Shanghai United Imaging Intelligence Co., Ltd.
℅ Zhao Xiaojing
Quality & Regulatory Manager
No. 199, Huanke Road
Shanghai, Shanghai 201210
CHINA

January 15, 2021

Re: K193271
Trade/Device Name: uAI EasyTriage-Rib
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: December 8, 2020
Received: December 8, 2020

Dear Zhao Xiaojing:

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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K193271

Device Name

uAI EasyTriage-Rib

Indications for Use *(Describe)*

uAI EasyTriage-Rib is a radiological computer-assisted triage and notification software device for analysis of CT chest images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing trauma studies with suspected positive findings of multiple (3 or more) acute rib fracture(s).

uAI EasyTriage-Rib uses an artificial intelligence algorithm to analyze images and highlight studies with suspected multiple (3 or more) acute rib fracture(s) in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The user is presented with notifications of cases with suspected 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 uAI EasyTriage-Rib, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Notified radiologists who read the original medical images are responsible for the diagnostic decision.

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

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K193271

Shanghai United Imaging Intelligence Co., Ltd.'s uAI EasyTriage-Rib

Submitter:

Shanghai United Imaging Intelligence Co., Ltd.
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Phone: +86 13917486296
Contact Person: ZHAO Xiaojing

Date Prepared: January 14, 2021

Name of Device: uAI EasyTriage-Rib

Common or Usual Name/ Classification Name: Radiological Computer-Assisted Prioritization Software For Lesions

Regulatory Class: Class II

Product Code: QFM (21 C.F.R. 892.2080)

Predicate Device: Zebra Medical Vision Ltd.'s HealthVCF (K192901)

Device Description

uAI EasyTriage-Rib is a radiological computer-assisted triage and notification software device indicated for analysis of CT chest 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 multiple (3 or more) acute rib fractures. The device consists of the following two modules: (1) uAI EasyTriage-Rib Server; and (2) uAI EasyTriage-Rib Studylist Application that provides the user interface in which notifications from the application are received.

Intended Use / Indications for Use

uAI EasyTriage-Rib is a radiological computer-assisted triage and notification software device for analysis of CT chest images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing trauma studies with suspected positive findings of multiple (3 or more) acute rib fractures.

uAI EasyTriage-Rib uses an artificial intelligence algorithm to analyze images and highlight studies with suspected multiple (3 or more) acute rib fractures in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The user is presented with notifications of cases with suspected 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 uAI EasyTriage-Rib, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Notified radiologists who read the original medical images are responsible for the diagnostic decision.

Justification for Time Criticality of Indication

The device aims to triage multiple (3 or more) rib fractures since the condition of multiple rib fractures is time sensitive in clinical practice. Specifically,

- The presence of 3 or more rib fractures is highly predictive of poor clinical outcomes including respiratory failure and overall mortality [1-10].
- The presence of 3 or more rib fractures is incorporated into US clinical guidelines for trauma patient management [1, 11, 15-24].
- Flail chest, which occurs in a subset of patients with 3 or more rib fractures, is a potentially life threatening condition that requires prompt management [1, 14,15, 25-28].

Accordingly, rib fracture is a time-critical condition that is appropriate to prioritize for review. In this setting, high sensitivity is a crucial consideration so that all appropriate cases may be identified and promptly interpreted.

Comparison of Technological Characteristics with the Predicate Device

HealthVCF (K192901) is the predicate device. The subject and predicate device are both radiological computer-assisted triage and notification software. Both devices are artificial intelligence algorithms incorporated software packages that analyze CT images for fracture(s). Both devices process images intended to aid in prioritization and triage of radiological medical images. The subject device is intended to provide notifications for cases with suspected positive findings of multiple (3 or more) acute rib fractures by analysis of CT chest images and the predicate device is intended to analyze chest and abdominal CT scans and flags those that are suggestive of the presence of at least one vertebral compression at the exam level. This difference does not affect the intended use of both devices, which is to prioritize time-sensitive fractures for trained clinician review.

Both software devices provide passive notifications to a clinician of the availability of time sensitive radiological medical images for review based on computer aided image analysis performed by the device's AI algorithm. The subject device flags cases with the suspected positive findings on the Studylist Application on the workstations of the radiologist. Those notifications work in parallel to the standard of care. They prompt the radiologist to start preemptive triage of a flagged case, upon which he may turn to the local PACS to perform the review. In addition, both devices show preview images for positive findings.

The predicate and subject devices process CT images using similar techniques and a similar artificial intelligence algorithm. Specifically, the subject and predicate software utilize a deep learning algorithm trained on medical images. The deep-learning process allows for high accuracy in the detection of initial suspect positive findings. As a system, the uAI EasyTriage-Rib raises the same types of safety and effectiveness questions as the predicate; namely, accurate detection of findings within the reviewed and processed study on which a physician can base a clinically useful triage/prioritization assessment considering all available clinical information.

It is important to note that, like the predicate, the device does not remove cases from a reading queue. Again, both devices operate in parallel with the standard of care, which remains the default option for all cases.

A table comparing the key features of the subject and predicate devices is provided below.

Technological Characteristics	**Subject Device uAI EasyTriage-Rib (K193271)**	**Predicate Device HealthVCF (K192901)**	**Summary**
Indication for Use/Intended Use	uAI EasyTriage-Rib is a radiological computer-assisted triage and notification software device for analysis of CT chest images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing trauma studies with suspected positive findings of multiple (3 or more) acute rib fractures. uAI EasyTriage-Rib uses an artificial intelligence algorithm to analyze images and highlight studies with suspected multiple (3 or more) acute rib fractures in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The user is presented with notifications of cases with suspected findings.	HealthVCF is a passive notification for prioritization-only, parallel-workflow software tool used by clinicians to prioritize specific patients within the standard-of-care bone health setting for suspected vertebral compression fractures. HealthVCF uses an artificial intelligence algorithm to analyze chest and abdominal CT scans and flags those that are suggestive of the presence of at least one vertebral compression at the exam level. These flags are viewed by the clinician in Bone Health and Fracture Liaison Service programs in the medical setting via a worklist application on their Picture	Similar except for lesion type. Both findings are appropriately time sensitive. Performance data will support uAI EasyTriage-Rib indications.

Technological Characteristics	Subject Device uAI EasyTriage-Rib (K193271)	Predicate Device HealthVCF (K192901)	Summary
	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 uAI EasyTriage-Rib, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Notified radiologists who read the original medical images are responsible for the diagnostic decision.	Archiving and Communication System (PACS). HealthVCF does not send a proactive alert directly to the user. HealthVCF does not provide diagnostic information beyond triage and prioritization, it does not remove cases from the radiology worklist, and should not be used in place of full patient evaluation, or relied upon to make or confirm diagnosis.	
Notification-only, parallel workflow tool	Yes	Yes	Same, both devices produce passive notifications
User	Radiologist	Bone Health Clinician	Radiologists are common users for products under product code QFM for Radiological Computer-Assisted Prioritization Software For Lesions
Identify patients with pre-specified clinical condition	Yes	Yes	Same
Clinical condition	Multiple (3 or more) acute rib fractures	Vertebral compression fracture	Different but both findings

Technological Characteristics	Subject Device uAI EasyTriage-Rib (K193271)	Predicate Device HealthVCF (K192901)	Summary
			indicate pre-specified clinical conditions for triage
Alert to finding	Yes; notification flagged for review	Yes; notification flagged for review	Same
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Same
Modality	CT	CT	Same
Body part	Chest	Chest and abdomen	Similar, both include “chest”.
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Aids prompt identification of cases with indicated findings	Yes	Yes	Same
Where results are received	Workstation	PACS / Workstation	Different but both provide a passive notification to the workstation of the presence of suspected finding in the scan.

Performance Data

UII conducted a retrospective, blinded, multicenter study with the uAI EasyTriage-Rib software with the primary endpoint to evaluate the software’s performance in identifying CT chest images containing multiple (3 or more) acute rib fractures in 200 cases from multiple US clinical sites. The 200 cases had >1mm slice thickness and were from GE and Siemens scanners. The sensitivity was 92.7% (95% CI: 84.8%-97.3%) and specificity was 84.7% (95% CI: 77.0%-90.7%). The AUC was 0.939 (95% CI: 0.906, 0.972).

An important consideration with these data is the presence of chronic rib fractures in the

dataset and the difficulty in distinguishing these findings from acute rib fractures, resulting in a decrease of specificity when acute fractures are the target condition. Specifically, certain chronic fractures can present as a pseudoarthrosis and/or malunion, findings that are difficult to distinguish from acute fractures. Accordingly, such findings are clinically relevant to review so as to exclude acute fracture.

Overall, the benefit-risk profile is favorable, and reflects the benefit of detecting 3 or more acute rib fractures with the high degree of sensitivity, and alerting the radiologist to the presence of this low incidence condition so that the study can be promptly interpreted.

In addition, a secondary endpoint measure was uAI EasyTriage-Rib's potential clinical benefit of worklist prioritization. For that purpose, we tested all the 76 true positive studies from clinical data set to compare the time-to-notification metric with Zebra Medical Vision Ltd.'s HealthVCF (K192901). The uAI EasyTriage-Rib time-to-notification is defined from the beginning of downloading the DICOM data from the PACS to the time of notification shown in the Studylist.

As shown in the table below, the average time-to-notification of uAI EasyTriage-Rib among 76 true positive studies 69.56 seconds is comparable to the time-to-notification of the HealthVCF software documented for an average of 61.36 seconds, suggesting that the radiologist can receive a notification timely on the status of studies with potential rib fracture findings with the help of uAI EasyTriage-Rib.

Time-to-notification	**Average performance time (seconds)**
uAI EasyTriage-Rib	69.56
HealthVCF	61.36

In summary, the performance on 200 cases establishes the achievement of effective triage by the uAI EasyTriage-Rib as well as effective notification functionality of the application, as compared to the time-to-notification of HealthVCF. The results show that it can detect rib fractures and reach the preset standard.

Conclusions

The uAI EasyTriage-Rib is as safe and effective as the HealthVCF. The uAI EasyTriage-Rib has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the uAI EasyTriage-Rib and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the uAI EasyTriage-Rib is as safe and effective as the HealthVCF. Thus, the uAI EasyTriage-Rib is substantially equivalent.

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