FDA-approved Artificial Intelligence and Machine Learning-enabled medical devices: An updated landscape from 1995 to 2023

Ray P, Gupta P, Dubey A, Kumar J, Shaikh J, Koumas A

INTRODUCTION

- Recent advancements in artificial intelligence (AI) and machine learning (ML) have revolutionized the landscape of medical devices, leading to a surge in U.S. Food and Drug Administration (USFDA) approved AI/ML-enabled technologies.[1]
- Rising adaptation of AI/ML-enabled medical devices is driven by their demonstrated ability to improve diagnostic accuracy, treatment efficiency, and patient outcomes, supported by advancements in technology, regulatory aid, and growing patient acceptance.[1,2]
- USFDA provides an updated list of AI/ML-enabled medical devices marketed in the U.S. as a resource to the public. [3]
- Understanding the dynamic evolutionary pattern, regulatory landscape, and data gaps in AI/ML-enabled medical device approvals is crucial for decision-making among healthcare professionals, regulatory bodies, and industry stakeholders.[1,2]

OBJECTIVES

- To comprehensively analyze the landscape of USFDA-approved AI/ML-enabled medical devices
- To offer insights into the patterns and trends of their evolution, data gaps in regulatory approval, and practical applicability within healthcare settings by tracing the timeline from early approvals in 1995 to recent breakthroughs in 2023.

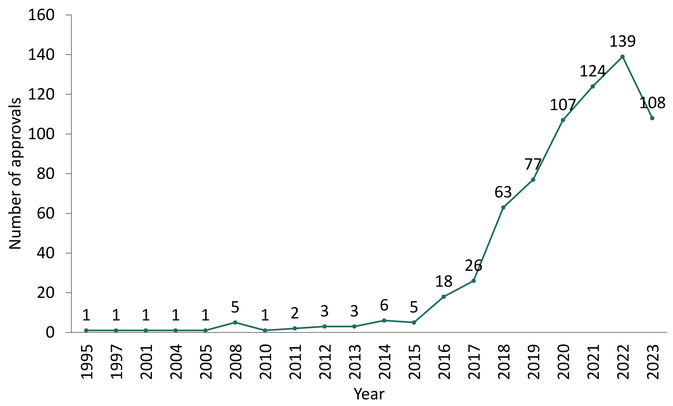
METHODS

- All AI/ML-enabled medical devices approved by the USFDA from 1995 to July 2023 were extracted using the summary data from the USFDA electronic database.
- The list of devices was compiled based on their date of approval, indication type, approval type, device class, intended use, type of algorithm, and employed mobile application.
- Descriptive statistics were used to analyze the data.

RESULTS

- A total of 692 AI/ML-enabled medical devices were approved by 27 July 2023. Approvals notably surged from 2015 (n=5) to 2023 (n=108), with the highest number recorded in 2022 (n=139) **(Figure 1)**.

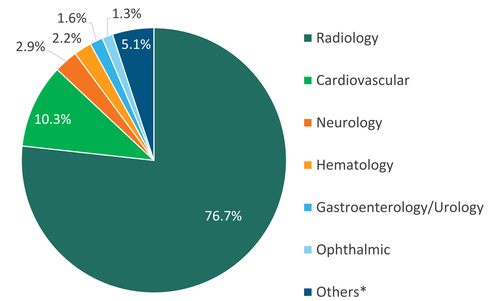
Figure 1. Number of AI-ML enabled devices approved from 1995 – 2023



RESULTS (CONTD.)

- The highest percentage of medical devices were applied in **radiology** (76.7%), followed by **cardiovascular** (10.3%) and **neurology** (2.9%) indications **(Figure 2).**

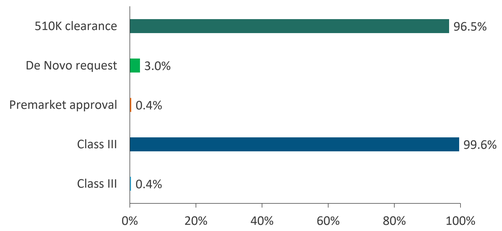
Figure 2. Indications for types of devices approved



**Others include anesthesiology, clinical chemistry, general and plastic surgery, microbiology, pathology, general hospital, ear, nose and throat, dental, immunology, obstetrics and gynecology, and orthopedic.*

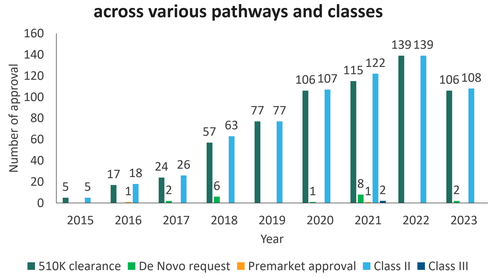
- Most of the devices were approved under the 510(k) premarket notification pathway (96.5%), followed by DEN request (3.0%) and PMA (0.4%) **(Figure 3a).**

Figure 3a. Medical devices approved through various regulatory pathways and regulatory classes (1995 – 2023)



- From 2015 – 2023, almost all the devices (99.6%) were classified as Class II medical devices and Class III (0.4%) **(Figure 3b)**, suggesting stricter regulations and greater testing required to seek USFDA approval since these devices posed moderate potential harm to the patients.

Figure 3b. Trend in approvals of devices from 2015 to 2023 across various pathways and classes



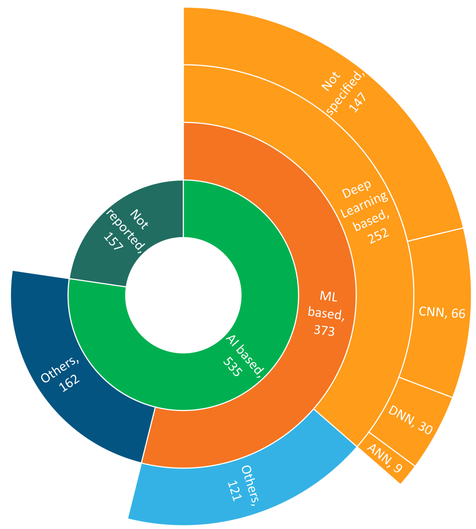
- The majority of devices (97.8%) were prescription devices requiring physician supervision, while 1.0% were over-the-counter (OTC), and 0.4% were for both prescription and OTC use **(Table 1).**
- The devices were commonly applied for image reconstruction (63.7%) or to provide diagnostic assistance (48.1%) to the intended users **(Table 1).**

Table 1. AI/ML-Enabled Device Usage Across Indications

Indication	Image Reconstruction	Diagnostic assistance	Prescription use	Over-the-counter use
Radiology	57.1%	36.3%	76.4%	-
Cardiovascular	1.3%	5.1%	9.4%	0.6%
Neurology	0.4%	1.3%	2.9%	-
Hematology	1.6%	1.7%	1.9%	0.1%
Gastroenterology /Urology	0.6%	0.3%	1.6%	-
Ophthalmic	0.9%	1.2%	1.3%	-
Others	1.9%	2.2%	4.3%	0.3%
Total	63.7%	48.1%	97.8%	1.0%

- The primary algorithm employed for these devices was **deep learning (36.4%)**, of which the **convolutional neural network** was most used **(26.2%) (Figure 5).**

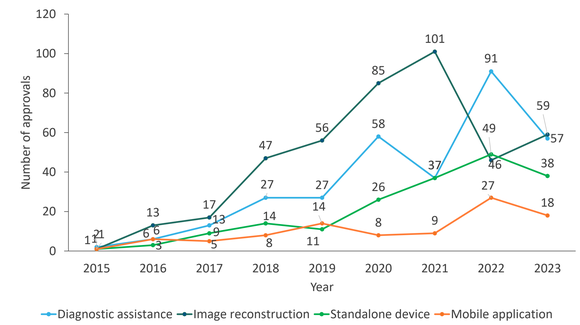
Figure 5. Algorithm utilized in various AI-ML-enabled devices



RESULTS (CONTD.)

- Number of approvals varied across different applications from 2015 to 2023 **(Figure 4).** Out of 692 devices, only 14% of medical devices were equipped with mobile applications.

Figure 4: Trends in applications of AI-ML-enabled devices from 2015 to 2023



- Siemens Medical Solutions USA (n=36), Canon Medical Systems Corporation (n=22), and Aidoc Medical, Ltd. (n=19) had the highest number of approvals for AI/ML-enabled medical devices **(Table 2).**

Table 2. Top 10 companies building AI/ML- enabled devices

Company	Number of devices approved
Siemens Medical Solutions USA, Inc.	36
Canon Medical Systems Corporation	22
Aidoc Medical, Ltd.	19
GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC	16
GE Medical Systems, LLC	15
Shanghai United Imaging Healthcare Co., Ltd.	12
Zebra Medical Vision Ltd.	9
GE Medical Systems SCS	9
Viz.AI, Inc.	9
Quantib B.V.	8

CONCLUSIONS

- Our research showed a notable increase in FDA-approved AI/ML-enabled medical devices from 2015 to 2023, showing the advancements in technology, regulatory support, and growing patient acceptance of such devices.
- In this study, we provide critical insights into technological progress, evolutionary dynamics, and the transformative impact of AI/ML in medical devices.
- Most of these devices were employed in radiology and cardiovascular medicine, with predominant application in image reconstruction.
- Deep learning algorithms were commonly deployed in these devices due to their robust adaptability for advancing diagnostic capabilities.

DISCLOSURES

- All authors represented here are employees of Axtria.
- This study was funded in its entirety by Axtria Inc.

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