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Research Article

Keywords: Artificial intelligence; medical devices; regulatory science; cross-sectional study; clinical evaluation

Posted Date: November 10th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11655299/v1

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Additional Declarations: The authors declare no competing interests.

What Has Artificial Intelligence Brought to Clinical Practice? A Cross-Sectional Analysis of FDA-Authorised Devices, 2021–2026

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Abstract

Background Artificial intelligence (AI) is entering defined diagnostic and decision-support tasks. The regulatory authorisation record can show the pace and distribution of this development, while selected clinical studies help explain what individual applications contribute to care.

Methods We conducted a cross-sectional study of the official Food and Drug Administration (FDA) artificial intelligence-enabled device list, accessed on 6 November 2026. Unique submission identifiers were grouped by final decision year, lead panel and regulatory pathway. The primary period was 2021–2025; 2026 decisions through 29 June were reported separately.

Results . The primary cohort contained 1,087 records: 129 in 2021, 162 in 2022, 226 in 2023, 235 in 2024 and 335 in 2025, a 159.7% increase. Radiology accounted for 863 records (79.4%), cardiovascular devices for 91 (8.4%) and neurology for 50 (4.6%). The 510(k)-pathway accounted for 1,055 records (97.1%), De Novo for 24 (2.2%) and premarket approval for eight (0.7%). A further 181 records had partial-year 2026 decisions.

Conclusions . The FDA record documents rapid growth in listed AI-enabled authorisations, concentrated in radiology but extending across multiple specialties. Clinical contributions are task-specific and include detection and diagnostic workflow support. Authorisation establishes a regulatory basis and sustained patient benefit require separate evidence.

Keywords . Artificial intelligence; medical devices; regulatory science; cross-sectional study; clinical evaluation

Introduction

Artificial intelligence (AI) is becoming part of the clinical tools used to interpret images, assess physiological signals and support decisions at the point of care.[1] Early consultation systems and computer-assisted imaging established its foundations, but the immediate clinical interest concerns the pace and scope of recent development.[2,3]

The recent expansion is visible in the regulatory record. In the official FDA list captured for this study, annual AI-enabled submission records increased from 129 in 2021 to 335 in 2025, a 159.7% rise across the five complete calendar years. This trajectory describes increasing listed authorisation activity; it does not quantify clinical uptake.[4]

Recent authorisations also illustrate the different ways AI can enter a consultation or procedure. In 2021, FDA authorised tools for real-time colonic lesion detection and assistance with identifying suspicious regions on prostate biopsy slides. By 2024, authorised applications included adjunctive assessment of suspicious skin lesions to support referral decisions and notification of possible low left ventricular ejection fraction.[4–8] These examples place AI within endoscopic video, digital pathology, optical lesion assessment and cardiac evaluation, with a defined clinical role for each device rather than a single general-purpose function.

For clinicians, the significance lies in the decisions these tools inform: where to direct attention, which tissue to review, whether a lesion needs referral, and when further cardiac assessment is needed. Selected studies report improved detection or reduced immunostain use, alongside trade-offs such as lower specificity.[9–11] Their clinical contribution must therefore be interpreted through the intended task, the study population and the consequences of errors.[12,13]

FDA oversight provides the framework for marketing authorisation and, where applicable, planned software changes.[14–18] We used that regulatory record to examine how the recent expansion of AI-enabled tools is distributed across medicine. This cross-sectional analysis describes unique FDA-listed submission records from 2021–2025, with a separate partial-year update for 2026, and places the findings alongside selected clinical evidence.

Methods

Design and source

We conducted a cross-sectional database study of the official FDA List of Artificial Intelligence-Enabled Medical Devices, accessed on November 2026. This list was the sole source of regulatory counts. The captured resource contained 1,614 unique submission identifiers, with the most recent listed decision dated 29 June 2026. The primary analysis included final decisions from 1 January 2021 to 31 December 2025. Earlier records provided historical context, and 2026 records formed a separate partial-year update (Figure 1). Inclusion reflected identification in the FDA resource rather than an independent assessment of each product's AI architecture.[4]

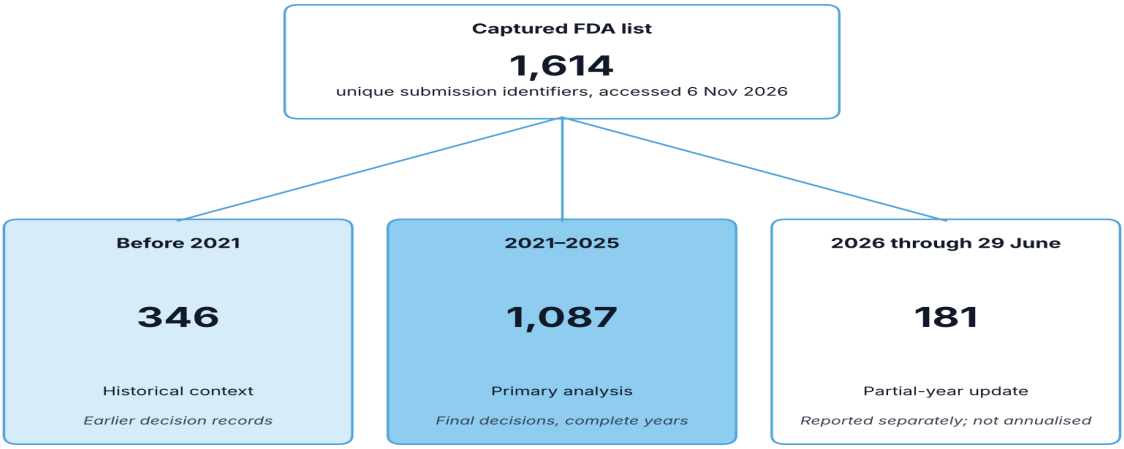


Figure 1. Study population by decision period.

Extraction and classification

We extracted the listed decision date, submission identifier, device name, company, lead panel and primary product code. Records were grouped by the year of final decision. The row-level dataset and source capture were retained. [4]

The counting unit was the unique regulatory submission identifier. Accordingly, the dataset does not identify a corresponding number of unique algorithms, products or hospital installations. Submission type was classified from the identifier: K for 510(k), DEN for De Novo and P for premarket approval; /S identified supplements. This was a descriptive classification rather than a full review of every underlying regulatory decision.[14–16]

Specialty distributions followed the FDA lead-panel designation. These assignments locate regulatory review and may differ from the clinical service using a device. The grouped category "other panels" was used only for display. Foundation-model and large-language-model functionality could not be classified reliably from the analysed fields; absence of such a label was not interpreted as absence of the technology.[4]

Analysis and contextual evidence

We described annual counts and proportions, using all 1,087 primary records for overall distributions and each year's records for annual shares. Relative growth was calculated as (2025 count − 2021 count)/2021 count × 100. Percentages were rounded to one decimal place. No inferential tests, forecasts or estimates of national adoption were performed.

Four device families were selected purposively to illustrate the clinical roles behind the regulatory record: colonic lesion detection, prostate pathology assistance, suspicious skin lesion assessment and low ejection fraction notification. Intended uses were checked against FDA summaries; published primary studies supplied the reported clinical endpoints. These examples contextualised the landscape and were not a systematic evidence review, representative sample or ranking. Study versions and clinical settings could differ from the particular United States authorisation.[5–11]

Ethics and data governance

This study analysed only public regulatory records and published aggregate study findings. No individual patient records were accessed and no human participants were involved. Institutional ethics review was therefore not required.

Results

Annual authorisation activity

The FDA capture contained 346 records with decisions before 2021, 1,087 during 2021–2025 and 181 during 2026 through 29 June (Figure 1). Complete-year counts were 129, 162, 226, 235 and 335, respectively. The increase from 2021 to 2025 was 206 records, or 159.7%, with a higher count in each successive year (Table 1; Figure 2).

Table 1. Annual submission records by regulatory pathway

Decision year	All records	510(k)	De Novo	Premarket approval
2021	129	122	6	1
2022	162	160	1	1
2023	226	219	6	1
2024	235	225	9	1
2025	335	329	2	4
2021–2025 subtotal	1087	1055	24	8
2026*	181	176	4	1

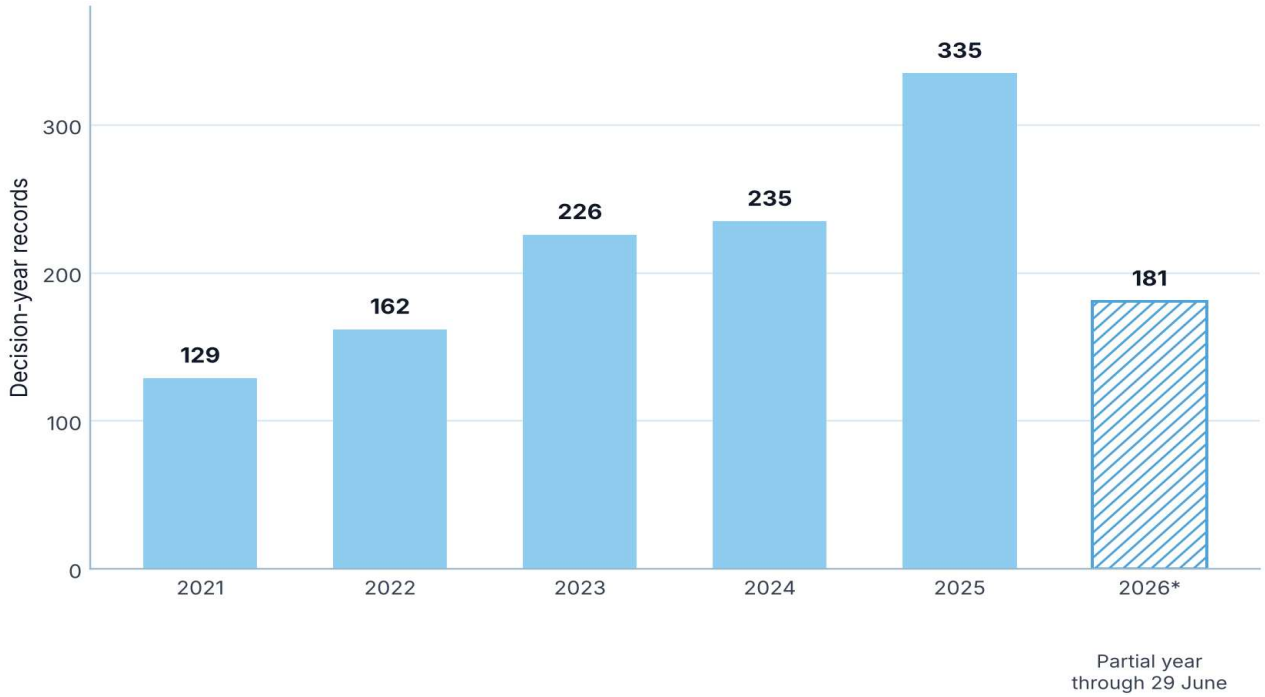
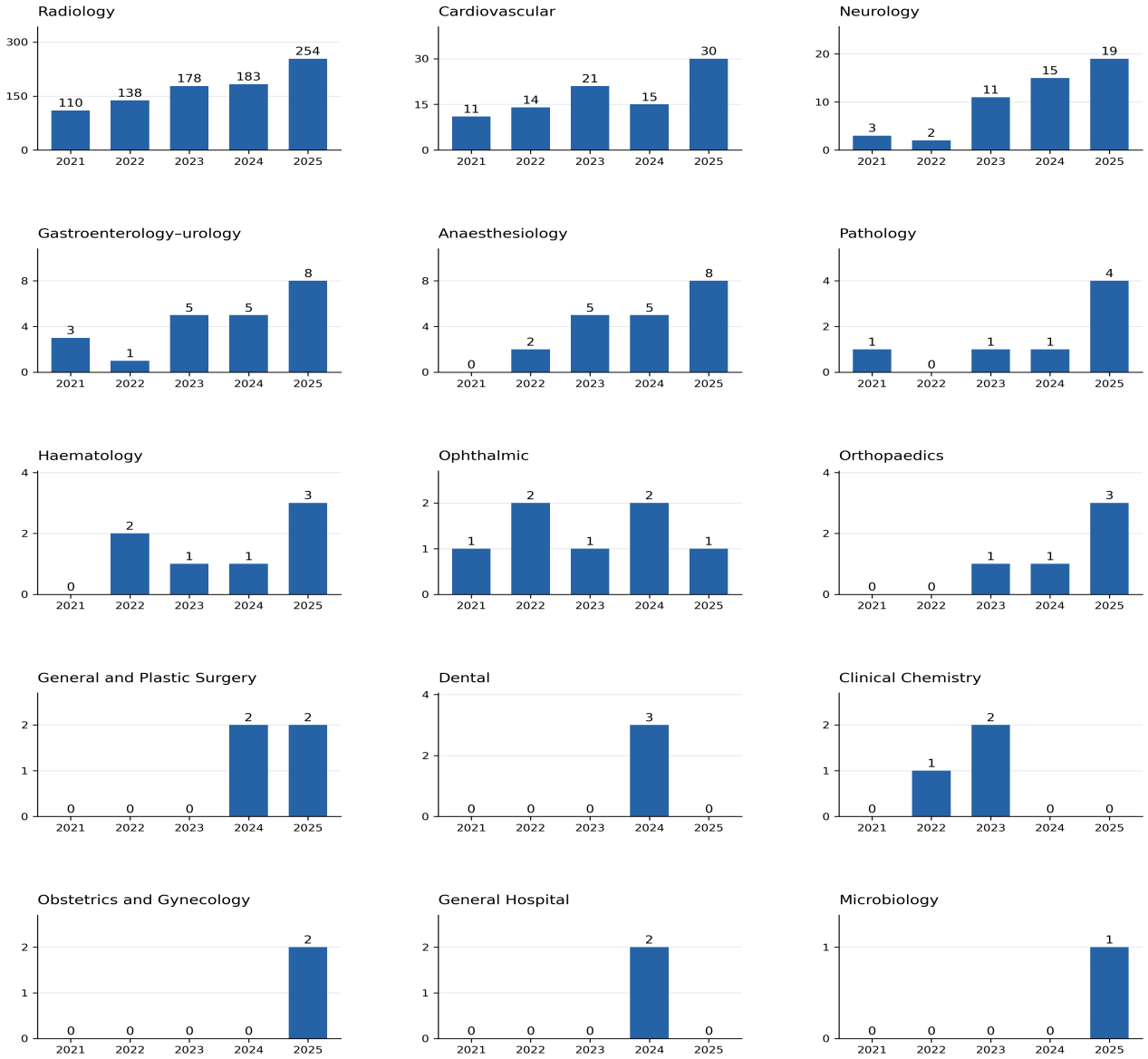


Figure 2. Annual authorisation records captured in the FDA list from 2021 to 2026.

Specialties represented in the FDA record

Radiology accounted for 863 of 1,087 records (79.4%), followed by cardiovascular devices (91; 8.4%), neurology (50; 4.6%), gastroenterology–urology group (22; 2.0%) and anaesthesiology (20; 1.8%). The remaining 41 records (3.8%) were distributed across ten panels. Radiology counts increased from 110 in 2021 to 254 in 2025, while its annual share fell from 85.3% to 75.8%. Cardiovascular counts increased from 11 to 30 and neurology counts from three to 19 (Figure 3).[4]

Fifteen FDA lead panels were represented. Among the smaller groups, pathology, haematology and ophthalmic devices each contributed seven records, orthopaedics five, obstetrics and gynaecology two and microbiology one.[4]



Each panel has its own vertical scale. Compare trends within panels, not bar heights between panels.

Source: FDA public AI-enabled device list, accessed 6 November 2026. Unique submission records; list not comprehensive.

Figure 3. Specialty trends in separate panels

Submission types and the partial update

Most primary-period records followed the 510(k) pathway: 1,055 (97.1%), compared with 24 De Novo records (2.2%) and eight premarket approval records (0.7%). The latter comprised four original approvals and four separately listed supplements. The 510(k) pathway predominated in every complete year (Table 1; Figure 4). The partial 2026 update contained 176 510(k), four De Novo and one original premarket approval record. These are identifier-derived distributions within the FDA list.[4]

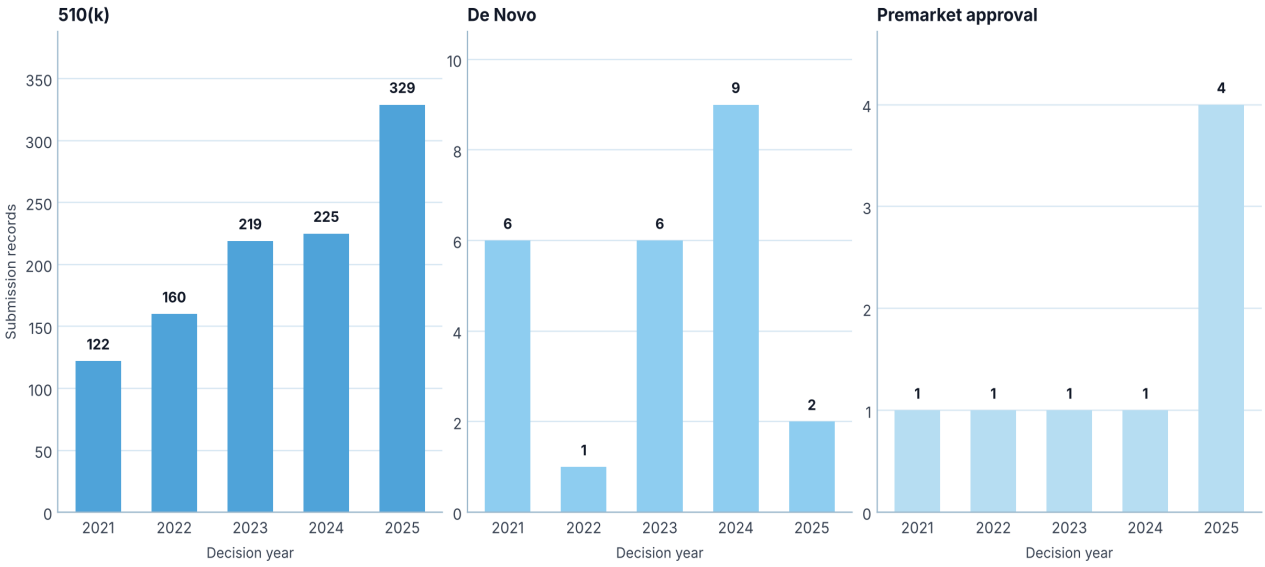


Figure 4. Submission types by decision year

Clinical roles illustrated by selected authorised devices

The selected FDA summaries described real-time assistance with colonic lesion detection, adjunctive review of prostate biopsy images, assessment of already suspicious skin lesions to support referral, and notification of possible low ejection fraction. These examples locate AI within specific diagnostic decisions. They do not constitute a functional classification of all devices in the cohort.[5–8]

Outcomes not measured by the list

The list identified regulatory decisions and device families but did not provide hospital installation counts, examination volumes, clinician use or patient outcomes across the cohort. It also supplied no denominator of unsuccessful or pending applications. Adoption rates, rejection rates and a common percentage of clinical success were therefore not estimated. The separately selected clinical evidence is presented in Table 2 and Figure 6.

Discussion

Artificial intelligence is advancing across many fields, and medicine is among them. The marked expansion in listed AI-enabled authorisations over successive years, and the further records in the current year, provide promising signals of growing regulatory activity. Although these authorisations are concentrated in a few specialties, the best use of AI may also be possible in other specialties, which the list cannot establish. Authorisations on the FDA list rose in every complete year of this study, but a rising count is not evidence that clinical practice has changed. The findings below separate what the list shows from what it cannot. The main finding is a marked expansion in listed AI-enabled authorisations over five complete calendar years, concentrated in a few specialties. Annual records rose from 129 to 335, radiology contributed 79.4% of the primary cohort and 510(k) accounted for 97.1%. Together, these findings document a growing regulatory basis for bringing AI-enabled devices to market. The selected clinical examples explain what this can mean in practice: assistance with finding lesions, reviewing tissue, assessing suspicious skin lesions and identifying a possible cardiac abnormality. Their benefits must be assessed at the level of the clinical task.[4–11]

Where the expansion is concentrated

Radiology's 863 records identify imaging as the largest area of listed regulatory activity. Its count increased from 110 to 254 between 2021 and 2025 even as its share of annual decisions declined. Thus, the reduction in proportional dominance occurred alongside more radiology authorisations, rather than a contraction in the count. Cardiovascular and neurology records also increased across the period. These findings support a description of growth beyond the largest panel, but they do not establish which specialty obtained the greatest clinical benefit (Figure 3).[4]

The smaller groups are also clinically relevant. Gastroenterology–urology contributed 22 records, anaesthesiology 20 and pathology seven, while the skin assessment example was reviewed under the general and plastic surgery panel.[4] A low panel count can coexist with a clinically meaningful application, as the selected pathology study illustrates.[10] Conversely, a high count does not demonstrate widespread use or superior outcomes

What FDA authorisation makes available

FDA authorisation provides permission to market a device for its authorised intended use under the applicable pathway. The predominance of 510(k) in this cohort describes how listed products reached that stage; it does not show that one pathway produces better clinical outcomes than another. Clearance, De Novo classification and premarket approval involve different regulatory determinations (Figure 5).[14–16 17]

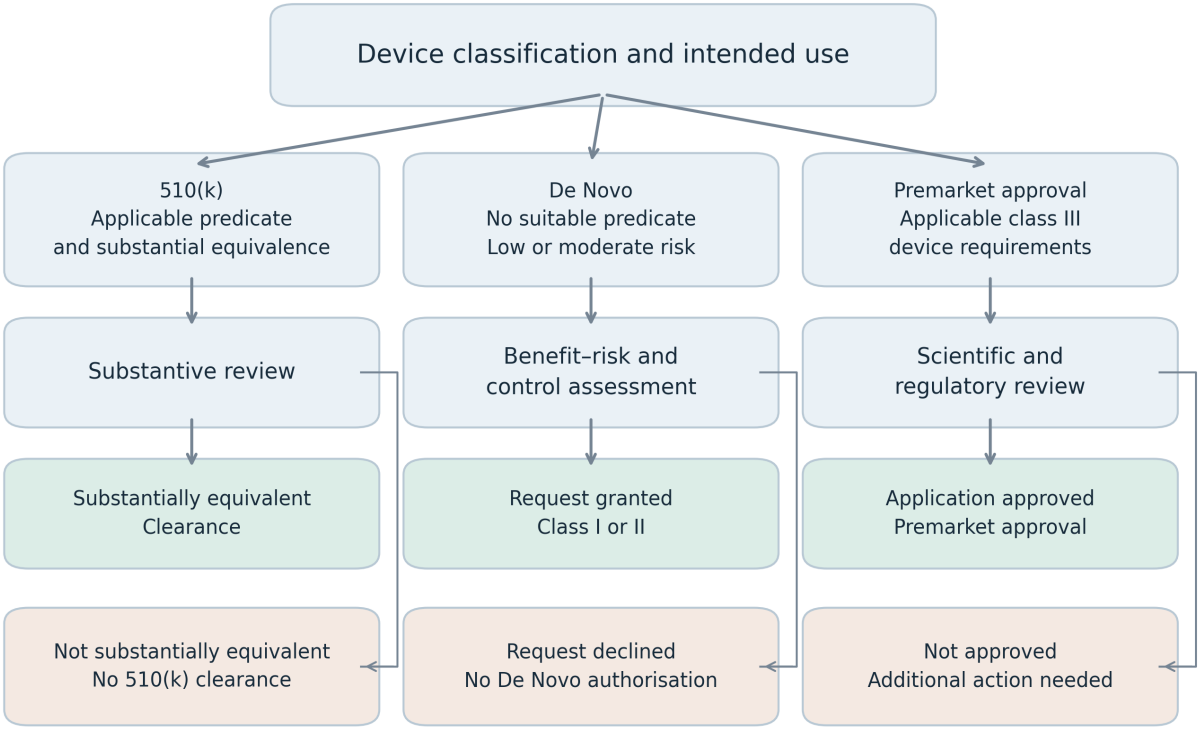


Figure 5. Overview of regulatory review pathways.

A further regulatory issue is how an authorised tool changes over time. The 2022 legislation provided for predetermined change control plans, and FDA's guidance describes prospective review of specified modifications and their validation. A manufacturer may implement covered changes consistently with an authorised plan without a separate marketing submission for each change. This makes the authorised version, permitted modifications and performance in use important to clinical interpretation. It does not establish that any particular update improves care.[18]

From market availability to clinical use

The earlier experience with commercial mammography assistance illustrates why marketing and implementation require separate assessment. Fenton and colleagues associated use of an earlier computer-aided detection system with lower specificity and more biopsies, without a significant increase in cancer detection. This observational finding should not be generalised to all contemporary AI, but it shows why regulatory availability alone cannot substitute for evaluation in practice.[19]

The present FDA counts cannot measure the subsequent extent of use. Multiple authorisations can belong to the same product family, and neither the eligible population nor the number of installations is recorded. The selected prostate pathology implementation study demonstrates use in a defined service; it is not evidence of national uptake.[10] The authorisation trajectory should therefore be read as a measure of listed regulatory activity, with adoption and clinical outcomes considered separately.

What medicine gains in the selected clinical settings

The clinical examples show benefits that a clinician can recognise, while also defining the limits of those benefits. They were selected to illustrate different uses, not to estimate the proportion of effective devices in the cohort (Table 2; Figure 6).[5–11]

In the randomised colonoscopy trial, adenoma detection was 54.8% with assistance and 40.4% with control examination. The demonstrated contribution was improved detection during the procedure; the trial did not establish a mortality benefit. This is evidence for a defined endoscopic task rather than for every gastroenterology device.[9]

In the prospective prostate pathology study, AI-assisted review reduced immunostain use per detected cancer at the patient level (relative risk 0.55; 95% confidence interval 0.39–0.72). Assessment time was not significantly reduced. The finding therefore supports a contribution to a diagnostic workflow, with the pathologist retaining diagnostic responsibility, rather than a general claim that AI makes pathology faster.[6,10]

In the skin lesion reader study, diagnostic sensitivity increased from 71.1% to 81.7%, while referral specificity fell from 44.2% to 32.4%. The improvement in detecting malignancy was accompanied by a trade-off in referral decisions. Because these were reader-study endpoints, the result should not be presented as a demonstrated reduction in missed cancers or specialist waiting times in routine practice.[11]

The FDA low ejection fraction summary reported sensitivity of 74.7% and specificity of 77.5% for its notification function. This supports interpretation as a prompt for further assessment within the authorised use; it does not establish improved treatment or patient outcomes. It illustrates a clinical role for AI-enabled signal assessment beyond image interpretation, with performance that remains specific to the task and validation population.[8]

Table 2. Clinical evidence for selected authorised device families

Clinical task and regulatory link	Study design and population	Reported endpoint	Interpretation and limitation
Colonoscopy lesion detection GI Genius DEN200055[5]	Randomised trial 685 participants Italy[9]	Adenoma detection rate 54.8% assisted vs 40.4% control	Detection endpoint; no mortality benefit established by this trial.
Prostate biopsy assistance Paige Prostate family DEN200080[6]	Prospective implementation 82 patients Biweekly allocation[10]	Immunostain use per detected cancer Patient-level relative risk 0.55 95% CI 0.39–0.72	Small study; no significant assessment-time reduction. Pathologist retains diagnostic responsibility.
Suspicious skin lesion assessment DermaSensor DEN230008[7]	Reader study 108 primary-care physicians 100 lesion cases[11]	Diagnostic sensitivity 71.1% unaided vs 81.7% assisted Referral specificity 44.2% vs 32.4%	Sensitivity and referral specificity are different endpoints. Adjunct for suspicious lesions in adults aged ≥40; not population screening.
Low ejection fraction notification Eko tool K233409[8]	FDA validation summary 3,456 subjects; 307 records excluded for poor signal[8]	Sensitivity 74.7% 95% CI 69.4–79.6 Specificity 77.5% 95% CI 75.9–79.0	Positive predictive value 25.7%. Notification prompts further assessment; does not replace echocardiography or confirm heart failure.

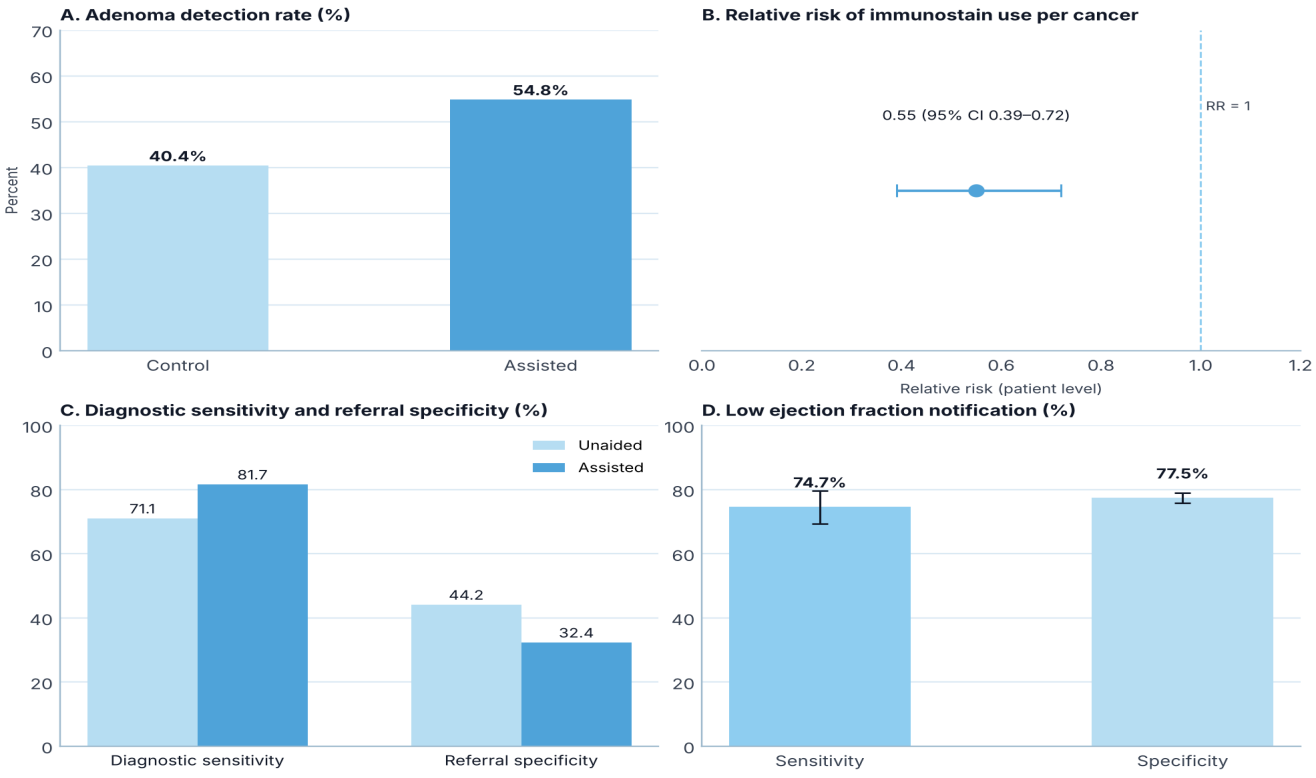


Figure 6. Selected clinical endpoints for authorized device families.

A useful clinical contribution differs by specialty. In endoscopy it may be an additional detected lesion; in pathology, less use of immunostaining; in primary care, information that influences referral or further assessment. The relevant benefit is the change in the patient's care or the diagnostic workflow, considered alongside errors and additional investigations. The reported endpoints support specific applications, but they cannot be pooled into a single AI success percentage or extrapolated to every FDA-listed record.[5–11]

Where the gaps remain

Two gaps are visible from this analysis. The first is uneven representation: radiology dominates the list, while several panels contribute only a small number of records. Sparse listing does not establish absence of useful tools, and the combined gastroenterology–urology designation cannot be treated as an organ-specific measure of availability. The second is a gap between the information recorded by the regulator and the information needed to judge clinical value. The dataset does not measure utilisation, comparative patient outcomes or sustained performance for all listed devices. Even a well-represented specialty therefore cannot be ranked as the most clinically successful on the basis of authorisation counts.[4]

A further information gap concerns newer model types. The FDA list states that methods to identify and tag foundation-model functionality are being explored. The fields used here do not support a reliable count of generative AI or large-language-model devices. Their absence from a label cannot be used to claim that they are absent from clinical medicine, and the present findings cannot establish their clinical contribution.[4]

The next step is to connect each intended use and software version to evidence from the setting in which it is used. The selected examples suggest relevant questions: does assistance increase meaningful detection, reduce unnecessary diagnostic work, or improve the decision to investigate or refer? Evaluation also needs to consider false positives, missed cases and the performance of the clinician–device combination. Quality management and cybersecurity remain part of this assessment. [20,21]

Limitations

The FDA resource is non-comprehensive and identifies devices partly through terminology in public summaries or classification. Later additions can change historical annual counts.[4]

Submission identifiers do not resolve unique algorithms, product families or versions. Lead panels do not provide a detailed classification of clinical applications, and pathway identifiers do not replace review of individual regulatory documents. Foundation-model and large-language-model functionality could not be classified reliably, so no conclusion about their presence or absence across the cohort was drawn.[4]

The four clinical examples were purposively selected, and their findings are not representative of all 1,087 primary records. No systematic search, formal risk-of-bias assessment or meta-analysis was undertaken. Studies may concern international practice or configurations that differ from the authorised United States version. Computational reconciliation reduced transcription risk but did not replace independent human extraction. The cross-sectional design describes regulatory patterns and cannot establish the causes of growth, national adoption or cohort-wide clinical effectiveness.

Conclusion

The FDA-authorised device record spans multiple medical specialties, with listed activity rising from 129 records in 2021 to 335 in 2025 and remaining concentrated in radiology. Selected clinical evidence shows what some applications can contribute: improved lesion detection, reduced immunostain use and support for further assessment, with diagnostic trade-offs. The regulatory expansion is established; its clinical value must be judged through the intended use, the evidence for that task and the experience of patients and clinicians in practice.

Declarations

Data availability: The analysis dataset, source capture, aggregate counts and figure-building code accompany this manuscript.

Ethics No individual patient data were accessed, and no human participants were involved; the study used only public regulatory records and published aggregate data.

Artificial intelligence assistance. Generative artificial intelligence was used to assist source retrieval, drafting, coding and figure preparation.

Author contributions: Malik Muhammad Makki contributed to conceptualisation, methodology, data curation, formal analysis, writing (original draft), supervision and project administration. Samia Yunas contributed to data curation, validation, and writing (review and editing). Both authors reviewed and approved the final manuscript.

Funding: No funding was received for this study.

Conflicts of interest: The authors declare no conflicts of interest.

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