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

July 10, 2020

Re: K193294
Trade/Device Name: AI-Rad Companion Engine
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 26, 2020
Received: June 29, 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

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)*

K193294

Device Name
AI-Rad Companion Engine

Indications for Use *(Describe)*

AI-Rad Companion Engine is a software platform that provides basic visualization and enables external post-processing extensions for medical images used for diagnostic purposes.

The software platform is designed to support technicians and trained physicians in qualitative and quantitative measurement and analysis of clinical data. The software platform provides the means for viewing, storing and transferring data into other systems such as PACS systems.

The software platform also provides an interface to integrate additional Siemens Healthineers' clinical processing extensions.

AI-Rad Companion Engine functionality includes:

- Interface for multi-modality and multi-vendor Input/Output of DICOM data
- Check of data validity using information of DICOM tags
- Interface for extensions that provide post-processing functionality
- Confirmation user interface for visualization of medical images processed by extensions
- Configuration user interface for configuration of the medical device and extensions

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
FOR
AI-RAD COMPANION ENGINE

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

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code: 65-1A
Malvern, PA 19355
Registration Number: 2240869

Manufacturing Site

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

2. Contact Person

Lauren Bentley
Senior Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code: 65-3
Malvern, PA 19335
Phone: +1 (610) 241 - 6736
Email: lauren.bentley@siemens-healthineers.com

3. Device Name and Classification

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

4. Predicate Device

Product Name:	AI-Rad Companion (Engine)
Propriety Trade Name:	AI-Rad Companion (Engine)
510(k) Number:	K183272
Clearance Date:	February 1, 2019
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	LLZ
Recall Information:	N/A

5. Intended Use

AI-Rad Companion Engine is a software platform that provides basic visualization and enables external post-processing extensions for medical images used for diagnostic purposes.

The software platform is designed to support technicians and trained physicians in qualitative and quantitative measurement and analysis of clinical data. The software platform provides means for storing of data and for transferring data into other systems such as PACS systems.

The software platform also provides an interface to integrate additional Siemens Healthineers' clinical processing extensions.

AI-Rad Companion Engine functionality includes:

- Interface for multi-modality and multi-vendor Input / Output of DICOM Data
- Check of data validity using information of DICOM tags
- Interface for extensions that provide post-processing functionality
- Confirmation user interface for visualization of medical images processed by extensions
- Configuration user interface for configuration of the medical device and extensions

6. Device Description

AI-Rad Companion Engine, as previously cleared under K183272, has been enhanced in version VA20. AI-Rad Companion Engine still provides the platform for all clinical extensions of the AI Rad Companion system and still falls under the same classification regulation as the predicate device. The engine supports DICOM communication, enabling post-processing extensions for medical images to be used for diagnostic purposes.

AI-Rad Companion Engine will receive the imaging data to be processed either from an imaging modality or via auto-routing from the PACS system or a DICOM gateway. The results of the AIRC Extensions will be sent back to a configurable target node also utilizing DICOM standards. The means of data transfer will be handled by the "teamplay" infrastructure. Teamplay Images is an MDDS product, intended for data transfer, display and online storage of medical images and related data.

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

1. Support of software version VA20:
    a. Support for additional clinical extensions
    b. Modified workflow to increase the usability within AI-Rad Companion as well as with respect to informing the user regarding the status of clinical extensions
2. Subject device claims list

7. Technological Characteristics

The subject device, AI-Rad Companion Engine with new software version VA20, is substantially equivalent to the predicate device with regard to the indications for use, software, operational environment, programming language, operating system, performance, image visualization, image manipulation, distribution, archiving and extendibility to post-processing applications.

AI-Rad Companion Engine VA20 offers enhancements and improvements to the existing predicate device, AI-Rad Companion (Engine) (K183272). While these enhancements offer usability enhancements and additional access to new post-processing clinical extensions compared to the predicate device, the conclusions from verification and validation data suggest that these modifications maintain an equivalent safety and performance profile to the predicate device.

8. Nonclinical Bench Testing

Non-clinical tests were conducted to test the functionality of AI-Rad Companion Engine version VA20. Software validation and bench testing have been conducted to 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 demonstrated that AI-Rad Companion 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 1** 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 1: 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, 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. The 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 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 Engine VA20. 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 or its modifications.

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 clinical images.

11. Substantial Equivalence and Conclusion

AI-Rad Companion Engine version VA20 is substantially equivalent to the follow predicate device (**Table 2**):

Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
AI-Rad Companion (Engine)	K183272	February 1, 2019	LLZ

Table 2: Predicate device for AI-Rad Companion Engine VA20

AI-Rad Companion Engine with software version VA20 has the same indications for use and similar technological characteristics compared to the predicate device, AI-Rad Companion (Engine) (K183272). While the new version offers enhancements and improvements to enable the integration with new post-processing clinical extensions, the same fundamental characteristics such as image visualization and image manipulation are the same as the predicate device. The results of all testing conducted was found acceptable to support the claim of substantial equivalence.

The predicate device was cleared based on non-clinical supportive information including bench testing and software validations. The results of these tests demonstrate that the predicate device is adequate for the intended use. The comparison technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use and is therefore substantially equivalent to the predicate device.