Regulation and Monitoring

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Slide credit: Rebecca Boiarsky





You develop an AI algorithm related to healthcare. What factors should be considered before we let you run loose?

Outline

- **Food and Drug Administration** (25 mins)
- **Gray areas** (15 mins)
- **Other legal avenues** (10 mins)



How can we make Data 146 better for you?

Learning Objective: Understand current regulatory processes and challenges moving forward

Overview of Regulatory Bodies

- **Food and Drug Administration (FDA) in the United States**
- European Medicines Agency (EMA) & CE Marking (EU)
- MHRA (UK)
- Health Canada (Canada)
- National Medical Products Administration (NMPA, China)
- International regulatory harmonization efforts (IMDRF, WHO, OECD AI Principles)

What is the FDA?



What is the FDA?

- Food and Drug Administration is a **federal agency** of the Department of Health and Human Services
- Responsible for “protecting and promoting **public health**”
- Main job is **enforcement** of Federal Food, Drug, and Cosmetic Act (FD&C) created in 1938



What does the FDA have to do with AI?

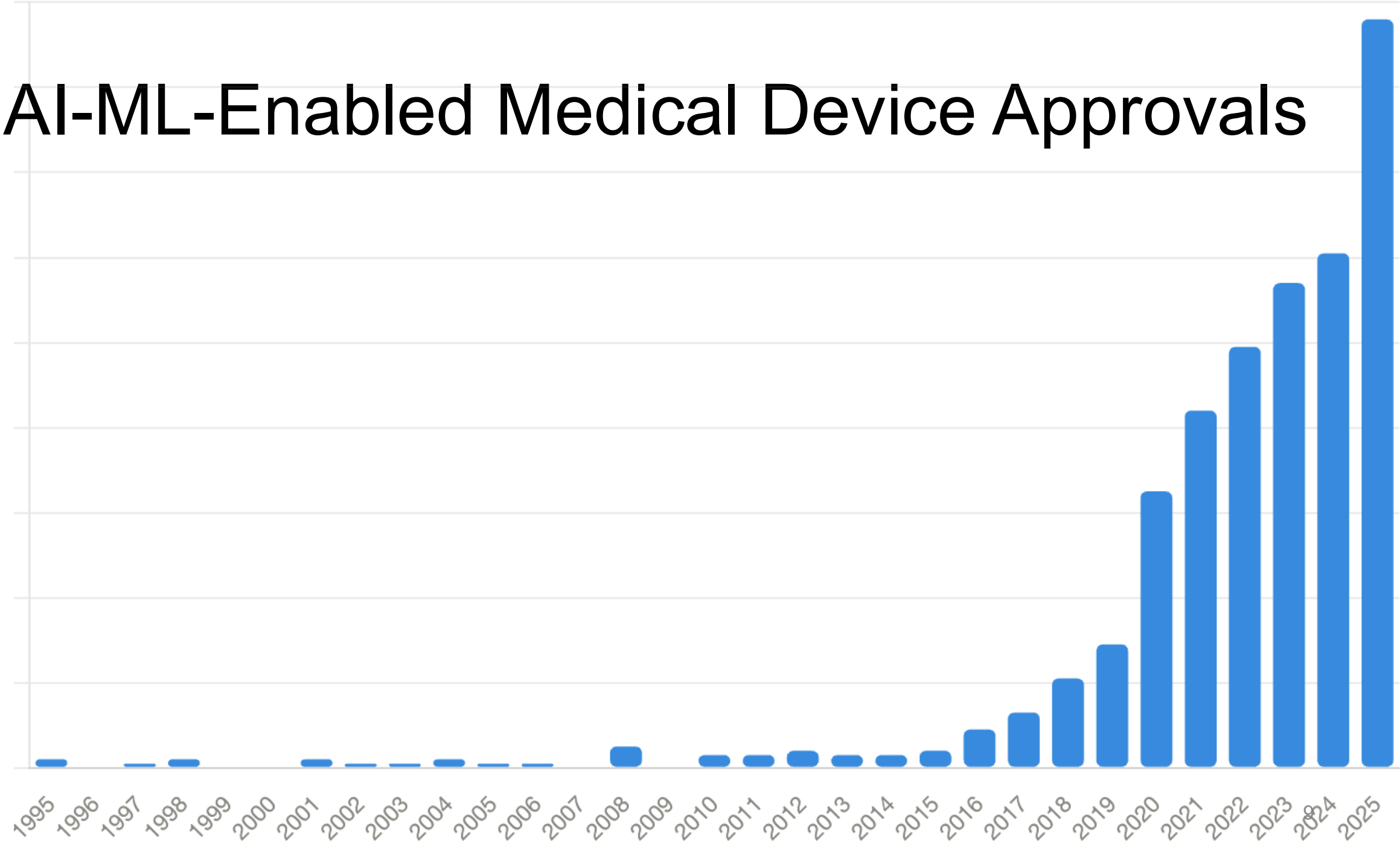
- Algorithms are considered “medical devices” because they affect patient health and safety
- Many premarket **regulatory pathways**:
  - Premarket approval (PMA)
  - Premarket clearance (510(k))
  - De Novo classification
  - Breakthrough device designation
- **Modifications** to medical devices often require premarket review too, depending on the risk posed to patients



Software as a Medical Device (SaMD)

- SaMD refers to **software intended for medical purposes** that performs these functions without being part of a hardware medical device.
- Modifications to SaMD would require review if the change:
  - significantly affects device performance, or safety and effectiveness
  - the modification is to the device's intended use
  - the modification introduces a major change to the SaMD algorithm.
- **Critical question**: when does a continuously learning AI/ML SaMD require a premarket submission for an algorithm change?

AI-ML-Enabled Medical Device Approvals



How many FDA approved AI/ML-Enabled Medical devices are there?

A. < 100

B. 100-1000

C. 1000-5000

D. 5000-10k

E. 10k+

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A. < 100

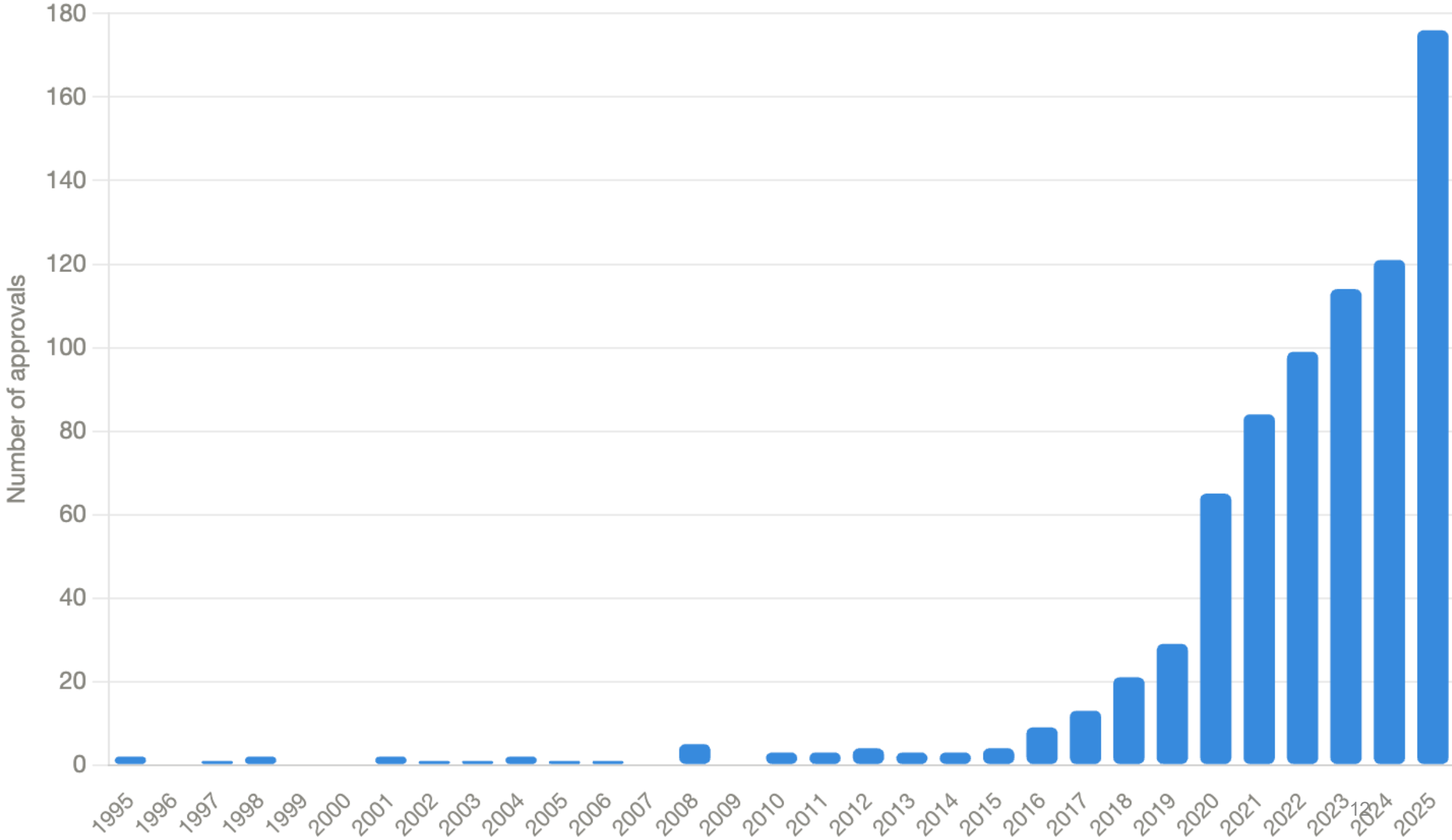
B. 100-1000

C. 1000-5000 (1014 as of Dec 2025)

D. 5000-10k

E. 10k+

Source: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices


Number of approvals
180
160
140
120
100
80
60
40
20
0
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
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2020
2021
2022
2023
2024
2025

What area has the most approved devices?

A. Radiology
B. Cardiovascular
C. Neurology
D. Hematology
E. Pathology

What area has the most approved devices?

A. **Radiology: 797**
B. Cardiovascular: 100
C. Neurology: 57
D. Hematology: 17
E. Pathology: 10

Panel (Lead)	Count
Radiology	797
Cardiovascular	100
Neurology	57
Anesthesiology	28
Gastroenterology-Urology	27
Hematology	17
Pathology	10
Orthopedic	7
Ophthalmic	7
General and Plastic Surgery	6
Clinical Chemistry	6
Obstetrics and Gynecology	4
Microbiology	4
Dental	4
General Hospital	3
Clinical Toxcicology	3

Source: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

2019: FDA put out discussion paper & request for feedback



https://www.fda.gov/media/122535/download

2021: FDA publishes its action plan



https://www.fda.gov/media/145022/download

Risk Categorization for SaMD

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

Figure 1: SaMD IMDRF risk categorization

4 FDA Regulatory Pathways

1. Premarket approval (PMA)
2. Premarket clearance (510(k))
3. De Novo classification
4. Breakthrough device designation

Premarket approval (PMA)

- Most stringent pathway
- Required for Class III (high-risk) devices
- Demands clinical trial data demonstrating safety and effectiveness
- Requires thorough scientific review

Premarket approval (PMA)

- **Claire OCT system**: intraoperative imaging device designed for breast cancer margin assessment during breast-conserving surgery (lumpectomy)
- Class III device
- TIME's Best Inventions of 2026
- Pivotal trials demonstrated an 88.1% margin accuracy

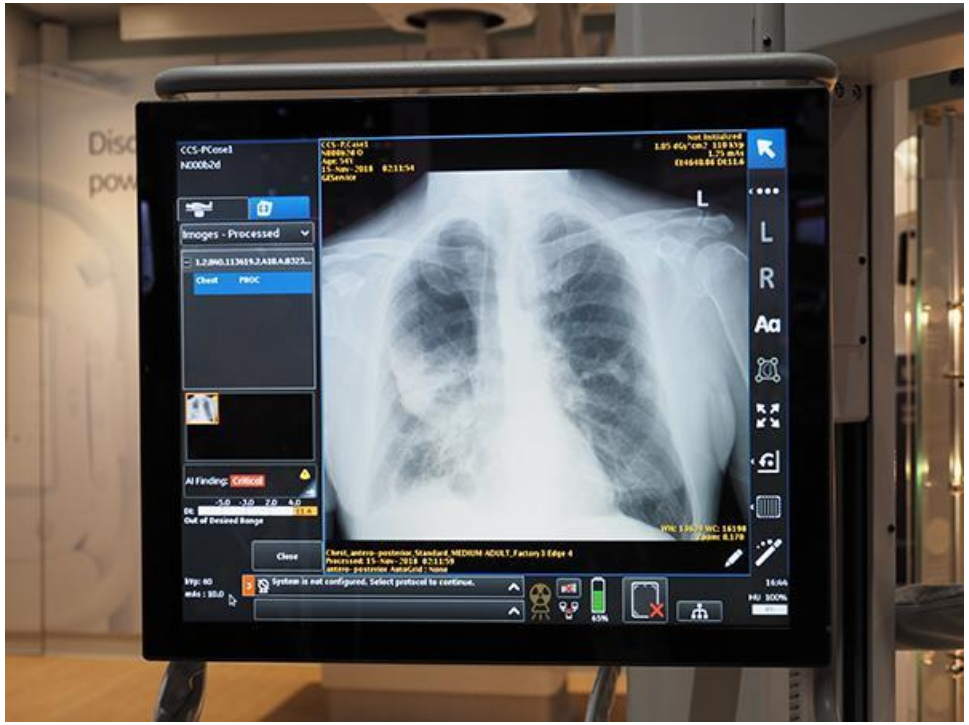


Premarket clearance (510(k))

- For devices substantially equivalent to already marketed devices
- Commonly used for moderate-risk (Class II) devices
- Faster than PMA process
- Requires demonstration of substantial equivalence to predicate device

Premarket clearance (510(k))

- **GE Critical Care Suite**: Analyzes chest X-rays for pneumothorax, identifies suspicious images, and helps prioritize cases for radiologist review
- Assist clinicians, not independently diagnose



FDA doc: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K223491

U.S. FOOD & DRUG ADMINISTRATION



GE Medical Systems, LLC
℅ Chris Paulik
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

May 25, 2023

Re: K223491
Trade/Device Name: Critical Care Suite with Pneumothorax Detection AI Algorithm
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QBS
Dated: April 26, 2023
Received: April 27, 2023

Dear Chris Paulik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database

De Novo Classification

- For novel devices with no predicate
- Creates new classification and regulatory controls
- Used when device is low to moderate risk but no equivalent exists
- Establishes special controls for the device type

De Novo Classification

- Viz.ai ContaCT: AI software that **analyzes CT images** to identify potential stroke and alerts specialists, creating a new regulatory category



Breakthrough Device Designation

- Expedited review for innovative technologies
- For devices providing more effective treatment/diagnosis of life-threatening conditions
- Provides priority review and interactive communication
- Can be used alongside other pathways

Breakthrough Device Designation

- Caption Health's Caption AI: Ultrasound software that **guides users** to capture diagnostic-quality cardiac **ultrasounds** (received both Breakthrough designation and 510(k) clearance)



What about modifications?

What about modifications?

1. **Performance** modifications: Changes that improve algorithm performance without altering intended use
2. **Intended use** modifications: Changes to the software's clinical functionality, condition targeted, or patient population
3. **Input** modifications: Changes to the type of input data used

Other Considerations

- **Post-Market Surveillance**: AI-based devices require real-world performance monitoring due to evolving datasets.
- **Bias, Fairness, and Generalizability**: Regulators focus on ensuring diverse training data and mitigating biases.
- **Explainability vs. Regulatory Acceptance**: Trade-offs between model transparency and black-box AI models.

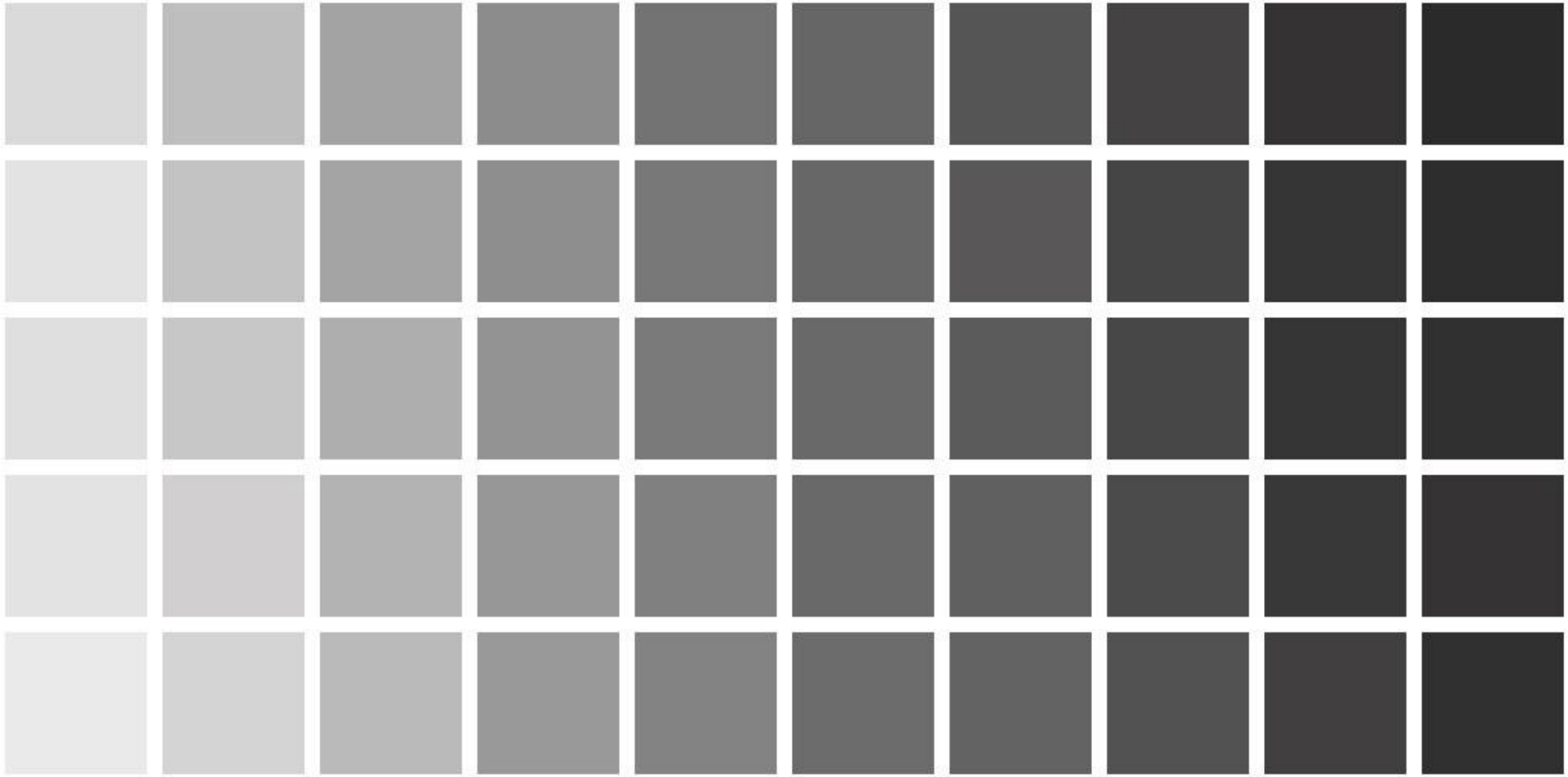
Other Regulatory Bodies

- European Medicines Agency (EMA) & CE Marking (EU)
  - Risk-based classification system, similar to FDA
  - Stricter post-market surveillance compared to FDA
- MHRA (UK)
  - Similar to EMA but with AI-specific regulations
  - Focus on transparency, accountability, and lifecycle monitoring
- Health Canada (Canada)
  - Similar risk classification system, emphasis on post-market surveillance
- National Medical Products Administration (NMPA, China)
  - Local clinical validation and data sovereignty requirements
  - Stricter approval process compared to FDA/EMA
- International regulatory harmonization efforts (IMDRF, WHO, OECD AI Principles)



https://www.gov.uk/government/consultations/ai-regulation-a-pro-innovation-approach-policy-proposals/outcome/a-pro-innovation-approach-to-ai-regulation-government-response#executive-summary

Gray Areas



Gray Areas

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Chatbot (GPT, Claude, Gemini, etc) gives out medical advice.

IC My stomach hurts (5/10 pain) and it's been a few days. My diet hasn't changed. I'm a 33 year old woman.

Stomach pain lasting several days requires medical attention. Possible causes include:

- Gastritis or peptic ulcer
- Food poisoning (though symptoms usually resolve faster)
- Irritable bowel syndrome
- Appendicitis (particularly if pain localizes to lower right abdomen)
- Gallstones (especially if pain follows fatty meals)
- Gynecological issues (ovarian cysts, endometriosis)

Please see a doctor soon, as persistent abdominal pain needs proper evaluation. In the meantime:

- Note pain location, timing, and what makes it better/worse
- Stay hydrated
- Avoid alcohol, spicy foods, and NSAIDs
- Try a heating pad for temporary relief

This isn't medical advice - a healthcare provider can properly diagnose and treat your condition.

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Hospitals using AI-assisted scribing or message drafting.

Who is accountable besides the FDA?

- Doctors decide if they want to use an AI model
- Patients decide if they consent to an AI model being used on them
- Insurance providers can determine whether an AI model is covered
- Consumer protection agencies can launch investigations
- Governments can pass laws


Trust Nurses Not AI
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Trust Nurses Not AI
Patients are NOT Algorithms
RN

California AB 1979

- Sponsored by CA Nurses' Union
- Requires **"reasonable steps"** to maintain a human clinical judgement when AI is used in clinical care
- AI heath chatbot companies are subject to health information **privacy regulations**
- AI tools **cannot act independently** in clinical tasks like assessments, diagnoses, or clinical decision-making

https://legiscan.com/CA/text/AB1979/id/3399966

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Signed into law
Sept 30, 2026

https://legiscan.com/CA/text/AB1979/id/3399966

California AB 2575

- Sponsored by the CA Nurses' Union
- Protect workers' right to use professional judgement and **override** clinical decision support systems
- Prohibit developers of AI models to use healthcare worker as way to **sever legal liability**
- Workers facing **retaliation** could file with California Labor Commissioner

https://calmatters.digitaldemocracy.org/bills/ca_202520260ab2575

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Vetoed by Gov Newsom
Sept 30, 2026

https://calmatters.digitaldemocracy.org/bills/ca_2

California leads the US in regulating AI

- **SB 1120 (2024)**: AI must use individual's attributes to make decision
- **AB 3030 (2024)**: Clinicians must disclose when AI is used for clinical communications
- **AB 489 (2025)**: AI cannot imply health advice is being given by a real person

What other state has the most active AI and health pilot programs?

What's going on in Utah?

- **Oct 2025**: Utah authorized Doctronic to use AI renew medications for chronic conditions without requiring a physician to sign off (still in Phase 1)
- **March 2026**: Nolla can initiate topical acne treatment from facial photographs using AI (two physicians prospective review right now)
- **Oct 2026**: August AI can use AI to renew medications for stable chronic conditions (prospective approve first 250, retrospective review next 1000, then audit 5%)

Federal AI Policies

- **Blueprint for AI Bill of Rights** (2022): Non-binding, five principles
- **Biden Executive Order 14110** (2023, revoked in 2025): Share safety test results with federal agencies, direct relevant federal agencies
- **ONC HTI-1** (2023): Patients can see their health data, developer transparency, modern standards for health IT
- **ONC HTI-5** (2026): Deregulatory measure, cut compliance costs

You develop an AI algorithm related to healthcare. What factors should be considered before we let you run loose?

Factors to consider

- What is the performance of the algorithm?
- Who the evaluation was done on vs general population?
- How high-stakes is the setting?
- Is there a historical precedent of similar algorithms?
- What are your credentials?
- Who will be using the algorithm and what are their rights?
- Is this purely medical or general purpose?
- What are the consequences if we don’t allow this algorithm?

Discussion

- How should regulators balance innovation with safety?
- To what extent is the FDA equipped to perform regulation for AI in medicine? Where is it ill-equipped?
- How do we navigate academic-industry collaborations on regulatory compliance?
- What does this mean for you as a student working on AI/ML projects in healthcare?

Summary

- ✓**Food and Drug Administration**
- ✓**Gray areas**
- ✓**Other legal avenues**



How can we make Data 146 better for you?

Next class: Ethics and bias