Infervision Medical Technology Co., Ltd.
℅ Mr. Matt Deng
Director
Infervision US, Inc.
1900 Market Street
PHILADELPHIA PA 19103

August 12, 2021

Re: K211179
Trade/Device Name: InferRead CT Stroke.AI
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: July 8, 2021
Received: July 12, 2021

Dear Mr. 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 and Part 809); 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)*
K211179

Device Name
InferRead CT Stroke.AI

Indications for Use *(Describe)*
InferRead CT Stroke.AI is a radiological computer aided triage and notification software for use in the analysis of Non-Enhanced Head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging suspected positive findings of intracranial hemorrhage (ICH).

InferRead CT Stroke.AI uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with a worklist with marked cases of suspected ICH findings. The device does not alter the original medical image, does not remove cases from queue, and is not intended to be used as a diagnostic device. If the clinician does not view the case, or if a case is not flagged, cases remain to be processed per the standard of care.

The results of InferRead CT Stroke.AI are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Infervision Medical Technology Co., Ltd. K211179

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

Submitter: Infervision Medical Technology Co., Ltd.
Room B401, 4th Floor, Building 1,
No. 12 Shangdi Information Road,
Haidian District, Beijing, 100085, China
Phone: +86 10-86462323

Primary Contact: Matt Deng
Email: matt.deng@infervision.ai
Phone: 919-886-6082

Second Primary Contact: Frank Wu
Email: frank.wu@infervision.ai
Phone: 857-988-1888

Company Contact: Xiaoyan Fan
Email: fxiaoyan@infervision.com
Phone: +86 13810508664

Date Prepared: April 8, 2021

Device Name and Classification

Trade Name: InferRead CT Stroke.AI
Common Name: Radiological computer aided triage and notification software
Classification: Class II
Regulation Number: 21 CFR 892.2080, Radiological computer aided triage and notification software
Classification Panel: Radiology
Product Code: QAS

Predicate Device:

Primary Predicate	
Trade Name	BriefCase
510(k) Submitter/Holder	Aidoc
Class	Class II
Regulation Number	21 CFR 892.2080
Classification Panel	Radiology
Product Code	QAS

Device Description

InferRead CT Stroke.AI is a radiological computer-assisted triage and notification software device. The software device is a computer program with a deep learning algorithm running on Ubuntu operating system. The device can be deployed as an onsite server in the hospital and the user interacts with the software from a client workstation. The device can be broken down into 4 modules, the NeoViewer, Docking Toolbox, RePACS, and DLServer.

The Docking Toolbox module receives DICOM series and inspects the series against a list of requirements. Series that pass the requirements are sent into the system for prediction for intracranial hemorrhage. Series are processed in a first-in-first-out order. When hemorrhage is detected, the system marks the case in the work list prompting the user to conduct preemptive triage and prioritization.

When the user refreshes the page, cases with suspected findings will be marked with an indicator. Cases are identified, such as by Name and Patient ID. The user may filter and sort by suspected ICH and identify the case. A preview is available but is not intended for primary diagnosis and a radiologist must review the case per their standard process. The suspected cases assist in triaging intracranial hemorrhage cases sooner than standard of care practice alone.

Intended Use/Indications for Use

InferRead CT Stroke.AI is a radiological computer aided triage and notification software for use in the analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging suspected positive findings of intracranial hemorrhage (ICH).

InferRead CT Stroke.AI uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with a worklist with marked cases of suspected ICH findings. The device does not alter the original medical image, does not remove cases from queue, and is not intended to be used as a diagnostic device. If the clinician does not view the case, or if a case is not flagged, cases remain to be processed per the standard of care.

The results of InferRead CT Stroke.AI are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Comparison of Technological Characteristics

The subject and predicate devices are radiological computer-assisted triage and notification software. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and workstations. Both devices process images intended to aid in prioritization and triage of non-enhanced head CT cases with intracranial hemorrhage. Both have the same intended use and indications for use for flagging suspected cases, and indicating to the clinician for review.

The predicate device sends pop up notifications and compressed previews to the workstations of radiologist. The subject device doesn't send pop up notifications as the predicate device. Instead, to fulfill the notification, the subject device visually marks the case in the worklist, indicating to a radiologist the need to review those images for ICH. For both devices, the user must be alert and receptive to the outputs of the device. Similarly to predicate device, the subject device also works in parallel to the standard of care. The indication prompts preemptive triage of the flagged case where the radiologist may decide to perform evaluation. Similarly, if the notification is rejected, the case remains in their standard queue to be handled per their standard of care.

The subject device provides a viewer on the workstation allowing the radiologist to preview the DICOM similarly to the compressed preview of the subject device. This viewer allows the user to Scroll through series. Similar to the predicate, the preview is for informational purposes only and not for diagnostic use. The notified clinicians are responsible for using the local imaging system for viewing the original images and engage the referring clinician for diagnosis and treatment decisions.

The subject and predicate software utilizes a deep learning algorithm trained on medical images. The subject device raises the same type of safety and effectiveness questions as the predicate. That is, accurate detection of intracranial hemorrhage within the study on which a physician can base a clinically useful triage/prioritization assessment considering all available clinical information. Like the predicate, the subject device does not remove cases from reading queue. Both devices operate in parallel with the standard of care, which remains the default option for all cases.

Detailed Comparison of the Subject and Predicate Devices

Item	**InferRead CT Stroke.AI** ***(Subject Device)***	**Aidoc Briefcase ICH (K180647)** ***(Predicate Device)***	**Comparison**
Intended Use / Indications for Use	InferRead CT Stroke.AI is a radiological computer aided triage and notification software for use in the analysis of Non-Enhanced Head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging suspected positive findings of intracranial hemorrhage (ICH). InferRead CT Stroke.AI uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with a worklist with marked cases of suspected ICH findings. The device does not alter the original medical	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH). BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH	InferRead CT Stroke.AI and the previously cleared BriefCase (K180647) have the same intended use and\indications for use in terms of finding suspected intracranial hemorrhage in non contrast head CT, flagging suspected cases, and indicating the case to the attention of the clinician.

	image, does not remove cases from queue, and is not intended to be used as a diagnostic device. If the clinician does not view the case, or if a case is not flagged, cases remain to be processed per the standard of care. The results of InferRead CT Stroke.AI are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	
User Population	Radiologist	Radiologist	Both are designed to be used by the radiologist, prompt the radiologist to start preemptive triage of a flagged case
Anatomical Region of Interest	Head	Head	Both are indicated for use in analysis of non-enhanced head CT
Data Acquisition Protocol	Non contrast CT scan of the head	Non contrast CT scan of the head or neck	Both are indicated for use in analysis of non-enhanced head CT
View DICOM data	DICOM information about the patient, study and current image	DICOM information about the patient, study and current image	Both display DICOM information for informational purposes only

Segmentation of region of interest	No; device does not mark, highlight, or direct users' attention to a specific location in the original image	No; device does not mark, highlight, or direct users' attention to a specific location in the original image	Neither marks, highlights or directs attention to a specific location in the original image
Algorithm	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images	Both use artificial intelligence algorithm with a database of images
Notification / Prioritization	Yes, Case level indicator	Yes, pop-up notifications, case level indicator	In both, the suspected cases are indicated to the user. The subject device provides case level indicator and allow the user to sort suspected cases to the top.
Preview Images	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes The device operates in parallel with the standard of care, which remains the default option for all cases	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes The device operates in parallel with the standard of care, which remains the default option for all cases	Both allow the user to view the image. The device is intended to work in parallel with standard of care.
Alteration of original image	No	No	Neither alters the original image.
Removal of cases from worklist queue	No	No	Neither removes cases from the worklist queue.

Performance Data

Infervision conducted a retrospective study to assess the clinical performance and notification functionality of the InferRead CT Stroke.AI software. The study evaluated the InferRead deep learning algorithm in terms of sensitivity and specificity with respect to a ground truth, as established by trained neuro-radiologists, in the detection of intracranial hemorrhage (ICH) in the brain. In addition, the study reported and compared the InferRead time-to-notification and the Time-to-open-exam for the standard of care. The InferRead time-to-notification includes the time to receive the DICOM scan, analyze and the worklist application shows the results. The standard of care time-to-open-exam consisted of the time from the initial scan of the patient to when the radiologist first opens the exam for review.

A total of 369 non-contrast brain CT scans (studies) were obtained from three hospitals in the U.S. There were approximately equal numbers of positive and negative cases (51.5% of images with ICH and 48.5% without ICH, respectively) included in the analysis. Comparing the InferRead software output to the ground truth, the sensitivity and specificity of InferRead CT Stroke.AI are 0.916 (95% CI: 0.867-0.951) and 0.922 (95% CI: 0.872-0.957), which are significantly higher than the 80% null hypothesis (p values < 0.001). This study met the pre-specified performance goals of 80% for sensitivity and specificity.

In addition, the area under the receiver operating characteristic curve (AUC) was 0.962, demonstrating the clinical utility and potential benefits of the InferRead software based on the imaging study results.

The InferRead time-to-notification is 1.07 ± 0.57 (mean ± SD) minutes, which is substantially lower than the standard of care time-to-open-exam of 75.4±192.7 minutes (P < 0.001). This validation study shows that InferRead CT Stroke.AI is both safe and effective.

Conclusions

Based on the technological comparison, the major difference is that the subject device marks the suspected case in the work list instead of a pop up notification. In both cases, the user must be receptive to the visual outputs of the device. After comparison, we do not find different issues of safety or effectiveness. In the same way as the predicate, the subject also uses deep learning algorithm to process images and predict intracranial hemorrhage. The intended use of the two are the same.

The performance testing demonstrated that the subject device performed similarly. These results show that the subject device does not have significant differences and is as safe and effective as a legally marketed predicate device.