Ever Fortune.AI, Co., Ltd.
Dr. Ti-Hao Wang
Chief Technology Officer
8F. No. 360, Sec.1 Jingmao Rd., Beitun Dist.
Taichung City, 406040
Taiwan

December 6, 2024

Re: K241923
Trade/Device Name: EFAI Neurosuite CT Midline Shift Assessment System (MLS-CT-100)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: June 21, 2024
Received: November 18, 2024

Dear Dr. 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.

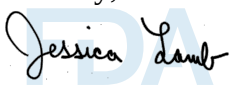
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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 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, Ph.D
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241923

Device Name

EFAI NEUROSUITE CT MIDLINE SHIFT ASSESSMENT SYSTEM (MLS-CT-100)

Indications for Use *(Describe)*

EFAI NEUROSUITE CT MIDLINE SHIFT ASSESSMENT SYSTEM (EFAI MLSCT) is a software workflow tool designed to aid in prioritizing the clinical assessment of non-contrast head CT cases with features suggestive of midline shift (MLS) in individuals aged 18 years and above. EFAI MLSCT analyzes cases using deep learning algorithms to identify suspected MLS findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

EFAI MLSCT is not intended to direct attention to specific portions of an image or to anomalies other than MLS. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out MLS 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

1. General Information

510(k) Sponsor	Ever Fortune.AI Co., Ltd.
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Applicant	Joseph Chang
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Correspondence Person	Ti-Hao Wang
Contact Information	886-04-23213838 #168 thothwang@gmail.com tihao.wang@everfortune.ai
Date Prepared	November, 2024

2. Proposed Device

Proprietary Name	EFAI NEUROSUITE CT MIDLINE SHIFT ASSESSMENT SYSTEM (MLS-CT-100)
Common Name	EFAI MLSCT
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	qER
Premarket Notification	K200921
Classification Name	Radiological computer-assisted triage and notification software
Regulation Number	21 CFR 892.2080
Product Code	QAS
Regulatory Class	II

4. Device Description

EFAI NEUROSUITE CT MIDLINE SHIFT ASSESSMENT SYSTEM (EFAI MLSCT) 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 MLS are identified.

Through the use of EFAI MLSCT, a radiologist is able to review studies with features suggestive of MLS 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 NEUROSUITE CT MIDLINE SHIFT ASSESSMENT SYSTEM (EFAI MLSCT) is a software workflow tool designed to aid in prioritizing the clinical assessment of non-contrast head CT cases with features suggestive of midline shift (MLS) in individuals aged 18 years and above. EFAI MLSCT analyzes cases using deep learning algorithms to identify suspected MLS findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage.

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

6. Comparison of Technological Characteristics with Predicate Device

Feature/ Function	**Proposed Device:** EFAI MLSCT	**Predicate Device:** *qER* *(K200921)*
Intended Use/Indication for Use	EFAI NEUROSUITE CT MIDLINE SHIFT ASSESSMENT SYSTEM (EFAI MLSCT) is a software workflow tool designed to aid in	qER is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT images.

	prioritizing the clinical assessment of non-contrast head CT cases with features suggestive of midline shift (MLS) in individuals aged 18 years and above. EFAI MLSCT analyzes cases using deep learning algorithms to identify suspected MLS findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI MLSCT is not intended to direct attention to specific portions of an image or to anomalies other than MLS. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out MLS or otherwise preclude clinical assessment of CT studies.	The device is intended to assist hospital networks and trained medical specialists in workflow triage by flagging the following suspected positive findings of pathologies in head CT images: intracranial hemorrhage, mass effect, midline shift and cranial fracture. qER uses an artificial intelligence algorithm to analyze images on a standalone cloud-based application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include non-diagnostic preview images that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of the device 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.
Classification/ Product Code	21 CFR 892.2080/QAS	21 CFR 892.2080/QAS
Anatomical region of interest	Head	Head
Data acquisition protocol	Non contrast CT scan of the head	Non contrast CT scan of the head
Segmentation of region of interest	No; device does not mark, highlight, or direct users' attention to a specific location in the original image.	No; device does not mark, highlight, or direct users' attention to a specific location in the original image.
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.

Notification/ Prioritization	Yes, with midline shift as the only output, there are no controls for the user to select the finding or combination of findings for triage	Yes, with controls for the user to select the finding or combination of findings for triage
Preview images	No	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains the default option for all cases.
Alteration of original image	No	No
Removal of cases from worklist queue	No	No
Abnormalities triaged	finding: midline shift	Four findings: Intracranial haemorrhage, Mass effect, midline shift, cranial fracture and ICH
User control over triage	Triages non-contrast CT scan only when midline shift is identified. No user control for configuring the triage finding.	Triages non-contrast CT scan when any of the 4 abnormalities are identified. Notification/ prioritization with user provided control for configuring the triage finding or combination of finding(s)
Device Deployment	deployed only on-premise	Performs de-identification of studies on-premise and pushes them to the cloud module for analysis.

7. Performance Data

Performance of the EFAI MLSCT 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 MLSCT with a pre-determined primary and secondary endpoint and

performance goals to evaluate the performance of the EFAI MLSCT in identifying midline shift (MLS) from non-contrast head computed tomography (CT) scans on a validation dataset of 300 cases (102 positives and 198 negatives) consecutively collected from multiple clinical sites across the United States (U.S.). Each case included only one CT study. None of the cases was used as part of the EFAI MLSCT model development or analytical validation testing, as the U.S. cases were solely collected for this study, while the model development and validation utilized cases from Taiwan.

The study population contained 51.67% females and 48.33% males, and the mean age of cases was 59.46 years. The CT scanner manufacturers of images were acquired from Siemens, Toshiba, GE Medical Systems, Philips, and Canon Medical Systems. Potential confounding cases in the dataset include artifact, poor patient position issue, intracranial hemorrhage, ischemic-stroke and related features, space-occupying lesions, and others.

The presence of MLS 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 MLSCT by itself, in the absence of any interaction with a clinician, can provide case-level notifications with features suggestive of MLS with satisfactory results. The EFAI MLSCT was able to demonstrate sensitivity and specificity of 0.961 (95% CI=0.903-0.985) and 0.955 (95% CI=0.916-0.973) respectively, along with an AUROC of 0.983 (95% CI=0.967-0.996), which is substantially equivalent to the predicate device (qER, K200921). The secondary endpoint of the observed system processing time per study is 62.04 seconds (95% CI=60.65-63.44) on average and was significantly less than the pre-specified performance goal.

In addition, the results of the subgroup analysis, which included different genders, age groups, race or ethnicity groups, CT manufacturer groups, and CT slice thickness groups, demonstrated that EFAI MLSCT 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 poor patient position issue) and radiologic findings (including intracranial hemorrhage, ischemic-stroke and related features, space-occupying lesions, and others) 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 mild to severe levels of MLS, revealed that EFAI MLSCT maintains stable performance. In conclusion, the results demonstrate that the EFAI MLSCT device is determined to be substantially equivalent in safety and effectiveness to the predicate device.

8. Safety & Effectiveness

EFAI MLSCT 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 MLSCT performance has been validated using retrospective data from case data and through the use of Reader comparison analysis.

9. Substantial Equivalence

The EFAI MLSCT has minor differences compared to the predicate device. These differences are related to the Intended Use, user control for triage configuration and inclusion of preview images in notifications.

The indications for use statement for the subject device is substantially similar to the cleared indications for Qure Ai's qER device. The overall effect of both the subject and predicate devices—namely, the workflow triaging of CT images by flagging suspected findings of pathologies in head CT images—remains the same. Although the subject device is intended to flag midline shift only without user control for configuring the triage finding, whereas the predicate flags mass effect, midline shift, cranial fractures, and ICH with user control for configuring the triage finding or combination of findings, this difference does not raise new questions of safety or effectiveness.

Both the subject and predicate devices use an artificial intelligence algorithm to analyze images and highlight cases with detected pathologies, alongside the ongoing standard of care image interpretation. The subject device provides notifications for cases with suspected findings without preview images, whereas the predicate provides notifications that include preview images for informational purposes only, not intended for diagnostic use beyond notification. Since clinicians can and should view the original CT before making a final determination on a case, with or without the sent preview images, the differences in notification outputs do not introduce new risks. Thus, the proposed device does not raise new questions of safety or efficacy, as the risks and technology used by both devices are the same and are mitigated similarly.

The predicate devices can be deployed either on client premises (on-premise) or on cloud servers (on-cloud). For on-cloud mode, an on-premise gateway interfaces with HIPAA-compliant cloud servers. The subject device, however, is exclusively deployed on-premise and does not interface with cloud servers, thereby no new risks or safety issues arise.

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 MLSCT raises no new questions of safety and effectiveness and demonstrates substantial equivalence to the predicate device.