January 28, 2026

Ever Fortune.AI, Co., Ltd.
Ti-Hao Wang
Chief Technology Officer
8F., No.360, Sec. 1, Jingmao Rd., Beitun Dist.
Taichung City, 406040
Taiwan

Re: K251306
Trade/Device Name: Seg Pro V3 (RT-300)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: December 29, 2025
Received: December 29, 2025

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251306

Please provide the device trade name(s).

Seg Pro V3 (RT-300)

Please provide your Indications for Use below.

Seg Pro V3 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 DICOM images. Seg Pro V3 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. Seg Pro V3 must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. Seg Pro V3 is not intended to be used for decision making or to detect lesions.

Seg Pro V3 is an adjunct tool and is not intended to replace a clinician's judgment and manual contouring of the normal organs on DICOM images. Clinicians must not use the software generated output alone without review as the primary interpretation.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. General Information

510(k) Sponsor	Ever Fortune.AI Co., Ltd.
Address	8F., No.360, Sec. 1, Jingmao Rd., Beitun Dist., Taichung City 406040, Taiwan
Applicant	Joseph Chang
Contact Information	886-04-23213838 #216 joseph.chang@everfortune.ai
Correspondence Person	Ti-Hao Wang
Contact Information	886-04-23213838 #168 thothwang@gmail.com tihao.wang@everfortune.ai
Date Prepared	January 28, 2026

2. Proposed Device

Proprietary Name	Seg Pro V3 (RT-300)
Common Name	Seg Pro V3
Classification Name	Radiological Image Processing Software For Radiation Therapy
Regulation Number	21 CFR 892.2050
Product Code	QKB
Regulatory Class	II

3. Predicate Device

Proprietary Name	EFAI RTSUITE CT HCAP-Segmentation System
Premarket Notification	K231928
Classification Name	Radiological Image Processing Software For Radiation Therapy
Regulation Number	21 CFR 892.2050
Product Code	QKB
Regulatory Class	II

4. Reference Device

Proprietary Name	AutoContour RADAC V4
Premarket Notification	K242729
Classification Name	Radiological Image Processing Software For Radiation Therapy
Regulation Number	21 CFR 892.2050
Product Code	QKB
Regulatory Class	II

5. Device Description

The proposed device, Seg Pro V3, is a standalone software that is designed to be used by trained radiation oncology professionals to automatically delineate (segment/contour) organs-at-risk (OARs) on DICOM images. This auto-contouring of OARs is intended to facilitate radiation therapy workflows.

The device receives 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 must be used in conjunction with a DICOM-compliant treatment planning system (TPS) to review and edit results. Once data is routed to Seg Pro V3, 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. Seg Pro V3 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.

6. Intended Use / Indications for Use

Seg Pro V3 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 DICOM images. Seg Pro V3 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. Seg Pro V3 must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. Seg Pro V3 is not intended to be used for decision making or to detect lesions.

Seg Pro V3 is an adjunct tool and is not intended to replace a clinician's judgment and manual contouring of the normal organs on DICOM images. Clinicians must not use the software generated output alone without review as the primary interpretation.

7. Comparison of Technological Characteristics with Predicate Device

A reference device, AutoContour RADAC V4 (K242729), is included in this submission to support the evaluation of additional technological characteristics relevant to the subject device, such as MR image segmentation and multi-modality input handling. The reference device performs automatic contouring on CT and MR images using DICOM-compliant data and machine learning algorithms. The reference device is not cited to establish substantial equivalence in intended use. A comparative analysis is provided in the following section.

Feature/ Function	Proposed Device	Predicate Device	Reference Device	Comparison
Company	Ever Fortune.AI Co., Ltd. (EFAI)	Ever Fortune.AI Co., Ltd. (EFAI)	Radformation, Inc.	N/A
Device Name	Seg Pro V3	EFAI HCAPSeg	AutoContour RADAC V4	N/A
510k Number	K251306	K231928	K242729	N/A
Regulation No.	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Identical
Classification	II	II	II	Identical
Product Code	QKB	QKB	QKB	Identical
Intended Use/Indication for Use	Seg Pro V3 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 DICOM	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	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.	The proposed and predicate devices share the same intended use: assisting trained radiation oncology professionals in generating initial contours of organs at risk (OARs) for radiation therapy planning. While the proposed device supports both CT and MR images and the predicate device supports only CT, this difference in

	images. Seg Pro V3 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. Seg Pro V3 must be used in conjunction with a DICOM-compliant treatment planning system to review and edit results generated. Seg Pro V3 is not intended to be used for decision making or to detect lesions. Seg Pro V3 is an adjunct tool and is not intended to replace a clinician's judgment and manual contouring of the normal organs on DICOM images. Clinicians must not use the software generated output alone without review as the primary interpretation.	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.		imaging modality does not alter the intended use or raise new questions of safety or effectiveness. The reference device is not included in this comparison, as it is not used to establish substantial equivalence in intended use.
Segmentation (Contouring) Technology	Deep learning	Deep learning	Deep learning	Identical
Operating System	Linux Ubuntu 22.04.5 LTS	Linux Ubuntu 20.04	Windows based .NET front-end application that also serves as agent Uploader supporting	The proposed and predicate devices are Linux-based

			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.	Radiation treatment planners	All devices are intended for use by trained radiation therapy professionals. User groups are functionally equivalent.
Supported Modalities	CT or MR	CT	CT or MR input for contouring or registration/fusion. PET/CT input for registration/fusion only. DICOM RTSTRUCT for output	The proposed device supports both CT and MR images, while the predicate device supports only CT. The reference device also supports CT and MR for contouring and fusion. The proposed device aligns with the performance of commercially available products on the market, specifically Reference Devices.
	CT models include 166 organs-at-risk (OARs) across	CT models include 80 OARs across the head-and-neck,	CT or MR input for contouring of anatomical	Both the proposed and predicate devices cover the

Number of OARs and Anatomy Covered	the head-and-neck, chest, and abdomen-and-pelvis regions. MRI models include 16 OARs in the head and male pelvis regions. **CT Models:** ● Head-and-Neck (53) ● Chest (69) ● Abdomen-and-Pelvis (44) **MRI Models:** ● Head (11) ● Pelvis male (5) ** Each OAR is assigned to a single anatomical region based on the top-down order from head to pelvis.	chest, and abdomen-and-pelvis regions. **CT Models:** ● Head-and-Neck (53) ● Chest (13) ● Abdomen-and-Pelvis (14) ** Each OAR is assigned to a single anatomical region based on the top-down order from head to pelvis.	regions: Head and Neck, Thorax, Abdomen and Pelvis	head/neck, chest, and abdomen/pelvis regions. The proposed device includes a greater number of OARs and supports MR-based models, which is consistent with reference device capabilities.
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	Identical
Automated Workflow	Seg Pro V3 automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	EFAI HCAPSeg automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	Automatically contour, allow the user to review and modify, generate DICOM-compliant structure set data.	All devices support automatic contouring with DICOM-RT output.
User Interface	No	No	Yes	The proposed and predicate devices have no user interface.

8. Performance Data

Performance of the Seg Pro V3 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."

Clinical validation was conducted by independent clinical users representative of the intended end-user population. The results demonstrated that Seg Pro V3 operates as intended within a clinical workflow and supports its intended use as an adjunct tool for radiation therapy treatment planning.

In addition, a standalone performance evaluation was conducted to assess the Organ-at-Risk (OAR) contouring capabilities of Seg Pro V3. The observed results indicated that Seg Pro V3 by itself, in the absence of any interaction with a clinician, can contour developed OARs with satisfactory results.

The dataset comprised 175 cases consecutively collected from the Cancer Imaging Archive (TCIA) datasets, all meeting the predefined inclusion criteria. All data used during the standalone performance evaluation were acquired independently from product development training and internal testing.

The study population contained 28.0% females, 60.6% males, and 11.4% with unspecified gender. The mean age was 55.5 years old with standard deviation (SD) of 12.0 years old. The acquired data encompasses imaging manufacturers such as GE (44.0%), Siemens (46.4%), Philips (10.9%), and Others (1.7%). Race and ethnic distribution within the study data patient population was unavailable. The dataset included a diverse range of cancer types, such as brain tumors, head-and-neck, pancreatic, colorectal, lung, breast, bladder, prostate, stomach, gynecologic cancers, sarcomas, and metastatic tumors of various origins. Tumor locations and cancer stages varied widely across cases.

Each OAR contour used as ground truth (GT) was independently generated by three board-certified radiation oncologists. The acceptance criteria were defined as statistical superiority of the mean Dice Similarity Coefficient (DSC) over the predefined thresholds of 0.80, 0.65, and 0.50 for large-, medium-, and small-volume structures, respectively.

The overall performance demonstrated a mean DSC of 0.85. Superiority testing indicated that Seg Pro V3 met the primary endpoint, defined as the lower bound of the 95% confidence interval (CI) for the mean DSC exceeding the corresponding reference standard threshold. The observed mean DSC values of 0.90, 0.86, and 0.73 for large-, medium-, and small-volume structures, respectively. Additionally, the overall median 95% Hausdorff Distance (HD) was 2.62 mm, with corresponding medians of 3.01 mm, 2.57 mm, and 2.27 mm for large-, medium-, and small-volume structures, respectively.

Performance across subgroups such as gender, age group, imaging manufacturer, imaging slice thickness, MR sequence type, MR magnetic field strength, and suboptimal image quality conditions was further assessed to support the consistency and reliability of Seg Pro V3 under diverse clinical and imaging protocols.

Lastly, the DSC performance of individual OARs, along with the target performance (pass criteria) for each OAR, are shown in the following tables.

CT OAR	Size	Pass Criteria	Number of Cases	Mean DSC	SD of Mean DSC	Lower Bound 95% CI
Bone_Pelvic	Large	0.80	34	0.92	0.02	0.909
Bone_Pelvic_L	Large	0.80	34	0.91	0.02	0.898
Bone_Pelvic_R	Large	0.80	34	0.91	0.03	0.904
Bowel	Medium	0.65	34	0.89	0.02	0.881
Bowel_Large	Medium	0.65	34	0.87	0.04	0.860
Bowel_Small	Medium	0.65	34	0.85	0.03	0.841
Chestwall	Large	0.80	32	0.87	0.03	0.856
Chestwall_L	Large	0.80	32	0.86	0.03	0.851
Chestwall_R	Large	0.80	32	0.87	0.03	0.860
Clavicle_L	Medium	0.65	32	0.85	0.08	0.824
Clavicle_R	Medium	0.65	32	0.85	0.06	0.828
Femur_L	Large	0.80	34	0.91	0.04	0.898
Femur_R	Large	0.80	34	0.92	0.04	0.903
GI_Tract	Large	0.80	34	0.92	0.02	0.913
Glnd_Adrenal_L	Small	0.50	34	0.71	0.08	0.687
Glnd_Adrenal_R	Small	0.50	34	0.73	0.09	0.695
Gluteus	Large	0.80	34	0.91	0.02	0.907
Gluteus_Max_L	Medium	0.65	34	0.89	0.03	0.885
Gluteus_Max_R	Medium	0.65	34	0.90	0.03	0.893
Gluteus_Med_L	Medium	0.65	34	0.89	0.03	0.883
Gluteus_Med_R	Medium	0.65	34	0.90	0.02	0.889
Gluteus_Min_L	Medium	0.65	34	0.87	0.03	0.864
Gluteus_Min_R	Medium	0.65	34	0.88	0.03	0.867
Humerus_L	Large	0.80	32	0.90	0.18	0.833
Humerus_R	Large	0.80	32	0.92	0.08	0.893
Iliopsoas_L	Large	0.80	34	0.92	0.02	0.914
Iliopsoas_R	Large	0.80	34	0.93	0.02	0.923

Lung_LLL	Medium	0.65	32	0.91	0.07	0.879
Lung_LUL	Medium	0.65	32	0.90	0.03	0.893
Lung_RLL	Medium	0.65	32	0.92	0.02	0.911
Lung_RML	Medium	0.65	32	0.88	0.04	0.867
Lung_RUL	Medium	0.65	32	0.91	0.03	0.903
Lungs	Large	0.80	32	0.96	0.02	0.955
Rib01_L	Medium	0.65	32	0.87	0.09	0.841
Rib01_R	Medium	0.65	32	0.89	0.06	0.869
Rib02_L	Medium	0.65	32	0.88	0.08	0.848
Rib02_R	Medium	0.65	32	0.87	0.08	0.836
Rib03_L	Medium	0.65	32	0.89	0.06	0.866
Rib03_R	Medium	0.65	32	0.86	0.08	0.829
Rib04_L	Medium	0.65	32	0.86	0.08	0.835
Rib04_R	Medium	0.65	32	0.85	0.06	0.826
Rib05_L	Medium	0.65	32	0.87	0.06	0.845
Rib05_R	Medium	0.65	32	0.89	0.05	0.870
Rib06_L	Medium	0.65	32	0.87	0.05	0.856
Rib06_R	Medium	0.65	32	0.86	0.05	0.845
Rib07_L	Medium	0.65	32	0.86	0.05	0.840
Rib07_R	Medium	0.65	32	0.86	0.06	0.834
Rib08_L	Medium	0.65	32	0.86	0.05	0.840
Rib08_R	Medium	0.65	32	0.83	0.11	0.791
Rib09_L	Medium	0.65	32	0.86	0.05	0.846
Rib09_R	Medium	0.65	32	0.86	0.07	0.832
Rib10_L	Medium	0.65	32	0.87	0.05	0.848
Rib10_R	Medium	0.65	32	0.84	0.04	0.827
Rib11_L	Medium	0.65	32	0.84	0.06	0.817
Rib11_R	Medium	0.65	32	0.82	0.05	0.804
Rib12_L	Medium	0.65	32	0.85	0.07	0.831
Rib12_R	Medium	0.65	32	0.87	0.09	0.841
Ribs	Large	0.80	32	0.89	0.08	0.865
Ribs_L	Large	0.80	32	0.89	0.17	0.826
Ribs_R	Large	0.80	32	0.89	0.07	0.866
Sacrum	Large	0.80	34	0.91	0.03	0.896
Scapula_L	Medium	0.65	32	0.82	0.05	0.800

Scapula_R	Medium	0.65	32	0.80	0.04	0.789
Sternum	Medium	0.65	32	0.85	0.03	0.843
VB_L	Large	0.80	34	0.92	0.04	0.905
VB_L1	Medium	0.65	34	0.87	0.05	0.850
VB_L2	Medium	0.65	34	0.88	0.05	0.866
VB_L3	Medium	0.65	34	0.85	0.06	0.827
VB_L4	Medium	0.65	34	0.86	0.05	0.844
VB_L5	Medium	0.65	34	0.86	0.05	0.844
VB_LS	Large	0.80	34	0.89	0.04	0.880
VB_S	Medium	0.65	34	0.86	0.03	0.849
VB_S1	Large	0.80	34	0.85	0.05	0.830
VB_T	Large	0.80	32	0.93	0.03	0.923
VB_T01	Medium	0.65	32	0.84	0.08	0.810
VB_T02	Medium	0.65	32	0.86	0.06	0.836
VB_T03	Medium	0.65	32	0.85	0.05	0.834
VB_T04	Medium	0.65	32	0.86	0.04	0.846
VB_T05	Medium	0.65	32	0.86	0.04	0.848
VB_T06	Medium	0.65	32	0.84	0.05	0.827
VB_T07	Medium	0.65	32	0.85	0.05	0.834
VB_T08	Medium	0.65	32	0.86	0.06	0.836
VB_T09	Medium	0.65	32	0.86	0.04	0.845
VB_T10	Medium	0.65	32	0.87	0.04	0.855
VB_T11	Medium	0.65	32	0.83	0.04	0.812
VB_T12	Medium	0.65	32	0.85	0.12	0.807

SD, standard deviation. CI, confidence interval.

MR OAR	Size	Pass Criteria	Number of Cases	Mean DSC	SD of Mean DSC	Lower Bound 95% CI
Bladder	Large	0.80	36	0.91	0.05	0.892
Brainstem	Medium	0.65	76	0.90	0.04	0.893
Eye_L	Medium	0.65	76	0.91	0.04	0.904
Eye_R	Medium	0.65	76	0.91	0.05	0.894
Hippocampus_L	Medium	0.65	76	0.77	0.09	0.746
Hippocampus_R	Medium	0.65	76	0.77	0.09	0.751

Lens_L	Small	0.50	75	0.74	0.22	0.689
Lens_R	Small	0.50	75	0.74	0.25	0.677
OpticChiasm	Small	0.50	76	0.72	0.16	0.682
OpticNrv_L	Small	0.50	76	0.73	0.20	0.683
OpticNrv_R	Small	0.50	76	0.73	0.17	0.688
PenileBulb	Small	0.50	30	0.76	0.27	0.654
Pituitary	Small	0.50	75	0.72	0.29	0.651
Prostate	Medium	0.65	36	0.89	0.04	0.876
Rectum	Medium	0.65	36	0.85	0.11	0.814
SeminalVes	Medium	0.65	31	0.76	0.20	0.684
SD, standard deviation. CI, confidence interval.						

In conclusion, the results demonstrate that the Seg Pro V3 device is substantially equivalent to the predicate device in terms of safety and effectiveness, and that Seg Pro V3 demonstrates consistent and reliable performance under clinical conditions for its intended use.

Seg Pro V3 has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements and to meet the requirements associated with ISO 14971:2019 Medical devices — Application of risk management to medical devices.

9. Substantial Equivalence

The indications for use statement for the subject device is substantially equivalent to that of the predicate device, EFAI HCAPSeg. Both devices assist trained radiation oncology professionals by providing initial contours of organs at risk (OARs) to support radiation therapy treatment planning. They are intended for use on adult patients, must be used with a DICOM-compliant treatment planning system, and are not intended for clinical decision-making or lesion detection.

The subject and predicate devices share the same core technical characteristics, including the use of deep learning algorithms to generate contours of OARs from DICOM images, automatic output of DICOM-RT structure sets, and integration into clinical workflows without a user interface. Both devices are designed to operate fully automatically and require use with a DICOM-compliant treatment planning system.

The subject device also supports MR images in addition to CT. However, both modalities are DICOM images processed using the same contouring architecture, and this difference does not alter the intended use or impact clinical workflow. The OARs identified by both devices are associated with the same anatomical regions commonly used in radiation therapy planning, and the outputs are intended to support similar clinical applications. Thus, the proposed device does not raise new questions of safety or effectiveness, as the risks and technology used by both devices are the same and are mitigated similarly.

10. Predetermined Change Control Plan

This Predetermined Change Control Plan (PCCP) includes a planned modification to the Seg Pro V3 system involving the re-training of the deep learning model using newly acquired clinical data to improve performance in auto-contouring organs at risk (OARs). This modification is limited to a controlled model-weight update through re-training using clinically verified Real-World Data (RWD), without any changes to the model architecture, inference pipeline, pre- or post-processing, or any other device functions. Re-training may be initiated only when predefined PCCP triggers are met, including documented performance degradation associated with real-world distribution shifts and the availability of qualified clinical data.

In accordance with the PCCP-defined change control process, the updated model will undergo re-execution of software verification and performance validation activities. These activities follow the predefined testing procedures and acceptance criteria specified in the PCCP to ensure that all permitted modifications are assessed in a consistent, objective, and risk-appropriate manner, and that the re-trained model continues to meet the safety and effectiveness profile of the cleared device.

The PCCP does not introduce any new risks and all permitted modifications are limited to controlled model-weight updates, which are managed through predefined testing procedures to mitigate potential risks such as performance shift, overfitting, or unintended bias.

A summary of the permitted modification category, associated scenarios, and operational controls defined in this PCCP is provided in the table below:

Modification	Model weight updates via retraining on representative real-world datasets intended to correct performance degradation at local or global scales.
Testing Method	Predefined verification and validation using prospectively collected real-world data and the Golden dataset, including quantitative performance metrics (e.g., DSC), subgroup analyses, and post-deployment clinical monitoring with predefined acceptance criteria and rollback controls.
Device Update Procedure	Re-trained models are deployed via controlled global and constrained local strategies, guided by predefined triggers, verification and validation criteria. This process is supported by rigorous data management, including the regulated expansion and retirement of real-world and Golden test datasets, ensuring continued safety, effectiveness, and substantial equivalence. Controlled user notification via established communication procedures, including advance release notices, version documentation updates, and standardized rollback notifications, in accordance with the PCCP.

11. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, the Seg Pro V3 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety and effectiveness.