October 12, 2018

Siemens Medical Solutions USA, Inc.
Cordell Fields
Regulatory Specialist
65 Valley Stream Parkway 65-1A
MALVERN, PA 19355

Re: K182129
Trade/Device Name: MAGNETOM Sola
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: October 2, 2018
Received: October 3, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4 Indications for Use Statement

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)*

K182129

Device Name

MAGNETOM Sola

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 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.

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Section 5 510(k) Summary

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

I. General Information

Establishment Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared August 3, 2018

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

Contact Person Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
Cordell.Fields@siemens-healthineers.com

Device Name MAGNETOM Sola

Trade Name MAGNETOM Sola

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

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

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

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.

Device Description

MAGNETOM Sola with XJ gradient system is similar to the predicate device MAGNETOM Aera with *syngo* MR E11C (K153343) except for some new and modified software and hardware. A high level summary of the hardware and software compared to the MAGNETOM Aera with *syngo* MR E11C device is included below:

Hardware

New Hardware

- Main components such as:
  - magnet
  - gradient coil
  - patient table (fixed and mobile)
- New coils:
  - Body Coil
  - BM Head/Neck 20
  - BM Spine 48
  - BM Spine 32
  - UltraFlex Large 18
  - UltraFlex Small 18

  - Shoulder Shape 16
  - TX/RX Knee 18
  - BM Spine 24
  - BM Body 12
  - Peripheral Angio 16
  - Head/Neck 16 MR Coil 1.5T (Same as with predicate device, MAGNETOM Aera)
- Other components such as:
  - helium compressor
  - cover includes new touch displays and redesigned control island
  - computers and monitor
  - Respiratory Sensors (respiratory sensor loops)
  - camera
  - Multi-Channel Interface

Modified Hardware

- Main components such as gradient power amplifier and patient communication unit as well as 32 independent RF channels
- Other components such as RF power amplifier, magnet supervision, electronic cabinet and measurement control components

Software

New Features and Applications

- SliceAdjust (framework for pulse sequence types which allows applying adjustment settings dynamically to measured sub-volumes during the measurement.)
- Whole-Body Dot Engine (supports multi-region examinations with consistent settings for spatial resolution, image contrast, and breath-hold capacity)
- Compressed Sensing GRASP-VIBE (conduct dynamic contrast-enhanced abdominal exams in free breathing)
- CoilShim (reduces patient induced strongly localized B0 inhomogeneities by generating the respective anatomy-specific B0 field with local shim coil elements integrated in the local Rx coil BM Head/Neck 20

- GOKnee3D (examination which comprises the AutoAlign knee localizer and two SPACE with CAIPIRINHA sequences to support fast high-resolution 3D exams of the knee)
- SPACE with CAIPIRINHA (3D SPACE pulse sequence type now offers the iPAT mode CAIPIRINHA)
- Respiratory Sensor Support (support for respiratory triggered measurements is provided in several SE-, GRE- and EPI-based pulse sequence types)
- MRSim / Synthetic CT (provides MR pulse sequences for the creation of Synthetic CT images based on the MR image input)
- Cardiac Dot Flow Add-In (extension of Cardiac Dot Engine to support blood flow measurements)
- PCASL mode (extension of ASL pulse sequence types by a new blood labeling mode)
- SMS in TSE (Simultaneous Multi Slice (SMS) support for TSE)

New Software / Platform

- Software platform (new software version *syngo* MR XA11A based on the Numaris/X software which combines the software of the predicate device and the reference device with modifications and extensions as well as changed structure and design of the user interface and changed post processing integration.)
- General workflow (scanning tab-card / left-hand side (LHS) and viewing and processing tab-card / right-hand side (RHS) concept with single / dual monitor workflow where patient handling and scanning is separated from post-processing and data handling. The scanning tab-card / “LHS” contains scan-related elements such as the Scheduler and scan UI and displays the inline processed images. At the viewing and processing tab-card / on the “RHS” additional results can be generated in the form of basic and advanced post-processing including data handling and result distribution.)
- User role concept (five user roles with different rights)
- Distribution step (allows the selection of data sets for archiving and DICOM transfer within MR View&GO)
- 4D Viewing (allows the visualization of 4D data such as different phases, b-values or echoes of one DICOM series within MR View&GO and allows temporal (phase navigation in 4D data sets) and spatial scrolling.)
- Launcher Step (starts an advanced application as a viewing and processing tab-card / on the RHS)
- Multiframe DICOM format (now available in addition with improvements in performance, application support, navigation and data interchange.)

- Touch positioning (Select&GO 2.0) (to position the exam region in the isocenter by using the touch displays integrated in the system cover. Select&GO 2.0 has been extended to additional body area positions if dedicated coils are plugged in)

Modified Features and Applications

- Compressed Sensing Cardiac Cine (An option to enable Compressed Sensing Cardiac Cine is integrated into the BEAT pulse sequence type. The total acceleration factor is a user-interface parameter that controls the degree of k-space under-sampling. Compressed Sensing Cardiac Cine can be performed in single-shot and in multi-shot mode.)
- RetroGating (Compressed Sensing Cardiac Cine acquisitions which split the data acquisition over multiple heartbeats can now be configured to perform complete sampling of the cardiac cycle without prior definition of an acquisition window. Combination with arrhythmia rejection is possible.)
- Dixon fat/water separation (improvement for a more robust assignment of local fat and water regions to the respective image)
- Pre-Scan-Normalize (Improvements with the goal to correct MRI images for local coil sensitivity variations and to generate homogenous MRI images. Three different matrix sizes are available now.)
- iPAT / TSE Reference Scan (Improvements in the VIBE and in the HASTE pulse sequence types to improve the image quality. Changes in the VIBE pulse sequence type concern the k-space reordering, the external GRE reference scan and the minimal slice oversampling. Changes in the HASTE, TSE, FAST_TSE and TSE_DIXON pulse sequence types includes the possibility to use a reference scan “TSE/Separate” for GRAPPA acquisition and reconstruction)
- HeartFreeze (extended to support multiple repeats and averaging of the same slice acquired at the same phase of the cardiac cycle in combination with non-selective inversion recovery imaging)
- Care Bolus in Angio Dot Engine (workflow support for bolus administration (bolus detection))
- MRCP in SPACE (improvement of image quality for MR Cholangiopancreatography (MRCP) acquisitions based on the SPACE pulse sequence type)
- MR Elastography (Replacement of existing masking by a masking that is performed on the pre-scan images used also within the pre-scan normalize (PSN) functionality. Optimization of pulse sequence type timing. Changes in MEG time period (no longer fixed to the wavelength of the MEG and also implementation of a reduced MEG period))

Modified (general) Software / Platform

- Scheduler (two components (Patient Registration and Scheduler) consolidated.)
- Table Positioning Mode (Automated movement of table provided on examination level so that the scan is performed in the magnet isocenter. Additionally the "LocalRange" positioning mode can be used for smaller regions like e.g. the heart or the brain.)
- Spectroscopy Add-in (enables planning on non-distortion corrected images for spectroscopy.)
- MR View&GO (For quality assurance, image viewing, basic post-processing, printing and result distribution. The functionality is provided in workflow steps which provide guidance, allow independent work and does not require any reloading of data. Addition of Mosaic View (view mode to scroll through dimensions instead of space) and 4D Movie Toolbar (movie toolbar is usable to navigate through the 4th dimension))
- Prior Handling (for the display of available priors)
- System Start and Shutdown (improvements with a System Start Timer and shutdown unattended by the user)
- Dot Cockpit (additional features for handling of scan pulse sequences and offline Dot Cockpit)

Other Modifications and / or Minor Changes

- SAR Assistant (two additional options for selection)
- Noise masking (to remove the noise floor in outer regions)
- MAGNETOM RT Pro Edition marketing bundle (extension of the bundle)
- MAGNETOM Sola Cardiovascular Edition marketing bundle (bundle of components for cardiovascular MR imaging with extension with additional components)
- Siemens "BioMatrix" (BioMatrix consists of three core technologies, Sensors, Tuners and Interfaces, all of which address different aspects of patient bio-variability with extension with additional components)
- Siemens „Healthineers" (new Siemens brand)
- Improved Adjustments (frequency adjustment optimized for more reliable water peak detection, and FastView adjustments extended to be available for all kind of data selectable in the user interface)

- Cooling Cabinet (increased cooling capacity and improvements)
- BEAT_IRTTT (extends BEAT_IRT sequence with a multi-slice functionality and introduces some parameters. “TTT” stands for the extension of BEAT_IRT to three dimensions)
- Vacuum pump (automatic switching mechanism)
- teamplay Protocols Interface (interface to support external pulse sequences management systems)
- Unilateral Hip (added in Large Joint Dot Engine) (user workflow optimized, since information/settings from the patient registration are taken)
- GRE RefScan (external GRE RefScan has been extended to multiple pulse sequence types)
- Asymmetric saturation pulses (support for regional saturation with an asymmetric shape has been added for BOLD imaging)
- CP Mode modification (“RF Transmit Mode” is provided as part of the patient registration based on IEC 60601-2-33)
- MR Breast Biopsy (support of breast coils has been changed)

Technological Characteristics

MAGNETOM Sola with XJ gradient system has different technological characteristics than the predicate device MAGNETOM Aera (K153343; cleared April 15, 2016). New and modified software with respect to the predicate device systems and the different technological characteristics are described.

The subject device is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

MAGNETOM Sola with XJ gradient system conforms to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

This submission includes new and modified hardware including new coils in comparison to the predicate device.

Nonclinical Tests

The following performance testing was conducted on the subject device

- Sample clinical images were taken in particular for the coils
- Software verification and validation testing was completed in accordance with the FDA guidance document, “*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*”

- Performance tests were completed in accordance with the FDA guidance document, “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices” dated November 18, 2016
- Verification & Validation was completed for hardware modifications

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

Clinical Tests

A clinical study of 40 individuals was conducted to determine the nerve stimulation thresholds used to limit the gradient system output. The observed parameters were used to set the PNS (Peripheral Nerve Stimulation) threshold level which is required in IEC 60601-2-33.

No additional clinical tests were conducted to support the subject device and the substantial equivalence argument; however, sample clinical images were provided to support the new coils of the subject device per the MR guidance document.

Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 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 in hardware and software development, testing and product labeling. To minimize risks, Siemens adheres to recognized and established industry practices and standards, such as the IEC 60601-1 series, to minimize electrical and mechanical risk. Furthermore, the operators are healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Sola with XJ gradient system conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regard to performance and safety as recommended by the respective MR FDA Guidance Document as stated in the following table.

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 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. 3.2:2015	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-10	ISO
5-96	General	Medical devices – Application of usability engineering to medical devices	62366 Edition 1.0 2015	AAMI ANSI IEC
13-32	Software	Medical device software - Software life cycle processes	62304:2006	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
2-156	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1:2009/(R) 2013	AAMI ANSI ISO

Substantial Equivalence

MAGNETOM Sola with XJ gradient system includes most of the features of the predicate device and additional new and modified hardware and software as noted above.

Predicate device	**FDA Clearance Number and Date**	**Product code**	**Manufacturer**
MAGNETOM Aera with *syngo* MR E11C	K153343, cleared April 15, 2016	LNH LNI,MOS	Siemens AG / Siemens Healthcare GmbH
Reference Devices	**FDA Clearance Number and Date**	**Product code**	**Manufacturer**
MAGNETOM Vida with software *syngo* MR XA10A	K170396, cleared June 14, 2017	LNH LNI,MOS	Siemens Healthcare GmbH
MAGNETOM Amira with *syngo* MR E11S	K173600 cleared December 19, 2017	LNH LNI,MOS	Siemens Shenzhen Magnetic Resonance Ltd.

Conclusion as to Substantial Equivalence

MAGNETOM Sola with XJ gradient system has the same intended use and different technological characteristics than the predicate device system, MAGNETOM Aera with *syngo* MR E11C, with respect to the magnetic resonance features and functionalities. While there are some technical features that vary with respect to the predicate device MR System, the conclusions from all verification and validation data suggest that the features with different technological characteristics from the predicate device bear an equivalent safety and performance profile as that of the predicate device and the reference devices.

MAGNETOM Sola does not introduce any new issues of safety or effectiveness. Therefore, Siemens is of the opinion that MAGNETOM Sola with XJ gradient system is substantially equivalent to the legally marketed predicate device MAGNETOM Aera with software *syngo* MR E11C (K153343, cleared on April 15, 2016).