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

August 8, 2023

Re: K232100
Trade/Device Name: EFAI Pacs Picture Archiving and Communication System Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 10, 2023
Received: July 14, 2023

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

Jessica Lamb, PhD
Assistant Director
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)*
K232100

Device Name
EFAI PACS PICTURE ARCHIVING AND COMMUNICATION SYSTEM PRO

Indications for Use *(Describe)*
EFAI PACS PRO 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 PRO 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.

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"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."

K232100 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
Contact Information	886-04-23213838 #216 joseph.chang@everfortune.ai
Correspondence Person	Ti-Hao Wang, CTO
Contact Information	886-04-23213838 #168 tihao.wang@everfortune.ai
Date Prepared	July 10, 2023

2. Proposed Device

Proprietary Name	EFAI PACS PICTURE ARCHIVING AND COMMUNICATION SYSTEM PRO (EFAI PACS PRO)
Common Name	EFAI PACS PRO
Classification Name	**System, Image Processing, Radiological**
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Proprietary Name	EFAI PACS PICTURE ARCHIVING AND COMMUNICATION SYSTEM (EFAI PACS)
Premarket Notification	K211257

Classification Name	**System, Image Processing, Radiological**
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	LLZ
Regulatory Class	II

4. Device Description

The software is a stand-alone software as medical device (Stand-alone SaMD) which provides instant services for clinicians able to use web browsers at client stations to search and view medical data of desired patients 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.

5. Intended Use

EFAI PACS PRO 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 PRO 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.

6. *Comparison of Technological Characteristics with Predicate Device*

Table below provides a comparison of the intended use and key technological features of EFAI PACS PRO with that of the Primary Predicate, EFAI PACS (K211257).

Table-Comparison with the Predicate Device.

Company	Ever Fortune.AI Co., Ltd. (EFAI)	Ever Fortune.AI Co., Ltd. (EFAI)
Device Name	EFAI PACS PRO	EFAI PACS
510k Number	Pending	K211257
Regulation No.	21CFR 892.2050	21CFR 892.2050
Classification	II	II

Product Code	LLZ	LLZ
Intended Use/Indication for Use	EFAI PACS PRO 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 PRO 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.	EFAI PACS 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 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.
Device Property	Stand-alone Software	Stand-alone Software
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
Transfer/Storage /Display of Medical Images	Yes	Yes
DICOM Compliant (Images file format)	Yes	Yes
Worklists	Yes	Yes

Filter and Search capabilities	Yes	Yes
Image analysis and review capability	Yes	Yes.
View DICOM data	Yes	Yes
Window/level determination	Yes	Yes
Window/level presets	Yes	Yes
Adjust window/level	Yes	Yes
Measuring tools (General image measurements)	Yes	Yes
Text and graphical annotation functionalities	Yes	Yes (Only provides Point Annotation: single point measurement)

7. Performance Data - Non-Clinical

To demonstrate safety and effectiveness of EFAI PACS PRO 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 PRO 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.

8. Conclusion

Based on the information submitted in this premarket notification, and based on the intended use, technological characteristics, and performance testing, the EFAI PACS PRO raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.