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

September 8, 2022

Re: K222076
Trade/Device Name: EFAI ChestSuite XR Pleural Effusion 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: July 13, 2022
Received: July 14, 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

Enclosure

Section 4. Indications for Use Statement (Form FDA 3881)

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)*
K222076

Device Name
EFAI Chestsuite XR Pleural Effusion Assessment System

Indications for Use *(Describe)*
EFAI Chestsuite XR Pleural Effusion Assessment System is a software workflow tool designed to aid the clinical assessment of adult (18 years of age or older) Chest X-Ray cases with features suggestive of pleural effusion in the medical care environment. EFAI Chestsuite XR Pleural Effusion Assessment System analyzes cases using an artificial intelligence algorithm to identify suspected findings on chest x-ray images taken in PA position. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI Chestsuite XR Pleural Effusion Assessment System 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 pleural effusion 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

(K222076)

Section 5. 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
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Correspondence Person	Ti-Hao Wang, MD
Contact Information	886-04-23213838 #168 tihao.wang@everfortune.ai
Date Prepared	July 13, 2022

2. Proposed Device

Proprietary Name	EFAI ChestSuite XR Pleural Effusion Assessment System
Common Name	EFAI PUEXR 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	HealthCXR
Premarket Notification	K192320
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 Pleural Effusion Assessment System, 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 pleural effusion 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 Chestsuite XR Pleural Effusion Assessment System 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;

EFAI Chestsuite XR Pleural Effusion Assessment System is a software-only device which operates in four stages - data transfer, data preprocessing, AI inference and data post processing. The workflow of the device begins with applying a number of filtering rules based on image characteristics and DICOM tags to ensure only eligible images are analyzed by the algorithm. The image preprocessing unit ensures that all the input data are normalized (image size, contrast) such that it is ready for the algorithm to conduct the analysis. The AI inference generates an assessment which is then post-processed into a JSON message and transferred to an API server. The software is packaged as a docker container such that it can be installed and deployed to both a physical or virtual machine.

5. Intended Use

EFAI Chestsuite XR Pleural Effusion Assessment System is a software workflow tool designed to aid the clinical assessment of adult (18 years of age or older) Chest X-Ray cases with features suggestive of pleural effusion in the medical care environment. EFAI Chestsuite XR Pleural Effusion Assessment System analyzes cases using an artificial intelligence algorithm to identify suspected findings on chest x-ray images taken in PA position. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI Chestsuite XR Pleural Effusion Assessment System 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 pleural effusion 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 Chestsuite XR Pleural Effusion Assessment System with that of the Primary Predicate, HealthCXR (K192320).

Table - Comparison with the Predicate Device.

Company	Ever Fortune.AI Co., Ltd. (EFAI)	Zebra Medical Vision Ltd.
Device Name	EFAI Chestsuite XR Pleural Effusion Assessment System	HealthCXR
510k Number	K222076	K192320
Regulation No.	21CFR 892.2080	21CFR 892.2080
Classification	II	II
Product Code	QFM	QFM
Intended Use/Indication for Use	EFAI Chestsuite XR Pleural Effusion Assessment System is a software workflow tool designed to aid the clinical assessment of adult (18 years of age or older) Chest X-Ray cases with features suggestive of pleural effusion in the medical care environment. EFAI Chestsuite XR Pleural Effusion Assessment System analyzes cases using an artificial intelligence algorithm to identify suspected findings on chest x-ray images taken in PA position. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. EFAI Chestsuite XR Pleural Effusion Assessment System 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 pleural effusion or otherwise preclude clinical assessment of	The Zebra HealthCXR device is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of pleural effusion in the medical care environment. HealthCXR 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. HealthCXR 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 pleural effusion or otherwise preclude clinical assessment of X-Ray cases.

	X-Ray cases.	
Intended user	Radiologist	Radiologist
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	Pleural Effusion	Pleural Effusion
Alert to finding	Yes; Passive notification flagged for review	Yes; notification flagged for review on hospital worklist
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 / Workstation	PACS / Workstation

The proposed device, EFAI Chestsuite XR Pleural Effusion Assessment System, is substantially equivalent to the claimed predicate, HealthCXR (K192320).

7. Performance Data

Performance of the EFAI Chestsuite XR Pleural Effusion Assessment System 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 the recently published "Content of Premarket Submissions for Devices Software Functions (11-04-2021), and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices."

To establish the performance of EFAI Chestsuite XR Pleural Effusion Assessment System, the performance was validated by clinical and nonclinical tests.

Nonclinical Tests

The company conducted an internal validation test to assess the performance of the EFAI Chestsuite XR Pleural Effusion Assessment System. A total of 1454 images were retrospectively collected between 2006 to 2018 from Taiwan. Ground-truthing (classified into positive and negative of pleural effusion) was done by three board-certified radiologists.

Summary of results: The AUC was 0.9517 (95% CI=0.9369-0.9666) with a sensitivity as 0.9013 (95% CI=0.8881-0.9132) and a specificity as 0.8869 (95% CI=0.8776-0.8957) for assessing pleural effusion. By confirming that the AUC, sensitivity, and specificity all exceed the prespecified performance goals, the performance of the algorithm of EFAI Chestsuite XR Pleural Effusion Assessment System was validated.

Clinical Tests

A standalone performance test was also performed. The test was conducted to compare the pleural effusion classification performance and processing time of EFAI Chestsuite XR Pleural Effusion Assessment System against the predicate device, HealthCXR. All data used during the standalone performance evaluation was acquired independently from product development training and internal testing. Each patient included only one image. The dataset included a retrospective cohort of 600 anonymized Chest X-ray images consecutively collected from multiple institutions in US and OUS (286 cases positive for pleural effusion and 314 cases negative for pleural effusion). The images were acquired from more than 15 X-Ray scanner manufacturers, including Samsung Electronics, SHIMADZU, TOSHIBA, KONICA MINOLTA, GE Healthcare, etc. The X-Ray is taken in a standard chest X-ray protocol in PA view. The confounding factors in this dataset include atelectasis, airspace disease, air-fluid level, blebs, fracture, infiltrate, mass, miliary disease, pneumonia, post-op change, pseudotumor, and pulmonary fibrosis.

Three US board-certified radiologists determined the presence of pleural effusion in each case independently. The majority agreement was used as the reference standard (ground truth). The performance acceptance criteria were set such that the lower bounds of both

sensitivity and specificity should exceed 0.80 and the lower bound of the AUC should exceed 0.95.
Summary of results: The dataset included 44.3% female and 55.3% male, and the mean age of cases was 58.7 years. Overall, the EFAI Chestsuite XR Pleural Effusion Assessment System was able to demonstrate sensitivity and specificity of 0.9510 (95% CI=0.9195-0.9706) and 0.9745 (95% CI=0.9505-0.9870) respectively, as well as an AUC of 0.9712 (95% CI=0.9538-0.9885). The average performance time of the EFAI Chestsuite XR Pleural Effusion Assessment System was 19.6 seconds and was comparable with the predicate device HealthCXR (K192320, 27.76 seconds). Clinical subgroup analysis was performed for the gender, data source (US and OUS), scanner manufacturers, size, and location of pleural effusion, and demonstrated consistent performance for the device across all subgroups. The results demonstrate that the EFAI Chestsuite XR Pleural Effusion Assessment System device is as safe and effective as the predicate device HealthCXR.

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 Chestsuite XR Pleural Effusion Assessment System 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.