Ever Fortune.AI Co., Ltd.
℅ Cheng Ming-Fong
Chairman
8F., No. 573, Sec. 2, Taiwan Blvd., West Dist.
Taichung City, 403020
TAIWAN

Re: K213731
Trade/Device Name: EFAI CARDIOSUITE SPECT Myocardial Perfusion Agile Workflows
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, LLZ
Dated: March 18, 2022
Received: April 4, 2022

Dear Cheng 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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*
K213731

Device Name
EFAI CARDIOSUITE SPECT MYOCARDIAL PERFUSION AGILE WORKFLOWS

Indications for Use *(Describe)*

EFAI CARDIOSUITE SPECT MYOCARDIAL PERFUSION AGILE WORKFLOWS is an image processing software that provides analysis on DICOM images acquired from GE Medical Systems Nuclear Quantitative Perfusion SPECT software to support appropriately trained healthcare professionals in the evaluation and assessment of myocardial perfusions.

It provides the following functionality:

- Segmentation of the Bull's Eye images from the original DICOM
- Analysis of the Bull's Eye images to help assess perfusion
- Custom settings to generate text reports

The results of this processing may be used to aid in evaluating and assessing myocardial perfusions.

The system is an adjunct tool for GE Medical Systems Nuclear Quantitative Perfusion SPECT software.

Type of Use *(Select one or both, as applicable)*

[X] 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

K213731

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

I. Submitter

Company:	**EverFortune.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
Correspondence Person:	Ming-Fong, Chen (Chairman) ra99@everfortuneai.com.tw
Applicant Person:	Jenna Hsiao (RA) ra05@everfortuneai.com.tw
Date Prepared:	May 18th, 2022

II. Name of the Device

Name of Device:	EFAI CARDIOSUITE SPECT Myocardial Perfusion Agile Workflows
Common Name:	EFAI SPECT Workflows
Classification Name:	Emission Computed Tomography System
Review Panel	Radiology
Proposed Classification:	Device Class: II Product Code: KPS, LLZ Regulation Number: 21 CFR §892.1200

III. Predicate Device

AutoQUANT® Plus manufactured by *ADAC LABORATORIES* under **K040326**

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

Predicate Classification: Class II / KPS / 21 CFR §892.1200

IV. Device Description

The device allows users to interact with the software application via a web interface to upload, inspect, assess myocardial perfusion from Bull's Eye images. The user can change the quantitative settings to correct for numerical calculations and clinical adjustments.

The device is designed to take images produced by GE Medical Systems Nuclear Quantitative Perfusion SPECT software and process the data to provide both numerical analysis of the Bull's Eye images to help assess for myocardial perfusions, and generate a report based on the users report settings and preference.

The algorithm segments bull's eye images from SPECT images generated by GE's workstation and conducts quantitative analysis based on the color settings set by the user. The color scale is designed to follow GE's design convention, where the color red is indicative of a normal condition and blue representing severe perfusion. Each of the 17 segments would produce a quantitative evaluation under rest and stress conditions based on the color scale. The clinician would then design and fill in diagnosis terminologies that is best suited for each associated numerical results of each segment and generate a template report documenting the patient's condition.

Intended User Population

The intended users of the device are trained nuclear radiologists.

Intended Patient Population

The target population of the device are patients who receive cardiac SPECT imaging.

Description of user interface and outputs

The device displays Bull's Eye images of the heart along with myocardial segments overlaid on top to allow end users to assess myocardial perfusions. The device interacts with DICOM files generated from GE Medical Systems software workstation. The results and settings are displayed via a web interface where the end user uploads files, inspect quantitative results, adjust settings and generate a report.

V. Intended Use / Indications For Use

EFAI CARDIOSUITE SPECT MYOCARDIAL PERFUSION AGILE WORKFLOWS is an image processing software that provides analysis on DICOM images acquired from GE Medical Systems Nuclear Quantitative Perfusion SPECT software to support appropriately trained healthcare professionals in the evaluation and assessment of myocardial perfusions.

It provides the following functionality:

- Segmentation of the Bull's Eye images from the original DICOM
- Analysis of the Bull's Eye images to help assess perfusion
- Custom settings to generate text reports

The results of this processing may be used to aid in evaluating and assessing myocardial perfusions.

The system is an adjunct tool for GE Medical Systems Nuclear Quantitative Perfusion SPECT software.

VI. Comparison of Technological Characteristics with Predicate Device

The following table compares the *EFAI SPECT Workflows* to the predicate device with respect to intended use, indications for use, principles of operation, 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.

The subject device and predicate devices share the same technological characteristics:

- Interface is able to review, transfer, process, storage and report of myocardial perfusion SPECT images;
- Used to receive the SPECT image data;
- Generation of display and report the Nuclear Medicine Cardiology medical images

Table – Comparison Table			
	Proposed Device	**Predicate Device**	
Attribute	**EFAI SPECT Workflows (K213731)**	**AutoQUANT® Plus (K040326)**	**Difference**
Manufacturer	Ever Fortune.AI Co., Ltd.	ADAC LABORATORIES	**NA**
Regulation Number	21 CFR §890.1200	21 CFR §890.1200	**Same**
Regulatory Class	Class II	Class II	**Same**
Product Code	KPS	KPS	**Same**
Device Property	Software (SaMD)	Software applications (Module)	**Same**
Intended Use / Indications for Use			
EFAI SPECT Workflows (K213731)	EFAI CARDIOSUITE SPECT MYOCARDIAL PERFUSION AGILE WORKFLOWS is an image processing software that provides analysis on DICOM images acquired from GE Medical Systems Nuclear Quantitative Perfusion SPECT software to support appropriately trained healthcare professionals in the evaluation and assessment of myocardial perfusions. It provides the following functionality: • Segmentation of the Bull's Eye images from the original DICOM • Analysis of the Bull's Eye images to help assess perfusion • Custom settings to generate text reports The results of this processing may be used to aid in evaluating and assessing myocardial perfusions. The system is an adjunct tool for GE Medical Systems Nuclear Quantitative Perfusion SPECT software.		
AutoQUANT® Plus (K040326)	AutoQUANT® Plus applications are intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. AutoQUAINT® Plus may be used in multiple settings including the hospital, clinic, doctors office, or remotely via dial up. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.		

Data Type / Device Source	EFAI SPECT Workflows (K213731)	AutoQUANT® Plus (K040326)	Difference
Applied Body Parts	Left Ventricle	Left Ventricle	**Same**
Data File Type	Nuclear Medicine Cardiology SPECT Perfusion Image	Nuclear Medicine Cardiology SPECT Perfusion Image	**Same**
Data Device Source	GE Medical System Israel, Functional Imaging : **Myovation S**oftware, K201103	All types of cardiac SPECT dataset; Nuclear Medicine Cardiology medical images	**Similar.** **The data sources both came from similar type of SPECT device.**
Input Data (Image Modality)	GE SPECT Scanning (Bull's eye image in DICOM file)	All type Cardiac SPECT raw data (Nuclear Medicine Cardiology medical images in DICOM SC file)	**No Significant Difference.** **The proposed device acquires the GE SPECT scanning images;** **The predicate device acquires the cardiac SPECT raw data.** **Both devices can receive SPECT scanning & data.**
Output Format (Report Modality)	Texts and Pictures; Web page, HTML; Structured Text File.	DICOM SC for snapshots saved to the database; TIFF or PNG for screen captures saved to a folder on a local drive; Output files are for PowerPoint use only. Any other usage of output files (outside of PowerPoint) is not supported.	**Similar type output format in pictures format;** **The proposed device has conducted the software test report to ensure the functionalities is safe and effective.**
Data Storage	Report format can be store (PDF, word, TXT) in Database Unit.	Storage of all generated results in a separate review file. Available formats are:	**Similar.** **The proposed device is used the texts and pictures file format**

		TIFF, JPEG, PNG, BMP, DICOM SC.	**stored in Database Unit; The predicate device is used the snapshot file saved in the local patient database. Both devices can store the SPECT images.**
Features/Functions	**EFAI SPECT Workflows (K213731)**	**AutoQUANT® Plus (K040326)**	**Difference**
Segmentation Algorithm	YES Hough Transform (Segmentation of the Bull's Eye Image)	YES (Ventricular Segmentation)	**Both devices include segmentation algorithm.**
Orientation Method	NO	YES	**No orientation method was used in proposed device. The difference does not raise any new questions of safety or effectiveness.**
Segmental Perfusion Scores (Stress, Rest)	YES (Based on 17- Segment)	YES (Based on 17- or 20- Segment)	**Same in 17- segment perfusion scores.**
Processing Functions	Segmentation of the Bull's Eye images from the original DICOM : - Stress/Rest Score - Percentage extent of the defect in the polar map Analysis of the Bull's Eye images to help assess perfusion : - Color bar react in each of the 17-segments, classified	Quantitative Perfusion SPECT (QPS) & Quantitative Gated SPECT (QGS) : - Determine the location, orientation, and anatomical extent of the left ventricle of the heart - Construct 3D contour maps of the heart - Calculate the heart volume - Calculate lung/heart ratio	**The processing function shares the same clinical use including:** - **17-Segment mapper** - **Calculation and display of polar map** - **Stress/ Rest Score** **The target of region on the Visual Score on two devices are not same, however both of two**

	into 4 categories (Max/Min/Mean/Median) - Color Bar for user to adjust threshold of scoring, number of split (3/4/5) - Area diagnosis of the evaluation for coronary heart disease	- Calculate Transient Ischemic Dilation (TID) Quantitative Blood Pool SPECT (QBS) : - Generation left and right valve plans and ventricular endocardial surfaces - Calculation left and right valve ventricular volumes - Calculate left and right ventricular ejection fractions - Calculation and display of polar maps Quantitative Perfusion Change (QPC)	**devices are aimed to score the region of perfusion polar maps.**
Interface Functions	Custom settings to generate text reports : - Modify and approve the report - Download the report - Report filter setting - Select and edit the clinical findings	- ARG (automatic report generation) - QARG (for reporting purposes	**Similar.** **Two devices can generate and edit the report for the users.**

VII. Performance Data – Non-Clinical

The following performance data were provided in support of the substantial equivalence determination.

To demonstrate safety and effectiveness of *EFAI SPECT Workflows* 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 SPECT Workflows* 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

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

- Principle of Operation;
- Indications for Use;
- Fundamental scientific technology;
- Non-clinical performance testing;
- Safety and effectiveness.

VII. Statement of Substantial Equivalence

EverFortune.AI Co., Ltd. Choose the *AutoQUANT® Plus* (K040326) as a predicate device.

AutoQUANT® Plus is a suite of application are intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets.

The proposed device is available to assess “bull’s eye” images to show whether there are any potential areas of perfusion defects and automatically generates a report for clinicians; the predicate device integrates 2 functionalities, Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) into a single application for LV (Left Ventricle) extraction and analysis.

Both devices can assist clinicians in assessing bull’s eye images and generating report, increasing the work efficiency.

EFAI SPECT Workflows is substantial equivalence to the function of storing, quantifying and report the nuclear medicine cardiology medical images with predicate device - *AutoQUANT® Plus*.

EFAI SPECT Workflows does not raise different questions of safety and effectiveness than associated with the predicate device.

IX. Conclusion

EFAI SPECT workflows is submitted the information in this premarket notification, including the performance testing and predicate device comparisons support the safety of the device; the verification and validation activities demonstrate that *EFAI SPECT Workflows* perform as intended in the specific use conditions. The difference between the proposed device and predicate devices do not affect the indication for use, safety and effectiveness. And no issues are raised regarding safety regarding safety and effectiveness.

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 *AutoQUANT® Plus* is substantial equivalent to and perform as well as the predicate device *EFAI SPECT workflows*.