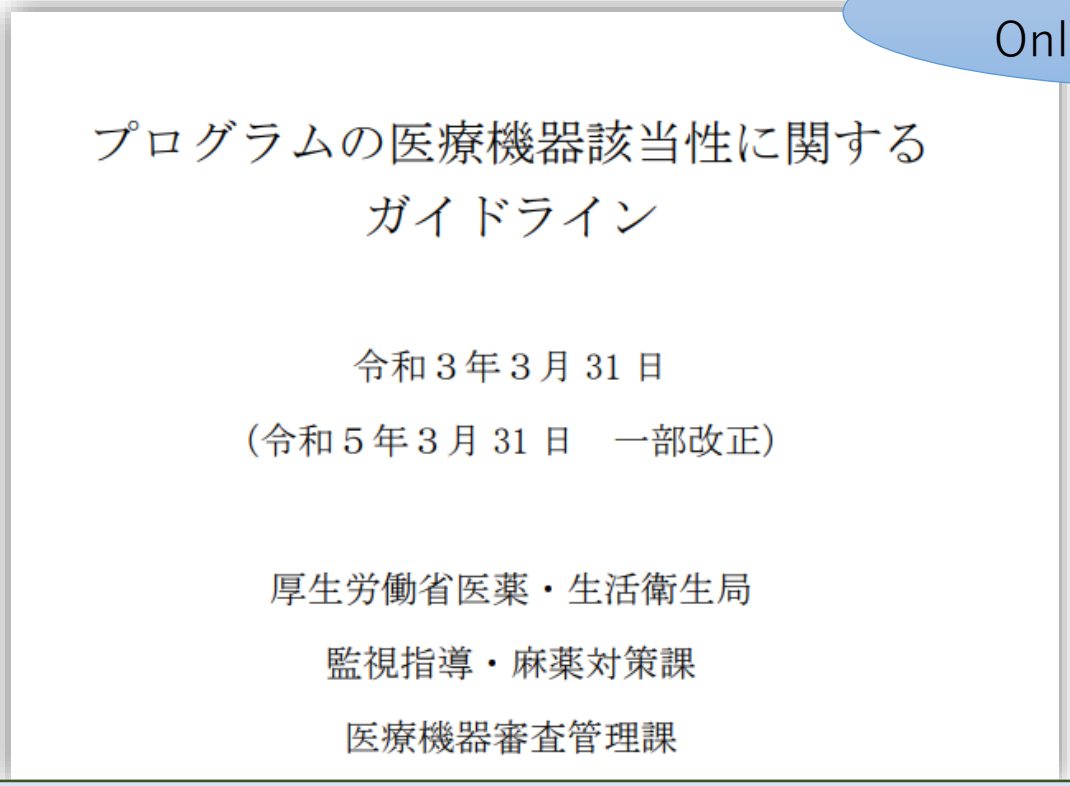
Contribution to patient outcome

- Equivalent efficacy to current practice
- Higher efficacy to current practice
- Effect on patients not addressed by current practice

etc…

Documents

Sorry
Only Japanese now



プログラムの医療機器該当性に関する
ガイドライン

令和３年３月 31 日

（令和５年３月 31 日　一部改正）

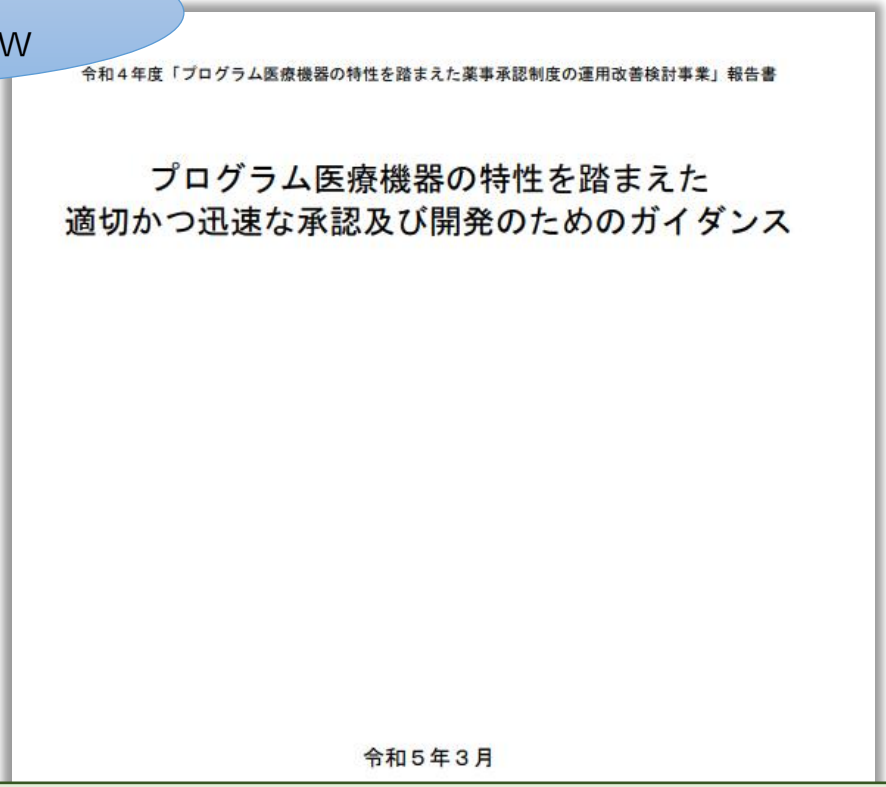
厚生労働省医薬・生活衛生局

監視指導・麻薬対策課

医療機器審査管理課

It contains basic concepts and examples regarding the medical device eligibility of the software, as well as a flowchart for making decisions.

https://www.pmda.go.jp/files/000240364.pdf



令和４年度「プログラム医療機器の特性を踏まえた薬事承認制度の運用改善検討事業」報告書

プログラム医療機器の特性を踏まえた
適切かつ迅速な承認及び開発のためのガイダンス

令和５年３月

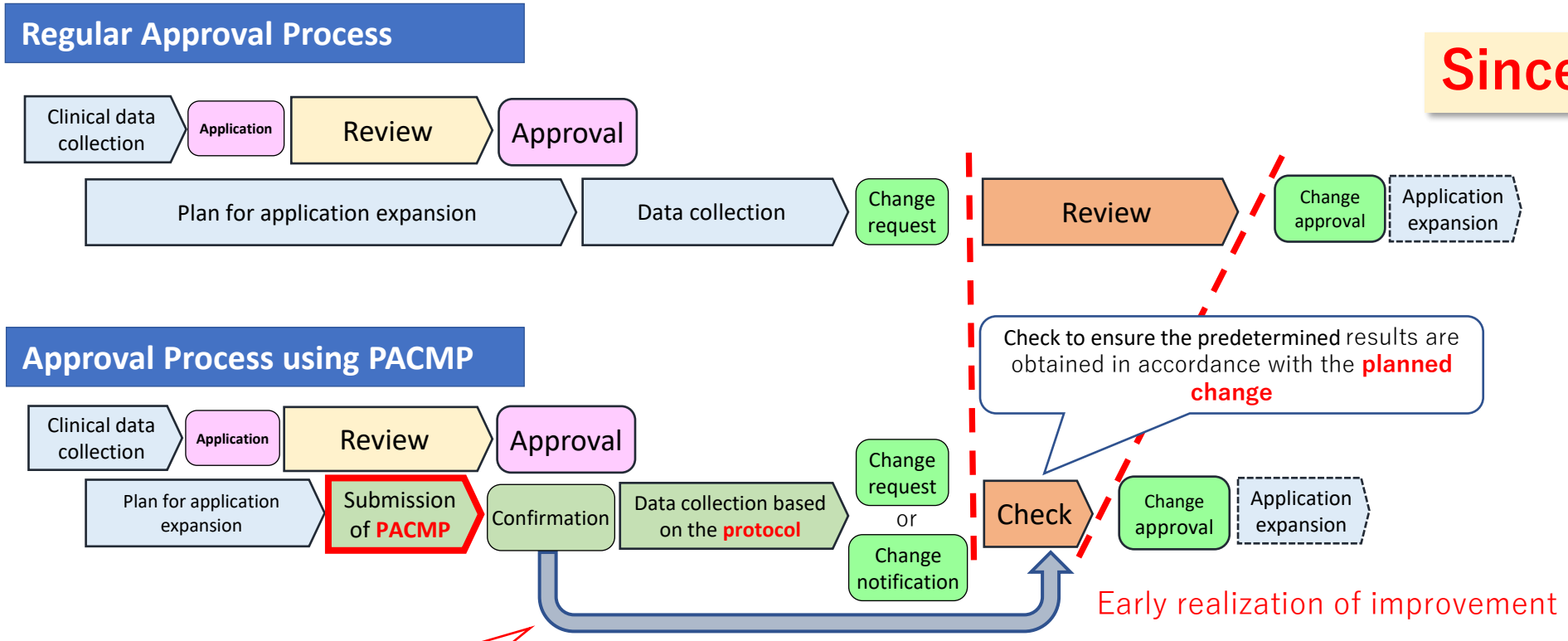
It contains ideas on how to organize requirements for evaluation based on clinical needs, an important concept in the development and evaluation of medical devices.

https://www.pmda.go.jp/files/000252822.pdf

Post-Approval Change Management Protocol (PACMP)

Post-Approval Change Management Protocol (PACMP) is introduced for medical devices to enable continuous improvements through product lifecycle.

Since 1st Sep 2020



Following things are assumed ;

- Re-use the evaluation data used for approval
- Modify the MLMD algorithms and hyper parameters for same MLMD model

Thank you for your kind attention!

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