Siemens Medical Solutions, USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN PA 19355

January 18, 2019

Re: K183254
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 and MOS
Dated: November 19, 2018
Received: November 21, 2018

Dear Mr. 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,

Michael D. O'Hara For

Robert 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)*

K183254

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.

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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 November 19, 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:	K181433, cleared October 19, 2018
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 XA11B includes new and modified component, features and software compared to the predicate device, MAGNETOM Vida with *syngo* MR XA11A. A high level summary of the new and modified features is provided below:

Hardware

New Hardware

- Nose Marker for Inline Motion Correction

Software

New Features and Applications

- TFL with Inline Motion Correction: Tracking of motion of the head during 3D MPRAGE head scans with a nose marker and a camera system. The MR system uses the tracking information to compensate for the detected motion.

- GOLiver: 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.
- 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.
- 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.
- Angio TOF with Compressed Sensing: The Compressed Sensing (CS) functionality is now available for TOF MRA within the BEAT pulse sequence type. 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.
- 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: 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.
- RT Respiratory self-gating for FL3D_VIBE: Non-contrast abdominal and thoracic examination in free breathing with reduced blur induced by respiratory motion.

Other Modifications and / or Minor Changes

- Turbo Suite is a marketing bundle of components for accelerated MR imaging offered for the MAGNETOM Vida MR systems.
- Noise masking: a mechanism to remove the noise floor in outer regions is now available for RESOLVE and QDWI.

7. Technological Characteristics

The subject device, MAGNETOM Vida with software *syngo* MR XA11B, 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 XA11B 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 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/modified component 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 XA11B 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
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

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
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 XA11B is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product code	Manufacturer
MAGNETOM Vida with *syngo* MR XA11A	K181433, cleared October 19, 2018	LNH LNI,MOS	Siemens Healthcare GmbH

MAGNETOM Vida with *syngo* MR XA11B includes features already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product code	Manufacturer
Biograph mMR with *syngo* MR E11P	K163234, cleared February 28, 2017	OUO LNH, LNI, KPS	Siemens Healthcare GmbH
syngo.via VB30A[2] 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 XA11B has the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Vida with *syngo* MR XA11A, with respect to the magnetic resonance features and functionalities. While there are some differences in technical features

[2] Change released by internal documentation based on *syngo*.via VB10 (K150843).

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 XA11B is substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA11A (K181433, cleared on October 19, 2018).