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

September 10 , 2021

Re: K211257
Trade/Device Name: EFAI PACS Picture Archiving and Communication System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 29, 2021
Received: August 2, 2021

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, Ph.D.
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)*

K211257

Device Name

EFAI PACS PICTURE ARCHIVING AND COMMUNICATION SYSTEM

Indications for Use *(Describe)*

EFAI PACS PICTURE ARCHIVING AND COMMUNICATION SYSTEM is intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The EFAI PACS PICTURE ARCHIVING AND COMMUNICATION SYSTEM displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM standard, with the exception of mammography. It provides the capability to store images and patient information from OEM equipment, and perform filtering, digital manipulation and quantitative measurements. The client software is designed to run on standard personal and business computers. The product is intended to be used by trained medical professionals, including but not limited to radiologists, oncologists, and physicians. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

K211257

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

5.1 Submitter Information

Company:	CHEN MING-FONG Chairman EVER FORTUNE.AI Co., Ltd. Rm. D, 8 F., No. 573, Sec. 2, Taiwan Blvd., West Dist., Taichung City 403020, Taiwan Telephone: (886)-4-2321-3838 Fax: (886)-4-2322-9797 ra05@everfortuneai.com.tw
Contact:	CHEN MING-FONG Chairman EVER FORTUNE.AI Co., Ltd. Rm. D, 8 F., No. 573, Sec. 2, Taiwan Blvd. West Dist., Taichung City 403020, Taiwan Telephone: (886)-4-2321-3838 Fax:(886)-4-2322-9797 ra05@everfortuneai.com.tw
Date Summary Prepared:	April 20, 2021

5.2 Name of the Device

The product name "EFAI PACS Picture Archiving and Communication System" will be replaced by "*EFAI PACS*" abbreviation in the whole document.

Trade Name:	EFAI PACS Picture Archiving and Communication System (or EFAI PACS)
Common Name:	EFAI PACS Picture Archiving and Communication System (or EFAI PACS)

Classification Name:	Radiology
Review Panel:	Radiology
Regulation:	892.2050 - Medical image management and processing system
Class:	Class II
Product Code:	LLZ

5.3 Equivalence Claimed to Predicate Device

The *EFAI PACS* is equivalent to the Arterys Viewer (K171544), manufactured by Arterys Inc. is provided as primary predicate device.

5.4 Indication for Use

EFAI PACS Picture Archiving and Communication System is intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The EFAI PACS Picture Archiving and Communication System displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM standard, with the exception of mammography. It provides the capability to store images and patient information from OEM equipment, and perform filtering, digital manipulation and quantitative measurements. The client software is designed to run on standard personal and business computers. The product is intended to be used by trained medical professionals, including but not limited to radiologists, oncologists, and physicians. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings.

5.5 Device Description

The software is a stand-alone software as medical device (Stand-alone SaMD) which provide to instant services for clinician can able to use web browser at client stations to search and view medical data of desired patient which is stored in the software. The software also provides the following visualization, annotation and quantification functionalities which can be applied to the images on the web browser at client stations:

Visualization Functionalities:

a). 2D image view
b). Zoom ratio adjust
c). Pan
d). Window Level and Window Width adjust
e). Positive & Negative film effect
f). Mirror Flip

g). Multi-screen display
h). Cine Loop Play

Annotation Functionality:

Point Annotation

Quantification Functionalities:

a). Distance measurement
b). Area measurements
c). Angle measurement
d). Single Point measurement

5.6 Substantial Equivalence

The following table compares the *EFAI PACS* to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5.1: Comparison Table

Attribute	EFAI PACS	Arterys Viewer (K171544)	Comparison
Device Name/510(k) #	EFAI PACS Picture Archiving and Communication System (Ever Fortune.AI Co., Ltd.) / K#TBD	Arterys Viewer (Arterys Inc.) / K171544	--
Support Mammography	No	No	Same
Device Property	Stand-alone Software	Stand-alone Software	Same
Classification	- Class II - Picture archiving and communications system - LLZ (21 CFR 892.2050)	- Class II - Picture archiving and communications system - LLZ (21 CFR 892.2050)	Same
Operating System (Web accessible)	Client server architecture using Linux server and web	Client server architecture using Linux server and web	Same

	browser client (Web-based only)	browser client (Web-based only)	
Image Source	Medical data from original equipment manufacturers (OEMs) that support the DICOM standard	Medical data from original equipment manufacturers (OEMs) that support the DICOM standard	Same
Transfer/Storage/Display of Medical Images	Yes	Yes	Same
Network Access	Web browser connects to existing PACS	Web browser connects to existing PACS	Same
Image storage/Compression (Image Data Compression)	Support JPEG2000 and compression	Support JPEG2000 and compression	Same
Mammography Use	No support for the examination modality files of mammography	No support for the examination modality files of mammography	Same
DICOM Compliant (Images file format)	Yes	Yes	Same
Worklists	Yes	Yes	Same
Filter and Search capabilities	Yes	Yes	Same
Ability to search studies	Yes	Yes	Same
Image analysis and review capability	Yes	Yes	Same
Zoom in/Out	Yes	Yes. Default settings can zoom interactively	Same
View DICOM data	Yes	Yes. You can view the DICOM information about the patient and study, and the pixel information	Same

Window/level determination	Yes. Window width/length in menu	Yes. Let the user adjust W/L	Same
Window/level presets	Yes	Yes	Same
Adjust window/level	Yes	Yes	Same
Measuring tools (General image measurements)	Yes	Yes. Linear, area, and pixel intensity and location of a point	Same
Custom filters	Yes	Yes. Can set filters to affect the studies listed	Same
Set reading state	Yes. Study description in menu icon	Yes	Same

5.7 Performance Data – Non-Clinical

To demonstrate safety and effectiveness of *EFAI PACS* and to show substantial equivalence to the predicate device, Ever Fortune completed the non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The *EFAI PACS* 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 - In Compliance with.
- Application of usability engineering to medical devices - Part 1 per IEC 62366-1 - In Compliance with.
- Guidance on the application of usability engineering to medical devices per IEC 62366-2 - In Compliance with.

5.8 Performance Date - Clinical

EFAI PACS did not require clinical study since substantial equivalence to the currently market and predicate device was demonstrated with the following attribute:

- Design features;
- Indications for Use;
- Fundamental scientific technology;
- Non-clinical performance testing;
- Safety and effectiveness.

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

Based on the requirements recommended by FDA regarding the Clinical Evaluation, Ever Fortune has conducted the Clinical Evaluation for the EFAI PACS, the Clinical Evaluation Plan, Report and the adverse event data base search results are provided as Attachment 31 (EFAI PACS P-CKEVIEWER001), Attachment 32 (EFAI PACS R-CKE-VIEWER001), Attachment 15 – 18 CER Annex I-FDA Recall_LLZ_2011-2021). The three clinical articles mentioned in the CEP and CER are uploaded to the Reference section.

5.9 Statement of Substantial Equivalence

The *EFAI PACS* has the same intended use as the Arterys Viewer, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the *EFAI PACS* is as safe and effective as the predicate device. Therefore, the *EFAI PACS* is substantially equivalent to the predicate device.