U.S. FOOD & DRUG ADMINISTRATION

February 24, 2023

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

Re: K213805
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: January 27, 2023
Received: January 27, 2023

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/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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K213805

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 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.

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
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: February 16, 2023

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

2. Contact Information

Martin Rajchel
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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:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

4. Legally Marketed Predicate Devices

i. Predicate for MAGNETOM Vida with software *syngo* XA31A and pulse sequence MR Fingerprinting

Trade name:	MAGNETOM Vida
510(k) Number:	K203443
Clearance Date	March 31, 2021
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

ii. Predicate for MAGNETOM Vida with software *syngo* XA20A and pulse sequence MR Fingerprinting

Trade name:	MAGNETOM Vida
510(k) Number:	K192924
Clearance Date:	March 11, 2020
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

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

The subject devices, MAGNETOM Vida with software *syngo* MR XA31A, and MAGNETOM Vida with *syngo* MR XA20A, with the new pulse sequence MR Fingerprinting (MRF) consists of slightly modified software that are similar to

what is currently offered in the predicate devices, MAGNETOM Vida with *syngo* MR XA31A (K203443) and MAGNETOM Vida with *syngo* MR XA20A (K192924) respectively.

The subject devices MAGNETOM Vida with software *syngo* MR XA31A, and MAGNETOM Vida with *syngo* MR XA20A includes features that were cleared under K203443 and K192924 respectively. In addition to these features, the subject devices include a new pulse sequence type called MR Fingerprinting (MRF), a method that permits the simultaneous non-invasive quantification mapping of MRF-derived T1 and T2 relaxation times of brain tissue. The MRF is not intended to yield the ground truth T1 and T2 relaxation times of brain tissue.

7. Substantial Equivalence

MAGNETOM Vida with software *syngo* MR XA31A and the pulse sequence MRF is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA31A	K203443, cleared March 31, 2021	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Vida with software *syngo* MR XA20A and the pulse sequence MRF is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA20A	K192924, cleared March 11, 2020	LNH LNI, MOS	Siemens Healthcare GmbH

The software sequence for MRF is identical in the device software versions *syngo* MR XA31A and *syngo* MR XA20A.

8. Technological Characteristics

The MR Fingerprinting (MRF) is the one new function within software versions *syngo* MR XA20A and *syngo* MR XA31A for MAGNETOM Vida.

There are differences in technological characteristics between the subject devices and predicate devices. The underlying software (*syngo* MR XA20A and *syngo* MR XA31A) are identical to the predicate, and the inclusion of MRF is the only difference in terms of technological characteristics.

The subject device conforms to the standard for medical device software (IEC 62304) and other relevant IEC and NEMA standards

9. Nonclinical Tests

The following performance testing was conducted on the subject device.

Performance Test	Tested Software	Source/Rationale
Sample clinical images	New feature “MR Fingerprinting” with the new 2D FISP MR-Fingerprinting pulse sequence type as part of the software version syngo MR XA20A and syngo MR XA31A*.	Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (November 2016)
Performance bench test	Phantom and volunteer testing for quantitative evaluation of MRF-derived T1 and T2 values	
Software verification and validation	New feature “MR Fingerprinting” with the new 2D FISP MR-Fingerprinting pulse sequence type as part of the software version syngo MR XA20A and syngo MR XA31A.	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)

* The tests were performed with the MR Fingerprinting (MRF) software sequence implemented in syngo MR XA20A. As the MR Fingerprinting (MRF) software sequence is identical between syngo MR XA20A and syngo MR XA31A, the clinical results are also valid for syngo MR XA31A.

For the performance test ‘Sample clinical images’, MRF T1 and T2 maps from volunteers were acquired to confirm the MRF sequence was executed successfully, and the resulting images were free of any obvious artifacts or degradations.

For the ‘Performance bench test’ repeated MRF T1 and T2 maps were acquired as part of a controlled study setup in phantom and healthy volunteers to evaluate the quantitative performance in terms of precision (repeatability and reproducibility).

The process ‘Software verification and validation’ comprises systematic testing according to the MRF test specification. MRF T1 and T2 maps were retrieved using on a quantitative phantom to confirm that the results were stable and parametric values were reproducible across different systems within specified ranges.

The results from each set of tests demonstrate that the devices perform as intended and is thus substantially equivalent to the predicate devices to which they have been compared.

10. Clinical Tests

A study was performed with 3 healthy volunteers who were scanned multiple times using multiple systems to show the repeatability and reproducibility of the T1 and T2 maps acquired on the subject device and other MAGNETOM 3T scanners. In addition, several clinical patient cases were provided which demonstrated a longitudinal use case scenario, i.e., repeated scans from the same subject to observe changes over time.

The tests were performed with the MR Fingerprinting (MRF) software sequence implemented in syngo MR XA20A. As the MR Fingerprinting (MRF) software sequence is identical between syngo MR XA20A and syngo MR XA31A, the clinical results are also valid for syngo MR XA31A.

Clinical publications were referenced to provide additional clinical information on the new MR Fingerprinting method.

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 devices.

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 Healthineers 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 Vida with software *syngo* MR XA31A and MAGNETOM Vida with software *syngo* MR XA20A 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, Ed. 4.0:2014	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	ISO
5-114	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

12. Conclusion to Substantial Equivalence

MAGNETOM Vida with software *syngo* MR XA31A and the new pulse sequence MRF has the same intended use and similar technological characteristics compared to the predicate device, MAGNETOM Vida with *syngo* MR XA31A (K203443), with respect to the magnetic resonance features and functionalities. Similarly, MAGNETOM Vida with software *syngo* MR XA20A and the new pulse sequence MRF has the same intended use and similar technological

characteristics compared to the predicate device MAGNETOM Vida with *syngo* MR XA20A (K192924).

The difference between the subject device and predicate device is the addition of the new pulse sequence “MRF”. The difference has been tested and the conclusions from the non-clinical and clinical data suggests that the feature bears an equivalent safety and performance profile to that of the predicate device.

Siemens believes that the addition of the new pulse sequence “MRF” to MAGNETOM Vida with software *syngo* MR XA31A and MAGNETOM Vida with software *syngo* MR XA20A is substantially equivalent to the currently marketed devices MAGNETOM Vida with software *syngo* MR XA31A (K203443, cleared on March 31, 2021) and MAGNETOM Vida with software *syngo* MR XA20A (K192924, cleared on March 11, 2020) respectively.