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Simeng Zhu
Henry Ford Health, SZhu1@hfhs.org

Marissa Gilbert
Henry Ford Health, mgilber6@hfhs.org

Indrin J. Chetty
Henry Ford Health, ICHETTY1@hfhs.org

Farzan Siddiqui
Henry Ford Health, fsiddiq2@hfhs.org

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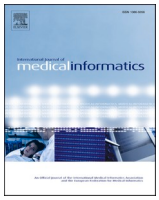

The 2021 landscape of FDA-approved artificial intelligence/machine learning-enabled medical devices: An analysis of the characteristics and intended use

Simeng Zhu, Marissa Gilbert, Indrin Chetty, Farzan Siddiqui *

Department of Radiation Oncology, Henry Ford Cancer Institute, Detroit, MI, USA

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ABSTRACT

Background: Machine learning (ML), a type of artificial intelligence (AI) technology that uses a data-driven approach for pattern recognition, has been shown to be beneficial for many tasks across healthcare. To characterize the commercial availability of AI/ML applications in the clinic, we performed a detailed analysis of AI/ML-enabled medical devices approved/cleared by the US Food and Drug Administration (FDA) by June 2021.
Methods/Materials: The publicly available approval letters by the FDA on 343 AI/ML-enabled medical devices compiled by the agency were reviewed. The characteristics of the devices and the patterns of their intended use were analyzed, and basic descriptive statistical analysis was performed on the aggregated data.
Results: Most devices were reviewed by radiology (70.3%) and cardiovascular (12.0%) medical specialty panels. The growth of these devices sharply rose since the mid-2010s. Most (95.0%) devices were cleared under the 510 (k) premarket notification pathway, and 69.4% were software as a medical device (SaMD). Of the 241 radiology-related devices, the most common applications were for diagnostic assistance (48.5%) and image reconstruction (14.1%). Of the 117 radiology-related devices for diagnostic assistance, 20.5% were developed for breast lesion assessment and 14.5% for cardiac function assessment on echocardiogram. Of the 41 cardiology-related devices, the most common applications were electrocardiography-based arrhythmia detection (46.3%) and hemodynamics & vital signs monitoring (26.8%).
Conclusion: In this study, we characterized the patterns and trends of AI/ML-enabled medical devices approved or cleared by the FDA. To our knowledge, this is the most up-to-date and comprehensive analysis of the landscape as of 2021.

1. Introduction

Artificial Intelligence and machine learning (AI/ML) algorithms, with their ability to automatically recognize and learn patterns from data, have recently emerged as a promising technology that can potentially leverage the recent advancement in "big data" to allow more efficient and precise delivery of healthcare [1–3].

Research studies involving AI/ML algorithms for problems in health and medicine grew sharply in the past decade [4], a period in which three significant enabling events occurred: the advancement of the field of deep learning [5], digitization of healthcare data in massive quantities [6], and the growing availability of advanced hardware equipped with computational capabilities powerful enough for developing AI/ML algorithms [7].

While most studies in this area focused on developing and validating AI/ML algorithms for their respective use cases, few have investigated the degree to which the growing progress in AI/ML research has been translated into commercially available tools for clinics [8–11]. In the United States, when a device (including software) is intended to diagnose, mitigate, treat, cure, or prevent a disease, it is considered a medical device and must be approved or cleared in a risk-stratified fashion (Table 1) by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA), the regulatory agency responsible for certifying the commercial distribution of the devices.

To characterize the AI/ML medical device landscape as of 2021, we performed an in-depth analysis of the recently published list by the FDA of 343 AI/ML-enabled medical devices cleared or approved as of June 2021 [14] (to reduce redundancy, we will refer to both FDA-cleared and

* Corresponding author at: 2800 W. Grand Blvd., Detroit, MI 48202, USA.
E-mail address: fsiddiq2@hfhs.org (F. Siddiqui).

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Table 1
Summary of the risk-based medical device regulation by the US Food and Drug Administration.

Definition and Regulatory Pathways for Medical Devices of Different Classes		
	Definition	Possible regulatory pathways (if not except)
Class I	Low- to moderate-risk medical devices under general controls by the FDA*	510(k) premarket notification, De Novo request
Class II	Moderate- to high-risk medical devices under general controls and Special Controls	510(k) premarket notification, De Novo request
Class III	High-risk medical devices (which typically support or sustain human life) under general controls and Premarket Approval (PMA)	Premarket approval
Common Regulatory Pathways for Medical Devices by the FDA		
Premarket approval [12]	The most stringent type of submission application for which all nonclinical and clinical studies supporting the safety and effectiveness of the medical devices are required. A successful application results in "approval" of the new device by the FDA.	
510(k) premarket notification [12]	Submission pathway aiming to demonstrate that a new device is as safe and effective as, or substantially equivalent to, a legally marketed device (referred to as a predicate device). A successful application results in "clearance" of the new device by the FDA.	
De Novo request [13]	Submission pathway for novel class I and II medical devices for which there are no legally marketed predicate devices.	

*FDA = Food and Drug Administration.

-approved devices as "approved" for the rest of the manuscript).

2. Materials and methods

2.1. Source of data

In September 2021, the United States FDA's Digital Health Center of Excellence published a list consisting of 343 AI/ML-enabled medical devices approved by the agency as of June 2021 [14]. While the exact criteria for creating the list were not specified, the FDA website defined artificial intelligence as "a device or product that can imitate intelligent behavior or mimic human learning and reasoning" [15].

The list contains basic information for each device, including the decision date for approval, submission number, name of the device, name of the company, product code, and the lead medical specialty review panel. To offer additional insights on the details of the devices, two research assistants independently reviewed each device's publicly available approval letter and recorded the following information in a database: device class (I, II, or III), submission type (510(k) premarket notification, De Novo request, or premarket application pathway), whether the device is implanted, whether the device is life-sustaining/support, a summary of intended use, whether the device is software only, the type of AI algorithm used, whether the device can be used in mobile devices, and primary user (clinician, patient, or both). Conflicting information was resolved by discussion until a consensus was reached. To ensure data consistency, only data from the FDA approval letters were used for analysis, and no additional information (e.g. marketing materials or publications) was sought.

2.2. Further analysis for radiology and cardiovascular devices

An initial inspection of the original list revealed that "radiology" and "cardiovascular" represent the two most common medical specialty review panels. To further characterize the trends and patterns of functions of the devices in these two categories, we performed additional categorization and subcategorization based on the devices' intended use. For radiology devices, we created 11 main categories based on their intended use: diagnostic and triage assistance, image reconstruction, image segmentation and labeling, imaging device, radiation therapy planning, image storage and process software, surgery planning, image acquisition assistance, image registration, patient positioning, and linear accelerator. In addition, we further classified the radiology devices within the "diagnostic and triage assistance" category based on the type of abnormality or lesion. For cardiovascular devices, we created five categories based on their intended use: electrocardiography (ECG)-based arrhythmia detection, hemodynamic & vital signs monitoring, stethoscope-based auscultation analysis, coronary artery disease detection, and others. These categories for radiology and cardiovascular devices were created by the authors to efficiently classify these devices based on their intended uses and product codes with the goal of using as few mutually exclusive categories as possible.

Finally, we performed various basic descriptive statistical analyses for the aggregated data.

2.3. Assessment of medical AI/ML-related research activity

Since academic research is an important driving factor for innovations in industry, the trend of research output of medical AI/ML was assessed. PubMed was queried for the number of AI/ML-related scientific papers published annually, and a scatterplot was generated to assess the temporal trend. The following keywords were used during the PubMed search query: ("machine learning" OR "artificial intelligence") AND ("medicine" OR "medical" OR "clinical" OR "healthcare").

3. Results

3.1. Overall characteristics of the devices

A total of 343 medical devices were included for analysis (raw data and the database that we created can be found in Appendix A). Seven (2.0%) devices were approved before 2010, and the numbers of approvals increased in consecutive years since then, except from 2014 to 2015 (Fig. 1). The numbers of approvals from 2016 to 2021 were 16 (4.7%), 26 (7.6%), 61 (17.8%), 75 (21.9%), 100 (29.2%), and 38 (11.1%), respectively (Fig. 1). Of note, the number of approvals for the year 2021 is lower than the actual amount since the list of AI/ML-enabled devices did not include those approved after June 2021.

All 343 devices were classified as class II by the FDA, and no device was considered implanted or life-sustaining/support device. Three hundred and twenty-six (95.0%) devices were approved under the 510(k) premarket notification process, followed by De Novo request (n = 16, 4.7%) and premarket approval (n = 1, 0.3%) (Table 2). Two hundred and thirty-eight (69.4%) devices were software as a medical device (SaMD). The FDA approval summaries of 152 (44.3%) devices did not mention AI or specify any specific AI algorithm. Fifty-four (39.9%) mentioned "AI" only, and 137 specified the types of algorithms in more detail than "AI" (examples include "machine learning", "convolutional neural network", "deep learning"). Forty-four (12.8%) devices were enabled for use on mobile devices. Clinician, patient, and both were the primary users for 322 (93.9%), 10 (2.9%), and 11 (3.2%) devices, respectively.

The most common product codes were LLZ (medical image management and processing system), JAK (computed tomography x-ray system), QAS (radiological computer-aided triage and notification software), QIH (medical image management and processing system), and IYN (ultrasonic pulsed Doppler imaging system), each with 91 (26.5%), 27 (7.8%), 21 (6.1%), 14 (4.0%), and 13 (3.8%) devices, respectively.

Each device was assigned one lead medical specialty review panel. The involved panels (with numbers of approved devices) include radiology (n = 241, 70.3%), cardiovascular (n = 41, 12.0%), hematology (n = 13, 3.8%), neurology (n = 12, 3.5%), ophthalmic (n = 6, 1.7%), general and plastic surgery (n = 5, 1.5%), clinical chemistry (n = 5,

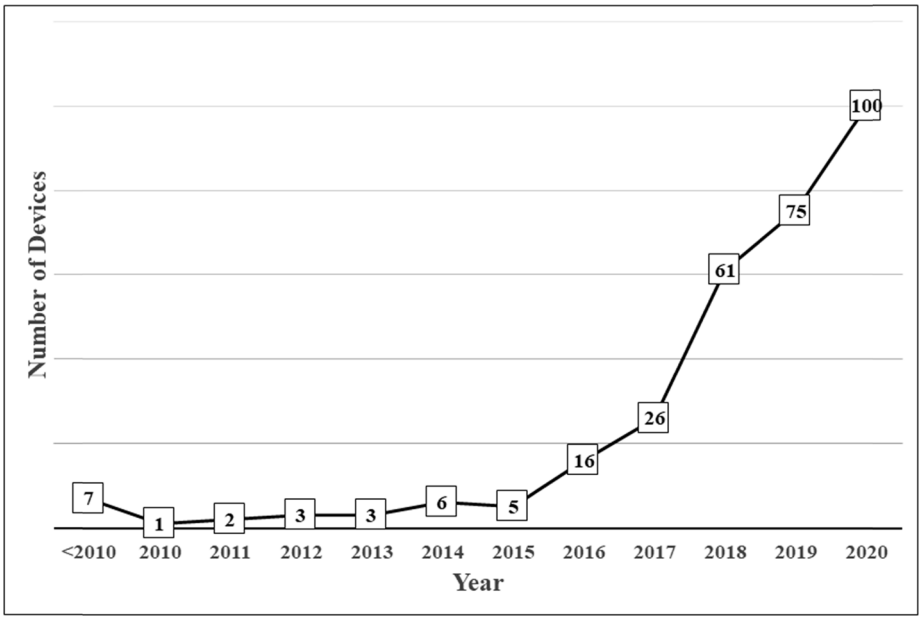

Fig. 1. The number of FDA-approved AI/ML-enabled medical devices per year.

Table 2
General characterizes of the AI/ML-enabled medical devices.

Class of Device	N = 343	%
I	0	0
II	343	100
III	0	0
Type of Submission		
510(k) premarket notification	326	95.0
De Novo request	16	4.7
Premarket approval	1	0.3
Algorithm description		
Did not specify	152	44.3
Mentioned "AI" only	54	15.7
Mentioned specific algorithm beyond "AI"	137	39.9
Software Only		
Yes	238	69.4
No	105	30.6
Mobile Application		
Yes	44	12.8
No	299	87.2
Type of User		
Clinician	322	93.9
Patient	10	2.9
Combination	11	3.2

1.5%), microbiology (n = 5, 1.5%), gastroenterology-urology (n = 4, 1.2%), anesthesiology (n = 4, 1.2%), general hospital (n = 3, 0.9%), obstetrics and gynecology (n = 1, 0.3%), orthopedic (n = 1, 0.3%), dental (n = 1, 0.3%), and pathology (n = 1, 0.3%) (Fig. 2). Out of the 19 total medical specialty panels for medical device classification at the FDA, all but 4 were represented, with the exception of chemistry, immunology, physical medicine, and toxicology [16].

The 16 devices approved under the De Novo request pathway represent 8 unique specialties (details can be found in the Supplemental Materials). Of the 16 new product codes created by this mechanism, 8 were used for 510(k) clearances among the remaining devices in this study, with each code used by a median of 2 (range, 1–20) other devices. The most notable example is the product code QAS (radiological computer-assisted triage and notification software), created in 2018

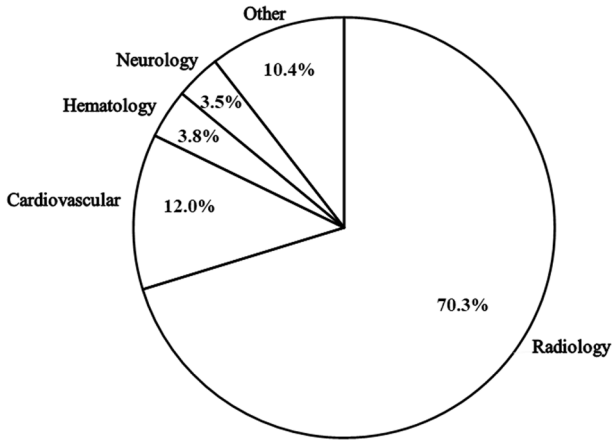

Fig. 2. Lead medical specialty review panels for the AI/ML-enabled devices.

with the approval of Viz.AI Inc.'s ContaCT product [17], has been used as the primary product code for 20 other devices included in this study.

3.2. Details of radiology devices

Among the 241 devices approved by radiology as the lead panel, the most common application was for diagnostic and triage assistance, accounting for 117 (48.5%) devices, followed by 34 (14.1%) for image reconstruction, 27 (11.2%) for image segmentation and labeling, 16 (6.6%) for imaging devices, and 15 (6.2%) for radiation therapy planning (Table 3). Of the 117 devices intended for diagnostic and triage assistance, 24 (20.5%), 17 (14.5%), 13 (11.1%), 11 (9.4%), and 9 (7.7%) were developed for the assessment of breast lesions, cardiac function on echocardiogram, intracranial hemorrhage, stroke, and pulmonary nodule, respectively (Table 3).

3.3. Details of cardiovascular devices

Of the 41 devices approved by cardiology as the lead panel, the most common applications were ECG-based arrhythmia detection (n = 19, 46.3%) and hemodynamics & vital signs monitoring (n = 11, 26.8%)

Table 3
Intended use for radiology-related AI/ML-enabled medical devices.

Categories for intended use	Subcategory (if available)	Number and percentage of devices
Diagnostic and triage assistance		117 (48.5%)
	Breast lesion detection	*24 (20.5%)*
	Echocardiogram analysis	*17 (14.5%)*
	Intracranial hemorrhage detection	*13 (11.1%)*
	Stroke detection	*11 (9,4%)*
	Pulmonary nodule detection	*9 (7.7%)*
	Fracture detection	*7 (6.0%)*
	Pneumothorax detection	*4 (3.4%)*
	Pulmonary embolism detection	*2 (1.7%)*
	Others	*30 (25.6%)*
Image reconstruction		34 (14.1%)
Image segmentation and labeling		27 (11.2%)
Imaging device		16 (6.6%)
Radiation therapy planning		15 (6.2%)
Image storage and processing		12 (5.0%)
Surgery planning		8 (3.3%)
Image acquisition assistance		4 (1.7%)
Image registration		4 (1.7%)
Patient positioning		3 (1.2%)
Linear accelerator		1 (0.4%)

Note: The percentages (in italics) reported for subcategories of diagnostic and triage assistance were calculated with respect to 117, the total number of devices within this main category.

Table 4
Intended use for cardiovascular AI/ML-enabled medical devices.

Categories for intended use	Number and percentage of devices
ECG-based arrythmia detection	19 (46.3%)
Hemodynamics & vital signs monitoring	11 (26.8%)
Stethoscope-based auscultation analysis	4 (9.8%)
Coronary artery disease detection	3 (7.3%)
Others	4 (9.8%)

Abbreviations: ECG = electrocardiogram.

(Table 4).

3.4. Mobile and patient-use devices

The 44 devices enabled for mobile devices represent 9 medical specialties, with radiology (n = 13, 29.5%), cardiovascular (n = 11, 25.0%), neurology (n = 6, 13.6%) and clinical chemistry (n = 4, 9.1%) being the most common. The 21 devices intended (whether exclusively or not) for patient use represent 7 specialties, with cardiovascular (n = 10, 47.6%), general hospital (n = 3, 7.3%), and hematology (n = 3, 7.3%) being the most common. Compared with the distribution of medical specialties for the entire cohort of devices, the distributions for these two subsets are more evenly distributed.

In addition, there is a high degree of overlap between the 44 mobile-enabled and 21 patient use devices, with 12 that fall into both categories simultaneously. Of these 12 devices, the most common intended uses were diabetes care-related (n = 5), ECG-based arrythmia detection (n = 2), and stethoscope-based cardiac auscultation (n = 2).

3.5. Medical AI/ML-related research activity

The numbers of annually published AI/ML-related scientific papers for years 2010 to 2021 were shown in Fig. 3, which demonstrated an accelerated growth beginning in the mid-2010 s.

4. Discussion

AI/ML technologies experienced significant growth in the past decade and are starting to impact multiple industries, including healthcare. To describe the characteristics of AI/ML-enabled medical devices currently approved for marketing in the US, we performed a thorough analysis of such devices approved by the FDA up to mid-2021."

4.1. Comparison to prior studies

The scope of the devices included for analysis in this study is broader than those used in similar efforts in the past – we included devices considered to be "AL/ML-enabled" by the FDA's Digital Health Center of Excellence, whereas the ones in prior studies were "AI/ML-based", generally limited to those with wordings such as "machine learning", "neural network", and "artificial intelligence" in public FDA documents [8–11]. As shown by results in Section 3.1, the reports for 152 (44.3%) AI/ML-enabled devices in our study did not mention any AI/ML-related keywords, suggesting that AI/ML might not be the principal focus for these devices. The expanded timeline and broader inclusion criteria make the current study the most comprehensive thus far (Table 5). In addition, compared to previous studies, we performed a more in-depth categorization of the intended uses for devices reviewed by radiology and cardiovascular panels at the FDA.

4.2. Comparison to research output

Our results showed that the number of approved AI/ML-enabled devices has been consistently increasing since the mid-2010 s, concordant with prior findings [8–11], and a similar pattern was observed in the growth of AI/ML-related medical research (Fig. 3). The similarity of growth patterns suggests the responsiveness of industry and regulatory bodies to translate AI/ML medical research into commercially available products. The rapid growth of AI/ML research and medical device development since the mid-2010 s can be likely attributed to the publication of two landmark papers: Krizhevsky et al.'s pioneering work on AlexNet in 2012 [19], which popularized the use of convolutional neural networks for image processing tasks, and Ronneberger et al.'s impactful work on U-Net in 2015, which was specifically designed for medical image segmentation, an important task in medical image processing [20].

Another interesting observation from our results was that, of the FDA documents that mentioned specific types of AI/ML algorithms in use, they were predominantly deep convolutional neural networks, the most common type of algorithms used for image-based tasks [5]. This is consistent with the fact most intended uses for the devices were image-based tasks, such as image classification and segmentation. Other popular machine learning algorithms, such as transformers [21] and long short-term memory (LSTM) [22], have not been commonly incorporated in the FDA approved devices.

4.3. Medical specialties

Not surprisingly, 82% of the approved devices were related to radiology and cardiology. The concentration of AI/ML-enabled devices in these two medical specialties can be likely explained by the heavy use of digital medical data (such as digital medical imaging data and electrocardiogram) and the significant role played by pattern recognition in making diagnoses. A similar trend was observed in a recent bibliometric study which showed that, in 83,979 scientific articles on AI/ML in the field of medicine, the four most common medical specialties were radiology, oncology, neuroimaging, and ophthalmology (in descending order) [23].

One of the possible key driving factors making radiology the leader

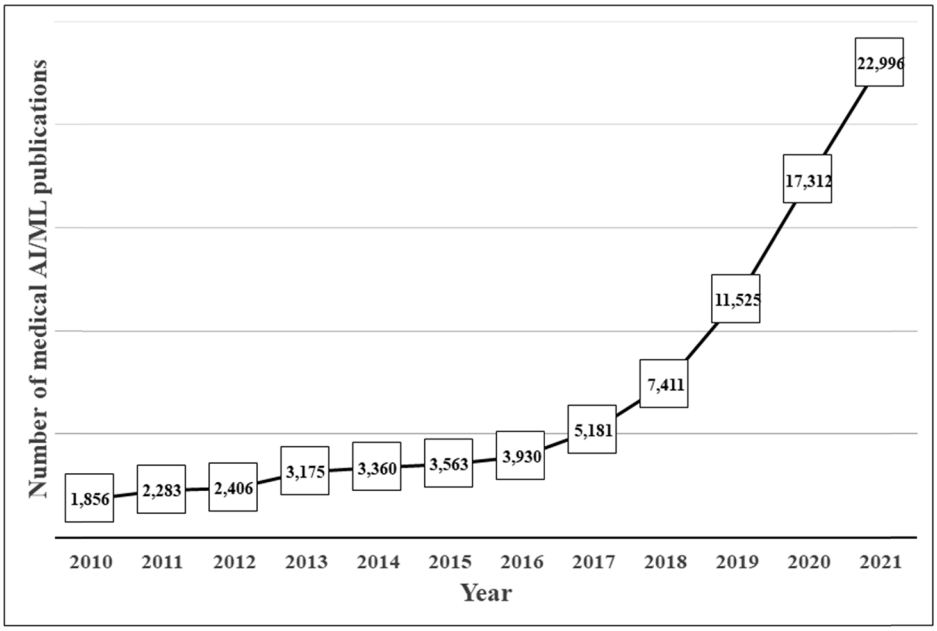

Fig. 3. The temporal growth of published medical AI/ML scientific papers.

Table 5
Comparison between the current study and prior investigations.

Study	Inclusion criteria for devices	Time frame of FDA approval	Number of devices
Benjamens et al. [8]	Official FDA announcement contains any of the following expressions: "machine learning", "deep learning", "deep neural networks", "artificial intelligence", "AI"	January 2010 - March 2020	29
Muehlematter et al.[9]	FDA documents contain any of the following expressions: "artificial intelligen*", "machine learning", "deep learning", "neural network", "convolutional neural, algorithm"	January 2015 - March 2020	222 (US), 240 (Europe)
Lyell et al.[10]	Internet web pages contain: ("artificial intelligence" OR "ai" OR "machine learning" OR "deep learning") AND ("FDA approved" OR "FDA approves" OR "FDA approval")	Up until February 2020	49
Wu et al.[11]	FDA documents containing "AI keywords", devices included in Benjamens et al.'s work [8], and an online database maintained by the American College of Radiology [18]	January 2015 - December 2020	130
Our study	"AI/ML-Enabled" as determined by the FDA's Digital Health Center of Excellence	Up until June 2021	343

in the development of AI/ML-enabled devices is that many pioneering experts recognized at a very early phase of the recent "AI revolution" the opportunity to apply the advancement made in the realm of AI/ML algorithms to the workflow of radiology [24,25]. The computer vision tasks in which modern AI/ML algorithms excel (e.g. image classification, image segmentation, object detection) bear a strong resemblance to many daily tasks of a diagnostic radiologist. In addition, efforts like the 2018 National Institute of Health/Radiological Society of North America/American College of Radiology/National Academy of Medicine workshop on the roadmap for research on AI/ML in medical imaging are critical for setting priorities and building collaborative efforts among various stakeholders of radiology [26].

In the analysis of the distribution of represented medical specialties, it is interesting to note that pathology, another specialty that was expected to be impacted by the development of AI/ML algorithms along with radiology [27], only has one approved device. (We are aware of the recent approval of the second device in this category, Paige Prostate by Paige.AI, in September 2021; however, to keep our discussion consistent, we are excluding it from our analysis.) Although lacking value determination and reimbursement structures have been proposed as potential reasons for the slow adoption of digital pathology [3,28], it is beyond the scope of the current work to investigate the scientific or regulatory factors that contributed to the low number of pathology-related AI/ML devices. We hope future work will shed light on this curious area.

Lindsell et al. proposed that AI/ML algorithm development should be "about matching the algorithm to the problem, and not the other way" [29]. While our data is not suited to assess this criterion on the AI/ML-enabled devices, we performed a detailed analysis of the intended uses for radiology and cardiovascular devices. We showed that, of the 241 radiology-related devices, they were well balanced between those assisting diagnosis/triage (48%) and those for image processing and manipulation (52%). Of the 117 radiology devices approved for assisting diagnosis/triage, the most common indication was for breast lesion detection (21%), one of the most common anatomic sites for diagnostic imaging. Of the 41 cardiovascular devices, almost half (46%) were developed for arrhythmia detection on ECG, the most performed diagnostic procedure in cardiovascular medicine. Although rule-based algorithms to automatically interpret ECGs have existed for decades, the clinical adoption has been low due to poor accuracy; however, the application of deep learning for this purpose has significantly improved the accuracy [30].

4.4. Regulatory considerations

Due to the relative lenient regulatory process, 510(k) clearance is the most common pathway for medical devices in the US, with about 96% devices cleared under this mechanism [31]. Our cohort had a similar

proportion of 95%. However, when vendors try to market novel devices with no available predicate device for the 510(k) pathway, they would have to undergo the De Novo request process (Table 1). As shown in Section 3.1, of the newly created product codes from the 16 De Novo devices in this study, QAS gets used the most frequently by later 510(k) clearances, and most of these devices are designed for detecting intracranial hemorrhages (ICH). The underlying reason for the high number of devices under this product code is likely multifactorial: (1) with a high fatality rate if undetected, ICH is an emergent condition where a timely interpretation of the radiologic image is critical, hence there is a clinical need for rapid triage of scans, (2) deep learning has been shown to be an effective method for detecting ICHs, with reported area under the ROC curves ranging from 0.85 to 0.99 [32,33].

While this study is focused entirely on FDA-approved AI/ML devices, Muehlematter et al. compared the 222 FDA-approved devices in the US and 240 CE-marked devices in Europe [9]. One observation of interest was that, of the 124 devices commonly approved in both continents, the majority (80) were first approved in Europe, suggesting potentially relatively less rigorous evaluation in Europe. This could be a topic of interest for future investigations.

4.5. Strengths, limitations, and future directions

This study analyzed the characteristics and intended use of 343 AI/ML-enabled medical devices approved by the FDA as of June 2021. Compared to prior published studies on this topic so far [8–11], the list of devices included in this study is the most exhaustive and up-to-date, and our categorization on the intended use is the most detailed as we further investigated the categories and subcategories within the two most common medical specialties (radiology and cardiovascular) that constitute 82.3% of the approved devices. In addition, our data source is homogeneous because the list of the devices was compiled by the FDA and the analysis was based solely on the documents from the agency.

Our study has several limitations. First, our analysis was based entirely on the publicly available FDA approval letters for medical devices which were considered "AI/ML-enabled" by the agency. While the intent of this practice to ensure data consistency, many additional insightful information (such as details of the algorithms and their performance results) and devices approved after June 2021 could not be considered. Second, although FDA approval status allows commercial distribution, we cannot determine the actual levels of availability and clinical deployment in healthcare facilities, making it difficult to assess the real-world impact of AI/ML devices. Third, our analysis was limited to devices approved by the FDA, thereby reducing the generalizability of our conclusions.

To provide the general medical community and patients with fundamental information on the current landscape of this the approved AI/ML devices, we limited the scope of this study to an overall characterization of such devices without delving into details beyond the FDA documents. We hope this study could aid future investigations on more in-depth topics of interest. Potential future directions may include assessment of the clinical impacts made by AI/ML devices, optimal workflow integration for these devices, comparison of the AI/ML algorithms deployed in the devices, experience of the users (healthcare providers and/or patients) of these devices, etc.

5. Conclusion

Our results showed a rapid increase of FDA-approved AI/ML-enabled medical devices since the mid-2010s, most of which were class II devices cleared under the 510(k) pathway. Radiology and cardiovascular medicine are the two most represented medical specialties, and we provided an overview of the patterns of the devices' intended use. We hope future specialty-specific efforts will provide additional insight into the clinical impact AI/ML algorithms have made in the clinic.

6. Summary table

6.1. What was already known on this topic

- The development of AI/ML algorithms for healthcare applications has significantly grown in the past decade.
- Approval or clearance by the FDA is required for a medical device to be commercialized in the US.

6.2. What this study added to our knowledge

- Most of the AI/ML-enabled medical devices approved or cleared by the FDA are in the field of radiology and cardiovascular medicine.
- The number of AI/ML-enabled medical devices approved or cleared per year largely reflects the increase in research output.
- The indications for these devices generally reflect areas of clinical need.

Author contributions

S.Z. conceived of the presented idea. S.Z. and M.G. performed the data acquisition and analysis. I.C. and F.S. verified the analytical methods. S.Z. wrote the manuscript with support from M.G.. I.C. and F.S. supervised the project.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijmedinf.2022.104828.

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