September 13, 2022

Siemens Medical Solutions USA, Inc.
% Alina Goodman
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN PA 19355

Re: K221733
Trade/Device Name: MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: June 9, 2022
Received: June 15, 2022

Dear Alina Goodman:

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,

**Daniel M. Krainak, Ph.D.**
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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.*

Submission Number *(if known)*

K221733

Device Name

MAGNETOM Sola;
MAGNETOM Altea;
MAGNETOM Sola Fit

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.***

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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

K221733

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:**
June 9th, 2022

**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

Alina Goodman
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
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Phone: +1(317)371-8593
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## 3. Device Name and Classification

| | |
|---|---|
| **Device/ Trade name:** | MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit with *syngo* MR XA51A |
| **Classification Name:** | Magnetic Resonance Diagnostic Device (MRDD) |
| **Classification Panel:** | Radiology |
| **CFR Code:** | 21 CFR § 892.1000 |
| **Classification:** | II |
| **Product Code:** | Primary: LNH<br>Secondary: LNI, MOS |

## 4. Legally Marketed Predicate Device

| | |
|---|---|
| **Trade name:** | MAGNETOM Vida with *syngo* MR XA50A |
| **510(k) Number:** | K213693 |
| **Classification Name:** | Magnetic Resonance Diagnostic Device (MRDD) |
| **Classification Panel:** | Radiology |
| **CFR Code:** | 21 CFR § 892.1000 |
| **Classification:** | II |
| **Product Code:** | Primary: LNH<br>Secondary: LNI, MOS |

## 5. Intended 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.

## 6. Device Description

The subject devices, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit with software syngo MR XA51A, consist of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Vida with syngo MR XA50A (K213693). A high-level summary of the new and modified hardware and software is provided below:

**Hardware**

New Features and Application

- The **myExam 3D Camera** feature supports the radiographer and/or the technician with the positioning of the patient during the examination

**Software**

New Features and Applications

- **myExam_Autopilot** is a simplified scan workflow designed for enabling less-MRI experience users to complete MRI routine Brain and Knee examinations successfully.
- **Open Recon Framework** interface allows to apply container-based reconstruction algorithms on the reconstruction systems. The Open Recon Framework **only allows FDA cleared 3rd party algorithms** to be imported for clinical use.

Modified Features and Applications

- **myExam Angio Advanced Assist** for Test Bolus examinations supports the clinical user in planning and execution of peripheral angiography examinations.

The user is guided in the multi-station planning and the correct timing of the angiography measurement using the Angio Advanced Bolus Timing Addin.

- **Beat Sensor** Cardiac triggering is a physiological triggering technique based on the pilot tone technology that has been adapted in the subject devices to allow for cardiac triggering with a wide range of sequences typically used in MRI examinations of the heart and great vessels

## 7. Substantial Equivalence

MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit with software *syngo* MR XA51A is substantially equivalent to the following predicate device:

| Predicate Device | FDA Clearance Number and Date | Product Code | Manufacturer |
|---|---|---|---|
| MAGNETOM Vida with *syngo* MR XA50A | K213693, cleared on February 25, 2022 | LNH<br>LNI, MOS | Siemens Healthcare GmbH |

## 8. Technological Characteristics

The subject devices, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit with software *syngo* MR XA51A, 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. These 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.

## 9. Nonclinical Tests

The following performance testing was conducted on the subject devices.

| Performance Test | Tested Hardware or Software | Source/Rationale for test | Acceptance Criteria | Overall Result | For Details please refer to |
|---|---|---|---|---|---|
| Software verification and validation | mainly new and modified software features | Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices | Verification and Validation tests are met | Passed | **V&V-List** see Attachment 10_4 |
| Electrical, mechanical, structural, and related system safety test | complete system | - AAMI / ANSI ES60601-1<br>- IEC 60601-2-33 | Tests according to applicable standard are met/passed | Passed | **IEC testing** see Attachment 12 |
| Electrical safety and electromagnetic compatibility (EMC) | complete system | IEC 60601-1-2 | EMC requirements are met/passed | Passed | **IEC testing** see Attachment 12 |

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.

## 10. Clinical Tests / Publications

No additional clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided. Furthermore, no additional clinical publications were needed referenced to provide information on the use of the following features and functions, since this was sufficiently done for the predicate device.

## 11. 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, MAGNETOM Altea, MAGNETOM Sola Fit with software *syngo* MR XA51A 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 II (ES/ EMC) | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) | ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) | ANSI AAMI |
| 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 |
| 5-40 | General I (QS/ RM) | Medical devices - Application of risk management to medical devices | 14971 Second edition 2007-03-01 | 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. Conclusion as to Substantial Equivalence

MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit with software *syngo* MR XA51A has the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Vida with *syngo* MR XA50A, 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, MAGNETOM Altea, MAGNETOM Sola Fit with software *syngo* MR XA51A is substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA50A (K213693, cleared on February 25, 2022).