DATA SCIENCE INSTITUTE®
AMERICAN COLLEGE OF RADIOLOGY

Overview of FDA Regulatory Framework

Po-Hao (Howard) Chen, MD, MBA
June 23, 2020

Disclosure

- I have no financial conflict of interest with respect to the contents of this presentation.

FDA Regulatory Framework

In the next 10 minutes, this presentation will:

- Provide an introduction to medical device classifications
- Describe the major pathways for “Software as medical devices” towards marketing
- Outline the needs surrounding an amended process, and the FDA’s proposal.

Why Does This Matter?

- Machine learning algorithms are considered medical devices.

- Software as a Medical Device (SaMD) → "**software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device**"

Classification

- Significance of information provided by software
- State of healthcare situation

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

International Medical Device Regulators Forum Classification (https://imdrf.org)

- In the US, FDA considers classes III and IV equivalently.

Source: https://www.fda.gov/medical-devices/

What is 510(k) Premarket Notification?

- Most Class I and some Class II are exempt.
- Prove “substantial equivalence” to a legally marketed device
- Prove safety and efficacy
  - Less rigorous than premarket approval (PMA).
  - Only a small percentage of 510(k)s require prospective data to support the application.
- FDA “cleared” not “approved” – but can be legally marketed and sold in US.

Source: https://www.fda.gov/medical-devices/

What is *De novo* classification?

- Automatic Class III Designation
- After receiving “No substantial equivalence device” during a 510(k) application, or may be pursued electively.
- Low to moderate risk
- May be pursued electively
- May be used for future 510(k)
- May be marketed (FDA cleared)

Source: https://www.fda.gov/medical-devices/

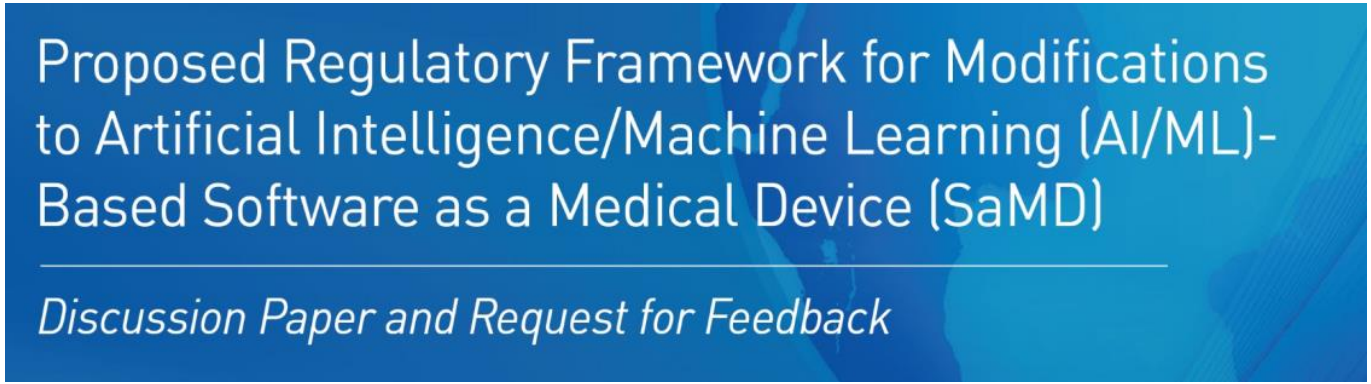
What is Premarket Approval (PMA)?

- Most stringent type of device marketing application by US FDA.
- Applies to most class III devices.
- Non-clinical (safety) and prospective clinical data (safety + effectiveness) usually required.
- Considered FDA approved.

Modifying the AI Model

- If software is altered, potentially need new 510(k) submission.
- Machine learning models are dissimilar to typical software, for instance:
  - Adding more/different training data changes performance without changing code.
  - Potential need to individualize deployments
  - Input data may be generated by hardware that currently do not exist

AI / ML is an Area of Active Discussion in FDA



FDA U.S. FOOD & DRUG ADMINISTRATION

DATA SCIENCE INSTITUTE®
AMERICAN COLLEGE OF RADIOLOGY

Predetermined Change Control

- Submitted during initial premarket review.
- **SaMD Pre-Specification (SPS)** – Defines regions of future potential changes.
- **Algorithm Change Protocol (ACP)** – Defines methods to achieve and appropriately control the risks of the anticipated modifications.

Summary

- Machine learning models are considered software-as-medical-device (SaMD)
- Many marketed imaging AI models have already gone through the complex FDA review process
- A proper regulatory balance in AI/ML change control remains an open question.