Ever Fortune. AI Co., Ltd.
Chen Ming-Fong
Chairman
Rm. D, 8F , NO. 573, Sec. 2, Taiwan Blvd., West Dist.
TAICHUNG, 403020
TAIWAN

April 4, 2022

Re: K212624
Trade/Device Name: EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 9, 2022
Received: March 14, 2022

Dear Chen Ming-Fong:

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,

For

Thalia T. Mills
Division Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K212624

Device Name
EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment System

Indications for Use *(Describe)*

EFAI Intelligent Cardiothoracic Ratio Assessment System (or iCTR) is a software for use by hospital and clinics to automatically assess the cardiothoracic ratio (CTR) of a chest X-ray image from the X-ray imager subject.

The iCTR is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR of a chest X-ray image in posterior-anterior (PA) chest view using an artificial intelligence algorithm.

Intended users of the software are aimed to the physicians or other licensed practitioners in the healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services.

The system is suitable for adults between 20 - 80 years of age.

Its results are not intended to be used on a stand-alone basis for clinical-decision making or otherwise preclude clinical assessment of cardiothoracic ratio (CTR) 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

K212624

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

I. Submitter

Company:	**EVER FORTUNE.AI Co., Ltd.** 8 F., No. 573, Sec. 2, Taiwan Blvd., West Dist., Taichung City 403020, Taiwan Phone: (886)-4-2322-6363 Fax: (886)-4-2322-9797 ra99@everfortuneai.com.tw
Contact:	*MING-FONG, CHEN (Chairman)* ra99@everfortuneai.com.tw
Date Prepared:	March 09, 2022

II. Name of the Device

Name of Device:	EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment System
Common Name:	EFAI iCTR
Classification Name:	Medical image management and processing system
Review Panel:	Radiology
Regulation:	21 CFR 892.2050
Device Class:	Class II
Product Code:	QIH

III. Predicate Device

Name	Manufacturer	510(K)#
Imbio RV/LV Software	Imbio, LLC	K203256

The *EFAI iCTR* is equivalent to the *Imbio RV/LV Software (K203256)*, manufactured by *Imbio, LLC* is provided as primary predicate device. The predicate has not been subject to a design-related recall. No references device was used in this submission.

IV. Device Description

The iCTR is a non-invasive software medical device designed to be installed on the computer with specific system requirements. It is a radiological computer-assisted software system that automatically analyzes DICOM chest X-ray images in PA view and outputs the CTR through an artificial intelligence algorithm. The structure report includes a preview of the compressed chest X-ray image with the automatically-derived CTR result and annotation line, indicating the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity, and the trajectory of CTR records. The trajectory of CTR does not implement a predictive or prognostic feature.

V. Indications for Use

EFAI Intelligent Cardiothoracic Ratio Assessment System (or iCTR) is a software for use by hospital and clinics to automatically assess the cardiothoracic ratio (CTR) of a chest X-ray image from the X-ray imager subject. The iCTR is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR of a chest X-ray image in posterior-anterior (PA) chest view using an artificial intelligence algorithm.

Intended users of the software are aimed to the physicians or other licensed practitioners in the healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. The system is suitable for adults between 20 - 80 years of age.

Its results are not intended to be used on a stand-alone basis for clinical-decision making or otherwise preclude clinical assessment of cardiothoracic ratio (CTR) cases.

VI. Comparison of Technical Characteristics with Predicate Device

The following table compares the *EFAI iCTR* to the predicate device with respect to intended use, indications for use, technological characteristics, device modalities and forms the basis for the determination of substantial equivalence. The comparison table shows that the subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table - Comparison Table			
Feature	**EFAI iCTR (K212624)**	**Imbio RV/LV Software (K203256)**	**Difference**
Manufacturer	Ever Fortune.AI Co., Ltd.	Imbio LLC	**NA**
Regulation Number	21 CFR §890.2050	21 CFR §890.2050	**Same**
Regulatory Class	Class II	Class II	**Same**
Product Code	QIH	QIH	**Same**
Regulation Name	Medical image management and processing system	Medical image management and processing system	**Same**
Device Property	SaMD	SaMD	**Same**
Intended Use / Indications For Use			
EFAI iCTR (K212624)	EFAI Intelligent Cardiothoracic Ratio Assessment System (or iCTR) is a software for use by hospital and clinics to automatically assess the cardiothoracic ratio (CTR) of a chest X-ray image from the X-ray imager subject. The iCTR is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR of a chest X-ray image in posterior-anterior (PA) chest view using an artificial intelligence algorithm. Intended users of the software are aimed to the physicians or other licensed practitioners in the healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. The system is suitable for adults between 20 - 80 years of age. Its results are not intended to be used on a stand-alone basis for clinical-decision making or otherwise preclude clinical assessment of cardiothoracic ratio (CTR) cases.		
Imbio RV/LV Software (K203256)	The Imbio RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the		

	ventricles. The RV/LV software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.		
Technical Characteristics	**EFAI iCTR (K212624)**	**Imbio RV/LV Software (K203256)**	**Difference**
Input	Post-anterior (PA) view chest X-ray image	Non-gated, CT Pulmonary angiography images	**Yes, there is difference. The proposed device used chest x-ray images in PA view as input to identify the maximal diameters of the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity. The primary device used CTPA images as input to identify the maximal diameters of the right and left ventricles of the heart. The verification report can verify the difference does not raise the impact of the safety and effectiveness. Both of the devices are in DICOM images as input.**
Output	Reports, DICOM Secondary Capture series	Reports, DICOM Secondary Capture series	**Same**
Report Structure	Report will be output in the DICOM and JSON file format which is structured with	Report will be output in DICOM file format which is structured with following	**Similar. The subject device is intended to output the maximal inner border diameter of thoracic cavity**

	following information and function tool: 1) CTR 2) adjustable annotation line (maximal inner border diameter of thoracic cavity and maximal diameter of heart) 3) the trajectory of CTR (including chest X-ray)	information and function tool: 1) the RV/LV Annotated Image Series (the slices with the maximum ventricular diameters, the RV/LV Ratio, and the individual ventricular measurements if available.) 2) the RV/LV Summary Report	**and heart. The predicate device is intended to output the maximum ventricular diameters.** **The report structure both can demonstrate the annotation line and subject image in DICOM format.**
Intended Users	Physicians or other licensed practitioners in the healthcare institutions	Thoracic Radiologists, General Radiologists, Pulmonologists, Cardiologists, imaging technologists under the supervision of a physician, or researchers	**Yes, there is difference. The proposed device is intended to provide the trained clinicians to use but no limited in the doctor specialists. The predicate device is intended to provide the radiologists and cardiologist and imaging technologists to use. The difference does not raise no impact of the safety and effectiveness.**
Target Population	Adults of 20-80 years old	No restrictions	**Yes, there is a difference. Proposed device only intended use for the patient in the adults of 20-80 years old. The validation report can verify the difference does raise no impact of the safety and effectiveness.**

Imaging Modality	Chest X-ray in Digital Radiography (DR)	Computed Tomography Pulmonary Angiography (CTPA) images	**Yes, there is a difference. Despite two compared devices is present with the different imaging modality. The verification & validation result has shown no impact raise in the safety and effectiveness.**
Intended Use Environment	Healthcare institutions (Clinics, hospitals, healthcare facilities, residential care facilities and long-term care services)	No restrictions	**Yes, there is a difference. The usability report can verify the different environment does not raise the impact of safety and effectiveness.**
Software device that operates on off-the-shelf hardware	Yes	Yes	**Same**
Software devices uses software algorithms for image	Yes	Yes	**Same**
Diameter Measurement	Yes - Automated	Yes - Automated	**Same**
Storage	Saved in JSON and DICOM file format text for DICOM and DICOM file format	Saved in PDF and DICOM compatible format	**They have same DICOM format storage. The storage of subject device in JASON format has been validated through the system test. There is no impact on safety or effectiveness of the subject device.**

Software Requirement	Ubuntu 18.04 (Web browser : chrome 88.0.4324.182 or above)	Imbio ICCP (Cloud)	**Yes, there is a difference. The operating system has been validated through the verification and validation. There is no impact on safety or effectiveness of the subject device.**

VII. Performance Data – Clinical Testing

EFAI iCTR Software was developed and tested in accordance with EFAI's Design Control processes and has been subjected to extensive safety and performance testing. EFAI iCTR Software verification and validation test results established that the device meets its design requirements and intended use. Specifically, software verification was conducted at unit, module, and system integration levels. Extensive algorithm development and software verification testing assessed the performance characteristics of the algorithm including EFAI iCTR accuracy, risk management, and overall functional performance. Images and cases used for verification testing were carefully separated from training algorithms.

Results of the EFAI iCTR were compared to evaluation by a panel of expert readers. That study met the pre-defined acceptance criteria and found that the observed accuracy estimates for the software were greater than 95% for identification of the imaging mode and the view.

The EFAI iCTR encompasses three quality control models and two annotation models. The quality control models are capable of filtering out non-chest X-ray images (Sensitivity 0.99, Accuracy 0.99), filtering out the non-PA view chest X-ray images(Sensitivity 0.99, Accuracy 0.97), and presenting with message for images with unclear boundary whose threshold is <0.5; the annotation models are able to draw two annotation lines, one indicating maximal transverse diameter of the heart (root-mean-square-
error 8.81mm)and other indicating the maximal inner diameter of the thoracic cavity(root-mean-square-error 14.3mm).

For clinical performance testing, we included at least a total of 840 eligible PA CXR images of adults (20 to 80 years old) patients from three participating sites (280 per site). We used accuracy to evaluate the agreement between EFAI iCTR-derived and physician derived CTR. The accuracy of EFAI iCTR system is 0.95.

As the result shown, the performance testing demonstrates that the EFAI Intelligent Cardiothoracic Ratio Assessment System performs as expected and in a manner that is substantially equivalent to the predicate device

VIII. Performance Data – Non-Clinical

To demonstrate safety and effectiveness of *EFAI iCTR* and to show substantial equivalence to the predicate device, EFAI completed the non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The *EFAI iCTR* passed the testing in accordance with internal requirements,
national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Software verification and validation per IEC 62304/FDA Guidance
- Application of usability engineering to medical devices - Part 1 per IEC 62366-1
- Guidance on the application of usability engineering to medical devices per IEC 62366-2

The clinical evaluation is conducted on the device following FDA Guidance “Software as a Medical Device (SAMD): Clinical Evaluation” (IMDRF/SaMD WG/N41FINAL:2017).

IX. Statement of Substantial Equivalence

Ever Fortune.AI Co., Ltd. Choose the *Imbio RV/LV Software (K203256)* as a predicate device. *Imbio RV/LV Software*, a software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. The RV/LV software provides the user with annotated images showing ventricular measurements.
EFAI iCTR is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR of a chest X-ray image in posterior-anterior (PA) chest view using an artificial intelligence algorithm. is a software for use by hospital and clinics to automatically assess the cardiothoracic ratio (CTR) of a chest X-ray image from the X-ray imager subject.
The subject device shares the similar intended use and device functions to perform the physical measurement on the ratio of maximum horizontal diameter as the primary device.

X. Conclusion

The result of the comparison of the design, intended use and testing results with the software release acceptance criteria, EverFortune.AI is the opinion, that *Imbio RV/LV software* is substantial equivalent to and perform as well as the predicate device *EFAI iCTR*.