



May 16, 2025

Infervision Medical Technology Co., Ltd.
% Matt Deng
Official Correspondent
Room B401, 4th Floor, Building 1,
No.12 Shangdi Information Road, Haidian District
BEIJING, CHINA 100085

Re: K240554
Trade/Device Name: InferRead Lung CT.AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: OEB, QIH
Dated: April 3, 2025
Received: April 15, 2025

Dear Matt Deng:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lu Jiang". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K240554

Device Name

InferRead Lung CT.AI

Indications for Use (Describe)

InferRead Lung CT.AI is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules $\geq 4\text{mm}$ during the review of CT examinations of the chest on an asymptomatic population ≥ 55 years old. InferRead Lung CT.AI requires that both lungs be in the field of view. InferRead Lung CT.AI provides adjunctive information and is not intended to be used without the original CT series.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K240554

Infervision Medical Technology Co., Ltd.

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: Infervision Medical Technology Co., Ltd.
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Regulatory Manager

Date Prepared: May 16, 2025

Device Name and Classification

Trade Name: InferRead Lung CT.AI
Classification: Class II
510(k) Number: K240554
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Common Name: Lung Computed Tomography System, Computer-Aided Detection
Classification Panel: Radiology
Product Code: OEB, QIH

Primary Predicate Device:

Trade Name: InferRead Lung CT.AI
Classification: Class II
510(k) Number: K192880
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Common Name: Lung Computed Tomography System, Computer-Aided Detection
Classification Panel: Radiology
Product Code: OEB, LLZ

Secondary Predicate Device:

Trade Name Lung Nodule Assessment and Comparison Option (LNA)

Classification	Class II
510(k) Number	K162484
Regulation Number:	21 CFR 892.2050
Regulation Name:	Medical Image Management And Processing System
Common Name	System, Image Processing, Radiological
Classification Panel	Radiology
Product Code	LLZ, JAK

Reference device is:

Trade Name	ClearRead CT
Classification	Class II
510(k) Number	K221612
Regulation Number:	21 CFR 892.2050
Regulation Name:	Medical Image Management And Processing System
Common Name	Lung Computed Tomography System, Computer-Aided Detection
Classification Panel	Radiology
Product Code	OEB, LLZ

Device Description

InferRead Lung CT.AI uses the deep learning (DL) technology to perform nodule detection. It is a dedicated post-processing application that generates CAdE marks as an overlay on original CT scans. The software can be installed in a healthcare facility or a cloud-based platform and is comprised of computer-assisted reading tools designed to aid radiologists in detecting, segmenting, measuring and localizing actionable pulmonary nodules that are 4mm or above during the review of chest CT examinations of asymptomatic populations, with enhanced capabilities for pulmonary nodule follow-up comparison and lung analysis. InferRead Lung CT.AI provides auxiliary information and is not intended to be used if the original CT series is not available.

Indications for Use

InferRead Lung CT.AI is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules $\geq 4\text{mm}$ during the review of CT examinations of the chest on an asymptomatic population ≥ 55 years old. InferRead Lung CT.AI requires that both lungs be in the field of view. InferRead Lung CT.AI provides adjunctive information and is not intended to be used without the original CT series.

Substantial Equivalence

Infervision Medical Technology Co., Ltd. asserts that InferRead Lung CT.AI is substantially equivalent in both intended use and technical characteristics to the cited predicate devices. The variations in design and performance compared to the predicate devices do not impact the safety or effectiveness of InferRead Lung CT.AI for its intended use. Table below lists the predicate devices alongside the subject device, including their respective Product Codes and Indications for Use.

Detailed Comparison of the Subject and Predicate/Reference Devices

Item	Subject Device: InferRead Lung CT.AI	Primary Predicate: InferRead Lung CT.AI (K192880)	Secondary Predicate: Lung Nodule Assessment and Comparison Option (LNA)(K162484)	Reference Device: ClearRead CT(K221612)
Indications for Use	InferRead Lung CT.AI is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules $\geq$ 4mm during the review of CT examinations of the chest on an asymptomatic population $\geq$ 55 years old. InferRead Lung CT.AI requires that both lungs be in the field of view. InferRead Lung CT.AI provides adjunctive information and is not intended to be used without the original CT series.	InferRead Lung CT.AI is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during the review of CT examinations of the chest on an asymptomatic population. InferRead Lung CT.AI requires that both lungs be in the field of view. InferRead Lung CT.AI provides adjunctive information and is not intended to be used without the original CT series.	The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.	ClearRead CT is comprised of computer-assisted reading tools designed to aid the radiologist in the detection and characterization of pulmonary nodules during the review of screening and surveillance (low-dose) CT examinations of the chest on a non-oncological patient population. ClearRead CT requires both lungs be in the field of view and is not intended for monitoring patients undergoing therapy for lung cancer or limited field of view CT scans. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.
Product Code	OEB, QIH	OEB, LLZ	LLZ, JAK	OEB, LLZ
User Access Point	Post Processing Application	Post Processing Application	Post Processing Application	Post Processing Application
Image Input	DICOM	DICOM	DICOM	DICOM
Type of Scans	CT	CT	CT	CT
Anatomical Region	Chest	Chest	Chest	Chest
Automatically Locate and Identify Lung Nodules	Yes	Yes	Yes	Yes
Modifies the Original CT scan	No	No	No	No
Automatic calculation of measurements	The maximum axial plane longest diameter and shortest diameter, the mean	The maximum and axial plane longest diameter, mean diameter and volume	Short axis- longest diameter perpendicular to the long axis on the	Volume, maximum, minimum, average axial plane diameters

for each segmented nodule	diameter, volume, mean densities information are provided.	information are provided.	slice(mm) Long Axis- Longest diameter on an axial slice (mm) Average\ Max 3D \ Effective diameter (mm) Volume(mm3) Mean densities (HU)	
Temporal Comparison (Nodule Matching)	Yes, automatic	No	Yes, Semi-Automatic	Yes, Fully Automatic
Segmentation of lungs and lung lobes	Yes	No	Yes	Yes
Nodule location	Yes	No	No	Yes
Reporting results	Yes	No	Yes	Yes

Key features identified that differ from the predicate are discussed below. The newly introduced features have been validated and does not compromise the device’s safety and effectiveness.

Nodule location:

This feature displays the lobar location of each detected pulmonary nodule. It relies on the same nodule-detection algorithm used in predicate device K192880 and serves to enhance physicians’ ability to accurately localize detected nodules.

Nodule density:

Compared with predicate device K192880, this product additionally provides nodule density information for detected nodules. Nodule density is objectively quantified based on CT-derived Hounsfield Unit (HU) values.

Nodule registration between prior and current scan:

If prior scans are available for a case, the software will automatically match identified nodules between the current series and the prior series, and display each nodule’s change status as one of the following: “Increased, Decreased New Disappeared, No Change”. Physicians may manually adjust the matching results if needed.

Performance testing:

InferVision Medical Technology Co., Ltd. has assessed and tested the product and has passed all predetermined testing criteria. The plans for validation tests were designed to evaluate outputs by InferRead CT Lung.AI and followed the procedures documented in the validation test plan. Validation tests indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Regarding the performance of the AI outputs, the nodule detection and segmentation functions were consistent with the predicate product (K192880), as verified through consistency testing. For the newly added functions, including nodule registration, nodule localization and lung lobe segmentation, we conducted standalone performance testing. The detailed results are as follows:

Nodule Registration Standalone Performance Test

InferRead Lung CT.AI was evaluated in a Nodule Registration standalone test that contained 98 lung cancers screening cases with 206 nodule pairs. InferRead Lung CT.AI achieved an overall nodule Match Rate of 0.970 (95%CI: 0.947-0.994). In the scan interval subgroup analysis, the nodule match rates were as follows: 0.976 (95%CI: 0.911-1.0) for the 0-6 month interval, 1.000 (95%CI: N/A) for the 6-12 month interval, and 0.938 (95%CI: 0.880-0.997) for the 12-24 month interval.

Nodule Lobe Localization Standalone Performance Test

InferRead Lung CT.AI was evaluated in a Nodule Lobe Localization standalone test that contained 94 lung cancer screening scans with 188 nodules. InferRead Lung CT.AI achieved an overall Lobe Localization Accuracy Rate of 0.957 (95%CI: 0.929-0.986).

Lung Lobe Segmentation Standalone Performance Test

InferRead Lung CT.AI was evaluated in a Lung Lobe Segmentation standalone test that contained 22 lung cancer screening cases with 110 lung lobes. The test results for pulmonary lobe segmentation showed that the average Dice Coefficient was 0.966 (95%CI: 0.962 to 0.969).

Other Non-Clinical Testing Summary

InferRead Lung CT.AI was designed and developed by Infervision Medical Technology Co., Ltd. in accordance with applicable requirements, design controls, and relevant standards. It has demonstrated substantial equivalence to the predicate device. Non-clinical testing has demonstrated that InferRead Lung CT.AI complies with the following FDA-recognized consensus standards:

- IEC 62304:2006+A1:2015
- ISO 14971:2019
- AAMI TIR57:2016

The substantial equivalence of InferRead Lung CT.AI has been demonstrated through verification and validation testing in accordance with applicable specifications, acceptance criteria, and performance standards. The traceability analysis provides traceability between the requirement specifications, design specifications, risks, and verification testing of the subject device. All requirements and risk controls have been successfully verified and traced. A comprehensive risk analysis was performed for the subject device and appropriate risk controls have been implemented to mitigate hazards.

Software verification and validation activities were conducted in accordance with *IEC 62304:2006+A1:2015 – Medical device software – Software lifecycle processes* and *ISO 14971:2019 Medical devices – Application of risk management to medical devices*, and in accordance with relevant FDA guidance documents, *Guidance for the Content of Premarket Submissions for Device Software Functions* (issued June 14, 2023), and *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (issued September 27, 2023).

Cybersecurity and vulnerability analyses were conducted, and it has been determined that InferRead Lung CT.AI conforms to the cybersecurity requirements.

The following processes were followed and applied during the design and development of InferRead Lung CT.AI:

- Risk Analysis
- Unit Testing
- Integration Testing
- System Testing
- Performance Testing
- Software Verification & Validation
- Cybersecurity Testing and Analysis

InferRead Lung CT.AI was tested and was found to be substantially equivalent for the intended use, intended users, intended patient population, and use environments, as demonstrated through verification and validation testing evaluating its clinical usage and performance. Validation testing was performed to ensure that the final product meets the requirements for the specified clinical application and performs as intended to meet users' needs, while demonstrating substantial equivalence to the predicate device.

Conclusion

In preparing this 510(k) submission, Infervision Medical Technology Co., Ltd. has meticulously considered the relevant statutory and regulatory requirements and believes that the information provided herein meets the criteria for demonstrating substantial equivalence in terms of design features, fundamental technology, indications for use, and the safety and effectiveness of the device. Furthermore, verification and validation testing have been conducted to confirm that the device meets its intended use and specifications when operated as intended.