Siemens Medical Solutions USA, Inc.
% Ms. Lauren Bentley
Senior Manager, Regulatory Affairs
40 Liberty Blvd. Mail Code 65-3
MALVERN PA 19355

November 6, 2020

Re: K193562
Trade/Device Name: AI-Rad Companion Organs RT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QKB
Dated: September 29, 2020
Received: September 30, 2020

Dear Ms. Bentley:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193562

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.

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510(k) SUMMARY
FOR
AI-RAD COMPANION ORGANS RT

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Prepared: September 29, 2020
K193562

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

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3. Device Name and Classification

Product Name:	AI-Rad Companion Organs RT
Trade Name:	AI-Rad Companion Organs RT
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QKB

4. Predicate Device

Product Name:	AccuContour
Propriety Trade Name:	AccuContour
510(k) Number:	K191928
Clearance Date:	February 28, 2020
Classification Name:	Picture archiving and communications system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QKB
Recall Information:	There have been no recalls for this device

5. 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.

6. 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

7. Substantially Equivalent (SE) Comparison 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 is a dedicated solution for auto-contouring, minimizing the need of user interaction, while AccuContour additionally provides (among other features) manual contouring capabilities, treatment evaluation and treatment adaption.

The subject device, AI-Rad Companion Organs RT, is substantially equivalent with regards to performance and some technology of the predicate. AI-Rad Companion Organs RT and AccuContour 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 has been enhanced from the algorithm in syngo.via RT Image Suite (K192065). syngo.via RT Image Suite serves as a reference device within this submission and a dedicated comparison of technological characteristics is provided.

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**	**Xiamen Manteia LTD.**	**Siemens**
Device Name	**AI-Rad Companion Organs RT**	**AccuContour**	**syngo.via RT Image Suite**
510(k) Number	**K193562**	**K191928**	**K192065**
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	It is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.	syngo.via RT Image Suite is a 3D and 4D image visualization, multi-modality manipulation and contouring tool that helps the preparation and response assessment of treatments such as, but not limited to those performed with radiation (for example, Brachytherapy, Particle Therapy, External Beam Radiation Therapy). It provides tools to efficiently view existing contours, create, edit, modify, copy contours of regions of the body, such as but not limited to, skin outline, targets and organs-at-risk. It also provides functionalities to create and modify simple treatment plans. Contours, images and treatment plans can subsequently be exported to a Treatment Planning System. The software combines

	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.		following digital image processing and visualization tools: • Multi-modality viewing and contouring of anatomical, functional, and multi-parametric images such as but not limited to CT, PET, PET/CT, MRI, Linac Cone Beam CT (CBCT) images and dose distributions • Multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP), volume rendering technique (VRT) • Freehand and semi-automatic contouring of regions-of-interest on any orientation including oblique • Creation of contours on any type of images without prior assignment of a planning CT • Manual and semi-automatic registration using rigid and deformable registration • Supports the user in comparing, contouring, and adapting contours based on datasets acquired with different imaging modalities and at different time points • Supports the user in comparing images and contours of different patients • Supports multi-modality image fusion • Visualization and contouring of moving tumors and organs • Management of points of interest including but not limited to the isocenter • Management of simple treatment plans • Generation of a synthetic CT based on multiple pre-define MR acquisitions

Segmentation Feature & Technological Characteristics			
Algorithm	Deep Learning	Deep Learning	Atlas-based, machine learning and deep-learning based contouring
Segmentation of Organ at Risk in the Anatomic Regions	Head & Neck, Thorax, Abdomen & Pelvis	Head & Neck, Thorax, Abdomen & Pelvis	Head & Neck, Thorax, Abdomen & Pelvis
Compatible Modality	CT Images	Non-Contrast CT	CT Images
Compatible Scanner Models	No Limitation on scanner model, DICOM compliance required.	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM compliance required.
Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.
Contraindications	-Adult use only	-Adult use only -Not intended to be used as a stand-alone diagnostic device	There are no known specific situations that contraindicate the use of this device.
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	Any patient type for whom relevant multimodality images and segment (non-contrast) CT images are available.	Any patient type for whom the relevant modality scan data is 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. However, AccuContour can be used for treatment evaluation and treatment adaptation.	Limited to patients previously selected for Radiation Therapy.
Software Architecture	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.	Cloud and/or Server based	Client-server architecture where the server processes and renders the data. Client provides the UI for interactive image viewing and processing
Deployment Feature	Cloud Deployment	Cloud Deployment and Server	On-premise/standalone deployment
Organ Templates	Creating, editing and deletion of organ templates. Customize predefined structure database with mapping to international nomenclature schemes.	No information publicly available.	Creating, editing and deletion of structure 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.	AccuContour automatically processes input image data	Rapid Results workflow feature allows the configuration of automatic organ contouring and optionally send DICOM-RT files to a target DICOM-Node for further processing.
Contour visualization and editing feature	AI-Rad Companion Organs RT provides basic result preview of automatic	AccuContour provides basic result preview of automatic	syngo.via RT Image Suite provides advanced contour visualization feature of

	segmentation results, and no editing feature of the automatic segmented contour.	segmentation results. Manual contouring is possible.	contours and manual editing feature
Segmentation Performance	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 device were equivalent as well as the overall performance compared to the predicate device.	The segmentation performance was validated using datasets from China and the USA using three major vendors (GE, Siemens and Phillips). The segmentation accuracy is evaluated using DICE coefficient.	The target performance was validated using 32 cases with various fields of view. To objectively evaluate the target performance, the DICE coefficient & the absolute symmetric surface distance (ASSD) were evaluated. The segmentation performance of the subject and predicate device were equivalent.
User Interface – Results Preview (Confirmation)	Basic visualization functionality of original data and generated contours	Basic result preview of automatic segmentation results. Manual contouring is possible.	Standard visualization tools (window levels, MPR, MIP, VRT). Manual contouring is possible.
User Interface Configuration	Configuration UI	Configuration menu	syngo.via GUI
Human Factors	Design to be used by trained clinicians.	Design to be used by trained clinicians.	Design to be used by trained clinicians.

Table 3: Indications for Use and Segmentation Feature Comparison

8. Nonclinical Bench Testing

Non-clinical tests were conducted to assess 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 Organs RT 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 4 below.

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
5-40	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

Table 4: Voluntary Consensus 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 requirements 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.

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 demonstrated equivalent performance in comparison to the predicate device. 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 subject device achieved a median DICE score > 80% across all automatically contoured organs at risk with a median 95% Hausdorff (HD) value of 2.0 mm. In a sub-cohort analysis performance results were found to be consistent on CT data across multiple vendors. In comparison to the predicate device, AccuContour, both the DICE score and HD value were similar in nature and achieves appropriate quality not only for the unmodified organs but also for the newly supported automatically contoured organs and structures. The results of both devices are shown in the following Table. As we can see, the performance of the subject device and predicate device are comparable in DICE and Hausdorff Distance.

	DICE	95% Hausdorff Distance (HD)
AccuContour (K191928)	0.85 – 0.95	≤ 3.5 mm
AI-Rad Companion Organs RT VA20	MED: 0.85	MED: 2.0 mm

Table5. Performance comparison between subject device and predicate device

9. Clinical Tests

No clinical tests were conducted to test the performance and functionality of the features introduced within AI-Rad Companion Organs RT. Verification and validation of the algorithm 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.

10. 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 14971:2007 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.

Furthermore, the device is intended for healthcare professionals familiar with the post processing of computed tomography images in the context of radiation oncology.

11. Substantial Equivalence and Conclusion

AI-Rad Companion Organs RT is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
AccuContour	K191928	February 28, 2020	QKB

Table 6: Predicate for AI-Rad Companion Organs RT

The intended use of the predicate device and the subject device are equivalent. The two devices process the same form of CT DICOM data, are agnostic with respect to the CT machine and Treatment Planning System. The main difference is that AI-Rad Companion Organs RT is a dedicated solution for auto-contouring while AccuContour (K191928), additionally provides (among other features) manual contouring capabilities and image registration. AccuContour is used additionally for treatment evaluation and treatment adaption. From a performance perspective both devices provide automatic organ-at-risk contouring using deep learning method in head and neck, thorax, abdomen and pelvis (for both male and female) regions. Both devices are able to contour organ-at-risk using GE, Siemens and Philips scanners. Additionally, both devices have comparable DICE and HD values when compared to the ground truth. Due to the above-mentioned attributes, AI-Rad Companion Organs RT is substantially equivalent to the predicate device, AccuContour, and does not raise any additional concerns to the safety or effectiveness of the subject device.