Siemens Medical Solutions USA, Inc.
% Kira Kuzmenchuk
Regulatory Affairs Specialist
40 Liberty Blvd. Mail Code 65-3
MALVERN PA 19355

Re: K221305
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, 2022
Received: September 12, 2022

Dear Kira Kuzmenchuk:

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 (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 located 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.

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

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

for

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

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)*

K221305

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 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 adult patients are considered to be valid input.

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: October 11, 2022

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

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

2. Contact Person

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Regulatory Affairs Specialist
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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:	K193562
Clearance Date:	November 6, 2020
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	QKB
Recall Information:	N/A

5. Reference Device

Product Name:	Contour ProtégéAI
Common Name:	Medical Imaging Software
510(k) Number:	K213976
Clearance Date:	February 3, 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

6. Indications for Use

AI-Rad Companion Organs RT is a post-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 adult patients are considered to be valid input.

7. Device Description

AI-Rad Companion Organs RT is a post-processing software used to automatically contour DICOM CT imaging data using deep-learning-based algorithms. AI-Rad Companion Organs RT contouring workflow supports CT input data and produces RTSTRUCT outputs. The configuration of the organ database and organ templates defining the organs and structures to be contoured based on the input DICOM data is managed via a configuration interface. 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.

The output of AI-Rad Companion Organs RT, in the form of RTSTRUCT objects, are intended to be used by trained medical professionals. The output of 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 application.

At a high-level, AI-Rad Companion Organs RT includes the following functionality:

1. Automated contouring of Organs at Risk (OAR) workflow
    a. Input –DICOM CT
    b. Output – DICOM RTSTRUCT
2. Organ Templates configuration (incl. Organ Database)
3. Web-based preview of contouring results to accept or reject the generated contours

8. Substantially Equivalent (SE) and Technological Characteristics

The indented use of the predicate device and the subject device are equivalent. The main difference is that AI-Rad Companion Organs RT VA40 adds the additional analysis of 29 head & neck structures compared to the predicate, AI-Rad Companion Organs RT (K193562). AI-Rad Companion Organs RT VA40 and AI-Rad Companion Organs RT VA20 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 deep learning algorithm within AI-Rad Companion Organs RT VA20 has been enhanced from the algorithm in AI-Rad Companion Organs RT VA20 (K193562). All models contained within AI-Rad Companion Organs RT VA40 and AI-Rad Companion Organs RT VA20 (K193562) 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 head &

neck structures algorithm within AI-Rad Companion Organs RT VA40 is comparable to the algorithm in Contour ProtégéAI (K213976).

The risk analysis and non-clinical data support that the subject device's performance is comparable to the predicate device and does not raise different questions of the safety and effectiveness.

	Subject Device	Predicate Device	Reference Device
Device Manufacturer	**Siemens**	**Siemens**	**MIM Software Inc.**
Device Name	**AI-Rad Companion Organs RT (SW Version VA40)**	**AI-Rad Companion Organs RT (SW Version VA20)**	**Contour ProtégéAI**
510(k) Number	**K221305**	**K193562**	**K213976**
Indications for Use	AI-Rad Companion Organs RT is a post-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,	AI-Rad Companion Organs RT is a post-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,	Trained medical professionals use Contour ProtégéAI as a tool to assist in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. In addition, Contour ProtégéAI supports the following indications: • Creation of contours using machine-learning algorithms for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contour to radiation

	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 adult patients are considered to be valid input.	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 adult patients are considered to be valid input.	therapy treatment planning systems, and archiving contours for patient follow-up and management. • Segmenting normal structures across a variety of CT anatomical locations • And segmenting normal structures of the prostate, seminal vesicles, and urethra within T2-weighted MR images. Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.
Algorithm	Deep Learning	Deep Learning	Marchine-learning
Segmentation of Organ at Risk in the Anatomic Regions	Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes (108 OAR)	Head & Neck, Thorax, Abdomen & Pelvis (79 OAR)	Head & Neck, Prostate, Thorax, Abdomen, Lungs & Liver, MRT structures (spleen, pelvic lymph nodes, descending aorta, bone)
Compatible Modality	CT Images	CT Images	CT & MR
Compatible Scanner Models	No Limitation on scanner model, DICOM compliance required.	No Limitation on scanner model, DICOM compliance required.	No information publicly available

Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM compliance required.	No information publicly available
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. More specifically, the software is validated on previously acquired CT DICOM volumes for radiation therapy treatment planning, including, head and neck, thorax, abdomen, and pelvis.	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 neck, thorax, abdomen, and pelvis.	No information publicly 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.	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 in the Cloud. The UI is provided using a web-based interface.	Server-based application supporting Linux-based OS and Local deployment on Windows or Mac
Deployment Feature	Edge & Cloud Deployment	Cloud Deployment	Cloud-based or locally deployed
Organ Templates	Creating, editing and deletion of organ templates. Customize	Creating, editing and deletion of organ templates. Customize	No information publicly available

	predefined structure database with mapping to international nomenclature schemes.	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.	Automatic contouring working using machine-learning
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	The target performance was validated using 113 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 target performance was validated using 113 cases distributed to two cohorts. Cohort A-Clinical Routine Treatment Planning CT (Siemens; Head and Neck, Thorax and Abdomen Pelvis) and Cohort B-Multi Vendor Coverage (GE and Phillips; Head and Neck). 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	739 CT Images from 12 clinical sites were used for testing. The mean and standard deviation Dice coefficients, along with the lower 95th percentile confidence bound were calculated.

		device were equivalent as well as the overall performance compared to the predicate device.	
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 VA40 is substantially equivalent to the currently marketed device, AI-Rad Companion Organs RT VA20 (K193562).

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. Non-clinical performance testing demonstrates that AI-Rad Companion Organs RT complies with appropriate FDA guidance documents as well as with the following voluntary FDA recognized Consensus Standards (**Table 2)**.

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
5-114	General	Medical Devices – Application of usability engineering to medical devices [including Corrigendum 1 (2016)]	62366-1: 2015-02	IEC
5-125	General	Medical Devices – application of risk management to medical devices	14971:2007	ISO

13-79	Software/ Informatics	Medical device software – software life cycle processes [Including Amendment 1 (2016)]	62304: 2006/A1:2016	AAMI ANSI IEC
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 (2016)	NEMA
12-261	Radiology	Information Technology – Digital Compression and coding of continuous -tone still images: Requirements and Guidelines [including: Technical Corrigendum 1(2005)]	10918-1 1994-02-15	ISO IEC
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 for a Major Level of Concern software, per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, 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 algorithm underwent a scientific evaluation. The results of clinical data-based software validation for the subject device AI-Rad Companion Organs RT (SW VA40) demonstrated equivalent performance in comparison to the predicate device (SW VA20, K193562). The performance of the head & neck lymph node contouring algorithm is comparable to the reference device, Contour ProtégéAI (MIM Software Inc., K213976). A complete scientific evaluation report is provided in support of the device modifications.

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= 113, data from multiple clinical sites across the North American, South American 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 the subject device demonstrate comparable performance compared to the predicate device when aggregate performance over all organs is considered with known limitations described in the Labeling. As the morphological appearance of lymph nodes in the head and neck region and in the pelvic region are similar, we compared the OAR segmentation accuracy of head and neck lymph nodes of the subject device AIRC Organs RT (SW VA40) to the pelvic lymph nodes of the reference device Contour ProtégéAI (MIM Software Inc., K213976). For this evaluation dice coefficient was calculated by considering all head and neck lymph nodes as a single composite class and then aggregated over all patients.

The performance results of the subject device for new organs is comparable to the reference device. Here comparable is defined such that the lower bound of 95th percentile confidence interval of the subject device segmentation is greater than 0.1 Dice lower than the mean of predicate/reference device segmentation.

In a sub-cohort analysis performance results were found to be consistent on CT data across multiple vendors and for gender subgroups. The results of subject and predicate device for overlapping organs are shown in the following Table 4. The subject device achieved a median DICE score of 0.85 with a median ASSD of 0.93 in comparison to the predicate device achieving a median DICE score of 0.85 with a median ASSD of 0.94 for existing organs. As we can see, the performance of the subject device and predicate device are comparable in DICE and ASSD. The results of subject and reference device for non-overlapping organs are shown in the following Table 5. As we can see, the performance of the subject device for non-overlapping organs is comparable in DICE to the reference device.

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 lower bound of 95th percentile CI of the segmentation is greater than 0.1 Dice lower than the mean of the predicate device segmentation
Head & Neck Lymph Nodes	• The overall fail rate of each organ/anatomical structures is smaller than 15% • The lower bound of 95th percentile CI of the segmentation is greater than 0.1 Dice lower than the mean of the reference device segmentation

Table 3: Acceptance Criteria of AIRC Organs RT VA40

	DICE		ASSD	
	Median	**95% CI (Bootstrap)**	**Median**	**95% CI (Bootstrap)**
AI-Rad Companion Organs RT VA40	0.85	[80.23,84.61]	0.93	[0.86,1.14]
AI-Rad Companion Organs RT VA20	0.85	N.A	0.94	[0.85.1.16]

Table 4: Performance comparison between subject device and predicate device

	AI-Rad Companion Organs RT VA40 (Head and Neck lymph node class)			**Contour ProtégéAI from MIM Software Inc (Pelvic lymph node class)**		
	Sample Size: 60 # of Datasites: 5			**Sample Size: 739 # of Datasites: 12**		
	Avg	Std	95 % CI Bootstrap	Avg	Std	95 % CI Bootstrap
Dice [%]	81.32	3.45	[80.32,82.12]	80	4	[77,N.A]

ASSD [mm]	1.06	0.38	[0.99,1.19]	N.A.	N.A.	N.A.

Table 5: Performance comparison between subject device and reference device

	Cohort A	Cohort B
# of Subject	73	40
# of Clinical Sites	3 (Germany: 14, Brazil: 59)	4 (Canada: 40)
Sex	Male: 25 Female: 48	Male: 19 Female: 21
Age	>40: 7 Unknown: 66 *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
Body Region	Head & Neck: 24 Thorax: 19 Abdomen Pelvis: 30	Head & Neck: 40
Slice Thickness	<1 to > 3	<1 to >3

Table 6: Validation Data Information

# of Datasets	160
Data Origin	Stanford (US): 15 NNord (DE): 4 UKH (DE): 25 HCG (IND): 116
Sex	Male: 12 Female: 17 Unknown: 131
Age	<30 : 1 30 – 50: 3 50 – 70: 2 >= 70: 3 Unknown: 152* *unknown due to data minimization on customer site
Manufacturer	Siemens: 103 GE: 50 Unknown: 7
Slice Thickness	<= 1: 1 1 – 2: 12 2 – 3 : 141 >3: 6

Table 7: Training Dataset Characteristics for Head & Neck

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 VA20 (K193562). In addition, the proposed device performs comparably to the reference device, Contour ProtégéAI (MIM Software Inc., K213976).