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

November 8, 2022

Re: K221552
Trade/Device Name: EFAI ChestSuite XR Pneumothorax Assessment System
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: October 3, 2022
Received: October 4, 2022

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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)*
K221552

Device Name
EFAI Chestsuite XR Pneumothorax Assessment System

Indications for Use *(Describe)*
EFAI PNXXR is a software workflow tool designed to aid the clinical assessment of adult (22 years of age or older) Posteroanterior (PA) view Chest X-Ray cases with features suggestive of pneumothorax in the medical care environment. EFAI PNXXR analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI PNXXR 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 pneumothorax or otherwise preclude clinical assessment of X-Ray 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.

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510(k) Summary

1. General Information

K221552

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
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Correspondence Person	Ti-Hao Wang, MD
Contact Information	886-04-23213838 #168 tihao.wang@everfortune.ai
Date Prepared	May 31, 2022

2. Proposed Device

Proprietary Name	EFAI ChestSuite XR Pneumothorax Assessment System v1.0
Common Name	EFAI PNXXR v1.0
Classification Name	Radiological Computer-Assisted Prioritization Software For Lesions
Regulation Number	21 CFR 892.2080
Regulation Name	Radiological Computer Aided Triage and Notification Software
Product Code	QFM
Regulatory Class	II

3. Predicate Device

Proprietary Name	red dot™
Premarket Notification	K191556
Classification Name	Radiological Computer-Assisted Prioritization Software For Lesions
Regulation Number	21 CFR 892.2080
Regulation Name	Radiological Computer Aided Triage and Notification Software
Product Code	QFM
Regulatory Class	II

4. Device Description

EFAI ChestSuite XR Pneumothorax Assessment System, herein referred to as EFAI PNXXR, is a radiological computer-assisted triage and notification software system. The software uses deep learning techniques to automatically analyze PA chest x-rays and sends notification messages to the picture archiving and communication system (PACS)/workstation to allow suspicious findings of pneumothorax to be identified.

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 X-ray. The device aims to aid in prioritization and triage of radiological medical images only.

The deployment environment is recommended to be in a local network with an existing hospital-grade IT system in place. EFAI PNXXR should be installed on a specialized server supporting deep learning processing. The configurations are only being operated by the manufacturer:

- Local network setting of input and output destinations;

5. Intended Use / Indications for Use

EFAI PNXXR is a software workflow tool designed to aid the clinical assessment of adult (22 years of age or older) Posteroanterior (PA) view Chest X-Ray cases with features suggestive of pneumothorax in the medical care environment. EFAI PNXXR analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI PNXXR 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 pneumothorax or otherwise preclude clinical assessment of X-Ray cases.

6. Comparison of Technological Characteristics with Predicate Device

Table below provides a comparison of the intended use and key technological features of EFAI PNXXR with that of the Primary Predicate, red dot™ (K191556).

Table - Comparison with the Predicate Device.

Company	Ever Fortune.AI Co., Ltd. (EFAI)	Behold.AI Technologies Limited
Device Name	EFAI PNXXR	red dot™
510k Number	K221552	K191556
Regulation No.	21CFR 892.2080	21CFR 892.2080
Classification	II	II
Product Code	QFM	QFM
Intended Use/Indication for Use	EFAI PNXXR is a software workflow tool designed to aid the clinical assessment of adult (22 years of age or older) Posteroanterior (PA) view Chest X-Ray cases with features suggestive of pneumothorax in the medical care environment. EFAI PNXXR analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI PNXXR 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 pneumothorax or otherwise preclude clinical assessment of X-Ray cases.	The red dot™ software platform is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of Pneumothorax in the medical care environment. red dot™ analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. red dot™ is not intended to direct attention to specific portions of an image or to anomalies other than Pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pneumothorax or otherwise preclude clinical assessment of X-Ray cases.
Intended user	Hospital networks and trained clinicians	Hospital networks and trained clinicians

Supported Modalities	X-Ray (PA view)	X-Ray (PA or AP view)
Body Part	Chest	Chest
Artificial Intelligence Algorithm	Yes	Yes
Limited to analysis of imaging data	Yes	Yes
Aids prompt identification of cases with indicated findings	Yes	Yes
Image Input	DICOM	DICOM
Identify patients with a pre-specified clinical condition	Yes	Yes
Clinical condition	Pneumothorax	Pneumothorax
Alert to finding	Passive notification flagged for review	Passive notification flagged for review
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist
Where results are received	PACS / RIS / EPR /Workstation	PACS / RIS / EPR / Workstation

The proposed device, EFAI PNXXR, is substantially equivalent to the claimed predicate, red dot™ (K191556).

7. Performance Data

Performance of the EFAI PNXXR v1.0 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."*

To establish the standalone performance of EFAI PNXXR, a retrospective, blinded, multicenter study was performed to compare the pneumothorax classification performance and processing time of EFAI PNXXR against the predicate device, red dot™ (Behold.AI, K191556). The standalone dataset consists of 800 anonymized Chest X-ray images consecutively collected from 3 institutions from the US and 1 institution from the OUS. Neither of the datasets were used as part of the EFAI PNXXR model development or analytical validation testing.

The standalone dataset included pneumothorax positive (n=182) and negative cases (n=618). The cases were acquired from several X-Ray scanner manufacturers, including Samsung Electronics, Shimadzu, Toshiba, Canon Inc., Fujifilm Corporation, GE Healthcare, Konica Minolta, Philips Medical Systems, Swissray, etc. The X-Ray is taken in a standard chest X-ray protocol in PA view. Confounding cases in the dataset include possible confounders as the following: Air-fluid Level, Airspace Disease, Atelectasis, Blebs, Cardiomegaly, Fracture, Infiltrate, Mass, Nodule, Obstructive Airways Disease, Pleural Effusion, Pneumonia, Scoliosis and Image Quality Issues.

Three US board-certified radiologists determined the presence of pneumothorax in each case independently. The reference standard (ground truth) was generated by the majority agreement between the three board-certified radiologists. The performance acceptance criteria were set such that the lower bounds of 95% confidence intervals of both sensitivity and specificity should exceed 0.8.
Summary of results: The dataset included 56.50% males and 43.25% females, and the mean age of cases was 50.2 years. Overall, the EFAI PNXXR was able to demonstrate sensitivity and specificity of 0.97 (95% CI=0.94-0.99) and 0.98 (95% CI=0.96-0.99) respectively, as well as an AUC of 0.99 (95% CI=0.98-1.00), which is substantially equivalent to the predicate device (Behold.ai red dot™ (K191556). The average performance time of the EFAI PNXXR was 23.3 seconds with a 95% CI of [23.2, 23.4] and was comparable with the predicate device, red dot™ (Behold.AI, K191556, 29.3 seconds). The subgroup analysis included gender, age, manufacturer, data source (US and OUS), size and location of pneumothorax, and demonstrated consistent performance for the device across all subgroups.
The table below provides a more detailed description of the performance across different manufacturers.

Table. Sensitivity and specificity of EFAI PNXXR by manufacturer

Manufacturer	EFAI PNXXR	
	Sensitivity (95% Wilson CI)	**Specificity (95% Wilson CI)**
Samsung Electronics	1.00 (0.86, 1.00]	0.99 (0.97, 1.00)
Shimadzu	0.98 (0.91, 1.00)	0.99 (0.95, 1.00)
Toshiba	1.00 (0.90, 1.00]	0.99 (0.95, 1.00)
Others [a, b]	0.94 (0.85, 0.97)	0.81 (0.66, 0.91)

[a] *Other X-ray manufacturers include Canon Inc., Fujifilm Corporation, GE Healthcare, Konica Minolta, Philips Medical Systems, Swissray, etc.*
[b] *Manufacturers are merged into the category "Others" if the number of cases (Non-PNX Cases or PNX Cases) were less than or equal to five in the study.*

We also evaluated cases with image quality issues or radiologic findings other than pneumothorax, to see if these possible confounders systematically affect the software's performance. We found the device performs consistently and reliably under these circumstances. The results demonstrate that the EFAI PNXXR device is as safe and effective as the predicate device red dot™.

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 PNXXR v1.0 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.