Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Professional
40 Liberty Blvd., Mail Code 65-1A
MALVERN PA 19355

February 28, 2020

Re: K192496
Trade/Device Name: MAGNETOM Sola, MAGNETOM Altea, and 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: January 23, 2020
Received: January 28, 2020

Dear Cordell Fields:

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, PhD.
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)*
K192496

Device Name
MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit

Indications for Use *(Describe)*
Your 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.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display 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.

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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
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared:

September 9, 2019

Manufacturer:

Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany
Registration Number: 3002808157
For MAGNETOM Sola and MAGNETOM Altea:
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

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3. Device Name and Classification

Device name:	MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit
Trade name:	MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit
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 Device

Trade name:	MAGNETOM Sola
510(k) Number:	MAGNETOM Sola
Clearance Date:	K181322, K182129, cleared October 5, 2018 (K181322), October 12, 2018 (K182129)
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

5. Intended Use

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

Your 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.

Your 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

MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit with software *syngo* MR XA20A includes new and modified hardware and software compared to the predicate device, MAGNETOM Sola with software *syngo* MR XA11A. A high level summary of the hardware and software is provided below:

Hardware

Hardware

- Computer
- Nose Marker for Inline Motion Correction

Coils

- BM Body 18: The new BM Body 18 coil is a receive coil with 18 elements and is based on the Body 18 coil, (cleared with K101347). It is a general purpose coil.
  The BM Body 18 coil can be used with two different cables of different length; this capability was introduced with the BM Body 12 coil.

Software

Features and Applications

- SMS for TSE_DIXON: Simultaneous excitation and acquisition of multiple slices with the Simultaneous multi-slice (SMS) technique for TSE Dixon imaging.
- GOLiver is a set of optimized pulse sequence for fast and efficient imaging of the abdomen / liver. It is designed to provide consistent exam slots and to reduce the workload for the user in abdominal / liver MRI.
- Angio TOF with Compressed Sensing (CS): The Compressed Sensing (CS) functionality is now available for TOF MRA within the BEAT pulse sequence type for the 1.5 T MR systems. Scan time can be reduced by an incoherent undersampling of k-space data. The usage of CS as well as the acceleration factor and further options can be freely selected by the user.
- RT Respiratory self-gating for FL3D_VIBE: Non-contrast abdominal and thoracic examination in free breathing with reduced blur induced by respiratory motion.
- SMS for RESOLVE and QDWI: Simultaneous excitation and acquisition of multiple slices with the Simultaneous multi-slice (SMS) technique for readout-

segmented echo planar imaging (RESOLVE) and quiet diffusion weighted imaging (QDWI).
- SPACE with Compressed Sensing (CS): The Compressed Sensing (CS) functionality is now available for the SPACE pulse sequence type. Scan time can be reduced by the incoherent under-sampling of the k-space data. The usage of CS as well as the acceleration factor and other options can be freely selected by the user.
- SEMAC: SEMAC is a method for metal artifact correction in ortho imaging of patients with whole joint replacement. Using Compressed Sensing the acquisition can be accelerated.
- TSE_MDME: A special variant of the TSE pulse sequence type which acquires several contrasts (with different TI and TE, i.e. Multi Delay Multi Echo) within a single sequence.
- TFL (3D MPRAGE), TSE and GRE with Inline Motion Correction: 3D MPRAGE, TSE and GRE with Inline Motion Correction: Tracking of motion of the head during head scans with a nose marker and a camera system. The MR system uses the tracking information to compensate for the detected motion.
- EP_SEG_PHS: pulse sequence type EP_SEG_PHS, based on BEAT_EPI and modified with a silent period that can be used by external devices/applications for synchronization with the MR imaging
- GRE_PHS: pulse sequence type GRE_PHS, is a GRE pulse sequence type, modified to provide a silent period that can be used by external devices/applications for synchronization with the MR imaging.
- GRE_Proj: The GRE projection pulse sequence type “” allows the acquisition of 1-D projection data for different orientations.
- GOKnee2D: GOKnee2D is a set of multi-band pulse sequence types with Simultaneous Multislice TSE for fast and efficient imaging of the knee. It is designed to provide consistent exam slots and to reduce the workload for the user in Knee MRI.
- BEAT_interactive: The BEAT_Interactive pulse sequence type is a modification of the BEAT_IRTTT pulse sequence type in order to interactively increase the slice thickness and switch on and off a magnetization pulse that the user can select prior to the measurement start.
- EP2D_SE_MRE: As an alternative of greMRE, EP2D_SE_MRE pulse sequence type is based on single-shot EP2D_SE_MRE sequence. It offers acquisition of multiple slices in a single, short breath-hold, and it is more robust against signal dephasing effects while providing comparable relative stiffness values.
- ZOOMit DWI: *syngo* ZOOMit based on EPI diffusion allows diffusion weighted imaging (DWI) while avoiding signal and artifacts from surrounding tissue. The feature is now available for 1-ch-systems and enables improved robustness to infolding artifacts from tissue from outside the excited region.

- SPACE Flair Improvements: SPACE pulse sequence type offers a magnetization preparation mode for brain imaging with FLAIR contrast (FLuid Attenuated Inversion Recovery); improving the image quality of FLAIR images.
- External Phase Correction Scan for EPI Diffusion: Separate N/2 Nyquist ghost correction acquisition method for diffusion imaging in the presence of fat.
- MR Breast Biopsy Workflow improvements: The changes made to MR Breast Biopsy application target two areas: the improved readability of planning results and the ability to handle the planning of multiple biopsy targets.
- GOBrain / GOBrain+: GOBrain (brain examination in short acquisition time) GOBrain+ (adaptation of GOBrain pulse sequences)

Software / Platform

- Dot Cockpit: MR Protocol Manager as part of a scanner fleet with connection via a share.
- Access-i: The interface Access-i allows 3rd party devices to establish a bi-directional communication with the MR scanner via a secure local network connection, supporting data transfer to and triggering of data acquisition from the 3rd party device. It enables the 3rd party client to control and edit a measurement program on the MR.
- Table positioning mode: A new table positioning mode “FIX” is introduced which complements the existing table positioning modes ISO and LOC to support workflows in which the user needs to be in control of a defined Z-position at which measurements get executed.

Other Modifications and / or Minor Changes

- MAGNETOM Sola Fit: The MAGNETOM Sola Fit is a new MRI System which is the result of an upgrade from a MAGNETOM Aera.
- BM Body 12: For MR examinations of head and neck in situations where a rigid rf head coil cannot be used, e.g. with patients positioned in thermoplastic masks used for radiotherapy planning, aiming at higher signal-to-noise and spatial resolution as what can be achieved with 4-channel Flex rf coils
- Body 18: For MR examinations of head and neck in situations, where a rigid rf head coil cannot be used, e.g. with patients positioned in thermoplastic masks used for radiotherapy planning, aiming at higher signal-to-noise and spatial resolution than what can be achieved with 4-channel Flex rf coils
- UltraFlex Large 18, UltraFlex Small 18: For MR examinations of head and neck in situations, where a rigid rf head coil cannot be used, e.g. with patients positioned in thermoplastic masks used for radiotherapy planning, aiming at higher signal-to-noise and spatial resolution than what can be achieved with 4-channel Flex rf coils
- Broad band / narrow band online supervision: The broadband/narrowband supervision checks the correctness of the measurement values used for the

SAR calculation. With *syngo* MR XA20A, the supervision cycle is reduced significantly.
- LiverLab Dot Engine - debundling: LiverLab is now offered separately as standalone workflow and is also still available as part of the Abdomen Dot Engine.
- The 1.5T system MAGNETOM Altea is made available to the marked with software *syngo* MR XA20A.

7. Substantial Equivalence

MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit with software *syngo* MR XA20A are substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola with *syngo* MR XA11A	K181322, K182129, cleared October 5, 2018 (K181322), October 12, 2018 (K182129)	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit with software *syngo* MR XA20A includes hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Aera with software *syngo* MR E11C-AP01	K182299 cleared October 26, 2018	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Aera with *syngo* MR E11C-AP02	K163312 cleared January 27, 2017	LNH, LNI, MOS	Siemens AG / Siemens Healthcare GmbH
MAGNETOM Aera with *syngo* MR E11C	K153343 cleared April 15, 2016	LNH	Siemens AG / Siemens Healthcare GmbH
MAGNETOM Vida with software *syngo* MR XA11B	K183254 cleared January 18, 2019	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Skyra with *syngo* MR D13C	K123510 cleared May 17, 2013	LNH	Siemens AG
MAGNETOM Lumina with syngo MR XA11B	K183244 cleared January 24, 2019	LNH LNI, MOS	Siemens Healthcare GmbH

8. Technological Characteristics

The subject devices, MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit with software *syngo* MR XA20A, 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.

While there are some differences in technological characteristics between the subject devices and predicate device, including new and modified hardware and software, these differences have been tested and the conclusions 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
Sample clinical images	coils, new and modified software features	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessments by sample clinical images. In some cases a comparison of the image quality / quantitative data was made.	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	
Performance bench test	mainly new and modified hardware	
Software verification and validation	mainly new and modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Biocompatibility	surface of applied parts	ISO 10993-1
Electrical, mechanical, structural, and related system safety test	complete system	- AAMI / ANSI ES60601-1 - IEC 60601-2-33
Electrical safety and electromagnetic compatibility (EMC)	complete system	IEC 60601-1-2

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

10. Clinical Tests

No additional clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided. Clinical publications were referenced to provide information on the use of some features and functions.

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 and MAGNETOM Sola Fit with software *syngo* MR XA20A conform 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	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, Ed. 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. 3.2:2015	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971, Ed. 2:2007-10	ISO
5-114	General	Medical devices – Application of usability engineering to medical devices	62366, Ed. 1.0:2015	AAMI ANSI IEC
13-79	Software	Medical device software - Software life cycle processes	62304:2015-06	AAMI ANSI IEC

12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA
12-288	Radiology	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)	MS 9:2008	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20:2016	NEMA
2-220	Biocompatibility	Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process (Biocompatibility)	10993-1:2009	AAMI ANSI ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Sola, MAGNETOM Altea and MAGNETOM Sola Fit with software *syngo* MR XA20A have the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Sola with *syngo* MR XA11A. While there are some differences in technilogical characteristics/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 and MAGNETOM Sola Fit with software *syngo* MR XA20A are substantially equivalent to the currently marketed predicate device MAGNETOM Sola with software *syngo* MR XA11A (K181322, K182129, cleared on October 5, 2018 (K181322), October 12, 2018 (K182129)).