October 23, 2023

Siemens Medical Solutions U.S.A.
% Kira Morales
Regulatory Affairs Manager
40 Liberty Blvd.
Malvern, PA 19355

Re: K232305
Trade/Device Name: AI-Rad Companion Brain MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: July 31, 2023
Received: August 1, 2023

Dear Kira Morales:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232305

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:
- Automated segmentation and quantitative analysis of individual brain structures and white matter hyperintensities
- Quantitative comparison of brain structure with normative data from a healthy population
- Presentation of results of 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.

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510(k) SUMMARY
FOR
AI-Rad Companion Brain MR

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: July 31, 2023

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 193552
Registration Number: 2240869

Manufacturing Site

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

2. Contact Person

Kira Morales
Regulatory Affairs Manager
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19335
Phone: +1 (484) 901 - 9471
Email: kira.morales@siemens-healthineers.com

3. Device Name and Classification

Product Name:	AI-Rad Companion Brain MR
Trade Name:	AI-Rad Companion Brain MR
Classification Name:	Medical Image Management and Processing System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050

Device Class: Class II
Product Code: QIH

4. Predicate Device

Product Name:	AI-Rad Companion Brain MR
Propriety Trade Name:	AI-Rad Companion Brain MR
510(k) Number:	K213706
Clearance Date:	April 15, 2022
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
Primary Product Code:	QIH
Recall Information:	N/A

5. Reference Device

Product Name:	icobrain
510(k) Number:	K192130
Clearance Date:	December 13, 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

6. Indications for 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.

- Automated segmentation and quantitative analysis of individual brain structures and white matter hyperintensities
- 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

7. Device Description

AI-Rad Companion Brain MR VA50 is an enhancement to the predicate, AI-Rad Companion Brain MR VA40 (K213706). Just as in the predicate, the brain morphometry feature of 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. From a predefined list of brain structures (e.g. Hippocampus, Caudate, Left Frontal Gray Matter, etc.) volumetric properties are calculated as absolute and normalized volumes with respect to the total intracranial volume. The normalized values are compared against age-matched mean and standard deviations obtained from a population of healthy reference subjects. The deviation from this reference population can be visualized as 3D overlay map or out-of-range flag next to the quantitative values.

Additionally, identical to the predicate, the white matter hyperintensities feature addresses the automatic quantification and visual assessment of white matter hyperintensities on the basis of T1 MPRAGE and T2 weighted FLAIR datasets. The detected WMH can be visualized as a 3D overlay map and the quantification in count and volume as per 4 brain regions in the report.

8. Substantially Equivalent (SE) and Technological Characteristics

The intended use of the predicate device and the subject device are equivalent. The main difference is that AI-Rad Companion Brain MR VA50 adds the additional features of the Brain Morphometry follow-up feature and White Matter Hyperintensities Follow-up as compared to the predicate, AI-Rad Companion Brain MR VA40.

The subject device, AI-Rad Companion Brain MR VA50 is substantially equivalent with regard to the intended use and technical characteristics compared to the predicate device, AI-Rad Companion Brain MR VA50 (K213706) with respect to the software features, functionalities, and core algorithms. The additional features, enhancements and improvements provided in AI-Rad Companion Brain MR VA50 increase the usability and reduce the complexity of the imaging workflow for the clinical user.

Icobrain serves as a reference device within this submission and a dedicated comparison of technological characteristics is provided. Siemens Healthineers has determined that AI-Rad Companion Brain MR VA50 is comparable to icobrain (K192130) as it has similar technological and performance characteristics with respect to the white matter hyperintensities feature (cleared in predicate K213706) and white matter hyperintensities follow-up feature. Comparable to the subject device, icobrain produces reports for the segmentation and volumetric analysis of FLAIR white matter hyperintensities in the peri-ventricular, juxta-cortical, infra-tentorial, and deep white matter hyperintensity regions. Comparable to the white matter hyperintensities follow-up feature, Icobrain identifies volume changes (new or enlarging) of white matter hyperintensities between two images at two different time points within the 4 brain regions and produces a progression map indicating the location of the new or enlarged area, a total count of new or enlarged areas and a total volume of new or enlarged areas. AI-Rad Companion Brain MR VA50 used equivalent validation methodology to analyze the performance of the white matter hyperintensities follow-up feature compared to icobrain (K192130).

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: AI-Rad Companion Brain MR VA50A	**Predicate Device:** AI-Rad Companion Brain MR VA40 **(K213706)**	**Reference Device: icobrain (**K192130**)**
Indications for 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 and white matter hyperintensities • 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	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 and white matter hyperintensities • 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	icobrain is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR or NCCT images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR or NCCT images. icobrain consists of two distinct image processing pipelines: icobrain cross and icobrain long. icobrain cross is intended to provide volumes from MR or NCCT images acquired at a single time point. icobrain long is intended to provide changes in volumes between two MR images that were acquired on the same scanner,

			with the same image acquisition protocol and with same contrast at two different timepoints. The results of icobrain cross cannot be compared with the results of icobrain long.
Brain Morphometry	Pre-processing functionality for automatic segmentation and volumetry of MPRAGE data.	Pre-processing functionality for automatic segmentation and volumetry of MPRAGE data.	Image processing for automatic segmentation and volumetry of MPRAGE data.
Brain White Matter Hyperintensities Segmentation	AI-Rad Companion Brain MR White Matter Hyperintensities (WMH) includes segmentation and quantification of White Matter Hyperintensities on the basis of T1-weighted MPRAGE and T2-weighted FLAIR datasets as input.	Pre-processing functionality for automatic segmentation and volumetry of MPRAGE and FLAIR data.	Image processing for automatic segmentation and volumetry of FLAIR data.
Brain White Matter Hyperintensities Quantification	The WMH report contains visualization of WMH (3D overlay of WMH map) and numeric results of count and volume of WMH as per four brain regions periventricular, juxtacortial, infratentorial and deep white matter.	The WMH report contains visualization of WMH (3D overlay of WMH map) and numeric results of count and volume of WMH as per four brain regions periventricular, juxtacortial, infratentorial and deep white matter.	Unnormalized volume and volume changes of FLAIR white matter hyperintensities as per 4 brain regions

Follow-up	The longitudinal assessment of Brain MR images from two timepoints provides the rate of change of volumes of brain structures and the count and volume of new or enlarged WMH.	The follow-up feature is not available in the equivalent device (AI-Rad Companion Brain MR VA40)	Assessment of New/Enlarging lesion count
Brain White Matter Hyperintensities Map	Calculation of white matter hyperintensities map fused with the processed FLAIR data User customizable color labels for the overlay map.	Calculation of white matter hyperintensities map fused with the processed FLAIR data User customizable color labels for the overlay map.	Calculation of white matter hyperintensities map overlaid with the FLAIR data
Brain Morphometry: Quantification	Calculation of label maps (display of brain segmentation) and partially combined label maps (fused with the processed MPRAGE data).	Calculation of label maps (display of brain segmentation) and partially combined label maps (fused with the processed MPRAGE data).	Normalized and unnormalized volume and volume changes of different brain structures.
Brain Morphometry: Deviation Map and Label map	• Deviation results include deviation map, which presents different brain regions, color-coded to indicate the degree of deviation from the average age- and gender-matched normative volume. • Label results include the label map, which shows different brain regions using different colors.	• Deviation results include deviation map, which presents different brain regions, color-coded to indicate the degree of deviation from the average age- and gender-matched normative volume. • Label results include the label map, which shows different brain regions using different colors.	Not available
Distribution & Archiving	Creation of an image series for morphometry and WMH reports. Automatic transfer of generated maps and	Creation of an image series for morphometry and WMH reports. Automatic transfer of generated maps and	Automatic transfer of generated image series and report to a PACS system.

	reports to a PACS system.	reports to a PACS system.	
Architecture	Cloud-based and on-edge deployment in the institution premise. For Edge deployment, the data processing is performed within the institution whereas logging, institution management, and audit logging are performed in the cloud.	Cloud-based and on-edge deployment in the institution premise. For Edge deployment, the data processing is performed within the institution whereas logging, institution management, and audit logging are performed in the cloud.	Cloud only solution with no components deployed on customer premise.
Communication	PACS (DICOM compatible)	PACS (DICOM compatible)	PACS (DICOM compatible)
User interface	Configuration UI User can activate or deactivate the processing of brain MR cases in AI-Rad Companion Engine. If you activate AI-Rad Companion Brain MR, then the brain MR cases uploaded to AI-Rad Companion Engine are processed and is displayed in the Patient List. You can manually adjust the settings available in the General Settings screen. If you deactivate AI-Rad Companion Brain MR, then no brain MR cases are processed in AI-Rad Companion Engine. The settings available in the General Settings screen are not displayed. To activate or deactivate AI-Rad Companion Brain MR, see Configuring AI-Rad	Configuration UI User can activate or deactivate the processing of brain MR cases in AI-Rad Companion Engine. If you activate AI-Rad Companion Brain MR, then the brain MR cases uploaded to AI-Rad Companion Engine are processed and is displayed in the Patient List. You can manually adjust the settings available in the General Settings screen. If you deactivate AI-Rad Companion Brain MR, then no brain MR cases are processed in AI-Rad Companion Engine. The settings available in the General Settings screen are not displayed. To activate or deactivate AI-Rad Companion Brain MR, see Configuring AI-Rad	Not available

	Companion in the AI-Rad Companion Engine Instructions for Use. Longitudinal (Follow-up) configurations and Support for output in different orientations are added. Conformation UI On the Results Preview, user can confirm or decline the results and send them to the PACS. All changes are temporarily saved until the case is sent to the PACS.	Companion in the AI-Rad Companion Engine Instructions for Use. Conformation UI On the Results Preview, user can confirm or decline the results and send them to the PACS. All changes are temporarily saved until the case is sent to the PACS.	
Software requirement/Operating system	AI-Rad Companion Brain MR was tested on Microsoft Windows 10. AI-Rad Companion Brain MR is not validated on any other operating system, for example, MAC. AI-Rad Companion Brain MR is not validated for use with touch screen or mobile devices. AI-Rad Companion Notifier requires a 64-bit Windows Operating System (Windows 10 recommended). It is recommended to use Google Chrome as a preferred web browser for use with AI-Rad Companion Brain MR.	AI-Rad Companion Brain MR was tested on Microsoft Windows 10. AI-Rad Companion Brain MR is not validated on any other operating system, for example, MAC. AI-Rad Companion Brain MR is not validated for use with touch screen or mobile devices. AI-Rad Companion Notifier requires a 64-bit Windows Operating System (Windows 10 recommended). It is recommended to use Google Chrome as a preferred web browser for use with AI-Rad Companion Brain MR.	Not available
System deployment	Cloud based deployment Edge deployment Platform	Cloud based deployment Edge deployment Platform	Cloud Only Solution

DICOM SR/SC/PDF	AI-Rad Companion Brain MR exports the numerical reports (DICOM SR, DICOM SC and PDF) in both manual and automatic confirmation.	Data transfer is handled by the teamplay Images infrastructure and uses the DICOM standard. The results are sent back to a configurable target node via the teamplay digital health platform infrastructure in accordance with the DICOM standards.	DICOM structured report

Table 1: Comparison table for AI-Rad Companion Brain MR VA50, predicate device AI-Rad Companion Brain MR VA40 (K213706) and reference device icobrain (K192130)

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 VA50 is substantially equivalent to the currently marketed device, AI-Rad Companion Brain MR VA40

9. 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. Non-clinical performance testing demonstrates that AI-Rad Companion Brain MR complies with appropriate FDA guidance documents as well as with the following voluntary FDA recognized Consensus Standards (**Table 2)**.

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
5-129	General	Medical Devices – Application of usability engineering to medical devices [including Corrigendum 1 (2016)]	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC
5-125	General	Medical Devices – application of risk management to medical devices	ISO 14971 Third Edition 2019-12	ISO
13-79	Software/ Informatics	Medical device software – software life cycle processes [Including Amendment 1 (2016)]	IEC 62304 Edition 1.1 2015-06	AAMI ANSI IEC

			CONSOLIDATED VERSION	
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 2021e	NEMA
5-134	General	Medical devices – symbols to be used with information to be supplied by the manufacturer – Part 1: General Requirements	15223-1 Fourth edition 2021-07	ISO IEC
13-97	Software/ Informatics	Health software – Part 1: General requirements for product safety	82304-1 Edition 1.0 2016-10	IEC

Table 2: List of recognized 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.

10. Performance Software Validation

AI-Rad Companion Brain MR VA50A brain morphometry feature is identical to the predicate device AI-Rad Companion Brain MR VA20A.

AI-Rad Companion Brain MR VA50A White Matter Hyperintensities (WMH) segmentation feature is identical to the predicate device AI-Rad Companion Brain MR VA40A

In AI-Rad Companion Brain MR VA50A 2 features were added as below:

- The Brain Morphometry follow-up feature
- White Matter Hyperintensities Follow-up

Brain Morphometry Follow-Up Feature

The Brain Morphometry follow-up feature of the subject device automatically calculates the atrophy range in percentage for each segmented brain structure using the Brain Morphometry feature. The Brain Morphometry follow-up feature takes the two MPRAGE scans from two time-points of the same patient as input and calculates atrophy rates between timepoints. Brain morphometry follow-up consists of atrophy rate calculation Morphometry follow-up does not include any machine learning or deep learning component therefore it is verified by V&V testing, and no additional evaluation is provided in this document.

White Matter Hyperintensities Follow-Up Feature

To validation AI-Rad Companion Brain MR software from a clinical perspective, the white matter hyperintensities follow-up feature underwent a scientific evaluation. The results of clinical data-based software validation for the subject device AI-Rad Companion Brain demonstrated equivalent performance in comparison to the reference device and literature. A complete scientific evaluation report is provided in support of the device modifications. The brain morphometry & white matter hyperintensities algorithms, unchanged from the predicate, did not undergo a new scientific evaluation.

Performance testing for AI-Rad Companion Brain MR WMH follow-up was performed on Siemens Healthineers test data from 75 subjects, which included Multiple Sclerosis patients (MS) and Alzheimer's patients (AD). Testing data had more female subjects as Multiple Sclerosis occurs in females more as compare to male subjects. and a balanced distribution with respect to age of the patient according to target patient population and field strength of the MR scanner used. For each dataset, three sets of ground truth of white matter hyperintensity changes between two time points are annotated manually. Each set is annotated by a disjoin group of annotator, reviewer and clinical expert, with the expert randomly assigned per case. For each test dataset, the three initial annotations are annotated by three different in-house annotators, then each initial annotation is reviewed by the in-house reviewer. Afterwards, each initial annotation is reviewed by the referred clinical expert.

Acceptance Criteria:

Validation Type	Acceptance Criteria
Volumetric Segmentation Accuracy	A PCC >= 0.77 is considered as a passed case for volumetric segmentation accuracy
Voxel-wise Segmentation Accuracy	A mean Dice score >=0.47 is considered as a passed case for segmentation quality
WMH Change Region-wise Segmentation Accuracy	A median F1-score >=0.69 is considered a passed case

Summary Performance data, Standard Deviations & CIs:

	Volumetric Segmentation	Voxel-wise Segmentation	WMH Lesion-wise Segmentation
	PCC	Dice	F1-score
AVG	0.94	0.50	0.69
STD	n.a.	0.22	0.13
95% CI	[0.83,0.98]	[0.42,0.57]	[0.633,0.733]

Testing Data Information:

	Testing Cohort
# Subjects	75
# Studies	150 (2 scans per subject)
# of Females	56
# of Males	19
Age Range	25-88
Medical Indication	MS: 60 Alzheimer's: 15
Scan Protocol	T1w MPRAGE T2w FLAIR
Field Strength	3.0T
Manufacturer	Siemens
Data Origin	UPenn: (US): 15 ADNI (US): 15 Lausanne (EU): 22 Prague (EU): 23

Standard Annotation Process:

For each dataset, three sets of ground truth of white matter hyperintensity changes between two time points are annotated manually. Each set is annotated by a disjoint group of annotator, reviewer, and clinical expert, with the expert randomly assigned per case to minimize annotation bias. For each test dataset, the three initial annotations are annotated by three different in-house annotators. Then, each initial annotation is reviewed by the in-house reviewer. Afterwards, each initial annotation is reviewed by the referred clinical expert. The clinical expert reviews and corrects the initial annotation of the changed WMH areas according to the annotation protocol. If the corrections are significant and time-consuming, the corrections are communicated to the annotator for correction and then re-reviewed.

Testing & Training Data Independence:

WMH follow-up algorithm does not include any machine learning/ deep learning component. The training data used for the fine tuning the hyper parameters of WMH follow-up algorithm is independent of the data used to test the white matter hyperintensity algorithm follow up algorithm.

11. Summary of Nonclinical Tests

Based on the nonclinical performance documented within the Scientific Evaluation, AI-Rad Companion Brain MR VA50 was found to have a safety and effectiveness profile that is similar to the predicate. Since the predicate device was cleared based on the results of the prior conducted scientific evaluation, the same methodology was required to support the substantial equivalence. The nonclinical data and verification and validation results supports the safety and effectiveness of the subject device in that it should performs comparable to the predicate device that is currently marketed.

12. Summary of Clinical Tests

The predicate (K213706) was not validated using clinical tests and therefore 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. No animal testing has been performed on the subject device.

13. 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 14971:2019 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.