Siemens Medical Solutions USA, Inc.
% Milind Dhamankar, M.D.
Senior Clinical Affairs Specialist
40 Liberty Boulevard
MALVERN PA 19355

February 15, 2019

Re: K183222
Trade/Device Name: MAGNETOM Terra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: January 29, 2019
Received: January 30, 2019

Dear Dr. Dhamankar:

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

SIEMENS

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)*
k183222

Device Name
MAGNETOM Terra

Indications for Use *(Describe)*

The MAGNETOM Terra system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, and that displays the internal structure and/or function of the head or extremities. Other physical parameters derived from the images may also be produced.

Additionally the MAGNETOM Terra is intended to produce Sodium images for the head and Phosphorus spectroscopic images and/or spectra for whole body, excluding the head.

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.

The device is intended for patients > 30 kg/66 lbs.

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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510(k) Summary: MAGNETOM Terra

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: November 19, 2018

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.

1. General Information

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

Manufacturing Site:
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Establishment Registration Number: 3002808157

Contract Manufacturers:

Quality Electrodynamics for 1Tx28Rx Knee Coil 7T Clinic coil
6655 Beta Drive, Suite 100
Mayfield Village, OH 44143, USA
Establishment Registration Number: 3007350713

Nova Medical, Inc. for 1Tx32Rx Head Coil 7T Clinic coil
150 West Street Suite 201
Wilmington, MA 01887, USA
Establishment Registration Number: 3004531751

Rapid Biomedical GmbH for:
31P/1H TxRx Flex Loop 7T
23Na 1Tx32Rx Head 7T
Technologiepark Wuerzburg-Rimpar
Kettelerstraße 3-11
D-97222 Rimpar, Germany
Establishment Registration Number: 3005049692

2. Contact Person:

Milind Dhamankar, M.D.
Senior Clinical Affairs Specialist
Siemens Medical Solutions USA, Inc.
Phone: (610) 448-6467
E-mail: mailto:milind.dhamankar@siemens-healthineers.com

3. Device Name and Classification:

Common / Usual Name	7T Magnetic Resonance Imaging system
Trade Name	MAGNETOM Terra with *syngo* MR E12U
Classification Name	Magnetic Resonance Diagnostic Device (MRDD),
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1000
Device Class:	II
Primary Product Code:	LNH
Secondary Product Code:	LNI, MOS

4. Intended Use

The MAGNETOM Terra system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, and that displays the internal structure and/or function of the head or extremities. Other physical parameters derived from the images may also be produced.

Additionally the MAGNETOM Terra is intended to produce Sodium images for the head and Phosphorus spectroscopic images and/or spectra for whole body, excluding the head.

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.

The device is intended for patients > 30 kg/66 lbs.

5. Device Description:

MAGNETOM Terra is a 60 cm bore Magnetic Resonance Imaging system with an actively shielded 7T superconducting magnet. With the interplay of the magnetic field, gradients, radio frequency (RF) transmitter and receiver coil and software this magnetic resonance scanner produces transverse, sagittal, coronal and oblique cross sectional images that represent the spatial distribution of protons with spin.

Additionally the MAGNETOM Terra produce Sodium images for the head and Phosphorus spectroscopic images and/or spectra for the whole body, excluding the head.

For MAGNETOM Terra four local transmit/receive coils for the specific applications are available, these are:

1Tx32Rx Head Coil 7T Clinic; 1Tx28Rx Knee Coil 7T Clinic;

31P/1H TxRx Flex Loop 7T; 23Na 1Tx32Rx Head 7T

Device Modifications

The modifications that are new to the subject device supporting Sodium imaging (23Na) of the head and Phosphorus (31P) spectroscopic images and/or spectra of the whole body, excluding the head.

Hardware

Sodium Imaging of Head

- New RF Power Amplifier for Multi Nuclear Purpose: The RF transmit/receive system of the subject device is modified to enable using of two nuclei (23Na and 31P) besides H-imaging.
- New Coil: 23Na 1Tx32Rx Head 7T double resonant Head Coil for Sodium imaging of the head.

Phosphorus (31P) spectroscopy / Spectroscopic imaging for the whole body, excluding the head.

- New RF Power Amplifier for Multi Nuclear Purpose as mentioned above.
- New Coil: 31P/1H TxRx Flex Loop 7T double resonant loop coil for Phosphorus spectroscopy and Phosphorus imaging of the whole body excluding the head.

Software

Sodium Imaging of the Head

- New pulse sequence type UTE for Sodium head imaging is added to the subject device based on the on the reference device Biograph mMR with *syngo* MR E11P (K172531, cleared November 14, 2017)

- Modified pulse sequence type GRE to enable Sodium head imaging.

Phosphorus (31P) spectroscopy / Spectroscopic imaging for the whole body excluding the head

- New Software Package "Multi Nuclear Spectroscopy" providing Multi Nuclear Support and Spectroscopy Postprocessing applications identical to that of the reference device MAGNETOM Prisma with *syngo* MR E11C-AP04 (cleared with K173592, February 13, 2018).
- New pulse sequence types FID and CSI_FID were added to the subject device based on the on the reference device MAGNETOM Prisma with *syngo* MR E11C-AP04 (cleared with K173592, February 13, 2018).

Modifications to existing software *syngo* MR E11K (K170840).

- Modified SPACE pulse sequence type with CAIPIRINHA acquisition technique named as CAIPIRINHA SPACE
- RESOLVE and qDWI with slice acceleration technique (SMS)
- Further security hardening based on *syngo* MR E11C (latest cleared with MR E11C-AP04 (K173592, cleared February 13. 2018)
- Dual monitor support, to support the user with more efficient use of Dot Cockpit and post-processing parallel to the examination, a second monitor will be offered at the Acquisition Workplace.

6. Technological Characteristics

The subject device, MAGNETOM Terra with *syngo* MR E12U, has different technological characteristics compared to the predicate device, MAGNETOM Terra with *syngo* MR E11K, (K170840 cleared October 12, 2017).

The system and its software were modified to implement new capabilities for Phosphorus spectroscopy of the whole body, excluding the head and Sodium imaging of the head. Two new local Tx/Rx coils are available to support the new applications.

The MAGNETOM Terra with *syngo* MR E12U conforms to the standard for software medical devices (IEC 62304:2015) and IEC as well as NEMA standards.

While there are some differences in technological characteristics between the subject device and predicate device, risk/hazard analysis and non-clinical data support that the addition of new software applications and hardware does not raise different questions of safety and effectiveness.

7. Nonclinical Tests

The following performance testing was conducted on the subject device

- Sample clinical images or Phosphorus spectra were acquired for all modified / new pulse sequences and local coils,

- Image quality assessments of the new Sodium head imaging capabilities, were completed during system test,
- Performance Tests according to IEC 62464-1 as well as surface heating test for the new local coils were completed,
- 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”.

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.

8. Clinical Tests

No additional clinical tests were conducted to support the subject device and the substantial equivalence argument; however, sample clinical images are provided to support the new coils as well as the new and modified hardware and software features of the subject device per the MR guidance document, “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices”. Clinical publications were referenced to provide information on the clinical performance of Sodium head imaging and 31P spectroscopy capabilities.

In addition to providing clinical sample images for the new features of the subject device, reports from one U.S. board-certified radiologist have been provided. The radiologist reviewed Sodium head images of heathy volunteers and patient with respect to their diagnostic quality. Comments on any observed artifacts and concerns have also been included.

9. 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 to potential hazards in a risk analysis beginning early in the design phase and continuing throughout the development of the product. These risks are controlled via measures realized in software development, SW 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.

The MAGNETOM Terra with *syngo* MR E12U conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards 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 2007-03-01	ISO
5-96	General	Medical devices – Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC
13-79	Software	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06	IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4-2010	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	Biocom-patibility	Biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1:2009/(R) 2013	AAMI ANSI ISO

10. Substantial Equivalence

MAGNETOM Terra with *syngo* MR E12U includes most of the features of the predicate device and additional new and modified hardware and software as noted below.

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Terra with *syngo* MR E11K Please note the following parts of the MAGNETOM Terra System are the predicate device parts related to: • System Architecture • RF transmit/receive system • Gradient System • SAR Management and Control System • Computer Systems • Software *syngo* MR E12U • Local Coils • Patient table • Magnet • Cover • Physiological Measurement Devices • Patient communication devices	K170840 cleared October 12, 2017	LNH, LNI, MOS	Siemens AG / Siemens Healthcare GmbH
Reference Devices	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Prisma with *syngo* MR E11C-AP04 Please note the following parts of the MAGNETOM Prisma are the reference device parts related to: • Multi Nuclear Option • Spectroscopy • Security Improvements • Dual Monitor Support • SPACE with CAIPIRINHA acquisition technique	K173592, cleared February 13. 2018	LNH, LNI, MOS	Siemens AG / Siemens Healthcare GmbH
Biograph mMR with *syngo* MR E11P Please note the following parts of the Biograph mMR are the reference device parts related to: • Pulse sequence type	K172531, cleared November 14, 2017	OUO, LNH, LNI, KPS	Siemens AG / Siemens Healthcare GmbH
31P/1H Dual Tuned Surface Coil 3T Reference device parts related to: 31P/1H TxRx Flex Loop 7T double resonant loop coil for Phosphorus spectroscopy of the body and extremities	K102348, cleared December 22, 2010	MOS	Rapid Biomedical GmbH
23Na/1H Head Coil 3T Reference device parts related to: 23Na 1Tx32Rx Head 7T double resonant Head Coil for Sodium imaging of the head	K102748, cleared May 13, 2011	MOS	Rapid Biomedical GmbH

12. Conclusion as to Substantial Equivalence

The modifications to the MAGNETOM Terra with *syngo* MR E12U do not alter the fundamental scientific technology of the magnetic resonance diagnostic device. The modifications extends capability of the cleared MAGNETOM Terra (K170840) to include Phosphorus (31P) spectroscopic capabilities for whole body excluding the head as well as Sodium (23Na) head imaging. These capabilities are a subset of the general use of a MRDD, rather than a new intended use and adds no significant risk to the general Indications for Use of the MAGNETOM Terra.

The MAGNETOM Terra with *syngo* MR E12U has different technological characteristics than the predicate device, MAGNETOM Terra with *syngo* MR E11K (K170840 cleared October 12, 2017), with respect to the Phosphorus spectroscopy and Sodium head imaging.

The predicate device was cleared based on non-clinical supportive information and clinical images and data. The comparison of technological characteristics, non-clinical performance data, software validation data, and supporting literature for the clinical performance of Sodium head imaging and Phosphorus spectroscopy demonstrates that the modifications to the predicate device will be as safe and effective when compared to the predicate device that is currently marketed for the same general intended use. Therefore the subject device is substantially equivalent to the predicate device.

In summary, MAGNETOM Terra with *syngo* MR E12U has extended functionalities compared to the predicate device and within the general intended use. Based on the aforementioned information the modifications do not introduce any new issues of safety or effectiveness. Therefore, Siemens is of the opinion that MAGNETOM Terra with *syngo* MR E12U does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed device MAGNETOM Terra with *syngo* MR E11K (K170840 cleared October 12, 2017).