*electronics*

MDPI

*Article*

# FDA-Approved Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices: An Updated Landscape

**Geeta Joshi [1,2], Aditi Jain [3], Shalini Reddy Araveeti [4], Sabina Adhikari [5], Harshit Garg [1] and Mukund Bhandari [6,*]**

[1] Department of Urology, UTHealth San Antonio, San Antonio, TX 78229, USA; joshig@uthscsa.edu (G.J.); gargh@uthscsa.edu (H.G.)
[2] Department of Medical Education, UTHealth San Antonio, San Antonio, TX 78229, USA
[3] Department of Obstetrics and Gynecology, UTHealth San Antonio, San Antonio, TX 78229, USA
[4] New England College, Henniker, NH 03242, USA
[5] Department of Computer Science, Texas A&M University, College Station, TX 77843, USA; adhikaris3@tamu.edu
[6] Greehey Children Cancer Research Institute, UTHealth San Antonio, San Antonio, TX 78229, USA
* Correspondence: bhandarim@livemail.uthscsa.edu

**Abstract:** As artificial intelligence (AI) has been highly advancing in the last decade, machine learning (ML)-enabled medical devices are increasingly used in healthcare. In this study, we collected publicly available information on AI/ML-enabled medical devices approved by the FDA in the United States, as of the latest update on 19 October 2023. We performed comprehensive analysis of a total of 691 FDA-approved artificial intelligence and machine learning (AI/ML)-enabled medical devices and offer an in-depth analysis of clearance pathways, approval timeline, regulation type, medical specialty, decision type, recall history, etc. We found a significant surge in approvals since 2018, with clear dominance of the radiology specialty in the application of machine learning tools, attributed to the abundant data from routine clinical data. The study also reveals a reliance on the 510(k)-clearance pathway, emphasizing its basis on substantial equivalence and often bypassing the need for new clinical trials. Also, it notes an underrepresentation of pediatric-focused devices and trials, suggesting an opportunity for expansion in this demographic. Moreover, the geographical limitation of clinical trials, primarily within the United States, points to a need for more globally inclusive trials to encompass diverse patient demographics. This analysis not only maps the current landscape of AI/ML-enabled medical devices but also pinpoints trends, potential gaps, and areas for future exploration, clinical trial practices, and regulatory approaches. In conclusion, our analysis sheds light on the current state of FDA-approved AI/ML-enabled medical devices and prevailing trends, contributing to a wider comprehension.

**Keywords:** machine learning; artificial intelligence; FDA; medical devices; AI; ML; clinical trials; radiology



**Citation:** Joshi, G.; Jain, A.; Araveeti, S.R.; Adhikari, S.; Garg, H.; Bhandari, M. FDA-Approved Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices: An Updated Landscape. *Electronics* **2024**, *13*, 498. https://doi.org/10.3390/electronics13030498

Academic Editors: Hamido Fujita, Tun-Wen Pai and Andres Hernandez-Matamoros

Received: 15 December 2023
Revised: 11 January 2024
Accepted: 16 January 2024
Published: 24 January 2024



## 1. Introduction

The term "artificial intelligence" (AI) was first introduced by John McCarthy in 1956 during a seminal conference for a summer research project [1]. AI is characterized as the ability of a computer program to perform a wide array of tasks that typically require human intelligence. These tasks include, but are not limited to, reasoning and learning. With the widespread integration of AI applications, the field has evolved, encompassing several significant subsets as depicted in Supplementary Figure S1. However, it is critical to note that terminologies within this domain, specifically artificial intelligence, machine learning (ML), and deep learning (DL), have often been used interchangeably.

Machine learning, a subset of AI, involves systems that can assimilate knowledge from data over time and use this information to make predictions upon the introduction of new, unseen datasets. Another subset, deep learning (DL), employs sophisticated algorithms

known as neural networks, which are designed to mimic the neural structures of the human brain [2]. These algorithms are widely applied in numerous fields, including, but not limited to, speech recognition, computer vision, drug discovery, and genomics [3]. The efficacy and robustness of these models are substantially enhanced as they are exposed to more comprehensive, diverse, and heterogeneous data, enabling the models to achieve greater accuracy and reliability in their predictive capabilities [4].

Machine learning has garnered widespread utilization in medical research, primarily due to its ability to extract pertinent clinical insights from the voluminous data generated within the healthcare sector daily [5]. There has been a notable trend in integrating machine learning models into medical devices [6,7], reflecting the growing influence of computational technology in various aspects of healthcare and clinical diagnostics.

In the United States, adherence to regulatory standards is mandatory for the commercial operation of technologically advanced medical devices and tools. The Food and Drug Administration (FDA) regulates medical devices and approves their market entry majorly through one of three distinct regulatory pathways, De Novo (DEN) review [8] or Premarket Approval (PMA) [9] or Premarket Notification 510(k) clearance [10], each detailed in the following paragraphs and summarized in Supplementary Table S1.

A De Novo petition is a regulatory pathway provided by the U.S. Food and Drug Administration (FDA) for innovative medical apparatuses lacking a legally marketed predicate device [8]. This pathway is employed when general controls alone, or in conjunction with special controls, offer reasonable assurance of the device's safety and effectiveness, yet there is no existing product for comparison (substantial equivalence). The De Novo procedure permits these pioneering devices to be classified as either Class I or Class II, thereby facilitating their marketing and potential utilization as predicates in future 510(k) submissions. The petition must encompass comprehensive information about the device, including its intended purpose, description, and supportive data. Upon evaluation, the FDA may assign the device to an appropriate category based on its risk profile, thereby permitting its marketing if it satisfies the criteria of safety and effectiveness [8].

In short, Premarket Approval (PMA) is a strict regulatory process employed by the Food and Drug Administration (FDA) to assess the safety and efficacy of medical devices falling under the Class III category. These devices, which pose the highest level of risk, include those that are crucial for supporting or sustaining human life, as well as those that may potentially present an unreasonable risk of illness or injury [9]. In order to obtain PMA, the applicant, typically the owner or authorized entity, must submit a comprehensive application containing valid scientific evidence. This evidence encompasses non-clinical laboratory studies and clinical investigations, which are necessary to validate the safety and effectiveness of the device for its intended use. The guidelines for PMA are outlined in Title 21 Code of Federal Regulations Part 814. Failure to comply with these requirements results in the device being deemed adulterated and ineligible for marketing [9].

Premarket Notification 510(k) is a regulatory process required by the U.S. Food and Drug Administration (FDA) for Class I, II, and III medical devices that do not require Premarket Approval (PMA). The procedure entails the submission of a 510(k) to establish the device's safety and effectiveness on par with a legally marketed device (known as a predicate), thereby substantiating substantial equivalence [10]. This process is applicable to domestic manufacturers, specification developers, repackers, and relabelers, as well as foreign manufacturers or exporters introducing a device to the US market. A device is deemed substantially equivalent if it has the same intended use as the predicate and either possesses identical technological characteristics or, if dissimilar, does not give rise to new concerns regarding safety and effectiveness. Prior to commercial distribution in the US, the FDA's authorization, denoted by an order attesting to the device's substantial equivalence, is obligatory [10].

In recent years, certain medical software has been classified as medical devices, termed "software as a medical device" (SaMD). SaMD pertains to software that is utilized independently for medical purposes, distinct from hardware medical devices [11]. The increasing

utilization of SaMD across various technology platforms within the broader spectrum of medical device software has garnered global regulatory attention. The International Medical Device Regulators Forum (IMDRF), in collaboration with the FDA as a key participant, has developed a standardized framework for SaMD. This framework encompasses the standardization of definitions, risk categorization, quality management, and clinical evaluation, with the objective of striking a balance between innovation and patient safety in the rapidly evolving domain of medical software. In essence, SaMD can be characterized as software that employs an algorithm (a system of logic, a collection of regulations, or a blueprint) that functions on data input (digitized information) such as lab results, images, symptoms, etc. to generate an outcome that is intended for medical applications to inform, drive, diagnose, treat, etc., as specified by the SaMD producer [12].

Furthermore, there has been a notable increase in the emphasis placed on medical devices that integrate artificial intelligence and machine learning, especially in light of the recent emergence of large language models (LLMs) such as Generative Pre-trained Transformers (GPT), Llama, and others [13]. Nevertheless, up until 19 October 2023, no medical devices that utilize generative artificial intelligence or large language models have been granted official authorization by the FDA [7].

The rigorous approval process ensures that any machine-learning-augmented medical device adheres to safety and efficacy standards before its clinical use, thereby safeguarding public health while facilitating medical advancements [14].

In this article, we overview and discuss the most recent and current landscape of AI/ML-enabled medical devices approved by the FDA in the United States, reflecting developments up to the latest update on 19 October 2023, which included the addition of 171 new medical devices. In the following sections, we first discuss the data collection method with inclusion and exclusion criteria, followed by Section 3. The results are organized into subsections with separate themes, followed by a discussion and conclusion.

## 2. Materials and Methods

We compiled a list of FDA-approved AI/ML-enabled devices across medical disciplines and assembled corresponding information for each device using the FDA's publicly available data, as well as information provided by the specific manufacturers in their public notifications.

The inclusion criteria for AI/ML-based medical devices in our research encompass the devices listed on the FDA's webpage in its most recent update on 19 October 2023. Once the inclusion criteria were established, we used the unique submission number of each device and manually extracted all the important features of the AI/ML-enabled medical devices. These features include the date of approval, the number of days taken to obtain clearance, clearance type (approval path), regulation panel, decision type, the name of the manufacturing company that filed for clearance, the country where the manufacturing company is based, device name, device medical specialty, device type, and recall history as shown in Figure 1.

Additionally, wherever available, we also gathered clinical trial information such as study type, sampling method, age group of subjects, criteria for inclusion, the number of clinical trial locations, and the names of the countries where the clinical trials were conducted.

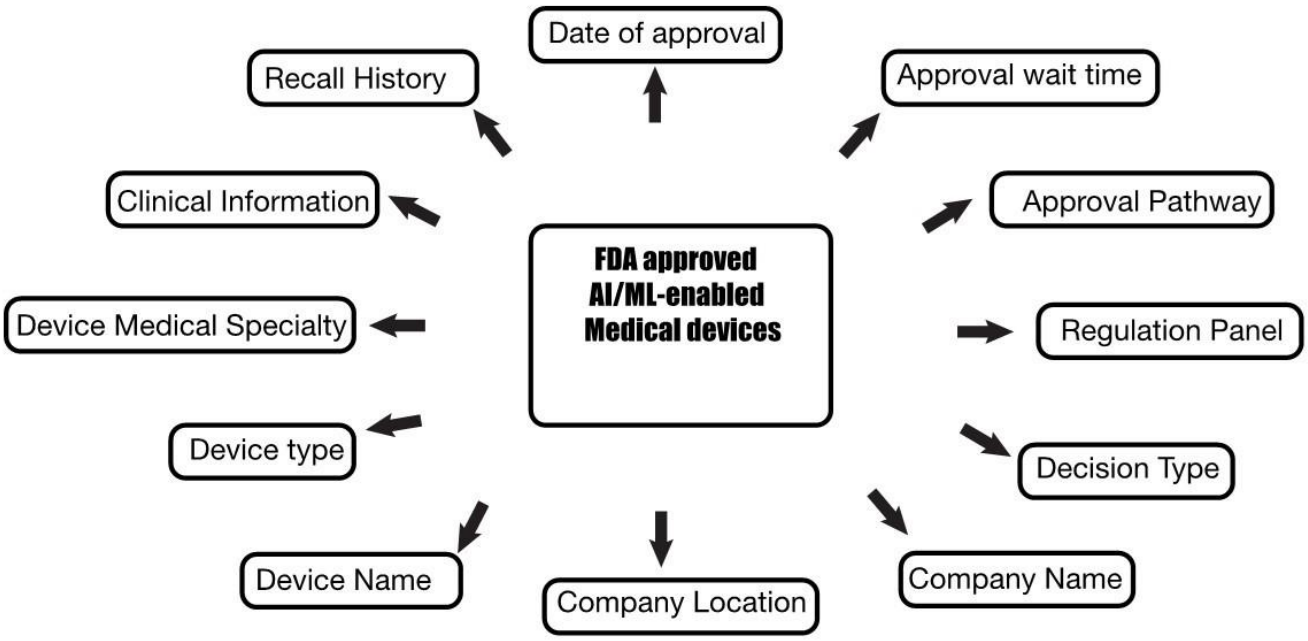



**Figure 1.** Schematic representation of the medical device features collected for FDA-approved AI/ML-Enabled Medical Devices, https://www.fda.gov/, accessed on 14 December 2023.

The list of AI/ML-enabled devices provided by the FDA is not exhaustive and comprehensive in its entirety because it does not include other AI/ML-based medical devices that have not yet been approved by the FDA or medical devices that are not categorized as AI/ML-based. Furthermore, AI/ML-enabled devices that are accredited, certified, or approved by other regulatory agencies inside or outside the USA are beyond the scope of this paper. Also, to date, there is no publicly available information on the number of AI/ML-enabled medical devices that have failed to obtain FDA approval. The FDA webpage states that most of the summaries available on the site are abridged for public access, provided by the application submitters, and may not necessarily contain comprehensive information. Additionally, there has been a surge in the interest in AI/ML-integrated medical devices, particularly following the recent rise of large language models (LLMs) like ChatGPT, Llama, etc. However, as of 19 October 2023, no medical devices employing generative AI, AGI, or LLMs have received authorization.

Data mining, visualization, and statistical analysis were performed using different R packages using R version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria) and RStudio.

## 3. Results

### *3.1. Overall Trends*

As of the latest update on 19 October 2023, the FDA has listed 691 approved AI/ML-enabled medical devices, out of which 108 (about 15%) were approved in the year 2023 (Figure 2). The trend in the number of approvals per year began to gain significant attention in 2016, and there has been an increase in the number of approved devices each year since then. Based on the current data, the highest number of approvals in a year so far was 139 AI/ML-enabled FDA-approved medical devices in 2022 (Figure 2). The first AI/ML-enabled medical device, PAPNET Testing System, obtained FDA approval in 1995 through Premarket Approval and is related to the pathology subspecialty.

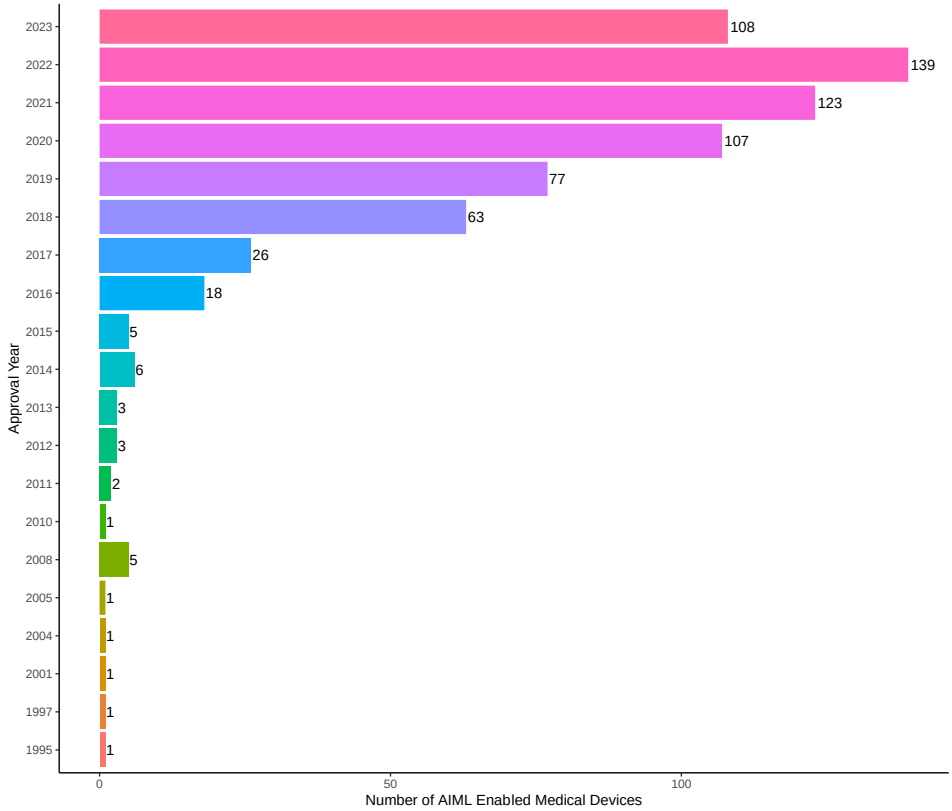
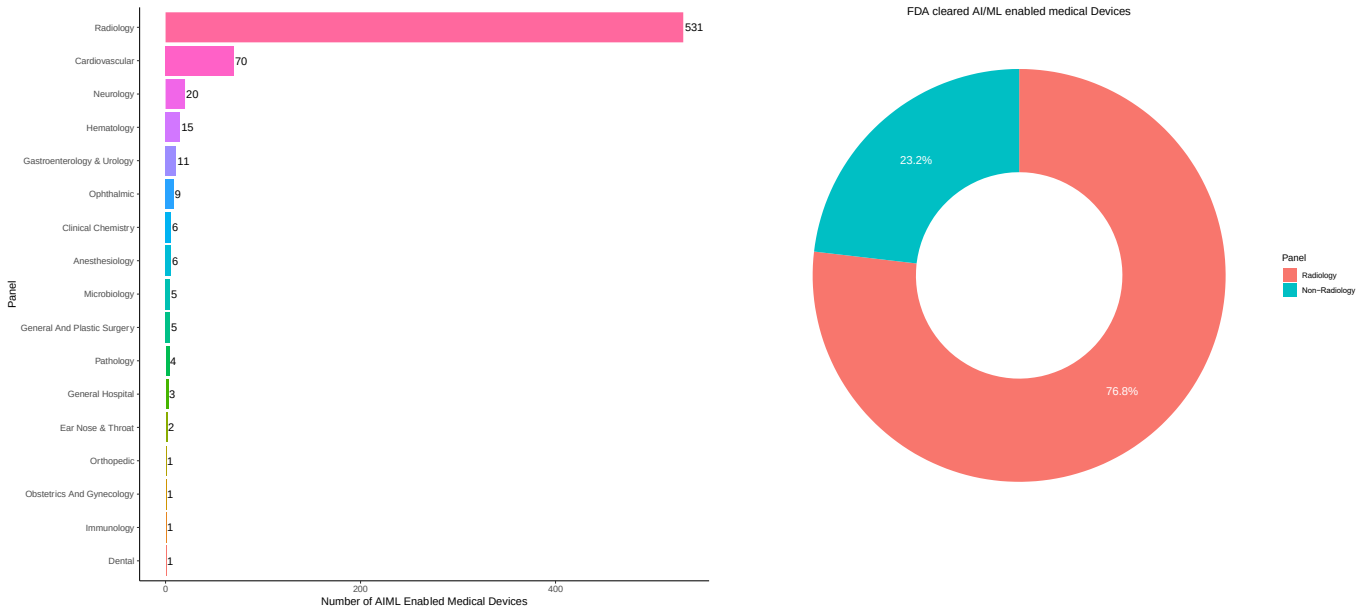



**Figure 2.** Graphical representation of the annual trends in FDA approval for AI/ML-enabled medical devices showcasing the surge in technological integration in healthcare.

### *3.2. Medical Subspecialties*

The FDA has approved AI/ML-enabled medical devices across many medical subspecialties (Figure 3a). An important insight from these data is that the majority, 531 (about 77%), of FDA-approved AI/ML-enabled medical devices belong to the radiology medical subspecialty. Radiology not only has the highest volume of submissions but has also witnessed the most consistent growth in AI/ML-enabled device submissions among all specialties. Radiology is followed by the cardiovascular subspecialty with 70 devices (about 10%), then neurology with 20 devices and hematology with 15 devices (Figure 3a,b). Other medical subspecialties include gastroenterology and urology with 11 devices, ophthalmology with 9 devices, anesthesiology and clinical chemistry with 6 devices each, microbiology and general and plastic surgery with 5 devices each, pathology with 4 devices, general hospital with 3 devices, ear, nose, and throat (ENT) with 2 devices, and dental, immunology, obstetrics and gynecology, and orthopedics with 1 device each. The two medical devices related to ENT were only listed in 2022 and 2023 (Figure 4).




(**a**) (**b**)

**Figure 3.** (**a**) Bar graph showing the number of approved devices categorized by medical panels, emphasizing the diversification and expansion of AI/ML applications across different medical specialties; (**b**) Donut plot illustrating the substantial dominance of radiology in the number of AI/ML-enabled device approvals compared to other medical specialties, underlining the field's innovation-driven nature.

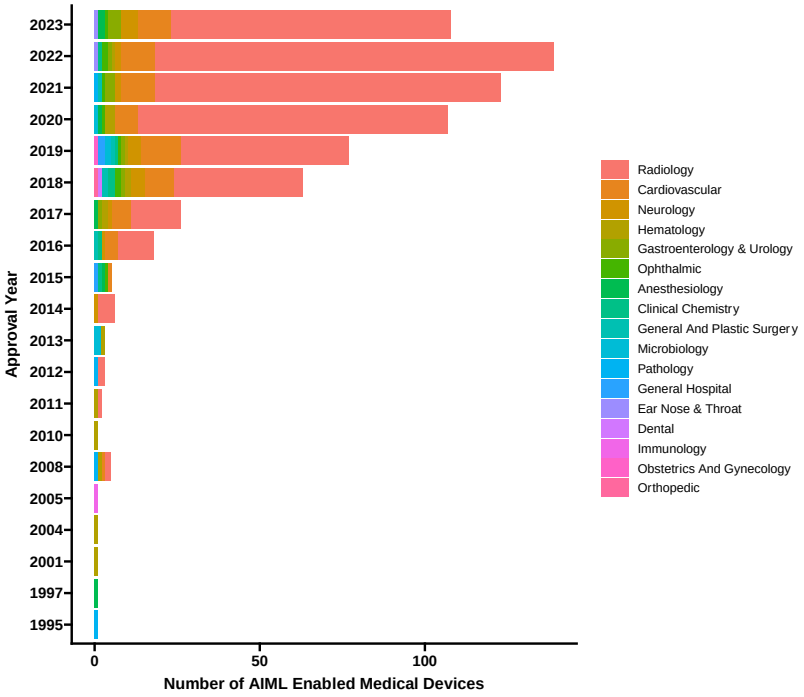



**Figure 4.** Graph depicting the evolution of approval numbers for various medical panels over the years, highlighting the dynamic growth and potential research and development focuses in these areas.

### *3.3. Device Classification*

The top device classes approved by the FDA include radiological image processing, radiological-image-processing software, computed tomography, computer-assisted triage

and notification software, ultrasonic imaging, and nuclear magnetic resonance imaging, as indicated by the primary product code (Figure 5, Supplementary Table S2).

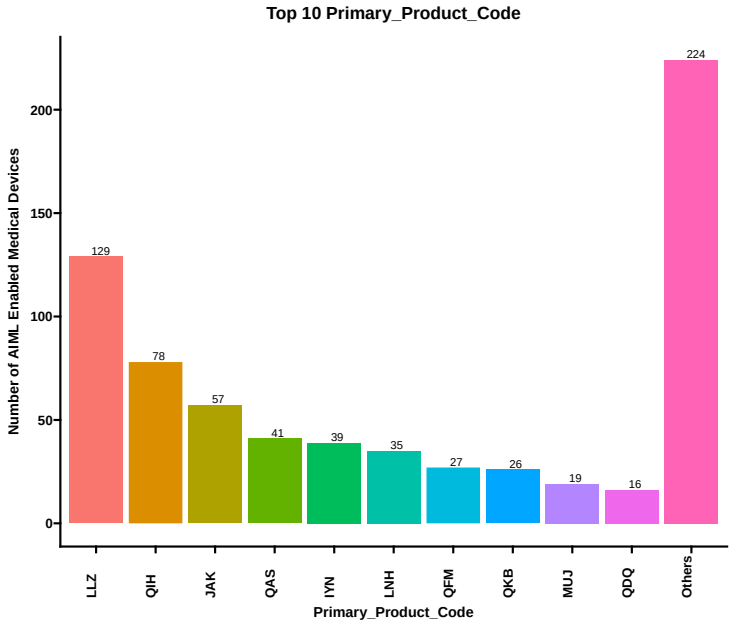
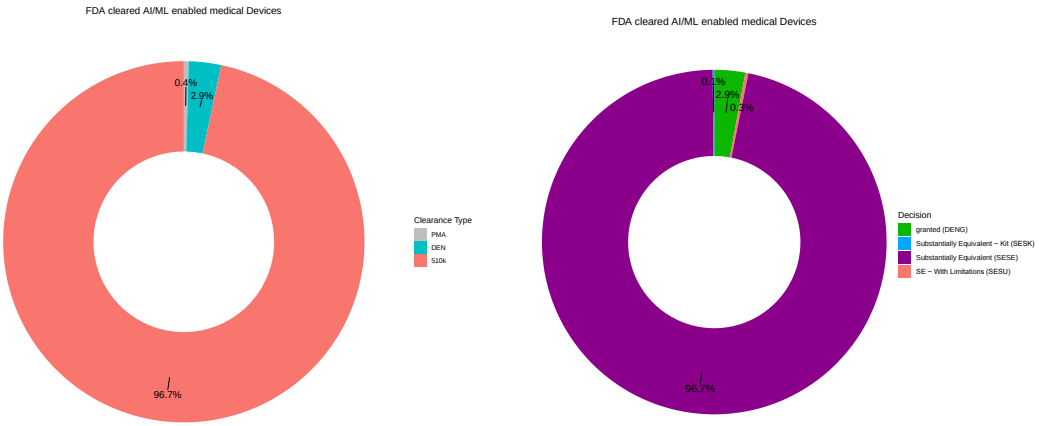



**Figure 5.** Bar chart presenting the distribution of approved devices based on their primary product codes, revealing the most common technological applications and innovations that have received FDA clearance.

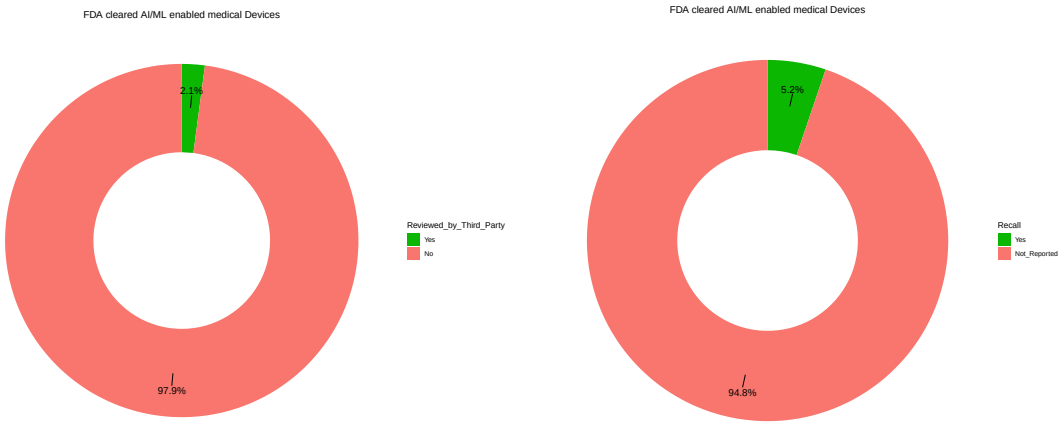
### *3.4. Clearance Pathway, Decision Type, and Recall Rate*

As of 19 October 2023, 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% of the total approved devices (Figure 6a). While the FDA's primary public health mission is to ensure the safety and effectiveness of innovative devices, approval decisions are frequently based on substantial equivalence to their predecessors of a similar kind. The FDA approved approximately 97% of AI/ML-enabled devices based on Substantial Equivalence (SESE) criteria, with other decision types making up the minority (Figure 6b). Similarly, the number of approved devices reviewed by a third party comprises only about 3% (Figure 6c). The FDA has occasionally issued recall notices for about 5% of AI/ML-enabled medical devices (Figure 6d), citing various concerns.




(**a**) (**b**)

**Figure 6.** *Cont.*

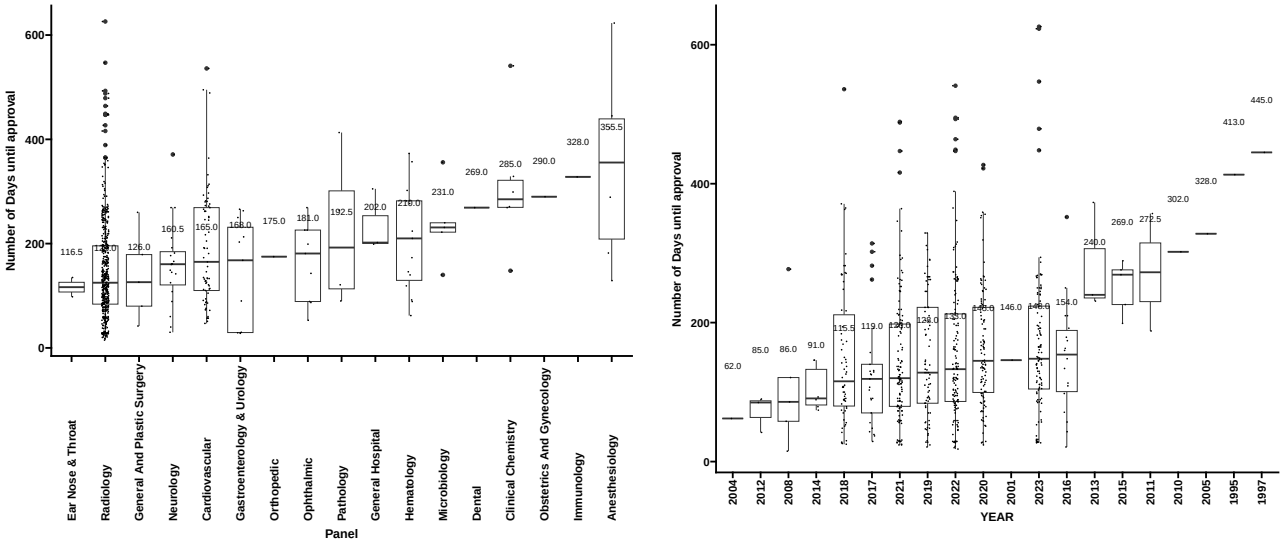



(**c**) (**d**)

**Figure 6.** (**a**) Plot displaying the various clearance types for AI/ML-enabled medical devices, with a dominant share by 510(k) submissions, followed by De Novo approvals and PMAs; (**b**) Chart illustrating the decision types associated with the approval of AI/ML-enabled medical devices, showing a high reliance on Substantial Equivalence (SESE) criteria; (**c**) Graph detailing the extent of 3rd party review involvement in the approval process, providing insight into the reliance on external expertise for decision making; (**d**) Plot showing the recall status of approved AI/ML-enabled medical devices, highlighting the safety and regulatory challenges encountered post-approval.

### *3.5. Approval Wait Time*

The approval wait time was calculated by counting the days passed between the date the FDA received the complete application and the decision date. The median wait time varied among different medical subspecialties and by decision year (Figure 7a,b). Devices related to ENT, radiology, and general and plastic surgery had shorter median wait times. Median wait times have averaged around 125 days since 2016.




(**a**) (**b**)

**Figure 7.** (**a**) Boxplot representing the distribution of approval wait times across different medical panels; values represent median wait time indicating the efficiency or complexity within each specialty's approval processes; (**b**) Box plot tracking the change in approval wait times over the years; values represent median wait times suggesting improvements or delays in the regulatory process.

### *3.6. Applicant Company*

At the time of application, there were altogether 295 applicants for all the AI/ML-enabled devices seeking FDA approval. Among them, GE Healthcare (Chicago, IL, USA), Siemens (Munich, Germany), and Canon (Tokyo, Japan) are the top three applicants, filing the greatest number of applications for FDA clearance (Figure 8). It should be noted that these data do not take into account company mergers, acquisitions, device rebranding, or company renaming.

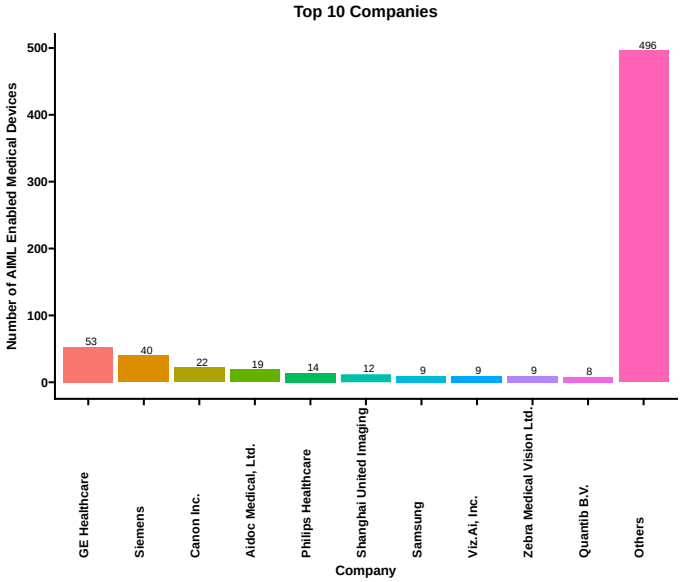
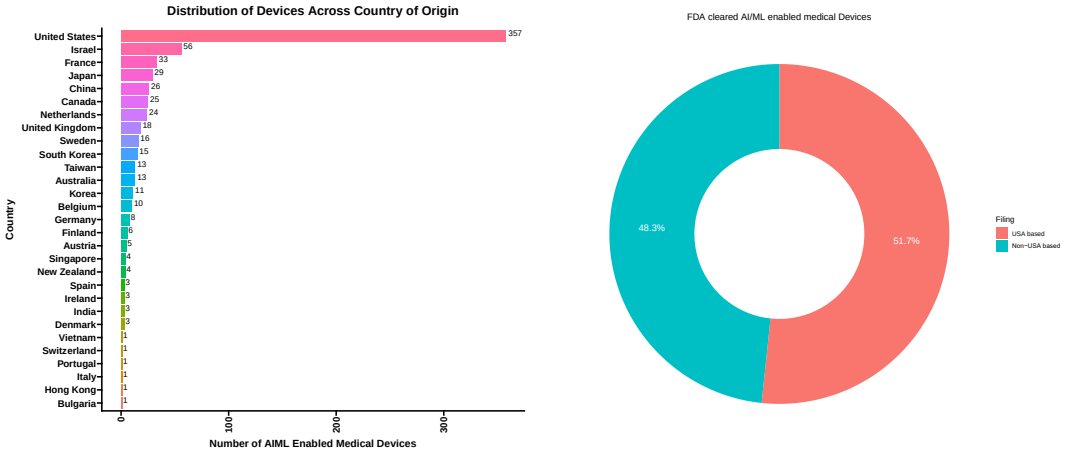



**Figure 8.** Bar chart ranking the top applicants of AI/ML-enabled medical devices, pointing to the active players pushing the boundaries of healthcare technology.

### *3.7. Leading Countries in AI/ML-Enabled Medical Devices*

Based on the applicant's country of origin, the USA leads the list with a total of 357 (approximately 52%) of FDA-approved AI/ML-enabled medical devices, followed by Israel with 56 devices (Figure 9a,b). France, Japan, and China complete the top five, with 33, 29, and 26 FDA-approved medical devices, respectively. Figure 10 serves as the summary plot for all the devices.




(**a**) (**b**)

**Figure 9.** (**a**) Global distribution of AI/ML-enabled medical device approvals, indicating the geographical hubs of medical technology innovation; (**b**) Comparative representation of the number of AI/ML-enabled medical device approvals within the USA versus other countries, highlighting the USA's role as a major innovator in the field.

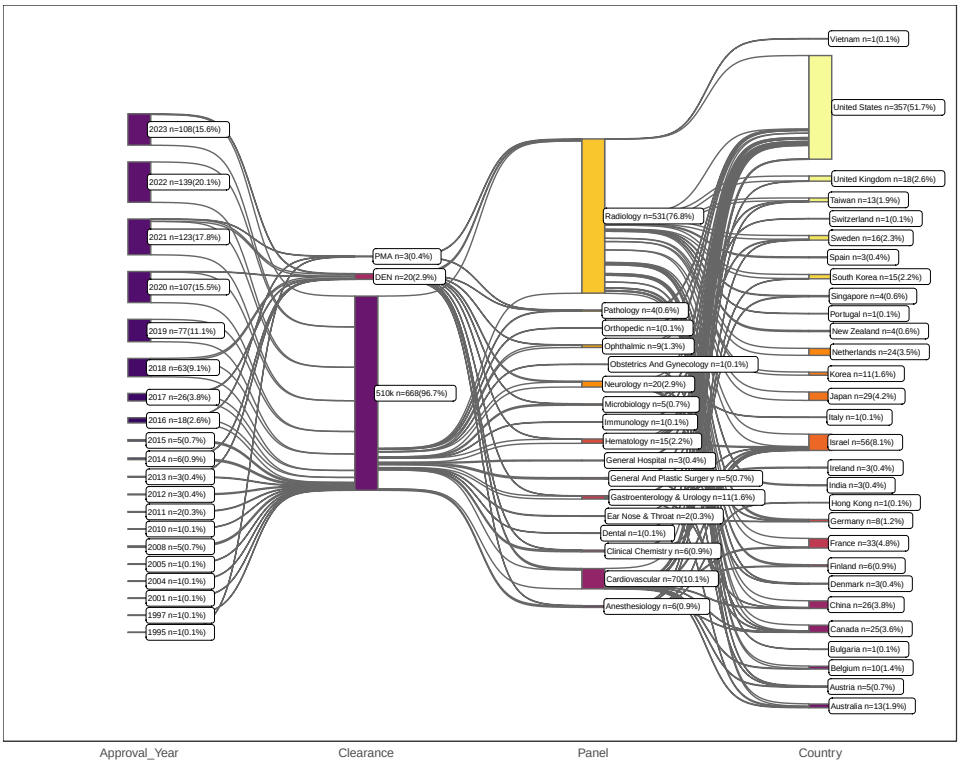



**Figure 10.** Comprehensive summary chart of AI/ML-Enabled Medical Devices approved by the FDA, encapsulating key information from approval trends to device types and clearance pathways.

### *3.8. Clinical Trials*

Only 22 (about 3.2%) AI/ML-enabled medical devices approved by the FDA reported conducting clinical trials, based on the information found in the summary descriptions of the marketing authorization document provided by the applicant company (Figure 11a). Among these 22 devices, interventional trials were conducted for 9 devices, and observational types of clinical trials were conducted for 13 devices (Figure 11b). The devices related to these clinical trials mainly belong to the cardiovascular and radiology medical specialties (Figure 11c). These clinical trials primarily enrolled adults or older adults as their subjects (Figure 11d). A medical device related to pediatric autism spectrum disorder diagnosis aid was specific to the child age group. All clinical trials were open to both males and females for enrollment, except one specifically for females, which was related to a breast-imaging system. The number of clinical trials for a device ranged from a single clinical trial to a total of four clinical trials and from a single location to 20 different locations (Figure 11e). Additionally, the total number of participants in these clinical trials ranged from 12 subjects up to 2105 subjects, depending on the medical device (Figure 11e). The device with the highest number of subjects in a clinical trial among these was the breast-imaging system, and the PIONEER-01 study was conducted in 16 different locations.

The data also show that clinical trials for 15 of these devices were conducted only in the USA, while clinical trials for 6 of these devices were conducted in two or more different countries (Figure 11f). The devices with clinical trial information are summarized in Figure 12.

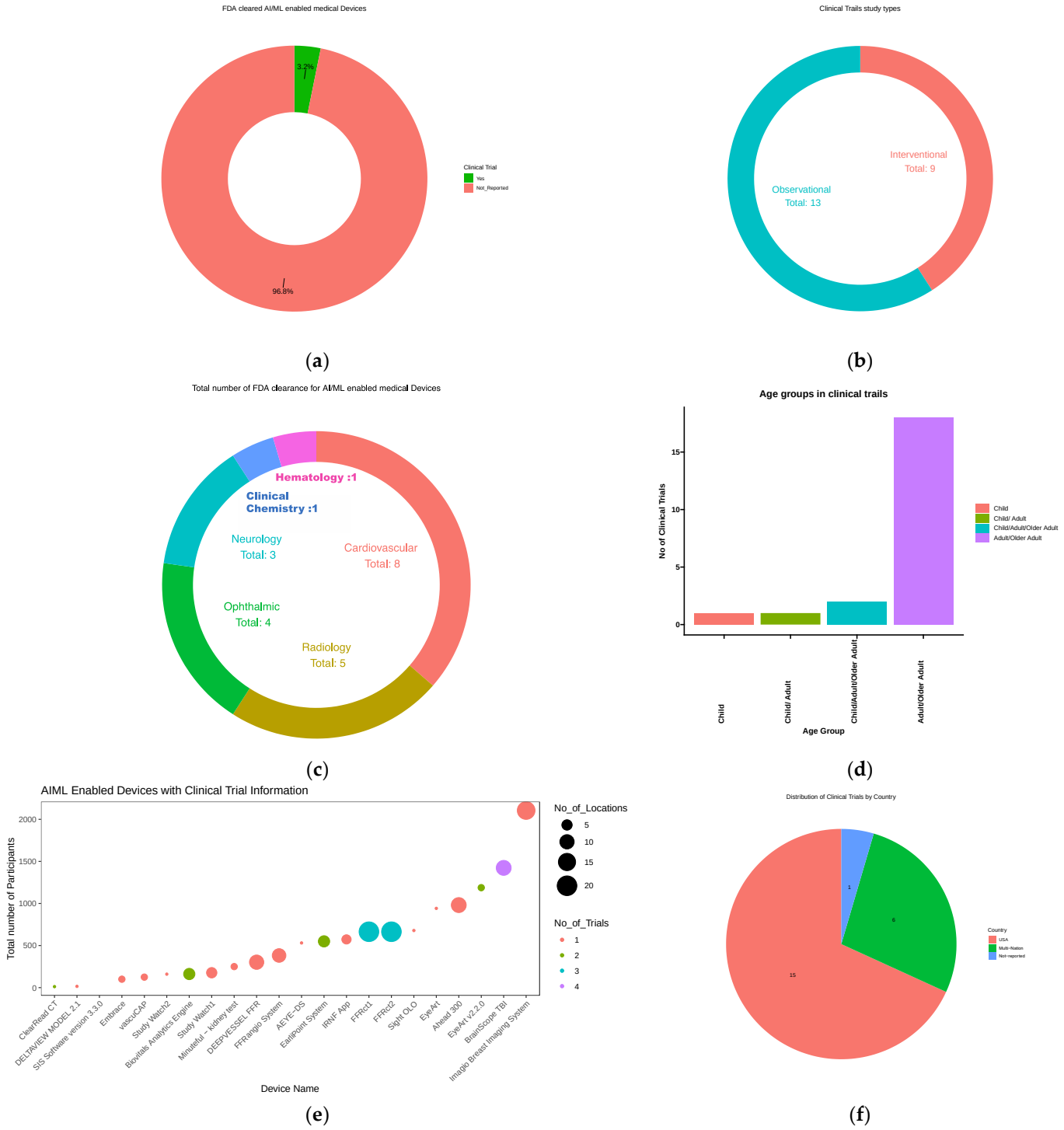



**Figure 11.** (**a**) Plot showing the proportion of approved devices that have accompanying clinical trial information, revealing insights into the evidence basis for these technologies; (**b**) Breakdown of devices with clinical trials, segmented by the type of trial conducted, offering a view into research methodologies; (**c**) Classifying the devices with clinical trials according to their respective medical panels, highlighting areas with more rigorous clinical validation; (**d**) Age group of clinical trial subjects, pinpointing potential gaps in population coverage, especially in pediatric and young adult groups; (**e**) Dot plot presenting an overview of clinical trials, including the number of participants, geographical locations, and quantity of trials, demonstrating the scale and scope of these critical studies; (**f**) Countries where clinical trials for these devices have been conducted, stressing the importance of geographical diversity in clinical research.

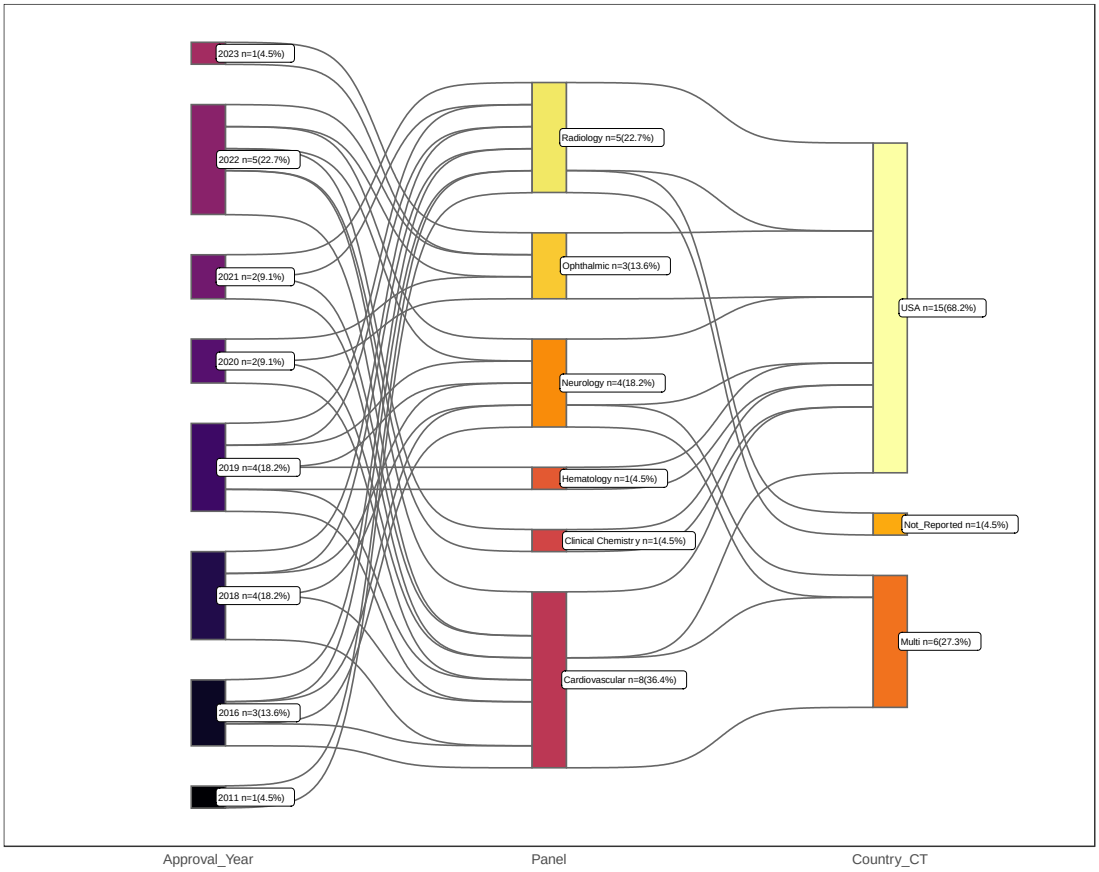



**Figure 12.** Summary visualization of AI/ML-enabled medical devices that includes clinical trials.

## 4. Discussion

In this study, we illustrated how the number of FDA-approved AI/ML-enabled medical devices has seen a consistent upsurge in the United States since the inaugural approval of such a device in 1995. A noteworthy increase in the authorization of these devices became prominent from 2018 onwards, accounting for approximately 90% of all approved devices. This substantial growth in the approval trajectory may be associated with the comprehensive evolution within the computing field, marked by advancements in hardware and software, the affordability of cloud storage solutions, the accessibility of expansive datasets, and significant investments from major corporations in fostering more sophisticated platforms [15–18].

Radiology emerges as the predominant specialty for the application of AI/ML-enabled medical devices. This prevalence is attributed to the routine prescription of radiological imaging in regular clinical assessments and successive patient consultations, thereby amassing substantial datasets [19]. These data reserves are invaluable, facilitating extensive research initiatives for scientists and providing a robust foundation for device manufacturers to innovate and enhance medical devices [20].

In terms of FDA approval, the majority of FDA approvals were approved through the 510(k)-clearance pathway, relying on the demonstration of substantial equivalence that circumvents the necessity for exhaustive clinical trials. Remarkably, only around 3% of the totality of approved devices have disclosed undertaking clinical trials, with a predominant focus on adult participants. Among these, the breast-imaging system emerged as the device with the most extensive number of participants enrolled in clinical trials. The comprehensive PIONEER-01 study encompassed a total of 16 distinct locations in the United States. The large number of subjects in this trial could be attributed to the higher incidence of breast cancer in the US, as breast cancer is the second most common cancer among women in the United States [21], and there is an increased effort in cancer surveillance by the

Centers for Disease Control and Prevention (CDC) [22]. However, clinical trial reports are lacking or not comprehensive for other AI/ML-enabled medical devices.

This trend suggests a potential shortfall in the sphere of medical specialties targeting pediatric and young adult demographics, either indicating a challenge in the development of AI/ML-enabled instruments for these age brackets or a lack of comprehensive inclusivity within the clinical trials.

Moreover, the geographical span of these clinical trials exhibits a considerable limitation, being confined within US borders. Such a restriction could overshadow the diverse heterogeneity integral to global subject samples involved in clinical examinations [23,24]. Moving forward, there is a pressing need to develop AI/ML-based medical devices for medical specialties that are lagging behind and also broaden the demographic and geographic spectrum of clinical trials to encompass a more representative global populace, including underrepresented communities, to address disparities.

This study is solely based on the data obtained from the FDA and, hence, comes with limitations. The FDA's list of AI/ML-enabled devices, updated as of 19 October 2023, lacks comprehensiveness as it does not include AI/ML-based medical devices awaiting FDA approval, medical devices that failed to obtain FDA approval, or medical devices that are not classified as AI/ML-based. Moreover, the FDA clarifies that the summaries provided are often condensed for public access, supplied by the applicants, and may not offer a comprehensive overview. Furthermore, AI/ML-enabled devices accredited, certified, or approved by other regulatory agencies within or outside the USA, such as the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, the Central Drugs Standard Control Organization (CDSCO) in India, the National Medical Products Administration (NMPA) in China, CE mark decentralized accredited private agencies in the European Union (EU), etc., are out of the scope of this study.

Despite these limitations, in this study, we provide a comprehensive representation of the AI/ML-enabled medical device landscape, encompassing an identification of trends, potential gaps, and areas for future exploration, clinical trial practices, and regulatory approaches. This analysis serves as a guide for further discussions on AI/ML-enabled medical devices, FDA regulations, disparities in clinical trials, and the ethics governing AI technologies.

Currently, the integration of artificial intelligence (AI) and machine learning (ML) into healthcare brings a host of ethical issues, including privacy and data security, the risk of perpetuating biases, a lack of transparency in AI algorithms, explainability, and concerns about patient consent and autonomy. These challenges are compounded by limited data availability, data drift, inclusivity, the need for retraining, and regulatory challenges in keeping pace with technological advancements [25]. Additionally, ensuring the safety and clinical validation of AI tools to prevent misdiagnoses and inappropriate treatments and maintaining fair and equal access to AI technologies in healthcare are crucial to avoiding increasing health disparities. This highlights the need for a balanced approach to leverage AI's benefits while addressing its challenges in healthcare.

In the near future, artificial intelligence, particularly through large language models (LLMs), is poised to transform the healthcare industry [13]. This transformation will enhance the experiences of healthcare professionals and patients by reducing health disparities, achieving relevant outcomes, optimizing resources, and ensuring transparent and comprehensible AI decisions through explainable AI (XAI) [26–28].

## 5. Conclusions

This article succinctly delineates the integration of artificial intelligence and machine learning into medical devices, highlighting the pertinent FDA approval channels. Furthermore, we have discussed major insights and summarized the spectrum of FDA-approved AI/ML-enabled medical devices, utilizing the limited publicly accessible information available up to the present date. Our analysis serves as a beacon, elucidating the current

landscape of AI/ML-enabled medical devices and prevailing trends, thereby contributing to a broader understanding.

**Supplementary Materials:** The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/electronics13030498/s1, Figure S1: Significant subsets of AI terminologies within the medical domain which are often used interchangeably; Table S1: FDA approval pathways and subpathways for AI/ML-based devices; Table S2: Primary product codes and related device classification.

**Author Contributions:** Conceptualization, M.B.; methodology, G.J. and M.B.; software, G.J., A.J., S.R.A., S.A. and H.G.; validation, M.B. and G.J.; formal analysis, G.J., A.J., S.R.A., S.A. and H.G.; investigation, M.B.; resources, G.J. and M.B.; data curation, G.J., A.J., S.R.A., S.A. and H.G.; writing—original draft preparation, G.J., A.J., S.R.A., S.A. and H.G.; writing—review and editing, G.J.; visualization, G.J., A.J., S.R.A., S.A. and H.G.; supervision, M.B. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research received no external funding.

**Institutional Review Board Statement:** Not applicable.

**Informed Consent Statement:** Not applicable.

**Data Availability Statement:** Data supporting reported results can be found on a publicly accessible FDA webpage (https://www.fda.gov/medical-devices, accessed on 19 October 2023).

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

## References

1. Artificial Intelligence (AI) Coined at Dartmouth. Celebrate Our 250th 2018. Available online: https://250.dartmouth.edu/highlights/artificial-intelligence-ai-coined-dartmouth (accessed on 4 December 2022).
2. Le Cun, Y.; Bengio, Y.; Hinton, G. Deep learning. *Nature* **2015**, *521*, 436–444. [CrossRef] [PubMed]
3. Kermany, D.S.; Goldbaum, M.; Cai, W.; Valentim, C.C.S.; Liang, H.; Baxter, S.L.; McKeown, A.; Yang, G.; Wu, X.; Yan, F.; et al. Identifying Medical Diagnoses and Treatable Diseases by Image-Based Deep Learning. *Cell* **2018**, *172*, 1122–1131.e9. [CrossRef] [PubMed]
4. McDermott, M.B.A.; Wang, S.; Marinsek, N.; Ranganath, R.; Foschini, L.; Ghassemi, M. Reproducibility in machine learning for health research: Still a ways to go. *Sci. Transl. Med.* **2021**, *13*, eabb1655. [CrossRef] [PubMed]
5. Screening for Early Detection—CPR22. Cancer Progress Report n.d. Available online: https://cancerprogressreport.aacr.org/progress/cpr22-contents/cpr22-screening-for-early-detection/ (accessed on 4 December 2022).
6. Zhu, S.; Gilbert, M.; Chetty, I.; Siddiqui, F. The 2021 landscape of FDA-approved artificial intelligence/machine learning-enabled medical devices: An analysis of the characteristics and intended use. *Int. J. Med. Inform.* **2022**, *165*, 104828. [CrossRef] [PubMed]
7. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. FDA, 2023. Available online: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices (accessed on 10 January 2024).
8. De Novo Classification Request. FDA, 2023. Available online: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request (accessed on 10 January 2024).
9. Premarket Approval (PMA). FDA, 2023. Available online: https://cacmap.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma (accessed on 23 October 2023).
10. Premarket Notification 510(k). FDA, 2023. Available online: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k (accessed on 23 October 2023).
11. Software as a Medical Device (SaMD): Clinical Evaluation | International Medical Device Regulators Forum 2017. Available online: https://www.imdrf.org/documents/software-medical-device-samd-clinical-evaluation (accessed on 10 January 2024).
12. Gerke, S.; Babic, B.; Evgeniou, T.; Cohen, I.G. The need for a system view to regulate artificial intelligence/machine learning-based software as medical device. *NPJ Digit. Med.* **2020**, *3*, 53. [CrossRef] [PubMed]
13. Clusmann, J.; Kolbinger, F.R.; Muti, H.S.; Carrero, Z.I.; Eckardt, J.-N.; Laleh, N.G.; Löffler, C.M.L.; Schwarzkopf, S.-C.; Unger, M.; Veldhuizen, G.P.; et al. The future landscape of large language models in medicine. *Commun. Med.* **2023**, *3*, 141. [CrossRef] [PubMed]
14. Overgaard, S.M.; Graham, M.G.; Brereton, T.; Pencina, M.J.; Halamka, J.D.; Vidal, D.E.; Economou-Zavlanos, N.J. Implementing quality management systems to close the AI translation gap and facilitate safe, ethical, and effective health AI solutions. *NPJ Digit. Med.* **2023**, *6*, 218. [CrossRef] [PubMed]
15. Zhang, A.; Xing, L.; Zou, J.; Wu, J.C. Shifting machine learning for healthcare from development to deployment and from models to data. *Nat. Biomed. Eng.* **2022**, *6*, 1330–1345. [CrossRef] [PubMed]

16. De Kok, J.W.T.M.; de la Hoz, M.Á.A.; de Jong, Y.; Brokke, V.; Elbers, P.W.G.; Thoral, P.; Castillejo, A.; Trenor, T.; Castellano, J.M.; Bronchalo, A.E.; et al. A guide to sharing open healthcare data under the General Data Protection Regulation. *Sci. Data* **2023**, *10*, 404. [CrossRef] [PubMed]
17. Kusunose, M.; Muto, K. Public attitudes toward cloud computing and willingness to share personal health records (PHRs) and genome data for health care research in Japan. *Hum. Genome Var.* **2023**, *10*, 11. [CrossRef] [PubMed]
18. Perkel, J.M. Terra takes the pain out of 'omics' computing in the cloud. *Nature* **2022**, *601*, 154–155. [CrossRef] [PubMed]
19. Hosny, A.; Parmar, C.; Quackenbush, J.; Schwartz, L.H.; Aerts, H.J.W.L. Artificial intelligence in radiology. *Nat. Rev. Cancer* **2018**, *18*, 500–510. [CrossRef] [PubMed]
20. Zhou, Y.; Chia, M.A.; Wagner, S.K.; Ayhan, M.S.; Williamson, D.J.; Struyven, R.R.; Liu, T.; Xu, M.; Lozano, M.G.; Woodward-Court, P.; et al. A foundation model for generalizable disease detection from retinal images. *Nature* **2023**, *622*, 156–163. [CrossRef] [PubMed]
21. CDCBreastCancer. Breast Cancer Statistics. Centers for Disease Control and Prevention, 2022. Available online: https://www.cdc.gov/cancer/breast/statistics/index.htm (accessed on 10 January 2024).
22. CDCBreastCancer. What CDC Is Doing about Breast Cancer. Centers for Disease Control and Prevention, 2023. Available online: https://www.cdc.gov/cancer/breast/what_cdc_is_doing/index.htm (accessed on 10 January 2024).
23. Bains, A.; Osathanugrah, P.; Sanjiv, N.; Chiu, C.; Fiorello, M.G.; Siegel, N.H.; Peeler, C.E.; Distefano, A.G.; Lee, H.J.; Ness, S.; et al. Diverse Research Teams and Underrepresented Groups in Clinical Studies. *JAMA Ophthalmol.* **2023**, *141*, 1037–1044. [CrossRef] [PubMed]
24. Office of the Commissioner. Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability. 2022. Available online: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations (accessed on 10 January 2024).
25. Shandhi, M.M.H.; Dunn, J.P. AI in medicine: Where are we now and where are we going? *CR Med.* **2022**, *3*, 100861. [CrossRef] [PubMed]
26. Rajpurkar, P.; Chen, E.; Banerjee, O.; Topol, E.J. AI in health and medicine. *Nat. Med.* **2022**, *28*, 31–38. [CrossRef] [PubMed]
27. Badal, K.; Lee, C.M.; Esserman, L.J. Guiding principles for the responsible development of artificial intelligence tools for healthcare. *Commun. Med.* **2023**, *3*, 47. [CrossRef] [PubMed]
28. Bienefeld, N.; Boss, J.M.; Lüthy, R.; Brodbeck, D.; Azzati, J.; Blaser, M.; Willms, J.; Keller, E. Solving the explainable AI conundrum by bridging clinicians' needs and developers' goals. *NPJ Digit. Med.* **2023**, *6*, 94. [CrossRef] [PubMed]