# New Challenges in Regulating Artificial Intelligence in Radiological Imaging

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# Overview of Regulation of Radiological AI/ML

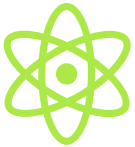
- Mission & Vision
- Key Regulatory Concepts
- Brief History
- New Challenges


# CDRH's Mission

- ✓ **Protect and promote public health**
- ✓ **Safe, effective, and high-quality devices**
- ✓ **Science-based information**
- ✓ **Facilitate innovation**

# Our Vision for Radiological AI/ML

Patients in the U.S. have access to high-quality, safe, and effective devices first in the world



The U.S. is the world's leader in regulatory science and technology development

Transparency and real-world evidence foster confidence in device performance

Policies that are consistent, transparent, and effective for public health

# Key Regulatory Concepts

- For new technologies, discussion of the
  - Benefits and risks, and
  - Potential risk mitigation through **general/special controls**

  helps determine the appropriate regulatory pathway and performance testing

# General and Special Controls

- General controls apply to all medical devices, unless exempted by regulation
  - Examples: registration and listing, and good manufacturing practices

- Alone are unlikely to provide a reasonable assurance of safety and effectiveness for radiological AI/ML devices

# General and Special Controls

- Special controls
  - When general controls alone are not sufficient
  - Experience and knowledge can be used establish device-specific risk mitigations
  - Examples:
    - Performance testing: “A thorough, quantitative evaluation of the diagnostic utility and quality of images/data acquired, or optimized, using the device”
    - Labeling: “A statement on upholding the As Low As Reasonably Achievable (ALARA) principle with a discussion on the associated device controls/options”

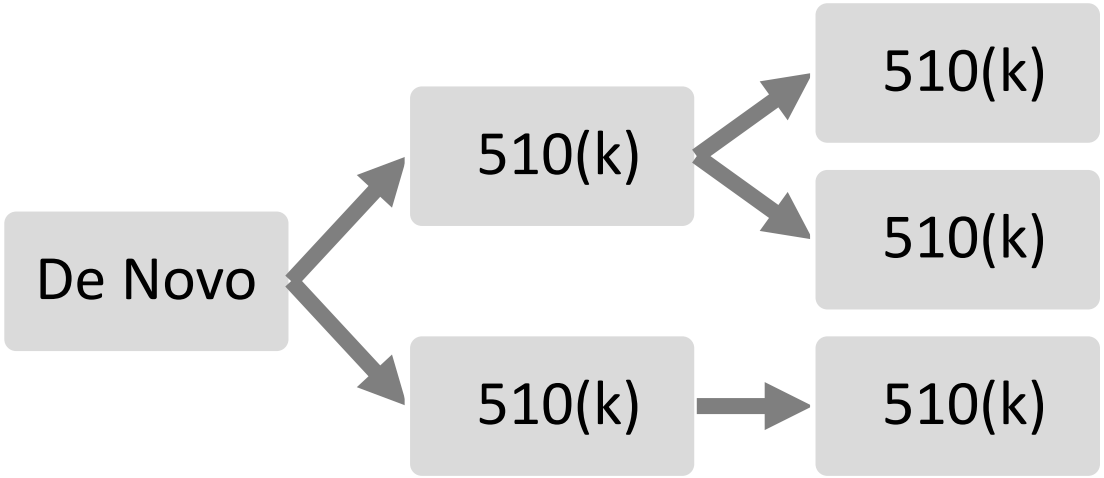
# Premarket Submission Pathways

| Pathway | Summary |
|---|---|
| **De Novo*** | Establishes the 510(k) pathway for a new device type if general/**special controls are sufficient for risk mitigation** |
| 510(k) | Evaluation of substantially equivalence of a device to a legally marketed predicate; FDA reviews intended use, technological characteristics, performance testing, and if **special controls** need to be addressed |
| Premarket Approval (PMA) | High-risk devices that already require a PMA; or general/special controls are not adequate for risk mitigation |

*A De Novo can also result in a 510(k) Exempt determination and/or a determination that general controls alone are sufficient for risk mitigation

# 510(k) & Special Controls

- Special controls provide consistency and transparency on the expectations for the validation of safety, effectiveness, and risk mitigations in future 510(k)s

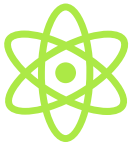


# Regulation of Radiological AI/ML

- How does experience and knowledge of
  - Benefits and risks
  - Risk mitigation through special controls, and
  - Validation / performance testing

  facilitate our mission and vision for radiological AI/ML?

Safety & Effectiveness



Best Science

Transparency & Confidence

Effective Policies

# Regulation of Radiological AI/ML


- Premarket Approvals for Computer Aided Detection (CADe)
  - 1998 – First PMA approval for mammography CADe
  - 1998 to 2017 – Additional approvals for specific dental, chest radiograph, mammography, and ultrasound indications
- **Experience** from regulating CADe and other uses of AI/ML for image processing tasks (e.g., segmentation) and 510(k)s for CT colon/chest CADe
- **Knowledge** from public meetings, research, guidance development, and public feedback

# Regulation of Radiological AI/ML


- Relied on experience and scientific knowledge to define **special controls** for risk mitigation
- Established the 510(k) regulatory pathway for more radiological AI/ML device types through De Novos and reclassification

# Regulation of Radiological AI/ML

1998 - 2017

2017 - 2020

- De Novos
  - 2017: Computer aided diagnosis (CADx) (DEN170022, QuantX)
  - 2018: Computer aided triage (CADt) (DEN170073, ContaCT)
  - 2018: Combined detection and diagnosis (CADe/x) (DEN180005, OsteoDetect)
  - Feb 2020: Radiological acquisition and/or optimization guidance systems (DEN190040, Caption Guidance)
- Reclassification
  - Jan 2020: Reclassification of CADe from PMA to 510(k)

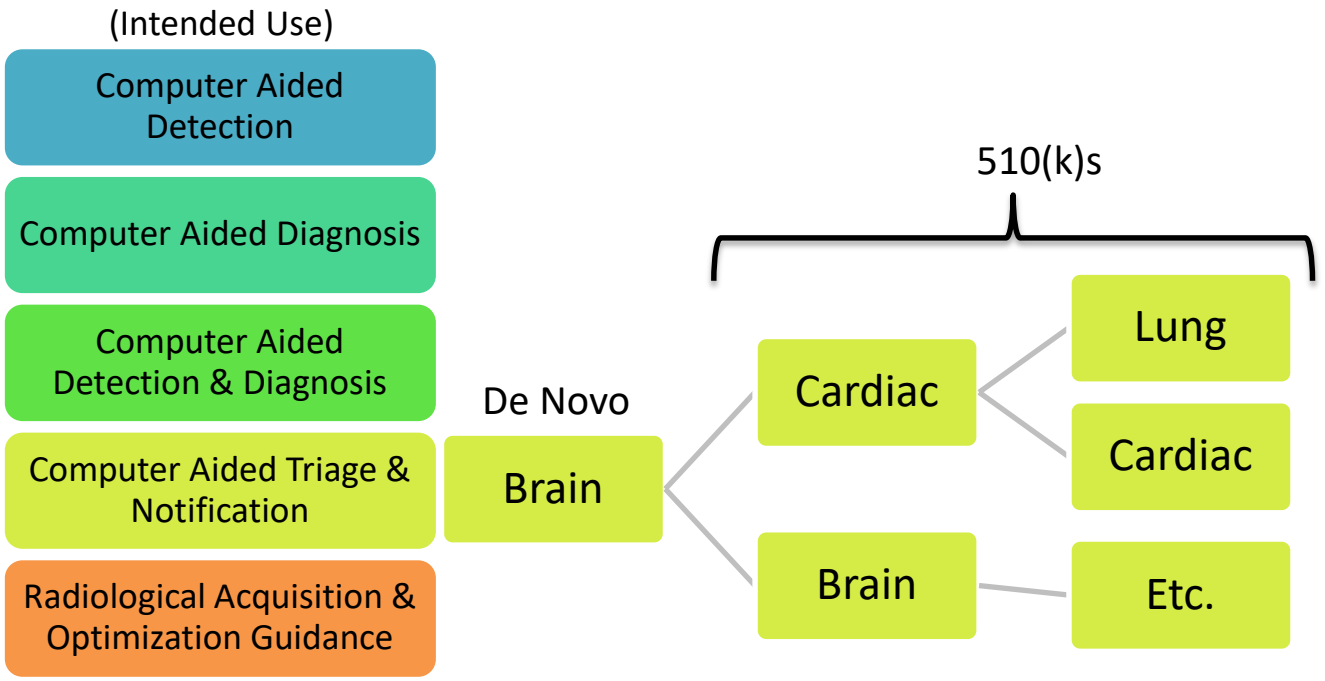
# Regulation of Radiological AI/ML

(Intended Use)

| | |
|---|---|
| Computer Aided Detection | • CADx: concurrent/sequential use to aid the identification of potential disease; 510(k) under 21 CFR 892.2050 or 892.2070 |
| Computer Aided Diagnosis | • CADx: concurrent/sequential use to aid the classification of lesions suspicious of cancer; 510(k) under 21 CFR 892.2060 |
| Computer Aided Detection & Diagnosis | • CADe/x: combined systems that both detect and provide a classification of potential disease; 510(k) under 21 CFR 892.2090 |
| Computer Aided Triage & Notification | • CADt: notification of potentially time sensitive findings – not CADe/x; 510(k) under 21 CFR 892.2080 |
| Radiological Acquisition & Optimization Guidance | • Aid the acquisition/optimization of images/diagnostic signals; 510(k) under 21 CFR 892.2100 |

# Regulation of Radiological AI/ML

- Special controls provide consistency and transparency on the expectations for the validation of safety, effectiveness, and risk mitigation in future 510(k)s



# Regulation of Radiological AI/ML


- Continue to refine policies for current technologies…
- Promote best practices…
  - Study designs that match the intended use/indications
  - Not tuning on the “validation” dataset
  - Pre-specified algorithm change and testing protocols
- Seek greater insight on post-market performance
- Engage with CDRH Digital Health efforts

# Regulation of Radiological AI/ML

1998 - 2017 | 2017 - 2020 | Future

- Many challenges – but this workshop is more specific!
- Proactively discuss
  - Benefit and risks
  - Potential risk mitigation through special controls, and
  - Validation / performance testing

  for autonomous AI/ML systems and AI/ML-guided image acquisition systems

# New Challenges

- Day 1: Autonomous AI/ML systems that automate some portion of the radiological imaging workflow
- Day 2: AI/ML-guided image acquisition systems that guide a non-expert user to acquire diagnostic quality images
- Both challenge the standard of care by introducing new questions of safety and effectiveness into an established radiological imaging workflow
- What risk mitigations and performance testing are appropriate?

# Example – Autonomous AI/ML

- **Device:** AI intended to identify a patient's condition as stable from images, without a radiologist's review to confirm
- **Benefits include**: Potential reduction in radiologists' workload allowing them to focus on more critical cases
- **Risks include**: Potential for false negatives and missing secondary findings the algorithm was not trained to identify
- **Challenging questions:**
  - What are approaches to establish an acceptable device performance?
  - What other risks are introduced for the radiological imaging workflow, patients, and healthcare providers?
  - What additional experience or knowledge do we need to develop sufficient risk mitigations?
  - Should real-world performance monitoring and QC be expected as AI becomes more autonomous?

# Example – AI Guided Imaging

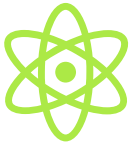
- **Device:** AI guided ultrasound intended to enable use by untrained operators in emergency settings
- **Benefits include**: Faster acquisition of diagnostic information that can be transmitted to a remote reading room
- **Risks include**: Failures may delay patient care or result in an incorrect diagnosis; lack of operator knowledge of ALARA
- **Challenging questions:**
  - What trade-off in image quality is acceptable?
  - What risks could be mitigated with just-in-time operator training?
  - What are potential mechanisms to assess real-world performance?
  - Can special controls be adapted to mitigate the risks in different scenarios?
  - What level of transparency will give users confidence in the AI?
  - What are the patient perspectives?

# Summary

- We're seeking feedback on the
  - Benefit-risks
  - Risk mitigations, and
  - Validation / performance testing

  for autonomous AI/ML systems and AI/ML-guided image acquisition systems to best inform policies that support our public health mission and vision

Safety & Effectiveness



Best Science

Transparency & Confidence

Effective Policies


FDA
U.S. FOOD & DRUG
ADMINISTRATION