Data-Driven Analysis of AI in Medical Device Software in China: Deep Learning and General AI Trends Based on Regulatory Data

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Abstract

Artificial intelligence (AI) in medical device software (MDSW) represents a transformative clinical technology, attracting increasing attention within both the medical community and the regulators. In this study, we leverage a data-driven approach to automatically extract and analyze AI-enabled medical devices (AIMD) from the National Medical Products Administration (NMPA) regulatory database. The continued increase in publicly available regulatory data requires scalable methods for analysis. Automation of regulatory information screening is essential to create reproducible insights that can be quickly updated in an ever changing medical device landscape. More than 4 million entries were assessed, identifying 2,174 MDSW registrations, including 531 standalone applications and 1,643 integrated within medical devices, of which 43 were AI-enabled. It was shown that the leading medical specialties utilizing AIMD include respiratory (20.5%), ophthalmology/endocrinology (12.8%), and orthopedics (10.3%). This approach greatly improves the speed of data extracting providing a greater ability to compare and contrast. This study provides the first extensive, data-driven exploration of AIMD in China, showcasing the potential of automated regulatory data analysis in understanding and advancing the landscape of AI in medical technology.

Keywords— software, data, Software as a Medical Device (SaMD), Software in a medical device (SiMD), AI-in-medical-device (AIMD), regulatory affairs, regulatory science

1 China's New Generation Artificial Intelligence Development Plan and Effect to Medical Devices

In 2017, China' s State Council released its *New Generation Artificial Intelligence Development Plan*, which set forth a strategic roadmap aimed at positioning the country as a global leader in artificial intelligence (AI) technologies.[1] Within the medical devices sector, China has emerged as a significant global producer and consumer, leveraging its large-scale manufacturing capabilities and distribution networks.[2] Given the country' s population of 1.41 billion in 2023, the demand for advanced medical technology is substantial.[3] The Chinese medical device market, valued at ¥629 billion RMB (approximately $88.7 billion USD) in 2019, more than doubled from ¥308 billion RMB in 2015.[4] China's long-term strategy

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Date of Publication	Regulatory Document
08/2015	Guidelines of medical device software registration and review[7]
07/2019	Key Points of Deep Learning Decision-making Assisting Medical Device Software review[8]
07/2021	Guidelines for the classification and designation of artificial intelligence medical software[9]
03/2022	Guidelines of medical device software registration and review[10]
08/2022	Guidelines for the classification and designation of artificial intelligence medical software[11]

Table 1: Chinese regulatory documents for medical device software

emphasizes the integration of AI and machine learning into medical domain, with the goal of enhancing clinical support through improved diagnostics and intervention management.[5] In line with this vision, the National Medical Products Administration (NMPA), China's regulatory authority for medical products, has enacted several regulations to support the development and oversight of AI-driven medical devices. Table 1 summarizes key regulatory documents issued by the NMPA in relation to AI-based medical device software.[6] The NMPA's first relevant guidance was issued in 2015, with a more comprehensive regulatory framework established in 2022. These regulations reference a range of national standards, including those governing software risk classification (YY/T 0664-2008), software engineering practices (GB/T 19003-2008), and medical device quality management (YY/T 0287-2003).[6]

Medical Device Software (MDSW) encompasses a broad range of applications that support clinical decisions, offering recommendations for diagnosis, prognosis, monitoring, and treatment. These include advanced tools for analyzing radiology images,[12] oncology software supporting genetic analysis,[13] ophthalmology solutions for image recognition,[14] and systems that assist in general medical decision-making.[15] Increasingly, machine learning (ML) models are deployed in areas like diabetes management[16] and tuberculosis diagnosis,[17] with studies showing that computer-aided MDSW can sometimes surpass human accuracy in certain diagnostic tasks, such as detecting tuberculosis and diabetic retinopathy.[18,19]

While prior research has explored the deployment of AI-enabled medical devices (AIMD) in various regulatory landscapes, including notable work on regulatory frameworks and device categorization methods,[20] our study introduces an innovative, fully automated approach. By leveraging advanced data science techniques, our methodology filters targeted devices directly from the NMPA regulatory database. This automated system enables rapid, comprehensive identification and analysis of AIMD in under one minute after establishing selection criteria, significantly enhancing the efficiency and precision of regulatory data analysis. This automated approach represents a substantial advancement over previous methods, which often involved manual data collection or semi-automated processes, making it a uniquely scalable and efficient solution for regulatory assessment.

China Software Medical Device Registration Process

Figure 1 provides an overview of the medical device registration process administered by the NMPA for various types of devices. The NMPA has also established expedited pathways, including the Innovation Approval,[21] Priority Review,[22] and Emergency Approval[23] processes. The final version of the "Innovation Approval Procedure for Medical Devices," published on 5 November 2018, outlines three criteria for fast-track approval: a) The applicant must have completed preliminary research on the product and developed a finalized prototype with comprehensive and traceable research data. b) The primary technical mechanism of the product must be novel, inventive, and hold significant clinical value, meaning that the product's performance or safety offers distinct advantages over existing alternatives. c) The applicant must either hold the patent for the core technology of the product in China or have obtained the right to use the patent in China through technology transfer.[21] Both domestic and foreign manufacturers are subject to the same application process for innovative device registration.
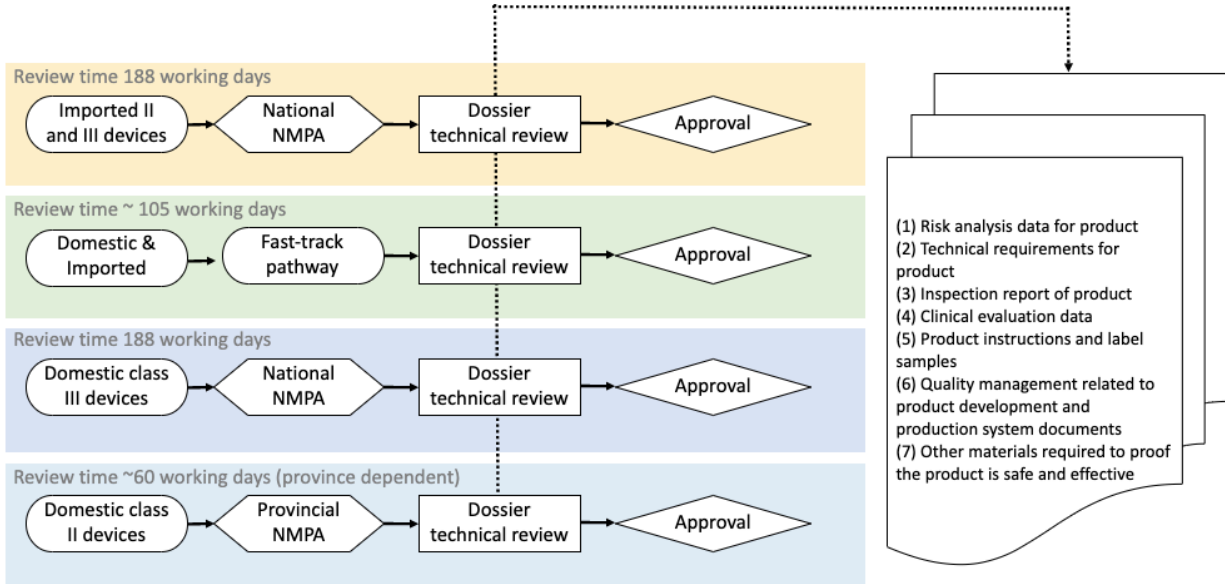
Figure 1: Medical device registration pathways set out by the NMPA. Imported and domestic devices relates to all class II and III devices, for Class I devices, only record-filing is required.

Unique Device Identification System and Database Background

The Unique Device Identification (UDI) system is a framework proposed by IMDRF and its intention is to adequately identify medical devices from manufacturing through distribution and patient use. Since joining the IMDRF in 2013 ,[24] China has been adopting and referencing international regulatory methods when formulating China regulations. China officially adopted the UDI System in 2019, as outlined by two key documents: (i) Pilot Project Plan for UDI System for Medical Devices (No.56, 2019)[25] and (ii) Rules for Unique Device Identification System (No. 66, 2019).[26] The NMPA is implementing the adoption of UDI in phases. The strategy is to start with devices that carry the highest risk (Class III) and then proceed to add lower risk devices in each new phase. In January 2021, nine categories of high-risk Class III medical devices were included in the first batch. From June 2022, the second batch of medical devices was included. As of August 2024, there are 4,045,039 products registered with UDI system, with most being general medical devices (96.34%), whilst in vitro medical devices (3.66%) are only making up a small amount of the total registrations.[27] The NMPA's UDI database is publicly accessible, allowing patients, healthcare providers, and regulatory authorities to quickly access information about a particular medical device.

Figure 2 illustrates the meaning of the number codes in China's UDI system.[28] A UDI code typically consists of a Device Identifier (UDI-DI) and a Production Identifier (UDI-PI). The UDI-DI refers to a unique numeric or alphanumeric code that is specific to a particular model of medical device and is also used as an access key to information stored in the database. The UDI-PI, on the other hand, identifies the unit of device production with a numeric or alphanumeric code. In China, the UDI-DI is composed of two parts: part I is assigned by the code-issuing agency, while part II is issued by the manufacturer.

Research Aim and Contribution

Our approach utilizes the NMPA's UDI (Unique Device Identification) database to perform an automated exploratory data analysis (EDA) of medical device software (MDSW), including software as a medical device (SaMD), software in a medical device (SiMD), and AI-enabled medical devices (AIMD). By employing a reproducible, data-driven methodology, our analysis can be completed in under one minute, significantly reducing human bias often present in manual selection processes.[20] This automated approach not only improves accuracy but also fosters standardization in device registration, aiding the NMPA in
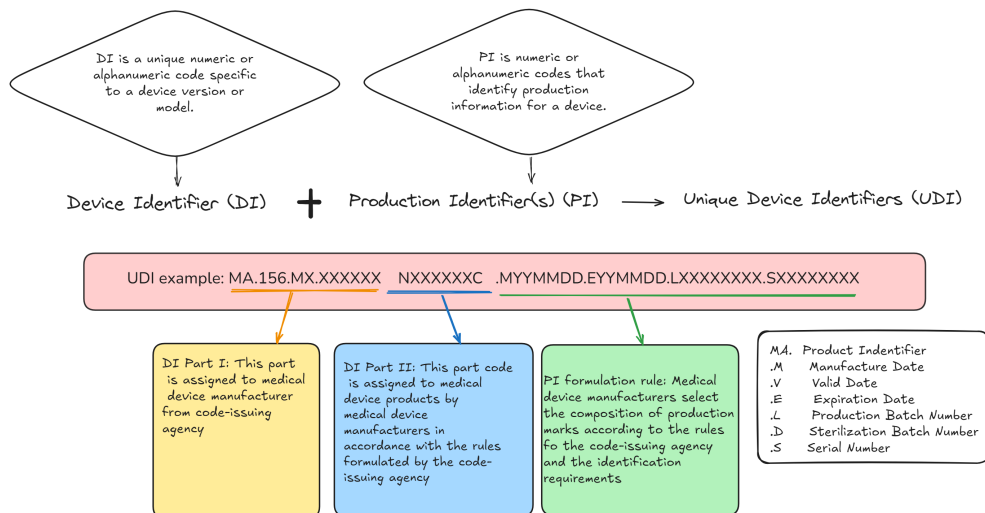
Figure 2: UDI code layout according to YY/T 1630-2018.

refining regulatory guidelines and enhancing data consistency.

The primary objective is to analyze the distribution of MDSW and AI-enabled devices across various medical specialties and applications, examining their origins, the ratio of imported vs. domestic products, and key companies contributing to this field. Our analysis also bridges computer science and medical expertise, providing insights into the most prevalent AI technologies and their medical domain applications, the reasons behind their adoption, and the algorithms commonly used. Additionally, this study demonstrates how, with a deep understanding of regulatory naming conventions, device classification rules, and regulatory principles, computer programs can perform comprehensive AI medical device analysis in seconds—an effective contribution to regulatory science. This approach, with its strong foundation in both regulatory knowledge and computational expertise, offers a scalable solution for automating and accelerating the analysis of other product types, making it a valuable tool for regulatory authorities. Researchers could also utilize the code to conduct other type of medical device research by simply changing product keywords and adjusting product code.

2 Methods

Definition of MDSW, SiMD, SaMD and AI software

Medical Device Software (MDSW) has seen widespread adoption in China and encompasses both Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD). The International Medical Device Regulators Forum (IMDRF) defines SaMD as software intended for one or more medical purposes, capable of performing these functions without being part of a hardware medical device.[29] In China, SaMD can be identified by a six-digit classification code beginning with the number 21, as outlined in the medical device catalogue,[30] which is provided in Appendix 1. SaMD functions independently as medical software, while Software-inclusive Medical Devices (SiMD) involve additional components, such as hardware, with the software and hardware working together.

According to NMPA Regulation Guiding Principles for Registration Review of Artificial Intelligence Medical Devices,[31] an AI medical device referred to medical device that utilises artificial intelligence technology to achieve its intended use (i.e., medical purposes) by using "medical device data." Medical device data refers to objective data generated by medical devices for medical purposes. This includes medical imaging data generated by medical imaging devices (such as X-ray, CT, MRI, ultrasound, endoscope, optical imaging and so on), physiological parameter data generated by the medical devices (such as ECG, EEG, blood pressure and so on), and in vitro diagnostic data (such as pathological images, microscopic images, invasive blood glucose waveform data and so on). Therefore, an AI medical device refers to a medical device that utilises artificial intelligence technology to process and analyse medical (device) data for medical purposes.
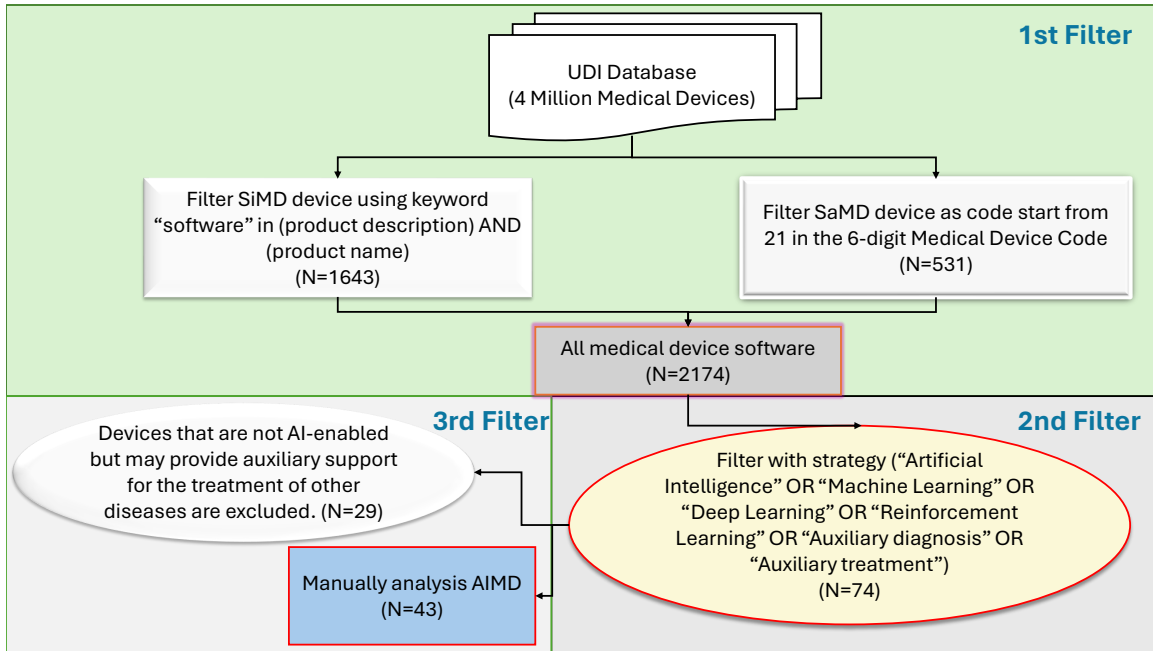
4

Figure 3: Flowchart for the selection process for the identification of software and AIMD

Pre-processing

Description of database

All data analysis was conducted using RStudio (version 2022.12.0, Posit Software, PBC). The exploratory data analysis was performed on the `UDID_FULL_RELEASE_20240801.zip` dataset obtained from the NMPA website.[32] The dataset contains information on medical devices registered with the NMPA UDI system from 2016 to 2024, consisting of approximately 4 million products, each of product labelled with 48 variables, such as product description, version number, generic name, specification, product number, device classification and so on.

Search Strategy

The data was filter using a two-layers strategy .[33] The first layer consisted of filtering out MDSW, filter with the keyword "software", whilst a second layer was applied to then identify AIMD from first layer result, using keywords shown in Figure 3. After generating the final list, the authors manually filtered it again to remove any devices that did not fall in the AI domain, for example, the devices are not AI-enabled by may provide auxiliary support for the treatment of other diseases.

From the total 4 million devices in UDI, we filtered out SaMD, SiMD and AIMD step by step. The filter process is shown in flowchart Figure 3. Medical device software includes all SaMD and SiMD. For SiMD, there are no specific classification code rule so we conducted a search with keywords "software" both in the product description or product name. For SaMD, it has been identified using R code begins with the number 21 in six-digit classification code. According to the Chinese regulation *Guiding principles for naming of medical software*,[34] devices which incorporate artificial intelligence must include in their name either the terms (i) Auxiliary diagnosis or (ii) Auxiliary treatment. For example, as indicated in the NMPA regulation, if the radiotherapy contouring software uses non-artificial intelligence technology, it is named "radiotherapy contouring software"; if it uses artificial intelligence technology, it is named "radiotherapy contouring auxiliary decision-making software". So we adopt keywords as searching strategy to filter devices based on the results from first step: (**"Artificial Intelligence" OR "Machine learning" OR "Deep learning" OR "Reinforcement learning" OR "Auxiliary diagnosis" OR "Auxiliary treatment"**).
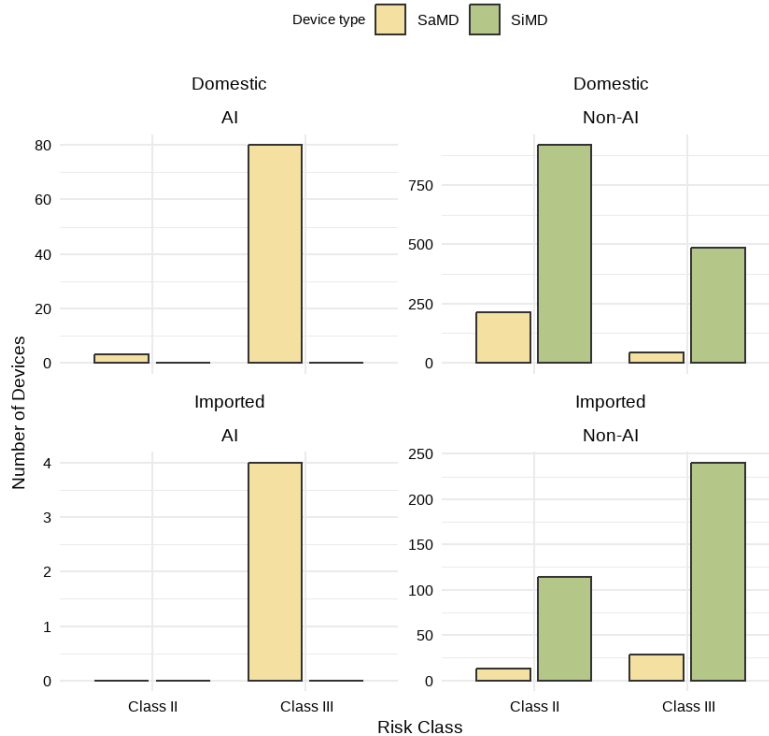
Figure 4: Domestic and Imported SaMD SiMD Devices: AI vs. Non-AI Distribution

3 Results

3.1 Devices amount and category

A total of 2,174 MDSW were identified, with 531 classified as SaMD and 1,643 as SiMD devices, as shown in Figure 4 . The majority of devices are domestic products, with the largest category being domestic SiMD Non-AI devices, comprising over 60% of the total of whole medical software. Imported SiMD non-AI devices accounts for 10%. AI devices are mostly shown in domestic SaMD, account for over 90% of all AI devices. We found that no device has been found utilize AI in SiMD.

In the filtered device list, we use each device register city and province, annotation for AI, non-AI, whether SaMD and SiMD and put into China map as shown in Figure 5, we can see in each province software registration amount in different province of china map.

For AI devices, Table 2 presents the distribution of AI device registrations across various provinces. The majority of registrations are for domestic Class III devices, which constitute approximately 70% of the total. This figure includes manufacturers both within and outside of Beijing, as per regulatory requirements mandating that all Class III devices must be registered in Beijing (national level). For Class II devices, the numbers decline progressively, with Guangdong and Hubei each accounting for around 8% of the total registrations. Additional contributions come from Zhejiang (5%), Tianjin (3%), and Jiangsu (2%), with Shanxi and Sichuan provinces each representing 1% of the total registrations.

3.2 Artificial intelligence devices and algorithms in Medical software

The authors cross-checked and validated the machine-filtered information, followed by a manual review to ensure accuracy. This process led to the development of a comprehensive database, which includes 43 AI-enabled devices, as shown in Figure 6. A detailed overview of these devices and their associated algorithms is provided in Appendix 2.

The top three medical specialities that use AI-enabled medical devices are respiratory (20.5%), Ophthalmology/Endocrinology (12.8%), and orthopedics (10.3%). Six AI-enabled medical devices (6 out of 43) have successfully utilized the innovation fast track pathway, which is eligible for underscoring the
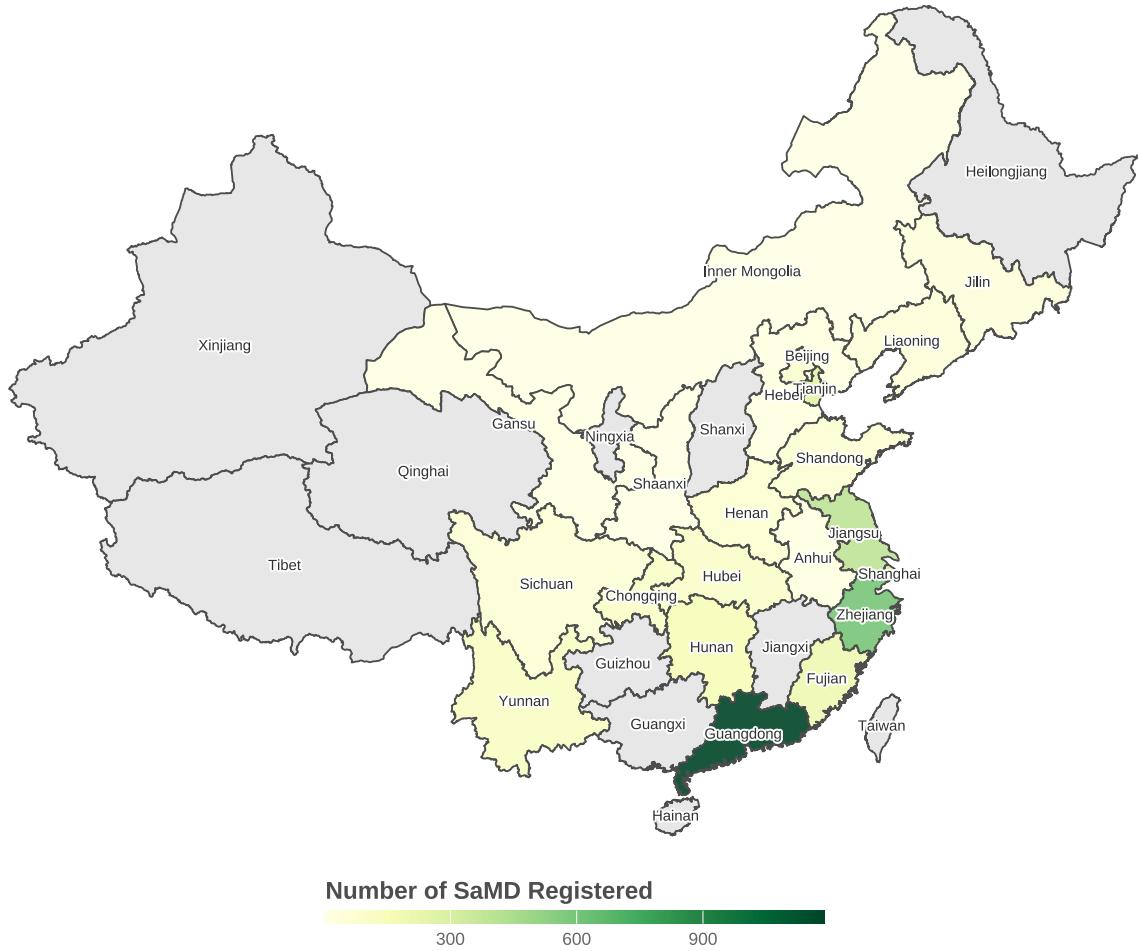
Figure 5: A geographic map of non-foreign medical device software are registration 2020–2024 ($n = 2{,}174$). The areas include mainland provinces as well as the indication of 许, which indicates products from the Special Administration Regions.

import_status	city	risk_class	n
domestic	National	Class III	41
domestic	Guangdong Province	Class II	8
domestic	Hubei Province	Class II	8
domestic	Zhejiang Province	Class II	5
imported	National	Class III	4
domestic	Tianjin Municipality	Class II	3
domestic	Jiangsu Province	Class II	2
domestic	Sichuan Province	Class II	1
domestic	Shanxi Province	Class II	1

Table 2: AIMD Distribution of Risk Class by City and Import Status

rapid advancement and regulatory approval of cutting-edge technologies in critical medical fields. All six devices are classified as Class III. All devices were registered after 2020, with the majority being registered in 2023 and 2024. This trend indicates that device registration activities are aligned with the regulations outlined in Table 1.

3.3 Artificial intelligence devices and algorithms across different medical domains

We reviewed each device in detail to label their underlying technology. Among the 43 AI-enabled medical devices (AIMD), we found that 32 utilize deep learning (DL), while 11 use general AI, as shown in Figure 7.

Deep learning (DL) is applied across a variety of medical specialties, including respiratory imaging, orthopedics, neurology, and the combined fields of ophthalmology and endocrinology, as well as in cardiology, general surgery, and neurosurgery. In contrast, fields such as gastroenterology, obstetrics and gynecology, and otolaryngology tend to rely more on general AI techniques. This distribution raises important questions about why certain AI technologies are adopted in specific medical specialties.

Medical imaging techniques vary by machine and medical application. CT provides detailed cross-sectional views of bones, tissues, and blood vessels.[35] MRI captures multi-planar images without radiation, ideal for diagnosing brain, spine, and musculoskeletal conditions. Ultrasound, using sound waves, is suited for real-time imaging of soft tissues and is portable for bedside use. Endoscopy allows visualization of internal cavities, enabling real-time diagnostics and interventions. Optical imaging, like fundus photography and OCT, is essential in ophthalmology for diagnosing retinal conditions.[36]

3.3.1 Deep learning and General AI algorithm analysis

General AI, encompasses a wide range of AI techniques and methods, including traditional machine learning algorithms (like decision trees, support vector machines), rule-based systems, and simple statistical models.[37] These techniques are applied to tasks where structured data, such as numerical or categorical data, can be analyzed to classify, predict, or detect patterns. Deep Learning, on the other hand, is a subset of machine learning that focuses on neural networks with multiple layers (also known as deep neural networks). Inspired by the human brain, these networks consist of interconnected layers of artificial neurons that learn to recognize features from raw data inputs through hierarchical abstraction.[38] Deep learning models excel in processing unstructured data, such as images, audio, and text, due to their ability to learn hierarchical representations of data features. Deep learning, with its ability to process large, complex, and unstructured datasets, is particularly suited for specialities including ophthalmology, and neurology, where medical imaging are complex.

3.3.2 Analysis of AI algorithm in certain medical specialty

We extract medical specialties information automatically by identifying the disease location from the generic names. According to the "Rules for Generic Names of Medical Devices" (Order No. 19),[39] characteristic terms describing specific attributes—such as the location of the disease where the software is used—are mandated to be included in the generic name. For example, a device named "Lung Nodule CT Image Auxiliary Detection Software" is classified under respiratory medicine, while "Chronic Glaucoma-like Optic Neuropathy Fundus Image Auxiliary Diagnosis Software" falls under ophthalmology.

We use this data-driven approach to minimize classification bias compared to methods that categorize devices based solely on the technology used. For example, previous work often blurs distinctions by classifying most software that utilize CT scans as radiology, which is not well-structured for future research.[40]

From result, we found that deep learning (DL) is widely used in specialties like respiratory, orthopedics, and neurology. CT scans, with their high resolution and structured data, are ideal for convolutional neural networks (CNNs).[41] CNNs excel at feature extraction and segmentation, especially in 3D data, making them effective for detecting fractures, tumors, and lung abnormalities in chest, abdomen, and brain imaging.

In respiratory, DL is applied to CT scans and X-rays for tasks like lung cancer detection and pneumonia diagnosis,[42] using supervised learning with labeled images. Orthopedics benefits from DL's ability to analyze X-rays, CTs, and MRIs for bone fractures and musculoskeletal conditions.[43] In neurology, DL analyzes brain MRIs to identify tumors, strokes, and Alzheimer's, using supervised learning with labeled data.[44] In gastroenterology, DL is applied to endoscopic images to detect polyps, while general AI handles structured data like blood tests.[45] Hepatology and endocrinology similarly rely on general AI for analyzing structured clinical data, such as liver function tests and hormone levels, aiding in disease monitoring and treatment planning.[46,47]

Figure 8 presents a visual representation using a human body diagram, with key medical specialties highlighted and labeled to indicate the specific AI methods and technologies used within each domain.

The diagram places these technologies directly near the anatomical regions they impact, offering a more intuitive understanding for readers.
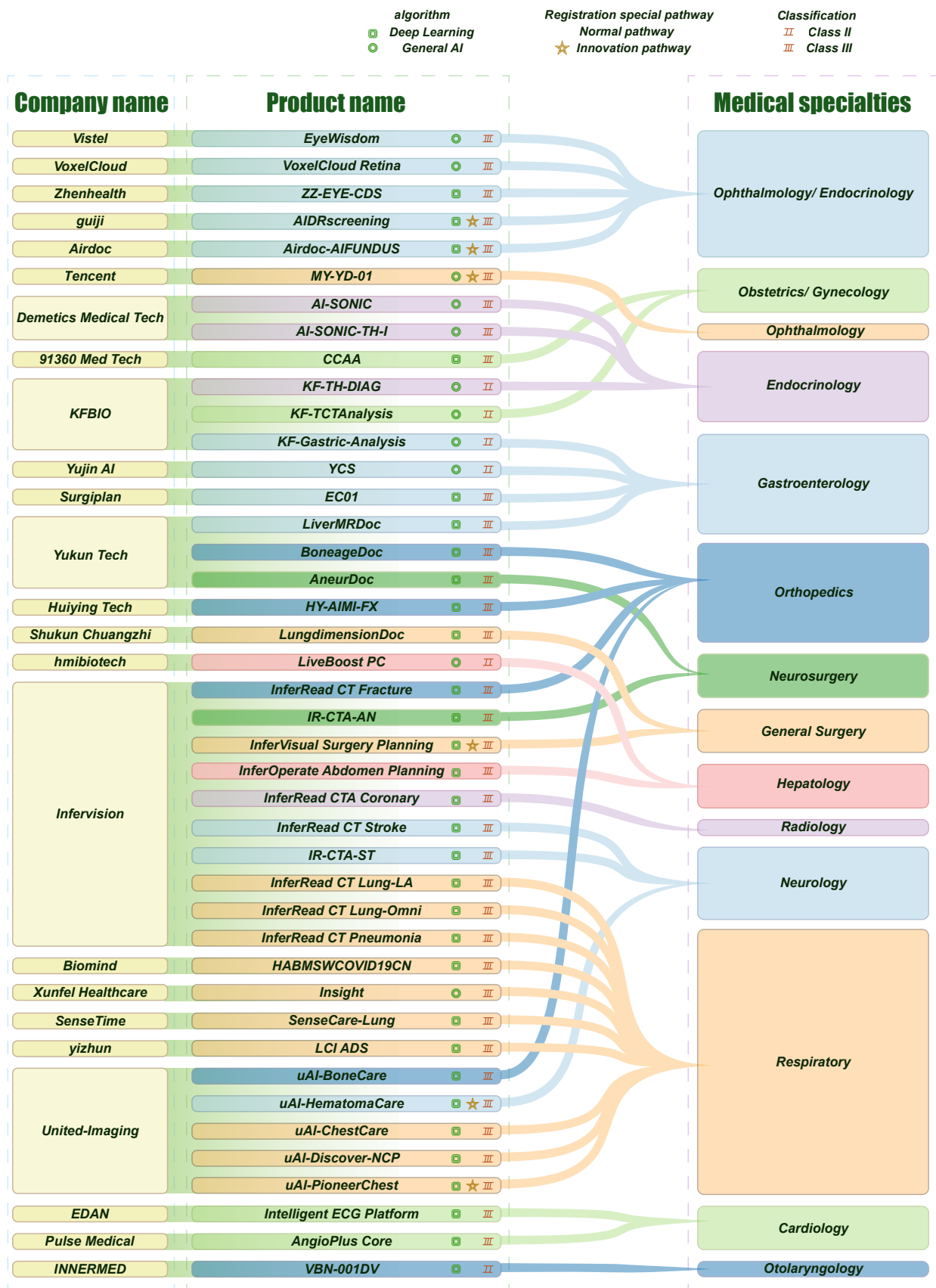
Figure 6: An alluvial diagram illustrating the types of 43 AI medical devices and the risk classifications along with the approval pathways within the NMPA regulatory framework
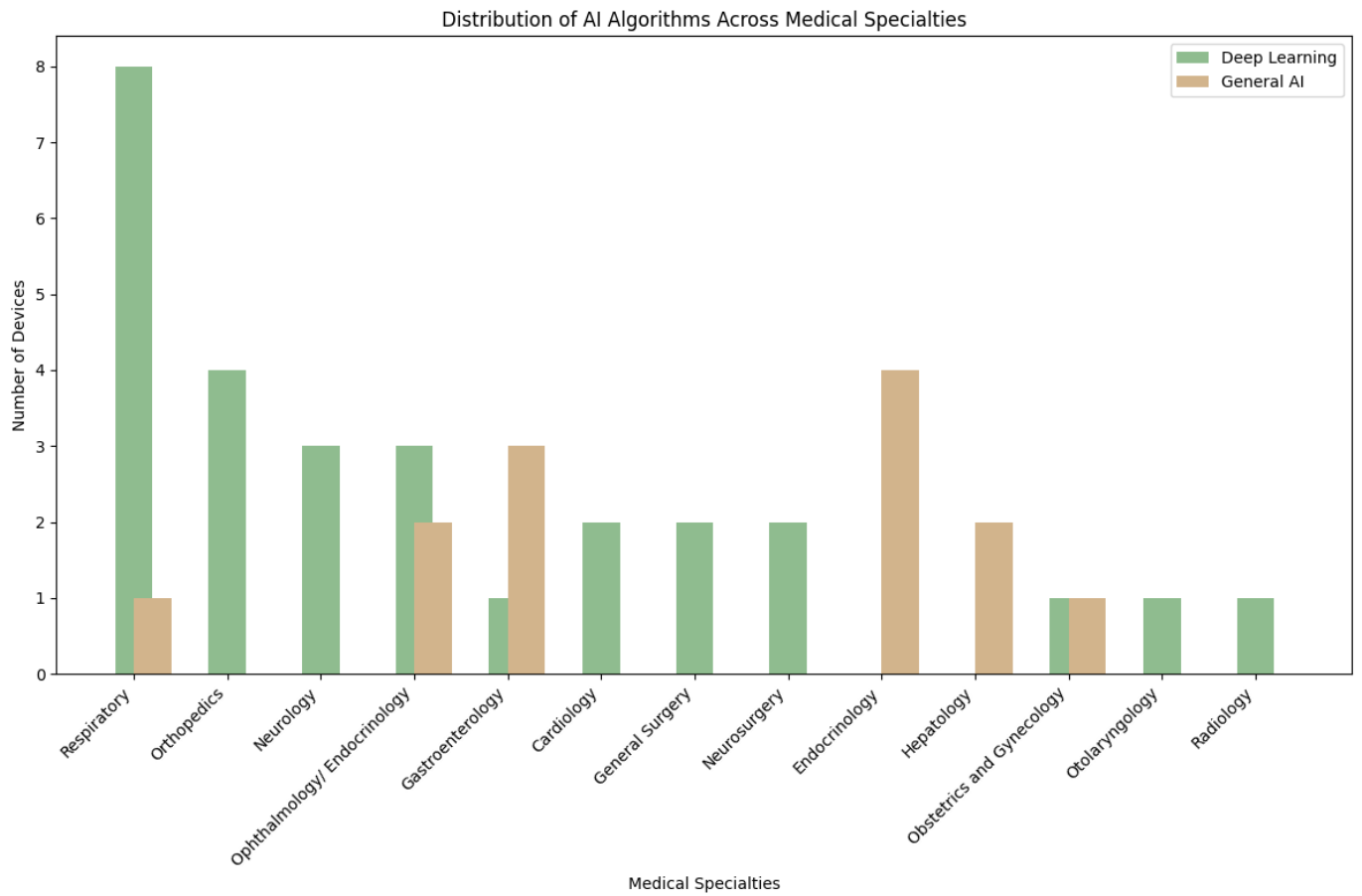
Figure 7: Distribution of AIMD on different medical specialty and algorithm

Endocrinology (GAI)
Data Type : Lab test data, blood
sugar and hormone levels
Reason for Using AI : General AI analyzes
structured data such as hormone and
glucose levels for predictive analytics.
Product example : AI-SONIC-TH-I, AI-SONIC,
KF-TH-DIAG
Regulatory function : Decision Support Software
- auxilary diagnosis, Image/Data Processing Software

Ophthalmology/Endocrinology
Data Type : Fundus images, OCT scans, (GAI)
blood tests
Reason for Using AI : DL for retinal image
analysis in ophthalmology; General AI
for blood sugar and hormone data in
endocrinology.
Product example : AIDRscreening, Airdoc-AIFUNDUS,
ZZ-EYE-CDS, EyeWisdom, VoxelCloud Retina,
Regulatory function : Decision Support Software
- auxilary diagnosis

Otolaryngology
Data Type : CT and MRI scans of head
and neck
Reason for Using AI : DL analyzes
head and neckimaging to detect
tumorsand sinus issues, requiring
detailed image analysis.
Product example : VBN-001DV
Regulatory function : Image/Data
Processing Software

Neurology
Data Type : MRI and CT scans
of the brain
Reason for Using AI : Analyzes
brain MRIs for conditions
like tumors and stroke,
benefiting from DL's pattern
recognition capabilities.
Product example : uAI-HematomaCare,
InferRead CT Stroke, IR-CTA-ST
Regulatory function : Decision Support
Software - Clinical triage, Decision
Support Software - auxilary diagnosis

Respiratory
Data Type : Deep learning analyzes
complex image data like CT scans and
X-rays for tasks such as lung cancer
detection and pneumonia diagnosis.
Reason for Using AI : Deep learning
analyzes complex image data like
CT scans and X-rays for tasks such
as lung cancer detection and pneumonia
diagnosis.
Product example : Insight, InferRead
CT Lung-Omni, uAI-ChestCare, LCI ADS,
uAI-PioneerChest
Regulatory function : Decision Support Software
- auxilary detection, Decision Support Software
- auxilary diagnosis, Decision Support Software
- Clinical triage

Radiology
Data Type : X-rays, CT scans, MRIs
Reason for Using AI : DL interprets
X-rays,CT, and MRI scans for tasks
like tumor and fracturedetection.
Product example : InferRead CTA
Coronary
Regulatory function:
Decision Support Software - auxilary
evaluation

Hepatology (GAI)
Data Type : Liver enzyme levels,
clinical data
Reason for Using AI : Uses
AI for pattern recognitionin
liver enzyme data,
helping assess disease
progression.
Product example :
InferOperate Abdomen
Planning, LiveBoost PC
Regulatory function :
Analysisand Mining
Products,Decision Support
Software - Surgical planning

Cardiology
Data Type : Echocardiograms,
ECGs, and cardia MRI scans
Reason for Using AI : Used for
analyzing echocardiograms and
ECGs, aiding in heart disease
diagnosis through DL's processing
of complex patterns.
Product example : AngioPlus Core,
Intelligent ECG Platform
Regulatory function : Analysis and
Mining Products, Image/Data
Processing Software

Gastroenterology (GAI)
Data Type : Endoscopic images,
liver enzyme levels
Reason for Using AI : DL for endoscopic
image analysis; General AI for blood
work and digestive health data analysis.
Product example : LiverMRDoc,
KF-TCTAnalysis, EC01, YCS
Regulatory function : Analysisand
Mining Products, Decision Support
Software - Clinical triage

**Obstetrics and
Gynecology** (GAI)
Data Type : Ultrasound
images, patient history,
lab results
Reason for Using AI : DL for fetal
ultrasound analysis; General AI
for reproductivehealth data analysis.
Product example : CCAA,KF-TCTAnalysis
Regulatory function : Analysisand
Mining Products

Orthopedics
Data Type : Radiographic images :
X-rays, CT scans, and MRIs
Reason for Using AI : Used to analyze
X-rays, CT, and MRI images for
bone fractures and joint issues
through accurate image recognition.
Product example : InferRead CT Fracture,
HY-AIMI-FX, uAI-BoneCare, BoneageDoc
Regulatory function : Decision Support
Software - Clinical triage, Decision
Support Software - auxilary diagnosis

General Surgery
Data Type : MRI and CT scans of
the brain and spine
Reason for Using AI : Provides precise image
analysis for braintumors and spinal issues,
essential for surgical planning
Product example : InferVisua, LungdimensionDoc
Regulatory function : Decision Support
Software - auxilary evaluation, Image/Data Processing
Software

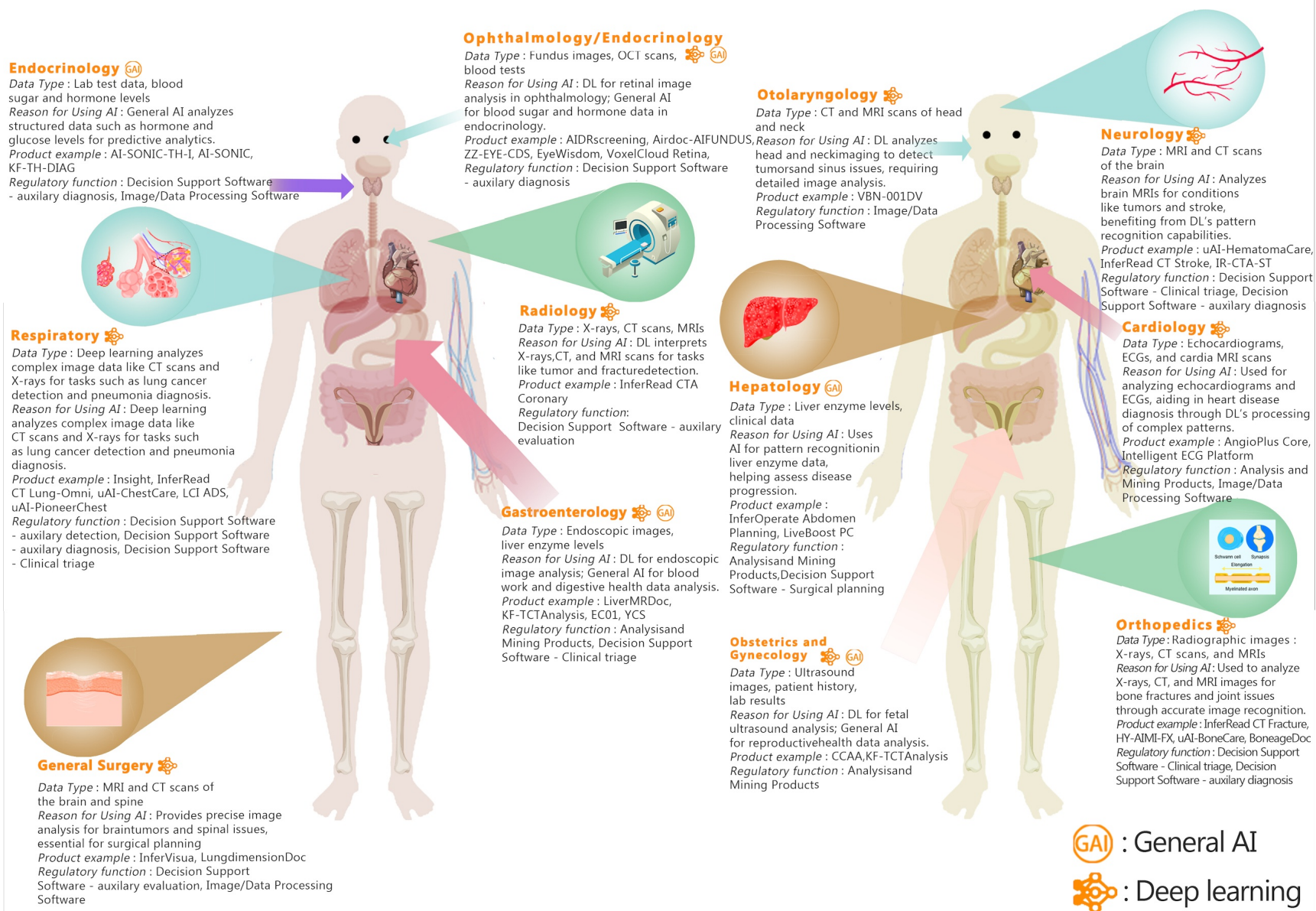(GAI) : General AI

: Deep learning

Figure 8: Applications of AI in Different Medical Specialties

3.3.3 Analysis of AI devices

From a functional standpoint, NMPA classifies AI-integrated software into specific functional categories, as outlined in Table 3. Of the 43 devices reviewed, 5 devices fall under the category of Image/Data Processing Software. For instance, INNERMED's VBN-001DV device falls into this category and is classified as Class II, despite incorporating deep learning components. This classification indicates that when the AI algorithm primarily enhances image quality or focuses on segmentation, the NMPA may assign a lower risk classification, reflecting the specific regulatory approach.

30 of the devices fall under the category of Decision Support Software, which is primarily designed to assist medical decision-making. This category can be further classified into subtypes based on functionality: auxiliary detection, auxiliary diagnosis, clinical triage, auxiliary evaluation, and surgical planning. For example, the "CT image-assisted triage software for intracranial hemorrhage" helps diagnose intracranial hemorrhage and supports triage decisions. The Insight, produced by Xunfel Healthcare, is one example. Although it does not utilize deep learning, it aids physicians by providing decision support for lung nodule detection in CT images, and the NMPA has classified it as Class III due to the function. Another device, the AI-SONIC-TH-I by Demetics Medical Tech, offers diagnostic support for thyroid nodule assessment using ultrasound images. Infervision's InferVisual Surgery Planning device provides surgical planning support, including the display, processing, measurement, and analysis of chest CT images. It can automatically identify pulmonary nodules of 4mm and larger, showing their spatial relationship to key anatomical structures—information that thoracic surgeons can use in planning lung surgeries. This device has been granted classification under the innovation pathway, reflecting its advanced functionality in surgical planning support.

5 of these devices are categorized as Analysis and Mining Products, which are primarily utilized for data analysis and mining. These devices normally process structured data through AI technology to help identify potential risk factors or predict disease progression. The "chronic liver disease risk calculation software" is used to assess the risk of chronic liver disease, supporting early clinical intervention.

Analysis of the classification trends for these devices reveals that those classified as Class III often incorporate more complex algorithm, or serve a critical clinical function beyond image enhancement, guiding physicians in decision-making rather than solely improving image quality. The fast-track pathway designation has been awarded to several devices, including uAI-HematomaCare and uAI-PioneerChest from United-Imaging in the areas of neurology and respiratory, respectively; AIDRscreening by Guiji in the field of ophthalmology/endocrinology; MY-YD-01 from Tencent, also in ophthalmology; InferVisual Surgery Planning by Infervision for general surgery; and Airdoc-AIFUNDUS from Airdoc, again in ophthalmology/endocrinology. This trend may underscore the growing importance of ophthalmological AI technologies in China and reflects a global market demand for innovative ophthalmic solutions.

3.4 International regulatory inconsistency

Table 4 presents the AI-enabled medical devices (AIMD) imported into China from other countries, with the majority originating from the USA. Most of these devices are categorized under radiology, and all are classified as Class III devices, regulated by the National Office in Beijing.

It should be noted that regulatory inconsistency of medical device across countries have been observed during the study. The same medical device could be classified differently in different regions based on the local regulatory environment. It was found that for example, the device that was registered by MIM software (whose Chinese license number is National20153211878) has been classified as class III[48] in China according to product code system (21-01-01). Nonetheless, this same device is classified as class II in USA, according to its USA 510(k) number K103576.[49] This finding might suggest that more stringent registration requirements exist in China for certain devices. In the USA, a classification II device is typically registered based on a predicate device that has already been approved, and the manufacturer must demonstrate that certain characteristics of the device are the same as those of the predicate device, and that the device will not pose any safety or effectiveness concerns. From a regulatory perspective, a higher classification normally implies more stringent requirements for manufacturers. For example, authorities may require more testing, including even clinical trials. In the case of MIM software, the higher classification (III) in China indicates that clinical evaluation and possibly clinical trials were needed. This is a regulatory challenge manufacturers need to consider when they plan to place their product in a global market.

Table 3: Divide AIMD by software function from NMPA regulation

Category	Description	Number of Devices
Decision Support Software	Devices used for assisting medical decision-making that apply an AI algorithm, such as software for lesion identification and drug dosage calculation.	30
- auxilary detection	Assists in detecting medical conditions, often using imaging data or other diagnostic inputs.	1
- auxilary diagnosis	Supports diagnosis processes by providing probabilistic assessments or condition classification.	16
- Clinical triage	Aids in triaging patients based on severity, prioritizing care delivery.	10
- auxilary evaluation	Offers evaluation support, such as predicting treatment outcomes or assessing patient risk factors.	1
- Surgical planning	Provides guidance and planning for surgical procedures through image analysis or patient-specific modeling.	2
Image/Data Processing Software	Devices used for medical imaging and data processing using AI algorithms, enabling tasks like image segmentation and fusion.	5
Analysis and Mining Products	Devices used to analyze and mine medical-related data, applicable in fields like drug development, medical research, and hospital information management.	5
Medical Assistant Products	Based on electronic health records or patient information, these devices use NLP and other technologies to make logical inferences about the patient's condition, often leveraging published knowledge maps.	-

4 Discussion

A key strength of this study is its application of data science methods to map license numbers and automate the filtering of devices, offering a reusable process that contrasts with manual approaches or keyword-based methods used in other studies,[20].[40] The data show that domestically-manufactured class III AI-enabled SaMDs far outnumber imported ones, while the difference in AI SiMDs between domestic and foreign devices is smaller. SiMDs, which integrate software with hardware (e.g., radiation therapy systems), may indicate that China's capability in AI-integrated hardware is not as strong as in pure software development. However, this interpretation requires further research.

Notably, China, the US, and the EU lack special approval pathways for AI medical devices, which are typically registered through standard procedures. In the US, 79.3% of AI devices are approved via the 510(k) clearance process, while in China, 88% of AI devices are classified as class III, requiring stricter regulatory scrutiny.

Among the six fast-track approvals in China, three focus on ophthalmology, reflecting the demand for AI technologies like Guiji's AIDR screening device for diabetic retinopathy. The global market for such diagnostic software is projected to grow steadily, indicating strong market acceptance in China, in line with the New Generation Artificial Intelligence Development Plan.[50]

General AI approaches are prevalent in specialties like gastroenterology and endocrinology, where structured data and well-established rules guide clinical decision-making. The interpretability and lower computational demands of traditional AI make it suitable for these fields, whereas deep learning is driving innovation in more complex diagnostic areas.

AI is currently absent in SiMDs, which typically focus on controlling hardware. Adding AI could increase system complexity and risk, making it harder to meet regulatory standards for safety and reliability. However, with advances in hardware and the development of lightweight AI algorithms, we may see AI integrated into SiMDs in the future. Techniques that improve AI explainability and

Table 4: Foreign companies with software devices.

Company	Country	Classification	medical specialty
Simemens Healthcare GmbH	USA	III	Radiology
Nucletron B.V.	Nerthland	III	Radiology
Vavian Medical System	USA	III	Radiology
MIM Software	USA	III	Radiology

predictability could help meet regulatory requirements for AI-enhanced SiMDs.

5 Conclusions

Benjamens et al.[40] manually reviewed FDA data and identified 64 AI/ML-based medical devices, validating the information through various sources. In comparison, Muehlematter et al.[51] found around 500 AI medical devices in the US and EU databases, though they did not specify their filtering or validation methods. Benjamens et al. also noted issues with the precision of keyword searches, highlighting the need for an AI labelling system for tracking devices.

To leverage data science for better regulatory analysis, a clear device labelling or coding system is essential. While China launched an AI medical device platform in 2019,[52] no aggregated AI medical database has been published. The FDA's has database of approved AI devices which is easier to track the AI devices. [53]

One limitation of this study stems not from our coding but from the NMPA UDI database itself, which compiles registered devices in multiple rounds or batches, potentially leaving some devices out of the dataset. This may account for slight differences between our results and those of previous studies.[20] This limitation affects the representativeness of our findings. Nonetheless, the NMPA UDI remains the most comprehensive dataset available for Chinese devices to date, highlighting the pressing need for a more complete, AI-focused regulatory database.[40]

As AI medical devices raise concerns about ethics, reproducibility, cybersecurity, and bias,[54] better tracking and surveillance through dedicated databases are increasingly necessary. Ethical issues such as algorithmic fairness and data privacy, along with potential impacts on the doctor-patient relationship, are significant challenges.[55] While the public has been captivated by AI advancements like ChatGPT,[56] the rapid growth of AI-enabled medical devices underscores the need for robust regulation and monitoring.

The fast-evolving field of AI in medical devices calls for a unified global regulatory response.[57] A standardized database and labelling system across regions would help track AI devices, improve patient safety, and streamline the integration of new technologies into healthcare.

Competing interests

The authors declare no competing interests.

DATA AVAILABILITY

The data that support the findings in this study is available on: https://github.com/Oxford-NIL/NMPA-analysis

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used ChatGPT 4o in order to edit sentence grammar. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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