

REGULATORY INTELLIGENCE REPORT

AI-Driven Medical Device Registration in the United States

Regulatory Intelligence Report | United States FDA

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JURISDICTION	REGULATORY BODY	TOPIC	AUTHOR	DATE
United States	FDA / CDRH	AI/ML Medical Devices	RegDesk Data Intelligence	July 2026

This report has been prepared by RegDesk Data Intelligence for informational purposes only. The regulatory landscape for AI/ML medical devices is evolving rapidly. Users should verify current requirements with the FDA and qualified regulatory counsel before making compliance decisions. All references are to publicly available FDA guidance documents and regulations.

Table of Contents

1.	Overview & Regulatory Framework	3
2.	Device Classification System	4
3.	Premarket Pathways for AI Devices	5
4.	AI/ML-Specific Regulatory Framework	6
5.	Key Guidance Documents	8
6.	Good Machine Learning Practice (GMLP)	9
7.	Submission Requirements for AI Devices	10
8.	Post-Market Requirements	11
9.	AI Device Authorization Statistics (Through Early 2025)	12
10.	Recent Developments (2023–2024)	13
—	References	14

1. Overview & Regulatory Framework

The FDA regulates AI-driven medical devices primarily under the **Software as a Medical Device (SaMD)** framework, in alignment with the International Medical Device Regulators Forum (IMDRF). The key regulatory body is the **Center for Devices and Radiological Health (CDRH)**.

AI/ML-based medical devices are regulated like any other medical device — the pathway depends on risk classification and substantial equivalence to predicate devices.

Key Regulatory Bodies & Frameworks

- **FDA / CDRH** — Primary regulatory authority for medical devices in the United States
- **IMDRF** — International Medical Device Regulators Forum; provides SaMD guidance framework
- **SaMD Framework** — Governs software-only medical devices including all AI/ML applications
- **21 CFR Part 820** — Quality System Regulation applicable to all device manufacturers

Regulatory Scope

AI/ML-based SaMD encompasses a broad range of applications including:

- Diagnostic imaging analysis (radiology, pathology, ophthalmology)
- Clinical decision support systems
- Remote patient monitoring with AI analysis
- AI-driven cardiac monitoring and arrhythmia detection
- Predictive analytics for patient deterioration
- Computer-aided detection and diagnosis (CAD) systems

FDA Evaluation Criteria for SaMD

FDA evaluates AI/ML-based SaMD based on three key dimensions:

- **Intended use** — What the software is intended to do
- **Healthcare situation/condition** — The clinical context in which it is used
- **State of the healthcare situation** — Whether the condition is critical, serious, or non-serious

2. Device Classification System

FDA classifies medical devices — including AI-driven devices — into three classes based on risk level and the regulatory controls necessary to provide reasonable assurance of safety and effectiveness.

Class	Risk Level	Regulatory Control	Common Pathway
Class I	Low	General controls	Exempt or 510(k)
Class II	Moderate	General + Special controls	510(k) or De Novo
Class III	High	Premarket approval	PMA

Most AI/ML medical devices fall into **Class II**, requiring 510(k) clearance or De Novo authorization.

Classification Criteria

Device classification depends on:

- **Intended use** — The objective intent of the device
- **Indications for use** — Specific conditions the device diagnoses, treats, monitors, or mitigates
- **Risk to patient** — Potential harm if the device fails or performs incorrectly
- **Predicate devices** — Existence of legally marketed devices with similar intended use

AI Device Classification Examples

AI Device Type	Typical Class	Pathway
AI-powered radiology image analysis (non-diagnostic aid)	Class II	510(k)
AI-based diabetic retinopathy screening (autonomous diagnosis)	Class II	De Novo
AI-driven cardiac monitoring in implantable devices	Class III	PMA
AI clinical decision support (physician confirms)	Class I/II	Exempt or 510(k)

3. Premarket Pathways for AI Devices

3.1 510(k) — Premarket Notification

Most common pathway for AI-driven devices. Requires demonstration of **substantial equivalence** to a legally marketed predicate device.

- FDA must clear within **90 days** (standard) or **30 days** (abbreviated/special)
- AI-specific consideration: the algorithm's training data, validation dataset, and performance metrics must be documented
- Substantial equivalence requires: same intended use AND same or different technological characteristics that do not raise new safety/effectiveness questions

3.2 De Novo — Novel Low-to-Moderate Risk

Used when no predicate exists but device is **low-to-moderate risk**.

- FDA classifies the device and sets special controls (often includes performance standards for AI)
- Growing pathway for novel AI diagnostics (e.g., first-of-kind AI imaging tools)
- Once granted, the authorized device becomes a predicate for future 510(k)s
- **Timeline:** ~150 days average

3.3 PMA — Premarket Approval

Required for **Class III AI devices** (high-risk, life-sustaining, or implantable).

- Most rigorous pathway — requires valid scientific evidence of safety and effectiveness
- Examples: AI-driven cardiac monitoring in implantable devices
- **Timeline:** 180 days FDA review

3.4 Breakthrough Device Designation

Available for AI devices that provide more effective treatment/diagnosis of life-threatening conditions.

- Grants **priority review**, more FDA interaction, rolling submission
- FDA has granted Breakthrough designation to dozens of AI diagnostic tools (radiology, pathology, cardiology)
- Does not change the regulatory pathway — only expedites review

Pathway	Typical Class	Key Requirement	Timeline
510(k)	Class II	Substantial equivalence to predicate	90 days
De Novo	Class II (new)	No predicate; low-to-moderate risk	~150 days
PMA	Class III	Valid scientific evidence	180 days
Breakthrough	Any class	Life-threatening condition + superior outcome	Priority

4. AI/ML-Specific Regulatory Framework

4.1 SaMD Definition & Applicability

Per IMDRF and FDA: SaMD is *"software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."*

AI-based SaMD is subject to all SaMD regulations. FDA evaluates:

- **Intended use**
- **Healthcare situation/condition**
- **State of the healthcare situation**

4.2 The AI/ML Action Plan (January 2021)

FDA published its *"Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device Action Plan"*, outlining 5 pillars:

1. **Tailored regulatory framework for adaptive AI/ML** — addressing "locked" vs. "adaptive" algorithms
2. **Good Machine Learning Practice (GMLP)** — standards for AI development
3. **Patient-centered approach** — transparency, algorithmic bias awareness
4. **Regulatory science methods** — real-world performance monitoring
5. **Real-world performance (RWP)** — post-market surveillance specific to AI

4.3 Predetermined Change Control Plan (PCCP)

Introduced in FDA Guidance (2023) — allows manufacturers to **pre-specify how an AI algorithm can change** without requiring a new 510(k).

PCCP must describe:

- The modifications anticipated
- The methodology for implementing them
- Performance evaluation methods

Critical for adaptive/learning AI systems.

4. AI/ML-Specific Regulatory Framework (continued)

4.4 Locked vs. Adaptive Algorithms

One of the most important distinctions in AI/ML device regulation is whether the algorithm is "locked" or "adaptive" after deployment.

Type	Definition	Regulatory Treatment
Locked	Algorithm does not change after deployment	Standard device review — changes require new submission
Adaptive	Algorithm continues to learn/change in production	PCCP required; more complex review process

Implications for Manufacturers

The locked vs. adaptive distinction has significant implications for product lifecycle management:

- **Locked algorithms:** Any change to the algorithm's logic, architecture, or training data typically requires a new 510(k) or PMA supplement
- **Adaptive algorithms:** Must have a PCCP in place that pre-defines permissible modifications, evaluation methods, and conditions under which a new submission is triggered
- **Continuous learning:** AI systems that learn in production require particularly robust monitoring and change management processes
- **Distribution shift:** Performance degradation due to changes in patient population or clinical practice must be monitored and reported

Key Takeaway: Manufacturers developing adaptive AI systems should engage with FDA early in development to discuss PCCP requirements and establish appropriate performance monitoring frameworks.

5. Key Guidance Documents

The following primary FDA guidance documents govern AI/ML medical device regulation in the United States:

#	Guidance Document	Date	Key Content
1	Proposed Regulatory Framework for AI/ML-Based SaMD	2019	Discussion paper; introduced locked vs. adaptive concepts
2	AI/ML Action Plan	Jan 2021	5-pillar roadmap for AI regulation
3	Good Machine Learning Practice (GMLP) Guiding Principles	Oct 2021	Joint FDA/Health Canada/MHRA principles
4	Marketing Submission Recommendations for AI/ML-Based SaMD (Draft)	Apr 2023	Practical submission guidance; PCCP details
5	Transparency for Machine Learning-Enabled Medical Devices (Draft)	Oct 2023	Labeling requirements for AI devices
6	AI-Enabled Device Software Functions: Lifecycle Management (Draft)	Dec 2023	Full lifecycle approach for AI devices

Regulatory Evolution Timeline

Year	Milestone
2019	FDA Discussion Paper on AI/ML SaMD framework — first formal regulatory thinking
2021 (Jan)	AI/ML Action Plan published — 5-pillar framework established
2021 (Oct)	GMLP Guiding Principles released jointly with Health Canada & MHRA
2023 (Apr)	Draft Marketing Submission Recommendations issued — first detailed submission guidance
2023 (Oct)	Draft Transparency Guidance — AI labeling requirements introduced
2023 (Dec)	Lifecycle Management Draft — full product lifecycle approach for AI
2024	Updated AI Action Plan; CDRH AI Strategic Plan; foundation model guidance in progress

6. Good Machine Learning Practice (GMLP)

The 10 GMLP principles were co-developed by FDA, Health Canada, and UK MHRA to establish international standards for AI/ML medical device development.

#	GMLP Principle
1	Multi-disciplinary expertise throughout the total product lifecycle
2	Good software engineering and security practices
3	Clinical study participants and datasets representative of intended patient population
4	Training data independence from test sets
5	Selected reference datasets based on best available methods
6	Model designed to ensure performance for intended clinical use
7	Focus on the needs of the patient/caregiver/provider
8	Enhance explainability to users
9	Deployed models perform as intended (real-world monitoring)
10	Risks from AI/ML addressed proportionally throughout device lifecycle

International Collaboration

The GMLP principles represent a landmark in international regulatory harmonization for AI:

- **FDA (United States)** — Center for Devices and Radiological Health (CDRH)
- **Health Canada** — Medical Devices Directorate
- **MHRA (United Kingdom)** — Medicines and Healthcare Products Regulatory Agency

This joint publication signals growing international alignment on AI device standards, complementing the EU AI Act and IMDRF SaMD frameworks.

Practical Implication: Manufacturers should incorporate GMLP principles from the earliest stages of AI development. FDA reviewers evaluate adherence to GMLP as part of premarket submissions for AI/ML devices.

7. Submission Requirements for AI Devices

Technical Documentation Required

Documentation Element	Required Detail
Algorithm description	Architecture, type (CNN, RNN, transformer, etc.), training methodology
Dataset characteristics	Size, demographics, geographic origin, inclusion/exclusion criteria
Data management	Preprocessing, augmentation, labeling methodology, inter-rater variability
Training/validation/test split	Must be independent; no data leakage between sets
Performance metrics	Sensitivity, specificity, AUC, F1-score, PPV, NPV
Subgroup analysis	Performance across age, sex, race/ethnicity, relevant clinical subgroups
Uncertainty quantification	Confidence scores, failure modes, edge cases
Cybersecurity	Per FDA's 2023 cybersecurity guidance (21 CFR Part 820)

Labeling Requirements (AI-Specific)

- Intended use and indications for use (specific to AI outputs)
- Description of AI outputs and their clinical meaning
- Known limitations and failure modes
- Instructions for human oversight of AI decisions
- Training data characteristics (if relevant to performance limitations)

Critical Note on Subgroup Analysis: FDA increasingly requires demonstration that AI performance is equitable across demographic subgroups. Algorithmic bias documentation is now a standard expectation for all AI/ML device submissions.

8. Post-Market Requirements

Real-World Performance Monitoring

FDA expects manufacturers to monitor AI performance in the real world. Significant performance degradation may trigger a recall or field corrective action.

Post-Market Surveillance (PMS)

Mandatory for Class II/III devices under **21 CFR Part 822**. AI-specific monitoring includes:

- **Distribution shift** — Changes in patient population characteristics over time
- **Dataset drift** — Changes in input data that affect algorithm performance
- **Demographic performance changes** — Differential performance across patient subgroups

Mandatory Device Reporting (MDR)

AI failures that cause or contribute to serious injury or death must be reported to FDA:

Event Type	Reporting Deadline	Regulation
Death or serious injury from device malfunction	30 days	21 CFR Part 803
Urgent safety issue requiring immediate remedial action	5 days	21 CFR Part 803
Device malfunctions likely to cause serious injury if recurred	30 days	21 CFR Part 803

Post-Market Monitoring Framework for AI Devices

Monitoring Component	Description	Frequency
Performance metrics tracking	Sensitivity, specificity, AUC vs. baseline	Continuous/quarterly
Input data monitoring	Statistical checks for data drift	Ongoing
Demographic subgroup analysis	Performance equity across patient groups	Quarterly/annually
Adverse event review	AI-attributed complaints and incidents	Ongoing
PCCP compliance	Verify changes stay within approved bounds	Per modification

9. AI Device Authorization Statistics (Through Early 2025)

500+

AI/ML devices authorized by FDA (Q1 2024)

~75%

Radiology/imaging share of AI clearances

~30%

Year-over-year growth since 2019

Pathway Distribution

Regulatory Pathway	Share of AI Device Authorizations	Trend
510(k) — Premarket Notification	~85%	Dominant, stable
De Novo — Novel Classification	~10%	Growing rapidly
PMA — Premarket Approval	~5%	Minority, high-risk devices

Therapeutic Area Breakdown

Therapeutic Area	Approximate Share	Notes
Radiology / Imaging	~75%	Largest category; CT, MRI, X-ray AI analysis
Cardiology	~8%	ECG analysis, arrhythmia detection
Pathology	~5%	Digital pathology, slide analysis
Ophthalmology	~4%	Retinal screening, diabetic retinopathy
Other	~8%	Neurology, oncology, genomics, etc.

Growth Trajectory: FDA has seen approximately 30% year-over-year growth in AI device authorizations since 2019, with the pace accelerating as generative AI and foundation models enter the medical space.

10. Recent Developments (2023–2024)

Development	Date	Key Impact
Executive Order on AI	Oct 2023	Directed HHS/FDA to develop standards for AI in healthcare within 365 days
FDA's 2024 AI Action Plan	2024	Updated roadmap building on 2021 plan; emphasis on foundation models and generative AI
CDRH AI Strategic Plan	2024	Committed to 10 actions including bias mitigation, transparency, and GMLP enforcement
VALID Act (proposed)	Pending	Legislation for new regulatory framework specifically for AI diagnostics; not yet passed as of early 2025
International harmonization	Ongoing	FDA actively aligning with EU AI Act (risk-based approach) and IMDRF SaMD framework

Emerging Issues & Future Outlook

- **Foundation Models & Generative AI:** Large language models and multimodal foundation models entering medical imaging and clinical decision support — FDA is developing specific guidance
- **Real-World Evidence:** Growing use of RWE to support AI device clearances and monitor post-market performance
- **Algorithmic Bias:** FDA increasingly focused on ensuring AI performance equity across demographic groups; CDRH AI Strategic Plan commits to bias mitigation actions
- **Cybersecurity:** 2023 FDA Cybersecurity Guidance now mandatory for all premarket submissions; AI devices present unique cybersecurity challenges
- **EU Alignment:** FDA and EMA/EU regulatory bodies are working toward harmonized frameworks for AI medical devices under the EU AI Act and EU MDR

Looking Ahead: The regulatory landscape for AI medical devices will continue to evolve rapidly through 2025–2026. Manufacturers should monitor FDA guidance updates closely and engage with CDRH early in product development.

References

#	Source	URL
1	FDA — AI/ML Action Plan (Jan 2021)	fda.gov/media/145022/download
2	FDA — Proposed Regulatory Framework for AI/ML SaMD (2019)	fda.gov/media/122535/download
3	FDA — Marketing Submission Recommendations for AI/ML SaMD (Draft, Apr 2023)	fda.gov/media/166703/download
4	FDA — Transparency for ML-Enabled Devices (Draft, Oct 2023)	fda.gov/media/173971/download
5	FDA — Lifecycle Management for AI-Enabled Device Software (Draft, Dec 2023)	fda.gov/media/174185/download
6	FDA/Health Canada/MHRA — Good Machine Learning Practice (Oct 2021)	fda.gov/.../good-machine-learning-practice...
7	IMDRF — SaMD: Clinical Evaluation (N41, 2017)	imdrf.org/.../samd-clinical-evaluation
8	FDA — Digital Health Policy Navigator	fda.gov/.../digital-health-policy-navigator
9	FDA — Predetermined Change Control Plans for AI/ML SaMD	fda.gov/.../predetermined-change-control-plan...
10	FDA — 510(k) Premarket Notification Overview	fda.gov/.../premarket-notification-510k
11	FDA — De Novo Classification Request	fda.gov/.../de-novo-classification-request
12	FDA — Breakthrough Device Designation	fda.gov/.../breakthrough-therapy
13	FDA — CDRH AI/ML-Based SaMD (tracker)	fda.gov/.../aiml-enabled-medical-devices
14	White House — Executive Order on AI (Oct 2023)	whitehouse.gov/.../executive-order-on-ai
15	FDA — Cybersecurity in Medical Devices (Sept 2023)	fda.gov/.../cybersecurity-medical-devices...
16	21 CFR Part 820 — Quality System Regulation	ecfr.gov/.../part-820
17	21 CFR Part 822 — Postmarket Surveillance	ecfr.gov/.../part-822
18	FDA — Digital Health Center of Excellence (DHCoE)	fda.gov/.../digital-health-center-excellence