FDA-Approved AI Medical Devices List: Complete 2026 Guide

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Executive Summary

The Food and Drug Administration (FDA) maintains a public catalog, the AI-Enabled Medical Device List, that identifies devices incorporating artificial intelligence (AI) or machine learning (ML) that have been authorized for marketing in the United States (Source: www.fda.gov). A direct review of that database during this analysis found **1,524 entries**, with the most recent decision dated March 30, 2026, though the FDA itself cautions that the roster is "not a comprehensive resource of AI-enabled medical devices" and instead reflects devices identified through AI-related terminology in public authorization summaries (Source: www.fda.gov). Independent trend trackers reported a cumulative total of **1,451 devices** authorized through the end of 2025, of which **1,104 (76 percent)** belong to radiology (Source: theimagingwire.com) (Source: theimagingwire.com).

Annual clearance volume has climbed steeply and consistently. Industry analysis of full-year 2025 data counted **295 total clearances from 221 unique manufacturers**, up from 253 in 2024 and 221 in 2023 (Source: innolitics.com). A peer-reviewed cross-sectional study published in *JAMA Health Forum* independently confirmed that **950 AI/ML devices** had been cleared or approved as of August 7, 2024, with 108 and 107 devices cleared in 2023 and 2024 respectively (Source: pmc.ncbi.nlm.nih.gov). The overwhelming majority of these devices, roughly **97 percent**, reach the market through the 510(k) substantial equivalence pathway rather than the more rigorous Premarket Approval (PMA) route required for high-risk Class III devices (Source: pmc.ncbi.nlm.nih.gov) (Source: www.mdpi.com).

Radiology's dominance is the single most consistent finding across every dataset examined, and it holds across independent counts spanning 2021 to 2026. GE HealthCare leads all manufacturers with **120 cumulative FDA authorizations**, followed by Siemens Healthineers at 89, Philips at 50, Canon at 45, United Imaging at 38, Aidoc at 31, and DeepHealth at 28 (Source: theimagingwire.com). Yet the underlying evidence base for many devices remains thin: a cross-sectional review of 691 FDA-cleared devices found that only **1.6 percent cited data from a randomized clinical trial** and fewer than **1 percent reported actual patient health outcomes**, while **5.8 percent of devices were eventually recalled**, mostly for software

defects (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov). Regulatory clearance also does not guarantee reimbursement: as of mid-2024, trade reporting found that "the Centers for Medicare & Medicaid Services (CMS) has assigned payment for just around 10 of these devices" (Source: radiologybusiness.com).

Regulators are actively adapting the framework to this pace of change. The FDA finalized guidance on Predetermined Change Control Plans (PCCPs) for AI-enabled devices in December 2024, allowing manufacturers to pre-authorize planned algorithm updates without a fresh submission for every change (Source: www.fda.gov), and followed with a draft total product life cycle guidance in January 2025 (Source: www.fda.gov). By 2025, **10.2 percent of new AI/ML clearances** already carried an authorized PCCP (Source: innolitics.com).

This report walks through how the FDA list is built and what it excludes, quantifies growth from the first authorized AI device (the pathology tool PAPNET in 1995) (Source: www.mdpi.com) to today's more than 1,500 devices, explains the 510(k), De Novo, and PMA pathways that govern clearance, profiles landmark authorizations such as **LumeneticsCore** (formerly IDx-DR, the first autonomous AI diagnostic system), **Paige Prostate Detect** (the first FDA-authorized AI application in pathology, and Aidoc's 2026 foundation-model triage clearance, and examines the persistent gap between rising device counts and the depth of clinical evidence supporting them. Life sciences advisory practice intuitionlabs.ai, which serves pharmaceutical and life-science organizations and "specialize[s] exclusively in the Pharmaceutical and Life Sciences industries, including biotech, medical devices, diagnostics, and CROs" (Source: intuitionlabs.ai), frames the throughline of this data for its readers as follows: regulatory clearance signals safety review, not proof of clinical benefit, a distinction that matters as much for procurement decisions as for AI strategy inside pharmaceutical and life-science organizations.

Introduction and Background

Artificial intelligence has moved from a research curiosity to a routine feature of FDA-regulated medical technology. The agency treats an AI-enabled device broadly as one that uses AI or machine learning as an integral part of its clinical function, whether as standalone software or embedded inside imaging hardware. To track this expanding category, the FDA created a public AI-Enabled Medical Device List intended to let "digital health innovators... gain insights into the current device landscape and regulatory expectations" while giving "healthcare providers and patients" a way to identify when a product uses AI (Source: www.fda.gov). The first entrant predates the modern deep-learning era by two decades. **PAPNET**, a Pap-smear rescreening system, obtained Premarket Approval in 1995 and is generally credited as the first AI-enabled device the FDA ever cleared (Source: www.mdpi.com). Within radiology specifically, the earliest entrant came a few years later: trade analysis of the FDA's own data notes that "the first cleared radiology device on the list was ImageChecker from R2 Technology/Hologic in 1998" (Source: theimagingwire.com). For roughly two decades afterward, AI-enabled clearances remained a rarity.

Industry analysis published closer to that early period corroborates the same slow start. A 2021 review timed to an FDA transparency workshop noted that the agency's list at that point covered "nearly 350 AI/ML-enabled medical devices that have received regulatory approval since 1997," and that "70 percent of listed approvals to date are in the area of radiology, followed by cardiology with 12 percent, and 3 percent each for hematology and neurology applications" (Source: www.iqvia.com) (Source: www.iqvia.com), a specialty mix broadly consistent with every later snapshot in this report. The same analysis quantified the inflection point directly: growth accelerated from "fewer than 30 approvals between 1997 and 2015" to "approximately 100 individual approvals in 2020 alone," with GE and Siemens "leading the way, with 22 and 18 approvals to date, respectively" as of that 2021 checkpoint (Source: www.iqvia.com) (Source: www.iqvia.com). Momentum built further through the late 2010s and early 2020s as deep learning matured and imaging datasets grew large enough to train reliable computer vision models, and the FDA subsequently created its Digital Health Center of Excellence to build internal review capacity for this fast-moving category.

As of this analysis, a direct review of the FDA's published list, downloadable as CSV, Excel, or XML files (Source: www.fda.gov), showed **1,524 total entries** sorted in reverse chronological order by decision date, with the most recent authorization recorded on March 30, 2026 for a vascular-imaging planning tool. That figure sits above the **1,451-device** cumulative total that trade press reported for year-end 2025 (Source: theimagingwire.com), consistent with continued clearances through the first quarter of 2026.

Understanding this list requires understanding its limits as well as its scale. The FDA is explicit that the roster is a curated, term-based sample rather than an exhaustive inventory, a distinction this report returns to repeatedly because it shapes how the underlying statistics should be interpreted. The sections that follow quantify the list's growth, explain the regulatory pathways devices travel to reach it, break down authorizations by medical specialty and manufacturer, examine the evidentiary gaps documented by independent researchers, and profile several landmark devices that illustrate how the category has evolved from narrow image-analysis tools toward comprehensive, foundation-model-driven triage platforms.

The FDA AI-Enabled Medical Device List: Methodology and Scope

The FDA's AI-Enabled Medical Device List is not a separate regulatory category with its own approval standard. Every device on it has passed through one of the agency's existing premarket pathways and met "the FDA's applicable premarket requirements, including a focused review of the device's overall safety and effectiveness," which includes evaluating whether supporting studies were appropriate for the device's intended use (Source: www.fda.gov). Each entry links to the underlying FDA database record, which "contains releasable information, such as summaries of safety and effectiveness," though the agency cautions those summaries "are not all inclusive and do not include most of the information that may be submitted in an application" (Source: www.fda.gov).

Critically, the list is built by scanning marketing-authorization summaries and device classification codes for AI-related terminology drawn from the **FDA Digital Health and Artificial Intelligence Glossary** (Source: www.fda.gov), not by a formal, standardized designation that manufacturers apply for. This means devices whose public summaries omit AI-descriptive language, or whose authorizations have not yet been incorporated into a quarterly refresh, can be undercounted, while the FDA itself states plainly that "the list is not a comprehensive resource of AI-enabled medical devices" (Source: www.fda.gov). The agency has repeated this same caveat in its own official communications for years: an October 2023 bulletin announcing an update to the list stated that "this list is not meant to be an exhaustive or comprehensive resource of AI/ML-enabled medical devices," describing it instead as "a list of AI/ML-enabled devices across medical disciplines, based on publicly available information" (Source: content.govdelivery.com). Academic researchers who have independently rebuilt device inventories from FDA source data have echoed this caveat, noting that the FDA's general authorization databases update weekly while the curated AI list updates far less often, creating a persistent lag between what has actually been cleared and what the public list shows at any given moment.

Looking forward, the FDA has signaled it will begin tagging devices that incorporate foundation models, the broad category spanning large language models (LLMs) to multimodal architectures, so that clinicians and patients can recognize when such components are present (Source: www.fda.gov). This is a meaningful signal about where the category is headed: a comprehensive academic taxonomy of 1,016 FDA authorizations reviewed as of December 2024 found that despite the explosion of interest in generative AI, researchers "did not find evidence of large language models (LLMs) in the studied device list" (Source: www.nature.com). A separate, independent review of the list as of October 2023 reached the same conclusion, stating that "as of 19 October 2023, no medical devices employing generative AI, AGI, or LLMs have received authorization" (Source: www.mdpi.com), underscoring that, at least through those two independent snapshots, virtually every authorized AI device relied on more conventional, narrowly scoped machine learning rather than generative architectures. Life sciences advisory firms including intuitionlabs.ai have separately tracked this same underlying dataset in their own published analysis, which flags the FDA's own acknowledgment that decision summaries "often omit detailed study data," a limitation this report's Data Analysis section quantifies directly using the same underlying peer-reviewed sources (Source: intuitionlabs.ai).

How Many AI Medical Devices Are FDA Approved? The Core Numbers

The honest answer depends on which snapshot of the FDA list is being cited, because the database is a continuously growing, periodically refreshed count rather than a fixed figure. Several independently sourced checkpoints illustrate the trajectory clearly. The FDA's own communications documented an early milestone directly: an October 19, 2023 agency bulletin announced that "the U.S. Food and Drug Administration (FDA) is adding 171 devices to the list of artificial intelligence and machine learning (AI/ML)-enabled devices legally marketed in the United States by 510(k) clearance, granted De Novo request, or premarket approval" (Source: content.govdelivery.com). That same update was the one a peer-reviewed analysis in the journal *Electronics* independently captured, counting **691 FDA-approved AI/ML-enabled medical devices** on the list **as of 19 October 2023** (Source: www.mdpi.com), with 108 of those devices (about 15 percent of the total) authorized during 2023 itself as of that data pull (Source: www.mdpi.com). By **7 August 2024**, an independent JAMA Health Forum study using linked FDA decision-summary and adverse-event data counted **950 AI/ML devices** cleared or approved, with 108 and 107 devices authorized in 2023 and 2024 respectively as of that point in the year (Source: pmc.ncbi.nlm.nih.gov). A separate trade outlet corroborated the same **950-device** figure for that period, describing it as a **37 percent increase** from the prior year's total of 692 devices (Source: pureclinical.eu) (Source: pureclinical.eu). An earlier trade-press checkpoint from May 2024 sits between those two figures: "On May 13, FDA added an additional 191 AI/ML-enabled devices to the list, bringing the total to 882," of which "128 are radiology focused" (Source: radiologybusiness.com) (Source: radiologybusiness.com).

By the end of 2025, trade analysis of the FDA's updated list put the cumulative total at **1,451 devices** authorized since the agency began tracking in 1995 (Source: theimagingwire.com). That same update showed that in the fourth quarter of 2025 alone, "the FDA cleared 72 AI-enabled medical devices, of which 55 (76%) were radiology devices" (Source: theimagingwire.com). A direct fetch of the FDA's live list during this analysis, reflecting authorizations through late March 2026, showed **1,524 total entries**, indicating continued growth of roughly 70 to 80 additional devices in the first quarter of 2026 alone. *Table 1* below traces the annual and cumulative growth pattern across these checkpoints.

Table 1 below summarizes the year-by-year growth in FDA AI/ML device authorizations as reported across independent sources, alongside the cumulative totals recorded at each checkpoint.

PERIOD	NEW AUTHORIZATIONS	CUMULATIVE TOTAL (APPROX.)	SOURCE
2022	91 to 139 (methodology-dependent)	~500 to 550	MDPI/Electronics counted **139** new devices in 2022, the highest single-year total in its dataset through October 2023 (Source: www.mdpi.com)
2023 (full year)	221	~910	Innolitics year-in-review
2023 (through Oct 19)	108 (171 added that update)	691	MDPI/Electronics (Source: www.mdpi.com); FDA bulletin (Source: content.govdelivery.com)
2024 (through May 13)	191 (single update)	882	Radiology Business (Source: radiologybusiness.com)
2024 (through Aug 7)	107 (year-to-date)	950	JAMA Health Forum / PMC (Source: pmc.ncbi.nlm.nih.gov)
2024 (full year)	253	~1,163	Innolitics year-in-review
2025 (full year)	**295**	**1,451**	Innolitics (Source: innolitics.com); TheImagingWire (Source: theimagingwire.com)
Q1 2026 (session snapshot)	~73 (implied)	**1,524**	Direct FDA list review, session fetch, decisions through March 30, 2026

The apparent inconsistency between the 108-device count MDPI reported for 2023 through mid-October and the 221-device full-year total Innolitics later reported for the same calendar year is worth noting explicitly rather than smoothing over. Some of that gap reflects devices authorized in the final quarter-plus of 2023 that had not yet been added to the FDA's list as of the MDPI team's October snapshot, and some likely reflects differing inclusion methodologies between independent research teams working from the same underlying, imperfectly labeled FDA source data. Both figures are directionally consistent with an accelerating trend: annual clearances have grown from fewer than 30 devices across an entire two-decade span through 2015 to nearly 300 in a single year a decade later, and the FDA itself, cross-referenced against the JAMA Health Forum figures, confirms that growth did not plateau through 2024 (Source: pmc.ncbi.nlm.nih.gov).

FDA Regulatory Pathways for AI Medical Devices Explained

Every device on the FDA's AI-enabled list, regardless of how sophisticated its underlying model, reached the market through one of three premarket pathways that apply to medical devices generally: **510(k) premarket notification**, **De Novo classification**, and **Premarket Approval (PMA)**. Understanding which pathway a given AI device used explains a great deal about how rigorously it was evaluated before reaching clinicians.

The **510(k) pathway** is by far the most common route. A 510(k) submission must demonstrate that a new device is "substantially equivalent" to a legally marketed predicate device, meaning it has "the same intended use as the predicate" and either the same technological characteristics or differences that "do not raise different questions of safety and effectiveness" (Source: www.fda.gov). The FDA notes that this substantial-equivalence determination "is usually made within 90 days and is made based on the information submitted by the submitter" (Source: www.fda.gov), a timeline broadly consistent with the 142-day median observed across all AI/ML clearance types in 2025. Because this pathway compares a new device to an existing predicate rather than requiring the device to independently prove clinical benefit from first principles, it is generally faster and less costly than PMA. Across the entire AI/ML device population studied through 2023, **96.7 percent were cleared via 510(k)**, compared with **2.9 percent via De Novo** and just **0.4 percent via PMA** (Source: pmc.ncbi.nlm.nih.gov), a distribution independently confirmed by the MDPI/Electronics analysis of the same period, which found "96.7% of the approved AI/ML-enabled devices were cleared via the 510(k) pathway. Only 2.9% were approved via De Novo, while Premarket Approval (PMA) was granted to about 0.4%" (Source: www.mdpi.com). The same analysis found the FDA approved

approximately 97 percent of these devices "based on Substantial Equivalence (SESE) criteria, with other decision types making up the minority," while third-party reviewers, private organizations the FDA authorizes to conduct certain 510(k) reviews, handled only about 3 percent of submissions (Source: www.mdpi.com) (Source: www.mdpi.com).

De Novo classification exists for genuinely novel, low-to-moderate-risk devices that have no legally marketed predicate to compare against. The FDA describes it as a pathway "to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device" (Source: www.fda.gov). Under the agency's formal performance goals, "the FDA's goal is to make a decision about a De Novo request in 150 review days," a considerably longer clock than the typical 510(k), reflecting the greater scrutiny a first-of-kind device requires (Source: www.fda.gov). Once granted, a De Novo device becomes a new predicate that later 510(k) submissions can cite. **PMA**, reserved for Class III devices carrying the highest risk, is comparatively rare among AI/ML devices and typically requires independent clinical evidence rather than a predicate comparison.

Two newer mechanisms materially shape how AI devices move through this system. The **Breakthrough Devices Program**, in place since 2016, grants priority FDA review to devices addressing unmet needs; STAT News reported that the agency "has handed out 'breakthrough' designation to more than 1,200 devices, including many powered by AI" in the decade since the program's creation (Source: www.statnews.com), reflecting the FDA's growing emphasis on AI tools that solve problems clinicians cannot readily solve unassisted. Separately, the **Predetermined Change Control Plan (PCCP)** framework addresses a problem unique to machine learning: unlike a fixed-function device, an AI model may be updated or retrained after clearance. Rather than forcing manufacturers back through a full resubmission for every model refresh, a PCCP lets a sponsor pre-specify, at the time of original clearance, "certain planned modifications to a device," the protocol for implementing them, and how their impact will be assessed (Source: www.fda.gov). The PCCP framework builds directly on a broader foundation: in 2021 the FDA, Health Canada, and MHRA "jointly identified 10 guiding principles" for Good Machine Learning Practice before narrowing that work into the five PCCP-specific principles described below (Source: www.fda.gov).

This framework has moved through a deliberate multi-year rollout: the FDA published an AI/ML Action Plan in January 2021, Good Machine Learning Practice guiding principles jointly with Health Canada and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) in October 2021 (Source: www.fda.gov), draft PCCP guidance in April 2023, PCCP-specific guiding principles in October 2023, transparency guiding principles in June 2024, and **finalized its PCCP guidance for AI-enabled device software functions in December 2024** (Source: www.fda.gov), followed by a broader draft total product life cycle guidance in January 2025 (Source: www.fda.gov). Adoption has been swift among sponsors: of the 295 AI/ML devices cleared in 2025, **30 devices, or 10.2 percent, included an authorized PCCP** (Source: innolitics.com), a mechanism the FDA, Health Canada, and MHRA jointly frame around five guiding principles: focused and bounded scope, risk-based design, evidence-based justification, transparency, and a total-product-life-cycle perspective (Source: www.fda.gov).

FDA-Approved AI Devices by Specialty and Leading Companies

Radiology's grip on FDA-authorized AI is the most durable pattern in the entire dataset, holding steady across every independent count regardless of when the snapshot was taken. In the *JAMA Health Forum* dataset covering devices through 2023, radiology accounted for **531 of 691 devices, or 76.9 percent** (Source: pmc.ncbi.nlm.nih.gov), a figure nearly identical to the MDPI/Electronics team's independent count of "531 (about 77%)" over the same period (Source: www.mdpi.com). The same dataset put cardiovascular medicine second at 70 devices (10.1 percent), followed by neurology at 20 devices (2.9 percent), hematology at 15 devices (2.2 percent), and gastroenterology-urology at 11 devices (1.6 percent) (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov). Beyond those top specialties, the independent MDPI/Electronics count found a similar long tail, with "ophthalmology with 9 devices, anesthesiology and clinical chemistry with 6 devices each," and a further spread across microbiology, general and plastic surgery, pathology, general hospital, and several single-digit specialties (Source: www.mdpi.com). By 2025, the trade press reported that "radiology secured 75% of authorizations" for the year, compared with 73 percent in 2024 and 80 percent in 2023 (Source: theimagingwire.com). A separately conducted year-in-review of 2025's 295 clearances put radiology's annual share at **71.5 percent (211 of 295 devices)**, with cardiovascular a distant second at 8.8 percent and neurology third at 4.7 percent (Source: innolitics.com). An independent May 2024 trade-press checkpoint framed the imaging share even more starkly, noting that "almost 80% of all approved AI medical devices are related to medical imaging in some way" (Source: radiologybusiness.com).

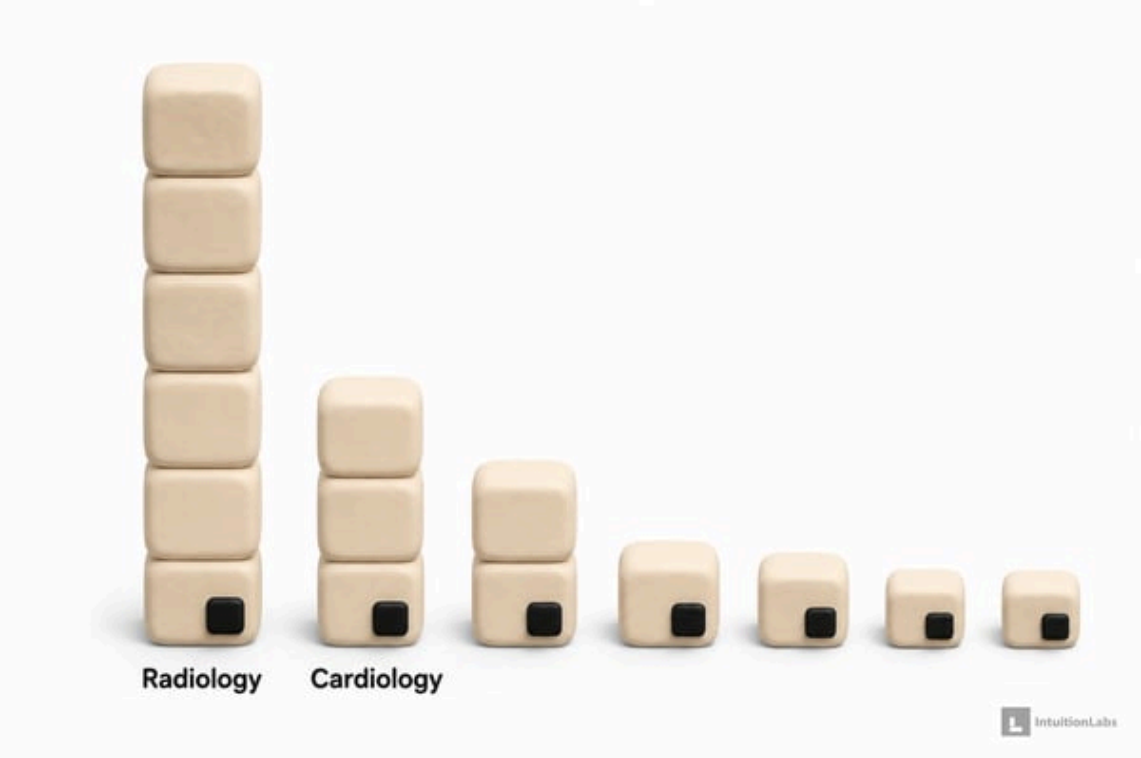

Table 2 below breaks down 2025's full-year clearances by medical specialty panel, based on the year-in-review analysis of all 295 authorizations.

MEDICAL PANEL	2025 CLEARANCES	SHARE OF 2025 TOTAL
Radiology	211	71.5%
Cardiovascular	26	8.8%
Neurology	14	4.7%
Orthopedic	10	3.4%
Gastroenterology/Urology	7	2.4%
Clinical Chemistry	6	2.0%
Anesthesiology	5	1.7%
Other specialties	16	5.5%

Source: Innolitics 2025 year-in-review analysis of FDA 510(k), De Novo, and Breakthrough Device data (Source: innolitics.com).

Radiology's dominance traces directly to data availability: digital imaging has existed in structured, machine-readable form for decades, giving computer-vision developers an enormous head start over specialties where clinical data remains unstructured or fragmented across paper records and free-text notes. Within radiology, the single most common device category by FDA product code is **QIH, "Radiological Computer Assisted Detection/Diagnosis,"** which alone accounted for 75 of the 295 total 2025 clearances, more than a quarter of everything cleared that year (Source: innolitics.com). The next most frequent codes that year were **IYN**, ultrasound systems, with 19 clearances, **LNH**, MRI systems, with 16, **MYN**, picture archiving and communication systems, with 14, and **QAS**, radiological computer-assisted triage, also with 14 (Source: innolitics.com) (Source: innolitics.com), a spread that illustrates how imaging hardware itself, not just standalone analysis software, increasingly ships with embedded AI.

Company-level concentration tells a complementary story about where imaging-hardware incumbents versus AI-native startups compete. By cumulative device count through the end of 2025, **GE HealthCare leads with 120 authorizations**, encompassing acquisitions such as Bay Labs, BK Medical, Caption Health, MIM Software, icometrix, and Spectronic Medical, followed by **Siemens Healthineers at 89** (including Varian), **Philips at 50**, **Canon at 45**, **United Imaging at 38**, **Aidoc at 31**, and **DeepHealth at 28** (Source: theimagingwire.com) (Source: theimagingwire.com). That leadership traces back years: as early as mid-2021, an independent analysis found "the broader GE and Siemens organizations leading the way, with 22 and 18 approvals to date, respectively" (Source: www.iqvia.com). But single-year snapshots reveal a very different competitive picture: in 2025 alone, Shanghai United Imaging Healthcare led all manufacturers with 10 new clearances (Source: innolitics.com), and **183 of the 221 manufacturers active that year received only a single clearance**, evidence of "a thriving startup scene and a low barrier to entry for innovative ideas" (Source: innolitics.com). A comparable, earlier applicant census reached a consistent conclusion: through October 2023, "there were altogether 295 applicants for all the AI/ML-enabled devices seeking FDA approval," with GE Healthcare, Siemens, and Canon named as the three companies "filing the greatest number of applications for FDA clearance" (Source: www.mdpi.com) (Source: www.mdpi.com). Geographically, that same analysis found the United States accounted for **357 devices, approximately 52 percent** of the total, with Israel a distant second at 56 devices (Source: www.mdpi.com). Median approval wait times, meanwhile, "have averaged around 125 days since 2016," with ENT, radiology, and general and plastic surgery devices tending to clear fastest (Source: www.mdpi.com). Also worth noting: the *JAMA Health Forum* data show how recently most of this activity has occurred, with 437 devices (63.2 percent) cleared between 1995 and 2021, against 254 devices (36.8 percent) cleared in 2021 or later (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov).

Data Analysis and Evidence

Rising device counts and rising evidentiary rigor are not the same thing, and the gap between them is the most consequential finding in the independent literature on FDA-cleared AI. The most detailed study of this question, published in *JAMA Health Forum* in September 2025, analyzed premarket and postmarket data for all 691 AI/ML devices cleared through July 2023. It found that manufacturers' summaries "frequently unreported" basic evidentiary elements, including study design for **323 devices (46.7 percent)**, training sample size for 385 devices (53.3 percent), and demographic representation for 660 devices (95.5 percent) (Source: pmc.ncbi.nlm.nih.gov). Only six devices, **1.6 percent of the sample**, cited data from a randomized clinical trial, and just three devices, less than 1 percent, reported actual patient health outcomes rather than purely analytical performance metrics such as sensitivity or specificity (Source: pmc.ncbi.nlm.nih.gov). Where studies did exist, they skewed heavily retrospective and observational rather than prospective or comparative: of devices reporting a data collection method, 82.6 percent relied on retrospective data against just 16.1 percent prospective (Source: pmc.ncbi.nlm.nih.gov), and only 272 devices, 39.4 percent, were associated with any peer-reviewed publication at all (Source: pmc.ncbi.nlm.nih.gov). Formal bias or fairness assessment, checking whether performance varies by race, sex, or age, was documented for only 60 devices, or 8.7 percent of the sample (Source: pmc.ncbi.nlm.nih.gov). The same research team also noted a structural wrinkle in how the 510(k) pathway is used for this category: "one-third of AI/ML devices cleared through the 510(k) pathway originate from non-AI/ML devices" that were subsequently modified to add AI functionality (Source: pmc.ncbi.nlm.nih.gov).

Postmarket surveillance data show a similarly uneven picture. Premarket safety assessments were documented for only **195 of 691 devices (28.2 percent)**, and postmarket adverse events, including one reported patient death, were recorded for 36 devices, or **5.2 percent** (Source: pmc.ncbi.nlm.nih.gov). Formal recalls, tracked separately, touched **40 devices (5.8 percent) across 113 recall actions, primarily due to software issues** rather than hardware failures (Source: pmc.ncbi.nlm.nih.gov), a figure closely matched by the independent MDPI/Electronics analysis, which found the FDA "has occasionally issued recall notices for about 5% of AI/ML-enabled medical devices" over a comparable window (Source: www.mdpi.com).

Separately, a taxonomy analysis published in *npj Digital Medicine* dissected the *type* of AI work these devices actually perform rather than the rigor of their evidence base. Reviewing 1,016 FDA authorizations issued through December 20, 2024, researchers grouped these into **736 unique devices** and found that **621 (84.4 percent) use medical images as their core data input**, 107 (14.5 percent) use physiological signals such as ECG or EEG traces, and only a handful use genomic or tabular electronic health record data (Source: www.nature.com) (Source: www.nature.com). Within the imaging subset, "Radiology was the lead review panel for the majority (88.2%), followed by Neurology (2.9%) and Hematology (1.9%)" (Source: www.nature.com). Functionally, **85.6 percent of devices perform analysis of existing data** rather than generating new data such as enhanced or synthesized images, and the large majority, 84.1 percent, assist with patient assessment tasks like diagnosis and monitoring rather than direct clinical intervention. Among the smaller set of devices that use AI to generate rather than analyze data, the dominant application is straightforward image improvement: "84 (79.2%; 11.4% of all devices) perform image enhancement," such as denoising or AI-based reconstruction (Source: www.nature.com). The same taxonomy also tracked how device design has shifted over time: "quantification/feature localization is the most common AI function subclass, but its prevalence peaked at 81% of devices in 2016 and has declined to 51% in 2024" (Source: www.nature.com), evidence that newer entrants increasingly perform triage, detection, or diagnosis rather than simple measurement.

Innolitics' 2025 full-year analysis adds a workflow-relevant metric largely absent from the peer-reviewed literature: regulatory review speed. The **median time from submission to clearance in 2025 was 142 days**, with 24.1 percent of devices clearing in under 90 days and 22 percent taking longer than 200 days for more complex submissions (Source: innolitics.com). Clearance volume was also remarkably steady month to month, with "monthly totals ranging from 19 to 34" across 2025 (Source: innolitics.com). Software as a Medical Device (SaMD) devices, meaning standalone software not bundled with dedicated hardware, made up **62 percent** of 2025's clearances, and **63 percent of all devices cleared that year were diagnostic** rather than therapeutic in intent (Source: innolitics.com). Read together with the evidence-reporting gaps above, the picture that emerges is one of a fast, procedurally efficient clearance system layered onto comparatively thin premarket clinical evidence and inconsistent postmarket monitoring, a tension regulators, health systems, and life sciences consultancies advising on AI procurement must all weigh explicitly rather than assume away.

Case Studies and Real-World Examples

PAPNET Testing System (1995): The First AI-Enabled Device

Long before "AI-enabled" became a distinct FDA tracking category, the **PAPNET Testing System** obtained Premarket Approval in 1995 as a pathology tool for rescreening Pap smears (Source: www.mdpi.com). Its PMA pathway, the strictest of the three routes, reflected the FDA's caution toward a genuinely novel technology with no predicate to compare against. For roughly two decades after PAPNET, AI-enabled clearances remained sporadic, with fewer than 30 devices authorized in total through 2015 (Source: www.iqvia.com), underscoring how recent the current surge really is relative to the technology's actual regulatory origin.

LumineticsCore, formerly IDx-DR (2018): The First Autonomous AI Diagnostic

In April 2018, the FDA granted a De Novo request for **IDx-DR**, now marketed as LumineticsCore, making it "the first autonomous, AI-based diagnostic system authorized for commercialization by the FDA" (Source: www.digitaldiagnostics.com). Unlike prior decision-support tools that merely flagged findings for clinician review, LumineticsCore renders a diagnostic determination for diabetic retinopathy without a specialist interpreting the image, screening adults with diabetes directly in a primary care office. The device addressed a documented access gap: more than 30 million Americans have diabetes, and an estimated 24,000 lose vision each year to diabetic retinopathy, a complication that is largely preventable if caught early (Source: www.digitaldiagnostics.com). The clearance moved through the FDA's Breakthrough Devices program following a pivotal clinical trial conducted at 10 primary care sites across the United States (Source: www.digitaldiagnostics.com), the kind of prospective, multi-site clinical evidence that, per the JAMA Health Forum findings above, remains uncommon across the broader AI/ML device population.

Paige Prostate Detect (2021): The First FDA-Authorized AI in Pathology

Where LumineticsCore established the precedent for autonomous diagnosis in ophthalmology, **Paige Prostate Detect** did the analogous work in anatomic pathology. It was "the first AI-based software application in pathology to receive FDA approval to aid in the primary diagnosis of prostate cancer" (Source: www.paige.ai), assisting pathologists reviewing digitized whole-slide images of prostate needle biopsies in flagging tissue regions suspicious for cancer. Independent validation studies cited by the manufacturer reported a **70 percent reduction in diagnostic error** among pathologists using the tool (Source: www.paige.ai). The company has since built on that first authorization with three FDA Breakthrough Device designations for adjacent pathology applications spanning breast and pan-cancer detection (Source: www.paige.ai), illustrating how an initial De Novo-style authorization in a new specialty can seed a broader clearance pipeline, much as PAPNET and LumineticsCore did for their respective fields.

Viz.ai ICH Plus (2024): Extending Autonomous Triage to Neurovascular Emergencies

In February 2024, **Viz.ai** received 510(k) clearance for **Viz ICH Plus**, an algorithm that automates identification, labeling, and volumetric quantification of intracerebral hemorrhage on non-contrast CT scans, output clinicians use to make time-sensitive treatment decisions (Source: www.viz.ai). Intracerebral hemorrhage accounts for up to 15 percent of all strokes and carries high morbidity and mortality, making rapid, accurate volume measurement clinically consequential (Source: www.viz.ai). The clearance built on the company's platform, which by 2024 already covered more than 230 million lives across over 1,500 hospitals and health systems in the United States and Europe (Source: www.viz.ai), illustrating how neurovascular AI has scaled from single-algorithm stroke detection tools into a broad care-coordination platform spanning multiple conditions.

Aidoc CARE (2026): A Foundation-Model Triage Clearance

The most recent landmark authorization examined in this report reflects the shift the FDA itself has flagged toward foundation-model-based devices. **Aidoc** announced that the FDA "cleared the healthcare industry's first comprehensive AI triage solution," combining 11 newly cleared indications with three previously cleared ones into a single workflow built on the company's **CARE** foundation model (Source: www.aidoc.com). In its FDA-reviewed pivotal study, the 11 indications achieved a mean sensitivity of 97 percent, up to 98.5 percent, and mean specificity of 98 percent, up to 99.7 percent (Source: www.aidoc.com). The clearance sits atop a platform that Aidoc said had analyzed more than 100 million patient cases and described as "the most widely deployed clinical AI platform in healthcare" (Source: www.aidoc.com). This case is instructive precisely because it sits at the leading edge of the architectural shift the *npj Digital Medicine* taxonomy anticipated: a single underlying model supporting many simultaneous clinical indications, a structural departure from the single-purpose detection algorithms that have historically dominated the FDA's AI-enabled list.

Implications and Future Directions

Three converging forces will shape the next phase of FDA-authorized AI in medicine. First, the architecture of the devices themselves is shifting from narrow, single-task detection algorithms toward multi-indication and, eventually, foundation-model-based systems, a transition the Aidoc CARE clearance exemplifies and one the FDA has explicitly prepared for by announcing plans to tag devices incorporating foundation models on future updates to its public list (Source: www.fda.gov). This mirrors a broader pattern the *npj Digital Medicine* taxonomy documented directly: newer authorizations already skew away from simple quantification toward triage, detection, and diagnosis functions, and "the percentage of authorizations that represent updated versions of existing devices has averaged 34% over 2022 to 2024, compared to 14% between 2017 and 2019" (Source: www.nature.com). STAT News reported in mid-2026 that the FDA's breakthrough device pipeline was increasingly filling with generative AI-powered tools, including devices aimed at drafting radiology reports, a functional category distinct from the detection-and-quantification work that has defined the field to date. Whether the evidentiary standards applied to narrow computer-vision tools translate cleanly to generative, multi-purpose systems is an open regulatory question that the FDA's draft total product life cycle guidance, issued in January 2025, begins to address but has not fully resolved as of this writing.

Second, the regulatory apparatus for managing post-clearance model updates is still maturing in practice even as its policy foundation solidifies. The five PCCP guiding principles, jointly issued by the FDA, Health Canada, and the UK's MHRA, aim to let manufacturers "align regulatory processes with the rapid and ongoing approach to change management" that machine learning models require (Source: www.fda.gov), but with only roughly one in ten new clearances currently using a PCCP, most sponsors still default to the traditional model of static, resubmission-triggered updates. As adoption climbs from that 10.2 percent baseline, expect closer scrutiny of how well pre-specified change protocols actually perform once models are retrained on real-world data drawn from diverse patient populations and imaging equipment, an area where the underlying evidentiary gaps documented in the Data Analysis section above become directly relevant to whether postmarket model drift can be reliably detected.

Third, clearance is only the first of two gates a device must pass before it changes clinical practice at scale, and the second gate sits with payers rather than the FDA. As of mid-2024, trade reporting on the FDA's list found that "currently, the Centers for Medicare & Medicaid Services (CMS) has assigned payment for just around 10 of these devices," prompting "more than a dozen" patient advocacy and medical professional groups to petition congressional appropriators for a defined reimbursement pathway for AI in radiology (Source: radiologybusiness.com). For life sciences organizations and health systems evaluating AI procurement, this argues for treating FDA clearance status as a necessary but insufficient signal on two separate fronts, clinical evidence and payer coverage, and for building independent evidence review into vendor selection rather than relying on regulatory status alone as a proxy for either clinical validity or commercial viability. Advisory practices such as intuitionlabs.ai, which works with pharmaceutical and life-science organizations on AI governance and regulatory-adjacent technology decisions and is led by a team with "deep industry knowledge with cutting-edge AI and software engineering expertise" (Source: intuitionlabs.ai), frame this precisely as a governance question: understanding what a given FDA pathway does and does not certify, on both safety and payment, is a prerequisite for responsible internal adoption of AI-enabled clinical tools, separate from the question of which vendor or platform an organization ultimately selects.

Frequently Asked Questions (FAQs)

How many AI medical devices are FDA approved? As of a direct review of the FDA's AI-Enabled Medical Device List conducted for this report, the list contained **1,524 entries**, with the most recent decision dated March 30, 2026 (Source: www.fda.gov). Trade analysis of the FDA's year-end 2025 update separately reported a cumulative total of **1,451 devices** authorized since 1995 (Source: theimagingwire.com). Because the FDA updates the list periodically rather than continuously, any figure cited should be understood as a snapshot rather than a permanently fixed number.

What is the difference between "FDA approved" and "FDA cleared" for AI medical devices? The two terms describe different pathways and are not interchangeable. "Cleared" refers to devices that went through 510(k) premarket notification, demonstrating substantial equivalence to a predicate device (Source: www.fda.gov), which describes roughly 97 percent of AI/ML devices on the FDA's list (Source: pmc.ncbi.nlm.nih.gov). "Approved"

technically refers to devices that went through Premarket Approval, a small minority of AI devices reserved for higher-risk Class III products. "Authorized" is the FDA's own preferred umbrella term covering all three pathways, including De Novo classification.

What is the FDA AI/ML-enabled medical device database, and how current is it? It is a curated public list maintained by the FDA's Digital Health Center of Excellence, downloadable as CSV, Excel, or XML files, that links each entry to its underlying 510(k), De Novo, or PMA database record (Source: www.fda.gov). The FDA states plainly that devices "authorized but for which decision summaries have not been published within the data collection period will be incorporated into a subsequent update," and its own official bulletins repeat that the roster is not meant to be "an exhaustive or comprehensive resource of AI/ML-enabled medical devices" (Source: content.govdelivery.com), meaning the list lags the true count of authorized devices by some margin at any given time.

What is the FDA's approval process for AI medical devices? Nearly every AI device follows one of three tracks: **510(k)** clearance based on substantial equivalence to a predicate device, used by roughly 97 percent of devices; **De Novo** classification for genuinely novel low-to-moderate-risk devices lacking a predicate; or **Premarket Approval**, the most rigorous track, reserved for high-risk Class III devices. Many sponsors also seek **Breakthrough Device** designation for priority review, a program that has granted status to more than 1,200 devices since 2016 (Source: www.statnews.com), and increasingly include a **Predetermined Change Control Plan** to pre-authorize future model updates (Source: www.fda.gov).

Which medical specialty has the most FDA-approved AI devices? Radiology, by a wide and consistent margin. It has accounted for between 71.5 percent and 80 percent of annual clearances across every year examined in this report and roughly 76 to 80 percent of the cumulative device population (Source: theimagingwire.com) (Source: innolitics.com).

Are large language models (LLMs) or generative AI included in FDA medical device clearances? As of the most recent comprehensive academic taxonomy, covering authorizations through December 2024, researchers found no evidence of LLM-based devices among FDA-authorized AI/ML products (Source: www.nature.com). That is changing quickly: STAT News reported the FDA's breakthrough device pipeline was filling with generative AI tools by mid-2026, and the FDA has announced plans to begin tagging foundation-model-based devices on future list updates (Source: www.fda.gov).

Conclusion

The FDA's AI-Enabled Medical Device List has grown from a handful of authorizations in the mid-2010s to well over 1,500 entries by early 2026, a trajectory driven overwhelmingly by radiology imaging tools cleared through the streamlined 510(k) pathway. That growth is real, consistent across every independent dataset examined in this report, and shows no sign of slowing: 2025 alone produced 295 new clearances from 221 unique manufacturers, a pace regulators have worked to accommodate through new mechanisms like Predetermined Change Control Plans rather than resist. At the same time, the evidentiary record behind many of these devices remains uneven. Randomized trial data, patient-outcome reporting, and demographic transparency are each documented in only a small minority of authorization summaries, a gap that peer-reviewed researchers, not device critics with an axe to grind, have independently and repeatedly quantified.

Neither of these facts cancels the other out. A rapidly growing, procedurally efficient clearance pathway and a thin premarket evidence base can, and currently do, coexist within the same regulatory system, and a growing device count coexists with a payer landscape that has covered only a small fraction of these tools with dedicated reimbursement. For clinicians, health system procurement teams, and life sciences organizations building AI strategy, the practical takeaway is to treat FDA authorization as confirmation that a device met the applicable requirements of its 510(k), De Novo, or PMA pathway, not as an independent guarantee of clinical benefit equivalent to what a randomized controlled trial would provide, and not as a guarantee that the device will be reimbursed. The distinction between "cleared," "approved," and "authorized" is not pedantic; it maps directly onto how much independent clinical evidence a given device was required to generate before reaching a hospital or clinic.

Looking ahead, the most consequential open question is how the current framework, built primarily around narrow, single-task detection and quantification algorithms, will adapt to the foundation-model and generative AI systems now entering the FDA's breakthrough device pipeline. The agency's own signal that it intends to tag foundation-model-based devices on future list updates, paired with its January 2025 draft total product life cycle guidance, suggests regulators are aware of the shift and actively building toward it. Whether the safety and evidentiary standards that have applied to the first 1,500-plus AI devices translate cleanly to that next generation of multi-purpose, continuously updating systems will shape not just how many devices appear on the FDA's list in the years ahead, but how much confidence clinicians, patients, and the organizations that deploy these tools can reasonably place in it.

Tags: fda approved ai medical devices list, fda cleared ai medical devices, ai medical devices 2026, fda ai ml enabled medical device database, 510k clearance ai devices, ai radiology devices fda, fda breakthrough devices program, predetermined change control plan, fda de novo pathway, medical device regulation ai

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Contact founder Adrien Laurent and team at intuitionlabs.ai/contact for a consultation.

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