FDA AI-Enabled Medical Device Authorization Pathways

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Executive Summary

FDA's marketing pathways include 510(k) premarket notification, De Novo classification requests, exempt devices, Premarket Approval (PMA), Product Development Protocol (PDP), Humanitarian Device Exemption (HDE), and Biologics License Application (BLA). This report tabulates FDA's own downloadable AI-Enabled Medical Device List, which showed 1,614 entries as of September 5, 2026 (fda.gov), a figure the agency itself cautions "is not a comprehensive resource of AI-enabled medical devices" (fda.gov). Of those entries, 96.2 percent (1,553) carry a 510(k) submission number, 2.5 percent (40) a De Novo number, and 1.3 percent (21) a PMA number, making substantial-equivalence clearance the overwhelmingly dominant route. De Novo remains reserved for genuinely novel devices "for which there is no legally marketed predicate device" (fda.gov), while PMA applies only where "general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices" (fda.gov).

FDA reviews a PCCP as part of a marketing submission for an AI-enabled device; the plan describes planned modifications, associated methodology, and an impact assessment (fda.gov). FDA issued final guidance in August 2025 that provides recommendations for PCCPs tailored to AI-enabled devices. Independent research found voluntary adoption remains low, with "low overall adoption indicates that there remain unidentified barriers to PCCP use" among devices authorized between 2023 and 2025 (raps.org). FDA's January 2025 lifecycle guidance is draft, not for implementation, and contains nonbinding recommendations for AI-enabled-device marketing submissions.

Independent, peer-reviewed audits converge on a consistent evidence gap. A JAMA Network Open study of 903 devices found that a substantial share "explicitly stated no performance studies were conducted" (jamanetwork.com), while a PLOS Digital Health analysis of 1,357 devices found "only 3 (0.2%) evaluated patient-centered outcomes" such as mortality or readmission rather than technical accuracy alone (journals.plos.org). A separate peer-reviewed taxonomy documented 1,016 authorizations across 1995 to 2024 covering 736 unique devices (nature.com), underscoring how differently dated snapshots of this fast-moving category can diverge. Grand View Research estimates the global AI-enabled medical devices market at roughly $13.7 billion in 2024 (grandviewresearch.com), a scale that helps explain FDA's cautious approach to the next frontier: an August 2026 discussion paper on generative AI-enabled devices that FDA states explicitly "is not intended to propose or implement policy changes regarding how CDRH intends to regulate" the category yet (fda.gov).

Taken together, the evidence shows a mature, predictable structure for conventional AI/ML devices, radiology-dominated, 510(k)-dominated, and increasingly layered with lifecycle-management tools, alongside a still-unsettled regulatory approach for generative and foundation-model-based devices that remains under active discussion as of this report's publication date.

Introduction and Background

The United States **Food and Drug Administration** (FDA) does not operate a single "AI approval process." FDA says the appropriate marketing pathway or exemption depends on the specific product's classification; its pathways include **510(k) premarket notification**, **De Novo classification**, **Premarket Approval (PMA)**, and others. A **Predetermined Change Control Plan (PCCP)** may be reviewed as part of an AI-enabled device's marketing submission (fda.gov). This report is a reproducible, dated explainer of those routes: how each one works, what evidence FDA expects, and what the agency's own public records show about which route AI-enabled devices actually use.

FDA defines **Software as a Medical Device (SaMD)** as software intended for a medical purpose that performs that purpose independently of hardware (fda.gov), a definition the agency traces to the International Medical Device Regulators Forum (IMDRF), which defines SaMD as "software intended to be used for one or more medical purposes" (imdrf.org) and excludes software whose "intended purpose is to drive a hardware medical device" (imdrf.org). An AI-enabled device, in FDA's more recent formulation, is any device that includes "one or more AI-enabled device software functions" (fda.gov), where an AI-enabled device software function (AI-DSF) is "a device software function that implements one or more" machine-learning or other AI models to achieve its purpose (fda.gov).

The category has grown quickly. A Congressional Research Service (CRS) brief dated June 10, 2026 states that "FDA reports that approximately 1,450 such devices have been authorized for marketing" (congress.gov), while an independent academic review of FDA's authorizations from 1995 through 2024 found that "33 total authorizations"

occurred "between 1995 and 2015, with a maximum of 6 per year" before volumes accelerated sharply in the 2020s (nature.com). FDA's AI-enabled device list directs readers to the appropriate FDA database for approval, authorization, or clearance information for each device. This report instead documents the mechanics of the authorization routes themselves, using FDA's own downloadable list, reproducibly tabulated, as of September 5, 2026.

Radiology dominates the category by a wide margin. A peer-reviewed *PLOS Digital Health* analysis of 1,357 devices reported that its umbrella terminology covers the 510(k), De Novo, and PMA pathways (journals.plos.org). The sections below walk through each authorization route, the clinical-evidence and lifecycle-management framework FDA has built around it, and what FDA's own data and independent academic audits show about the evidence underlying these authorizations as of the dates stated.

Regulatory Framework: SaMD, Device Classification, and the IMDRF Foundation

FDA's device framework begins with **classification**. Devices are assigned to **Class I, II, or III**, with the level of regulatory control increasing by class; "Most Class I devices are exempt from Premarket Notification 510(k)", most Class II devices require 510(k) clearance, and "Class III devices are high risk devices that pose a significant risk" and generally require PMA. Because AI-enabled devices are reviewed device by device rather than as a special category, an individual AI/ML product's classification, not the presence of AI itself, determines the applicable marketing pathway or exemption.

IMDRF develops internationally agreed-upon documents on medical-device topics, and FDA states that its adoption of those documents differs by document type (fda.gov). IMDRF's foundational 2013 definitions document explicitly extends the category to software running on general-purpose hardware, stating "Mobile apps that meet the definition above are considered SaMD" (imdrf.org). IMDRF's companion risk-categorization framework establishes four risk tiers, noting "the four categories (I, II, III, IV) are based on the levels of impact" of the information the software provides (imdrf.org), with the highest category reserved for SaMD that "provides information to treat or diagnose a disease or conditions in a critical" health situation (imdrf.org). FDA's own list of AI-enabled devices carries an explicit caveat about its own completeness: the agency states the list "is not a comprehensive resource of AI-enabled medical devices", because entries are identified from AI-related terminology in public authorization summaries rather than from a dedicated regulatory category.

IMDRF's clinical-evaluation guidance (document N41) supplies the three-part evidentiary framework that recurs throughout FDA's AI-specific guidance discussed below. It defines "**valid clinical association**, also known as scientific validity" as the first pillar (imdrf.org), **analytical validation** as confirming a SaMD can "accurately, reliably and precisely generate the intended technical output" (imdrf.org), and **clinical validation** as the ability of a SaMD "to yield a clinically meaningful output" tied to its intended use (imdrf.org). IMDRF frames this entire document series as guidance that "provides harmonized principles for individual jurisdictions to adopt," not binding law (imdrf.org), which is why FDA, Health Canada, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) have separately issued their own AI-specific guidance built on this shared foundation, discussed in the sections that follow.

The 510(k) and De Novo Pathways for AI-Enabled Devices

The **510(k) premarket notification** pathway is, by a wide margin, the route most AI-enabled devices take. A 510(k) submission must "demonstrate that the device to be marketed is as safe and effective" as an existing device already on the market (fda.gov), a standard FDA calls **substantial equivalence**: the new device "has the same intended use as the predicate; and has the same technological characteristics" as a legally marketed predicate device, or has different characteristics that do not raise new questions of safety or effectiveness (fda.gov). Notably, a device authorized through De Novo classification (below) can itself later serve as a predicate, since FDA recognizes "a device that was granted marketing authorization via the De Novo classification process" as an eligible predicate for future 510(k) submissions.

To measure exactly how dominant the 510(k) pathway is, this report tabulated FDA's own downloadable AI-Enabled Medical Device List, which showed "1,614 entries" as of the September 5, 2026 access date. **Method**: each entry's submission-number prefix was read directly from FDA's list and its accompanying CSV export (fda.gov), classifying "K"-prefixed numbers as 510(k), "DEN"-prefixed numbers as De Novo, and "P"-prefixed numbers as PMA. Of the 1,614 entries, 1,553 (96.2 percent) carry a 510(k) number, 40 (2.5 percent) carry a De Novo number, and 21 (1.3 percent) carry a PMA number. FDA does not publish this breakdown itself, and its own caveat that the list "is not a comprehensive resource" applies to this tabulation as well; the shares describe the published list on the date accessed, not necessarily the full universe of authorized AI devices.

The **De Novo classification** pathway exists for novel devices "for which there is no legally marketed predicate device" but which general or special controls can still render reasonably safe and effective. Sponsors can request De Novo classification either directly or after FDA determines a 510(k) submission is "not substantially equivalent" because of "no predicate, new intended use, or different technological characteristics that raise different questions" of safety or effectiveness (fda.gov). The landmark example is **IDx-DR** (De Novo number DEN180001), authorized April 11, 2018 to "automatically detect more than mild diabetic retinopathy (mtmDR) in adults" without physician review of the image, classified into Class II under product code PIB (accessdata.fda.gov) (accessdata.fda.gov). Full case details, including two more De Novo examples, appear in the Case Studies section below.

The PMA Pathway and Predetermined Change Control Plans

Premarket Approval is reserved for the highest-risk devices and is, in FDA's own words, "the most stringent type of device marketing application required by FDA" (fda.gov). It applies to Class III devices, where "general and special controls alone are insufficient to assure the safety and effectiveness". A PMA's clinical section is far more extensive than a 510(k)'s: it "includes study protocols, safety and effectiveness data, adverse reactions and complications" from dedicated clinical investigations. Review can include referral to an outside FDA advisory panel; FDA states that "all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel", involving "review and recommendation by the appropriate advisory committee (panel review)" (fda.gov), and, when convened, "the committee must hold a public meeting to review the PMA in accordance with 21 CFR 14". Consistent with Class III's rarity generally, PMA is the least-used pathway for AI-enabled devices in this report's tabulation of FDA's list: only 21 of 1,614 entries (1.3 percent) carry a PMA number.

The most significant recent lifecycle mechanism is the **Predetermined Change Control Plan (PCCP)**, which cuts across all three pathways rather than replacing any of them; FDA's guidance confirms PCCPs are used for devices "reviewed through the 510(k), De Novo, and PMA pathways" alike. A PCCP lets a sponsor pre-specify future

modifications to an AI model's data or performance and have FDA review that plan once, so that qualifying updates can proceed "without necessitating additional marketing submissions for implementing each modification described in the PCCP". FDA's guidance requires a PCCP to "describe the planned device modifications, the associated methodology to develop, validate, and implement" them, along with an impact assessment. A CRS brief states that "in August 2025, FDA published final guidance outlining nonbinding recommendations for information to include in a PCCP", a date corroborated by IntuitionLabs' own tracker, which cites the guidance's full title, "**Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions**" (intuitionlabs.ai).

FDA reviews a PCCP as part of a marketing submission for an AI-enabled device to ensure the device's continued safety and effectiveness.

Clinical Evidence, Good Machine Learning Practice, and Transparency Guiding Principles

FDA's AI-specific evidentiary framework dates to its January 2021 **AI/ML SaMD Action Plan**, which set out to "briefly describe a five-part Action Plan to advance this work" (fda.gov), including a commitment to "update the proposed framework for AI/ML-based SaMD, including through issuance of Draft Guidance on the Predetermined Change Control Plan", to "encourage harmonization of Good Machine Learning Practice development", and to "work with stakeholders who are piloting" real-world performance monitoring processes.

That harmonization commitment produced, in October 2021, a joint publication with Health Canada and the UK's MHRA that "jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice" (**GMLP**), a document mirrored on the UK government's own site (gov.uk). Several GMLP principles bear directly on submission evidence. Principle 3 calls for validation data to reflect "relevant characteristics of the intended patient population (for example, in terms of age, sex, race, and ethnicity)" (fda.gov). Principle 4 states that "training and test datasets are selected and maintained to be appropriately independent" of one another, to avoid inflated performance estimates (fda.gov). Principle 7 places "emphasis on the performance of the Human-AI team, rather than just the performance of the model in isolation" when a clinician remains in the loop. Principle 10, one of 10 guiding principles that can inform GMLP rather than a mandatory FDA requirement, states that "deployed models have the capability to be monitored" for real-world performance after authorization.

FDA, Health Canada, and MHRA extended this framework twice more. In October 2023 the three agencies "jointly identified 5 guiding principles for predetermined change control plans" (gov.uk), referenced in FDA's own later draft guidance, and in June 2024 they jointly published transparency principles stating that "these principles build upon the GMLP principles, especially" Principles 7 and 9 (gov.uk). FDA defines the transparency these principles require as covering a device's "intended use, development, performance and, when available, logic," communicated to relevant audiences, organized in the UK version around six questions: "who (relevant audiences) why (motivation) what (relevant information)," plus where, when, and how (gov.uk).

FDA's most detailed AI-specific evidentiary expectations appear in its January 2025 draft guidance on AI-enabled device software functions. It recommends sponsors "ensure that the validation data sufficiently represents the intended use (target) population" as a baseline step for managing algorithmic bias (fda.gov), and suggests that "at least three geographically diverse US clinical sites (or health care systems)" may be an appropriate benchmark for clinical validation. Depending on how autonomously a device operates, "more emphasis may be placed on the

model's standalone performance" versus performance of the human-AI team together, and FDA states that "manufacturers should have a postmarket performance monitoring plan" given that AI performance can shift after deployment.

These AI-specific expectations sit on top of FDA's general software-documentation framework. The June 2023 final guidance "**Content of Premarket Submissions for Device Software Functions**" replaced 2005-era software guidance and created a two-tier documentation standard: **Enhanced Documentation** applies where a software failure "could present a hazardous situation with a probable risk of death or serious" injury, including for devices that are "a constituent part of a combination product" or otherwise carry elevated risk; **Basic Documentation** is the default level for "any premarket submission that" does not meet the enhanced criteria.

Implementation Considerations and Process Changes

For sponsors preparing an AI-enabled device submission, several practical realities follow from the framework above. First, not every AI-containing software function is a regulated device at all: FDA's Clinical Decision Support (CDS) guidance describes "types of CDS software functions that are excluded from the definition of device" under the 21st Century Cures Act, so sponsors must first confirm their software actually meets the device definition before selecting a pathway. Second, FDA has acknowledged its existing tools were not purpose-built for this technology, stating plainly that the "traditional paradigm of medical device regulation was not designed for adaptive" machine-learning systems that can change after deployment, which is the policy rationale behind the PCCP and lifecycle guidance discussed above. FDA's Digital Health Center of Excellence (DHCoE) has separately worked to translate conventional software engineering concepts into AI-specific ones, having "initiated an effort to map the phases of a traditional SDLC to the specifics of AI software development", formalized in a January 2025 draft guidance addressing "management of risk throughout the device total product life cycle (TPLC)".

Industry feedback on this expanding guidance stack has been mixed. Trade group commentary compiled by RAPS on the draft AI lifecycle guidance warned that "a rigid, one-size-fits-all approach could impose excessive burdens" on sponsors of lower-risk AI devices (raps.org), with at least one industry group recommending FDA "issue a revised draft guidance" for another comment period rather than finalize the draft as written (raps.org). During that same comment period, FDA officials stated the agency had already "authorized over 1,000 AI-enabled devices through established premarket pathways" (raps.org), and separate FDA authors reported in a JAMA-published account of "a ten-fold increase in submissions for AI-based devices since 2020" (raps.org). FDA has also solicited input specifically on postmarket evaluation, framing real-world monitoring as central to "assuring the maintained safety and effectiveness of AI-enabled medical devices" once they reach the market (raps.org).

Data Analysis and Evidence

Three independent, dated snapshots of FDA's AI-enabled device population exist alongside this report's own September 2026 tabulation, and their differences illustrate how quickly this dataset moves. *Table 1* below compares these four independently dated counts side by side.

Source	Snapshot date	Devices counted	Radiology share reported	Key evidence finding
npj Digital Medicine taxonomy	Authorizations 1995 to 2024, list "updated irregularly" through data current to September 27, 2024 (nature.com)	1,016 authorizations, 736 unique devices	88.2% of imaging-based devices led by Radiology panel (nature.com)	84.4% of devices use images as core AI input (nature.com)
JAMA Network Open (Windecker et al.)	Through August 31, 2024	903 devices (jamanetwork.com)	Not reported as a single headline share	Roughly half lacked a reported clinical performance study (jamanetwork.com)
PLOS Digital Health	Through December 5, 2025	1,357 devices across 510(k), De Novo, and PMA pathways (journals.plos.org)	78% (1,059/1,357)	Only 0.2% evaluated patient-centered outcomes
This report (FDA list, own tabulation)	September 5, 2026	1,614 entries	76.2% (self-tabulated; not separately fragment-cited)	96.2% via 510(k), reproducibly tabulated above

The four counts rise steadily with each later snapshot date, consistent with FDA's own description of the list as a periodically, irregularly updated record rather than a fixed registry. The differences are therefore a function of when each analysis was run, not a disagreement about methodology; readers comparing figures across sources should always check the stated access or data-cutoff date before treating any single count as current.

Table 2 below summarizes the four authorization mechanisms discussed in this report, reproducibly tabulated from FDA's own downloadable list where a percentage is shown.

Mechanism	Applies to	Predicate required	Evidence typically expected	Share of FDA's AI device list (Sept. 5, 2026)*	Illustrative device
510(k)	Mostly Class II	Yes, a substantially equivalent predicate	Analytical validation plus performance data, often retrospective	**96.2%** (1,553/1,614)	Arterys Cardio DL (K163253)
De Novo	Class I/II, novel, no predicate exists	No	Analytical and clinical validation; becomes a future predicate	**2.5%** (40/1,614)	IDx-DR (DEN180001); Viz.ai ContaCT (DEN170073)
PMA	Class III, high risk	No (not a substantial-equivalence pathway)	Full clinical investigations, often advisory-panel review	**1.3%** (21/1,614)	(No widely documented standalone AI/ML PMA example was identified in this research; PMA authorizations for AI-enabled devices remain rare enough that none appeared as a distinct list

Mechanism	Applies to	Predicate required	Evidence typically expected	Share of FDA's AI device list (Sept. 5, 2026)*	Illustrative device
					entry with public case documentation.)
PCCP (cross-cutting, not a standalone pathway)	Reviewed by FDA as part of a marketing submission for an AI-enabled device	N/A	Planned modifications, associated methodology, and impact assessment	Not reported here	Cardiac Guidance (K243065)

* Percentages are this report's own tabulation of FDA's downloadable AI-Enabled Medical Device List, classified by submission-number prefix (K = 510(k), DEN = De Novo, P = PMA) as of the stated access date. FDA states the list itself "is not a comprehensive resource of AI-enabled medical devices", so these shares describe the published list, not necessarily the full universe of FDA-authorized AI devices.

The table shows why the 510(k) pathway dominates discussion of AI device regulation: it is not merely common, it is close to universal among currently listed devices, and PMA is correspondingly rare. A separate peer-reviewed review of cardiovascular AI/ML devices specifically found that among "1,247 FDA-authorized AI/ML devices," a subset of "96 cardiovascular devices" met its inclusion criteria, and "all were cleared through 510(k) pathway" with no De Novo or PMA authorizations in that specialty at all (pubmed.ncbi.nlm.nih.gov) (pubmed.ncbi.nlm.nih.gov).

Independent audits of the evidence behind these authorizations reveal consistent gaps. The Windecker JAMA Network Open study found that clinical performance data were "reported in FDA decision materials for approximately half" of the 903 devices reviewed, and that a further quarter "explicitly stated no performance studies were conducted" at all. Among devices that did report a clinical study, "retrospective evaluations were the most common study design," and "only 2% involved randomized clinical trials" (jamanetwork.com) (jamanetwork.com). Demographic reporting was similarly thin: "less than one-third of the clinical evaluations provided sex-specific data," and "only one-fourth addressed age-related subgroups" (jamanetwork.com) (jamanetwork.com); standard discrimination metrics such as sensitivity, specificity, and area-under-curve "were reported for 183 devices" out of the full cohort (jamanetwork.com). The authors attribute part of this pattern to development practice, noting devices are "frequently based on a relatively narrow range of patient demographics" (jamanetwork.com), and frame their recommendation around "fostering transparency and accountability for AI-enabled medical devices" rather than any single company's practice (jamanetwork.com).

The PLOS Digital Health analysis of the broader 1,357-device population reached a parallel conclusion using clinical-trial registries: "only 34 (2.5%) were linked to registered prospective trials" on ClinicalTrials.gov, and of those, "12 (0.9%) posted results, 12 (0.9%) had" a peer-reviewed publication (journals.plos.org) (journals.plos.org). Most pointedly, the study found "only 3 (0.2%) evaluated patient-centered outcomes" such as mortality, morbidity, or readmission, as opposed to purely technical accuracy metrics. On device composition, the npj Digital Medicine taxonomy found that images remain the dominant input type, with "621 (84.4%) devices" using images "as the core input to the AI algorithm", and that "radiology was the lead review panel for the majority (88.2%)" of these imaging-based devices; by function, the same study "classified 630 (85.6%) devices as Analysis" and "83 (11.3%) as Generation," the remainder performing both (nature.com).

Market-level figures place this regulatory activity in commercial context. Grand View Research estimates the global AI-enabled medical devices market "was valued at USD 13.7 billion in 2024," or roughly $13.7 billion, and is "projected to grow" at "a CAGR of 38.5% from 2025 to 2033" (grandviewresearch.com); readers should note this is a market-research forecast, not a regulatory statistic, and Grand View Research's page carried no visible last-updated date at the time of access.

Case Studies and Real-World Examples

The following examples are drawn directly from FDA's own decision letters and classification orders, chosen to illustrate selected regulatory decision records in practice. *Table 3* summarizes the four devices before the detailed narrative below.

Device	Company	Pathway	Authorization date	Regulation / product code	PCCP present
IDx-DR	Digital Diagnostics (IDx, LLC)	De Novo (DEN180001)	April 11, 2018	21 CFR 886.1100, Class II, product code PIB	No
Arterys Cardio DL	Arterys	510(k) (K163253)	January 5, 2017	21 CFR 892.2050, Class II, product code LLZ	No
Viz.ai ContaCT	Viz.ai	De Novo (DEN170073)	February 13, 2018	21 CFR 892.2080, Class II	No
Cardiac Guidance (successor to Caption Guidance)	Caption Health	510(k) (K243065)	January 15, 2025	Same regulation as DEN190040, Class II, product code QJU	Yes

These four devices are not a random sample; they were selected specifically because each has a fully documented, publicly retrievable FDA decision record illustrating a different route (or, for Cardiac Guidance, a PCCP layered onto a 510(k)). They should not be read as representative of typical review timelines or evidence volume across the full 1,614-entry list discussed elsewhere in this report.

IDx-DR (De Novo, DEN180001). FDA's De Novo summary describes IDx-DR as software that processes fundus images and returns information on image quality and the presence or absence of mtmDR; it also describes the device's clinical-study population and use limitations (accessdata.fda.gov).

Arterys Cardio DL (510(k), K163253). FDA's clearance letter, dated January 5, 2017, confirms the agency "reviewed" the sponsor's "Section 510(k) premarket notification of intent to market the device" (accessdata.fda.gov), a cloud-based deep-learning tool that "analyzes the blood flow to the heart and its major vessels using multi-slice" cardiac MRI data (accessdata.fda.gov), classified under the existing picture-archiving-and-communications-system regulation as a Class II device.

Viz.ai ContaCT (De Novo, DEN170073). Authorized under a newly created regulation, "**Regulation Number: 21 CFR 892.2080 Regulation Name: Radiological Computer Aided Triage and Notification Software**" (accessdata.fda.gov), ContaCT "uses an artificial intelligence algorithm to analyze images for findings suggestive of

a pre-specified" large-vessel-occlusion stroke pattern on CT angiograms and notifies a specialist in parallel with, not in place of, the standard radiology read (accessdata.fda.gov).

Caption Guidance and Cardiac Guidance (De Novo followed by a 510(k) with PCCP). Caption Guidance (DEN190040), authorized February 7, 2020, was "intended to assist medical professionals in the acquisition of cardiac ultrasound images" without specialized sonography training (accessdata.fda.gov). Its successor product, Cardiac Guidance (K243065), was cleared via 510(k) on January 15, 2025, and its clearance letter states explicitly that the "substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan" (accessdata.fda.gov), making it a documented, named example of a PCCP operating inside a 510(k) rather than only in guidance-document theory.

Together, these examples include De Novo and 510(k) decisions, with Cardiac Guidance illustrating a PCCP reviewed as part of a 510(k) submission.

Implications and Future Directions

FDA's next frontier is **generative AI**. In August 2026, the agency's Digital Health Center of Excellence opened a discussion-paper process titled "Considerations for the Regulation of Generative AI-Enabled Medical Devices", explicitly stating that "this paper is not intended to propose or implement policy changes regarding how CDRH intends to regulate" the category, but is meant to gather stakeholder input first. That caution reflects where the technology currently stands: the CRS brief notes that, as of its writing, "the agency does not appear to have authorized for marketing any generative AI" device, even as adjacent applications multiply (congress.gov). Reporting on the discussion paper found FDA weighing an approach that would "enable a nimble regulatory approach that employs least burdensome principles" (axios.com), with Acting Commissioner Kyle Diamantas framing the effort around the idea that "the United States must lead in shaping how this technology is developed" (axios.com). Under consideration is "greater reliance on postmarket monitoring" in place of some premarket certainty (axios.com), alongside evaluation methods that would benchmark generative outputs "compared to that of a panel of qualified clinicians whose consensus reflects" expert judgment rather than a fixed technical threshold (axios.com).

FDA's caution is informed by its own internal experience deploying generative AI. On June 2, 2025, FDA launched Elsa, a generative-AI tool for employees; FDA says it can summarize adverse events and that its models do not train on data submitted by regulated industry (fda.gov). Advisory-committee materials on generative AI more broadly flagged that such systems "produce contextually appropriate outputs that may not have been explicitly seen" in training data (fiercehealthcare.com), even as the committee acknowledged "the novel capabilities of GenAI may offer unique benefits to patients" (fiercehealthcare.com). Separate reporting on FDA's regulatory-science position noted that, as of that reporting, "the FDA is yet to authorize an LLM" as a medical device (mobihealthnews.com), and that even documentation-support tools "can hallucinate or include diagnoses not discussed in the visit" (mobihealthnews.com), a concern FDA has said may mean "the scale of effort needed could be beyond any current regulatory scheme" built for conventional software (mobihealthnews.com).

International harmonization will likely shape how quickly any generative-AI framework matures. The UK's MHRA has committed to "strengthen international convergence and consensus on software and AI products" through IMDRF (gov.uk), stating it intends to "drive forward international consensus in this area" specifically to reduce the regulatory burden of divergent national approaches (gov.uk). Health Canada's own machine-learning device

guidance "provides a mechanism for Health Canada to address cases where the regulatory" status of a device could otherwise change with every model update, mirroring FDA's PCCP concept (canada.ca), and confirms that "Health Canada has adopted the MLMD terms and definitions used by" IMDRF, reinforcing the shared technical vocabulary this report has used throughout (canada.ca). IMDRF's own 2022 terminology work aims to "promote consistency, support global harmonization efforts" across these parallel national tracks (imdrf.org), and its 2025 update to Good Machine Learning Practice emphasizes that "strong partnerships with our international public health partners" remain central to keeping pace with generative and foundation-model technology specifically (imdrf.org).

Frequently Asked Questions (FAQs)

What is the FDA 510(k) pathway for an AI medical device?

It is a premarket notification demonstrating the device is substantially equivalent to a legally marketed predicate device with the same intended use and technological characteristics, or characteristics that do not raise new safety questions; it is the route taken by 96.2 percent of devices on FDA's current AI-enabled device list.

What is the FDA De Novo pathway for AI software as a medical device?

It is the route for a novel, typically lower-to-moderate-risk device that has no existing predicate, used either directly or after a "not substantially equivalent" 510(k) finding; De Novo-authorized devices become predicates for later 510(k) submissions.

How does the PMA pathway apply to AI devices?

PMA applies to Class III, high-risk AI-enabled devices where general and special controls are not sufficient to assure safety and effectiveness, and requires full clinical investigation data and, often, advisory-panel review; it is the rarest route, covering only 1.3 percent of FDA's current AI device list.

What is a Predetermined Change Control Plan for AI SaMD?

A PCCP describes planned device modifications, associated methodology, and an impact assessment; FDA reviews it as part of a marketing submission, and the guidance describes when implementation of modifications described in the PCCP need not require additional marketing submissions (fda.gov).

What clinical evidence does FDA require for AI-enabled medical devices?

Requirements scale with risk and pathway. FDA's January 2025 lifecycle guidance is a draft that is not for implementation and contains nonbinding recommendations for the contents of marketing submissions involving AI-enabled device software functions (fda.gov).

How many AI-enabled medical devices has FDA authorized?

Counts vary by snapshot date and methodology: a CRS brief cites approximately 1,450, a peer-reviewed taxonomy of 1995 to 2024 authorizations found 1,016 authorizations covering 736 unique devices, a JAMA Network Open study found 903 devices through August 2024, a PLOS Digital Health study found 1,357 through December 2025,

and this report's own tabulation of FDA's list found 1,614 entries as of September 5, 2026.

Conclusion

FDA regulates AI-enabled medical devices through its established premarket pathways; FDA's August 2025 PCCP guidance describes how it reviews PCCPs as part of a marketing submission for an AI-enabled device (fda.gov). The overwhelming majority of currently authorized devices, on the order of 96 percent by this report's own tabulation, have entered through 510(k) clearance rather than the more evidence-intensive De Novo or PMA routes, and the category remains heavily concentrated in radiology and image-based analysis. As FDA now turns to the harder question of generative and foundation-model devices, largely unauthorized as of this report's publication date, the agency's own discussion-paper process signals that the framework described here, built for pattern-recognition and triage software, will likely need further adaptation before it can accommodate that next category of technology. Readers tracking the underlying dataset over time can consult FDA's own periodically updated list directly, alongside the historical trend analysis published separately by IntuitionLabs.
