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

February 20, 2025

Re: K242821
Trade/Device Name: EFAI Chestsuite XR Malpositioned ETT Assessment System (ETT-XR-100)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: January 14, 2024
Received: January 14, 2025

Dear Wang Ti-Hao:

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.

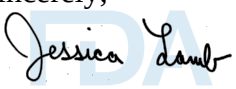
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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, PhD
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)*
K242821

Device Name
EFAI CHESTSUITE XR MALPOSITIONED ETT ASSESSMENT SYSTEM (ETT-XR-100)

Indications for Use *(Describe)*
EFAI CHESTSUITE XR MALPOSITIONED ETT ASSESSMENT SYSTEM (EFAI ETTXR) is a radiological computer-aided triage and notification software indicated for use in the analysis of chest X-ray (CXR) images in adults. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of vertically malpositioned endotracheal tube (ETT) in relation to the carina. Findings are flagged when the ETT distal tip is assessed as being more than 7 cm above the carina, less than 3 cm above the carina, or when it is below the carina (i.e in the right or left mainstem bronchus). The device assesses solely the vertical position of the ETT distal tip relative to the carina, does not factor patient positioning, and cannot detect esophageal intubation. The device is tested in the single lumen endotracheal tube, while it may trigger a false prioritization alert in the case of properly positioned double lumen ETT.

EFAI ETTXR analyzes cases using deep learning algorithms to identify suspected malpositioned ETT findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI ETTXR is not intended to direct attention to specific portions of an image or to 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 malpositioned ETT or otherwise preclude clinical assessment of chest radiographs.

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	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	January, 2025

2. Proposed Device

Proprietary Name	EFAI CHESTSUITE XR MALPOSITIONED ETT ASSESSMENT SYSTEM (ETT-XR-100)
Common Name	EFAI ETTXR
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	Briefcase
Premarket Notification	K221330
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 CHESTSUITE XR MALPOSITIONED ETT ASSESSMENT SYSTEM (EFAI ETTXR) is a radiological computer-assisted triage and notification software system. The software uses deep learning techniques to automatically analyze chest radiographs and alerts the PACS/RIS workstation once images with features suggestive of malpositioned ETT are identified.

Through the use of EFAI ETTXR, a radiologist is able to review studies with features suggestive of malpositioned ETT 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 radiographs. The device aims to aid in prioritization and triage of radiological medical images only.

5. Intended Use / Indications for Use

EFAI CHESTSUITE XR MALPOSITIONED ETT ASSESSMENT SYSTEM (EFAI ETTXR) is a radiological computer-aided triage and notification software indicated for use in the analysis of chest X-ray (CXR) images in adults. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of vertically malpositioned endotracheal tube (ETT) in relation to the carina. Findings are flagged when the ETT distal tip is assessed as being more than 7 cm above the carina, less than 3 cm above the carina, or when it is below the carina (i.e in the right or left mainstem bronchus). The device assesses solely the vertical position of the ETT distal tip relative to the carina, does not factor patient positioning, and cannot detect esophageal intubation. The device is tested in the single lumen endotracheal tube, while it may trigger a false prioritization alert in the case of properly positioned double lumen ETT.

EFAI ETTXR analyzes cases using deep learning algorithms to identify suspected malpositioned ETT findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI ETTXR is not intended to direct attention to specific portions of an image or to 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 malpositioned ETT or otherwise preclude clinical assessment of chest radiographs.

6. Comparison of Technological Characteristics with Predicate Device

Feature/ Function	Proposed Device: EFAI ETTXR	Predicate Device: *BriefCase (K221330)*
Intended Use/Indication for Use	EFAI CHESTSUITE XR MALPOSITIONED ETT ASSESSMENT SYSTEM (EFAI ETTXR) is a radiological computer-aided triage and notification software indicated for use in the analysis of chest X-ray (CXR) images in adults. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of vertically malpositioned endotracheal tube (ETT) in relation to the carina. Findings are flagged when the ETT distal tip is assessed as being more than 7 cm above the carina, less than 3 cm above the carina, or when it is below the carina (i.e in the right or left mainstem bronchus). The device assesses solely the vertical position of the ETT distal tip relative to the carina, does not factor patient positioning, and cannot detect esophageal intubation. The device is tested in the single lumen endotracheal tube, while it may trigger a false prioritization alert in the case of properly positioned double lumen ETT. EFAI ETTXR analyzes cases using deep learning algorithms to identify suspected malpositioned ETT findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI ETTXR is not intended to direct attention to specific portions of an image or to anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical	BriefCase is a radiological computeraided triage and notification software indicated for use in the analysis of frontal chest X-ray (CXR) 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 communicating suspected positive cases of vertically malpositioned endotracheal tube (ETT) in relation to the carina. Findings are flagged when the ETT distal tip is assessed as being more than 5 cm above the carina, less than 2 cm above the carina, or when it is below the carina (i.e in the right or left mainstem bronchus). The device assesses solely the vertical position of the ETT distal tip relative to the carina, does not factor patient positioning, and cannot detect esophageal intubation. The device does not provide results when the carina is not well-visualized on the x-ray image. The device does not discriminate types of ETTs, as such a properly positioned double lumen ETT may trigger a false prioritization alert. 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

	decision-making nor is it intended to rule out malpositioned ETT or otherwise preclude clinical assessment of chest radiographs.	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	Chest
Data acquisition protocol	Chest X-ray (AP view)	Frontal Chest X-ray (CXR)
Images format	DICOM	DICOM
Interference with standard workflow	No. No cases are removed from Worklist or deprioritized.	No. No cases are removed from desktop app or deprioritized
Algorithm	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.

7. Performance Data

Performance of the EFAI ETTXR 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 ETTXR with a pre-determined primary and secondary endpoint and performance goals to evaluate the performance of the EFAI ETTXR in identifying malpositioned Endotracheal Tube (ETT) from chest x-ray images on a validation dataset of 940 studies consecutively collected from multiple clinical sites across the United States. Each patient included only one study. None of the studies was used as part of the EFAI ETTXR model development or analytical validation testing.

The study population contained 49.57% females and 50.43% males, and the mean age of cases was 57.9 years. Cases included White, Black or African American, Hispanic, Asian, Multiracial, and other races or ethnicities. The X-ray images were obtained from manufacturers such as Philips, Canon, Carestream Health, Samsung Electronics, Siemens, and others.

The determination of malpositioned ETT in each case was independently assessed by three U.S. board-certified radiologists, with cases classified as positive for malpositioned ETT. Cases where the ETT was correctly positioned or with no ETT were classified as negative. The reference standard (ground truth) was based on the majority agreement among the three U.S. board-certified radiologists, resulting in 259 positive cases and 681 negative cases (Correctly Positioned ETT: 316, With No ETT: 365). Primary endpoints were sensitivity and specificity with an 80% performance goal.

The observed results of the standalone performance validation study demonstrated that EFAI ETTXR by itself, in the absence of any interaction with a clinician, can provide case-level notifications with features suggestive of malpositioned ETT with satisfactory results. The performance evaluation conducted exclusively on AP view showed EFAI ETTXR demonstrated a sensitivity and specificity of 0.890 (95% CI=0.846-0.923) and 0.935 (95% CI=0.909-0.954) respectively, which is substantially equivalent to the predicate device (BriefCase, K221330). The secondary endpoint of the observed system processing time per study is 2.49 minutes (95% CI=2.43-2.56 minutes) 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, and X-ray manufacturer groups, demonstrated that EFAI ETTXR consistently performed high performance, underscoring its reliability and effectiveness across diverse subgroups. Furthermore, we also evaluated the device's performance in cases with other (non-ETT) tubes, lines, and life support devices, lung diseases (cavitary lung lesions, lung abscesses, lung masses, nodules, pleural effusion, pneumonia, pneumothorax, and pulmonary edema), image quality issues (poor patient's position, artifact present, field of view issues, and

missing anatomy), post op (surgery or implants), and other diseases to assess the impact of these potential confounding factors. The device consistently performed reliably across these circumstances.

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

8. Safety & Effectiveness

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

9. Substantial Equivalence

The indications for use statement for the subject device is substantially similar to the cleared indications for use statement for BriefCase (K221330*)*. Both the subject and predicate devices are used for triaging chest radiographs by identifying suspected malpositioned endotracheal tubes (ETTs) relative to the carina. Both devices include specific criteria for ETT positioning and provide similar support for clinical decision-making.

Both devices target the same user population, focus on the chest as the anatomical region of interest, utilize chest X-rays (CXR) as the data acquisition protocol, support notifications as a parallel workflow tool, and use DICOM format for images. They also employ similar artificial intelligence algorithms for analyzing images. Regarding interference with standard workflow, neither device removes or deprioritizes cases from the workflow.

EFAI ETTXR has minor technical differences compared to the predicate device. The predicate device provides preview images within their notification while the proposed device provides notification as a text based JSON file. However, both devices are designed to provide case-level outputs for triage and prioritization purposes and intended to be used in conjunction with full images, thus 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 ETTXR raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.