

Let's figure SaMD out together!



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Speaker Disclaimer

- The opinions possibly expressed by the presenter's dogs about FedEx, UPS and the USPS delivery personnel may contribute to the content of today's webinar, albeit irrelevant in nature.



Agenda – Learning Outcomes

- List FDA Definitions vs Approvals: when does either apply/approval process.
- Name two regulations and examples in use today.
- Describe the future of SaMD and how to envision its use in clinical practice.

Definitions and Approvals

Simply put

- Software that is a device that is not a component of another medical device

More definitively defined:

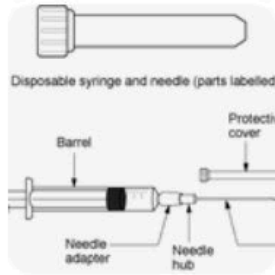
- There are three types of software related to medical devices
 - Software in a Medical Device
 - Software used in the manufacture or maintenance of a medical device
 - Software as a Medical Device (SaMD)
- The International Medical Device Regulators Forum (IMDRF) states:
"software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

The 2013 IMDRF document states:

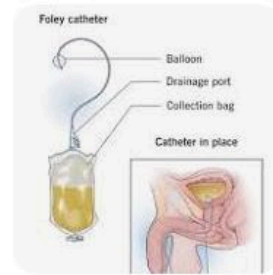
- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms
- “without being part of” means software not necessary for a hardware medical device to achieve its intended medical purpose;
- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.
- SaMD may be used in combination (e.g., as a module) with other products including medical devices;
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software
- Mobile apps that meet the definition above are considered SaMD.

Define Medical Device

Medical device examples



Syringe



Catheter



Medical glove



Tongue
Depressors



Infusion pump



Oxygen mask

According to IMDRF and thus the FDA

A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, **software**, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:





- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;
- and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Other considerations

- SaMD may also:
 - provide means and suggestions for mitigation of a disease;
 - provide information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities;
 - be an aid to diagnosis, screening, monitoring, determination of predisposition;
 - prognosis, prediction, determination of physiological status.

Approval – First is it a device (based on risk)

- There is a Digital Health Policy Navigator to guide you to the following possible outcomes

Icon	Outcome	Meaning
	LIKELY NOT A DEVICE	Device requirements do not apply if the software function is not a device.
	LIKELY FDA INTENDS TO EXERCISE ENFORCEMENT DISCRETION	Some software functions may meet the definition of a device, but because they pose a lower risk, the software function may fall within FDA's enforcement discretion policy (meaning that the FDA does not intend to enforce applicable requirements under the FD&C Act at this time).
	LIKELY THE FOCUS OF FDA'S REGULATORY OVERSIGHT	The software function is a device and its functionality could pose a risk to a patient's safety if the device were to not function as intended. Devices may be subject to requirements such as premarket authorization (e.g., premarket notification (section 510(k) of the FD&C Act), De Novo (section 513(f)(3) of the FD&C Act), premarket approval (section 515 of the FD&C Act)), adverse event reporting (section 519 of the FD&C Act), among others.
	Your product may be a device. Go to Step #.	More information is needed to identify the relevant policies. Go to the next Step.

Regulations and current use examples

The Food Drug & Cosmetic Act

- 510(k) of the FD&C Act: Pre-market authorization
 - Not considered "approved," but "cleared" because it is similar to device already on market prior to substantially equivalent" prior to May 28, 1976
- 513(f)(3) of the FD&C Act: De Novo
 - The [Food and Drug Administration Modernization Act of 1997](#) created section 513(f)(2) of the FD&C Act.
 - Automatically classified as Class III because there was no already-existing device for a 510k submission, but general controls could provide a reasonable assurance of safety and effectiveness.

FD&C Act: the 515 Process

- **Task A:** Collect existing scientific information in the public domain and/or from scientific experts in the medical community and assess the risks versus benefits of the medical device type subject to the classification;
- **Task B:** Convene a meeting of the medical device advisory committee (panel) to request input on the classification of the device type;
- **Task C:** Issue a proposed order (proposed classification) reclassifying the device type into Class I or II, or, if retaining the device in class III, calling for [Premarket Approvals (PMAs)];
- **Task D:** Review and consider comments submitted by the public;
- **Task E:** Issue a final order (final classification) reclassifying the device type into Class I, or II, or, if retaining the device in class III, calling for PMAs.

Classes of Devices

- Class I devices are typically exempt from submission of a premarket notification, or 510(k).
- Class II devices typically require FDA clearance of a 510(k) to permit the device to be marketed and sold in the United States (US).
- Class III devices, which tend to be higher risk and first-of-a-kind devices, require FDA approval in the form of a premarket approval (PMA) application.

What's in the future?

It's here

- CPT 92229: Imaging of retina for detection or monitoring of disease; point-of-care autonomous [machine] analysis and report, unilateral or bilateral
- In the 2022 Final Rule: <https://www.federalregister.gov/d/2021-23972/p-367>, a discussion on pricing:
 - Several commenters raised the issue of software as a medical device (SaMD) and stated that it should be considered a direct PE expense similar to other medical equipment. Commenters stated that even though SaMD does not require physical space in an office or administrative staff hours to maintain it, SaMD does require ongoing upgrades, improvements, and security mitigation, as well as the same regulatory oversight by the Food and Drug Administration (FDA) as hardware medical devices. Commenters stated that the legal, regulatory, and financial burdens incumbent of a SaMD manufacturer are no different than those of hardware medical device manufacturers.

List of Approved AI-ML Enabled Medical Devices

October 19, 2023 update: 171 Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices were added to the list below. Of those newly added to the list, 155 are devices with final decision dates between August 1, 2022, and July 30, 2023, and 16 are devices from prior periods identified through a refinement of methods used to generate this list.

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Date of Final Decision	Submission Number	Device	Company	Panel (Lead)	Primary Product Code
07/27/2023	K231195	Brainomix 360 Triage ICH	Brainomix Limited	Radiology	QAS
07/26/2023	K231038	Global Hypoperfusion Index (GHI) Algorithm	Edwards Lifesciences, LLC	Cardiovascular	QNL
07/25/2023	K223473	ME-APDS™; MAGENTIQ-COLO™	Magentiq Eye LTD	Gastroenterology/Urology	QNP

A Few Facts re the Final 2024 MFPS

RPM, RTM – speaking of SaMD (discuss!)

- RPM
 - established patient only
 - 16 days of data remain for 99453/99454
- RTM
 - No requirement of established patient
 - Mistake in proposed 2024 rule that 98980 and 98981 be included in 16 days' data collection requirement
 - OTAs and PTAs can perform under general supervision, not direct

Questions?

Resources

- FDA: <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>
- <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>
- <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator>
- <https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act>
- Foley Lardner: <https://www.foley.com/en/general/software-medical-device-samd-series>
- <https://www.federalregister.gov/documents/2021/11/19/2021-23972/medicare-program-cy-2022-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>