



December 22, 2023

Siemens Medical Solutions USA, Inc.
Milind Dhamankar
Clinical Affairs Professional
40 Liberty Boulevard
Malvern, PA 19355

Re: K232535

Trade/Device Name: MAGNETOM Sola; MAGNETOM Altea
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: December 6, 2023
Received: December 6, 2023

Dear Milind Dhamankar:

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

Indications for Use

Submission Number (if known)

K232535

Device Name

MAGNETOM Sola;
MAGNETOM Altea

Indications for Use (Describe)

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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

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

1. General Information

Establishment: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: August 09, 2023

Manufacturer: Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Registration Number: 3002808157

Siemens Shenzhen Magnetic Resonance LTD.
Siemens MRI Center
Hi-Tech Industrial Park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057
P.R. CHINA
Registration Number: 3004754211

2. Contact Information

Milind Dhamankar
Clinical Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Phone: +1(610) 517-9484
Fax: (610) 448-6547
E-mail: milind.dhamankar@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name: MAGNETOM Sola

	MAGNETOM Altea
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

4. Legally Marketed Predicate and Reference Device

4.1. Predicate Device

Trade name:	MAGNETOM Sola
510(k) Number:	K221733
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

4.2. Reference Device

Trade name:	MAGNETOM Altea
510(k) Number:	K221733
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

4. Intended Use / Indications for Use

The indications for use for the subject devices are the same as the predicate device:

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

5. Device Description

The subject devices, MAGNETOM Sola and MAGNETOM Altea with software syngo MR XA61A, consist of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Sola with syngo MR XA51A (K221733).

A high-level summary of the new and modified hardware and software is provided below:

Hardware

Modified Hardware:

- Host computers ((syngo MR Acquisition Workplace (MRAWP) and syngo MR Workplace (MRWP))
- MaRS (Measurement and Reconstruction System) computer – for MAGNETOM Sola only
- myExam 3D Camera

Software

New Features and Applications:

- GRE_PC
- Physiologging
- Deep Resolve Boost HASTE
- Deep Resolve Boost EPI Diffusion
- Complex Averaging
- myExam Implant Suite

Modified Features and Applications:

- OpenRecon Framework.
- BEAT_nav (re-naming only).
- Low SAR Protocols – SAR adoptive MR protocols to perform knee, spine, heart and brain examinations with 50% of the max allowed SAR values in normal mode for head and whole-body SAR.

6. Substantial Equivalence

MAGNETOM Sola and MAGNETOM Altea with software *syngo* MR XA61A are substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola with <i>syngo</i> MR XA51A	K221733 on September 13, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH
Reference Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Altea with <i>syngo</i> MR XA51A	K221733 on September 13, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH

7. Technological Characteristics

The subject devices, MAGNETOM Sola and MAGNETOM Altea with software *syngo* MR XA61A, are substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

The subject devices conform to the standard for medical device software (IEC 62304) and other relevant IEC and NEMA standards.

There are some differences in technological characteristics between the subject device and predicate device, including new and modified hardware/software. Here is summary of differences:

Summary hardware comparison table for the subject and predicate/reference device

Hardware	Subject Devices	Predicate Device	Reference Devices
-----------------	------------------------	-------------------------	--------------------------

	MAGNETOM Sola MAGNETOM Altea with software <i>syngo</i> MR XA61A	MAGNETOM Sola with <i>syngo</i> MR XA51A (K221733)	MAGNETOM Altea with <i>syngo</i> MR XA51A (K221733)
Magnet System	Yes	Yes	Yes
RF System	Yes	Yes	Yes
Transmission technique	Yes	Yes	Yes
Gradient System	Yes	Yes	Yes
Patient Table	Yes	Yes	Yes
Multi-Nuclear Option - Supported Nuclei	No	No	No
Computer	Yes Modified compared to predicate device: - New MRAWP and MRWP - New MaRS hardware for MAGNETOM Sola	Yes	Yes
Coils	Yes	Yes	Yes
Other HW components	Yes Modified compared to predicate device: - myExam 3D Camera functionality extension	Yes	Yes

Summary software comparison table for the subject and predicate devices

Software	Subject Devices MAGNETOM Sola MAGNETOM Altea with software <i>syngo</i> MR XA61A	Predicate Device MAGNETOM Sola with <i>syngo</i> MR XA51A (K221733)
Sequences		
SE-based pulse sequence types	New feature - Deep Resolve Boost for HASTE	Yes
GRE-based/Steady-State pulse sequence types	New or modified pulse sequences: - BEAT_NAV pulse sequence re-naming - GRE_PC new pulse sequence	Yes
EPI-based pulse sequence types	New features - Physiologging for EP2D_BOLD and EP2D_PACE - Deep Resolve Boost for EP2D_DIFF	Yes

	- Complex Averaging for EP2D_DIFF	
Spectroscopy pulse sequence types	Yes	Yes
Feature and Applications		
Other features and applications such as: -Application Suites -myExam Assists -Other Imaging Applications	New feature: - myExam Implant Suite	Yes
User interface and user interaction	Yes	Yes
Viewing and post-processing	Yes	Yes
Workflow and software utilization	Yes	Yes
Patient Management	Yes	Yes
Scan Modes and Pulse Sequences	Yes	Yes
Scanning	Yes	Yes
Reconstruction	Modified feature: - OpenRecon Framework	Yes
Image Display	Yes	Yes
File/Data Management	Yes	Yes

The differences have been tested and the conclusion from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate device.

8. Nonclinical Tests

The following **performance testing** was conducted on the subject devices:

Performance Test	Tested Hardware or Software	Source/Rationale for test
Software verification and validation	New or modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Sample clinical images	New or modified software features	Guidance for submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessment by sample clinical images	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	
Physiologging Verification Report	Physiologging	New Feature Introduction
myExam 3D Camera Validation and Verification Report	myExam 3D Camera	Modified hardware
myExam Implant Suite Validation and Verification Report	myExam Implant Suite	New feature Introduction

AI Features/Applications training and validation:

The information below shows an executive summary of training and validation dataset of the AI features:

	Deep Resolve Boost:	Deep Resolve Sharp:
Training and Validation data	• TSE: more than 25,000 slices • HASTE: pre-trained on the TSE dataset and refined with more than 10,000 HASTE slices • EPI Diffusion: more than 1,000,000 slices The data covered a broad range of body parts, contrasts, fat suppression techniques, orientations, and field strength.	on more than 10,000 high resolution 2D images. The data covered a broad range of body parts, contrasts, fat suppression techniques, orientations, and field strength.
Test Statistics and Test Results Summary	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR) and structural similarity index (SSIM). Most importantly, the performance was evaluated by visual comparisons to evaluate e.g., aliasing artifacts, image sharpness and denoising levels.	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM), and perceptual loss. In addition, the feature has been verified and validated by inhouse tests. These tests include visual rating and an evaluation of image sharpness by intensity profile comparisons of reconstructions with and without Deep Resolve Sharp.
Equipment	1.5T and 3T MRI systems	
Clinical Subgroups	No clinical subgroups have been defined for the collected dataset.	
Demographic Distribution	Due to reasons of data privacy, we did not record gender, age and ethnicity during data collection.	
Reference Standard	The acquired datasets (as described above) represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation and augmentation. This process includes further under-sampling of the data by discarding k-space lines, lowering of the SNR level by addition Restricted of noise and mirroring of k-space data.	The acquired datasets represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation. k-space data has been cropped such that only the center part of the data was used as input. With this method corresponding low-resolution data as input and high-resolution data as output / ground truth were created for training and validation.

The results from each set of tests demonstrate that the devices perform as intended and are thus substantially equivalent to the predicate device to which it has been compared.

9. Clinical Tests / Publications

No clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided.

Furthermore, additional clinical publications were referenced to provide information on the use of the following features and functions:

Feature	Publications
Deep Resolve Boost EPI Diffusion	[1] Bae SH et al., Clinical feasibility of accelerated diffusion weighted imaging of the abdomen with deep learning reconstruction: Comparison with conventional diffusion weighted imaging, <i>Eur J Radiol.</i>, 154 (2022) [2] Lee EJ et al., Feasibility of deep learning k-space-to-image reconstruction for diffusion weighted imaging in patients with breast cancers: Focus on image quality and reduced scan time, <i>Eur J Radiol.</i>, 157 (2022) [3] Afat S et al., Acquisition time reduction of diffusion-weighted liver imaging using deep learning image reconstruction. <i>Diagn Interv Imaging</i>, (2022). [4] Benkert T et al., Improved Clinical Diffusion Weighted Imaging by Combining Deep Learning Reconstruction, Partial Fourier, and Super Resolution, <i>ISMRM</i> (2022) [5] Kim et al., Deep Learning–Accelerated Liver Diffusion-Weighted Imaging - Intraindividual Comparison and Additional Phantom Study of Free-Breathing and Respiratory-Triggering Acquisitions, <i>Invest Radiol</i> (2023)
Deep Resolve Boost HASTE	[1] Herrmann J et al., Diagnostic Confidence and Feasibility of a Deep Learning Accelerated HASTE Sequence of the Abdomen in a Single Breath-Hold, <i>Investigative Radiology</i>, Volume 56, Number 5, May 2021. [2] Shanbhogue K et al. Accelerated single-shot T2-weighted fat-suppressed (FS) MRI of the liver with deep learning-based image reconstruction: qualitative and quantitative comparison of image quality with conventional T2-weighted FS sequence. <i>Eur Radiol.</i> 2021 May 7. [3] Herrmann J et al., Development and Evaluation of Deep Learning-Accelerated Single-Breath-Hold Abdominal HASTE at 3 T Using Variable Refocusing Flip Angles. <i>Invest Radiol.</i> 2021 Apr 22. [4] Han S et al., Evaluation of HASTE T2 weighted image with reduced echo time for detecting focal liver lesions in patients at risk of developing hepatocellular carcinoma. <i>Eur J Radiol.</i> 2022 Nov 1;157:110588. [5] Mule S et al., Fast T2-weighted liver MRI: Image quality and solid focal lesions conspicuity using a deep learning accelerated single breath-hold HASTE fat-suppressed sequence. <i>Diagn Interv Imaging.</i> 2022 Oct;103(10):479-485. [6] Ginocchio LA et al., Accelerated T2-weighted MRI of the liver at 3 T using a single-shot technique with deep

	learning-based image reconstruction: impact on the image quality and lesion detection. Abdom Radiol (NY). 2022 Sep 28. [7] Herrmann J et al., Comprehensive clinical evaluation of a deep learning-accelerated, single-breath-hold abdominal HASTE at 1.5 T and 3 T. Acad Radiol. 2022 Apr 22:S1076-6332(22)00195-7. [8] Ichinohe F. et al., Usefulness of Breath-Hold Fat-Suppressed T2-Weighted Images With Deep Learning-Based Reconstruction of the Liver, Invest Radiol., 2022
GRE_PC	[1] Guenther C. et al. Ristretto MRE: A generalized multi-shot GRE-MRE sequence. NMR Biomed 2019; 32:e4049.
Complex Averaging	[1] Walsh DO, Gmitro AF, Marcellin MW. Adaptive reconstruction of phased array MR imagery. Magn Reson Med. 2000 May 1;43(5):682–90. [2] Kordbacheh H, Seethamraju RT, Weiland E, Kiefer B, Nickel MD, Chulroek T, et al. Image quality and diagnostic accuracy of complex-averaged high b value images in diffusion-weighted MRI of prostate cancer. Abdom Radiol (NY). 2019;44(6):2244–53

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 a risk analysis in compliance with ISO 14971, to identify and provide mitigation of potential hazards early in the design cycle and continuously throughout the development of the product. Siemens Healthcare GmbH adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Sola and MAGNETOM Altea with software *syngo* MR XA61A conforms to the following FDA recognized and international IEC, ISO and NEMA standards:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-4	General	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012	AAMI / ANSI
19-8	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2 Edition 4.0:2014-02	IEC

12-295	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	60601-2-33 Ed. 3.2 b:2015	IEC
5-125	General	Medical devices - Application of risk management to medical devices	14971 Third Edition 2019-12	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1:2015	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC
12-195	Radiology	NEMA MS 6-2008 (R2014) Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	MS 6-2008 (R2014)	NEMA
12-342	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20 (2021e)	NEMA
2-258	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1 Fifth edition 2018-08	AAMI ANSI ISO

11. Conclusion as to Substantial Equivalence

MAGNETOM Sola and MAGNETOM Altea with software *syngo* MR XA61A has the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Sola with *syngo* MR XA51A, with respect to the magnetic resonance features and functionalities. While there are some differences in technical features compared to the predicate device, the differences have been tested and the conclusions from all verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device and reference devices.

Siemens believes that MAGNETOM Sola and MAGNETOM Altea with software *syngo* MR XA61A are substantially equivalent to the currently marketed device MAGNETOM Sola with software *syngo* MR XA51A (K221733 on September 13, 2022).