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Current Status of FDA-Approved Medical Devices and Algorithms Based on Artificial Intelligence

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ABSTRACT: Since we are still in the beginning stages of this technological revolution, a lot of people are holding out hope that artificial intelligence and machine learning will improve medical diagnosis, management, and treatment when they are initially released. On the other hand, there are a lot of challenges that might prevent the use of machine learning and artificial intelligence in clinical settings, most notably in the field of AI regulation.

The Food and Drug Administration (FDA) of the United States has given its approval to a number of AI/ML-based medical devices and algorithms that are now available. As a result, we provide an overview of these products. By making it abundantly evident if a medical equipment is based on artificial intelligence or machine learning, our objective was to bring attention to the significance of regulatory agencies. After doing a thorough cross-check and validation of all approvals, we were able to identify sixty-four AI/ML-based medical devices and algorithms that have been authorized by the FDA. In the official notice made by the FDA, just 32 of those individuals included any terms relating to artificial intelligence or machine learning. Sixteen (17.56%) got de novo route clearance, while one (2.4%) gained premarket approval (PMA) clearance. The bulk of the substances were authorized by the FDA with a 623(k) clearance, which accounted for 85.9% of the total. These technologies were created for the fields of Radiology, Cardiology, and Internal Medicine/General Practice, respectively, with 42 (53.7%), 32 (34.2%), and 18 (22.5%) being the most notable examples. With the introduction of the first complete and open access database of medical solutions that are solely based on artificial intelligence and machine learning, we have received approval from the Food and Drug Administration. Ongoing updates will be made to the database whenever possible.

KEYWORDS: Drug Administration, premarket approval, artificial intelligence, machine learning

I. INTRODUCTION

The decade of the 2010s has seen an increase in the number of research and publications that have been written about the potential applications of artificial intelligence (AI) and machine learning (ML) in the field of medicine and healthcare (AI/ML). The number of articles in the field of life sciences that describe artificial intelligence and machine learning increased from 600 in the year 2010 to 13,500 in the year 2025. The expectations are high, and experts anticipate that AI/ML will show promise for diagnosing, managing, and treating a broad range of medical diseases yet we are only at the beginning of the age of artificial intelligence and machine learning.

The use of technologies that are based on artificial intelligence and machine learning has been shown to be beneficial to a variety of medical specializations, including radiology, cancer, ophthalmology, and general medical decision-making. It has been shown that machine learning models may, among other things, cut down on waiting times, enhance drug adherence, allow for the customization of insulin doses, and assist in the interpretation of magnetic resonance imaging.

Despite the fact that it has a great deal of potential, there are a great deal of challenges that must be overcome before AI and ML can be successfully used in clinical practice. For example, there are problems with the openness of these software programs, there is an inherent bias in the data that they are given, and there are concerns about how secure they are. In order to shape these hurdles, regulation of such technology is an essential component. Due to the fact that there have been various subtypes suggested for artificial intelligence, the very usage of the word AI has to be clarified further. Companies have a tendency to abuse the term artificial intelligence (AI) for the purpose of attracting more investments and improving their public image. However, in reality, they have built algorithms that are not based on AI or ML in and of themselves.

Current Status of FDA-Approved Medical Devices and Algorithms Based on Artificial Intelligence

In the United States, the Food and Drug Administration (FDA) and in Europe, the European Medicines Agency (EMA) have both been working to find a solution to the problem of how to manage and make use of artificial intelligence. This is due to the fact that research into the possible uses of artificial intelligence in the healthcare industry has shown a dramatic growth in both the number of projects that are using the technology and the number of firms that are creating software connected to it. We decided to utilize the Food and Drug Administration (FDA) as a case study because of the ground-breaking work that it has done in the deployment of medical technology that is based on artificial intelligence and machine learning (AI/ML). This work includes the development of a specific framework for AI/ML-based algorithms.

With regard to medical device licensing, the Food and Drug Administration (FDA) has severe regulatory standards due to the high-risk nature of these medical devices and the unknown effects of utilizing AI and ML for medical decision-making and data analysis. The developers of medical devices and algorithms that are based on artificial intelligence and machine learning are required to go through rigorous procedures that are both time and resource intensive. It is possible that this is the most significant obstacle that stands in the way of the use of AI and ML in the medical field.

The parent firm is required to submit the medical hardware or software to the Food and Drug Administration (FDA) for examination before it may be allowed to be sold lawfully in the United States market. The regulatory body offers three degrees of clearance for AI/ML-based algorithms that are geared toward medical applications. These levels are known as 623(k), premarket approval, and the de novo route. In order to be given all three levels of clearance, particular criteria must be met, as shown in Table 1.

Because of the severe regulatory criteria imposed by the FDA, the firms that are creating medical algorithms have significant obstacles when it comes to the development and marketing of these algorithms. In the past, the regulatory procedure was something that every new product had to go through. On the other hand, organizations are updating their algorithms in a much shorter amount of time,

Table 1. Details on the several forms that the Food and Drug Administration has given its stamp of approval to medical devices comprised of AI and ML.

Level of approval from the FDA	Detailed description
623 (k) authorization	When an algorithm is determined to be just as safe and effective as another, similarly advertised algorithm that is lawfully promoted, it is awarded a 623(k) clearance. In order to get this clearance, the submitter has to show that their work is substantially equivalent. You can't lawfully promote the algorithm that's seeking approval unless you can prove it's substantially comparable to the other algorithm.
Approval before sales begin	An application may be submitted for premarket approval of the algorithm associated with a Class III medical device Due to their significant potential effects on human health, the latter are subjected to more rigorous scientific and regulatory protocols to determine their effectiveness and safety. These procedures are rigorously designed to ensure their effectiveness and safety. Upon evaluating the application, the FDA will ascertain whether the device has enough scientific data to substantiate its safety and effectiveness. If so, they will provide permission. The applicant may proceed to market the product more widely upon approval.
route that is brand new	With regard to the de novo categorization, it is used for the purpose of categorizing those innovative medical devices that do not have any legally sold equivalents, but which provide appropriate safety and efficacy with general regulations. Before granting clearance and permitting the device to be sold on the market, the Food and Drug Administration (FDA) conducts a risk-based evaluation of the device in issue.

particularly recent days, the Food and Drug Administration has come to the realization that it may become difficult to continue with this approach. Accordingly, the Food and Drug Administration (FDA) began to contemplate the possibility of implementing "a total product lifecycle-based regulatory framework for these technologies." This framework would enable modifications to be made based on real-world learning and adaptation, while simultaneously guaranteeing that the software's safety and effectiveness as a medical device would be preserved.

A number of medical devices that make use of "locked" algorithms have been authorized or approved by the FDA up to this point. They define a "locked" algorithm as one that offers the same output each time the same input is applied to it and does not

change. This describes an algorithm that is considered to be "locked." However, many modern medical devices, particularly those that are based on artificial intelligence and machine learning, make use of algorithms that are capable of changing and adapting over time. The Food and Drug Administration (FDA) refers to these algorithms as adaptive algorithms, and the regulatory frameworks that are now in place were not meant to accommodate them. It is the potential of these AI/ML-based algorithms to continually learn that gives them their strength. Changes to the algorithm may not be discovered until after the device or software has been deployed for usage, and they might learn from experience in the real world.

A possible solution to this problem was suggested in the FDA's proposed regulatory framework for the year 2023, which "elaborates on a potential approach to premarket review for artificial intelligence and ML-driven software modifications." This framework was developed in an effort to address the problem. The Food and Drug Administration (FDA) acknowledges that these adaptive algorithms call for a regulatory strategy that encompasses the whole product lifecycle (TPLC), which enables a quick cycle of product innovation while also providing appropriate protections.

On the other hand, the FDA does not request that businesses label their technology as AI or ML-based, even if this is the case. In addition, some businesses make a point of mentioning that their technology is based on artificial intelligence and machine learning in the announcement of the FDA clearance or the particular machine learning approach that they used, while others do not. As we were working on this article ourselves, we were able to see this problem.

At the present, the review of the procedures for approval and implementation is complicated by a lack of clarity on the approval of AI/ML-based medical devices and algorithms. This is due to the fact that FDA releases do not explicitly identify the use of these technologies. Additionally, the search engine that is available on the website of the Food and Drug Administration (FDA) does not let users to conduct precise search queries inside FDA announcements and summaries, which makes the database much more difficult to access. It is reasonable to anticipate that regulatory organizations will offer a detailed description of such devices; they will also be responsible for the creation and maintenance of a detailed database that will enable appropriate search queries in order to evaluate the adoption of new approaches. All of these things have not been done by the FDA or any of the other regulatory authorities as of yet.

There are three goals that this paper intends to accomplish: (1) to provide an explanation of the artificial intelligence and machine learning-based medical devices and algorithms that are currently approved by the Food and Drug Administration (FDA); (2) to create a modern database of FDA approvals in this field that is open to submissions and has the potential to serve as the database that the FDA should keep; and (3) to raise awareness about the necessity for regulatory bodies to explicitly indicate whether a medical device makes use of AI/ML technology.

In order to accomplish this goal, we carried out an exhaustive search on the internet for announcements of FDA approvals of medical devices and algorithms that were based on artificial intelligence and machine learning. Following that, we performed a cross-check on each of these approvals on the FDA.gov website, which led to the creation of a database that is accessible to the general public and has the potential to be enlarged periodically.

To the best of our knowledge, this is the first complete library of medical technologies that are solely based on artificial intelligence and machine learning, and there are applications for these technologies across all medical disciplines. Additionally, we propose a set of criteria and a definition of what constitutes an artificial intelligence or machine learning-based medical device.

II. THE RESULT

Figure 1 is an infographic that provides a brief summary of the medical devices and algorithms that are being discussed. The online open access database provides a more in-depth review, along with following instructions to the formal notifications made by the FDA.

Radiology and cardiology are the two most prominent medical fields that have made significant advancements in AI and ML-based medical breakthroughs. Radiology has 25 (76.5%) and cardiology has 6 (20.3%) medical devices and algorithms that have been authorized by the FDA. Internal medicine and endocrinology, neurology, ophthalmology, emergency medicine, and cancer are the areas from which the remaining medical devices and algorithms may be categorized.

With the emergence of AI/ML-based solutions for globally applied image reading software, the area of radiology in the medical industry is the one that is setting the trends in terms of medical equipment and algorithms that have been authorized by the FDA. Consider the three algorithms that Artery's Inc. has developed: Artery's Cardio DL, Artery's Oncology DL, and Artery's MICA. These algorithms are examples

Table 2. AI/ML-based medicinal innovations that have been authorized by the FDA are included in this database.

	System or algorithm's name	System or algorithm's name	Briefly describe	The FDA's clearance type	Announcement includes algorithm mention	Medical specialty
1	Artery Cardiovascular DL	The Artery's Company, Inc.	Cardiovascular pictures from magnetic resonance imaging (MR) software	Premarket notice under section 623(k)	Learning at a Depth	X-ray
2	The EnsoNight	The company Enso Data, Inc.	Examining and diagnosing sleep disorders	Premarket notice under section 623(k)	algorithm that is automated	The field of neurology
3	Oncology of the Arteries, DL	The Artery's Company, Inc.	Application for medical diagnostic purposes	Premarket notice under section 623(k)	Learning at a Depth	X-ray
4	The idx	This is IDx LLC.	Examining and diagnosing sleep disorders	path in the de novo	Artificial Intelligence	The field of ophthalmology
5	This is ContaCT.	This is Viz.AI.	Detection of stroke by computed tomography	path in the de novo	Artificial Intelligence	X-ray
6	Peripheral imaging	Careful Medical, Inc.	Software for processing radiological images	Premarket notice under section 623(k)	Method based on deep neural networks	X-ray
7	Reconstruction of Images using Deep Learning	GE Healthcare Technologies, Inc.	Reconstruction of CT images	Premarket notice under section 623(k)	Learning at a Depth	X-ray
8	Intensive Care Unit	GE Healthcare Technologies, Inc.	Thorax evaluation using chest X-ray	Premarket notice under section 623(k)	Various algorithms for artificial intelligence	X-ray
9	The Software for Eko Analysis	The Company Behind Eko Devices, Inc.	Monitoring the Cardiac Pulse	Premarket notice under section 623(k)	Deep learning system	Cardiac medicine

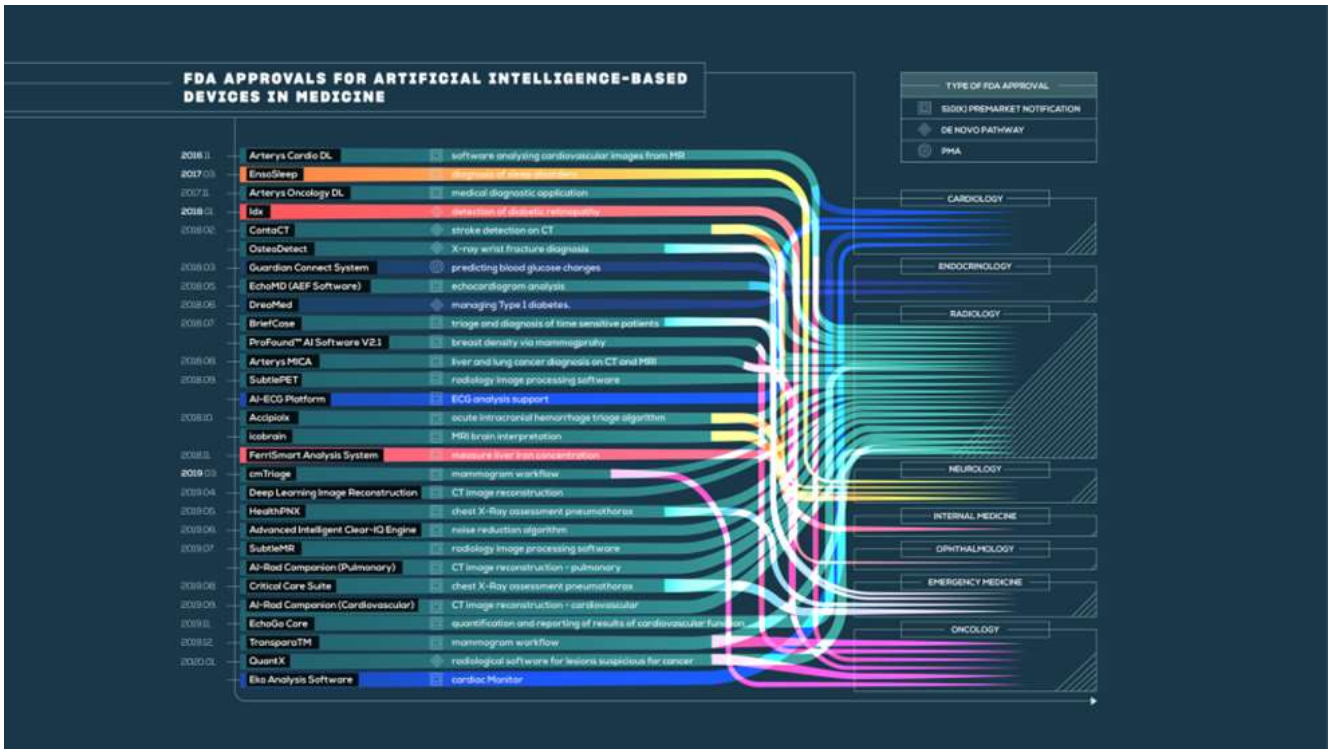

Fig. 1. A graphic depicting the nine medical innovations that rely on AI and ML that have been authorized by the FDA.

are a part of the process flow of picture archiving and communication systems offered by major suppliers including GE Healthcare (USA) and Siemens Healthineers AG (Germany). Cancer is one area where six out of fourteen algorithms may be used to. For mammography analysis, three algorithms are available: ProFoundTM AI Software V2.1, cmTriage, and TransparaTM. For CT-based lesion detection, three algorithms are available: Arterys cancer DL, Arterys MICA, and QuantX. Afterwards, two algorithms optimized for analyzing brain images are introduced. Among these algorithms, you may find improvements in the identification of stroke and bleeding using Accipiolx, icobrain, and ContaCT. With the goal of enhancing picture processing via the mitigation of radiation dose and noise, six algorithms are also included. Some of the algorithms included in this set include AI-Rad Companion (Pulmonary) and AI-Rad Companion (Cardiovascular), as well as SubtleMR, Deep Learning Image Reconstruction, SubtlePET, and Advanced Intelligent Clear-IQ Engine. Four other algorithms are dedicated to acute care; two of them, HealthPNX and Critical Care Suite, evaluate pneumothorax; OsteoDetect finds wrist fractures; and Aidoc Medical Briefcase triages chest, spine, and head injuries. These days, you may choose between two algorithms: EchoGo Core and EchoMD AEF Software (3)(4).

Heart exams, and the evaluation of cardiac ejection fraction in particular, may benefit from the application of both of these techniques.

Four algorithms and medical devices have been authorized by the FDA in the field of cardiology, which is another area that has seen significant breakthroughs. Advancements in the field of cardiac rhythm abnormality identification have received the lion's share of funding, with the AI-ECG Platform and Eko Analysis Software having received FDA clearance. The second method, Echo Go Core, and the third, EchoMD AEF software, both have applications in radiology.

Due to the large number of people affected by diabetes, it was crucial to find innovative ways to regulate blood glucose levels. The initial stages where the development of the Guardian Connect System by Medtronic and the DreaMed Diabetes system by DreaMed Diabetes etc. Additionally, the area of internal medicine has adopted an AI and ML-based system for interpreting test results. For this, we used the Ferri Smart Analysis System, developed by resonance health analysis service pty ltd, to find out how much iron was in my liver(5)(6).

Furthermore, the fields of neurology and radiology have a great deal of common ground in terms of certain pieces of equipment and algorithms. One of the many algorithms that share development with the Enso Sleep algorithm is its ability to diagnose sleep disorders.

It was with the release of Preventive's Body Guardian Remote Monitoring System that the first artificial intelligence and machine learning-based medical gadget was authorized by the Food and Drug Administration. In response to this, more expenditures were made in the development of innovations for the identification of anomalies in heart rhythm, which ultimately led to the creation of sixteen medical devices and algorithms for this purpose. The identification of cardiac murmurs is the primary emphasis of the other two algorithms in this field, which are referred to as eMurmer ID and CSD, respectively. The ECG App and

the Apple Irregular Rhythm Notification Feature are two algorithms that have been authorized by the FDA and are manufactured by Apple Inc., indicating that there is a clear indication of interest from international technology corporations.

The use of artificial intelligence and machine learning algorithms for the purpose of achieving quick interpretation of the most general values in medical care, which are the vital signs, was accomplished by Excel Medical Electronics, Spry Health, and Current Health. The Steth IO gadget, which analyzes heart and lung sounds, was developed by Stratoscientific, Inc. with the intention of providing more assistance to medical staff in general(6)(7).

Using two algorithms that are based on artificial intelligence and machine learning, BrainScope Company Inc. has launched AI/ML for the assessment of brain injuries. In the beginning, this business presented Ahead 100, which was an algorithm that was based on electroencephalography and was used to assess patients who had suffered a mild traumatic brain injury. There was additional development of this algorithm, which led to the release of BrainScope TBI. This algorithm is capable of being used for a wider range of traumatic brain injuries, ranging from structural damage (brain bleeds) to functional abnormalities (concussions). The gamified neurorehabilitation software known as MindMotion GO (MindMaze SA) is receiving further attention. This program was developed to assist in the rehabilitation of older individuals. This innovation improves functionality by using motion capture technology and an algorithm that is based on artificial intelligence and machine learning. The evaluation of memory loss in the elderly (Cantab Mobile, Cambridge Cognition Ltd.) and the monitoring of seizures (Embrace, Empatica Srl.) are two more areas of interest(8).

The medical discipline of psychiatry is in need of help based on artificial intelligence and machine learning since there is a high illness load and a scarcity of care providers. The diagnosis and classification of psychiatric problems are the primary focuses of research efforts, which are then followed by the subsequent development of treatment support systems. Two of these artificial intelligence and machine learning-based algorithms, namely QbCheck (QbTech AB) and ReSET-O (Pear Therapeutics Inc.), have reached the level of FDA clearance. Using QbCheck, medical professionals are able to provide evidence to support their diagnosis of attention deficit hyperactivity disorder (ADHD) or eliminate the possibility of the condition. This helps improve the quality of objective medical decisions in the field of psychiatry. On the other hand, ReSET-O can be utilized for patients who suffer from opioid use disorder. It is a mobile medical application that offers cognitive behavioral therapy for patients who are only prescribed the medication.

III. CONCLUSIONS

Considering that the era of artificial intelligence and machine learning is about to begin, it is of the utmost importance for the scientific and medical community to have a comprehensive understanding of which medical technologies are classified as AI and ML-based, as well as those that are regulated, in order to determine how these technologies may be incorporated into the arsenal that is utilized by medical professionals. As shown by our database, it is feasible to determine the criteria that must be met in order to classify a technology as being based on AI or ML. Furthermore, regulatory agencies are required to create their very own databases since this is a vital need.

There are several restrictions that apply to our method. Our goal was to determine the current status of medical devices that are based on artificial intelligence and machine learning, but we encountered three first barriers. Because businesses have a tendency to exaggerate the significance of their technology or just use the phrases artificial intelligence and machine learning in order to attract more investments, we decided to focus our attention only on regulated devices. The Food and Drug Administration (FDA) has shown leadership in the regulation of artificial intelligence and machine learning-based medical technology, and it has established rules about this topic. According to the assertions made in information sources that are open to the public, we were tasked with determining what should be regarded as an artificial intelligence or machine learning-based medical technology.

There is also the possibility that regulatory authorities may come up with a definition that is more specific on what really defines artificial intelligence and machine learning. Additionally, this would make it easier for developers, companies, researchers, journalists, and the general public to determine whether or not a system that has been certified is in fact based on artificial intelligence or machine learning. This would be a significant benefit.

Nevertheless, despite the fact that an increasing number of medical solutions that are based on artificial intelligence and machine learning are now available on the market, there is still the problem of putting those same ideas into practice. One of the challenges that may be connected to the difficulty of integrating these in medical practice is the presence of a number of impediments. Concerns about trusting new technology on the side of both patients and professionals are among these difficulties. Regulatory frameworks are another impediment.

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A paradigm shift is required in order to successfully deploy new technologies, especially those based on artificial intelligence and machine learning, in the healthcare industry. As was said before, important regulators play a critical role in the process of implementing these technologies.

It will become much more challenging to keep track of all the announcements that are pertinent when fresh approvals of medical technologies based on artificial intelligence and machine learning become accessible. It is our aim that this open-access database, which we have established and will continue to maintain, will prove to be a valuable resource for the scientific and medical community. It has the potential to serve as a reference for those who are working on software that is comparable to the one we have created, as well as for research reasons.

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