



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

July 30, 2020

Re: K193283

Trade/Device Name: AI-Rad Companion Prostate MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH, LNH
Dated: July 2, 2020
Received: July 6, 2020

Dear Lauren 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

Indications for Use

510(k) Number (if known)

K193283

Device Name

AI-Rad Companion Prostate MR

Indications for Use (Describe)

AI-Rad Companion Prostate MR is a post-processing image analysis software that assists clinicians in viewing, manipulating, analyzing and evaluating MR prostate images for US guided MR-US fusion biopsy support.

AI-Rad Companion Prostate MR provides the following functionalities:

- Automatic segmentation and quantitative analysis of the prostate gland
- Manual annotation of relevant findings
- Presentation and export of results for further processing and reporting

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 PROSTATE MR K193283

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: November 25, 2019

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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2. Contact Person

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3. Device Name and Classification

Product Name:	AI-Rad Companion Prostate MR
Trade Name:	AI-Rad Companion Prostate MR
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Secondary CFR Section:	21 CFR §892.1000
Device Class:	Class II
Product Code:	QIH
Secondary Product Code:	LNH

4. Predicate Device

Product Name:	<i>syngo.MR Applications</i>
Propriety Trade Name:	<i>syngo.MR Applications</i>
510(k) Number:	K180336
Clearance Date:	April 19, 2018
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Secondary CFR Section:	21 CFR §892.1000
Device Class:	Class II
Primary Product Code:	LLZ
Secondary Product Code:	LNH
Recall Information:	N/A

5. Intended Use

AI-Rad Companion Prostate MR is a post-processing image analysis software that assists clinicians in viewing, manipulating, analyzing and evaluating MR prostate images for biopsy support.

AI-Rad Companion Prostate MR provides the following functionalities:

- Automatic segmentation and quantitative analysis of the prostate gland
- Manual annotation of relevant findings
- Presentation and export of results for further processing and reporting

6. Device Description

AI-Rad Companion Prostate MR aims to assist the radiologist in the preparation of MR prostate images for targeted biopsies of the prostate gland using MR-Ultrasound fusion biopsy. It allows the radiologist to communicate the location and spatial extent of lesions and the prostate volume in prostate MR images to a urologist in order to help perform biopsies.

AI-Rad Companion Prostate MR is a cloud-based image processing software that provides quantitative and qualitative information based on prostate MR DICOM images. More specifically, it provides information on the prostate volume which can be used to support the planning of prostate biopsies in the case of ultrasound guided MR-US fusion biopsies of the prostate gland. It is enabled via artificial intelligence algorithms and a cloud infrastructure.

The primary features of AI-Rad Companion Prostate MR include:

- Automatic prostate segmentation and volume estimation, with the possibility of manual adjustments
- Manual determination of location and size of lesions in a suitable user interface
- Calculation of the PSA density, based on the input of the PSA value of the patient by the clinical user
- Export in a suitable format for reading and archiving in PACS, as well as in a second format that can be imported by ultrasound systems (e.g. RTStruct), allowing the urologist to perform targeted MR-US fusion biopsy

With current tools, it is challenging for the radiologist to show the urologist the location of the lesions to be biopsied. The radiologist can mark the lesion on the abstract sketch of the biopsy on the PI-RADS report. Based on this information, the urologist can draw the lesion on the MR images within his fusion biopsy planning software, where often information and accuracy are lost. If the radiologist chooses to draw the lesions for the urologist, the options are either to go to the biopsy machine or to a separate workstation provided by the biopsy software to draw the lesions.

As an update to the previously cleared device, the following modifications have been made:

1. Modified Indications for Use Statement
2. Automatic prostate segmentation and volume estimation, with the possibility of manual adjustments
3. Calculation of the PSA density, based on the input of the PSA value of the patient by the clinical user
4. Export in a suitable format for reading and archiving in PACS, as well as in a second format that can be imported by ultrasound systems (e.g. RTStruct), allowing the urologist to perform targeted MR-US fusion biopsy
5. Architectural enhancement for the clinical extension to be deployed with the AI-Rad Companion Engine platform in a cloud-based environment

7. Technological Characteristics

The subject device, AI-Rad Companion Prostate MR is substantially equivalent to the predicate device with regards to software, programming languages, operating system, performance and fundamental technology. AI-Rad Companion Prostate MR offers enhancements and improvements to the existing predicate device, *syngo*.MR Applications SMRVB30A (K180336).

While these enhancements and improvements offer additional image viewing and evaluation capabilities compared to the predicate device, the conclusions from all verification and validation data suggest that these modifications do not adversely affect the safety and effectiveness of the predicate device.

A tabular comparison of the subject device is provided in **Table 1** below.

Feature	Subject Device	Predicate Device	Comparison Results
	Siemens AI-Rad Companion Prostate MR	Siemens <i>syngo</i> .MR Applications (K180336)	
<i>Software</i>	AI-Rad Companion Prostate MR	<i>syngo</i> .MR Applications with SMRVB30A	Enhanced The subject device supports new software version offering improvements and enhancements over the predicate
<i>Organ Segmentation & Annotation</i>	Automated segmentation of the prostate gland with the possibility of manual adjustment and annotation	Manual measurements, segmentations and marks can be made within the prostate	Enhanced The subject device automates the prostate segmentation, while still permitting manual manipulation and annotation
<i>Image Communication</i>	DICOM compatible with RTStruct object	DICOM compatible	Enhanced to provide additional output format
<i>Configuration</i>	Confirmation UI	<i>syngo</i> .via GUI	Equivalent The subject device has been modified to specific functionality for the Prostate MR extension
<i>Confirmation</i>	Configuration UI	<i>syngo</i> .via GUI - configuration	Equivalent The subject device has been modified to expose configuration options of existent extensions.
<i>Architecture</i>	Cloud only solution with no components deployed on customer premise.	Client-server architecture where the server processes and renders the data from the connected modalities. Client provides the UI for interactive image viewing and processing.	Modified Architecture of the clinical extension is adapted to AI-Rad Companion Engine and cloud-based deployment.

Table 1: Predicate Device Comparison Table

8. Nonclinical Tests

Non-clinical tests were conducted to test the functionality of AI-Rad Companion Prostate MR. 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 Prostate MR has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrated that AI-Rad Companion Prostate MR complies with the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (May 11, 2005) as well as with the following voluntary FDA recognized Consensus Standards listed in **Table 2** 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 2: Voluntary Conformance Standards

Verification and Validation

Software documentation for a Moderate 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 (lifecycle) 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.

9. Clinical Tests

No clinical tests were conducted to test the performance and functionality of the modifications introduced within AI-Rad Companion Prostate MR. 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.

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 magnetic resonance images.

11. Substantial Equivalence and Conclusion

AI-Rad Companion Prostate MR version VA20 is substantially equivalent to the follow predicate device (Table3):

Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
syngo.MR Applications	K180336	April 19, 2018	LLZ, LNH

Table 3: Predicate device for AI-Rad Companion Prostate MR



AI-Rad Companion Prostate MR has the same intended use and basic technical characteristics compared to the predicate device, *syngo*.MR Applications SMRVB30A (K180336), with respect to the software features and functionalities. While AI-Rad Companion Prostate MR offers enhancements and improvements to the already cleared basic MR workflow and applications, the conclusions from all verification and validation data suggest that the modifications do not adversely impact the safety and effectiveness of the predicate device. The modifications and improvements enhance the user's workflow and reduce the complexity of certain MR imaging procedures. Siemens is of the opinion that AI-Rad Companion Prostate MR is substantially equivalent to the currently marketed device *syngo*.MR Applications SMRVB30A (K180336).