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

June 17, 2020

Re: K193290
Trade/Device Name: AI-Rad Companion Brain MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 15, 2020
Received: May 19, 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)*

K193290

Device Name
AI-Rad Companion Brain MR

Indications for Use *(Describe)*

AI-Rad Companion Brain MR is a post-processing image analysis software that assists clinicians in viewing, analyzing and evaluating MR brain images.

AI-Rad Companion Brain MR provides the following functionalities:

- Automatic segmentation and quantitative analysis of individual brain structures
- Quantitative comparison of each brain structure with normative data from a healthy population
- Presentation of results for reporting that includes all numerical values as well as visualization of these results

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) SUMMARY
# FOR
# AI-RAD COMPANION BRAIN MR

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
Malvern, PA 19355
Mail Code: 65-1A
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
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Malvern, PA 19335
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## 3. Device Name and Classification

| | |
|---|---|
| **Product Name:** | AI-Rad Companion Brain MR |
| **Trade Name:** | AI-Rad Companion Brain 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:** | LLZ |
| **Secondary Product Code:** | LNH |

## 4. Predicate Device

| | |
|---|---|
| Product Name: | *syngo*.MR Applications |
| Propriety Trade Name: | *syngo*.MR Applications |
| 510(k) Number: | K182904 |
| Clearance Date: | July 5, 2019 |
| 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 Brain MR is a post-processing image analysis software that assists clinicians in viewing, analyzing and evaluating MR brain images.

AI-Rad Companion Brain MR provides the following functionalities:

- Automatic segmentation and quantitative analysis of individual brain structures
- Quantitative comparison of each brain structure with normative data from a healthy population
- Presentation of results for reporting that includes all numerical values as well as visualization of these results.

## 6. Device Description

AI-Rad Companion Brain MR is an enhancement to the predicate, *syngo*.MR Application (K182904). Just as in the predicate, AI-Rad Companion Brain MR addresses the automatic quantification and visual assessment of the volumetric properties of various brain structures based on T1 MPRAGE datasets. These datasets are acquired as part of a typical head MR acquisition. The results are directly archived in PACS as this is the standard location for reading by radiologist. From a predefined list of 30 structures (e.g. Hippocampus, Caudate, Left Frontal Grey Matter, etc.), volumetric properties are calculated as absolute and normalized volumes with respect to the total intercranial volume. The normalized values for a given patient are compared

against age-matched mean and standard deviations obtained from a population of healthy reference subjects.

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

1. Modified Intended Use Statement
2. Addition of a customizable deviation map
3. 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 Brain MR is substantially equivalent with regards to software, programming language, operating system, performance and technology (including algorithms). AI-Rad Companion Brain MR offers enhancements and improvements to the existing predicate device, *syngo*.MR Applications: Brain Morphometry (K182904). While these enhancements offer additional visualization 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.

## 8. Nonclinical Tests

Non-clinical tests were conducted to test the functionality of AI-Rad Companion Brain 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 has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrates that AI-Rad Companion Brain 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 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 | 62304: 2006/A1:2016 | AAMI ANSI IEC |

| Recognition Number | Product Area | Title of Standard | Reference Number and Date | Standards Development Organization |
|---|---|---|---|---|
| | | processes [Including Amendment 1 (2016)] | | |
| 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 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 Brain 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 Brain MR is substantially equivalent to the follow predicate device (**Table 2**):

| Predicate Device | FDA Clearance Number | FDA Clearance Date | Main Product Code |
|---|---|---|---|
| *syngo*.MR Applications | K182904 | July 5, 2019 | LLZ |

*Table 2: Predicate device for AI-Rad Companion Brain MR*

AI-Rad Companion Brain MR has the same intended use and technical characteristics compared to the predicate device, *syngo*.MR Applications (K182904), with respect to the software features, functionalities and core algorithms. The enhancements and improvements provided in AI-Rad Companion Brain MR increase the usability and reduce the complexity of the imaging workflow for the clinical user. The conclusions from all verification and validation data suggest 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 the opinion that AI-Rad Companion Brain MR is substantially equivalent to the currently marketed device, *syngo*.MR. Applications (K182904).