Heuron Co., Ltd.
% John Smith
Partner
Hogan Lovells US LLP
Columbia Square 555 Thirteenth Street NW
Washington, District of Columbia 20004

May 15, 2024

Re: K233247
Trade/Device Name: Heuron ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: April 5, 2024
Received: April 5, 2024

Dear John Smith:

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.

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,

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K233247

Device Name
Heuron ICH

Indications for Use *(Describe)*

Heuron ICH is radiological computer-aided triage and notification software designed for the analysis of non-contrast head CT images in adults or transitional adolescents aged 18 and older. This device is intended to aid appropriately trained medical specialists and hospital networks in streamlining workflow by identifying and communicating suspected positive findings of Intracranial hemorrhage (ICH).

Heuron ICH employs an artificial intelligence algorithm to analyze non-contrast CT images, flagging cases with identified findings through a dedicated application that operates in parallel with the standard of care image interpretation process. Users receive notifications for cases with suspected findings, which include compressed preview images provided for informational purposes only and are not intended for diagnostic use beyond notification. Importantly, Heuron ICH does not modify the original medical images and is not intended to serve as a diagnostic device.

The results generated by Heuron ICH are intended to complement other patient information and assist medical specialists in prioritizing and triaging medical images. Notified medical specialists are responsible for viewing the full non-contrast CT images in accordance with established standard of care practices.

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.

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510(k) SUMMARY
Heuron Co., Ltd.'s Heuron ICH

Submitter information
Company's name: Heuron Co., Ltd.
Company's address: 10F, C, 150, Yeongdeungpo-ro, Yeongdeungpo-gu, Seoul, 07292, Republic of Korea
Owner/Operator number: 10080283

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Date Prepared: April 5, 2024

Name of Device: Heuron ICH
Common or Usual Name: Medical Imaging Software
Classification Name: Radiological Computer-Assisted Triage And Notification Software
Regulatory Class: Class II
Regulation number: 21 CFR 892.2080
Product Code: QAS

Predicate Device: BriefCase (K221240)

Device Description

Heuron ICH registers with the hospital's Picture Archiving and Communication System (PACS) using IP, Port, AE title, and TLS authentication details. It automatically receives Non-Contrast Computed Tomography (NCCT) images in DICOM format from PACS. Upon connection request from PACS to Heuron ICH, the system verifies the IP, Port, AE title, and TLS authentication information before accepting the image transmission. The product does not query PACS to retrieve images. Instead, it receives images automatically from PACS systems that are allowed access by registering a list (white list) of PACS systems capable of uploading images to the product.

The Heuron ICH is an artificial intelligence-based solution that analyzes non-contrast CT images and provides a notification of suspected positive cases of intracranial hemorrhage (ICH) for prioritization of review. Heuron ICH uses deep learning (DL) technique of a convolutional neural network (CNN). Dataset obtained from the RSNA (Radiological Society of North America) Brain CT Hemorrhage Challenge 2019 was used for training and development of the model. Once the DICOM images transmitted from PACS are uploaded to the Heuron ICH server, the images become accessible through the worklist. The worklist displays patient identification information (Patient ID, name, age, etc.) and analysis status for convenient reference. Images received by Heuron ICH server are analyzed in the order of reception.

During the analysis, if ICH is suspected, the server provides users with a notification. The notifications include compressed preview images, which are not to be used for diagnostic use, but only for informational purposes. It is important to note that the software does not provide segmentation, analysis, or intermediate outputs to users. These notifications can be sent to registered email addresses, mobile SMS, and through the mobile app push notification feature.

Intended Use / Indications for Use

Heuron ICH is radiological computer-aided triage and notification software designed for the analysis of non-contrast head CT images in adults or transitional adolescents aged 18 and older. This device is intended to

aid appropriately trained medical specialists and hospital networks in streamlining workflow by identifying and communicating suspected positive findings of Intracranial hemorrhage (ICH).

Heuron ICH employs an artificial intelligence algorithm to analyze non-contrast CT images, flagging cases with identified findings through a dedicated application that operates in parallel with the standard of care image interpretation process. Users receive notifications for cases with suspected findings, which include compressed preview images provided for informational purposes only and are not intended for diagnostic use beyond notification. Importantly, Heuron ICH does not modify the original medical images and is not intended to serve as a diagnostic device.

The results generated by Heuron ICH are intended to complement other patient information and assist medical specialists in prioritizing and triaging medical images. Notified medical specialists are responsible for viewing the full non-contrast CT images in accordance with established standard of care practices.

Summary of Technological Characteristics

Both subject and the primary predicate BriefCase device are radiological computer-assisted triage and notification software for ICH triage. Both devices import NCCT images and use artificial intelligence algorithms to identify suspected ICH to aid in prioritization and triage of radiological medical images. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. At a high level, the subject and predicate devices are based on the following same technological elements:

- Data import
- Image processing (identification of suspected ICH)
- Notification is provided

Similar to the predicate device's algorithms, ICH triage does not externalize any internal segmentation, analysis, or intermediate outputs used in determining if a suspected ICH is present in the NCCT, nor does the algorithm mark the analyzed NCCT image. Like the predicate, the subject devices neither remove cases from the standard of care reading queue nor deprioritize cases. The following technological differences exist between the subject and predicate devices:

- There are differences in the learning method and learning data of artificial intelligence algorithms.

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

Device name	**Subject device** **Heuron ICH**	**Primary predicate device** **BriefCase (K221240)**
Manufacture	Heuron Co., Ltd.	Aidoc Medical, Ltd
Product code	QAS	QAS
Indications for Use	Heuron ICH is radiological computer-aided triage and notification software designed for the analysis of non-contrast head CT images in adults or transitional adolescents aged 18 and older. This device is intended to aid appropriately trained medical specialists and hospital networks in streamlining workflow by identifying and communicating suspected positive findings of Intracranial hemorrhage (ICH).	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of nonenhanced head CT images in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Intracranial hemorrhage (ICH) pathologies.

	Heuron ICH employs an artificial intelligence algorithm to analyze non-contrast CT images, flagging cases with identified findings through a dedicated application that operates in parallel with the standard of care image interpretation process. Users receive notifications for cases with suspected findings, which include compressed preview images provided for informational purposes only and are not intended for diagnostic use beyond notification. Importantly, Heuron ICH does not modify the original medical images and is not intended to serve as a diagnostic device. The results generated by Heuron ICH are intended to complement other patient information and assist medical specialists in prioritizing and triaging medical images. Notified medical specialists are responsible for viewing the full non-contrast CT images in accordance with established standard of care practices.	BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notification for 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 BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.
Anatomical region	Head	Head
User	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Compatible input data format and modality	Non-enhanced CT	Non-enhanced CT
Image format	DICOM	DICOM
Technical Implementation	AI/ML/Neural Network	AI/ML/Neural Network
Directs user to finding	No, the device does not highlight or direct a user's attention to a specific location in the image file.	No, the device does not highlight or direct a user's attention to a specific location in the image file.
Alteration of original image data	No	No
Notification/ Prioritization	Yes – PACS, Workstation, email, mobile (Push, SMS)	Yes – PACS, Workstation, email, mobile

Performance Data

Heuron conducted a retrospective, multi-center study using Heuron ICH software to evaluate the software's performance in detecting suspected intracranial hemorrhage in NCCT images. A total of 600 NCCT images were obtained from three different hospitals located in US for the study, which were newly acquired and

confirmed independent from the training and testing dataset used for model development. There were approximately equal numbers of positive and negative cases (46.2% images with ICH and 53.8% without ICH, respectively) included in the analysis.

For primary endpoint, the performance of Heuron ICH was evaluated by calculating sensitivity and specificity through comparing the software analysis results with the ground truth. The ground truth was determined by the two US board-certified neuroradiologists (truthers) interpretating each NCCT images, and in case of disagreement between the two truthers, a third truther reviewed the case for generating the final ground truth.

The standalone performance study results exceeded the acceptance criteria which were 80% for the lower bound of 95% Confidence Interval for both sensitivity and specificity. Sensitivity of Heuron ICH was 86.3% (95% CI: 81.9-90.3) and specificity was 87.6% (95% CI: 83.9-91.0). The lower bounds of each confidence interval exceeded 80%, thus the study met its goals for both sensitivity and specificity.

NPV was 88.1% and PPV was 85.6%.

Demographic information

Demographic		Total (N = 600)
Gender	Female	288 (48.0%)
	Male	312 (52.0%)
Age	≤65 years	263 (43.8%)
	>65 tears	337 (56.2%)
Race	Asian	26 (4.3%)
	Black or African American	35 (5.8%)
	White	496 (82.7%)
	Other	28 (4.7%)
	2 or more races	3 (0.5%)
	Declined	4 (0.7%)
	Unavailable	8 (1.3%)
Ethnicity	Hispanic	58 (9.7%)
	Not Hispanic	526 (87.7%)
	Declined	2 (0.3%)
	Unavailable	14 (2.3%)

Subgroup analysis

Slice thickness

Subgroup	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
< 2.5 mm	0.936 (0.910,0.958)	87.7 (82.9,92.0)	82.9 (77.6,87.6)
2.5 to 5 mm (inclusive)	0.974 (0.961,0.985)	89.1 (85.5,92.7)	95.0 (92.5,97.2)

Gender

Subgroup	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Female	0.915 (0.878,0.947)	79.8 (72.3,86.6)	87.0 (81.7,91.7)
Male	0.971 (0.954,0.984)	91.1 (86.7,94.9)	88.3 (83.1,92.9)

Age

Subgroup	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
≤ 65 years	0.955 (0.930,0.974)	84.5 (77.7,91.3)	90.0 (85.0,94.4)
> 65 years	0.940 (0.912,0.963)	87.4 (82.2,92.0)	85.3 (79.8,90.8)

Manufacturer

Subgroup	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
GE Healthcare	0.956 (0.920,0.982)	85.7 (78.0,92.3)	94.5 (89.9,98.2)
Siemens (slice thickness 2.5-5mm)*	0.982 (0.963,0.994)	93.7 (88.4, 97.9)	92.1 (87.1, 97.0)
Toshiba	0.978 (0.955,0.993)	82.4 (73.6,90.1)	97.3 (93.8,100.0)

*Siemens scanner CT images outside the slice thickness of 2.5-5mm will be automatically excluded from the analysis and such information on the non-processed data can be found on the device worklist with an icon with explanation pop-up.

Co-existing findings or abnormalities

Subgroup	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
No additional findings	0.962 (0.935,0.982)	89.1 (83.6,94.5)	90.9 (86.4,94.9)
Any finding	0.926 (0.897,0.951)	84.4 (79.0,89.8)	83.7 (77.6,89.1)

The secondary endpoints evaluated area under the receiver operating curve (AUC) and time-to-notification of this software. The AUC was 0.945 when compared with the consensus diagnosis from radiologists.

The time-to-notification, 60.3 seconds±39.3 seconds (range 9-161 seconds), was similar to other cleared devices. The time-to-notification was significantly shorter than the average time to notification as seen in the Standard of Care.

Conclusions

The Heuron ICH is a standalone software that provides intracranial hemorrhage triage and notification to medical specialists. Both the subject device and the predicate device have the same intended use and similar indications for use and technological characteristics. Both devices send notifications of suspected time critical cases and display unannotated, compressed preview image which is not intended for diagnostic use. Both devices are not intended for diagnostic purposes, and users are instructed to review the original images from the PACS.

The Original images remain unaltered, with no markings provided, and no reordering of prioritization is performed. Therefore, the software does not interfere with the standard of care medical specialists. Both the subject and predicate devices contribute to faster workflow times by triaging and notifying time critical cases of suspected ICH.

The performance of this software has been verified through standalone performance testing, demonstrating shorter time-to-notification compared to the standard of care. Therefore, Heuron ICH device is substantially equivalent to the predicate device.