April 8, 2024

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

Re: K240291
Trade/Device Name: EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME 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: January 31, 2024
Received: February 1, 2024

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240291

Device Name
EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM

Indications for Use *(Describe)*
EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM (EFAI AASCTA) is a radiological computer aided triage and notification software indicated for use in the analysis of chest or chest-abdomen CTA in adults aged 22 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) or aortic intramural hematoma (IMH) pathology.

EFAI AASCTA uses an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI AASCTA is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out AAS or otherwise preclude clinical assessment of computed tomography angiography cases.

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. 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
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Date Prepared	January, 2024

2. Proposed Device

Proprietary Name	EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM
Common Name	EFAI AASCTA
Classification Name	Radiological computer aided triage and notification software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

3. Predicate Device

Proprietary Name	BriefCase
Premarket Notification	K222329
Classification Name	Radiological computer aided triage and notification software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

4. Device Description

EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM (EFAI AASCTA) is a radiological computer-assisted triage and notification software system. The software uses deep learning techniques to automatically analyze chest or chest-abdomen CTA and alerts the PACS/RIS workstation once images with features suggestive of AD or IMH are identified.

Through the use of EFAI AASCTA, a radiologist is able to review studies with features suggestive of AD or IMH 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 chest or chest-abdomen CTA. The device aims to aid in prioritization and triage of radiological medical images only.

5. Intended Use / Indications for Use

EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM (EFAI AASCTA) is a radiological computer aided triage and notification software indicated for use in the analysis of chest or chest-abdomen CTA in adults aged 22 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) or aortic intramural hematoma (IMH) pathology.

EFAI AASCTA uses an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI AASCTA is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out AAS or otherwise preclude clinical assessment of computed tomography angiography cases.

6. Comparison of Technological Characteristics with Predicate Device

Feature/ Function	**Proposed Device:** EFAI AASCTA *(K240291)*	**Predicate Device:** *BriefCase* *(K222329)*
Intended Use/Indication for Use	EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM (EFAI	BriefCase is a radiological computer-aided triage and notification software indicated for use in the analysis

	AASCTA) is a radiological computer aided triage and notification software indicated for use in the analysis of chest or chest-abdomen CTA in adults aged 22 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) or aortic intramural hematoma (IMH) pathology. EFAI AASCTA uses an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI AASCTA is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out AAS or otherwise preclude clinical assessment of computed tomography angiography cases.	of CT exams with contrast (CTA and CT with contrast) that include the chest 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 communicating suspected positive cases of aortic dissection (AD) pathology. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications 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 the user's 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	Hospital networks and appropriately trained medical specialists	Hospital networks and appropriately trained medical specialists
Anatomical region of interest	Chest and thoracoabdominal	Chest, abdomen and thoracoabdominal
Data acquisition protocol	chest or chest-abdomen CTA	CT exams with contrast (CTA and CT with contrast) that include the chest
Notification-only (notification alerts), parallel workflow tool	Yes	Yes
Images format	DICOM	DICOM
Interference with standard workflow	No	No

Algorithm	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images

7. Performance Data

Performance of the EFAI AASCTA 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, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Ever Fortune.AI conducted a retrospective, blinded, multisite clinical validation study with the proposed device EFAI AASCTA with a pre-determined primary and secondary endpoint and performance goals to evaluate the performance of the EFAI AASCTA in identifying positive findings of aortic dissection (AD) or aortic intramural hematoma (IMH) from chest or chest-abdomen CTA scans on a validation dataset of 380 CTA studies (156 positives and 224 negatives) consecutively collected in the United States. None of the studies was used as part of the EFAI AASCTA model development or analytical validation testing.

The study population contained 51.58% females and 48.42% males, and the mean age of cases was 62.90 years. The CT scanner manufacturers of images were acquired from Philips, Toshiba, Siemens, GE, and others. Confounding cases in the dataset include possible confounders as follows: Artifact, Limited Field, Atherosclerotic Disease, Aortic Aneurysm, Arterial Dissection, and Vessel Disease.

The presence of AD or IMH in each case was determined independently by three U.S. board-certified radiologists, 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 (CIs) of both sensitivity and specificity should exceed 0.8.

The observed results of the standalone performance validation study demonstrated that EFAI AASCTA by itself, in the absence of any interaction with a clinician, can provide case-level notifications with features suggestive of positive findings (AD or IMH) with satisfactory results. The EFAI AASCTA was able to demonstrate sensitivity and specificity of 0.929 (95% CI=0.878-0.960) and 0.915 (95% CI=0.871-0.945) respectively, which is substantially equivalent to the predicate device (BriefCase, K222329). The secondary endpoint of the observed system processing time per study is 37.86 seconds (95% CI=35.22-40.50) on average and was comparable with the predicate device (38 seconds).

In addition, the results of the subgroup analysis, which included different genders, age groups, CT manufacturer groups, and CT slice thickness groups, demonstrated that EFAI AASCTA consistently performed high performance, underscoring its reliability and effectiveness across diverse subgroups. We also evaluated the device's performance in cases with image quality issues (including Artifact and Limited Field) and accompanying radiologic findings (including Atherosclerotic Disease, Aortic Aneurysm, Arterial Dissection, and Vessel Disease) to assess the impact of these potential confounders. The device consistently performed reliably across these circumstances. Furthermore, our analysis of the device's ability to identify specific characteristics of positive findings, including their type, Stanford classification, and location, revealed that EFAI AASCTA maintains stable performance. In conclusion, the results demonstrate that the EFAI AASCTA device is determined to be substantially equivalent in safety and effectiveness to the predicate device, BriefCase.

8. Safety & Effectiveness

EFAI AASCTA has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 Medical devices — Application of risk management to medical devices. The EFAI AASCTA performance has been validated using retrospective data from case data and through the use of Reader comparison analysis.

9. Conclusion

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