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

September 25, 2023

Re: K231928
Trade/Device Name: EFAI RTSUITE CT HCAP-Segmentation System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: August 31, 2023
Received: September 1, 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: 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)*
K231928

Device Name
EFAI RTSuite CT HCAP-Segmentation System

Indications for Use *(Describe)*
EFAI HCAPSeg 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 on non-contrast CT images. EFAI HCAPSeg 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 HCAPSeg must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. EFAI HCAPSeg is not intended to be used for decision making or to detect lesions.

EFAI HCAPSeg 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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510(k) Summary

K231928

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	June 28, 2023

2. Proposed Device

Proprietary Name	EFAI RTSuite CT HCAP-Segmentation System
Common Name	EFAI HCAPSeg
Classification Name	**Radiological Image Processing Software For Radiation Therapy**
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	EFAI RTSuite CT HN-Segmentation System
Premarket Notification	K220264
Classification Name	**Radiological Image Processing Software For Radiation Therapy**
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 HCAP-Segmentation System, herein referred to as EFAI HCAPSeg, is a standalone software that is designed to be used by trained radiation oncology professionals to automatically delineate 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 HCAPSeg, 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 HCAPSeg 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 HCAPSeg 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 on non-contrast CT images. EFAI HCAPSeg 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 HCAPSeg must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. EFAI HCAPSeg is not intended to be used for decision making or to detect lesions.

EFAI HCAPSeg 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 A below provides a comparison of the intended use and key technological features of EFAI HCAPSeg with that of the Predicate, EFAI HNSeg (K220264), as well as the reference devices.

Table A. Comparison with the Predicate and Reference Devices

Characteristic	Proposed Device	Predicate Device	Reference Device- 1	Reference Device- 2
Company	Ever Fortune.AI Co., Ltd. (EFAI)	Ever Fortune.AI Co., Ltd. (EFAI)	Xiamen Manteia Technology LTD.	Radformation, Inc.
Device Name	EFAI HCAPSeg	EFAI HNSeg	AccuContour™	AutoContour RADAC V2
510k Number	K231928	K220264	K191928	K220598
Regulation No.	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050
Classification	II	II	II	II
Product Code	QKB	QKB	QKB	QKB
Intended Use/Indication for Use	EFAI HCAPSeg 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 on non-contrast CT images. EFAI HCAPSeg is intended to be used on adult patients only.	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.	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.	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

	The contours are generated by deep-learning algorithms and then transferred to radiation therapy treatment planning systems. EFAI HCAPSeg must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. EFAI HCAPSeg is not intended to be used for decision making or to detect lesions. EFAI HCAPSeg 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.	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.		
Segmentation (Contouring) Technology	Deep learning	Deep learning	Deep learning	Deep learning
Operating System	Linux Ubuntu 20.04	Linux Ubuntu 20.04	Microsoft Windows	Windows based .NET front-end application that also serves as agent Uploader supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016. Cloud-based Server based automatic contouring

				application compatible with Linux. Windows python-based automatic contouring application supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016.
User Population	Trained medical professionals including, but not limited to, radiation oncologists, medical physicists, and dosimetrists.	Trained medical professionals including, but not limited to, radiation oncologists, medical physicists, and dosimetrists.	It is used by radiation oncology department.	Radiation treatment planners
Supported Modalities	Non-contrast CT	Non-contrast CT	Segmentation Features: Non-Contrast CT Registration Features: CT, MRI, PET	CT or MR input for contouring or registration/fusion. PET/CT input for registration/fusion only. DICOM RTSTRUCT for output
Localization and Definition of Objects (ROI)	Organ-at risk of head and neck, chest, abdomen, and pelvis	Organ-at risk of head and neck region	Organ-at-risk, including head and neck, thorax, abdomen and pelvis (for both male and female)	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning. CT or MR input for contouring of anatomical regions: Head and Neck, Thorax, Abdomen and Pelvis
Organ-at risk (OAR)	A_Aorta, A_Carotid_L, A_Carotid_R, Bladder, Bone_Mandible, BrachialPlex_L, BrachialPlex_R, Brain,	Brain, BrainStem, Esophagus, Eye_L, Eye_R, Lens_L, Lens_R, Mandible, OpticChiasm, OpticNerve_L, OpticNerve_R, OralCavity,	A_Aorta, Bladder, Bone_Mandible, BrachialPlex_L, BrachialPlex_R, Brain, Brainstem, Breast_L, Breast_R,	CT Models: A_Aorta, A_Aorta_Asc, A_Aorta_Dsc, A_LAD, Bladder, Bone_Ilium_L, Bone_Ilium_R,

	Brainstem, Breast_L, Breast_R, Bronchus_Prox, Cavity_Oral, Cochlea_L, Cochlea_R, Duodenum, Ear_Internal_L, Ear_Internal_R, Ear_Middle_L, Ear_Middle_R, Esophagus, Eye_L, Eye_R, FemurHeadNeck_L, FemurHeadNeck_R, Gallbladder, Glnd_Submand_L, Glnd_Submand_R, Glnd_Thyroid, Heart, Hippocampus_L, Hippocampus_R, IAC_L, IAC_R, Joint_TM_L, Joint_TM_R, Kidney_L, Kidney_R, Larynx, Lens_L, Lens_R, Liver, LN_Neck_IA, LN_Neck_IB_L, LN_Neck_IB_R, LN_Neck_II_L, LN_Neck_II_R, LN_Neck_III_L, LN_Neck_III_R, LN_Neck_IV_L, LN_Neck_IV_R, LN_Neck_V_L, LN_Neck_V_R, LN_Pelvics, Lobe_Temporal_L, Lobe_Temporal_R, Lung_L, Lung_R, OpticChiasm, OpticNrv_L, OpticNrv_R, Pancreas, Parotid_L, Parotid_R, PenileBulb, Pituitary, Prostate, Rectum, SeminalVes, Spc_Bowel, SpinalCanal, SpinalCord, Spleen, Stomach, Testis, Trachea, Uterus,	arotid_L, Parotid_R, SpinalCord, Thyroid, Trachea	Cavity_Oral, Cochlea_L, Cochlea_R, Duodenum, Ear_Internal_L, Ear_Internal_R, Ear_Middle_L, Ear_Middle_R, Esophagus, Eye_L, Eye_R, FemurHeadNeck_L, FemurHeadNeck_R, Glnd_Submand_L, Glnd_Submand_R, Glnd_Thyroid, Heart, Hippocampus_L, Hippocampus_R, IAC_L, IAC_R, Joint_TM_L, Joint_TM_R, Kidney_L, Kidney_R, Larynx, Lens_L, Lens_R, Liver, Lobe_Temporal_L, Lobe_Temporal_R, Lung_L, Lung_R, OpticChiasm, OpticNrv_L, OpticNrv_R, Pancreas, Parotid_L, Parotid_R, Pituitary, Prostate, Rectum, SeminalVes, Spc_Bowel, SpinalCanal, SpinalCord, Spleen, Stomach, Testis, Trachea, Vestibule_L, Vestibule_R	Bone_Mandible, Bowel_Bag, BrachialPlex_L, BrachialPlex_R, Brain, Brainstem, Breast_L, Breast_R, Bronchus, Carina, CaudaEquina, Cavity_Oral, Cochlea_L, Cochlea_R, Ear_Internal_L, Ear_Internal_R, Esophagus, External, Eye_L, Eye_R, Femur_L, Femur_R, Femur_RTOG_L, Femur_RTOG_R, Glnd_Lacrimal_L, Glnd_Lacrimal_R, Glnd_Submand_L, Glnd_Submand_R, Glnd_Thyroid, HDR_Cylinder, Heart, Humerus_L, Humerus_R, Kidney_L, Kidney_R, Kidney_Outer_L, Kidney_Outer_R, Larynx, Lens_L, Lens_R, Lips, LN_Ax_L, LN_Ax_R, LN_IMN_L, LN_IMN_R, LN_Neck_IA, LN_Neck_IB-V_L, LN_Neck_IB-V_R, LN_Neck_II_L, LN_Neck_II_R, LN_Neck_II-IV_L, LN_Neck_II-IV_R, LN_Neck_III_L, LN_Neck_III_R, LN_Neck_IV_L, LN_Neck_IV_R, LN_Neck_VIA, LN_Neck_VIIA_L, LN_Neck_VIIA_R,

	V_Venacava_I, Vestibule_L, Vestibule_R			LN_Neck_VIIB_L, LN_Neck_VIIB_R, LN_Pelvics, LN_Sclav_L, LN_Sclav_R, Liver, Lung_L, Lung_R, Marrow_Ilium_L, Marrow_Ilium_R, Musc_Constrict, OpticChiasm, OpticNrv_L, OpticNrv_R, Parotid_L, Parotid_R, PenileBulb, Pituitary, Prostate, Rectum, Rib, SeminalVes, SpinalCanal, SpinalCord, Stomach, Trachea, V_Venacava_S MR Models: OpticChiasm, OpticNrv_L, OpticNrv_R, Brainstem, Hippocampus_L, Hippocampus_R
Compatible Treatment Planning System	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required	No Limitation
Automated Workflow	EFAI HCAPSeg automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	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	Automatically contour, allow the user to review and modify, generate DICOM-compliant structure set data.
User Interface	No	No	Yes	Yes

7. Performance Data

Performance of the EFAI HCAPSeg 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 performance of the EFAI HCAPSeg, the performance was validated by clinical and nonclinical tests.

Nonclinical Tests

During the process of model development, a total of 1,846 adult cases were collected between 2008 and 2018 from the radiation oncology department in Taiwan. These cases were subsequently divided into training and testing datasets, consisting of 1,410 and 436 cases, respectively. These cases covered a range of body parts, including the Head & Neck, Chest, and/or Abdomen & Pelvis.

The demographic information for both the training and test datasets, including age, gender, and CT manufacturer are presented in ***Table B***. The data population included a balanced distribution between females and males. The acquired data encompasses CT manufacturers such as Siemens, GE Medical Systems, Philips, Toshiba.

Table B. Demographic Information for Training and Test Data Sets

	Training Dataset (n=1,410)	**Testing Dataset (n=436)**
Age		
18 - 49 years old	95	16
50 - 69 years old	772	219
Above 70 years old	235	64
N/A	308	137
Gender		
Female	563	110
Male	581	154
N/A	266	172
CT Manufacturer		
Siemens	914	289

GE Medical Systems	436	109
Philips	56	35
Toshiba	1	2
N/A	3	1

The company used the testing dataset to conduct an internal validation to assess the performance of the EFAI HCAPSeg. The process of ground-truthing, involving the manual contouring of each OAR, was undertaken by three board-certified radiation oncologists. The data collection and ground truth protocol was done following the identical procedures as those of the predicate device. ***Table C*** displays the number of images/cases per OAR for both the training and test datasets.

Table C. Number of Images/Cases per OAR for Training and Testing Datasets

OAR	Training Dataset		Testing Dataset	
	Number of Cases	Number of Images	Number of Cases	Number of Images
A_Aorta	1,091	77,731	119	7,030
A_Carotid_L	350	15,124	114	4,883
A_Carotid_R	347	11,883	114	4,118
Bladder	458	7,366	61	988
Bone_Mandible	667	17,013	66	1,457
BrachialPlex_L	474	17,909	113	3,903
BrachialPlex_R	473	16,978	113	3,643
Brain	484	22,154	66	2,894
Brainstem	484	11,126	66	1,403
Breast_L	350	14,049	76	2,832
Breast_R	347	14,495	75	2,727
Bronchus_Prox	353	7,523	113	2,315
Cavity_Oral	613	12,899	66	1,320
Cochlea_L	471	926	66	126
Cochlea_R	475	1,077	66	125
Duodenum	686	19,167	77	2,063
Ear_Internal_L	484	2,945	66	375

Ear_Internal_R	484	2,428	66	308
Ear_Middle_L	484	2,162	66	277
Ear_Middle_R	484	2,128	66	258
Esophagus	1,126	61,405	114	4,844
Eye_L	482	6,150	66	721
Eye_R	484	6,182	66	727
FemurHeadNeck_L	462	13,358	61	1,819
FemurHeadNeck_R	457	13,136	61	1,802
Gallbladder	309	3,095	168	1,609
Glnd_Submand_L	604	7,233	66	808
Glnd_Submand_R	592	7,343	66	788
Glnd_Thyroid	838	14,605	114	1,956
Heart	716	22,271	119	3,012
Hippocampus_L	478	4,653	66	534
Hippocampus_R	475	4,432	66	463
IAC_L	117	326	105	176
IAC_R	121	333	100	148
Joint_TM_L	481	2,339	66	229
Joint_TM_R	484	2,231	66	233
Kidney_L	762	22,347	119	3,310
Kidney_R	720	20,989	119	3,407
Larynx	723	13,548	114	2,134
Lens_L	475	1,716	66	214
Lens_R	476	1,628	66	203
Liver	853	37,523	119	5,061
LN_Neck_IA	98	484	73	297
LN_Neck_IB_L	98	1,385	73	905
LN_Neck_IB_R	98	1,376	73	960
LN_Neck_II_L	98	1,936	73	1,201

LN_Neck_II_R	98	1,937	73	1,201
LN_Neck_III_L	98	1,083	73	817
LN_Neck_III_R	98	1,082	73	817
LN_Neck_IV_L	98	1,220	73	1,003
LN_Neck_IV_R	98	1,219	73	1,003
LN_Neck_V_L	98	2,773	73	2,227
LN_Neck_V_R	98	2,768	73	2,227
LN_Pelvics	220	9,486	177	7,872
Lobe_Temporal_L	481	10,045	66	1,175
Lobe_Temporal_R	483	10,141	66	1,185
Lung_L	896	50,332	119	4,261
Lung_R	878	49,483	119	4,263
OpticChiasm	479	1,793	66	279
OpticNrv_L	479	1,832	66	255
OpticNrv_R	479	2,089	66	276
Pancreas	757	16,684	77	1,707
Parotid_L	515	12,722	66	1,513
Parotid_R	514	12,408	66	1,501
PenileBulb	91	430	73	333
Pituitary	475	1,419	66	197
Prostate	205	2,887	75	1,091
Rectum	456	12,836	61	1,779
SeminalVes	206	1,534	75	613
Spc_Bowel	737	51,228	77	6,304
SpinalCanal	1,269	119,225	157	12,760
SpinalCord	1,407	139,337	157	13,881
Spleen	793	21,027	119	3,051
Stomach	808	25,949	119	3,758
Testis	128	1,301	67	801

Trachea	876	31,998	76	2,543
Uterus	163	4,087	78	1,522
V_Venacava_I	510	24,117	119	3,201
Vestibule_L	470	1,035	66	133
Vestibule_R	480	1,002	66	113

Overall, the mean Dice coefficient (DSC) was 0.85 for OAR contouring compared to the ground truth (GT). This result, surpassing the pre-specified performance objectives, confirms the validation of the EFAI HCAPSeg algorithm's performance.

Clinical Tests

A standalone performance test was also performed. The test was conducted to compare the OAR contouring capabilities of EFAI HCAPSeg against the comparison device. The dataset used in this study comprised 157 non-contrast CT cases consecutively collected from the United States (U.S.), all meeting the established inclusion criteria. All data used during the standalone performance evaluation was acquired independently from product development training and internal testing.

The study population contained 30.57% females, 57.96% males, and 11.46% gender not reported. The mean age was 61.69 years old with standard deviation (SD) of 11.90 years old. The acquired data encompasses CT manufacturers such as GE (43.31%), Philips (36.30%), Siemens (9.55%), Toshiba (2.55%), PNS (0.64%), and not reported (7.64%). Location, Race and Ethnic distribution within the study data patient population was unavailable. The cancer types included head-and-neck cancer, pancreas cancer, colorectal cancer, lung cancer, breast cancer, bladder cancer, prostate cancer, stomach cancer, gynecologic cancer, sarcoma, and metastatic tumors from multiple origins.

Each of the OAR contouring was generated by three board-certified radiation oncologists as the ground truth (GT). The acceptance criteria were defined as the following:

- For OARs present in both EFAI HCAPSeg and the comparison device, the mean Dice coefficient (DSC) of OARs for each body part (Head & Neck, Chest, and Abdomen & Pelvis) should be non-inferior to that of the comparison device, with a pre-specified margin.
- For OARs unique to the EFAI HCAPSeg, the mean DSC of unique OARs should be superior to a pre-specified value.

The overall performance showed a mean DSC of 0.83 and the non-inferiority tests indicated that EFAI HCAPSeg successfully met the primary endpoint across all body parts. Specifically, EFAI HCAPSeg achieved mean DSC values of 0.80, 0.90, and 0.90 in Head & Neck, Chest, and Abdomen & Pelvis, respectively, while the comparison device yielded slightly lower values of 0.75, 0.84, and 0.82 for the same body parts. Furthermore, when considering OARs unique to EFAI HCAPSeg, the mean DSC value reached 0.82. As shown in ***Table D***, these results strongly indicate the successful attainment of the acceptance criteria for the primary endpoint was met.

Table D. DSC Performance of EFAI HCAPSeg

		EFAI HCAPSeg		Comparison Device		Statistical Result ‡
		Mean DSC	SD	Mean DSC	SD	p-value
OARs Present in Both EFAI HCAPSeg and the Comparison Device	Head & Neck	0.80	0.21	0.75	0.25	<.0001
	Chest	0.90	0.11	0.84	0.20	<.0001
	Abdomen & Pelvis	0.90	0.14	0.82	0.24	<.0001
OARs Unique to EFAI HCAPSeg	Unique OAR	0.82	0.19	-	-	<.0001

OAR, Organ-At-Risk; DSC, Dice Similarity Coefficient; SD, Standard Deviation.
‡ A statistical result includes outcomes obtained from data analysis using statistical methods, encompassing the non-inferiority test for OARs presented in both EFAI HCAPSeg and the Comparison Device, as well as the superiority test for OARs unique to EFAI HCAPSeg. When the p-value is <0.05, it indicates that EFAI HCAPSeg's performance is significantly non-inferior to or superior to the pre-specified performance, respectively.

In addition to the primary endpoint, the overall data showed a median 95% Hausdorff Distance (HD) of 2.23 mm. ***Table E*** further presents detailed insights into the 95% HD performance, including testing results across all body parts and the 95% HD values for the OARs unique to EFAI HCAPSeg.

Table E. 95% HD Performance of EFAI HCAPSeg

		EFAI HCAPSeg		Comparison Device		Statistical Result ‡
		Median 95% HD (mm)	Q1 - Q3 (mm)	Median 95% HD (mm)	Q1 - Q3 (mm)	p-value
OARs Present in Both EFAI HCAPSeg and the Comparison Device	Head & Neck	2.17	1.40 - 2.44	3.09	1.96 - 4.73	<.0001
	Chest	2.23	1.43 - 2.56	3.87	2.37 - 7.42	<.0001
	Abdomen & Pelvis	2.28	1.44 - 3.41	3.90	2.36 - 10.85	<.0001
OARs Unique to EFAI HCAPSeg	Unique OAR	2.24	1.00 - 4.69	-	-	<.0001

OAR, Organ-At-Risk; HD, Hausdorff Distance; Q1, First Quartile; Q3, Third Quartile.
The unit of measurement for the 95% HD is millimeters (mm).
‡ A statistical result includes outcomes obtained from data analysis using statistical methods, encompassing the non-inferiority test for OARs presented in both EFAI HCAPSeg and the Comparison Device, as well as the superiority test for OARs unique to EFAI HCAPSeg. When the p-value is <0.05, it indicates that EFAI HCAPSeg's performance is significantly non-inferior to or superior to the pre-specified performance, respectively.

Moreover, the DSC and 95% HD performance for subgroup analyses based on gender, age group, CT manufacturer, and CT slice thickness (***Table F***) showed that the device consistently and reliably performed under these circumstances.

Table F. DSC and 95% HD Performance of EFAI HCAPSeg across All Subgroups

		EFAI HCAPSeg			
		Mean DSC	SD	Median 95% HD (mm)	Q1 - Q3 (mm)
Gender	**Female**	0.83	0.23	2.28	1.40 - 3.30
	Male	0.85	0.17	2.23	1.39 - 3.16
Age Group	**18 - 49 y/o**	0.85	0.18	2.22	1.32 - 2.81
	50 - 69 y/o	0.83	0.23	2.28	1.40 - 3.38
	≥ 70 y/o	0.85	0.20	2.27	1.44 - 4.06
CT Manufacturer	**GE**	0.84	0.22	2.23	1.37 - 3.16
	Philips	0.82	0.19	2.24	1.41 - 3.15
	Siemens	0.89	0.15	2.29	1.42 - 3.31
	Others ‡	0.89	0.15	2.30	1.41 - 3.47
CT Slice Thickness	**0.5 - 3.0 mm**	0.84	0.15	2.24	1.43 - 3.13
	3.1 - 5.0 mm	0.83	0.23	2.20	1.33 - 3.05

DSC, Dice Similarity Coefficient; SD, Standard Deviation; Q1, First Quartile; Q3, Third Quartile.
The unit of measurement for the 95% HD is millimeters (mm).
‡ Other CT manufacturers include Toshiba and PNS.

Lastly, the DSC and 95% HD performance of individual OARs, alongside their Referenced Performance benchmarks, which represent the target performance for each OAR are shown in ***Table G***.

Table G. Individual OAR performance of EFAI HCAPSeg (Proposed Device)

OAR	DSC Performance			95% HD Performance		
	EFAI HCAPSeg		Referenced Performance §	EFAI HCAPSeg		Referenced Performance §
	Mean DSC	SD	Mean DSC	Median 95% HD (mm)	Q1 - Q3 (mm)	Median 95% HD
A_Aorta	0.86	0.04	0.26	2.36	2.08 - 3.43	66.60
A_Carotid_L †	0.71	0.20	0.65	5.46	2.21 - 10.13	≤ 3.50
A_Carotid_R †	0.67	0.21	0.65	5.63	2.52 - 8.14	≤ 3.50
Bladder	0.77	0.30	0.70	4.93	3.16 - 8.54	6.22
Bone_Mandible	0.89	0.04	0.81	2.23	2.05 - 2.35	4.32
BrachialPlex_L	0.72	0.02	0.63	2.22	2.04 - 2.40	8.45
BrachialPlex_R	0.71	0.03	0.62	2.25	2.13 - 3.33	9.67
Brain	0.99	0.04	0.86	1.36	1.15 - 2.18	3.96
Brainstem	0.92	0.07	0.75	3.17	2.49 - 3.47	5.75

Breast_L	0.89	0.03	0.78	3.15	1.60 - 6.33	10.86
Breast_R	0.89	0.03	0.78	2.38	2.14 - 4.76	11.54
Bronchus_Prox †	0.93	0.03	0.65	1.00	1.00 - 2.99	≤ 3.50
Cavity_Oral	0.92	0.12	0.78	2.28	1.35 - 4.13	7.70
Cochlea_L	0.65	0.26	0.45	2.11	1.35 - 2.32	3.96
Cochlea_R	0.70	0.21	0.51	2.09	1.33 - 2.33	3.96
Duodenum	0.74	0.24	0.57	6.49	2.44 - 20.81	27.41
Ear_Internal_L	0.85	0.08	0.71	1.48	1.24 - 2.25	3.97
Ear_Internal_R	0.84	0.14	0.69	1.46	1.22 - 2.24	3.97
Ear_Middle_L	0.83	0.16	0.67	2.15	1.37 - 2.30	4.87
Ear_Middle_R	0.84	0.16	0.68	1.43	1.23 - 2.19	3.97
Esophagus	0.84	0.08	0.71	2.50	2.08 - 7.36	6.01
Eye_L	0.94	0.14	0.80	1.37	1.23 - 2.21	3.95
Eye_R	0.92	0.19	0.79	1.33	1.16 - 2.30	3.95
FemurHeadNeck_L	0.95	0.15	0.82	2.21	1.37 - 2.45	4.86
FemurHeadNeck_R	0.92	0.14	0.76	2.30	1.42 - 3.02	5.69
Gallbladder †	0.81	0.31	0.65	1.00	1.00 - 2.93	≤ 3.50
Glnd_Submand_L	0.82	0.08	0.69	1.40	1.16 - 2.17	5.80
Glnd_Submand_R	0.74	0.19	0.67	1.35	1.21 - 2.10	5.83
Glnd_Thyroid	0.79	0.16	0.60	2.24	1.91 - 2.59	8.60
Heart	0.93	0.08	0.84	2.25	1.42 - 3.32	4.91
Hippocampus_L	0.69	0.27	0.54	1.50	1.28 - 2.29	5.13
Hippocampus_R	0.55	0.34	0.45	1.52	1.29 - 2.49	5.88
IAC_L	0.60	0.34	0.46	2.39	2.20 - 3.18	5.85
IAC_R	0.66	0.31	0.41	2.37	2.16 - 2.77	3.97
Joint_TM_L	0.63	0.28	0.50	3.06	2.36 - 3.45	4.93
Joint_TM_R	0.67	0.18	0.49	3.10	2.49 - 3.65	4.90
Kidney_L	0.93	0.17	0.78	1.36	1.21 - 2.37	4.88
Kidney_R	0.95	0.14	0.79	1.34	1.15 - 1.89	4.38
Larynx	0.83	0.11	0.66	2.44	2.18 - 3.54	6.46
Lens_L	0.78	0.28	0.69	2.11	1.43 - 2.26	3.96
Lens_R	0.80	0.31	0.70	2.20	1.44 - 2.39	3.95
Liver	0.95	0.02	0.86	2.02	1.31 - 2.41	4.95

LN_Neck_IA †	0.83	0.06	0.65	2.00	1.00 - 2.73	≤ 3.50
LN_Neck_IB_L †	0.90	0.03	0.65	1.87	1.10 - 2.24	≤ 3.50
LN_Neck_IB_R †	0.88	0.04	0.65	2.00	1.80 - 2.95	≤ 3.50
LN_Neck_II_L †	0.89	0.04	0.65	1.73	1.41 - 2.73	≤ 3.50
LN_Neck_II_R †	0.87	0.06	0.65	2.24	1.41 - 3.00	≤ 3.50
LN_Neck_III_L †	0.81	0.09	0.65	2.94	2.02 - 4.51	≤ 3.50
LN_Neck_III_R †	0.84	0.07	0.65	2.53	1.56 - 3.74	≤ 3.50
LN_Neck_IV_L †	0.81	0.11	0.65	3.10	2.19 - 4.16	≤ 3.50
LN_Neck_IV_R †	0.81	0.08	0.65	3.02	2.40 - 4.16	≤ 3.50
LN_Neck_V_L †	0.84	0.06	0.65	2.94	2.02 - 5.57	≤ 3.50
LN_Neck_V_R †	0.86	0.04	0.65	2.91	2.00 - 3.57	≤ 3.50
LN_Pelvics †	0.90	0.23	0.65	1.00	1.00 - 2.99	≤ 3.50
Lobe_Temporal_L	0.94	0.03	0.77	1.43	1.21 - 2.21	4.91
Lobe_Temporal_R	0.93	0.08	0.76	2.03	1.30 - 2.33	4.90
Lung_L	0.96	0.01	0.87	2.27	2.02 - 2.42	4.32
Lung_R	0.95	0.01	0.88	2.05	1.25 - 2.38	3.97
OpticChiasm	0.75	0.24	0.60	2.30	2.10 - 2.52	5.13
OpticNrv_L	0.68	0.25	0.56	2.24	1.59 - 2.36	3.97
OpticNrv_R	0.68	0.22	0.54	2.23	1.88 - 2.46	4.91
Pancreas	0.83	0.16	0.63	2.82	2.12 - 7.89	10.63
Parotid_L	0.87	0.14	0.74	2.08	1.38 - 2.27	6.52
Parotid_R	0.86	0.12	0.73	2.04	1.31 - 2.40	7.11
PenileBulb †	0.66	0.34	0.50	2.30	0.98 - 4.25	≤ 3.50
Pituitary	0.67	0.39	0.57	2.02	2.02 - 2.02	3.97
Prostate	0.79	0.21	0.41	2.43	2.10 - 5.10	7.36
Rectum	0.84	0.08	0.51	2.92	2.30 - 5.32	10.33
SeminalVes	0.92	0.12	0.46	2.07	1.37 - 3.57	6.04
Spc_Bowel	0.87	0.18	0.57	8.07	5.63 - 14.46	26.64
SpinalCanal	0.88	0.03	0.73	2.30	2.14 - 2.47	8.92
SpinalCord	0.90	0.02	0.78	2.16	1.43 - 2.37	5.84
Spleen	0.93	0.15	0.79	1.45	1.21 - 2.39	4.94
Stomach	0.85	0.12	0.80	2.89	2.22 - 7.10	5.82
Testis	0.82	0.29	0.31	5.46	3.16 - 22.56	40.74

Trachea	0.91	0.03	0.79	2.30	2.08 - 2.88	5.13
Uterus †	0.78	0.29	0.80	3.85	2.91 - 12.38	≤ 3.50
V_Venacava_I †	0.93	0.10	0.65	1.00	1.00 - 3.01	≤ 3.50
Vestibule_L	0.79	0.25	0.54	1.47	1.29 - 2.25	3.96
Vestibule_R	0.76	0.16	0.55	2.15	1.41 - 2.31	3.97

OAR, Organ-At-Risk; DSC, Dice Similarity Coefficient. HD, Hausdorff Distance; Q1, First Quartile; Q3, Third Quartile.
The unit of measurement for the 95% HD is millimeters (mm).
† OARs that are unique to EFAI HCAPSeg.
§ The referenced performance acts as the performance target for each individual OAR. The benchmark performance for OARs that are presented in both EFAI HCAPSeg and the comparison device is established as being non-inferior to the comparison device. As for OARs unique to EFAI HCAPSeg, the benchmark DSC performance is determined using values of 0.80/0.65/0.50 for large/medium/small volume structures.

8. Conclusion

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