



April 10, 2026

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

Re: K252548
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 9, 2026
Received: March 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

K252548

?

Please provide the device trade name(s).

?

AI-Rad Companion Organs RT

Please provide your Indications for Use below.

?

AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures, including known (diagnosed) brain metastases, using deep-learning-based algorithms.

Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including 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 qualified and trained medical professionals.

The software is not intended to be used for diagnostic purposes.

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

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

?



510(k) SUMMARY FOR AI-Rad Companion Organs RT K252548

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: March 6, 2026

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
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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: K242745
Clearance Date: March 27, 2025
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: **AutoContour Model RADAC V3**
Common Name: Medical Image Software
510(k) Number: K230685
Clearance Date: March 14, 2025
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-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

Product Name: **VBrain**
Common Name: Medical Image Segmentation Software
510(k) Number: K203235
Clearance Date: March 19, 2021
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

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, including known (diagnosed) brain metastases, using deep-learning-based algorithms.

Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including 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 qualified and trained medical professionals.

The software is not intended to be used for diagnostic purposes.

7. Device Description

AI-Rad Companion Organs RT provides automatic segmentation of pre-defined structures from DICOM CT or MR medical series, prior to dosimetry planning in radiation therapy. AI-Rad Companion Organs RT includes deep-learning algorithms to provide the contouring of organs and structures in the head & neck, thorax, abdomen, and pelvis regions on CT Images, and the contouring of organs and structures in the brain and male pelvis on MR images.

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, contours are created as DICOM Radiotherapy Structure Set (RTSS) objects and can be reviewed in a Result Preview UI, to either confirm or decline the results.

If the results are confirmed, the results are sent to the configured target node, typically a treatment planning system (TPS) or interactive contouring applications. If the results are declined, all contours of this case will be deleted, and the case will be completed.

Optionally, the user may select to directly transfer the contours to a configurable DICOM node, without the need of manual confirmation.

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.

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 (K242745).

- Modified Indications for Use
- Modified Intended Patient Population
- New MR-Brain Metastases contouring algorithm
- New MR Brain OAR contouring algorithm
- Modified CT contouring algorithm
- Modified MR Pelvis contouring algorithm
- Enhanced User Interface
- Multi-arc Support
- Updated Subject device Claims list

AI-Rad Companion Organs RT VA70 and AI-Rad Companion Organs RT VA60 both use a deep learning algorithm to support their AI claims. Additionally, they both process CT and MR data in DICOM format, and create outputs which can be used by any TPS system. The deep learning CT algorithm and MR Pelvis algorithms within AI-Rad Companion Organs RT VA70 has been enhanced from the algorithms in AI-Rad Companion Organs RT VA60 (K242745). Two new algorithms have been added for MR-Brain OAR contouring and MR-Brain Metastases contouring. All models contained within AI-Rad Companion Organs RT VA70 and AI-Rad Companion Organs RT VA60 (K242745) 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	K252548	K242745
Indications for Use	<p>AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures, including known (diagnosed) brain metastases, using deep-learning-based algorithms.</p> <p>Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including 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.</p> <p>The outputs of AI-Rad Companion Organs RT are intended to be used by qualified and trained medical professionals. The software is not intended to be used for diagnostic purposes.</p>	<p>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.</p> <p>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.</p> <p>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</p>
Algorithm	Deep Learning	Deep Learning
Segmentation of Organ at Risk in the Anatomic Regions	<p>CT: Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes</p> <p>MR: Pelvis, Brain & Metastases</p>	<p>CT: Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes</p> <p>MR: Pelvis</p>

Compatible Modality	CT & MR Images	CT & MR Images
Compatible Scanner Models	No Limitation on scanner model for CT. 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.
Target Population	The intended patient population is not subject to any restrictions. However, the algorithms are only validated for adult populations. In principle, 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.
CT Contouring Performance	The target performance was validated using 517 cases distributed to four cohorts. 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 devices & literature were equivalent as well as the overall performance compared to the predicate device.	CT: The target performance was validated using 579 cases distributed to four cohorts. 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 devices & literature were equivalent as well as the overall performance compared to the predicate device
MR Pelvis Contouring Performance	The target performance was validated using 153 cases distributed into T2W TSE and T1W DixonW. Different metrics, including 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).	The target performance was validated using 66 cases distributed into T2W TSE and T1W DixonW. Different metrics, including 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.
MR Brain OAR Contouring Performance	The target performance was validated using 46 cases in one cohort from T1W MPRAGE. Different metrics including 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).	Not applicable – comparison to reference devices
MR Brain Metastases	The target performance was validated using 60 cases in one	Not applicable – comparison to reference devices

	cohort from T1W MPRAGE. To assess the performance, of metastases contours, DICE coefficient and sensitivity percentage.	
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 qualified and 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 VA70 is substantially equivalent to the currently marketed device, AI-Rad Companion Organs RT (K242745).

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 VA70A) demonstrated equivalent performance in comparison to the predicate device (SW VA60A, K242745).

CT Contouring Algorithm Performance

The performance of the AI-Rad Companion Organs RT CT contouring algorithm has been validated in a retrospective performance study on CT data previously acquired for RT treatment planning (N= 469, 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
Existing Organs	<ul style="list-style-type: none"> The subject device in the selected reference metric has a higher value than the defined baseline value
New Organs	<ul style="list-style-type: none"> DICE and ASSD reference & baseline value comparison

Table 3: Acceptance Criteria of AIRC Organs RT VA70

The performance of the existing organs segmented using AI (excluding LAD and Heart) were tested and all organs passed the acceptance criteria.

A qualitative improvement was done to the Left Anterior Descending Artery (LAD) and Heart segmentation models by adding additional landmarks. The detailed performance evaluation of the updated LAD and Heart organs is below:

Structure Name	No.	Metric	AIRC Organs RT VA60x (predicate device)	AIRC Organs RT VA70x (Subject device)	Pass
LAD	57	ASSD (mm)	4.12	4.17	Yes
		MSD (mm)	2.8	2.9	Yes
Heart	57	Dice	0.92	0.93	Yes

Table 4: Detailed Performance evaluation of LAD & Heart in the subject device

Organ Name	NO.	Dice				ASSD (mm)			
		Avg.	Std.	Med.	95%CI	Avg.	Std.	Med.	95%CI
LCX	48	0.28	0.13	0.29	[0.24, 0.32]	3.8	1.5	3.8	[3.4, 4.3]
RCA	45	0.27	0.13	0.26	[0.23, 0.31]	4.7	2.4	4.1	[4.0, 5.4]

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

Testing Data	
Anatomical Region	Cardiac
Annotated Organs	LCX, RCA
# Datasets	48
Data Origin	USA: Chicago (21), TCIA (LIDC-IDRI) TCIA (LCTSC) Australia: Brisbane (21)
Manufacturer	Siemens Healthineers (10) GE MEDICAL SYSTEMS (5) Philips (20) Others/unknown (13)
Gender	Male (14) Female (27) unknown (7)
Slice Thickness	≤ 3 mm

Table 6: Validation Testing Data Information for new OARs

Training Data	
Anatomical Region	Thorax
Annotated Structure	LCX, RCA
# Datasets	434
Data Origin	USA: Medical University of South Carolina (90),

	Princeton Radiology (254) USA and EU: Maastricht University Medical Center & Harvard Medical School (90)
Manufacturer	Siemens Healthineers (417) unknown/other (17)
Slice Thickness	1.0 - 3.6 mm
Pixel Spacing	0.6 - 0.9 mm

Table 7: Training Dataset Characteristics

MR Pelvis Contouring Algorithm Performance

The performance of the AI-Rad Companion Organs RT MR Pelvis contouring algorithm has been validated in a retrospective performance study on MR data previously acquired for RT treatment planning (N= 153, data from multiple clinical sites across the North American, Australia and Europe). Compared to the previous version of the MR Pelvis algorithm (K232899), landmark detection and retraining with new dataset has been implemented for T2W model and testing datasets have been enlarged for T1 and T2 models. 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). The results of subject device were equivalent or had better performance than the predicate device.

The acceptance criteria is defined as the subject device in the selected reference metric has a higher value than the defined baseline value.

Organ Name	Ref. Standard	Comment	Avg. Ref. Value (Dice)	Baseline Value (Dice)	Avg. Ref. Value \pm Std. (ASSD)	Baseline Value (ASSD)
Anal Canal	AI-Rad Companion Organs RT VA50 (K232899)	Avg. Dice reported in FDA report summary	0.76	0.66	2.09 \pm 0.9	2.99
Bladder			0.91	0.81	1.44 \pm 0.89	2.33
Rectum			0.85	0.75	2.34 \pm 2.17	4.51
Penile Bulb			0.82	0.72	0.79 \pm 0.75	1.54
Seminal Vesicle			0.66	0.56	2.43 \pm 2.61	5.04
Prostate			0.85	0.75	1.56 \pm 0.54	2.1
Left Femur Head			0.94	0.84	0.85 \pm 0.59	1.44
Right Femur Head			0.94	0.84	0.88 \pm 0.54	1.42
Body			0.98	0.88	2.07 \pm 1.81	3.88

Table 8: Detailed Performance evaluation of new organs in the subject device

Testing Data		
Anatomical Region	Male Pelvis Organs at Risk	
Sequence	T1W Dixon	T2W TSE
Annotated Structures	Body, Femoral Head Right, Femoral Head Left	Anal Canal, Prostate, Rectum, Penile Bulb, Seminal Vesicle, Bladder
# Datasets	55	98
Data Origin	USA: Wisconsin (15) EU: Germany site 1 (6), Germany site 2 (9), Eastern EU site1 & site 2 (25) ¹	USA: Wisconsin (16), Princeton Radiology (9), Site 3 (18) ¹ , Site 4 (20) ¹ EU: France (4), Romania (1), Germany (3), Switzerland (1), Spain (1), Eastern EU site 1 & site 2 (24) ¹ Australia: Site 1 (1)
Manufacturer	Siemens Healthineers (30) Philips ¹ (25)	Siemens Healthineers (36) Philips ¹ (44) GE ¹ (18)
Field Strength	1.5T (19) 3.0T (36)	1.5T (32) 3.0T (66)
Slice Thickness	(1, 2] mm (30) (2, 3] mm (25)	≤ 1 mm (1) (2, 3] mm (72) (3, 3.5] mm (25)
Pixel Spacing	< 2 mm	< 1.25 mm
Age	45 years and older (34) unknown (21)	23 years and older (73) unknown (25)

Table 9: Validation Testing Data for Improved MR Pelvis Algorithm

Training Data	
Anatomical Region	Male Pelvis Organs at Risk

Sequence	T1W VIBE/Dixon	T2W TSE
Annotated Structures	Body, Femoral Head Right, Femoral Head Left	Anal Canal, Rectum, Penile Bulb, Seminal Vesicle, Bladder
# Datasets	219	275
Data Origin	USA: Wisconsin (59) EU: Austria (160)	USA: Wisconsin (60), Princeton Radiology (165), OHSU (50) ²
Manufacturer	Siemens Healthineers (219)	Siemens Healthineers (225) Philips ² (50)
Field Strength	1.5T (59) 3.0T (160)	1.5T (89) 3.0T (186)
Slice Thickness	< 2 mm	< 4 mm
Pixel Spacing	< 2 mm	< 1.25 mm
Age³	30 years and older	43 years and older

Table 10: Validation Testing Data for Improved MR Pelvis Algorithm

MR Brain OAR Contouring Algorithm Performance

The performance of the AI-Rad Companion Organs RT MR Brain OAR contouring algorithm has been validated in a retrospective performance study on MR data previously acquired for RT treatment planning (N= 46, data from multiple clinical sites across North American). The newly added algorithm computes segmentation masks of predefined anatomic structures for a given T1w MPRAGE, post-contrast (T1wPost) MR Image. The segmentation is performed on the region of interest (ROI) of the organs instead of the entire image volume. 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).

The acceptance criteria is defined as the subject device in the selected reference metric has a higher value than the defined baseline value defined in the reference devices or literature.

Organ Name	Reference Standard (Dice)	Comment	Ref. Value (Dice)	Baseline Value (Dice)	Reference Standard (ASSD)	Comment	Avg. Ref. Value \pm Std. (ASSD)	Baseline Value (ASSD)
Brainstem		Avg. Dice based on auto	0.90	0.80		Avg. MD value based on auto	0.9 \pm 0.16	1.06
Optic Chiasm			0.55	0.45			0.69 \pm 0.80	1.49

² Newly added data in the training cohort.

³ Due to data anonymization, the age information was not available for all data and therefore the provided age information is only based on available entries.

Optic Nerve Left	Turcas, Andrada et al. 2023	contouring solution MVision GBS™ device, Version 1.2.2	0.49	0.39	Turcas, Andrada et al. 2023	contouring solution MVision GBS™ device, Version 1.2.2	1.47±2.17	3.64
Optic Nerve Right			0.56	0.46			0.95±0.65	1.6
Lacrimal Gland Left			0.46	0.36			1.39±0.97	2.36
Lacrimal Gland Right			0.55	0.45			1.31±0.95	2.26
Pituitary Gland			0.61	0.51			0.94±0.26	1.2
Hippocampus Left			0.66	0.56			0.75±0.75	1.5
Hippocampus Right			0.71	0.61			0.67±0.47	1.14
Cornea Left	Radformati on Inc. (K230685)	Passing threshold reported in FDA summary report	0.50	0.40	AI-Rad Companion VA50 (K232899)	Avg. ASSD reported in FDA summary report	0.60±0.24	0.84
Cornea Right			0.50	0.40			0.62±0.17	0.79
Retina Left			0.50	0.40			0.60±0.24	0.84
Retina Right			0.50	0.40			0.62±0.17	0.79
Cochlea Left			0.50	0.40	n.a.	n.a.	n.a.	n.a.
Cochlea Right			0.50	0.40	n.a.	n.a.	n.a.	n.a.
Spinal Cord	AI-Rad Companion VA50 (K232899)	Avg. Dice reported in FDA summary report	0.68	0.58	AI-Rad Companion VA50 (K232899)	Avg. ASSD reported in FDA summary report	1.70±0.72	2.42
Eye Globe Left			0.90	0.80			0.60±0.24	0.84
Eye Globe Right			0.89	0.79			0.62±0.17	0.79
Lens Left			0.68	0.58			0.61±0.56	1.17
Lens Right			0.67	0.57			0.60±0.25	0.85

Table 11: Detailed Performance evaluation of new organs in the subject device

Testing Data	
Anatomical Region	Brain/Head
Sequence	T1W MPRAGE
Annotated Structures	Brainstem, Cochlea Left/ Right Cornea Left/ Right Eye Left/ Right Hippocampus Left/Right Optic Chiasm Lens Left/Right Lacrimal Gland Left/Right Optic Nerve Left/ Right Retina Left/ Right

	Pituitary Spinal Cord
# Datasets	46
Data Origin	USA: TCIA- GammaKnife-Hippocampal USA Site 2 (6) unknown (20)
Manufacturer	Siemens Healthineers (27) GE (19)
Gender	Male (8) Female (18) unknown: (20)
Field Strength	1.5T (39) 3.0T (7)
Slice Thickness	≤ 2.2 mm
Pixel Spacing	≤ 1.0 mm
Age	26 years and older (36) unknown (10)

Table 12: Validation Testing Data for MR Brain OAR contouring algorithm

Training Data	
Anatomical Region	Brain/Head
Sequence	T1W MPRAGE
Annotated Structures	Brainstem, Cochlea Left/ Right Cornea Left/ Right Eye Left/ Right Hippocampus Left/Right Optic Chiasm Lens Left/Right Lacrimal Gland Left/Right Optic Nerve Left/ Right Retina Left/ Right Pituitary Spinal Cord
# Datasets	278
Data Origin	USA: TCIA - GammaKnife-Hippocampal (110), TCIA – GLIS-RT (135), Ohio (25) Asia: India (8)
Manufacturer	Siemens Healthineers (238)

	GE (32) unknown (8)
Field Strength	1.5T (184) 3.0T (86) unknown (8)
Slice Thickness	0.9 – 4 mm
Pixel Spacing	0.4 – 1.2 mm
Age	19 years and older

Table 13: Validation Testing Data for Improved MR Brain OAR Algorithm

MR Brain Metastases Contouring Algorithm Performance

The performance of the AI-Rad Companion Organs RT MR Brain OAR contouring algorithm has been validated in a retrospective performance study on MR data previously acquired for RT treatment planning (N= 30, data from multiple clinical sites across North American). The newly added algorithm computes segmentation masks of parenchymal brain metastases for a given T1w MPRAGE near-1mm-isotropic, post-contrast (T1wPost) MR Image. The segmentation is performed on the region of interest (ROI) of the organs instead of the entire image volume. Ground truth annotations were established following RTOG and clinical guidelines using manual annotation. Lesion-wise dice coefficient and lesion-wise sensitivity were used as acceptance criteria for the performance of the algorithm. The baseline values are defined by subtracting the reference value using 5% error margin. The performance was also assessed on lesion-wise 95th percentile Hausdorff distance, false positive rate, false positive per metastasis and average sensitivity. The performance of the algorithm was compared to the reference device, VBrain (K203235).

Organ Name	Acceptance Criteria	Subject Device 95%CI Lower	Pass
Dice	≥ 70	0.72	Yes
Lesion-wise Sensitivity	≥ 85	0.86	Yes
FPR	≤ 5 false positive lesions per MRI	1.75	Yes
Lesion-wise HD95	≤ 2.94 mm	1.6 mm	Yes

Table 14: Baseline to Subject device value comparison

Organ Name	Additional Metrics	Subject Device Value
Brain Metastases (parenchymal)	FPR (FP/case)	1.93
	FPPM (FP/metastasis)	0.74
	Avg. Sensitivity (%)	91
	Avg. Lesion-wise HD95 (mm)	1.67

Table 15: Performance evaluation of MR Brain metastases on additional metrics

Testing Data	
Anatomical Region	Brain/Head
Sequence	MR T1 WMPRAGE
Annotated Structures	Intraparenchymal Metastases
# Datasets	60
# Metastases	266
Data Origin	USA: TCIA - GammaKnife-Hippocampal (11) EU: Switzerland (30) unknown (19)
Manufacturer	Siemens Healthineers (33) GE (27)
Gender	Male (24) Female (17) unknown (19)
Field Strength	1.5T (48) 3.0T (12)
Slice Thickness	≤ 1 mm (41) (1, 2] mm (18) (2– 2.2) mm (1)
Pixel Spacing	≤ 1 mm (41) (1, 2] mm (18) (2, 2.2] mm (1)
Age	17 years and older
Metastasis size	(0.01-0.25] cm ³ (183) (0.25-1.00] cm ³ (41) > 1 cm ³ (42)
Contrast	With Contrast (53) No Contrast (7)
# Metastases per case	[1]: 23 [2 - 5]: 25 [6 - 9]: 8 [10-20]: 3 [63]: 1
Edema Status	Edema: 29 No Edema: 176 Unknown: 61
Enhancement Pattern:	Ring-Enhancing: 56 Non-Ring-Enhancing: 208 Unknown: 2
Morphology	Primary Cystic: 24 Primary Solid: 201 Mixed Cystic-Solid: 41
Nodularity	Nodular: 261

	Non-Nodular: 1 Unknown: 4
Hemorrhagic	Likely Hemorrhagic: 25 Unlikely Hemorrhagic: 202 Unknown: 39

Table 16: Validation Testing Data for MR Brain Metastases contouring algorithm

Training Data	
Anatomical Region	Brain/Head
Sequence	T1W MPRAGE
Annotated Structures	Intraparenchymal Metastases
# Datasets	1931
Data Origin	USA: Michigan (765), NewYork (538), North Carolina (350), NewYork2 (178), NewJersey (32) Asia: Taiwan (10), India (59)
Manufacturer	Siemens Healthineers (1656) GE (138) Philips (100) unknown (31)
Field Strength	1.5T (858) 3.0T (294) unknown 1.5T or 3.0T (779)
Slice Thickness	0.4 – 6 mm
Pixel Spacing	0.2 – 1.5 mm
Age	18 years and older
Metastasis size	0.01-2 cm ³ (8765) > 2 cm ³ (1084)

Table 17: Validation Testing Data for Improved MR Brain Metastases Algorithm

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 VA60 (K242745).