Guidance on the Review and Approval of Artificial Intelligence(AI)-based Medical Devices

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MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evalution
Medical Device Evaluation Department

Revision History

Guidance on the Review and Approval of Artificial Intelligence(AI)-based Medical Devices (for Industry)

No. of Establishment/Amendment	Approval Date	Description
Guidance-0804-01	2017.11.23	Initial establishment
Guidance-0804-02	2019.10.30	Expanding applicable scope, adding explanation on comparison of substantial equivalence, etc.
Guidance-0804-03	2022. 5.12	Harmonization with IMDRF/AIMD WG/N67

This guidance explains or describes the position of the Ministry of Food and Drug Safety regarding the review and approval process for machine learning-enabled medical devices.

This guidance is not legally binding. Therefore, please be advised that despite the tone used in this document (use of "shall/should"), the stipulations in this document are not mandatory. In addition, the guidance was prepared based on scientific and technical facts and effective laws as of May 2022. Therefore, please be advised that the application of these facts and laws may differ depending on the latest revision or details of the case.

※ Guidance for Industry refers to the description of legislation or administrative rules offered to industry to aid their understanding or the proclamation of the stance of an administrative body in relation to certain civil affairs (Article 2 of the Regulations on the Management of Guidances, etc. of the Ministry of Food and Drug Safety)

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I. Introduction

1. Background and objective

Artificial intelligence (AI) is a branch of computer science, statistics, and engineering that uses algorithms or models to implement behaviors or perform tasks, such as learning, decision-making, and prediction. Machine learning (ML) is a branch of AI that analyzes data without using a programmed model. ML models can be developed using ML training algorithms through data analysis without programmed models.

ML-enabled medical devices (MLMD) can diagnose or predict diseases or provide customized treatment to a patient by learning medical big data and recognizing specific patterns based on ML. This guidance defines MLMD as medical devices that apply ML models.

This guidance was prepared to improve public convenience and work transparency related to review and approval, considering the need for managing MLMD based on Articles 2, 3, 6, 12, and 15 of the Medical Devices Act, Regulation on Approval, Notification, and Review of Medical Devices and Regulation on Items and Classification by Items of Medical Devices. In addition, the guidance presents matters related to the approval/review, particularly in preparation for the future development of medical devices.

2. Scope

This guidance applies to MLMD, in which ML-based AI technology is applied to diagnose, manage, or predict diseases by analyzing medical data. They also apply to AI software configured using hardware. For example, clinical decision supporting (CDS) and computer-aided detection/diagnosis (CAD) software fall under this category.

3. Definitions of terms

A. Machine Learning-enabled Medical Devices (MLMD)

A medical device that uses machine learning(ML), in part or in whole, to achieve its intended medical purpose.

B. Artificial Intelligence (AI)

A computer that uses logic, decision trees, ML , or deep learning to perform tasks that mimic human abilities, such as language comprehension, object and sound recognition, learning, and problem solving.

C. Medical Data

Various types of medical information, such as medical records or biometric information measured by medical devices, medical images, and genetic information, used to diagnose, manage, or predict diseases.

D. Training

Process intended to establish or to improve the parameters of a ML model, based on an ML training algorithm, by using training data. (Modified from ISO/IEC DIS 22989)

E. Training Data

A set of data that is used to train the ML model, which is not part of the test dataset.

F. Reference Standard

An objectively determined benchmark that is used as the expected result for comparison, assessment, training, etc.

G. Bias

Systematic difference in treatment of certain objects, people, or groups in comparison to others.

> Note 1 to entry: Treatment is any kind of action, including perception, observation, representation, prediction or decision. (ISO/IEC TR 24027:2021)
>
> Note : The term Bias is used in different ways in different fields. For example, in data science, bias is often defined with a statistical/mathematical meaning while in law, bias is often used to mean unfair or unfairly prejudiced/partial.

The ISO/IEC TR 24027 definition is a technical definition and is not synonymous with notions of being 'unfair' or not. Further information on the differences between bias and fairness is available in ISO/IEC TR 24027:2021.

ISO/IEC TR 24027 refers to systems having both "wanted" and "unwanted" bias depending on the intended purpose of an AI(-based) system. For instance, for an MLMD intended for the detection of leukemia, a wanted bias, would be bias toward the detection of leukemia over other pathologies; unwanted bias may include unintended differences in performance across different age groups in the intended patient population. As such, and depending on intended purpose, an MLMD that is more effective at the detection of leukemia in one age group over another might be an example of a device that has "unwanted" bias.

Sources of bias include:

- human cognitive biases (including automation bias, societal bias, and confirmation bias),
- data biases (including statistical bias, data processing bias, and data aggregation bias), and
- bias introduced by engineering decisions (e.g., during feature engineering, via algorithm selection, and model bias)

Further information on the types, and sources, of bias is provided in ISO/IEC TR 24027.

H. Test Dataset

A set of data that is never shown to the ML training algorithm during training, that is used to estimate the ML model's performance after training.

4. Product characteristics

The machine learning method is a method in which the software learns medical data and derives disease features on its own, so when a doctor inputs patient medical information into the MLMD, it can output diagnosis results using the disease features derived by the software. (Figure 1).

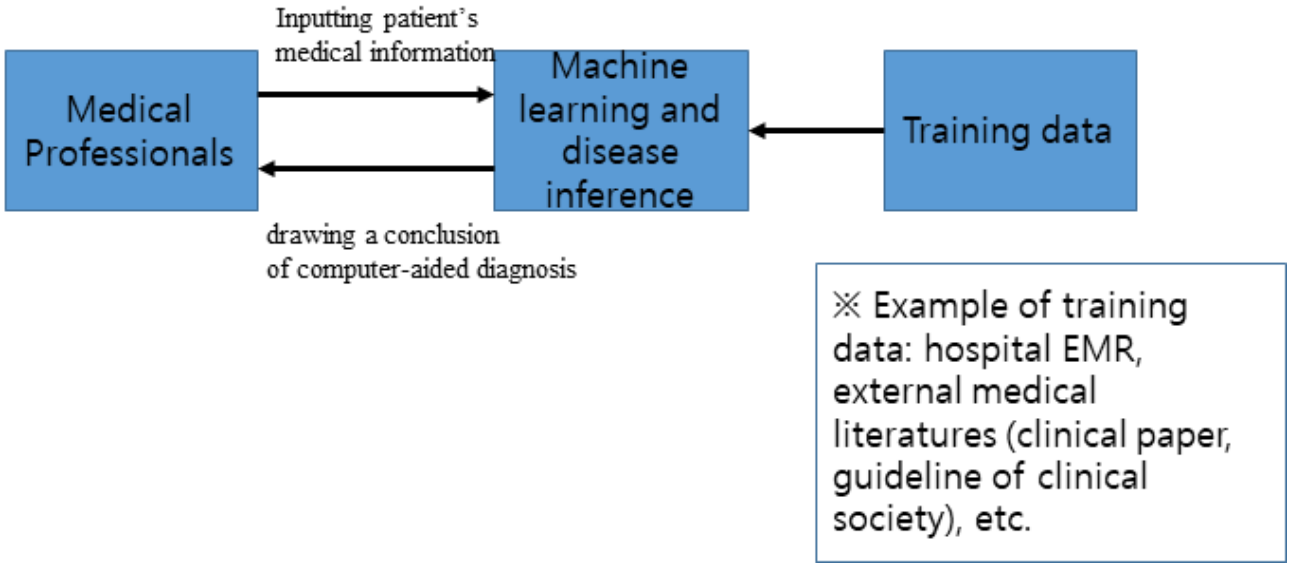

Figure 1. Characteristics of machine learning-based products.

Unlike existing medical software used for analyzing and analyzing and aiding detection or diagnosis of disease in medical images, a user or manufacturer can incorporate training data into MLMD using an ML method. This enables real-time algorithm modification and saves and uses data in the medical institution's server or external cloud server through a network by applying a cloud-computing technology[1].

[1] Computing that provides virtualized information technology (IT) resources using internet technology as a service.

II. Medical Device Classification and Criteria for MLMD

1. Overview

Software with ML technology are being actively developed. In addition, more advanced products equipped with diverse and complex functions are expected to emerge with the advancement of technology. Accordingly, this section presents the judgment criteria and control methods for medical devices by evaluating the need to manage currently developed and used products and products that are expected to emerge as medical devices.

2. Regulatory approach to software with machine learning technology

Software with ML technology provide a substantial amount of information to medical professionals or patients in real time and aid in decision-making. They can improve the satisfaction levels of medical professionals and patients by improving patient care quality and medical decision accuracy and efficiency.

The regulation of software with machine learning technology should be flexible enough to reflect the speed of technological advancement, frequent modifications and upgrades, and complex algorithms. Moreover, it should consider the users, including patients and medical professionals, and the software use environment.

Therefore, the Ministry of Food and Drug Safety aims to manage software that satisfy the definition of a medical device or those that could pose a risk to a patient if they do not function as intended. The necessity of managing software under medical device regulations will be reviewed continuously, considering the trend of future product development and the current status of use.

3. Criteria for determining medical devices

According to Article 2(1) of the Medical Devices Act, a medical device is an instrument, machine, apparatus, material, software, or any other similar product used alone or in combination with humans or animals, as specified below.

> Article 2 of the Medical Devices Act (Definitions):
>
> (1) The term "medical device" in this Act means an instrument, machine, apparatus, material, software, or any other similar products specified as follows, which are used alone or in combination for human beings or animals. Provided that drugs and quasi-drugs under the Pharmaceutical Affairs Act and prosthesis and orthosis among assistive devices for people with disabilities under Article 65 of the Act on Welfare of People with Disabilities shall be excluded here from:
>
> 1. A product intends to diagnose, cure, alleviate, treat, or prevent a disease
> 2. A product intends to diagnose, cure, alleviate, or correct an injury or impairment
> 3. A product intends to test, replace, or transform a structure or function
> 4. A product intends to control the conception

Categorizing whether software with ML technology is a medical device should be based on its intended use according to Article 2 of the Medical Devices Act and the following determinants of a hazard:

a) Whether software can cause harm to a patient when it does not work as intended

Medical software can harm public health if its accuracy is unguaranteed. For example, inputting or learning inaccurate and improper data or algorithm errors could lead to incorrect predictions of the possibility of a certain disease. Moreover, incorrect detection or marking of an abnormal area could directly affect the diagnosis and treatment results. In this case, the patient may not receive the necessary treatment or have problems, such as unnecessary examination, surgery, or drug prescription.

b) Whether software guarantees the clinical decision of a medical professional

In the case of a medical software that has not been verified for its safety and performance by the Ministry of Food and Drug Safety, medical professionals may diagnose diseases or determine treatment methods based on software with unverified accuracy and reliability; however, public health may be put at risk owing to incorrect diagnosis and treatment. Therefore, reviewing whether the evaluated area requires medical professional intervention is necessary. In addition, whether a medical professional is given reasonable opportunities to review the basis of the information or treatment recommendations should also be considered.

A medical professional should ensure that major decisions are not made based only on relevant recommendations when performing a clinical diagnosis or determining a treatment for a patient. Therefore, sufficient details should be provided regarding the source of the training data and relationship between the training data and results provided to ensure that a medical professional understands the clinical evidence for the information provided.

4. Specific scope and examples

The scope for medical and non-medical devices is presented below. The examples provided below are for reference only. Each case should be decided by considering the characteristics, situation, and scientific evidence for each product.

a) Software under the medical device category

1) Software that diagnoses, predicts, or monitors the possibility of diseases, including their presence and condition, or treats diseases using clinical information (e.g., size and location of tumor lesions) obtained by analyzing medical information based on medical big data.

2) Software that provides clinical information necessary for diagnosis and treatment by analyzing medical images, signals from in vitro diagnostic medical devices, and patterns or signals from signal acquisition systems (electrocardiograph, electroencephalograph, etc.)

<Examples of medical devices>

- Software that diagnoses the presence or progress (stage) of lung cancer by analyzing lung computed tomography (CT) image
- Software that diagnoses or predicts cardiac arrhythmia using electrocardiography test
- Software that calculates the probability of onset of a certain cancer based on medical information, including biopsy and electronic medical records (EMR)
- Software that diagnoses the presence of skin cancer by analyzing skin lesion images
- Software that predicts hypoglycemia by analyzing information, such as blood sugar data, food intake, and insulin injection
- Software that predicts or provides warnings, including alarms for emergencies, such as shortness of breath, by analyzing vital signs measured and compiled in an emergency room
- Screening software that detects and marks abnormal areas by analyzing stomach CT image
- Software that provides quantitative value for a particular characteristic of the blood vessel, such as blood flow velocity and blood vessel diameter, by analyzing medical images
- Software that establishes radiotherapy planning based on medical data

b) Software outside the medical device category

1) Software that supports the administrative work of a medical institution (management of wards, inventory, and handling of electronic procedures)

<Examples of non-medical devices>

- Software that collects and processes data for insurance claims
- Software that manages the medical care schedule of doctors, wards, and dosing time
- Software that supports medical bill claims and handles electronic procedures for patients in hospitals

2) Software intended for exercise, leisure activities, and general healthcare

Note: The detailed criteria shall be in accordance with the "Criteria for Determination Whether Medical Devices or Personal Health Care (wellness) Products."

<Example of non-medical devices>

- Software that encourages or promotes a healthy diet, exercise, weight loss, or a healthy lifestyle
  - ☞ Provides weight control and nutrition intake information for patients with chronic hypertension by collecting and analyzing health data
  - ☞ Provides aerobic exercise by collecting and analyzing health data

3) Software for education/research purposes

<Example of non-medical devices>

- Software intended only for research and education in universities and research institutions
  - ☞ Provides anatomy images or medical images for educating and training medical professionals

4) Software intended for managing medical records not related to the treatment and diagnosis of diseases

<Examples of non-medical devices>

- Software that saves and manages EMR
- Order communication system (OCS)
- Software for clinical research that supports and manage records including patient treatment, examination, and Institutional Review Board (IRB) review.

5) Software that provides a tool to organize and trace a patient's health or treatment information to a medical professional or helps a medical professional conveniently obtain medical information.

<Examples of non-medical devices>

- Software that provides a tool for searching or organizing information, including literature information related to prescription and medical care, to medical professionals without replacing or modifying information, such as previously prescribed medicine or treatment
  - ☞ Searches and shows the prescription of other patients and the list of prescribed medicines in the EMR system
  - ☞ Searches and shows the medical images of other patients similar to that of a patient in the EMR system
- Software that helps medical professionals conveniently access medical information related to a patient’s condition or treatment
  - ☞ Searches, summarizes, and shows standard treatment and clinical literature
  - ☞ Searches interaction among different drugs and allergic reaction to prevent adverse drug reaction

Note: Software can be classified as a medical device if it provides a new diagnosis or treatment option for a patient by reinterpreting various training data rather than just searching the training data (including providing priority and summary, etc.).

5. Management of software falling under the non-medical devices category

The Ministry of Food and Drug Safety conducts a survey or analysis of domestic and overseas data and a current status survey to decide on the necessity of applying regulations on medical devices; if the ministry identifies hazards regarding products under development, it can classify the product as a medical device for management. In this case, the MFDS will revise the guidance or notices by undergoing thorough discussion processes including collecting stakeholder opinions.

III. Considerations for the Approval and Review of MLMD

The following matters shall be considered upon the approval and review of MLMD. For more information on the factors to be considered upon the review and approval of Medical Device Software, refer to the MFDS provision titled “the Review and Approval of Medical Device Software.”

1. Essential requirements for application

Under “Performance,” fill out in the application form for review and approval, including the technical specifications of the cloud server operating environment, cloud service type, and security standard.

Write down the output information, update cycle of training data, and accuracy of diagnosis result in the primary performance, and provide a cloud-server operating environment and cloud service type when a cloud server is used. In addition, describe the data encryption and decryption process and policy on anonymity in the security specification.

Example inputs to the form:

1) Major functions

A. Medical image input and diagnosis result output

- Input information: lung CT image

- Output information: presence of lung cancer, severity of cancer, diagnosis accuracy, location of lung cancer (marking on CT image)

B. Training dataset

- Training data update cycle: 1 year by manufacturer

C. Performance

- Sensitivity: ○○% or higher, specificity: ○○% or higher

2. Validation of essential requirements and clinical effectiveness

For the performance and clinical effectiveness of MLMD, the sensitivity, specificity, positive predictive value, negative predictive value, receiver operating characteristic (ROC) curve, and area under the curve (AUC) can confirm the diagnostic accuracy of a product.

To maintain objectivity, the mutual independence of the data used for development and data used for validating the performance and clinical effectiveness should be considered.

<Example of Measures to verify performance and clinical effectiveness >

- Sensitivity

  Probability to identify those with the disease among people with the disease

- Specificity

  Probability to identify those without the disease among people without the disease

- Positive Predictive Value

  Fraction of those with a specific disease characteristic among the people classified with that specific disease characteristic

- Negative Predictive Value

  Fraction of those without a specific disease characteristic among the people classified without that specific disease characteristic

- Receiver Operating Characteristic (ROC) Curve

  ROC is a graph drawn using sensitivity and false-positive rate (1-specificity) based

on diagnostic test results. This curve can be used to assess the diagnostic performance on distinguishing positive or negative.

- Area Under the Curve (AUC)

  The AUC refers to an area under the ROC curve indicating diagnostic accuracy. In a range of 0.5 to 1.0, the closer the value to 1, the better the performance.

In addition, in cases where medical information is saved and transmitted through the network by applying a cloud-computing technology, the possibility of modification or loss of medical information and the occurrence of damage can be considered depending on the medical information security and cloud transmission.

Cybersecurity requirements for communications-enabled medical devices are covered in the "Guidance on Approval and Review for Cybersecurity of Medical Devices."

3. Clinical validation

The methods for clinical validation applicable to MLMD can be broadly divided into prospective, retrospective, and prospective/retrospective studies, where both studies are conducted in parallel. Appropriate clinical trial methods can be designed according to the product characteristics.

The data, clinical validation, clinical trial methods, clinical trial results, and criteria for clinical evaluation should be considered according to the "12-2 Data Related to Clinical Trial" of Article 29 (Requirements for Attachments) of the Regulation on the Review, Approval, and Notification of Medical Devices.

<Methods for clinical validation>

■ Prospective study

A method for tracing changes for a specific period of time after presetting the factors (risk factors) to be studied and observing the changes caused by the risk factors.

■ Retrospective study

A method of conducting a study without direct contact with study subjects. It is a clinical trial performed to verify the safety and effectiveness of medical devices using the medical data of subjects obtained through previous medical care or clinical trials rather than recruiting subjects.

Note : Relevant information, such as medical records, medical images, vital signs, pathological examinations, and genetic information of subjects and clinical trial results can be used in a retrospective study.

When designing a retrospective study, the test data should be independent of the data used in the product development process. Information related to sample data collection (collection method, collection place, collection format, collected items, etc.), test period of data, number of participants, and the inclusion and exclusion criteria for the sample data should be considered.

For medical devices that diagnose and predict a disease by analyzing the clinical information necessary for diagnosis and treatment in the patient's medical image, vital signs, and in vitro diagnostic results, the clinical efficacy can be confirmed by comparing the information with confirmed diagnostic results described in the electronic medical record(EMR) using data from Koreans. If there are no racial differences, data from Koreans may not be necessary.

4. Submission requirements

The documents to be submitted upon application for the approval for medical devices shall

be in accordance with Article 26 (Type and scope of documents to be reviewed, etc.), Article 28 (Waiver of Documents to be reviewed), and [Appendix 7] “Scope of Submissions including Technical Documents” of the Regulation on the Review, Approval, and Notification of Medical Devices.

In particular, the “Documents for Operating Principles” among the attachments may include information on the diagnosis algorithm (including ML) and principles and explanation of cloud-computing technology incorporating the characteristics of MLMD. For the “Documents for performance,” conformity assessment and verification and validation reports on the medical device software using the template [Appendix 13 Template] according to Article 29 (Requirements for Attachments) of the regulation shall be submitted following the information on the test overview and test method.

<Information to be described in the “verification and validation report on software”>

- Test overview

  Test data collection criteria, collection method, and amount of test data

- Test method

  - Criteria and method for establishing the reference standard (provide information, including the type of reference standard, documents, or papers referred)

    * Example of type of reference standard: In case of a medical device that detects lung cancer using chest x-ray image, establish the standard reference using medical images of a patient who diagnosed with lung cancer based on CT or MR imaging results.

  - Test items (accuracy, precision, etc.) and test standard (including standard setting method and its basis)

For the approval of MLMD, the device should be compared with a previously approved product according to [Appendix 7] of the regulation; documents for clinical trials should be submitted if the intended use and operating principles of the evaluated product differ from

those of the approved product. Submission of clinical trial results may be waived if the two products are equivalent.

An equivalence comparison of the evaluated and approved MLMD should be performed to compare their intended use, model used for ML, and characteristics of the training data. An equivalence comparison can be performed according to the following steps. In addition, the process flow can be used as a guide to determine the scope of the documents to be attached.

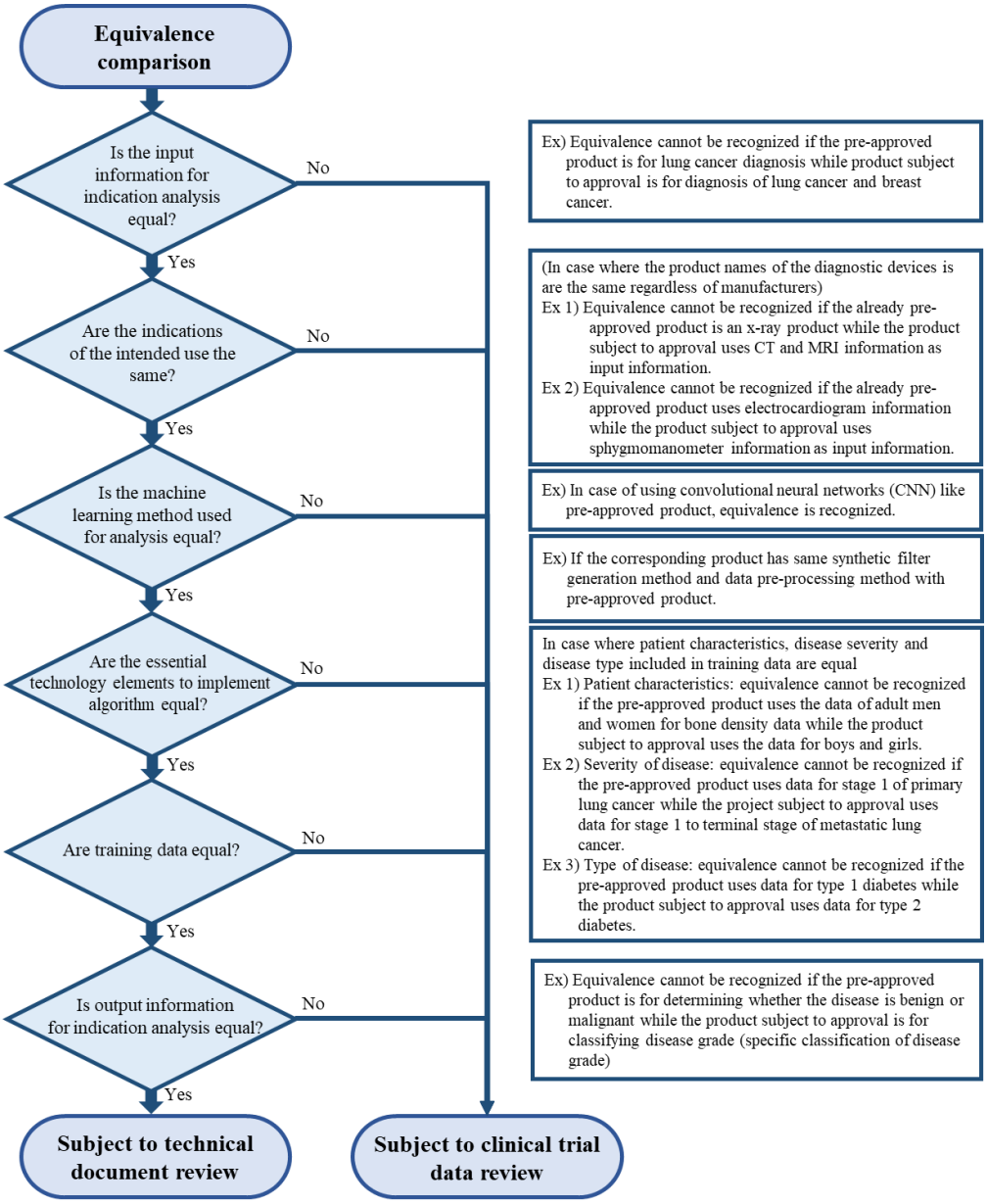

Figure 2. Process of comparison with pre-approved products.

For the “intended use,” the disease classification, specific conditions, and patients analyzed by a product shall be compared. As shown in Figure 2, equivalence is not recognized if the scope of indication differs; in this case, the clinical trial data must be submitted.

Two areas are compared for the operating principles, including the types of ML models applied to the product and characteristics of the training data (Figure 2).

Upon describing the operating principles for pre-approved products subject to approval, the classification of basic algorithms (CNN, RNN, GAN, etc.) and essential technology elements (synthetic filter, data preprocessing method, etc.) shall be described for comparison.

The product characteristics, such as the analysis method of the disease after training, can differ according to the nature of the training data in addition to the ML models.

Upon comparison of the operating principles of the working mechanism, patient characteristics (age, sex, etc.), severity of diseases, and type of diseases included in the training data shall be described for comparison.

However, when a machine learning algorithm is applied to MLMD for software functions unrelated to the purpose of use, such as disease diagnosis, intended use, and indication, the submission of clinical trial data may be exempted. Examples of such cases are presented below.

1) Applying to function of removing noise in medical image
2) Applying to function of removing noise in vital signs
3) Applying to function of managing patient’s schedule

[Appendix 7] < Scope of Submissions including Technical Documents> (in relation to Article 28)

<Electrical area>

Classification \ Documents to be submitted		1 Substantially equivalent item comparison table	2 Intended use	3 Operating principles	4-a Electricity	4-b Radiation	4-c Electronic wave	4-d Biological	4-e Performance	4-e Physical chemistry	4-f Safety	5 Clinical	6 Source, identification and background of development	7 Current status of use in other countries
1. New products	a. Different intended use	○	○	X	○	△ note 4)	○	X	○	○X	X	○	○	○
	b. Different operating principles	○	X	○	○	△ note 4)	○	X	○	○X	X	○	○	○
	c. Different raw materials	○	X	X	X	X	X	X	X	X	X	X	X	X
2. Improved products	d. Different performance	○	X	X	X	X	X	X	○	○X	X	△ note 1)	X	X
	e. Different test standards	○	X	X	○ note 2)	△ note 2), 4)	○ note 2)	X	X	X	X	X	X	X
	f. Different method of use	○	X	X	X	X	X	X	X	X	X	△ note 3)	○	○
3. Equivalent products		○	X	X	X	X	X	X	X	X	X	X	X	X

○: Documents that should be submitted, X: Documents exempted from submission △: Submissions that shall be reviewed by the products

Note 1) In case where improved performance can be verified only through clinical trial (ex: in case of partial change of performance by adding computer aided diagnosis (CAD) function to Software as Medical Devices)

Note 2) In case where the test standards exist other than that of the Minister of Food and Drug Safety approved

Note 3) In case where safety and effectiveness need to be verified due to difference of application area and manipulation method (ex: using electric stimulator used for lower nerve (peroneal nerve, femoral nerve, etc.) in brain and spinal cord to improve ambulation of patient with partial paralysis of lower limbs)

Note 4) "Documents for safety on radiation" is limited to radiation device.

※ In case where a medical device is packed in a set or combined or has parts which are in contact with body, "Documents for medical supplies" shall be submitted additionally.

5. Subject to change approval and certification

Medical Devices shall be subject to change approval and certification in accordance with Article 12 of Medical Devices when modification occurs regarding pre-approved products, in accordance with Article 6 of Medical Devices.

If a modification occurs regarding matters that affect safety and effectiveness, including the design of medical devices, documents for clinical trials, technical documents, or notice on the result of review of technical documents, shall be submitted in accordance with Article 26(3) of the Enforcement Rule of the Medical Devices Act.

However, criteria for change approval in MLMD are necessary, given that medical devices learn by themselves, resulting in frequent changes in performance.

Therefore, the change approval and certification process is exempt if the accuracy is improved by adding training data without the design modification of a medical device. However, in this case, the manufacturer should manage the training data and performance (accuracy) of the product under the manufacturing and quality management system to maintain product quality. Cases subject to changes in approval and certification are shown in the following examples.

a) Examples of cases subject to be reviewed on documents for clinical trial for change approval and certification

1) In case where the intended use is modified by adding indications
2) In case where the operating principles are modified due to the change in diagnostic algorithm (including ML)
3) In case where the operating principles are modified due to the change in kinds of medical information input
4) In cases where the intended use is modified owing to a change in the type of results provided (diagnostic details, diagnostic items, etc.)
5) Cases in which the diagnostic accuracy is changed to a level lower than the diagnostic accuracy range presented during approval and certification owing to changes in training data.

6) In case where there are major changes that impact the safety or effectiveness of a product

b) Examples of cases subject to technical document review for change approval and certification

1) Changes that have an impact on major performance of a medical device due to changes in development language and operating environment of the software
2) Changes that have an impact on major performance due to changes in matters not subject to clinical data review

Examples: addition of alarm function, addition of data storage function, development environment change, operating environment change, etc.

c) Examples of cases exempted from change approval and certification

1) In case where the accuracy level, which was previously approved, is improved with modification and expansion of training data without design modification of the product

6. Version control

Version control rules for MLMD can be divided into a manufacturer's management of product structure and design and other management tasks, such as adding training data.

The design modification of a product can be managed in the same way as the management of the general medical device software version; however, in cases where the version is changed owing to additional training data, an appropriate version control method shall be applied in accordance with the data control policy of a manufacturer and a medical institution, and the information should be written down in the application form for approval and review.

As listed in Table 3, the version control method for MLMD can be divided into major function changes, simple changes, minor changes, and training data changes.

In cases where performance (accuracy) changes owing to training data changes, it is managed

as a major function change. In contrast, if the change is made within the performance (accuracy) range written during approval, a manufacturer can autonomously control the version by setting the version control rule for training data change and version number may be expressed as “X” without need to mention the specific numbers in the application form for approval and review.

<Version Control Method>

Classification	Details (example)	Control method
Major function change	Change in operating principles, intended use, performance (applies to cases where the pre-approved performance (accuracy) changes beyond the previous range.)	Proceeding the change approval process
Simple change	Graphic user interface (GUI) design change	Proceeding the change approval process
Minor change	Bug correction, color and menu location change of GUI, etc.	Occasional report or annual report
Training dataset change	Training data change within the range of performance (accuracy) written during approval	Self-management by a manufacturer

7. Management policy on training dataset

MLMD requires various training data, including electronic medical records (EMR), medical literature (clinical papers, guidelines of clinical societies, etc.), and medical images to extract characteristics for diagnosing and predicting diseases, which may have an impact on the performance and effectiveness of a product.

Therefore, a manufacturer should establish a policy on data management to consistently maintain the effectiveness of training data. The timing for updating training data can be determined based on consultations between a manufacturer and a medical institution.

The data management policy is related to the planning of data acquisition by a manufacturer

and medical institution, defining an effective operating system, and planning for the acquired data. A system and plan for the data management principle, management organization, and quality control process should be established.

In particular, data management organizations are required to set quality control items, scope, and criteria related to training data and assess the quality of the product algorithm for training data that are added regularly or irregularly.

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