March 27, 2025

Siemens Healthcare GmbH
Kira Morales
Regulatory Affairs Manager
Henkestrasse 127
Erlangen, 91052
Germany

Re: K242745
Trade/Device Name: AI-Rad Companion Organs RT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: September 9, 2024
Received: September 11, 2024

Dear Kira Morales:

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)*

K242745

Device Name

AI-Rad Companion Organs RT

Indications for Use *(Describe)*

AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures using deep-learning-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 software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT.

The outputs 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.

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
FOR
AI-Rad Companion Organs RT
K242745

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: September 9, 2024

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. Submitter

Importer/Distributor

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Registration Number: 2240869

Manufacturing Site

Siemens Healthcare GmbH
Henkestrasse 127
Erlangen, Germany 91052
Registration Number: 3002808157

2. Contact Person

Kira Morales
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19335
Phone: +1 (484) 901 - 9471
Email: kira.morales@siemens-healthineers.com

3. Device Name and Classification

Product Name:	AI-Rad Companion Organs RT
Common Name:	Medical Imaging Software
Classification Name:	Medical Image Management and Processing System

Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QKB

4. Predicate Device

Product Name:	AI-Rad Companion Organs RT
Common Name:	Medical Imaging Software
510(k) Number:	K232899
Clearance Date:	April 3, 2024
Classification Name:	Medical Image Management and Processing System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	QKB
Recall Information:	N/A

5. Reference Devices

Product Name:	**Contour Protégé AI**
Common Name:	Medical Imaging Software
510(k) Number:	K231765
Clearance Date:	November 8, 2023
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	QKB

Product Name:	**Contour Protégé AI**
Common Name:	Medical Imaging Software
510(k) Number:	K223774
Clearance Date:	April 6, 2023
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	QKB

Product Name:	**AI Segmentation**
Common Name:	Medical Image Segmentation Software
510(k) Number:	K211881
Clearance Date:	September 2, 2021

Classification Name:	Medical charged-particle radiation therapy system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	MUJ

6. Indications for Use

AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures using deep-learning-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 software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT.

The outputs 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.

7. Device Description

AI-Rad Companion Organs RT provides automatic segmentation of pre-defined structures such as Organs-at-risk (OAR) from CT or MR medical series, prior to dosimetry planning in radiation therapy. AI-Rad Companion Organs RT is not intended to be used as a standalone diagnostic device and is not a clinical decision-making software.

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 DICOMRTSTRUCT 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 (e.g., the Treatment Planning System (TPS), which is the standard location for the planning of radiation therapy).

AI-Rad Companion Organs RT must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept the automatically generated contours. Then the output of AI-Rad Companion Organs RT must be reviewed and, where necessary, edited with appropriate software before accepting generated contours as input to treatment planning steps. The output of AI-Rad Companion Organs RT is intended to be used by qualified medical professionals, who can perform a complementary manual editing of the contours or add any new contours in the TPS (or any other interactive contouring application supporting DICOM-RT objects) as part of the routine clinical workflow.

8. Substantially Equivalent (SE) and Technological Characteristics

The intended use of the subject device is unchanged from the predicate device. The following modifications have been made in the subject device, compared to the predicate, AI-Rad Companion Organs RT (K232899).

- Enhanced CT contouring algorithm include 37 new organs & structures
- Multi Guideline Support and corresponding update to UI

AI-Rad Companion Organs RT VA60 and AI-Rad Companion Organs RT VA50 both use a deep learning algorithm to support their AI claims. Additionally, they both process CT and MR data in DICOM format, making them vendor agnostic and create outputs which can be used by any TPS system. The deep learning CT algorithm within AI-Rad Companion Organs RT VA60 has been enhanced from the algorithm in AI-Rad Companion Organs RT VA50 (K232899). All models contained within AI-Rad Companion Organs RT VA60 and AI-Rad Companion Organs RT VA50 (K232899) are locked and cannot be modified by the user.

The subject device, AI-Rad Companion Organs RT, is substantially equivalent with regards to the software features, functionalities, and core algorithms. The performance of the enhanced CT contouring algorithm has been validated against FDA/CE cleared devices or from literature.

The risk analysis and non-clinical data support that both devices perform equivalently and do not raise different questions of the safety and effectiveness.

	Subject Device	**Predicate Device**
Device Manufacturer	**Siemens**	**Siemens**
Device Name	**AI-Rad Companion Organs RT**	**AI-Rad Companion Organs RT**
510(k) Number	**K242745**	**K232899**
Indications for Use	AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures using deep-learning-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	AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures using deep-learning-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 software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT. The outputs 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	planning. AI-Rad Companion Organs RT must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT. The outputs 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
Algorithm	Deep Learning	Deep Learning
Segmentation of Organ at Risk in the Anatomic Regions	CT: Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes (203 OAR) MR: Pelvis (9 OAR)	CT: Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes (166 OAR) MR: Pelvis (9 OAR)
Compatible Modality	CT & MR Images	CT & MR Images
Compatible Scanner Models	No Limitation on scanner model for CT. Siemens Healthineers' data only for MR. DICOM compliance required.	No Limitation on scanner model for CT. Siemens Healthineers' data only for MR. DICOM compliance required.
Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM compliance required.
Contraindications	Adult use only	Adult use only
Target Population	AI-Rad Companion Organs RT is designed for use only in adult populations. AI-Rad Companion Organs RT is designed for any patient for whom relevant modality scans are available.	AI-Rad Companion Organs RT is designed for use only in adult populations. AI-Rad Companion Organs RT is designed for any patient for whom relevant modality scans are available.

Clinical condition the device is intended to diagnose, treat or manage	Limited to patients previously selected for Radiation Therapy.	Limited to patients previously selected for Radiation Therapy.
Software Architecture	AI-Rad Companion (Engine) architecture enabling the deployment of AI Rad Companion Organs RT using Edge and in the Cloud. The UI is provided using a web-based interface.	AI-Rad Companion (Engine) architecture enabling the deployment of AI Rad Companion Organs RT using Edge and in the Cloud. The UI is provided using a web-based interface.
Deployment Feature	Edge & Cloud Deployment	Edge & Cloud Deployment
Organ Templates	Creating, editing and deletion of organ templates. Customize predefined structure database with mapping to international nomenclature schemes.	Creating, editing and deletion of organ templates. Customize predefined structure database with mapping to international nomenclature schemes.
Automated workflow	AI-Rad Companion Organs RT automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	AI-Rad Companion Organs RT automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.
Contour visualization and editing feature	AI-Rad Companion Organs RT provides basic result preview of automatic segmentation results, and no editing feature of the automatic segmented contour.	AI-Rad Companion Organs RT provides basic result preview of automatic segmentation results, and no editing feature of the automatic segmented contour.
Segmentation Performance	MR: The algorithm is unchanged from the predicate and is separate from the CT algorithm therefore the performance is unchanged from the predicate. CT: The target performance was validated using 579 cases distributed to four cohorts. Both: To objectively evaluate the target performance, the DICE coefficient, the absolute symmetric surface distance (ASSD) and the fail rate was evaluated. The	MR: The target performance was validated using 66 cases to validate the overall performance of the MR contouring. CT: The target performance was validated using 414 cases distributed to three cohorts. Both: To objectively evaluate the target performance, the DICE coefficient, the absolute symmetric surface distance (ASSD) and the fail rate was evaluated. The segmentation performance of the

	segmentation performance of the subject was equivalent to the overall performance compared to the predicate, reference device and comparable literature & devices.	subject was equivalent to the overall performance compared to the predicate, reference device and comparable literature & devices.
User Interface – Results Preview (Confirmation)	Basic visualization functionality of original data and generated contours	Basic visualization functionality of original data and generated contours
User Interface Configuration	Configuration UI	Configuration UI
Automated Workflow to TPS	Results send to Confirmation UI & Optional bypassing of Confirmation UI to TPS	Results send to Confirmation UI & Optional bypassing of Confirmation UI to TPS
Human Factors	Design to be used by trained clinicians.	Design to be used by trained clinicians.

Table 1: Indications for Use and Segmentation Feature Comparison

The conclusions from all verification and validation data suggests that these enhancements are equivalent with respect to safety and effectiveness of the predicate device. These modifications do not change the intended use of the product. Siemens is of opinion that AI-Rad Companion Organs RT VA60 is substantially equivalent to the currently marketed device, AI-Rad Companion Organs RT (K232899).

9. Nonclinical Tests

Non-clinical tests were conducted to test the functionality of AI-Rad Companion Organs RT. Software validation and bench testing have been conducted to assess the performance claims as well as the claim of substantial equivalence to the predicate device.

AI-Rad Companion has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrates that AI-Rad Companion Organs RT complies with the FDA guidance document, "Guidance for the Content of Premarket Submissions for Device Software Functions" (June 2023) as well as with the following voluntary FDA recognized Consensus Standards listed in **Table 2.**

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
5-129	General	Medical Devices – Application of usability engineering to medical devices	62366-1 Ed 1.1 2020-06 CV	IEC
5-125	General	Medical Devices – application of risk	14971:2019-12	ISO

		management to medical devices		
13-79	Software/ Informatics	Medical device software – software life cycle processes [Including Amendment 1 (2016)]	62304 Ed 1.1 2015-06 CV	AAMI ANSI IEC
12-352	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 2023e	NEMA
5-134	General	Medical devices – symbols to be used with information to be supplied by the manufacturer – Part 1: General Requirements	15223-1 Fourth edition 2021-07	ISO IEC
13-97	Software/ Informatics	Health software – Part 1: General requirements for product safety	82304-1 Edition 1.0 2016-10	IEC
13-122	Software/ Informatics	Health software and Health IT system safety effectiveness and security	81001-5-1 Edition 1.0 2021-12	IEC
5-135	General	Medical devices – Information to be supplied by the manufacturer	20417 First edition 2021-04	ISO

Table 2: List of recognized standards

Verification and Validation

Software documentation level, per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on June 14, 2023, is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the subject device during product development.

Software bench testing in the form of Unit, System and Integration tests were performed to evaluate the performance and functionality of the new features and software updates. All testable requirements in the Requirement Specifications and the Risk Analysis have been successfully verified and traced in accordance with the Siemens Healthineers DH product development process. Human factor usability validation is addressed in system testing and usability validation test records. Software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

Siemens Healthineers adheres to the cybersecurity recommendations as defined the FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (September 2023) by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.

10. Performance Software Validation

To validate the AI-Rad Companion Organs RT software from clinical perspective, the auto-contouring algorithms underwent a scientific evaluation. The results of clinical data-based software validation for the subject device AI-Rad Companion Organs RT (SW VA60A) demonstrated equivalent performance in comparison to the predicate device (SW VA50A, K232899). The performance of the enhanced CT organ contouring algorithm is comparable to the predicate device and comparable reference literature and cleared devices. A complete scientific evaluation report is provided in support of the device modifications.

The MR Contouring algorithm contained within AI-Rad Companion Organs RT VA60 is identical to the predicate device AI-Rad Companion Organs RT VA50 (K232899).

CT Contouring Algorithm Performance

The performance of the AI-Rad Companion Organs RT has been validated in a retrospective performance study on CT data previously acquired for RT treatment planning (N= 579, data from multiple clinical sites across the North American, South American, Asia, Australia and Europe). Ground truth annotations were established following RTOG and clinical guidelines using manual annotation. The mean and standard deviation Dice coefficients, along with the lower 95th percentile confidence bound, were calculated for each organ in the subject device. The results of subject device were equivalent or had better performance than the predicate device. To encountered for different datasets, variation in annotation, we first calculate the average of multiple references or the average of anatomical region for the specific organ or anatomical region. We then define the baseline value by subtracting the reference value using 5% error margin in case of Dice and 0.1 mm in case of ASSD.

The performance results of the subject device for the new CT organs are comparable to the reference literature & cleared devices. Here equivalence for the new organs is defined such that the selected reference metric has a higher value than the defined baseline. For existing organs, the average (AVG) Dice score difference between the subject device and predicate device is smaller than 3%.

Validation Testing Subject	Acceptance Criteria
Organs in Predicate Device	• All the organs segmented in the predicate device are also segmented in the subject device • The average (AVG) Dice score difference between the subject and predicate device is smaller than 3%

New Organs for Subject Device	• The subject device in the selected reference metric has a higher value than the defined baseline value

Table 3: Acceptance Criteria of AIRC Organs RT VA50

	Dice (%)		
	Avg	Std	95% CI
Head & Neck	76.1	14.3	[75.1, 77.2]
Head & Neck lymph nodes	69.3	13.9	[68.7, 70.0]
Thorax	76.9	15.8	[76.2, 77.6]
Abdomen	87.3	10.1	[86.3, 88.2]
Pelvis	85.7	9.6	[85.0, 86.5]
Cardiac	75.6	15.1	[74.1, 77.1]

Table 3: Performance summary of the subject device CT contouring

Organ Name	**NO.**	**Dice (%)**				**ASSD (mm)**			
		AVG	**STD**	**MED**	**95%CI**	**AVG**	**STD**	**MED**	**95%CI**
Left Breast	30	90.4	3.8	91	[89, 91.8]	2.4	2.2	1.8	[1.5, 3.2]
Right Breast	30	90.2	3.7	90.8	[88.8, 91.5]	1.9	0.7	1.8	[1.7, 2.2]
Bowel Bag	33	95	3.6	96.5	[93.7, 96.3]	1.9	1.5	1.4	[1.4, 2.5]
Left Pelvic Bone	30	93.4	1.6	93.8	[92.8, 94]	0.6	0.2	0.5	[0.5, 0.6]
Right Pelvic Bone	30	93.9	1.3	94	[93.4, 94.4]	0.5	0.1	0.5	[0.4, 0.6]
Pituitary	30	75.8	7.4	77	[73.1, 78.6]	0.7	0.3	0.6	[0.5, 0.8]
Sacrum	30	90.7	4	91.9	[89.2, 92.2]	0.8	0.6	0.6	[0.5, 1]
Brainstem	30	88.4	2.5	88.8	[87.5, 89.3]	1	0.3	0.9	[0.9, 1.1]
Glottis	30	68	8.7	70.9	[64.8, 71.3]	1.2	0.4	1.1	[1.1, 1.4]
Supraglottic Larynx	30	80	5.9	81	[77.8, 82.20]	0.8	0.3	0.7	[0.7, 0.9]
Esophagus	30	85.6	4.2	86	[84, 87.2]	0.6	0.3	0.6	[0.5, 0.7]
Left Lacrimal Gland	30	72.1	7.3	71.3	[69.4, 74.9]	0.8	0.3	0.8	[0.7, 0.9]
Right Lacrimal Gland	30	69.9	12.4	73.6	[65.3, 74.6]	0.9	0.7	0.8	[0.7, 1.2]
Left Femur Head	30	95.2	1.1	95.2	[94.8, 95.6]	0.5	0.2	0.5	[0.5, 0.6]

Right Femur Head	30	94.9	1.3	95.1	[94.5, 95.4]	0.6	0.2	0.5	[0.5, 0.6]
Left Humeral Head	30	94.2	2.1	94.8	[93.4, 94.9]	0.7	0.3	0.6	[0.6, 0.8]
Right Humeral Head	30	94.6	3.2	95.4	[93.4, 95.8]	0.7	0.5	0.5	[0.5, 0.9]
MEDIASTINAL LN 10L	31	52.9	9.7	55.1	[49.4, 56.5]	1.2	0.6	1.1	[1, 1.5]
MEDIASTINAL LN 10R	31	50.2	9.5	50.6	[46.7, 53.7]	1.4	0.6	1.2	[1.1, 1.6]
MEDIASTINAL LN 1L	31	70.7	10	73	[67, 74.4]	2.4	1.2	1.9	[1.9, 2.8]
MEDIASTINAL LN 1R	31	66	12.8	67.9	[61.3, 70.7]	2.4	0.9	2.3	[2.1, 2.8]
MEDIASTINAL LN 2L	31	67.6	7.6	68.6	[64.8, 70.5]	1.4	0.4	1.3	[1.2, 1.5]
MEDIASTINAL LN 2R	31	55.5	13.6	56.9	[50.6, 60.5]	2.3	1.5	2	[1.7, 2.8]
MEDIASTINAL LN 3A	31	75.6	6.3	77.6	[73.3, 77.9]	1.6	0.4	1.5	[1.5, 1.8]
MEDIASTINAL LN 3P	31	65.9	6	66.5	[63.7, 68.1]	1.6	0.6	1.5	[1.4, 1.8]
MEDIASTINAL LN 4L	31	65.7	8.4	67.2	[62.6, 68.8]	1.4	0.7	1.1	[1.1, 1.7]
MEDIASTINAL LN 4R	31	72.8	8	74.6	[69.9, 75.7]	1.7	0.7	1.6	[1.4, 1.9]
MEDIASTINAL LN 5	31	61	14.8	65.7	[55.5, 66.4]	1.8	0.8	1.6	[1.5, 2.1]
MEDIASTINAL LN 6	31	58.8	14.8	62.5	[53.4, 64.2]	2	1.1	1.6	[1.6, 2.4]
MEDIASTINAL LN 7	31	59	7.6	61.3	[56.2, 61.8]	1.9	0.8	1.7	[1.6, 2.2]
MEDIASTINAL LN 8	31	65.8	8	67.9	[62.9, 68.8]	2	0.9	1.7	[1.7, 2.4]
MEDIASTINAL LN 9L	31	38.3	21.1	42.9	[30.6, 46.1]	5.3	4.4	3.7	[3.7, 6.9]
MEDIASTINAL LN 9R	29	38.8	15.6	38.5	[32.9, 44.7]	3.7	2	3.5	[2.9, 4.4]

Table 4: Detailed Performance evaluation of the new organs in the subject device

Test Cohort	
# Patients	244
(Data origin)	South/North America: 163 EU: 70 Asia: 6 Australia: 3 Unknown: 2
Gender	F: 111 M: 100 Unknown: 33
Manufacturer	GE: 29 Philips: 33 Siemens: 158 Other/Unknown: 24
Slice Thickness	<= 1: 10

	(1, 2]: 124 (2, 3]: 106 > 3: 4

Table 5: Validation Testing Data Information for new OARs

Cohort	**A**			**B**
	A.1	**A.2**	**A.3**	
# Patients	73	40	301	165
# Of clinical sites **(Data origin)**	3 Germany: 14 Brazil: 59	4 Canada: 40	12+ South/North America: 184 EU: 44 Asia: 33 Australia: 28 Unknown: 12	20+ South/North America: 100 EU: 51 Asia: 6 Australia: 3 Unknown: 5
Body Region	Head & Neck: 24 Thorax & Abdomen: 20 Pelvis: 29	Head & Neck: 40	Head & Neck: 50 Thorax: 81 Abdomen: 115 Pelvis: 55	Head & Neck: 40 Thorax: 69 Abdomen: 25 Pelvis: 31

Table 5: Validation Testing Data Information based on Cohort

Organ Group	**No. of Training**	**No. of Validation**
Lacrimal Glands Left	247	62
Lacrimal Glands Right		
Pituitary Gland	247	62
Humeral Head Left	207	52
Humeral Head Right		
Bowel Bag	544	25
Pelvic Bone Left	160	40
Pelvic Bone Right		
Sacrum	160	40
Mediastinal LN I Left	136	34
Mediastinal LN 1 Right		
Mediastinal LN II Left		

Mediastinal LN II Right		
Mediastinal LN III Anterior		
Mediastinal LN III Posterior		
Mediastinal LN IV Left		
Mediastinal LN IV Right		
Mediastinal LN V		
Mediastinal LN VI		
Mediastinal LN VII		
Mediastinal LN VIII		
Mediastinal LN IX Left		
Mediastinal LN IX Right		
Mediastinal LN X Left		
Mediastinal LN X Right		
Femoral Head Left	160	40
Femoral Head Right		
Brainstem	247	62
Esophagus	247	62
Breast Left Breast Right	172	44
Supraglottic Larynx	247	62
Glottis		

Table 6: Training Dataset Characteristics

Standard Annotation Process

In both the annotation process for the training and validation testing data, the annotation protocols for the OAR were defined following the applicable guidelines. The ground truth annotations were drawn manually by a team of experienced annotators mentored by radiologists or radiation oncologists using an internal annotation tool. Additionally, a quality assessment including review and correction of each annotation was done by a board-certified radiation oncologist using validated medical image annotation tools.

Validation Testing & Training Data Independence

The training data used for the training of the algorithm is independent of the data used to test the algorithm.

11. Clinical Tests

No clinical tests were conducted to test the performance and functionality of the modifications introduced within AI-Rad Companion Organs RT. Verification and validation of the enhancements and improvements have been performed and these modifications have been validated for their intended use. The data from these activities were used to support the subject device and the substantial equivalence argument. No animal testing has been performed on the subject device.

12. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device as compared to the predicate.

Risk management is ensured via ISO 14971:2019 compliance to identify and provide mitigation of potential hazards in a risk analysis early in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized during software development, testing and product labeling.

13. Conclusion

Based on the discussion and validation testing and performance data above, the proposed device is determined to be as safe and effective as its predicate device, AI-Rad Companion Organs RT VA50 (K232899).