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FDA's AI Medical Device List: Stats, Trends & Regulation

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Published by IntuitionLabs · 2025-11-10 · fda regulation · ai in medicine · medical devices · software as a medical device · 510(k) clearance · ai in radiology · medtech · digital health

Original article: <https://intuitionlabs.ai/articles/fda-ai-medical-device-tracker>



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FDA's AI Medical Device List: Stats, Trends & Regulation

Executive Summary

The FDA's **AI-Enabled Medical Devices List** (a public listing of FDA-authorized AI/ML-equipped devices) reflects a rapid, recent surge in such technologies under regulatory review. Only a handful of AI-based devices existed at the start of the 2010s, but approvals have escalated dramatically in the last five years: for example, the FDA cleared 6 AI/ML devices in 2015 versus 295 in 2025 (innolitics.com). The end-2025 figures cited in this article are a historical snapshot: the cumulative total was reported as **1,451** AI/ML devices (theimagingwire.com), driven largely by authorizations in imaging and signal analysis. The FDA list continues to change as additional decision summaries are published. The majority of these devices reside in **Radiology** (approximately 76% of listings, or 1,104 devices) (theimagingwire.com) (rad.washington.edu); cardiology accounts for about 9%, with neurology, hematology, and other specialties making up the rest. Nearly all cleared AI devices have entered via the 510(k) pathway (www.mdpi.com) (www.medtechdive.com), reflecting reliance on substantial-equivalence rather than costly **clinical trials**.

Despite growth in device count, multiple analyses caution that **evidence gaps** remain. For example, a 2025 study found that <2% of FDA-cleared AI/ML devices were supported by randomized clinical trials and most 510(k) summaries lack details on study design, sample sizes, and demographics (pmc.ncbi.nlm.nih.gov). Only about 5% of AI devices experienced any post-market adverse event report, and 5–6% were ever recalled (primarily for software bugs) (pmc.ncbi.nlm.nih.gov) (www.mdpi.com). A separate 2025 *npj Digital Medicine* study analyzing 1,016 authorizations found that transparency around AI/ML model characteristics remains limited, with many submissions lacking detail on training data composition and algorithm type (nature.com). These findings underscore the need for stronger life-cycle oversight and improved transparency. FDA issued final guidance, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions*, on August 18, 2025 (**FDA PCCP guidance**).

This report delves into the **history, current state, and future implications** of FDA's AI/ML device tracker: reviewing the regulatory framework, analyzing authorization trends and statistics (with tables), examining exemplar devices, and discussing the challenges ahead — all supported by extensive references. We cover both optimistic industry/innovation perspectives and critical safety/ethical viewpoints. The FDA's AI/ML devices list has become an essential resource for stakeholders, helping manufacturers, clinicians, and patients understand how AI is entering medical practice while highlighting where oversight must continue to evolve.

Introduction and Background

Artificial intelligence (AI) — broadly, software systems that **mimic human intelligence** — has been applied in medicine for decades, but recent advances in machine learning (ML) and data availability have accelerated its adoption in clinical devices (www.mdpi.com). The FDA explicitly **encourages** development of innovative AI-enabled medical devices, provided they remain “safe and effective” (www.fda.gov). To foster both innovation and transparency, in 2019–21 the FDA launched a curated *AI-Enabled Medical Device* list, publicly cataloguing

authorized devices that incorporate AI/ML (www.fda.gov). The list is updated periodically; devices whose decision summaries are not published during the relevant data-collection period may be incorporated in a subsequent update. Its purpose is to help stakeholders (manufacturers, researchers, clinicians, and patients) see which products use AI, understand regulatory expectations, and ensure that approved algorithms have undergone safety and effectiveness review (www.fda.gov).

Historical context: The very first FDA-cleared AI system was **PAPNET** (a Pap-smear rescreening tool) in 1995 (www.mdpi.com), but few followed until the 2010s. As late as 2015, only *half a dozen* FDA devices used AI (www.medtechdive.com). Rapid growth began after about 2016: from 2016–2023 AI/ML device authorizations grew at an ~49% annual rate (www.linkedin.com), reflecting both technological maturity and regulatory focus. By end-2023 the FDA's tracker listed over **690** devices (www.mdpi.com), growing to **950** by mid-2024 (www.linkedin.com). Third-party analyses reported 221 entries in 2023, 253 in 2024, and 295 in 2025, with an end-2025 historical snapshot of **1,451** entries (innolitics.com) (theimagingwire.com). These estimates should not be read as FDA-published totals of all AI-device authorizations. Thus, AI/ML is no longer niche: these algorithms now assist in **diagnostic imaging**, ECG interpretation, laboratory analysis, and more.

Definition of AI/ML devices: The FDA uses a broad definition: devices on the list must use AI or ML “for one or more functions integral to clinical care,” as standalone software or embedded in hardware (www.hhmglobal.com). In practice, identification relies on keywords. The FDA notes that the list is *not* comprehensive – rather, it includes products whose FDA summary descriptions (or classification codes) contain AI-related terms (www.fda.gov). For each device on the list, the tracker provides a link to the FDA's database entry, which includes releasable information like safety/effectiveness summaries (www.fda.gov). (These summaries, however, often omit detailed study data (pmc.ncbi.nlm.nih.gov).) The list encompasses both early “Guidance” apps (flagging images or data for clinician review) and more autonomous AI tools. To promote future transparency, the FDA has signaled plans to tag devices built on modern “foundation models” (e.g. **large language models**) once they appear, so users will know if e.g. an image-reader uses LLM-driven components (www.fda.gov) (www.hhmglobal.com).

Regulatory oversight: AI/ML devices generally fall under the Software as a Medical Device (SaMD) paradigm. Most have been **Class II** devices cleared via the 510(k) pathway (www.mdpi.com) (www.medtechdive.com), meaning the manufacturer demonstrated “substantial equivalence” to a predicate (pre-existing) device. Unlike PMA (premarket approval), a 510(k) submission must demonstrate substantial equivalence to a legally marketed predicate; FDA may require clinical performance data when applicable. The pathway can support a more streamlined route to market for some digital tools. The FDA's *Digital Health Center of Excellence*, launched in September 2020, has helped build expertise in evaluating these submissions ([FDA announcement](#)). The FDA has issued AI-enabled-device guidance. Its final August 2025 PCCP guidance recommends that manufacturers describe planned modifications, the methodology to develop, validate, and implement them, and an assessment of their impact; FDA reviews the PCCP as part of the relevant marketing submission ([FDA PCCP guidance](#)). FDA's January 2025 draft guidance on AI-enabled device software functions proposes recommendations for marketing-submission content and for design, development, and implementation across the total product life cycle ([FDA draft TPLC guidance](#)). FDA's final PCCP guidance applies to AI-enabled devices reviewed through the 510(k), De Novo, and PMA pathways. A third-party analysis reported that 10% of 2025 AI/ML 510(k) clearances included PCCPs; this figure is an

estimate for that analysis, not an FDA-published rate for the entire list (innolitics.com). These steps reflect the FDA's effort to balance faster innovation with patient protection, recognizing that AI tools may evolve over their lifecycle.

Regulatory Framework and the FDA AI/ML Devices Tracker

The FDA regulates AI/ML software under its existing medical device framework. In practice, many AI algorithms are deemed **Class II (moderate-risk)** and cleared via 510(k): indeed, by late 2023 roughly **97%** of cleared AI/ML devices used 510(k) (vs. 2–3% via De Novo or PMA) (www.mdpi.com). This mirrors general trends in medical software. The FDA's stated requirement is simply that the device "meets applicable premarket requirements," including a focused safety/effectiveness review (www.fda.gov). As an example, the FDA publicly notes that listed devices have passed a "focused review of the device's overall safety and effectiveness, including evaluation of study appropriateness for the device's intended use" (www.fda.gov). (However, FDA decision summaries often lack patient-outcome data (pmc.ncbi.nlm.nih.gov).)

The FDA list includes devices across multiple clinical panels, including radiology, cardiovascular, neurology, hematology, and others. FDA displays the list in reverse chronological order by Date of Final Decision and makes CSV and Excel downloads available. The aggregate totals, annual counts, specialty shares, and company counts cited in this article are third-party historical estimates based on the FDA list; they are not FDA-published totals or a complete market distribution. A reproducible analysis would require a retained FDA-file snapshot, its download date, and documented rules for counting entries, normalizing company names, and assigning panels.

This skew toward imaging reflects data availability and early digital adoption in radiology (www.medtechdive.com). In contrast, fields like ophthalmology or dentistry have very few AI devices listed. Third-party analyses of end-2025 FDA-list snapshots estimated the selected company counts below. These are estimates of list entries based on the analysts' counting and company-normalization methods, not FDA-published totals of company authorizations or a measure of market adoption. Table 1 summarizes those reported estimates:

Company	Cumulative Devices (end-2025)
GE HealthCare	120 (theimagingwire.com)
Siemens Healthineers	89 (theimagingwire.com)
Philips	50 (theimagingwire.com)
Canon	45 (theimagingwire.com)
United Imaging	38 (theimagingwire.com)
Aidoc	31 (theimagingwire.com)
DeepHealth	28 (theimagingwire.com)

Table 1: Third-party historical estimates of selected companies' cumulative entries on the FDA AI-enabled medical device list through end-2025 (source: The Imaging Wire's analysis of FDA data) (theimagingwire.com).

Data Trends and Analysis

The FDA list supports reproducible trend analysis only when the analyst retains a specific CSV or Excel download, its download date, and the rules used to count and classify entries. Because the list is not comprehensive and is updated periodically, its entries should not be described as all AI-device authorizations. At the time of review, the FDA page displayed a most recent final-decision date of March 30, 2026.

Many FDA-authorized AI-enabled devices are **decision-support tools** rather than fully autonomous diagnosticians. They may flag images or data for clinician review. Published analyses indicate that *pre-market evidence is often limited*: a 2025 JAMA study of 691 devices (through July 2023) found that **46.7%** of FDA summaries did not describe the study design, and **53.3%** omitted the sample size ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Only 6 devices (1.6%) cited a randomized clinical trial, and only 3 devices (<1%) reported actual patient health outcomes ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Most decision summaries focus on analytical performance (e.g. sensitivity/specificity) rather than clinical benefit ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). In short, the *quality of reported evidence* was incomplete in the 691-device cohort assessed through July 2023; this finding should not be generalized as an evidence audit of all devices subsequently added to the FDA list.

Post-market data are similarly sparse. Lin et al. report that only **28.2%** of device summaries mentioned any safety assessment, and **5.2%** noted adverse events after clearance (mostly malfunctions) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Over a follow-up period, 40 devices (5.8% of all AI devices) were ever recalled (totaling 113 recall actions) – typically due to software bugs or failures ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). There was even one reported patient death associated with an AI device in this dataset ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Thus, the FDA list identifies AI-enabled devices authorized for marketing, while published research highlights continuing needs for rigorous benefit-risk evaluation and post-market surveillance. The FDA itself acknowledges this in guidance, encouraging “Good Machine Learning Practices” (GMLP) such as representative training data, thorough validation, and ongoing monitoring (www.hhmglobal.com).

The authorization pathway statistics reflect these realities. The vast majority of AI/ML devices — about **97%** — are 510(k) clearances (www.mdpi.com) (www.medtechdive.com), using predicate devices to support substantial-equivalence determinations; clinical performance data may be required when applicable. Only 2–3% were cleared via De Novo (novel Class II without predicate), and ~0.4% via PMA (high-risk trials) (www.mdpi.com). However, 2025 data show review timelines are stabilizing: the **median clearance time was 142 days**, with 24% of submissions cleared in under 90 days (innolitics.com). Notably, novel devices *without predicates* have started to appear but remain rare. (For example, Aidoc's lung CT algorithm and the IDx-DR retinal system initially required De Novo authorization). In sum, the tracker data show a *massive influx* of AI tools into the FDA pipeline – but also underline that most rely on equivalence to prior devices and do not bring new clinical trial evidence.

Representative Case Studies

To illustrate how AI/ML enters the FDA framework, we highlight several notable devices from different domains:

- **IDx-DR (diabetic retinopathy screening):** In April 2018, the FDA granted *de novo* authorization to IDx's AI algorithm (IDx-DR) as the first autonomous AI to detect diabetic retinopathy from retinal images (www.fiercebiotech.com). Approval was based on a clinical study of ~900 patients; the software correctly

identified retinopathy ~90% of the time, with low false rates (www.fiercebiotech.com). As IDx's founder observed, "as the first of its kind...the system provides a roadmap for the safe and responsible use of AI in medicine" (www.fiercebiotech.com). This device exemplifies how companies can demonstrate *real-world impact*: by enabling primary-care offices to screen for eye disease, IDx-DR aims to extend specialist-level diagnosis to wider populations.

- **Caption Guidance (AI Ultrasound):** Bay Labs (now Caption Health, acquired by GE HealthCare in 2023) built an AI assistant for cardiac ultrasound. Using deep learning to guide image capture, the Caption Guidance system was cleared via De Novo (DEN190040, Feb 2020 (www.fda.gov)), after pivotal trials showing non-expert users could acquire cardiac images as effectively as sonographers. This illustrates AI being embedded in medical equipment, not just software: it augmented ultrasound hardware for cardiology and is now integrated into GE HealthCare's broader imaging portfolio.
- **Consumer Wearables (ECG Monitoring):** The FDA has cleared algorithms for consumer devices. Apple's Watch **AFib History** feature, cleared in 2022, is intended for users aged 22 and older who already have an AFib diagnosis; it analyzes pulse-rate data and provides retrospective estimates and trends of AFib burden. It is not intended to provide individual irregular-rhythm notifications or replace diagnosis, treatment, or monitoring ([FDA 510\(k\) summary K213971](#)). Apple's separate Irregular Rhythm Notification feature is the feature intended to notify users of possible AFib.
- **AI for Heart Sounds:** Eko Devices received 510(k) clearance in January 2020 for its AI-enhanced stethoscope software ("Eko Analysis Software") that analyzes heart sounds for murmurs and AFib (www.fda.gov). This represents AI applied at the bedside: Eko's device collects audio data and uses ML to flag abnormal heart rhythms, extending this technology beyond imaging to auscultation.
- **MRI and CT Imaging (Radiology AI):** Field leaders have introduced many such tools. For example, Philips' "MRCAT brain" – an AI-based MRI tool for brain imaging – was FDA-cleared in Jan 2020 (www.fda.gov). Similarly, companies like GE, Canon, and Siemens routinely clear dozens of AI modules for CT/MRI machines (noise reduction, lesion detection, etc.) each year, as seen by their high device counts.

These case examples show the spectrum of AI medical tools "in the wild". They range from specialized image-analysis apps to patient-facing monitors. Across cases, the common thread is demonstration of safety/effectiveness (usually against expert review) and meeting specific clinical needs (screening, triage, documentation).

- **RecoveryAI (patient-facing clinical AI):** RecoveryAI announced on March 3, 2026, that FDA had granted Breakthrough Device Designation to its physician-prescribed Virtual Care Assistants for post-operative recovery ([RecoveryAI announcement](#)). Breakthrough designation is not marketing authorization: designated devices must still meet FDA's safety-and-effectiveness standards to be authorized for marketing ([FDA Breakthrough Devices Program](#)).

The emergence of foundation models in FDA-cleared devices marks a turning point. While most authorized AI devices still use narrow machine-learned algorithms trained on medical data, the FDA plans to tag devices that incorporate foundation-model technology (LLMs, generative systems) in future updates to the tracker

(www.fda.gov) (www.hmglobal.com).

Discussion: Implications and Future Directions

The rapid growth of the FDA's AI/ML tracker reflects both innovation opportunities and regulatory challenges.

Transparency and Trust: By making the AI/ML device list public, the FDA signals its commitment to openness. Clinicians and patients can see when products use AI and find links to safety summaries (www.fda.gov). However, research shows that actual benefit-risk information is often poorly reported. For example, recent audits found *very limited* published evidence underpinning cleared devices (pmc.ncbi.nlm.nih.gov). A significant implication is that the FDA (and developers) must improve standardized reporting. Calls have emerged for **post-market surveillance** systems akin to those used for drugs. Notably, Lin et al. conclude that “dedicated regulatory pathways and postmarket surveillance” are needed given current evidence gaps (pmc.ncbi.nlm.nih.gov). The FDA is beginning to address this: new draft guidelines (2024–2025) emphasize performance metrics and continuous monitoring for adaptive AI (www.medtechdive.com) (www.medtechdive.com), while a recent FDA Health IT Strategy (2023) proposes using real-world performance data and registries for oversight.

Predetermined Change Control Plans (PCCPs): A major response is PCCPs. FDA issued final PCCP guidance for AI-enabled device software functions on August 18, 2025 ([FDA PCCP guidance](#)). The guidance recommends that PCCPs describe planned modifications, the methodology to develop, validate, and implement them, and an assessment of their impact on safety and effectiveness. FDA reviews a PCCP as part of the relevant marketing submission, allowing implementation of covered modifications without additional marketing submissions. Adoption is growing: in 2025, **10% of all AI/ML device clearances included PCCPs** (innolitics.com). In October 2023, the FDA, Health Canada and the UK's MHRA jointly published five guiding principles for PCCPs in ML-enabled devices, establishing an international framework ([FDA](#)) (ballardspahr.com). This shift signals a maturation in regulation — from static premarket review to life-cycle management of learning algorithms.

Global and Ethical Context: The FDA's approach sits within a broader international environment. The EU **AI Act** entered into force on 1 August 2024. AI systems that are safety components of, or are themselves, products covered by Annex I Union harmonisation legislation and that require third-party conformity assessment fall within the Act's high-risk category. The European Commission states that the rules for high-risk AI systems embedded in these regulated products have an extended transition period until **2 August 2028** ([European Commission: AI Act timeline](#)). Meanwhile, the FDA's January 2025 draft guidance provides recommendations for the content of marketing submissions for devices with AI-enabled software functions and proposes recommendations for their design, development, and implementation across the total product life cycle. The draft is non-binding and is not for implementation ([FDA draft TPLC guidance](#)). Ethicists continue to raise concerns about AI autonomy and bias: Arnold (2021) argued that AI in healthcare poses “libertarian paternalism” issues, challenging traditional autonomy and requiring active physician involvement in the discourse (pmc.ncbi.nlm.nih.gov). Issues like data privacy, algorithmic fairness, and explainability remain center-stage.

Market and Reimbursement: From an industry perspective, AI devices represent a large and growing market. Analysts project multi-billion-dollar value (one firm projects \$13.7B in 2024 to \$255B by 2033) (intuitionlabs.ai). However, meaningful clinical adoption hinges on reimbursement. Progress is being made: the CPT 2026 code set includes **288 new codes** covering digital health and AI services, and CMS has expanded payment policies for digital mental health treatment devices (ama-assn.org). Congress has also proposed a dedicated Medicare reimbursement pathway for AI diagnostic devices (medtechdive.com). CMS has acknowledged that current practice expense valuation does not adequately reflect the cost of SaaS and AI-driven technologies. Hospitals are also forming AI oversight committees, as experts recommend (www.hmglobal.com). To succeed, AI device makers must not only clear FDA but also demonstrate cost-effectiveness and integration with electronic health records (EHRs).

Foundation Models and Generative AI: The FDA's tracker states that the agency will explore methods to identify and tag medical devices that incorporate foundation models, including systems ranging from large language models to multimodal architectures, in a future update (www.fda.gov). The page does not establish a separate authorization pathway for generative AI devices. Any device seeking marketing authorization must meet the applicable FDA premarket requirements, including a focused review of overall safety and effectiveness for the device's intended use and technological characteristics.

Continued Monitoring & Adaptation: In summary, the FDA AI-Enabled Medical Device List shows a dynamic, periodically updated record of devices identified through public authorization summaries and classifications. It is not a comprehensive count of AI-device authorizations; any specialty distribution or growth estimate should be tied to a retained FDA-file snapshot and explicit counting method. The 2025 benefit-risk audit identified incomplete reporting in a separate 691-device cohort cleared through July 2023; it does not establish the evidentiary profile of all devices added later. Going forward, the FDA is refining its approaches through finalized PCCP guidance, draft TPLC-based submission recommendations, and international collaboration on AI principles. For AI systems covered by Article 6(1), including AI systems that are safety components of or are themselves products covered by Annex I Union harmonisation legislation, the European Commission states that the relevant high-risk rules have an extended transition period until August 2, 2028 ([European Commission: AI Act timeline](#)). Stakeholders should watch for how regulators tag emerging technologies (such as foundation-model and LLM-based devices) and adapt to the convergence of medical device regulation with broader AI governance frameworks.

Conclusion

The **FDA AI/ML in Medical Devices Tracker** encapsulates the state of AI-device innovation under U.S. regulation. It shows that AI-enabled devices are used across multiple clinical specialties, while also making clear that the list is a periodically updated, non-comprehensive resource rather than a count of all FDA-authorized AI devices ([FDA AI-Enabled Medical Device List](#)). The tracker's transparency is valuable: by aggregating device names, dates of final decision, companies, and links to approval, authorization, or clearance information, it provides a data-rich resource for analysis. From this analysis, several lessons emerge. First, third-party analyses of retained FDA-list snapshots have reported rapid growth and a large radiology share, but those estimates are not FDA-published totals or complete market distributions. The 2025 evidence audit cited above assessed a defined 691-device cohort cleared through July 2023 and should not be

generalized to all later list entries ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Second, FDA regulates AI-enabled devices through established pathways, including 510(k), De Novo, and PMA, and its final PCCP guidance supports lifecycle management of planned modifications. Third, ethical and safety experts warn that transparent reporting and robust monitoring are **still lagging** behind the hype ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Fourth, the FDA has stated that it will explore methods to identify and tag listed devices that incorporate foundation models in future updates, an area to monitor as medical-device AI evolves.

As hospitals and patients increasingly encounter AI-powered tools, understanding the FDA's AI/ML tracker is key. It identifies AI-enabled medical devices authorized for marketing in the United States and signals broader trends: where regulators are applying scrutiny and where gaps remain. Continued research – like the present report – must monitor this evolving landscape. Upcoming regulatory milestones — including the FDA's work on its draft TPLC guidance for AI devices, the EU AI Act's high-risk rules for Article 6(1) systems embedded in regulated products (subject to an extended transition period until August 2, 2028 ([European Commission: AI Act timeline](#))), and the FDA's planned tagging of foundation-model devices — will reshape the tracker and the compliance landscape. Stakeholders should use this resource as both a **snapshot** of what AI is already in use, and a **guide** pointing to where stronger evidence and governance will be required to ensure that these promising technologies truly benefit patient care.

References: Authoritative data and opinions in this report are drawn from FDA publications, peer-reviewed studies, industry analyses, and news sources. FDA guidance and device listings provide official definitions (www.fda.gov), while journals like *JAMA Health Forum*, *npj Digital Medicine*, and *Bioethics* highlight evidence gaps and ethical issues ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) ([nature.com](https://www.nature.com)) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Industry analyses from The Imaging Wire, Innolitics, and MedTech Dive quantify trends (theimagingwire.com) (innolitics.com) (rad.washington.edu). All claims above are supported by these sources.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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