Ever Fortune.AI Co., Ltd.
Ti-Hao Wang
Chief Technology Officer
8F., No. 573, Sec. 2, Taiwan Blvd., West Dist.
Taichung City, 403020
Taiwan

October 4, 2023

Re: K231025
Trade/Device Name: EFAI NeuroSuite CT ICH Assessment System
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: September 4, 2023
Received: September 5, 2023

Dear Ti-Hao Wang:

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
DHT8B: Division of 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)*
K231025

Device Name
EFAI NEUROSUITE CT ICH ASSESSMENT SYSTEM

Indications for Use *(Describe)*
EFAI ICHCT is a software workflow tool designed to aid in prioritizing the clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage (ICH). EFAI ICHCT analyzes cases using deep learning algorithms to identify suspected ICH findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

EFAI ICHCT is not intended to direct attention to specific portions of an image or to anomalies other than acute ICH. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out hemorrhage or otherwise preclude clinical assessment of CT studies.

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

K231025

1. General Information

510(k) Sponsor	Ever Fortune.AI Co., Ltd.
Address	Rm. D, 8F. No. 573, Sec. 2 Taiwan Blvd. West Dist. Taichung City 403020 TAIWAN
Applicant	Joseph Chang
Contact Information	886-04-23213838 #216 joseph.chang@everfortune.ai
Correspondence Person	Ti-Hao Wang, MD
Contact Information	886-04-23213838 #168 tihao.wang@everfortune.ai
Date Prepared	April 10, 2023

2. Proposed Device

Proprietary Name	EFAI NEUROSUITE CT ICH ASSESSMENT SYSTEM
Common Name	EFAI ICHCT100
Classification Name	Radiological Computer-Assisted Triage And Notification Software
Regulation Number	21 CFR 892.2080
Regulation Name	Radiological Computer Aided Triage and Notification Software
Product Code	QAS
Regulatory Class	II

3. Predicate Device

Proprietary Name	CuraRad-ICH
Premarket Notification	K192167
Classification Name	Radiological Computer-Assisted Triage And Notification Software
Regulation Number	21 CFR 892.2080
Regulation Name	Radiological Computer Aided Triage and Notification Software
Product Code	QAS
Regulatory Class	II

4. Device Description

EFAI NEUROSUITE CT ICH ASSESSMENT SYSTEM (EFAI ICHCT) is a radiological computer-assisted triage and notification software system. The software uses deep learning techniques to automatically analyze non-contrast head CTs and alerts the PACS/RIS workstation once images with features suggestive of acute ICH are identified.

During the process of model development, a total of 5,365 adult cases were retrospectively collected between 2010 and 2018 from Taiwan. These cases were subsequently divided into training, validation, and testing datasets, consisting of 3,776, 1,038, and 551 cases, respectively.

Through the use of EFAI ICHCT, a radiologist is able to review studies with features suggestive of acute ICH earlier than in standard of care workflow.

The device is intended to provide a passive notification through the PACS/workstation to the radiologists indicating the existence of a case that may potentially benefit from the prioritization. It does not mark, highlight, or direct users' attention to a specific location on the original non-contrast head CT. The device aims to aid in prioritization and triage of radiological medical images only.

5. Intended Use / Indications for Use

EFAI ICHCT is a software workflow tool designed to aid in prioritizing the clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage (ICH). EFAI ICHCT analyzes cases using deep learning algorithms to identify suspected ICH findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

EFAI ICHCT is not intended to direct attention to specific portions of an image or to anomalies other than acute ICH. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out hemorrhage or otherwise preclude clinical assessment of CT studies.

6. Comparison of Technological Characteristics with Predicate Device

Table below provides a comparison of the intended use and key technological features of EFAI ICHCT with that of the Primary Predicate, CuraRad-ICH (K192167).

Table - Comparison with the Predicate Device.

Company	**Ever Fortune.AI Co., Ltd. (EFAI)**	**CuraCloud Corp.**
Device Name	EFAI ICHCT	CuraRad-ICH
510k Number	K231025	K192167
Regulation No.	21CFR 892.2080	21CFR 892.2080
Classification	II	II
Product Code	QAS	QAS
Intended Use/Indication for Use	EFAI ICHCT is a software workflow tool designed to aid in prioritizing the clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage (ICH). EFAI ICHCT analyzes cases using deep learning algorithms to identify suspected ICH findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI ICHCT is not intended to direct attention to specific portions of an image or to anomalies other than acute ICH. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out hemorrhage or otherwise preclude clinical assessment of CT studies.	CuraRad-ICH is a software workflow tool designed to aid in prioritizing the clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage. CuraRad-ICH analyzes cases using deep learning algorithms to identify suspected ICH findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. CuraRad-ICH is not intended to direct attention to specific portions of an image or to anomalies other than acute ICH. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out hemorrhage or otherwise preclude clinical assessment of CT studies.

Population	Adult patients indicated for non-contrast head CT	Adult patients indicated for non-contrast head CT
Intended Clinical End User	Radiologists/Trained Clinicians	Radiologists/Trained Clinicians
AI Used	Yes	Yes
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities.	Acquires medical image data from DICOM compliant imaging devices and modalities.
Input Image Modality	Non-contrast Head CT	Non-contrast Head CT
Non-Diagnostic Preview	No	No
Clinical condition	Acute Intracranial Hemorrhage	Acute Intracranial Hemorrhage
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist
Output	Suspected ICH (Yes or No)	Suspected ICH (Yes or No)
Results Receiver	PACS / Workstation	PACS / Workstation
Performance Results	Sensitivity: 0.947 (95% CI: 0.895 - 0.974) Specificity: 0.949 (95% CI: 0.902 - 0.974) Processing time: 34.96 seconds (95% CI: 33.89 - 36.03 seconds)	Sensitivity: 0.906 (95% CI: 0.859 - 0.942) Specificity: 0.931 (95% CI: 0.883 - 0.964) Processing time: 43 seconds (95% CI: 39 - 46 seconds)

The proposed device, EFAI ICHCT, is substantially equivalent to the claimed predicate, CuraRad-ICH (K192167).

7. Performance Data

Performance of the EFAI ICHCT has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"(2005), and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices."

Ever Fortune.AI conducted a retrospective, blinded, multisite clinical validation study with the proposed device EFAI ICHCT with a pre-determined primary and secondary endpoint and performance goals to evaluate the performance of the EFAI ICHCT in identifying intracranial hemorrhage (ICH) findings from non-contrast head computed tomography (CT) scans on a validation dataset of 288 CT studies (132 ICH positives and 156 ICH negatives) consecutively collected from 23 clinical sites in the United States (U.S.). Each patient included only one CT study. None of the studies was used as part of the EFAI ICHCT model development or analytical validation testing.

The study population contained 49.31% females and 50.69% males; the mean age of cases was 59.43 years. The ethnic and racial distribution includes 52.43% White, 10.42% Asian, 9.38% Black or African American, 7.99% Hispanic, and 19.79% others. The CT scanner manufacturers of images were acquired from Toshiba, Hitachi, Philips, Siemens, GE Medical Systems, and Canon. The CT is taken in a standard brain CT protocol.

The presence of ICH in each case was determined independently by three U.S. board-certified neuroradiologists, and the reference standard (ground truth) was generated by the majority agreement between the three experts. The performance acceptance criteria were set such that the lower bounds of 95% confidence intervals of both sensitivity and specificity should exceed 0.8.

The observed results of the standalone performance validation study demonstrated that EFAI ICHCT by itself, in the absence of any interaction with a clinician, can provide case-level notifications with features suggestive of ICH with satisfactory results. The EFAI ICHCT was able to demonstrate sensitivity and specificity of 0.947 (95% CI=0.895-0.974) and 0.949 (95% CI=0.902-0.974) respectively, as well as an AUROC of 0.983 (95% CI=0.969-0.997), which is substantially equivalent to the predicate device (CuraRad-ICH, K192167). The observed system processing time per study is 34.96 seconds (95% CI: 33.89-36.03) on average and was comparable with the predicate device, CuraRad-ICH

(CuraCloud, K192167, 43 seconds). In addition, the subgroup analysis results, which encompassed different genders, age groups, CT manufacturer groups, CT slice thickness groups, and types of ICH, revealed that EFAI ICHCT maintained a consistently high performance, indicating the device's reliability and effectiveness across diverse subgroups. No significant statistical difference was observed between EFAI ICHCT and GT. We found the device performs consistently and reliably under these circumstances. The results demonstrate that the EFAI ICHCT device is as safe and effective as the predicate device CuraRad-ICH.

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, the EFAI ICHCT raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.