Beijing Infervision Technology Co., Ltd.
℅ Matt Deng
1900 Market St., 8th Floor
PHILADELPHIA, PA 19103

July 2, 2020

Re: K192880
Trade/Device Name: InferRead Lung CT.AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: OEB, LLZ
Dated: June 2, 2020
Received: June 3, 2020

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K192880

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 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Summary of 510(k)

## Beijing Infervision Technology Co., Ltd. K192880

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


| | |
|---|---|
| **Submitter:** | Beijing Infervision Technology Co., Ltd.<br>Room B401, 4th Floor, Building 1,<br>No.12 Shangdi Information Road,<br>Haidian District, Beijing, 100085<br>Phone: +86 10-86462323 |
| **Primary Contact:** | Mr. Matt Deng<br>Email: dyufeng@infervision.com<br>Phone: 919-491-5457 |
| **Company Contact:** | Xiaoyan Fan<br>Project Leader |
| **Date Prepared:** | July 1, 2020 |


### Device Name and Classification

| | |
|---|---|
| **Trade Name:** | InferRead Lung CT.AI |
| **Classification:** | Class II |
| **Regulation Number:** | 21 CFR 892.2050, Picture archiving and communications system |
| **Classification Panel:** | Radiology |
| **Product Code:** | OEB, LLZ |

### Predicate Device:

| | |
|---|---|
| **Trade Name** | ClearRead CT |
| **Classification** | Class II |
| **510(k) Number** | K161201 |
| **Regulation Number** | 21 CFR 892.2050, Picture archiving and communications system |
| **Classification Panel** | Radiology Panel |
| **Product Code** | OEB, LLZ |

**Device Description**

InferRead Lung CT.AI uses the Browser/Server architecture, and is provided as Software as a Service (SaaS) via a URL. The system integrates algorithm logic and database in the same server to ensure the simplicity of the system and the convenience of system maintenance. The server is able to accept chest CT images from a PACS system, Radiological Information System (RIS system) or directly from a CT scanner, analyze the images and provide output annotations regarding lung nodules. Users are then able to use an existing PACS system to view the annotations on their workstations. Dedicated servers can be located at hospitals and are directly connected to the hospital networks. The software consists of 4 modules which are Image reception (Docking Toolbox), Image predictive processing (DLServer), Image storage (RePACS) and Image display (NeoViewer).

**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 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.

**Risk Analysis Method**

The InferRead Lung CT.AI was assessed to determine risks to health associated with the use of the device. Risks related to safety and usability were considered. A risk analysis was conducted in accordance with ISO 14971:2007, Medical devices – Application of risk management to medical devices. Several risks were assessed, including, but not limited to device malfunction and improper use.

**Substantial Equivalence**

InferRead Lung CT.AI is substantially equivalent to the ClearRead CT (K161201) currently on the market.

The table below provides a detailed comparison of InferRead Lung CT.AI to the predicate device.

**Detailed Comparison of the Subject and Predicate Devices**

| Item | InferRead Lung CT.AI *(Subject Device)* | ClearRead CT (K161201) *(Predicate Device)* | Comparison |
|---|---|---|---|
| **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 | ClearRead CT™ is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during | The indications for use of InferRead Lung CT.AI are identical to the indications for use of the previously cleared ClearRead CT. |

| | | | |
|---|---|---|---|
| | 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. | review of CT examinations of the chest on an asymptomatic population. The ClearRead CT requires both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series. | |
| **Intended Use** | Computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest. | Computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest. | The intended use of InferRead Lung CT.AI is identical to the intended use of the previously cleared ClearRead CT. |
| **Accessories/Tools Required by the User (Platform)** | Must be used in conjunction with a PACS system or an Image Viewer that reads DICOM images. | Must be used in conjunction with a PACS system or an Image Viewer that reads DICOM images. | The accessories required by the user for InferRead Lung CT.AI are identical to the accessories required by the user for the previously cleared ClearRead CT. |
| **User Access Point** | Post Processing Application | Post Processing Application | The user access point of InferRead Lung CT.AI is identical to the user access point of the previously cleared ClearRead CT. |
| **Image Input** | DICOM | DICOM | The image input of InferRead Lung CT.AI is identical to the image input of the previously cleared ClearRead CT. |
| **Type of Scans** | CT | CT | The type of scans for InferRead Lung CT.AI are identical to the type of scans for the previously cleared ClearRead CT. |
| **Automatically Locate and Identify Lung Nodules** | Yes | Yes | The function of automatically locating and identifying lung nodules for InferRead Lung CT.AI is identical to the function of automatically locating and identifying |

| | | | |
|---|---|---|---|
| | | | lung nodules for the previously cleared ClearRead CT. |
| **Modifies the Original CT Scan** | No | Yes | According to the device description of the predicate device found in its 510K summary, “ClearRead CT is a dedicated post-processing application that generates a secondary vessel suppressed Lung CT series with CADe marks and associated region descriptors intended to aid the radiologist in the detection of pulmonary nodules.” ClearRead CT modifies the original scan by performing vessel suppression. On the contrary, InferRead Lung CT.AI does not modify the original scan, only shows the locations of pulmonary nodules.<br>This difference does not affect the intended use or safety and effectiveness of the device. |
| **Requires a Disjoint Comparison with the Original CT Scan** | No | Yes | Since ClearRead CT creates a secondary vessel suppressed Lung CT series, it requires the user to have an original CT series on a separate window. There are 2 series open at the same time. We refer to this setup as “disjoint comparison”. On the contrary, InferRead Lung CT.AI does not require 2 series open, as its CADe marks overlay with the original CT scan and can be toggled on and off. Therefore, InferRead Lung CT.AI does not require “disjoint comparison”<br>This difference does not affect the intended use or safety and effectiveness of the device. CT scans processed by |

| | | | |
|---|---|---|---|
| | | | InferRead Lung CT.AI display the original CT scans. |
| **Nodule Marking** | A bounding box is provided around nodules | A bounding box is provided around nodules | The function of providing a bounding box around nodules for InferRead Lung CT.AI is identical to the indications for use of the previously cleared ClearRead CT. |
| **Provides Nodule Characteristics** | Yes, the maximum axial plane longest diameter, mean diameter and volume information are provided. | Yes, the volume, maximum axial plane diameter, minimum axial plane diameter, and average density in Hounsfield units are provided. (from website) | InferRead Lung CT.AI has mean diameter measurement function that is not provided by predicate device. Mean diameter is the average of maximum axial plane diameter and minimum axial plane diameter. And this difference does not affect the safety and effectiveness of the device. |
| **Detection Target(s)** | Solid, Sub Solid (part solid and ground glass) nodules | Solid, Sub Solid (part solid and ground glass) nodules | The detection targets of InferRead Lung CT.AI are identical to the detection targets of the previously cleared ClearRead CT. They have the same definition principles for actionable nodules classification. |
| **Size of Detection Targets** | 4mm and above, supports visualization of nodules smaller than 4mm | 5mm and above, supports visualization of nodules smaller than 5mm | The InferRead Lung CT.AI detects smaller nodules. This difference does not affect the intended use or safety and effectiveness of the device. This difference has been addressed with the completion of stand-alone performance characteristics testing. |

**Testing Summary**

Non-clinical performance evaluation

Software testing was performed in accordance with General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002). Software testing which included unit testing, software integration testing and software system testing was performed on InferRead Lung CT.AI. It was demonstrated that InferRead Lung CT.AI, when used according to operating instructions, met all requirement specifications. All system functionalities were tested and passed. Measurement performance was validated on phantom and clinical data to assess reproducibility and accuracy. Standalone performance testing which included chest CT scans from patients who underwent lung cancer screening was performed to validate detection accuracy of InferRead Lung CT.AI. Results showed that InferRead Lung CT.AI had similar nodule detection sensitivity and FP/scan compared to those of the predicate device. Based on the results of verification and validation tests it is concluded that InferRead Lung CT.AI is effective and safe in the detection of nodules.

Clinical performance evaluation

A pivotal reader study which was a retrospective, fully crossed, multi-reader multi-case (MRMC) study was conducted to validate that the device conformed to the defined user needs and intended uses. A total of 10 board-certified radiologists and a collection of 249 scans were involved in the reader study. The purpose of the reader study was to validate that with the aided of InferRead Lung CT.AI radiologists' nodule detection performance could significantly improve without significantly increasing reading time at a significance level alpha of 0.05 (two-sided). The reader study measured the area under the curve (AUC) of the localization receiver operating characteristic (LROC) response when using InferRead Lung CT.AI relative to the unaided read. The study also measured the radiologists' interpretation time when using InferRead Lung CT.AI relative to unaided interpretations. Results showed that InferRead Lung CT.AI was found to significantly increase the AUC (Aided - Unaided: 0.073, 95%CI: 0.020, 0.125), indicating the detection performance through using the device is superior to the unaided read for detecting nodules. Moreover, InferRead Lung CT.AI was also found to decrease reading times (Aided - Unaided: -23s, 95%CI: -42, -3). In conclusion, the pivotal study showed that with the aided of InferRead Lung CT.AI radiologists' nodule detection performance could significantly improve without significantly increasing reading time.

**Substantial Equivalence Conclusions**

In conclusion, the intended use for InferRead Lung CT.AI is the same as that of the previously cleared ClearRead CT (K161201). The technological characteristics demonstrate that the InferRead Lung CT.AI is substantially equivalent to the previously cleared ClearRead CT (K161201), and the testing shows that the InferRead Lung CT.AI is substantially equivalent to the previously cleared ClearRead CT (K161201) and assures that the InferRead Lung CT.AI is as safe and effective as the previously cleared ClearRead CT (K161201).

**Conclusion**

The 510(k) Pre-market Notification for InferRead Lung CT.AI contains adequate information and data to determine that InferRead Lung CT.AI is as safe and effective as the legally marketed predicate device.