Ever Fortune.Ai, Co., Ltd.
Ti-Hao Wang
Chief Technology Officer
8f. # 360, Sec.1 Jingmao Rd., Beitun Dist.
Taichung City, 406040
Taiwan

October 30, 2026

Re: K263109
Trade/Device Name: Efai Neurosuite Cta Lvo Assessment System (lvo-cta-100)
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, 2026
Received: September 4, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263109

Please provide the device trade name(s).

EFAI NEUROSUITE CTA LVO ASSESSMENT SYSTEM (LVO-CTA-100)

Please provide your Indications for Use below.

EFAI NEUROSUITE CTA LVO ASSESSMENT SYSTEM (EFAI LVO) is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive ICA, MCA-M1, or MCA-M2 Large Vessel Occlusion (LVO) findings in head CTA images.

EFAI LVO uses an artificial intelligence algorithm to analyze images and highlight cases with suspected LVO in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of EFAI LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

1. General Information

510(k) Sponsor	Ever Fortune.AI Co., Ltd.
Address	8F., No.360, Sec. 1, Jingmao Rd., Beitun Dist., Taichung City 406040, Taiwan
Applicant	Joseph Chang
Contact Information	886-04-23213838 #216 joseph.chang@everfortune.ai
Correspondence Person	Ti-Hao Wang
Contact Information	886-04-23213838 #168 thothwang@gmail.com tihao.wang@everfortune.ai
Date Prepared	Sep. 04, 2026

2. Subject Device

Proprietary Name	EFAI NEUROSUITE CTA LVO ASSESSMENT SYSTEM (LVO-CTA-100)
Common Name	EFAI LVO
Classification Name	Radiological computer-assisted triage and notification software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

3. Predicate Device

Proprietary Name	Rapid LVO
Premarket Notification	K221248
Classification Name	Radiological computer-assisted triage and notification software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

4. Reference Device

Proprietary Name	syngo.CT LVO Detection
Premarket Notification	K243145
Classification Name	Radiological computer-assisted triage and notification software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

5. Device Description

EFAI NEUROSUITE CTA LVO ASSESSMENT SYSTEM (EFAI LVO) is a radiological computer-assisted triage and notification software system. The software uses deep learning techniques to automatically analyze contrast-enhanced head computed tomography angiography (CTA) and alerts the PACS/RIS workstation in parallel to the ongoing standard of care image interpretation.

Within the scope of this device, Large Vessel Occlusion (LVO) refers to vascular obstruction (total occlusion or high-grade stenosis) within the anterior circulation, targeted across three designated segments: ICA, MCA-M1, and MCA-M2. Through the use of EFAI LVO, a trained clinician is able to review studies with features suggestive of LVO in these segments earlier than in standard of care workflow.

The device is intended to provide a passive notification through the PACS/workstation to the trained clinicians 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 contrast-enhanced head CTA. The device aims to aid in prioritization and triage of radiological medical images only.

6. Intended Use / Indications for Use

EFAI NEUROSUITE CTA LVO ASSESSMENT SYSTEM (EFAI LVO) is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive ICA, MCA-M1, or MCA-M2 Large Vessel Occlusion (LVO) findings in head CTA images.

EFAI LVO uses an artificial intelligence algorithm to analyze images and highlight cases with suspected LVO in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of EFAI LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

7. Comparison of Technological Characteristics with Predicate Device

EFAI LVO does not raise new questions of safety or effectiveness compared to the predicate device, Rapid LVO (K221248). Both devices are radiological computer-aided triage and notification software applications for determining suspicion of Large Vessel Occlusion (LVO) using head CTA images.

Compared to the predicate device, EFAI LVO identifies an additional type of occlusion, the MCA-M2 segment, which does not raise a substantial difference in the indications for use nor different questions of safety and effectiveness, as this capability is identical to the reference device, syngo.CT LVO Detection (K243145).

While the subject device utilizes artificial intelligence learning algorithms rather than the traditional programming algorithms used by the predicate, this technological approach is also consistent with the reference device. Identification of suspected findings for these devices is for informational triage purposes and not for diagnostic use beyond notification.

The following table summarizes and compares the EFAI LVO, the predicate device (K221248), and the reference device (K243145):

Feature/ Function	**Subject Device:** EFAI LVO	**Predicate Device:** *Rapid LVO (K221248)*	**Reference Device:** *syngo.CT LVO Detection (K243145)*
Intended Use/ Indication for Use	EFAI NEUROSUITE CTA LVO ASSESSMENT SYSTEM (EFAI LVO) is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head	Rapid LVO is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained	syngo.CT LVO Detection is a radiological postprocessing application for the analysis of CT angiography (CTA) head images. syngo.CT LVO Detection supports

	images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive ICA, MCA-M1, or MCA-M2 Large Vessel Occlusion (LVO) findings in head CTA images. EFAI LVO uses an artificial intelligence algorithm to analyze images and highlight cases with suspected LVO in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of EFAI LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	radiologists in workflow triage by flagging and communication of suspected positive ICA or MCA-M1 Large Vessel Occlusion (LVO) findings in head CTA images. Rapid LVO uses a software algorithm to analyze images and highlight cases with suspected LVO on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. Notifications include compressed preview images. These 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 is not intended to be used as a diagnostic device. The results of Rapid LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage /prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	computer-aided triage, and it addresses vascular abortions in the CTA of the brain, commonly referred to as large vessel occlusion (LVO), in the ICA, M1, and M2 segment. It is intended for all patient populations of age ≥ 22 years, without any of the following contraindications: old infarcts or other diseases impacting the brain vasculature (for example, brain tumors), metal artifacts (for example, coils), surgical signs in the images. The output for triage is intended for informational purposes only. It is not intended for diagnostic use and does not alter the original medical image.
Stroke/Head	Stroke/Head	Intracranial Stroke/Head	Stroke/Head
Region of Interest	ICA, MCA-M1, and MCA-M2	ICA and MCA-M1	ICA, MCA-M1, and MCA-M2

Computer Platform	On-premises deployment	Standard off-the-shelf PC workstation/server; Virtual platform such as VMware	syngo.via platform
Imaging Type	CT Angiography	CT Angiography	CT Angiography
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities
SaMD	Artificial Intelligence learning algorithms	Traditional Algorithms	Artificial Intelligence learning algorithms
Pathways	External notification device	PACS, email, mobile	External notification device
Preview/ Prioritization	No image preview provided / The device provides informational case-level output for worklist prioritization.	Notification Message of Suspected LVO. Presentation of a compressed preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains.	No image preview provided; informational output only that does not highlight or direct attention to any portion of the image for worklist prioritization.
SoC Workflow	In parallel to the SoC	In parallel to the SoC	In parallel to the SoC
Original Image	No Alteration	No Alteration	No Alteration
Primary Users	Trained clinician	Clinician	Radiologists and clinical administrators

8. Performance Data

Performance of the EFAI LVO has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Software validation activities were conducted in compliance with IEC 62304:2006/A1:2015 (Medical device software – Software life cycle processes), ISO 14971:2019 (Application of risk management to medical devices), and 21 CFR 820.30 design controls, alongside FDA guidance documents, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Clinical validation was conducted by independent clinical users representative of the intended end-user population. The results demonstrated that EFAI LVO operates as intended within a clinical workflow and supports its intended use for worklist prioritization and triage of suspected Large Vessel Occlusions (LVO) in head CTA images.

Ever Fortune.AI conducted a retrospective, blinded, multisite standalone performance study to evaluate the subject device, EFAI LVO. The study included 313 consecutively collected head CTA cases from multiple U.S. clinical sites, with one case per patient, and no overlap from model development or internal testing. The reference standard was established via majority agreement among three U.S. board-certified radiologists, yielding 171 positive and 142 negative cases.

EFAI LVO exceeded the pre-specified 80% performance goal using the lower bound of the 95% confidence interval (CI) for sensitivity and specificity. The observed results were sensitivity: 0.96 (95% CI: 0.92–0.98) and specificity: 0.94 (95% CI: 0.88–0.97), with a PPV of 0.95, NPV of 0.95, and an AUROC of 0.96. Additionally, an analysis of total system processing time achieved a mean of 3.03 minutes (95% CI: 3.02–3.05), meeting the pre-specified goal of ≤ 3.5 minutes.

Moreover, subgroup analyses demonstrated consistent performance across demographic variables (sex, age, race and ethnicity), imaging acquisition parameters (CT manufacturer, CT slice thickness), and diverse concomitant imaging attributes, encompassing non-target vascular conditions, parenchymal pathologies, and technical quality artifacts.

In conclusion, the results demonstrate that EFAI LVO is substantially equivalent in safety and effectiveness to the predicate device.

9. Substantial Equivalence

The EFAI LVO is substantially equivalent to the predicate Rapid LVO (K221248) as both share an identical intended use for the triage and notification of suspected LVO findings in head CTA images. Technological differences, such as the use of artificial intelligence learning algorithms and the inclusion of the MCA-M2 segment, are directly supported by the reference device syngo.CT LVO (K243145) and do not raise new questions of safety or effectiveness.

Additionally, the subject device's passive notification design without image previews ensures that it remains an informational tool for worklist prioritization, operating strictly in parallel to the standard of care. Consequently, the EFAI LVO is as safe and effective as the legally marketed devices.

10. Conclusion

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