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ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN MEDICAL DEVICES: FDA REGULATORY PATHWAYS, TRENDS, AND THE CASE OF NEMOSCAN 510(K) CLEARANCE

Running title: AI/ML in Medical Devices: FDA Pathway and the NEMOSCAN 510K Case

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ABSTRACT

With the introduction of artificial intelligence (AI) and machine learning (ML) in medical device software, in particular software as a medical device (SaMD), healthcare continues to be reshaped. This review provides a historical overview of AI and the foundational principles of ML as well as the regulatory framework it currently undergoes to achieve all the medical devices enabled by AI/ML. It outlines 510(k), De Novo, and PMA regulatory pathways and recent efforts made to muster Good Machine Learning Practice (GMLP) on a global scale. The study also explores the tendencies of FDA approvals, especially in terms of device classification and manufacturer impact, as well as regulatory openness. Described in this case study is how the NemoScan (K232698) dental planning software has been brought to light as an example of practical FDA 510(k) clearance of the substantial equivalence. To ensure that upcoming technological changes and further use of AI/ML-based medical hardware turn out to be not only safe but also effective, the review culminates by mentioning disaster-based regulation and empirical data, as well as interdisciplinary collaboration.

INTRODUCTION

History Of Artificial Intelligence

Artificial intelligence (AI) is the history of fantasy fiction that turned to become a reality. Homer envisaged robot-like tripods that could serve gods, which were reflected in early AI thought. Philosophers such as Descartes were fascinated with the possibility of the creation of a so-called mechanical man, and Leibniz thought that problems that could only be solved by logic could be solved by machines, although he did not regard them as being able to think. The principles of logical computation were formed by Boole and Turing in 1847 and 1936, respectively, and the decision theory was objectified by Neumann and Morgenstern [1]. Artificial intelligence (AI) was initially characterized in 1950, but several drawbacks of early models did not allow its broad recognition and adaptation to medicine [2].

Artificial Intelligence

Artificial intelligence is a kind of computing that mainly addresses the transfer of humanlike intelligence and thinking into a machine that can help humans in numerous

ways. It includes such areas where machines can learn by themselves, adapt to a particular situation, and even rectify their own errors, i.e., machinery is able to think without being programmed [1].

Machine Learning

In machine learning (ML), there is this experiential type of learning also related to human intelligence, as well as the ability to learn and enhance analyses done through computational algorithms [3]. These algorithms are based on high volumes of both inputs and outputs of data, which the algorithm then analyzes to identify trends/patterns and thereby truly learns to train the machine to make recommendations or decisions independently. Once enough repetitions and adjustment of the algorithm take place, the machine is capable of processing an input as well as anticipating an output [4]. The outputs are then checked against a known body of results in order to evaluate the quality of the algorithm that is then fine-tuned iteratively until the ability to predict more outcomes is perfected [5].

In the United States, technological advancements in medical devices and equipment in the market must be able to meet the provisions of regulation. The three regulation technologies in particular that the Food and Drug Administration (FDA) applies in adopting the control of medical devices and marking them intelligently to be operational in the market involve Premarket Approval (PMA) [6], De Novo [7], and Premarket Notification 510(K) [8].

DE NOVO

Under the de novo grouping process, it was first created by the Congress under the Food and Drug Administration Modernization Act of 1997 (FDAMA) to promote the development of innovative medical peripherals and to set the gray area between 510(k) regulatory filing and a PMA application. Under the de novo classification process, it was first created by the Congress under the Food and Drug Administration Modernization Act of 1997 (FDAMA) to promote the development of innovative medical peripherals and to set an intermediate between a 510(k) submission and a PMA application. Through a successful de novo classification procedure, the new device is classified as either a class I or a class II device after undertaking a risk-based classification to determine whether general controls are all that is necessary to provide reasonable assurance that the device is safe and effective in the intended use (class I) or whether it is a combination of general and special controls that will result in reasonable assurance of safety and effectiveness (class II). They develop a new regulatory category (product code) to which a particular brand of medical device belongs that denotes the kind of controls that must be in place to prove safety and efficacy and where the new medical device is the initial predicate upon this new type of regulation, which may be filed as a predicate in future 510(k)s [9].

Premarket Approval

An FDA applicant has to take a premarket approval (PMA) to market a new or high-risk medical device. Approval will only come with adequate evidence that the device is safe and effective to be used for its intended purpose. PMAs often require clinical data, which in turn requires collection under an Investigational Device Exemption (IDE) that gives permission to use unapproved devices in trials. A PMA contains summaries of the clinical and nonclinical data, a description of a device, its intended use, a history of its marketing in the United States and abroad, proposed labeling, and manufacturing information. The production plant of a firm has to be examined so that its quality system

regulations are not defied and hence the acceptance of the production site [10].

510K

A 510(k) is an FDA premarket document that demonstrates that a device is as safe and effective as, or more properly, essentially the same as, a legally marketed device under section 513(i)(1)(A) of the FD&C Act. The company whose submission was submitted (the person submitting the submission) is supposed to compare its device with one or more legally marketed comparable devices and state and prove their substantial equivalence. A device that is lawfully marketed This gadget is not exempted under the 510(k) procedure; however, it was authorized to be destined by the De Novo classification course that was in the section 513(f)(2) (2) of the FD&C Act. It was also repackaged as a Class II or Class I device, or it was ascertained that it was SE in accordance with the 510(k) procedure. All of them were legal devices marketed prior to May 28, 1976. The gadget or gadgets on which the equivalence is wrung is normally the one that is advertised by the law. These are generally termed the predicate. Any device that is already approved to be sold can serve as a predicate, although more modern devices, which already have 510(k) clearance, are likely to be used as the starting point of an equivalence claim. To be marketed legally also means that the predicate is not one of the ones that contravene the FD&C Act. Before the submitter is allowed to take the gadget to the market, he/she must possess an order indicating that a certain device is SE. Once an SE has been found, the gadget can be registered in the United States. According to the data given by the submitter, SE determination usually takes 90 days [11].

Software as a medical device

Over the last few years some software used in medicine has been a medical device, referred to as software as a medical device (SaMD). SaMD refers to software that is used on its own to medically benefit without reference to hardware medical equipment. Software as a Medical Device in medicine (software), abbreviated SaMD, is software designed to be used medically but not as a hardware medical device. Gerke et al. (2020) offer a specific challenge related to the development of AI and machine learning (ML) in SaMD: the fact that such tools typically intervene in the already complex systems of care and interact dynamically with human beings. The U.S. FDA is only authorizing the usage of locked algorithms, i.e., algorithms that do not evolve with time, whereas adaptive algorithms, which can learn in the presence of new information, are still hard to control by the regulator because of the issues of safety and performance variability. The authors promote the idea that the traditional product-based regulatory approach cannot address retrained AI/ML-based SaMD and the need to switch to the system-level regulation, taking into account human factors, clinical environment, integration into the workflow, and ongoing performance supervision. They stress that real-world efficiency of SaMD is affected not only by the fact that the software works accurately but also by this particular implementation and application to practice, emphasizing the importance of the more extensive and dynamic regulatory framework, which could guarantee safety and performance in various healthcare environments [12].

Successful Machine Learning Methods to develop Medical Devices

The U.S. FDA, Health Canada, and the MHRA in the UK published ten principles to sustain the needs of Good Machine Learning Practice (GMLP) for medical gadgets consisting of artificial intelligence

(AI)/machine learning. These principles are intended to guarantee both safety and effectiveness and quality of such devices as well as to overcome the complex, iterative, and data-driven nature of these types of devices. They would serve as a basis on which the best practices would be developed, the innovation advocated, and would be used to shape future cooperation with the international authorities such as the IMDRF. The principles promote borrowing of best practices from other industries and adapting them to healthcare and the development of new ones exclusively applicable to medical technology. With the evolution of the AI/ML sector, GMLP is expected to follow, with the help of the international collaborations in ensuring the establishment of responsible innovation and regulatory alignment [13].

Guiding Principles

1. The total product has multi-disciplinary experience.

2. The security and software engineering are addressed prudently.

3. There is Representation of Data Sets and Clinical Study Population Information to the target population of the patients.

4. They do not overlap; the training set of data and test data are independent.

5. The choice of the reference datasets is accomplished by the consideration of the best available techniques.

6. The available data applies to the designing of a model, which provides what the machine is to be used on.

7. The attention is given to the efficacy of the human-AI team.

8. The performance of the device can be achieved with the help of the generation of evidence, which is carried out by testing the device in technically realistic conditions.

9. All the information presented in front of the users is understandable and is long overdue.

10. The retraining risks are controlled, and trained models are monitored in terms of their performance.

Preset Machine Learning-Enabled Medical Devices Change Control Plans

In 2021, the U.S. FDA, Health Canada, and the MHRA in the U.K. listed 10 guiding principles that should be used to guide Good Machine Learning Practice (GMLP) to work towards safe, effective, and high-quality AI/ML technologies capable of learning through use of the real world. Following GMLP, especially its principle 10, which highlights such factors as model monitoring and reinstatement risk management, they also came out with 5 principles that would guide the use of Predetermined Change Control Plans (PCCPs). The principles assist in dealing with modifications to the machine learning-enabled medical devices (MLMDs) to help in dealing with concerns about the safety and effectiveness of device solutions during the total product life cycle. Manufacturers propose PCCPs, which describe certain planned modifications, implementation procedures, and evaluation of effects. They facilitate in synchronizing the regulatory procedures with the speed of innovation of MLMD, facilitate risk management in time, and retain standards of regulation. Minefield (2017) quotes this in his document [14].

Guiding Principle

Specific and Limited

A PCCP describes particular, limited differences in the original usage statement of a medical device. It also covers the extent of

modification, safety strategy, measures to verify the changes, and measures to identify or undo undesired modifications.

Risk-Based

A PCCP should be designed and implemented on a risk management basis. This provides that both the cumulative and individual changes are suitable all through the lifecycle of the device.

Evidence-Based

Safety and effectiveness should be supported before and after the changes. The measurement and measurement practices applied must be scientific and relative to the risk.

Transparent

The status and performance of the device across the change are explained to the stakeholders in an effective way due to clear documentation and communication. The latter are data sources, testing results, and performance monitoring.

Total Lifecycle Product (TPLC) Perspective

A TPLC method enhances the quality of a PCCP by incorporating regulatory, quality, and risk management processes in the whole lifecycle of the device that ensure continuous safety and multi-sector involvement.

Transparency of Machine Learning-based Medical Devices

In 2021, jointly with the U.S. FDA and the UK MHRA, Health Canada also announced 10 Good Machine Learning Practice (GMLP) principles to inform the development of safe, effective, and high-quality AI/ML technologies. These principles assist in the ability of the devices to learn during the actual use of the devices and become improved in performance as time lapses. Based on GMLP,

Other transparency rules set up by the authorities include the following: give human-AI team performance the first priority (Principle 7), and offer users the necessary information in an understandable form (Principle 9).

Transparency sees to it that the fans are furnished with the proper use of information on an MLMD, its development, performance, and the reason behind it. Explainability refers to the well-being of which consumers are able to grasp the reasoning behind the description given in constructing the outputs or process of making a decision. Effective transparency: Transmittal of information in relation to risk and with the outcome involved,

• Takes into account the environment and needs of the targeted users,

• Applies the right media, timing, and strategies,

•Demands profound knowledge about users, settings, and processes.

Human-centered design helps to facilitate transparency, including those who are contractors to the development processes, due to its attention to the complete user experience. It assists in creation, affirmation, and making sure that the users are notified of all the important data concerned with the device.

Principles of transparency overview

Who: Target Audience Pyramid of Transparency

All the parties involved in the care of patients are supposed to be transparent.

The people using the machine (medical experts, etc.), The patients whom the device

applies in providing care, Leaders who judge and sustain patient performance

Why: Reasons to be Transparent

Transparency supports:

Safe and effective utilization of MLMDs, Center-directed care, the device risk analysis and review of benefit, Maintenance of the devices and prompt diagnosis of error or performance drop, Health equity via identification of bias Accordingly, health equity involves the identification of bias.

Greater user confidence and expanded MLMD technologies

What: pertinent Information to Post

To perceive an MLMD, it is important to share the extensive amount of information, such as

Device characterization and intended use, How the device integrates into clinical workflows, Clinical benefits and risks and performance metrics, Lifecycle risk management and capability Product development, The explanation of the logic of the model where possible (explainability), Limits, bias, confidence range, and data gaps of known nature, The safety and effectiveness preservation during the usage How safety and effectiveness are maintained throughout use

Where: Information Locations

Communication is made successful through the process of utilization of software interface to:

Give responsive and interactive information, bring personalization and flexibility of content, Provide information in various modes according to the requirement of the user.

When: When to Communicate

Identification of transparency in the product lifecycle should be held.

Supplying information according to various use phases, informing users on changes or updates of devices, Provision of selected information at the time of care or choice making

How: How to Assist Transparency

Human-centered design comes in handy by

Engaging users in an early design and development phase, having clear, easy-to-access, and act on information via the interface, enhancing constant communication and response to enhance knowledge [15].

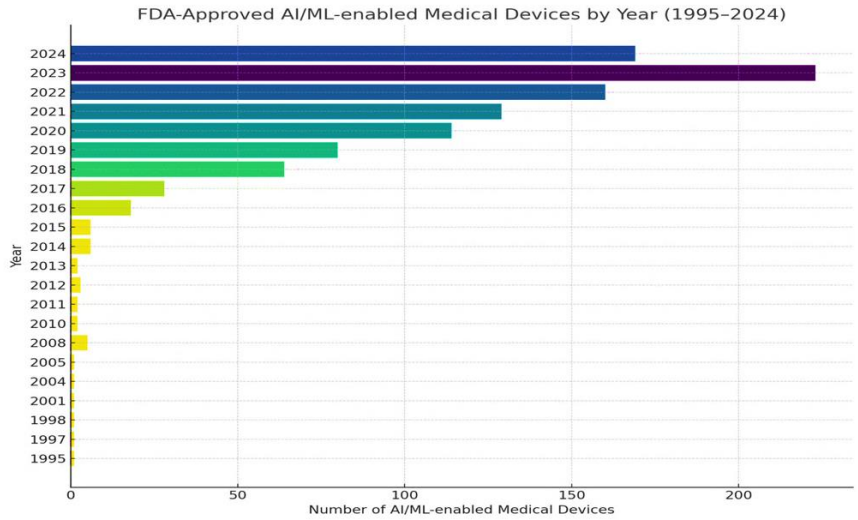
Materials and Methods

The review was founded on an extensive synthesis of existing regulatory literature and guidelines conferred by the FDA (Food and Drug Administration), publications that have undergone peer review, and official databases, such as the FDA Medical Device Databases. This report has been written based on qualitative data presented by U.S. FDA news (up to date as of March 25, 2025) and quantitative data on trends in the approval of devices, distribution by medical subspecialty, and regulatory pathways. The figures, charts, and classification data are taken based on the publicly available repositories that are considered within the FDA and then analyzed to have an idea of the trends of device approvals for various clinical applications. Further, the summary of 510(k) of NemoScan (K232698) was studied line by line, being an example of medical software that was cleared using the substantial equivalence criterion. FDA guidance documents, Health Canada, and MHRA guidance documents, including GMLP principles and PCCP frameworks, were critically reviewed in order to draw conclusions as to where guidance on adaptive algorithms may potentially go in the future.

RESULT

overall trends

As of the last update by March 25, 2025, the FDA has a list of 1,016 AI/ML-enabled medical devices, of which 169 (or c. 16.6%) are approved in 2024 (Graph 1). This trend in the figures of the number of approvals received per year has been causing great interest in the year 2016, and since then there has been an increment in the number of approved devices per year. Based on the current statistics, 223 of AI/ML-powered medical device approvals were done in a single year in 2023, which is the highest rate of approvals of AI/ML-powered medical devices permitted at the given period. Parkinson: The initial approved tool is the PAPNET Testing System, and it is an AI/ML-based medical device, and its approval was the 1995 Premarket Approval (PMA) tool, and it was associated with the pathology specialized area.

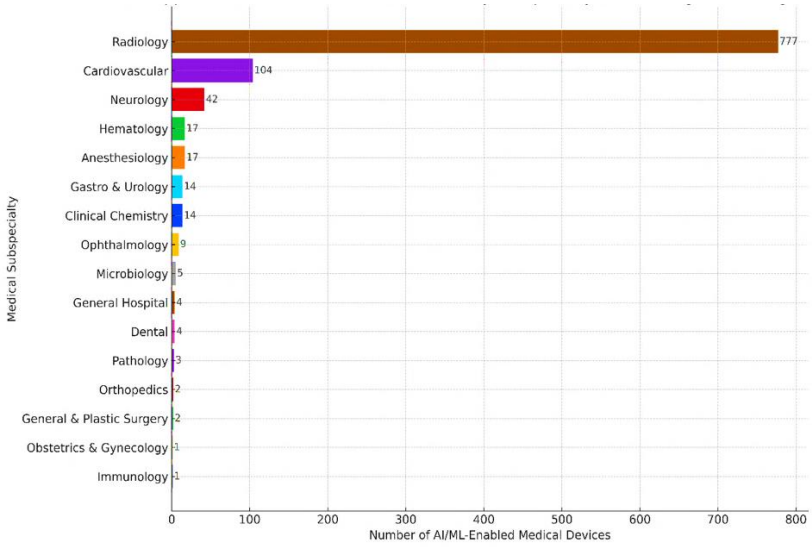


Graph 1: The outburst of the usage of technology in health care is mirrored in a diagrammatic representation of annual statistics of the FDA-approved AI/ML-based medical devices.

Medical Subspeciality

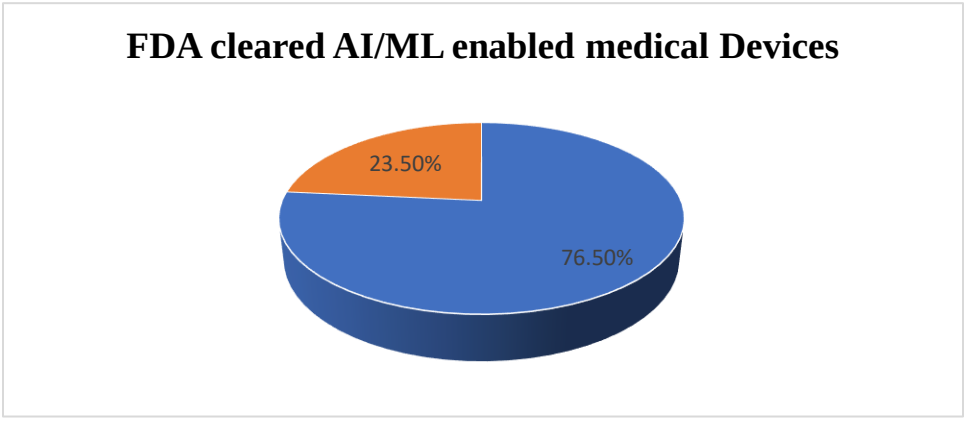
Its medicine is approved by the FDA to use in a great number of subspecialties of medicine with the use of AI/ML-enabled devices (Graph 2a, b). The other fact one can learn concerning these data is that the majority of them, i.e., 777 devices (roughly 76.5%), are of the subspecialty of radiology. Radiology received the highest number of submissions and showed the steady increase in the approvals of AI/ML-enabled devices in absolute terms across all areas. Thereafter, there are 104 devices, which are of the specialization of cardiovascular medicine (approximately 10.2 percent); 42 devices, which are of neurology specialization (approximately 4.1 percent); and 17 of hematology specialization (approximately 1.7 percent). Other medical subspecialties include anesthesiology (17 devices, 1.7 percent), gastroenterology and urology (14 devices, 1.4 percent), ophthalmology (9 devices, 0.9 percent), clinical chemistry (14 devices, 1.4 percent), microbiology (5 devices, 0.5 percent), general and plastic surgery (2 devices, 0.2 percent), pathology (3 devices, 0.3 percent), general hospital (4

devices, 0.4 percent), dentistry (4 devices, 0.4 percent), and immunology (1).



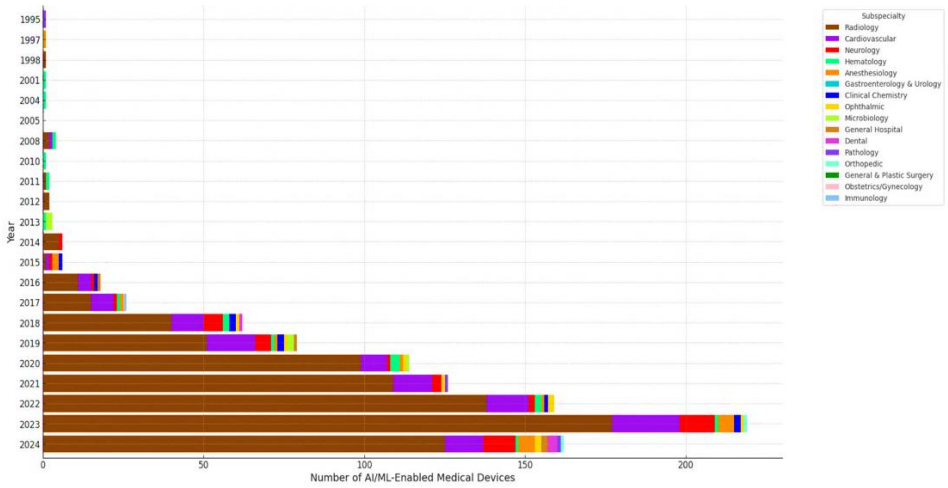
(a)

Graph 2a: Bar graph with the number of approved devices by the medical panel, with a focus on the increased usage of AI/ML in various fields of medicine



(b)

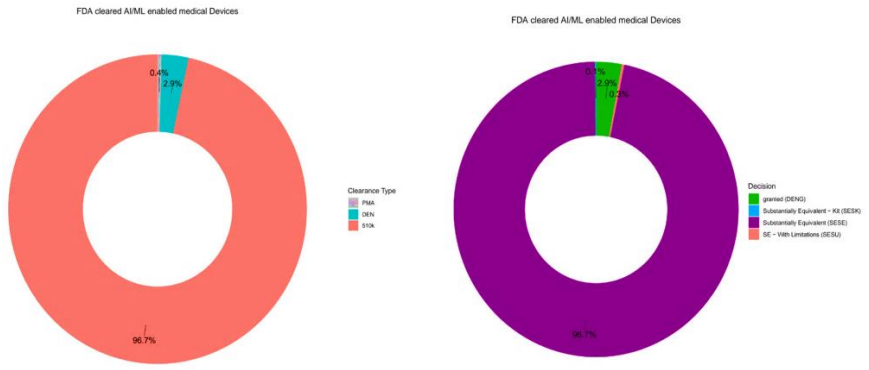
Graph 2b: The significance of the innovative quality of the field of focus is presented in a donut plot that highlights the immense prevalence of radiology in the quantity of AI/ML-enabled device approvals by the regulatory and moderation bodies in the field in comparison with the other medical specialties.



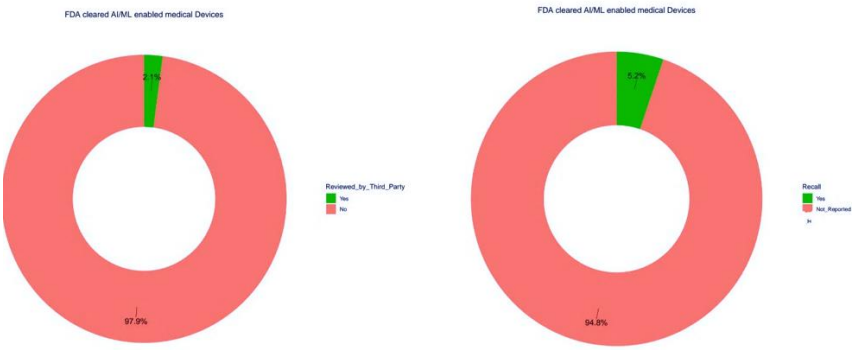
Graph 3: Graph showing the trend of the number of approvals given over the years to different medical panels, indicating the dynamic nature of such fields and the research and development focus of conducting such operations.

Recall Rate, Clearance Pathway, Decision type

So far, on March 25, 2025, 96.7 percent of all approved AI/ML-enabled devices were subjected to the FDA section 510(k) pathway. Most of them were cleared using the de novo clearance (2.9%) and the premarket approval (approximately 0.4% of the total approvals) of the equipment (Donut chart 4a). At the same time, though the main task of the FDA, being the protection of the population, is to ensure that the innovative medical objects used are not only harmless but effective, the permission to use such devices is given primarily based on the similarity to the predecessors of a similar character. The biggest proportion of the proportion of the approved devices based on the use of AI/ML was Substantial Equivalence (SESE), and the remainder of the decisions (Donut chart 4b). Similarly, only 3 percent (Donut chart 4c) of the certified devices go through the third-party examination. In some instances, approximately 5 percent (Donut chart 4d) of the AI/ML-associated health devices have been recalled by the FDA because of a variety of reasons.



(a) (b)

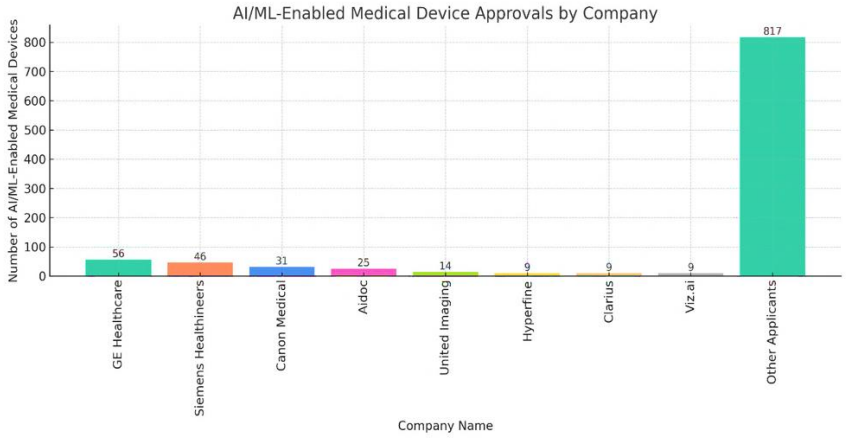


(c) (d)

Graph representing the clearance type of the AI/ML-enabled medical devices with the majority contribution by the 510(k), followed by the De Novo and PMA approvals; (b) the percentage of decision type of the approved medical devices with AI/ML, revealing high dependency on the Substantial Equivalence (SESE) consideration approach; (c) graph displaying the level of involvement of 3rd-party reviews to consider the decision regarding the approval of the AI/ML-enabled medical devices, which gives insight into how frequently external expertise is sought to make regulatory decisions; (d) graph representing the recall.

Applicant company

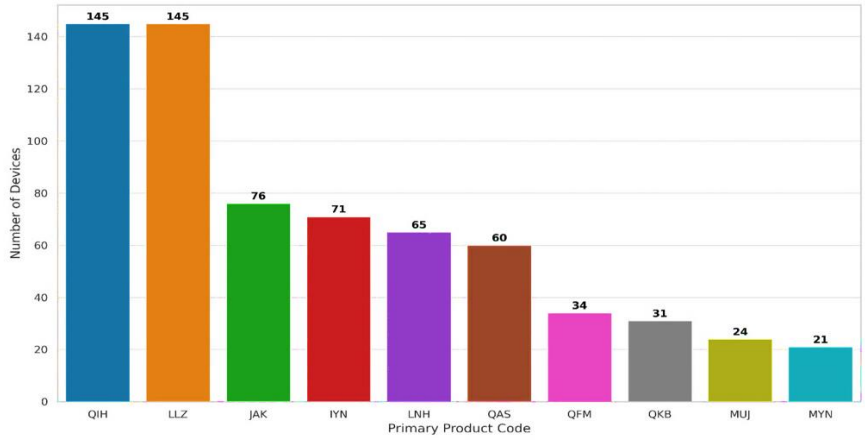
Some of the firms working on AI/ML-enabled medical devices cleared by the FDA include GE Healthcare, with 51 approvals after all the GE Medical System companies were merged under a single name. A close follower is Siemens Healthineers with 46 approvals and thus proves to play a large role in relation to AI in imaging and diagnosis. Canon Medical and Aidoc hold 31 and 25 approvals, respectively, and United Imaging brings up 14 approvals. Startup companies like Clarius, Viz.ai, or Hyperfine are also becoming a dominant force in the AI healthcare industry in terms of acquisitions, with 9 such approvals each. In addition to these top contributors, there are other applicants whose approval numbers are substantial, with a total number of 817 approvals, thus highlighting the industry-wide application of AI/ML technologies and their collaborative improvement within the medical device sector as well (Graph 5).



Graph 5: The top applications for AI/ML-enabled medical devices are shown in a bar chart, highlighting the companies actively advancing healthcare technology.

Devices categorization

Most common classes of which the FDA has approved and registered, which may be treated as an example, are offered according to the primary product code. These also entail computed tomography, computer-assisted triage and notification software, nuclear magnetic resonance imaging, radiological image processing, and radiological image processing software (Graph 6).



Graph 6: Bar plot of how many approved devices have been divided by their main product codes, which would show which sorts of technologies and innovations have been approved the most and which technological types have been cleared by the FDA.

NemoScan (K232698), a Web-Based Dental Implant Planning Software that are FDA 510(k) Cleared

Indications to Use

NemoScan is a dental implant and surgery planning program to be used by licensed dental personnel. It analyzes the imaging image (CBCT or CT) to predict and assess the patient's anatomy, placement of implants, position of instruments, and treatment possibilities in edentulous, partially edentulous, and dentate patients. It facilitates the design and export of surgically guided

designs to proven manufacturing facilities or point-of-care environments with validated CAM manufacturing processes and materials. The software is to be used in patients aged 12 years and older.

510k Summary

Date of Summary: 01/16/2024

The applicant/sponsor was Software Nemotec S.L., Av. Juan Caramuel, 1 28919 Legan, Madrid, Spain.

Person to Contact: Kevin Walls | Telephone: 1-720-962-5412 | email: kevin@reginsight.com

Device Information:

•TNC: NemoScan

• Common Name: Image Processing, Radiological System

• Class of device: Class II

• Product code: QIH

• Reg Regulation Number: 21 CFR 892.2050

• Name of classification: Medical image management and image processing system

Reference and Predicate Gadgets:

Primary Predicate Device: coDiagnostiX Implant Planning Software (K130724)

NemoScan (K192571): device of reference

The factors of use:

NemoScan is an oral applications software to support the design of dental implants and surgical procedures in an oral practitioner, and it is employed in dental practices to simulate and examine the craniomaxillofacial anatomy, site placement of the dental implants, site placement of surgical instruments, and surgical treatment planning in the situation of edentulous, partially edentulous, or dentition. It enables making surgical guides so as to direct implant formation, review, and design. Orders may be exported to vetted manufacturing facilities or can be done at the bedside on vetted and approved CAM processes on sterilizable and biocompatible materials. An indication of NemoScan is a prescription under the age of 12 years.

Device Description:

NemoScan is a dental implantology software, which is used in planning and diagnosis and is based on some DICOM data produced by a CT/CBCT scan and digitalization of a dental impression (in STL and PLY format). It is available in desktop, cloud, and web-based forms, and several surgical plan propositions may be carried out on an individual patient. Among the significant features, one may distinguish

- Importation of DICOM images and 3-dimensional (OBJ, PLY, STL)
- Putting together optical impression and CT/CBCT
- Slicing the anatomical objects (teeth, gums, bones, nerves, sinuses)
- Simulation Tooth removal
- Bone densitometry 3d
- Real-time anatomical measurements
- Designing of prosthesis and implants—virtual
- STL Format of its surgical guide exported

The machine does not handle the patient and the life-sustaining machines. This must come into being through fabrication, which will be executed through the process that is recommended by the FDA. This ability of the 3D manufacturing is neither regulated by the NemoScan software nor the issue of the user.

Substantial Equivalence:

NemoScan has the same general intended purpose as the predicate (K130724) and adds to it a web interface instead of a desktop. The two systems read slices of a CT scan and computerize implant planning and surgical guide design based on patient imaging data, implants, and the production of planning reports.

Distinctions of Predicate:

- NemoScan contains the design of the prostheses through the reference device through the prosthesis wizard.
- It is not based on the DWOS Synergy interface or gonyX manufacturing workflow (as is coDiagnostiX).
- NemoScan aims at the young adult and adult population, which is a portion of the general population.

Functionalities of Reference Device:

Features NemoScan (K192571) introduced included

- Immediate loading prosthesis
- Mesh transformation
- Photo mapping (and import of 3D photographs) (not medical application)

Performance Testing:

NemoScan (K232698) includes a report in which the performance testing of the product, software as medical equipment, is performed; all K192571 lacked performance testing of this type. The use of supporting peer-reviewed literature was used to prove safety and effectiveness in performing a risk assessment according to FDA guidance.

Non-Clinical Performance Data:

Process performance qualification (PPQ) was used to verify safe and successful production of surgical guides with a worst-case testing of representative designs. The procedure of centralized and point-of-care, as well as the materials and manufacturing processes, were all validated to be safe and effective to use as per the intended procedure.

Technological Characteristic comparison

The subject and predicate device is a planning and transfer tool that contains software with the possibility of transferring medical images and the design of 3D guides.

SUBJECT DEVICE—NemoScan

PREDICATE DEVICE 2—coDiagnostiX, Implant Planning Software (K130724)

REFERENCE DEVICE—NemoScan, Software Nemotec S.L., (K192571)

Inferences of nonclinical and clinical tests

The image treatment functions (e.g., crop, edit, calibrate) are only utilized on input images or photos and do not significantly meet the requirements of patients. All these features do not affect the safety or efficiency of the machine. Equally, the exporting tools, such as Analog Model, Virtual Pour-Up, and Model Builder, are not patient-facing and can also be used to export physical 3D models in order to perform inspection, thereby not influencing the safety or the functionality of the devices. The indications of subject and predicate devices are identical apart from trivial differences in wording. The differences between the devices in terms of functional and technical specifications are few, and they have no significant effect by way of safety or performance, and hence they are substantial equivalents.

Discussion

Based on our practice since 1995, when the first AI/ML-enabled medical device received authorization, there is an increasing trend in the number of FDA-approved AI/ML-powered medical devices in the US, which has an approximate volume. Since 2018, the process of authorization of these devices has

been characterized by a significant increase, as 90 percent of all authorizations relate to them at present. This increase in the approval trend could be attributed to the general conversions in the computing industry, which involved venturing into the hardware and software realms, the low cost of cloud-driven storage systems, the existence of huge stores of data, and huge investments that were placed in this industry by massive companies to come up with more advanced systems [16,17].

Radiology is the most relevant specialty when considering the involvement of the AI/ML-enabled device in use. It has also been explained by the fact that radiological imaging has become endemic to any typical clinical study and follow-up patient examination, PhD, in the generation of huge volumes of information. These data banks are invaluable, and in this way, a large-scale research project can be conducted by the researchers, and in addition, a powerful foundation can also be created to enhance the medical equipment made by manufacturers not only by innovators but also to better medical equipment [18].

The majority of AI/ML-enabled medical products received FDA approval through the 510(k) program; their certification system is based on the possibility of proving that the experts will have a sufficient degree of similarity about the product in question, where such similarity necessarily includes the lack of the need to undergo large clinical investigation. But it is quite shocking to state that of the total number of the approved devices, less than 3 percent of the total number of devices have been recorded to have carried out clinical trials, and the focus area concentrated more on the adults. The device out of them, and that is a breast imaging system, was the one that had the highest numbers of the participants under clinical trials. The full range of PIONEER-01 exploration involved a total of 16 various locations all around the territory of the United States. The reason why the number of people participating in this trial is small rests on the fact that the ratio of breast cancer was high in the U.S. because breast cancer is the second leading cancer of women, besides the fact that the Centers for Disease Control and Prevention (CDC) had made another emphasis on having cancer surveillance. Reports of clinical trials, on the other hand, are either not comprehensive or not available elsewhere on AI/ML-supported.

Moreover, the geographical scope of such clinical trials can be attributed to a pretty narrow range because this territory is limited by the territory of the U.S. Such a restriction would prevail in the broad nature of heterogeneity that the world samples constitute in the matter of clinical testing. Subsequent clinical trials will have to widen in terms of demographics and geography to reflect a more representative global population, including underrepresented communities, in the attempt to address disparities and the development of AI/ML-based medical devices in the medical specialties that are plateauing.

This is work that is solely based on the statistics that are available on the FDA, and hence this is accompanied by limitations. The FDA's list of AI/ML-enabled devices, which is updated through March 25, 2025, is not all-inclusive because it excludes medical devices that are not yet FDA-approved, medical devices that are in the FDA approval phase, and medical devices that are not classified as AI/ML-based. Furthermore, the FDA makes it clear that summaries can be as concise as feasible for the general public and that applicants are heavily relied upon to provide summaries because they might not be able to depict the big picture. Other regulatory agencies that have accredited, certified, or approved AI/ML-enabled devices besides the United States include the Pharmaceuticals

and Medical Devices Agency (PMDA) of Japan, the Central Drugs Standard Control Organization (CDSCO) of India, the National Medical Products Administration (NMPA) of China, and EU agencies that are not decentralized and privately accredited by the CE marking.

Despite that, this paper will provide an in-depth consideration of the market of AI/ML-based medical devices, including its trends, possible research gaps, possible future research areas, clinical trial logistics, and regulatory strategies. This discussion can be used to initiate the other topics on the possibility of clinical trial variations, FDA regulation of medical devices, and ethics of dealing with AI technologies.

Today, artificial intelligence (AI) and machine learning (ML)-based applications in the field of healthcare give rise to a wide range of ethical concerns, which include privacy/data protection and safety, the potential to reproduce biases, explainability and transparency of AI algorithms, and patient autonomy and consent. They are even aggravated by poor data availability, drift of data, inclusivity, the need to retrain, and even regulatory challenges to adapt to the technological environments. Furthermore, the safety and medical verification of the suggested AI devices to prevent misdiagnosis and inappropriate treatment and equality and inequality of access to AI services in the clinical practice also have to contribute to the prevention of the further aggravation of health inequalities. This is the reason why a balanced solution is needed to utilize the benefits of the AI and address the problems of the AI in terms of the healthcare industry.

One of the trends of the closest future, which will transform the healthcare market, namely, through large language models (LLMs), is artificial intelligence. The said transformation will enhance the experience of medical practitioners and patients due to reduced health disparities, the delivery of relevant outcomes, resource maximization, and an understandable interpretation of the AI decisions made due to XAI [19].

Conclusion

The use of AI and ML technologies in the sphere of health is showing its potential to transform the industry, and this is being accomplished via diagnostic tools, planning, triaging, and many more instruments. Our old and new software-based devices have been modified by the traditional regulatory authorities such as the FDA with their procedures or processes: 510(k), De Novo, and PMA. The fact that the vast majority (96.7%) of approvals are in the form of the 510(k) pathway indicates that the significance of substantial equivalence extends to AI/ML-enabled devices. Problems of controlling adaptive and constantly learning systems still remain despite the fact that the levels of regulation have been enhanced. It is possible to see the programs like GMLP and PCCPs as a step in the right direction to greater use of cyclical process-based supervision. As in the case with NemoScan, it can be seen that regulatory clearance can be achieved in sophisticated yet non-invasive planning software with the close consideration given to validation, risk assessment, and the equivalence to any predicate. The safety, efficacy, and transparency will be upheld in the form of evidence-based, convergent, and humanistic regulatory patterns as the AI technologies gain increased integration in medical practice.

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Conflict of Interest

The authors declare no conflict of interest related to this publication.

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