October 19, 2018

Siemens Medical Solutions USA, Inc.
Martin Rajchel
Regulatory Affairs Specialist
40 Liberty Boulevard
Mail Code 65-1A
MALVERN, PA 19355

Re: K181433
Trade/Device Name: MAGNETOM Vida
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: September 26, 2018
Received: September 27, 2018

Dear Martin Rajchel:

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

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)*

K181433

Device Name

MAGNETOM Vida

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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
May 31, 2018

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

2. Contact Information

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3. Device Name and Classification

Device Name:	MAGNETOM Vida
Trade Name:	MAGNETOM Vida
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

4. Legally Marketed Predicate Device

Trade Name:	MAGNETOM Vida
510(k) Number:	K170396, cleared June 14, 2017
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

5. Intended Use

The indications for use for the subject device 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 Vida with software *syngo* MR XA11A includes new and modified hardware and software compared to the predicate device, MAGNETOM Vida with *syngo* MR XA10A. A high level summary of the new and modified features is provided below:

Hardware

New Hardware

- New coils:
  - BM Body 12
  - BM Spine 24
  - Head/Neck 16
  - Head 32 MR Coil 3T
- Other components:
  - camera
  - computer
  - Multi-Channel Interface

Modified Hardware

- Main components such as 32 independent RF channels
- Other components such as Tx-Box / RF filter plate / transmit system

Software

New Features and Applications

- GOKnee3D (examination comprising 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 with the iPAT mode CAIPIRINHA)
- GOBrain (brain examination in short acquisition time)
- GOBrain+ (adaptation of GOBrain pulse sequences)
- MR Breast Biopsy (supports planning and execution of MR guided breast biopsies and wire localizations)
- 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)

Modified Features and Applications

- SliceAdjust (the framework support was extended to include additional pulse sequence types)
- 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.)
- iPAT / TSE Reference Scan (Changes in the TSE, FAST_TSE and TSE_DIXON pulse sequence types includes the possibility to use a reference scan “TSE/Separate” for GRAPPA acquisition and reconstruction)
- Care Bolus in Angio Dot Engine (workflow support for bolus administration (bolus detection))

- MRCP in SPACE (improvement of the image quality for MR Cholangiopancreatography (MRCP) acquisitions based on the SPACE pulse sequence type)
- MR Elastography:
  - Replacement of existing masking by masking performed on the prescan images used within the prescan/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)
- Respiratory Sensor Support (additional support for respiratory triggered measurements is provided in several SE-, GRE- and EPI-based pulse sequence types)

Modified (general) Software / Platform

- Single and dual monitor workflow (In the single monitor setup the features of the LHS monitor and RHS monitor are provided on separate tab-cards)
- Touch positioning (Select&GO 2.0) (extension to additional body area positions when dedicated coils are plugged in)
- Dot Cockpit (additional features for handling of scan pulse sequences and offline Dot Cockpit)
- MR View&GO (Addition of Mosaic View (view mode to scroll through dimensions instead of space) and 4D Movie Toolbar (movie toolbar to navigate the 4th dimension))

Other Modifications and / or Minor Changes

- 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 are taken from the patient registration)
- 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)

- SPAIR FatSat (new “SPAIR Breast” mode in several pulse sequence types and extension of “Abdomen&Pelvis” and “Thorax” modes)
- Compressed Sensing GRASP-VIBE (improvement of SPAIR fat saturation performance)
- MAGNETOM RT Pro Edition marketing bundle (extension of the bundle)
- Siemens “BioMatrix” (extension with additional components)

7. Technological Characteristics

The subject device, MAGNETOM Vida with software *syngo* MR XA11A, is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system, and performance.

MAGNETOM Vida with software *syngo* MR XA11A conforms to the standard for medical device software (IEC 62304:2006) and other relevant IEC and NEMA standards.

While there are some differences in technological characteristics between the subject device and predicate device, including new and modified software applications and hardware additions, 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.

8. Nonclinical Tests

The following performance testing was conducted on the subject device:

- Sample clinical images were taken for the new coils and new and modified software features.
- Image quality assessments of all new/modified pulse sequence types and algorithms were completed. In some cases a comparison of the image quality was made between the new/modified features and the predicate device features.
- 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*”, dated May 11, 2005.
- Performance tests were completed in accordance with the FDA guidance document, “*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*” dated November 18, 2016.

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.

9. Clinical Tests

No clinical tests were conducted to support substantial equivalence for the subject device; however, sample clinical images were provided to support the new coils and new/modified hardware and software features per the FDA guidance document "*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*", dated November 18, 2016. Clinical publications were referenced to provide information on the use of some features and functions.

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 ISO 14971:2007 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 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 risks. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Vida with software *syngo* MR XA11A 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	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

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
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

11. Substantial Equivalence

MAGNETOM Vida with software *syngo* MR XA11A is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product code	Manufacturer
MAGNETOM Vida with *syngo* MR XA10A	K170396, cleared June 14, 2017	LNH LNI,MOS	Siemens Healthcare GmbH

MAGNETOM Vida with *syngo* MR XA11A includes features already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product code	Manufacturer
MAGNETOM Skyra with *syngo* MR E11C-AP04	K173592, cleared February 13, 2018	LNH LNI,MOS	Siemens Healthcare GmbH
MAGNETOM Skyra with *syngo* MR E11C	K153343, cleared April 15, 2016	LNH LNI,MOS	Siemens AG / Siemens Healthcare GmbH
MAGNETOM Skyra with *syngo* MR E11C-AP02	K163312, cleared January 27, 2017	LNH LNI,MOS	Siemens Healthcare GmbH
Compressed Sensing GRASP-VIBE for MAGNETOM Vida with *syngo* MR XA10A	K173617, cleared March 30, 2018	LNH LNI,MOS	Siemens Healthcare GmbH
syngo.via VB30A based on *syngo*.via VB10A	*syngo*.via VB10A: K150843, cleared April 24, 2015	LLZ	Siemens Healthcare GmbH

12. Conclusion as to Substantial Equivalence

MAGNETOM Vida with software *syngo* MR XA11A has the same intended use and same technological characteristics as the predicate device system, MAGNETOM Vida with *syngo* MR XA10A, 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 Vida with software *syngo* MR XA11A is substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA10A (K170396, cleared on June 14, 2017).