Siemens Medical Solutions U.S.A.
℅ Kira Morales
Regulatory Affairs Manager
40 Liberty Blvd.
MALVERN, PA 19355

April 3, 2024

Re: K232899
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: March 1, 2024
Received: March 4, 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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232899

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 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 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.

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
FOR
AI-Rad Companion Organs RT

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: April 2, 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
Mail Code: 65-3
Registration Number: 2240869

Manufacturing Site

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Erlangen, Germany 91052
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2. Contact Person

Kira Morales
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Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19335
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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:	K221305
Clearance Date:	October 14, 2022
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:	**MRCAT Pelvis**
Common Name:	Medical Imaging Software
510(k) Number:	K182888
Clearance Date:	April 30, 2019
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

Product Name:	**RT Image Suite**
Common Name:	Medical Imaging Software
510(k) Number:	K220783
Clearance Date:	September 7, 2022
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

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:	**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 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 (e.g., the TPS, which is the standard location for the planning of radiation therapy).

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. The qualified medical professional 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 indented use of the predicate device and the subject device are equivalent. The two main difference compared to the predicate, AI-Rad Companion Organs RT (K221305):

- MR Contouring Algorithms
  - T1 Model for 3 target organs
  - T2 Model for 6 target organs
- Update CT contouring algorithm for 38 new organs

AI-Rad Companion Organs RT VA50 and AI-Rad Companion Organs RT VA40 both use a deep learning algorithm to support their AI claims. Additionally, they both process CT data in DICOM format, making them vendor agnostic and create outputs which can be used by any TPS system. The MR contouring has only been validated for Siemens Healthineers' scanner data. The deep learning CT algorithm within AI-Rad Companion Organs RT VA50 has been enhanced from the algorithm in AI-Rad Companion Organs RT VA40 (K221305). All models contained within AI-Rad Companion Organs RT VA50 and AI-Rad Companion Organs RT VA40 (K221305) 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 new MR contouring algorithm within AI-Rad Companion Organs RT VA50 is comparable to the algorithm in MRCAT Pelvis (K182888). The performance of the new CT contouring algorithms have 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**	**Reference Device**
Device Manufacturer	**Siemens**	**Siemens**	**Philips Medical Systems MR Finland**
Device Name	**AI-Rad Companion Organs RT**	**AI-Rad Companion Organs RT**	**MRCAT Pelvis**
510(k) Number	**TBD**	**K221305**	**K182888**
Indications for Use	AI-Rad Companion Organs RT is a post-	AI-Rad Companion Organs RT is a post-	MRCAT Pelvis is a software add-on for

	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	processing software intended to automatically contour DICOM CT imaging data 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 output of AI-Rad Companion Organs RT in the format of RTSTRUCT objects are intended to be used by trained medical professionals. The software is not intended to automatically detect or contour lesions. Only DICOM images of	Ingenia 1.5T and 3.0T MR systems. Intended Use: MRCAT imaging is intended to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning. Indications for use: MRCAT Pelvis is indicated for radiotherapy treatment planning of soft tissue cancers in the pelvic region.

		adult patients are considered to be valid input.	
Algorithm	Deep Learning	Deep Learning	Machine-learning
Segmentation of Organ at Risk in the Anatomic Regions	CT: Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes (166 OAR) MR: Pelvis (9 OAR)	CT: Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes (128 OAR)	Male and female pelvis, with soft-tissue cancer in the anatomical pelvic region below L1 vertebra, including (post-operative) prostate, rectum, anus, bladder and cervix
Compatible Modality	CT & MR Images	CT Images	MR
Compatible Scanner Models	No Limitation on scanner model for CT. Siemens Healthineers' data only for MR. DICOM compliance required.	No Limitation on scanner model, DICOM compliance required.	Ingenia 1.5T and 3.0T MR-RT, Ingenia Ambition 1.5T MR-RT and Ingenia Elition 3.0T MR-RT
Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM compliance required.
Contraindications	Adult use only	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. More specifically, the software is validated on previously acquired CT DICOM volumes for radiation therapy treatment planning, including, head and	No information publicly available

		neck, thorax, abdomen, and pelvis.	
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.	No information publicly available
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.	No information publicly available
Deployment Feature	Edge & Cloud Deployment	Edge & Cloud Deployment	No information publicly available
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.	No information publicly available
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.	Automatic contouring
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.	No information publicly available

Segmentation Performance	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 subject was equivalent to the overall performance compared to the predicate, reference device and comparable literature & devices.	The target performance was validated using 157 cases distributed to two cohorts. Cohort A is clinical routine treatment planning CT and it is split into two sub-cohort and Cohort B is PET-CT data. 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 subject and reference device were equivalent as well as the overall performance compared to the predicate device.	The mean and standard deviation Dice coefficients, along with the lower 95th percentile confidence bound were calculated.
User Interface – Results Preview (Confirmation)	Basic visualization functionality of original data and generated contours	Basic visualization functionality of original data and generated contours	No information publicly available
User Interface Configuration	Configuration UI	Configuration UI	No information publicly available
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	No information publicly available
Human Factors	Design to be used by trained clinicians.	Design to be used by trained clinicians.	Designed 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 VA50 is substantially equivalent to the currently marketed device, AI-Rad Companion Organs RT (K221305).

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 Software Contained in Medical Devices" (May 11, 2005) 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 management to medical devices	14971:2019-12	ISO
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
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 2022d	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

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 "Content of Premarket Submissions for Management for Cybersecurity in Medical Devices," issued October 2, 2014 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 VA50A) demonstrated equivalent performance in comparison to the predicate device (SW VA40A, K221305). The performance of the enhanced CT organ contouring algorithm is comparable to the predicate device and comparable reference literature and cleared devices. The performance of the MR contouring algorithms is compared to the reference device, MRCAT Pelvis (K182888). A complete scientific evaluation report is provided in support of the device modifications.

MR Contouring Algorithm Performance

The performance of the AI-Rad Companion Organs RT has been validated in a retrospective performance study on MR data previously acquired (N= 66, data from multiple clinical sites across North America & Europe). Ground truth annotations were established following RTOG and clinical guidelines using manual annotation. The dice coefficient and the absolute symmetric surface distance (ASSD), were determined to quantify the similarity between the automatically contoured OAR and the manually delineated contours (ground truth). We also introduce the failure rate in this section. The results of subject device were equivalent or had better performance than the predicate device.

To have a fair comparison between reference and subject device, we compute the average Dice coefficient only for common organs available in both devices (Prostate, Bladder, Rectum, Penile Bulb and Seminal Vesicle).

Validation Testing Subject	Acceptance Criteria
MR Contouring Organs	• The average segmentation accuracy (Dice value) of all subject device organs should be equivalent or better than the overall segmentation accuracy of the predicate device • The overall fail rate for each organ/anatomical structure is smaller than 15%

Table 3: Acceptance Criteria of AIRC Organs RT VA50

AI-Rad Companion Organs RT VA50A (MR Contouring)						
Dice [%]			**ASSD [mm]**			**Fail [%]**
Avg	Std	95 % CI Bootstrap	Avg	Std	95 % CI Bootstrap	2.75
85.75	6.48	[82.85, 87.58]	1.25	1.28	[0.95, 2.02]	

Table 4: Performance results of subject device

	Dice % Average	95% CI
AI-Rad Companion Organs RT VA50 – all organs	86	(83-88)
AI-Rad Companion Organs RT VA50 – common organs	82	(78-84)
MRCAT Pelvis (K182888) – all organs	77	(75-79)

Table 5: Performance results of subject device compared to the reference device

Organ Name	No. Study	Dice (%)					ASSD (mm)				
		AVG	STD	MED	95%CI		AVG	STD	MED	95%CI	
Bladder	36	91.32	6.85	93.48	(87.69	92.87)	0.91	1.82	0.43	(0.54	2.09)
Rectum	36	84.87	6.21	86.61	(82.56	86.67)	1.32	1.64	0.74	(0.97	2.23)
Anal Canal	36	75.78	7.43	77.43	(73.17	78.04)	1.19	0.65	1.01	(1.0	1.44)
Penile Bulb	36	82.29	6.89	82.61	(79.82	84.46)	0.55	0.46	0.41	(1.27	4.77)
Seminal Vesicle	36	66.08	18.65	72.97	(57.19	71.3)	2.06	3.63	1.1	(1.27	4.77)
Prostate	36	84.76	5.32	85.68	(82.59	86.44)	0.94	0.62	0.78	(0.78	1.27)
Femur Right	30	94.29	2.21	94.63	(92.94	94.82)	1.1	0.45	1.03	(0.99	1.37)
Femur Left	30	94.38	2.88	95.01	(92.68	95.09)	1.06	0.52	0.99	(0.94	1.36)
Body	30	98.01	1.88	98.89	(97.0	98.49)	2.12	1.74	1.2	(1.6	2.88)

Average	--	85.75	6.48	87.48	(82.85	87.58)	1.25	1.28	0.85	(0.95	2.02)

Table 6: Detailed Performance Results

	T1 Dixon W	T2 W TSE
# of Datasets	30	36
Data Origin	USA: 15 EU:15	USA: 25 EU: 11
Age	22 years and older	22 years and older
Manufacturer	Siemens Healthineers	Siemens Healthineers
Annotated Organs	Body Femoral Head Right Femoral Head Left	Anal Canal, Prostate, Rectum, Penile Bulb, Seminal Vesicle, Bladder
Slice Thickness	< 4mm	< 4mm
Field Strength	1.5T: 19 3.0T: 11	1.5T: 14 3.0T: 22

Table 7: Validation Testing Data Information

	T1 VIBE/Dixon W	T2 W TSE	Prostate (T2W)
# of Datasets	219	225	960
Data Origin	USA: 59 EU:160	USA: 225	USA & EU
Age	22 years and older	22 years and older	62 (average)
Manufacturer	Siemens Healthineers	Siemens Healthineers	Siemens Healthineers
Annotated Organs	Body Femoral Head Right Femoral Head Left	Anal Canal, Rectum, Penile Bulb, Seminal Vesicle, Bladder	Prostate
Field Strength	1.5T: 59 3.0T: 160	1.5T: 83 3.0T: 142	1.5T & 3.0T

Table 8: Training Dataset Characteristics

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= 414, 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 is 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	• Baseline value defined by subtracting the reference value using 5% error margin in case of Dice and 0.1 mm in case of ASSD • 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	76.5	12.8	[70.9, 80.8]
Head & Neck lymph nodes	69.2	9.5	[65.7. 72.5]
Thorax	82.1	8.4	[79.6, 83.9]
Abdomen	88.3	8.3	[80.9, 92.2]

Pelvis	84.0	6.5	[80.7, 86.7]

Table 4: Performance summary of the subject device CT contouring

Organ Name	No.	Dice (%)					ASSD (mm)				
		AVG	STD	MED	95%CI		AVG	STD	MED	95%CI	
Duodenum	76	77.3	10.4	79.7	[74.5,	79.3]	2.6	2	1.9	[2.2,	3.1]
Large Bowel	102	89.6	4.5	90.8	[88.7,	90.4]	2.1	2.6	1.4	[1.8,	2.9]
Sigmoid	74	79.9	10.6	82.2	[77.2,	82.1]	3.8	3.3	2.6	[3.1,	4.7]
Small Bowel	76	88.5	4.2	89.3	[87.4,	89.4]	1.3	0.7	1.1	[1.1,	1.5]
Uterus	25	87.8	4.2	87.8	[85.7,	89.1]	1.7	1.1	1.5	[1.4,	2.4]
Penile Bulb	30	74	9.1	75.5	[70.5,	77.0]	1.7	0.7	1.6	[1.4,	1.9]
Left Cochlea	25	74.8	16.1	77.8	[62.3,	78.6]	0.6	1.3	0.4	[0.3,	1.7]
Right Cochlea	25	79.9	4.8	81.7	[77.9,	81.7]	0.3	0.1	0.3	[0.3,	0.4]
Inferior Pharyngeal Constrictor Muscle	30	78.2	4.8	78.6	[76.4,	79.9]	0.8	0.3	0.7	[0.7,	0.9]
Middle Pharyngeal Constrictor Muscle	30	67.2	7.5	68.3	[64.4,	69.8]	0.9	0.3	0.8	[0.8,	1.1]
Superior Pharyngeal Constrictor Muscle	30	66.1	5.5	66.7	[64.1,	68.0]	0.8	0.2	0.8	[0.8,	0.9]
Thyroid	30	84.4	3.4	84.4	[83.2,	85.6]	0.7	0.2	0.7	[0.6,	0.7]
Pancreas	31	68.4	13.6	72.8	[62.9,	72.6]	3.5	2.5	2.7	[2.8,	4.6]
Stomach	31	90.7	4.2	91.6	[88.9,	92.0]	2	1.6	1.5	[1.6,	2.8]
Left Anterior Descending Coronary Artery	57	47.6	9.7	47.6	[45.1,	50.1]	4.1	3.8	2.9	[3.4,	5.4]
Left Atrium	57	86.1	4.8	86.9	[84.7,	87.2]	1.8	0.8	1.6	[1.6,	2.0]
Left Ventricle Endocardium	57	83.6	5.3	84.5	[81.9,	84.7]	2.3	0.8	2.2	[2.1,	2.5]
Left Ventricle	57	85.9	4.1	86.8	[84.8	86.9]	2.7	0.9	2.5	[2.5	2.9]
Right Atrium	57	79.5	8.8	80.9	[76.6,	81.3]	2.7	1.3	2.4	[2.4,	3.1]
Right Ventricle	57	83.4	3.4	84.2	[82.5,	84.3]	2.3	0.6	2.2	[2.2,	2.5]
Left Chest Wall	28	92.3	1.5	92.3	[91.7,	92.8]	1	0.2	0.9	[0.9,	1.1]
Right Chest Wall	28	92.6	1.2	92.5	[92.1,	93.1]	0.9	0.2	1	[0.9,	1.0]
Inferior Vena Cava	27	76.2	12.6	80	[70.2,	80.1]	2	1.7	1.5	[1.6,	3.0]
Proximal Bronchus	27	84.2	5	85.6	[81.8,	85.7]	1.1	0.4	1.1	[1.0,	1.3]
Pulmonary Artery	27	80	5.7	80.3	[77.4,	81.8]	2.3	0.9	2	[2.0,	2.7]
Spinal Canal	27	85.2	7.1	87.9	[81.0,	87.1]	1.3	2.2	0.7	[0.8,	2.9]
Superior Vena Cava	27	79	6.8	80.6	[76.0,	81.2]	1.5	0.8	1.3	[1.3,	1.9]
Trachea	27	88.7	4.5	89.7	[86.6,	90.1]	1	0.5	0.8	[0.8,	1.2]
Left Axilla Level I	24	81.5	5.4	82.7	[78.8,	83.3]	2.6	1.4	2	[2.2,	3.3]
Left Axilla Level II	24	79.2	6.7	80.3	[76.2,	81.6]	1.8	0.7	1.7	[1.6,	2.2]
Left Axilla Level III	24	75.4	4.1	75.6	[73.8,	77.1]	1.5	0.4	1.5	[1.3,	1.6]
Left Internal Mammary	24	58.6	8	60.5	[55.2,	61.6]	1.9	1.4	1.3	[1.4,	2.5]
Left Supraclavicular	24	79.5	8.3	81.8	[75.3,	82.2]	2	1.1	1.8	[1.7,	2.6]
Right Axilla Level I	24	80	7.1	82.3	[76.6,	82.4]	3	2.5	2.2	[2.3,	4.7]
Right Axilla Level II	24	77.6	6.9	77	[75.0,	80.4]	2	0.7	2.1	[1.7,	2.3]
Right Axilla Level III	24	75.9	7.6	77.4	[71.7,	78.3]	1.6	1	1.3	[1.4,	2.2]

Right Internal Mammary	24	62.6	9.4	64.1	[56.8,	65.3]	1.6	1.4	1.1	[1.2,	2.4]
Right Supraclavicular	24	79.7	6.7	80.9	[76.2,	81.8]	2	0.9	1.7	[1.7,	2.5]

Table 5: Detailed Performance evaluation of the new organs in the subject device

	Cohort A	Cohort B	Cohort C
# of Datasets	73	40	301
# of Clinical Sites	3 (Germany: 14, Brazil: 59)	4 (Canada: 40)	25 (NA: 165, EU: 44, Asia: 33, SA: 19, Australia: 28, Unknown: 12)
Sex	Male: 48 Female: 25	Male: 19 Female: 21	Male: 53 Female: 50 Unknown: 198
Age	<30 : 0 30 – 50: 0 50 – 70: 4 >= 70: 4 Unknown: 110 *unknown due to data minimization on customer site	<30: 0 30 – 50: 3 50 – 70: 25 >70: 12	
Manufacturer	Siemens: 73	GE: 18 Philips: 22	Siemens: 53 GE: 59 Philips: 119 Varian: 44 Others: 26
Body Region	Head & Neck: 24 Thorax & Abdomen: 20 Pelvis: 29	Head & Neck: 40	Head & Neck: 50 Thorax: 81 Abdomen: 115 Pelvis: 55
Slice Thickness	<= 1: 4 1 – 2: 48 2 – 3 : 20 >3: 1	<= 1: 0 1 – 2: 6 2 – 3 : 31 >3: 3	<= 1: 15 1 – 2: 153 2 – 3 : 118 >3: 15

Table 7: Validation Testing Data Information

Organ Group	No. Training	No. Validation
Cochlea	215	24
Thyroid	293	56
Constrictor Muscles	335	89
Chest Wall	48	12
LN Supraclavicular, Axilla Levels, Internal Mammaries	228	28

Duodenum, Bowels, Sigmoid	332	84
Stomach	371	92
Pancreas	369	92
Pulmonary Artery, Vena Cava, Trachea, Spinal Canal, Proximal Bronchus	113	34
Ventricles & Atriums	706	273
Descending Coronary Artery	252	45
Penile Bulb	854	213
Uterus	381	94

Table 8: 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 NRG/RTOG 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.

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 VA40 (K221305). In addition, the proposed device performs comparably to the reference device, MRCAT Pelvis (K182888).