September 24, 2024

Shanghai United Imaging Intelligence Co., Ltd.
% Nima Akhlaghi
Director, Digital Health, AI & Imaging Center Lead
MCRA Digital Health
803 7th Street NW, 3rd Floor
WASHINGTON, DISTRICT OF COLUMBIA 20001

Re: K242292
Trade/Device Name: uAI Easy Triage ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: August 1, 2024
Received: August 2, 2024

Dear Nima Akhlaghi:

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242292

Device Name

uAI Easy Triage ICH

Indications for Use *(Describe)*

uAI Easy Triage ICH is a radiological computer-assisted triage and notification software device indicated for analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected positive findings of Intracranial Hemorrhage (ICH).

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.

510 (k) SUMMARY

1. Date of Preparation:

August 01, 2024

2. Sponsor Identification

Shanghai United Imaging Intelligence Co., Ltd.
No. 701 Yunjin Road, Xuhui District, Shanghai, 200232,
PEOPLE'S REPUBLIC OF CHINA

Primary Contact Correspondent：
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3. Identification of Proposed Device

Trade Name: uAI Easy Triage ICH
Common Name: Radiological computer aided triage and notification software
Model(s): uAI Easy Triage ICH

Regulatory Information
Classification Name: Radiological computer aided triage and notification software
Classification: II
Product Code: QAS
Regulation Number: 21 CFR 892.2080
Review Panel: Radiology

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K221716
Device Name: CINA

5. Device Description

uAI Easy Triage ICH is a radiological computer-assisted triage and notification software intended to assist radiologists by flagging potential intracranial hemorrhage (ICH) in non-contrast head CT images. The Triage Software is a component of the uAI Easy Triage platform, a comprehensive medical imaging communication system designed to integrate and deploy specialized image processing applications.

The uAI Easy Triage ICH algorithm uses artificial intelligence CNN (convolutional neural networks) and advanced image processing to triage the non-contrast CT images for suspicious intracranial hemorrhage.

To train and internally test this ICH CADt device, a total of 9791 data points were collected from multiple sites as well as cases in China. Only cases that met the inclusion criteria were used. The reference standard (ground truth) was established in the form of ICH positive/negative by radiologists.

To clarify, 9791 cases were only used for training and internal testing and final validation data was from USA and independent from those used for training and internal testing.

6. Indications for use

uAI Easy Triage ICH is a radiological computer-assisted triage and notification software device indicated for analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected positive findings of Intracranial Hemorrhage (ICH).

7. Summary of Technological Characteristics

uAI Easy Triage ICH is a radiological computer-assisted triage and notification software intended to assist radiologists by flagging potential ICH in non-contrast head CT images. The software is a component of the uAI Easy Triage platform, a

comprehensive medical imaging communication system designed to integrate and deploy specialized image processing applications.

The uAI Easy Triage ICH alerts users to new studies with suspicious ICH findings via pop-up notifications. The software provides both active and passive notification mechanisms. Active notifications are presented as an alert icon with a count of pending cases, and an alert status bar displaying patient details, suspected findings, and the time of examination. Passive notifications are represented by an icon beside the patient's name in the list for cases with detected ICH findings. Additionally, the application offers a DICOM image preview feature for radiologists to review. This preview is strictly informational, devoid of diagnostic markers, and is not to be used for definitive diagnosis.

The uAI Easy Triage ICH embodies the core algorithmic technology that identifies image characteristics consistent with intracranial hemorrhage. The application reads DICOM files, verifies their compatibility with the prescribed acquisition protocols, executes the triage algorithm, and communicates findings in DICOM format, compatible with the uAI Easy Triage Platform.

Table 1 Substantial Equivalence Table

Item	Proposed Device uAI Easy Triage ICH	Predicate Device CINA（K221716）	Remark
Device Classification Name	Radiological Computer Aided Triage And Notification Software	Radiological Computer Aided Triage And Notification Software	Same
Product Code	QAS	QAS	Same
Regulation Number	21 CFR 892.2080	21 CFR 892.2080	Same
Device Class	II	II	Same
Classification Panel	Radiology	Radiology	Same
Intended Use/Indications for Use	uAI Easy Triage ICH is a radiological computer-assisted triage and notification software device indicated for analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by	Cina is a radiological computer aided triage and notification software indicated for use in the analysis of (1) non-enhanced head CT images and (2) CT angiography of the head. The device is intended to assist	Compared to predicate device, the proposed device provides one applications for ICH while the predicate device CINA (K221716) provides two applications for ICH and LVO. uAI Easy Triage ICH and the predicate device CINA(K221716) have the same intended use

Item	Proposed Device uAI Easy Triage ICH	Predicate Device CINA（K221716）	Remark
	flagging and prioritizing studies with suspected positive findings of Intracranial Hemorrhage (ICH).	hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) head CT angiography for large vessel occlusion (LVO) of the anterior circulation (distal ICA, MCA-M1 or proximal MCA-M2). Cina uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) LVO on a standalone Web application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO	and\indications for use in terms of finding suspected intracranial hemorrhage in non-enhanced head CT, flagging suspected cases, and indicating the case to the attention of the clinician.

Item	Proposed Device uAI Easy Triage ICH	Predicate Device CINA（K221716）	Remark
		findings. Notifications include compressed preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a diagnostic device. The results of Cina are intended to be used in conjunction with other patient information and based on professional judgement to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care.	

Item	Proposed Device uAI Easy Triage ICH	Predicate Device CINA（K221716）	Remark
User population	Radiologist	Radiologist	Same
Anatomical region of interest	Head	Head	Same
Data acquisition protocol	Non-contrast CT scan of the head	Non-contrast CT scan of the head or neck and CT angiogram images of the brain	Compared to predicate device, the proposed device supports non-contrast head CT data for ICH application while the predicate device support non-contrast head CT data for ICH application or neck and brain CT angiogram data for LVO application. The difference between the proposed device and the predicate device will not impact the safety and effectiveness of the subject device.
View DICOM data	DICOM information about the patient, study and current image	DICOM information about the patient, study and current image	Same
Segmentation of region of interest	No; device does not mark, highlight, or direct users' attention to a specific location in the	No; device does not mark, highlight, or direct users' attention to a specific location in the	Same

Item	Proposed Device uAI Easy Triage ICH	Predicate Device CINA（K221716）	Remark
	original image	original image	
Algorithm	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images	Same
Notification / Prioritization	Yes	Yes	Same
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.	Same
Alteration of original image	No	No	Same
Removal of	No	No	Same

Item	Proposed Device uAI Easy Triage ICH	Predicate Device CINA（K221716）	Remark
cases from worklist queue			
Structure	- ICH image processing applications - uAI Easy Triage Platform, including Alert Icon, Patient Management, and Image Viewer.	- LVO and ICH image processing applications - Cina Platform (worklist and Image Viewer)	Compared to predicate device, the proposed device have same software structure and add an alert icon module to pop-up the suspected positive findings of ICH. The difference between the proposed device and the predicate device will not impact the safety and effectiveness of the subject device.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
Not Applicable to the proposed device, because the device is stand-alone software.

Electrical Safety and Electromagnetic Compatibility (EMC)
Not Applicable to the proposed device, because the device is stand-alone software.

Software Verification and Validation
Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device.

Per FDA Guidance "GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES", dated June 14, 2023, the Level of Concern of the software contained in the proposed device is determined to be: Basic Documentation Level.

Those documentations include:

- Software Description
- Risk management File
- Software Requirements Specification (SRS)
- Software Architecture Diagram
- Software Development Environment Description
- Software Verification and Validation
- Software Version History
- Cybersecurity Documents

Animal Study
No animal study was required.

Clinical Studies
No clinical study was required.

Performance Testing

Algorithm training of uAI Portal software has been conducted on images collected from China as training dataset. The dataset ensures a variety of data for different gender,

age, equipment and CT protocol. Algorithm validation has been conducted on data from the USA. To validate the uAI Easy Triage ICH software from a clinical perspective, the AI-based algorithm contained in the product underwent a retrospective study to evaluate the performance of uAI Easy Triage ICH in terms of sensitivity, specificity and time to notification to identify/notify patients with suspected Intracranial Hemorrhage (ICH) processing non-contrast CT images.

Sensitivity and specificity of uAI Easy Triage ICH in processing of non-contrast head CT have been analyzed by comparison to a ground truth established by majority read of 3 U.S.-board-certified neuroradiologists.

A total of 295 non-contrast CT scans (studies) were obtained from different zip codes across four U.S. states. There were approximately equal numbers of positive and negative cases (147 of images with ICH and 148 without ICH, respectively) included in the analysis.

Regarding the validation of the algorithm, the test data was used independently from that used for training, tuning and internal testing dataset.

The validation data demographic information is summarized below.

Table 2 Clinical testing data subgroup information

Subgroup	Breakdown	Sample Size
Gender	Male	49%
	Female	51%
Age Ranges (Years)	18-45	17%
	45-65	36%
	65+	47%
Race Group	White	63%
	Black	18%
	others	19%
Equipment	GE	17%
	Philips	21%
	Siemens	62%
ICH Subtypes	Intraparenchymal Hemorrhage (IPH)	30%
	Intraventricular Hemorrhage (IVH)	17%
	Subarachnoid Hemorrhage (SAH)	24%
	Subdural Hemorrhage (SDH)	22%
	Extradural Hemorrhage (EDH)	0.3%

Comparing the uAI Easy Triage ICH software output to the ground truth, the sensitivity and specificity of uAI Easy Triage ICH are 92% (95% CI: 86%-96%) and 95% (95% CI: 90%-98%), respectively, exceeding the acceptance criteria of 80%.

Multiple subgroups of interest were considered in the analysis. In fact, the validation data was acquired from different regions across the U.S. to account for race/ethnicity

in the intended U.S. patient population. Detailed subgroup analysis were reported in the labeling.

The uAI Easy Triage ICH Time to Notification was measured during the study. The average Time to Notification in seconds was 41.1 with a 95% confidence interval (CI) for the mean equaling (40.1, 42.1).

In conclusion, the performance of the study for the validation of uAI Easy Triage ICH demonstrates that the device is effective for triage and notification as the performance levels (sensitivity and specificity) meet the predefined acceptance criteria and the time to notification of the device is similar to the predicate device's time.

Other Standards and Guidance

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set
- ISO 14971 Medical devices – Application of risk management to medical devices (Third Edition 2019-12).
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1 2015-06 CONSOLIDATED VERSION).
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Document issued on September 27, 2023).

9. Substantially Equivalent (SE) Conclusion

Compare to the predicate device, the subject device has a subset of the predicate application which resulted in a limited indication for use. The subject device has similar technological characteristics compare to the predicate device and the difference does not raise any new question of safety and effectiveness. Therefore the subject device is substantially equivalent to the proposed predicate.