



February 1, 2019

Siemens Medical Solutions USA, Inc.  
% Ms. Kimberly Mangum  
Regulatory Affairs Specialist  
40 Liberty Blvd.  
MALVERN PA 19355

Re: K183272

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, JAK  
Dated: November 21, 2018  
Received: November 23, 2018

Dear Ms. Mangum:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Rob 2. Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for  
Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K183272

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 extension 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 provides an interface to integrate 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 for 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: January 18, 2019

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

#### 1. Submitter

##### Importer/Distributor

Siemens Medical Solutions USA, Inc.  
40 Liberty Boulevard  
Malvern, PA 19355

##### Establishment Registration Number

2240869

##### Manufacturing Site

Siemens Healthcare GmbH  
Siemensstr. 1  
D-91301 Forchheim, Germany

##### Establishment Registration Number

3004977335

##### Contact Person

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Regulatory Affairs Specialist  
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#### 2. 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  
**Regulation Number:** 21 CFR §892.2050  
**Device Class:** Class II  
**Product Code:** LLZ  
**Secondary Product Code:** JAK

#### 3. Predicate Device

##### Primary Predicate Device:

**Product Name:** syngo.CT View&GO  
**Propriety Trade Name:** syngo.CT View&GO  
**510(k) Number:** K170952  
**Clearance Date:** April 28, 2017



**Classification Name:** Picture Archiving and Communications System  
**Classification Panel:** Radiology  
**Regulation Number:** 21 CFR §892.2050  
**Device Class:** Class II  
**Primary Product Code:** LLZ  
**Secondary Product Code:** JAK  
**Recall Information:** There are currently no recalls for this device

#### 4. Device Description

AI-Rad Companion (Engine) is a software platform that provides basic visualization and enables external post-processing extension for medical images used for diagnostic purposes. The software platform provides means for storing of data and for transferring data into other systems such as PACS systems. The software platform provides an interface to integrate processing extensions by supporting:

- Interface for multi-modality and multi-vendor Input / Output of DICOM Data
- Check of data validity using information for 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

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

- 1) Modified Indications for Use Statement
- 2) Support of software version VA10A:
  - a. Deployment of software on Siemens cloud infrastructure
  - b. Improved method to access and configure optional post-processing extensions
  - c. Modified workflow to visualize and confirm output of optional post-processing extension
- 3) Subject device claims list

AI-Rad Companion (Engine) is designed to support the operating user in qualitative and quantitative analysis of clinical data

#### 5. Indications for Use

AI-Rad Companion (Engine) is a software platform that provides basic visualization and enables external post-processing extension 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 provides an interface to integrate 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 for 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. Comparison of Technological Characteristics with the Predicate Device

The subject device AI-Rad Companion (Engine) is within the same classification regulation as the primary predicate device. The subject device supports a specific indication for use that is reflective of device specific performance, but the intended use and fundamental scientific technology remain unchanged from the primary predicate device.

A tabular comparison of the subject device and predicate devices is provided as **Table 1** below.

**Table 1: Predicate Device Comparable Properties**

Feature	Subject Device	Predicate Device (K170952)	Comparison Results
Software	Software version VA10A	SOMARIS/8 VB20A	<b>Equivalent.</b> The subject device supports a new version of software that is deployable on the Siemens cloud infrastructure
Extensibility	Extendable via additional post-processing extensions	Extendable via additional post-processing tools	<b>Equivalent.</b> The subject device has been modified to support extensions that can perform automated post-processing using artificial intelligence algorithms
Visualization	Standard visualization tools (window levels, MPR, MIP, VRT)	Standard visualization tools (window levels, MPR, MIP, VRT)	<b>Same</b>
Image Distribution and Archiving	In the Distribution step it is shown to which DICOM nodes a series will be sent when saving the case, or to which node a series has already been sent. The user can select (or deselect) whether a series will be sent to any DICOM node or to a subset of nodes.	Sending of DICOM data to DICOM nodes possible in the export functionality	<b>Equivalent.</b> The subject device has been modified to support transfer to a preconfigured DICOM node
User Interface Confirmation	Confirmation UI	syngo.via GUI	<b>Equivalent.</b> The subject device has been modified to provide only basic functionality for confirmation of processed results
User Interface Configuration	Configuration UI	syngo.via GUI - configuration	<b>Equivalent.</b> The subject device has been modified to expose configuration options of existent extensions
Archiving/Storing	CD-R, film, DVD, USB, Network	CD-R, film, DVD, USB, Network	<b>Equivalent.</b> The subject device has been modified to only store meta data
Communication	DICOM compatible	DICOM compatible	<b>Same</b>

## 7. Performance Data

### Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of AI-Rad Companion (Engine). Software validations and bench testing have been conducted to the performance claims as well as the claim of substantial equivalence to the predicate devices.

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 following voluntary FDA recognized Consensus Standards listed in **Table 2** below

**Table 2: Voluntary Conformance Standards**

Recognition Number	Product Area	Title of Standard	Publication Date	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-32	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1 <sup>st</sup> Edition)	08/20/2012	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	08/20/2012	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	06/27/2016	IEC
	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	2/3/2016	IEC

**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, and “Off-The-Shelf Software Use in Medical Devices” 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 AI-Rad Companion (Engine) software version VA10A during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Bench testing in the form of Unit, Subsystem and System Integration testing were performed to evaluate the performance and functionality of the new features and software updates. All testable requirements in the Engineering Requirements Specifications keys, Subsystem Requirements Specifications keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process. The software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans. Electrical safety and EMC testing requirements are addressed as part of the host system (CT device or PACS system) to ensure compliance with the application IEC standards.

Siemens conforms to the cybersecurity requirements 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. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital.

**Summary**

AI-Rad Companion (Engine) was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process and





clinical data based software validation . The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

#### **8. General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related Risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

#### **9. Conclusions**

AI-Rad Companion (Engine) has the same intended use as the primary predicate device. The indication for use has been modified to include a more succinct summary of device specific performance, but is still within the scope of the intended use and regulatory classification as the predicate devices. The fundamental technological characteristics such as image visualization and image manipulation are the same as the predicate device. The result 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 devices are adequate for the intended use. The comparison of 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. For the subject device, AI-Rad Companion (Engine), Siemens used the same testing with the same workflows as used to clear the predicate device to demonstrate safety and performance of the technical workflow. Since both devices were tested using the same methods, Siemens believes that the data generated from the AI-Rad Companion (Engine) software testing supports a finding of substantial equivalence.