OncoSoft. Co., Ltd.
Boram Kim
RA/QA Manager
37, Myeongmul-gil, Seodaemun-gu
SEOUL, 03776
KOREA, SOUTH

February 24, 2025

Re: K242994
Trade/Device Name: OncoStudio (OS-01)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: January 23, 2025
Received: January 23, 2025

Dear Boram Kim:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242994

Device Name

OncoStudio (OS-01)

Indications for Use *(Describe)*

OncoStudio provides deep-learning-based automatic contouring to organs at risk in DICOM-RT format from CT images. This software could be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

- Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis
- Generates DICOM-RT structure of contoured objects
- Manual Contouring
- Receive, transmit, store, retrieve, display, and process medical images and DICOM objects

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.

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

January 23, 2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: OncoSoft Co., Ltd.
- Address: 37, Myeongmul-gil, Seodaemun-gu, Seoul, Republic of Korea (03776)
- Contact Name: Boram Kim
- Telephone No.: +82-10-6305-7428
- Email Address: kbrstar@oncosoft.io

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

510(k) Number	K242994
Trade/Device/Model Name	OncoStudio / OS-01
Device Classification Name	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050
Classification Product Code	QKB
Device Class	Class II
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

Predicate Device

510(k) Number	K230685
Trade/Device/Model Name	AutoContour Model RADAC V3
Device Classification Name	Medical Image Management And Processing System
Regulation Number	21 CFR 892.2050
Classification Product Code	QKB
Device Class	Class II
510(k) Review Panel	Radiology

Reference Device

510(k) Number	K232899
Trade/Device/Model Name	AI-Rad Companion Organs RT
Device Classification Name	Medical Image Management And Processing System
Regulation Number	21 CFR 892.2050
Classification Product Code	QKB
Device Class	Class II
510(k) Review Panel	Radiology

These predicate devices have not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

OncoStudio is a standalone software that provides deep-learning-based automatic contouring to organs at risk in DICOM-RT format from CT images. This software could be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

- Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis
- Generates DICOM-RT structure of contoured objects
- Manual Contouring
- Receive, transmit, store, retrieve, display, and process medical images and DICOM objects

It also has the following general functions:

- Patient management;
- Review of processed images;
- Open and Save of files.

6. Indications for use [21 CFR 807.92(a)(5)]

OncoStudio provides deep-learning-based automatic contouring to organs at risk in DICOM-RT format from CT images. This software could be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

- Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis
- Generates DICOM-RT structure of contoured objects
- Manual Contouring
- Receive, transmit, store, retrieve, display, and process medical images and DICOM objects

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate devices which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the OncoStudio and the predicate devices:

[Table 1. Comparison of Proposed Device to Predicate Device and Reference Device]

Item	Subject Device	Predicate Device	Reference Device1	SE Note
	OncoStudio	AutoContour Model RADAC V3	AI-Rad Companion Organs RT	
Regulation Name	Medical Image Management And Processing System	Medical Image Management And Processing System	Medical Image Management And Processing System	-
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	-
Product Code	QKB	QKB	QKB	-
Class	II	II	II	-
510k Number	K242994	K230685	K232899	-
Indication for Use	OncoStudio provides deep-learning-based automatic contouring to organs at risk in DICOM-RT format from CT images. This software could be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed. • Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis • Generates DICOM-RT structure of contoured objects • Manual Contouring • Receive, transmit, store,	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning	AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR predefined structures using deep-leaming-based algorithms. Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including external beam radiation therapy treatment planning. AI-Rad Companion Organs RT must be used in conjunction with appropriate	Same

	retrieve, display, and process medical images and DICOM objects				software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT. The output of AI-Rad Companion Organs RT are intended to be used by trained medical professionals. The software is not intended to automatically detect or contour lesions.	
Regions of Interest(ROIs)	• A_Aorta • A_Carotid_L • A_Carotid_R • A_Coronary_R • A_Iliac_L • A_Iliac_R • A_LAD • A_Subclavian_L • A_Subclavian_R • Anus • Atrium_L • Atrium_R • Autochthon_L • Autochthon_R • Bag_Bowel • Bladder • Bone_Mandible • Bowel_Large • Bowel_Small • BrachialPlex_L • BrachialPlex_R • Brachiocephalic_Trunk • Brain • Brainstem • Breast_L • Breast_R	• LN_Sclav_L_RTOG • LN_Sclav_R_ESTRO • LN_Sclav_R_RTOG • Larynx • Lens_L • Lens_R • Liver • Lobe_Temporal_L • Lobe_Temporal_R • Lung_L • Lung_LLL • Lung_LUL • Lung_R • Lung_RLL • Lung_RML • Lung_RUL • OpticChiasm • OpticNrv_L • OpticNrv_R • Pancreas • Parotid_L • Parotid_R • Pharynx • Pituitary • Prostate • Rectum	• A_Aorta • A_Aorta_Asc • A_Aorta_Dsc • A_LAD • A_Pulmonary • Bladder • Bladder_F • Bone_Ilium_L • Bone_Ilium_R • Bone_Mandible • Bone_Pelvic • Bone_Skull • Bone_Sternum • Bowel • Bowel_Bag • Bowel_Large • Bowel_Small • BrachialPlex_L • BrachialPlex_R • Brain • Brainstem • Breast_L • Breast_R • Bronchus • BuccalMucosa • Carina	• LN_Ax_L • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_L • LN_Ax_L2_L3_L • LN_Ax_L2_L3_R • LN_Ax_L2_R • LN_Ax_L3_L • LN_Ax_L3_R • LN_Ax_R • LN_IMN_L • LN_IMN_R • LN_IMN_RC_L • LN_IMN_RC_R • LN_Inguinofem_L • LN_Inguinofem_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_II-V_L • LN_Neck_II-V_R • LN_Neck_III_L	(166 OARs) Full list of OAR is not provided	Different

	• Bronchus_L • Bronchus_R • CaudaEquina • Cavity_Oral • Clavicle_L • Clavicle_R • Cochlea_L • Cochlea_R • Colon • Kidney_Cortex_L • Kidney_Cortex_R • Costal_Cartilages • Duodenum • Esophagus • Eye_L • Eye_R • Femur_Head_L • Femur_Head_R • Femur_L • Femur_R • Gallbladder • Glnd_Adrenal_L • Glnd_Adrenal_R • Glnd_Submand_L • Glnd_Submand_R • Glnd_Thyroid • Gluteus_Maximus_L • Gluteus_Maximus_R • Gluteus_Medius_L • Gluteus_Medius_R • Gluteus_Minimus_L • Gluteus_Minimus_R • Heart • Hip_L • Hip_R • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • Iliopsoas_L • Iliopsoas_R • Joint_TM_L • Joint_TM_R • Kidney_L	• Rib01_L • Rib01_R • Rib02_L • Rib02_R • Rib03_L • Rib03_R • Rib04_L • Rib04_R • Rib05_L • Rib05_R • Rib06_L • Rib06_R • Rib07_L • Rib07_R • Rib08_L • Rib08_R • Rib09_L • Rib09_R • Rib10_L • Rib10_R • Rib11_L • Rib11_R • Rib12_L • Rib12_R • Sacrum • Scapula_L • Scapula_R • Colon_Sigmoid • Skull • SpinalCord • Spleen • Sternum • Stomach • Trachea • VB_C1 • VB_C2 • VB_C3 • VB_C4 • VB_C5 • VB_C6 • VB_C7 • VB_L1 • VB_L2 • VB_L3	• CaudaEquina • Cavity_Oral • Cavity_Oral_Ext • Chestwall_L • Chestwall_OAR • Chestwall_R • Chestwall_RC_L • Chestwall_RC_R • Cochlea_L • Cochlea_R • Colon_Sigmoid • Cornea_L • Cornea_R • Duodenum • Ear_Internal_L • Ear_Internal_R • Esophagus • External • Eye_L • Eye_R • Femur_Head_L • Femur_Head_R • Femur_L • Femur_R • Femur_RTOG_L • Femur_RTOG_R • GallBladder • Genitals_F • Genitals_M • Glnd_Lacrimal_L • Glnd_Lacrimal_R • Glnd_Submand_L • Glnd_Submand_R • Glnd_Thyroid • HDR_Cylinder • Heart • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • Kidney_L • Kidney_R • Kidney_Outer_L	• LN_Neck_III_R • LN_Neck_IV_L • LN_Neck_IV_R • LN_Neck_V_L • LN_Neck_V_R • LN_Neck_VIA • LN_Neck_VIIA_L • LN_Neck_VIIA_R • LN_Neck_VIIB_L • LN_Neck_VIIB_R • LN_Paraaortic • LN_Pelvics • LN_Pelvic_NRG • LN_Sclav_L • LN_Sclav_R • LN_Sclav_RADCOMP_L • LN_Sclav_RADCOMP_R • Lobe_Temporal_L • Lobe_Temporal_R • Lung_L • Lung_R • Macula_L • Macula_R • Marrow_Ilium_L • Marrow_Ilium_R • Musc_Constrict • Nipple_L • Nipple_R • OpticChiasm • OpticNrv_L • OpticNrv_R • Pancreas • Parotid_L • Parotid_R • PenileBulb • Pericardium • Pituitary • Prostate • Rectum • Rectum_F • Retina_L • Retina_R • Rib • Rib_L		

	• Kidney_R • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_L • LN_Ax_L2_R • LN_Ax_L3_L • LN_Ax_L3_R • LN_IMN_L • LN_IMN_R • LN_Neck_IA • LN_Neck_IB_L • LN_Neck_IB_R • LN_Neck_III_L • LN_Neck_III_R • LN_Neck_II_L • LN_Neck_II_R • LN_Neck_IVA_L • LN_Neck_IVA_R • LN_Neck_IVB_L • LN_Neck_IVB_R • LN_Neck_VA_L • LN_Neck_VA_R • LN_Neck_VBC_L • LN_Neck_VBC_R • LN_Sclav_L_ESTRO	• VB_L4 • VB_L5 • VB_S1 • VB_T01 • VB_T02 • VB_T03 • VB_T04 • VB_T05 • VB_T06 • VB_T07 • VB_T08 • VB_T09 • VB_T10 • VB_T11 • VB_T12 • V_Brachioceph_L • V_Brachioceph_R • V_Iliac_L • V_Iliac_R • V_Portal_And_Splenic • V_Pulmonary • V_Venacava_I • V_Venacava_S • Ventricle_L • Ventricle_R	• Kidney_Outer_R • Larynx • Larynx_Glottic • Larynx_NRG • Larynx_SG • Lens_L • Lens_R • Lips • Liver	• Rib_R • SeminalVes • SpinalCanal • SpinalCord • Spleen • Stomach • Trachea • UteroCervix • V_Venacava_I • V_Venacava_S • VB • VB_C1 • VB_C2 • VB_C3 • VB_C4 • VB_C5 • VB_C6 • VB_C7 • VB_L1 • VB_L2 • VB_L3 • VB_L4 • VB_L5 • VB_T01 • VB_T02 • VB_T03 • VB_T04 • VB_T05 • VB_T06 • VB_T07 • VB_T08 • VB_T09 • VB_T10 • VB_T11 • VB_T12		
Operating System	Local deployment on 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	Edge & Cloud Deployment	Different

		with Linux. Windows python-based automatic contouring application supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016.		
Image Format	DICOM	DICOM	DICOM	Same
General Functions	1) Deep learning contouring from Head & Neck, Thorax, Abdomen, and Pelvis 2) Generates DICOM-RT structure of contoured objects 3) Manual Contouring 4) Receive, transmit, store, retrieve, display, and process medical images and DICOM objects	1) Automatically contour various structures of interest for radiation therapy treatment planning 2) Allow the user to review and modify the resulting contours 3) Generate DICOM-compliant structure set data the can be imported into a radiation therapy treatment planning system	CT or MR series of images serve as input for AI-Rad Companion Organs RT and are acquired as part of a typical scanner acquisition. Once processed by the AI algorithms, generated contours in DICOM-RTSTRUCT format are reviewed in a confirmation window, allowing clinical user to confirm or reject the contours before sending to the target system. Optionally, the user may select to directly transfer the contours to a configurable DICOM node	Same
Algorithm	Deep Learning	Deep Learning	Deep Learning	Same
Compatible Modality	CT Images. DICOM RTSTRUCT for output	CT or MR input for contouring or registration/fusion. PET/CT input for registration/fusion only. DICOM RTSTRUCT for output	CT & MR Images	Equivalent
Segmentation of Organ	Head & Neck, Thorax, Abdomen, Pelvis	Head and Neck, Thorax, Abdomen, Pelvis	Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes	Same
Workflow	Automatically processes input image data contour organs	Automatically contour various structures of	AI-Rad Companion Organs RT	Same

	and DICOM sends generated RT Structure set	interest for radiation therapy treatment planning using machine learning based contouring	automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node	
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM 3.0 compliance required.	Same
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.	Same
Patient Population	Adult only	Adult only	Adult only	Same

The intended use of the predicate device and the subject device are equivalent. Both devices are intended to aid users to contour the body structure using artificial intelligence algorithm that can be used as an initial contouring for the clinicians to be confirmed by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

A detailed comparison shows the subject device is substantially equivalent in indications for use, image format, general functions, algorithm, segmentation of organs, workflow, compatible scanner models, compatible treatment planning system and patient population to the predicate device. The differences between the subject and the predicate devices do not raise any new questions regarding safety and effectiveness.

8. Non-Clinical Test summary

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

1) Software Validation

The OncoStudio contains basic document level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- "Content of Premarket Submissions for Device Software Functions," dated June 14, 2023.

2) Performance characteristics

We collected training data from mainly three datasets of source : OneMedNet, Yonsei Severance Hospital, and University Hospital Basel, Basel, Switzerland. OneMedNet is a purchased set of CT data, mainly comprised of U.S.A. population. Yonsei Severance Hospital is located in South Korea, and we collected mainly Eastern population data from this source. The Basel data is known as TotalSegmentator dataset, which is open for public at this moment.

The collected data comprises a total of 2,438 dataset, consisting of 315 datasets from the US, 871 from Korea, and 1,252 from Europe.

The data was constructed with various ethnics (White, Black, Asian, Hispanic, Latino, African, American, etc.), and the training model can be obtained by performing generalization without differences according to ethnicity.

We allocated 310 data as training dataset, which is more than one-tenth of the total 2,438 dataset, and used the remaining data(2128) for training.

For evaluation, we created a test dataset that was not involved in any kind of training process. The splitting was performed at the patient level to ensure that images from the same patient were not present in more than one dataset. A comprehensive audit was conducted to confirm the integrity of the data-splitting process and ensure that no patient overlap occurred between datasets.

Ground truth segmentations were established by three radiation oncologists following international clinical guidelines.

a) Ground Truthing

The ground truth annotations for the dataset of Yonsei Severance Hospital(Korea) and OneMedNet(U.S) were established by three different radiation oncologists with 3-20 years of clinical practice following RTOG and clinical guidelines using manual annotation. The radiation oncologists included associate professor, assistant professor, and radiation oncologist resident from two institutions (Yonsei Cancer Center, Samsung Seoul Hospital)

- Ground Truthing process
  - First, the 1 radiation oncologist manually delineated the organs
  - Second, segmentation results generated by 1 radiation oncologist are sequentially edited and confirmed by 2 radiation oncologists. In this editing process, the first radiation oncologist makes corrections, and the corrected results are received and finalized by another radiation oncologist.

In case of University Hospital Basel (Europe) dataset, the dataset is public data comprising 104 anatomical structures. A total of 1,368 CT images were randomly sampled from the years 2012, 2016, and 2020 from the University Hospital Basel through picture archiving and communication system (PACS). The Nora Imaging Platform was used for manual segmentation and further refinement of generated segmentations for ground truth. Segmentation was supervised by two physicians with 3 (M.S.) and 6 years (H.B.) of experience in body imaging, respectively.

b) Training

Out of a total of 2,438 images, 2,128 were allocated as training data. The allocated training data consists of 731 images from Yonsei Severance Hospital(Republic of Korea), 194 images from OneMedNet(U.S.A), and 1203 images from University Hospital Basel(Switzerland).

The training datasets consist of 62% of Contrast CT and 38% of Non-Contrast CT. The study population comprises 62% males and 38% females, with 22% under 49 years old, 47% aged 50–70 years, and 31% over 70 years old.

The data was constructed with various ethnics (White, Black, Asian, Hispanic, Latino, African, American, etc.), and the result can be obtained by performing generalization without performance differences according to ethnicity.

The acquired data encompasses CT manufacturers such as GE (2%), Siemens (72%), Philips (9%), Toshiba (11%), and unknown manufacturer(6%)

c) Segmentation Performance Test

A standalone performance test was conducted to compare the contouring capabilities of OncoStudio.

The dataset used in this test comprises a total of 310 CT images, with 140, 121, and 49 images collected from Yonsei Severance Hospital (Republic of Korea), OneMedNet (U.S.A.), and University Hospital Basel (Switzerland), respectively, each meeting the established inclusion criteria. All data used during the standalone performance evaluation was composed independently of product development training.

The images consist of 54% of Contrast CT and 46% of Non-Contrast CT. The study population comprises 58% males and 42% females, with 13% under 49 years old, 54% aged 50–70 years, and 28% over 70 years old.

The data was constructed with various ethnics (White, Black, Asian, Hispanic, Latino, African, American, etc.), and the result can be obtained by performing generalization without performance differences according to ethnicity.

The acquired data encompasses CT manufacturers such as GE (2%), Siemens (56%), Philips (14%), Toshiba (22%), and unknown manufacturer(6%)

Ground truth segmentations were established by three radiation oncologists following international clinical guidelines.

For the structures being compared, the mean Dice coefficient (DSC) of structures for each anatomical region (Head & Neck, Thorax, Abdomen, and Pelvis) should meet the established criteria.

3) Cybersecurity

- "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", on September 27, 2023

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the subject, predicate and reference devices, K230685 and K232899 that would adversely affect the use of the product. It is substantially equivalent to the predicate device in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the OncoStudio is substantially equivalent in safety and effectiveness to the predicate device as described herein.