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

April 28, 2022

Re: K220264
Trade/Device Name: EFAI RTSuite CT HN-Segmentation System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: January 28, 2022
Received: January 31, 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,

Julie Sullivan, PhD
Assistant 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)* K220264

Device Name
EFAI HNSeg

Indications for Use *(Describe)*

EFAI HNSeg is a software device intended to assist trained radiation oncology professionals, including, but not limited to, radiation oncologists, medical physicists, and dosimetrists, during their clinical workflows of radiation therapy treatment planning by providing initial contours of organs at risk in the head and neck region on non-contrast CT images. EFAI HNSeg is intended to be used on adult patients only.

The contours are generated by deep-learning algorithms and then transferred to radiation therapy treatment planning systems. EFAI HNSeg must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. EFAI HNSeg is not intended to be used for decision making or to detect lesions.

EFAI HNSeg is an adjunct tool and is not intended to replace a clinician's judgment and manual contouring of the normal organs on CT. Clinicians must not use the software generated output alone without review as the primary interpretation.

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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Section 5. 510(k) Summary

1. General Information

510(k) Sponsor	Ever Fortune.AI Co., Ltd.
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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	January 29, 2022

2. Proposed Device

Proprietary Name	EFAI RTSuite CT HN-Segmentation System v1.0
Common Name	EFAI HNSeg v1.0
Classification Name	Picture Archiving and Communications System
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QKB
Regulatory Class	II

3. Predicate Device

Proprietary Name	AccuContour
Premarket Notification	K191928
Classification Name	Picture Archiving and Communications System
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QKB
Regulatory Class	II

4. Device Description

EFAI RTSuite CT HN-Segmentation System, herein referred to as EFAI HNSeg, is a standalone software that is designed to be used by trained radiation oncology professionals to automatically delineate head-and-neck organs-at-risk (OARs) on CT images. This auto-contouring of OARs is intended to facilitate radiation therapy workflows.
The device receives CT images in DICOM format as input and automatically generates the contours of OARs, which are stored in DICOM format and in RTSTRUCT modality. The device does not offer a user interface and must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results. Once data is routed to EFAI HNSeg, the data will be processed and no user interaction is required, nor provided.

The deployment environment is recommended to be in a local network with an existing hospital-grade IT system in place. EFAI HNSeg 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;
- Presentation of labels and their color;
- Processed image management and output (RTSTRUCT) file management.

5. Intended Use

EFAI HNSeg is a software device intended to assist trained radiation oncology professionals, including, but not limited to, radiation oncologists, medical physicists, and dosimetrists, during their clinical workflows of radiation therapy treatment planning by providing initial contours of organs at risk in the head and neck region on non-contrast CT images. EFAI HNSeg is intended to be used on adult patients only.

The contours are generated by deep-learning algorithms and then transferred to radiation therapy treatment planning systems. EFAI HNSeg must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. EFAI HNSeg is not intended to be used for decision making or to detect lesions.

EFAI HNSeg is an adjunct tool and is not intended to replace a clinician's judgment and manual contouring of the normal organs on CT. Clinicians must not use the software generated output alone without review as the primary interpretation.

6. Comparison of Technological Characteristics with Predicate Device

Table below provides a comparison of the intended use and key technological features of EFAI HNSeg with that of the Primary Predicate, AccuContour™ (K191928).

Table - Comparison with the Predicate Device.

Company	Ever Fortune.AI Co., Ltd. (EFAI)	Xiamen Manteia Technology LTD.
Device Name	EFAI HNSeg	AccuContour™
510k Number	Pending	K191928
Regulation No.	21CFR 892.2050	21CFR 892.2050
Classification	II	II
Product Code	QKB	QKB
Intended Use/Indication for Use	EFAI HNSeg is a software device intended to assist trained radiation oncology professionals, including, but not limited to, radiation oncologists, medical physicists, and dosimetrists, during their clinical workflows of radiation therapy treatment planning by providing initial contours of organs at risk in the head and neck region on non-contrast CT images. EFAI HNSeg is intended to be used on adult patients only. The contours are generated by deep-learning algorithms and then transferred to radiation therapy treatment planning systems. EFAI HNSeg must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. EFAI HNSeg is not intended to be used for decision making or to detect lesions. EFAI HNSeg is an adjunct tool and is not intended to replace a clinician's judgment and manual contouring of the normal organs on CT. Clinicians must not use the software generated output alone without review as the primary interpretation.	It is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation. The product has two image process functions: (1) Deep learning contouring: it can automatically contour the organ-at-risk, including head and neck, thorax, abdomen and pelvis (for both male and female), (2) Automatic Registration, and (3) Manual Contour. It also has the following general functions: (1) Receive, add/edit/delete, transmit, input/export, medical images and DICOM data; (2) Patient management; (3) Review of processed images; (4) Open and save of files.
Segmentation (Contouring) Technology	Deep learning	Deep learning
Operating System	Linux Ubuntu 20.04	Microsoft Windows

User Population	Trained medical professionals including, but not limited to, radiation oncologists, medical physicists, and dosimetrists.	It is used by radiation oncology department.
Supported Modalities	Non-contrast CT	Segmentation Features: Non-Contrast CT Registration Features: CT, MRI, PET
Image Input	Complies with DICOM standard	Complies with DICOM standard
Compatible Scanner Models	No Limitation on scanner model DICOM 3.0 compliance required.	No Limitation on scanner model DICOM 3.0 compliance required.
Localization and Definition of Objects (ROI)	Organ-at risk of head and neck region	Organ-at-risk, including head and neck, thorax, abdomen and pelvis (for both male and female)
Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.
Automated Workflow	EFAI HNSeg automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	AccuContour automatically processes input image data
User Interface	No	Yes

The proposed device, EFAI HNSeg, is substantially equivalent to the claimed predicate, AccuContour™ (K191928).

7. Performance Data

Performance of the EFAI HNSeg 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 contour performance of EFAI HNSeg, a non-inferiority standalone performance test was performed. This non-inferiority test compared the mean Dice coefficient of the automatically generated head and neck OAR contours for EFAI HNSeg against that of the predicate device, AccuContour™. The results demonstrate that the EFAI HNSeg device was non-inferior to the predicate by at least a non-inferiority limit of 0.1 Dice, which was the largest

difference that is clinically acceptable based on previous studies, and thus we conclude that equivalence has been demonstrated.

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 HNSeg 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.