FDA REGULATION OF AI DEVICES IN RADIOLOGY:
AN OVERVIEW

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DISCLAIMER

This presentation is for educational purposes only and is not a substitute for legal advice on any particular matter.

Any individual seeking advice regarding the educational information in this presentation is urged to seek consultation with legal counsel.

FDA CLASSIFICATION OF DEVICES

Class I – Low Risk, Low Regulatory Burden

- "General controls" under the FD&C Act provide reasonable assurance of safety and effectiveness, including:
  - Establishment registration
  - Device listing
  - Quality System Regulation
  - Labeling requirements
  - Prohibitions against adulteration and misbranding
  - Reporting
- About 50% of the devices on the market are Class I
- About 75% of Class I devices are exempt from "premarket notification"

FDA CLASSIFICATION OF DEVICES

Class II – Moderate Risk, Moderate Regulatory Burden

- "Special controls" (in addition to general controls) provide reasonable assurance of safety and effectiveness
  - Premarket data requirements
  - Performance standards, post-market surveillance
  - Patient registries
  - Special labeling requirements
  - Device-specific guidance adherence
- Typically undergo "premarket notification" under "510(k)" process to demonstrate "substantial equivalence" to an existing device
- About 40% of devices on the market

FDA CLASSIFICATION OF DEVICES

Class III – High Risk, High Regulatory Burden, High Cost

- The “default” classification for all new devices (with exceptions)
- Includes devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a “potential” unreasonable risk of illness or injury
- Premarket Approval (PMA) under Section 515 of the FD&C Act
- PMA typically requires clinical trials, extensive nonclinical testing, manufacturing information, and pre-approval facility inspection
- Post-approval obligations include submitting PMA supplements for **material changes**, post-approval studies, annual reports, and enhanced post-market surveillance
- About 10% of devices on the market

FDA CLASSIFICATION OF DEVICES

Additional Points:

- **Classification is determined by a device's intended use and indications for use, not only by the device alone.**
- **A device's technology can fall into different classes depending on how the device is marketed and/or used.**
- **FDA can reclassify a device based on new information about risk.**

THE “DE NOVO” PROCESS

FDA Grants De Novo Request for One Predicate

There are several avenues through which a device’s sponsor can avoid default “Class III” classification.

One is through “De Novo Classification.”

Once FDA classifies one device as Class I or Class II through the De Novo process, that device serves as a “predicate” for future devices to obtain the same classification by demonstrating that the new device is “substantially equivalent” to the predicate.

In this way, each predicate starts a “lineage” of devices.

SUBSTANTIAL EQUIVALENCE

Based on Prior De Novo Approval – the 510(k) Pathway

New device sponsor demonstrates to FDA <u>either</u>:

1. **Same technological characteristics as the predicate.**

<u>or</u>

2. **Any different technological characteristics do not raise different questions of safety and effectiveness, and the device is at least as safe and effective as the predicate.**

This frequently involves a tabulated comparison of characteristics and a narrative explaining why the device raises no new questions of safety or effectiveness.

HOW DOES AI FIT IN?

FDA's 2024 Guidance on PCCPs

AI software and AI-enabled devices are fundamentally different from previous devices, in that they are anticipated to change over time.

In December 2024, FDA finalized guidance operationalizing a PCCP framework Congress authorized in 2022 through FDORA legislation, allowing sponsors to receive approval for a defined set of future changes as part of a single marketing submission, rather than submitting each change separately.

FDA had previously approved proposed PCCPs, but there was no formal guidance and acceptability was uncertain.

After FDA's 2024 guidance, PCCPs became more common in applications, but FDA was criticized as not publishing sufficiently clear rules regarding appropriate PCCPs.

AI IN RADIOLOGY SOFTWARE

Adoption of 21 CFR 892.2055

In June 2026, FDA adopted a regulation establishing a classification and predicate for "Radiological machine learning-based quantitative imaging software with predetermined change control plan."

This is the first regulatory device classification incorporating PCCPs into special controls.

Three core components of the PCCP:

- **Description of Modifications**
- **Modification Protocol**
- **Impact Assessment**

PCCP SPECIAL CONTROLS

Under 21 CFR 892.2055

- **Detailed description of algorithm**
- **Detailed description of training data**
- **Performance testing protocols and objective statistics demonstrating that software functions as intended**
- **Hazard analysis**
- **Description of planned modifications, risks of modifications, and mitigation efforts**
- **Detailed labeling for the user describing how the software functions, testing performance, intended use, risks, and predetermined changes**

TAKEAWAYS

- FDA has now issued regulations that provide formal regulatory detail regarding expectations for approval of AI software in radiology without the full “premarket approval” used for Class III devices.
- FDA will likely apply these principles to physical devices that are AI-enabled, not just software.
- AI-enabled software and devices are not risk-free.
- Key open questions: How will drift be detected? How will physicians be notified of updates? How will performance be monitored if results for subpopulations may differ from the training data?

TAKEAWAYS - SOFTWARE LABELING

Prospectively Required Software Documentation to Review

- Validated Patient Population, Performance Data, and Conclusions
- Intended User and Required Expertise
- Device Inputs and Outputs
- Compatible Imaging Hardware and Protocols
- Known Failure Modes and Limitations
- PCCP Disclosures – i.e., Planned Modifications

QUESTIONS?

If you have questions after this presentation, please contact me:

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