



Siemens Medical Solutions USA, Inc.
Milind Dhamankar
Senior Clinical Affairs Specialist
40 Liberty Boulevard, Mail Code 65-1A
Malvern, Pennsylvania 19355

October 12, 2017

Re: k170840

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: September 5, 2017
Received: April 5, 2017

Dear Milind 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,



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

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|---|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use | Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 <i>See PRA Statement below.</i> |
|---|--|

510(k) Number *(if known)* k170840

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. These images and the physical parameters derived from the images 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.

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

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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: March 20, 2017

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

2. **Contact Person:**

Milind Dhamankar, M.D.
Senior Clinical Affairs Specialist
Siemens Medical Solutions USA, Inc.
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3. **Device Name and Classification:**

| | |
|-------------------------|--|
| Common / Usual Name | 7T Magnetic Resonance Imaging system |
| Trade Name | MAGNETOM Terra |
| 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 indications for use of the subject device fall within the intended use of the predicate device. The intended use for the MAGNETOM Terra is as follows:

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. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist in diagnosis.

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

5. Predicate and Reference Device Information:

| Predicate Device | FDA Clearance Number | Product Code | Manufacturer |
|---|-----------------------------------|---------------|--------------------------------------|
| <p>MAGNETOM Trio A Tim System with syngo MR B19A</p> <p>Please note the following parts of the MAGNETOM Trio A Tim System are the predicate device parts related to:</p> <ul style="list-style-type: none"> • System Architecture • RF transmit/receive system | K123938 cleared February 12, 2013 | LNH, LNI, MOS | Siemens AG / Siemens Healthcare GmbH |
| Reference Devices | FDA Clearance Number | Product Code | Manufacturer |
| <p>MAGNETOM Verio with syngo MR D13A</p> <p>Please note the following parts of the MAGNETOM Verio are the reference device parts related to:</p> <ul style="list-style-type: none"> • SAR Management and Control System • Gradient Power Amplifier • Computer Systems | K121434 cleared November 5, 2012 | LNH, LNI, MOS | Siemens AG / Siemens Healthcare GmbH |
| <p>MAGNETOM Prisma with syngo MR E11C</p> <p>Please note the following parts of the MAGNETOM Prisma are the reference device parts related to:</p> <ul style="list-style-type: none"> • Software syngo MR E11K • Patient table • Magnet • Gradient Coil • Cover • Physiological Measurement Devices • Patient communication devices | K153343, cleared April 15, 2016 | LNH, LNI, MOS | Siemens AG / Siemens Healthcare GmbH |

6. 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. The MAGNETOM Terra uses two local coils 1Tx32Rx Head Coil 7T Clinic and 1Tx28Rx Knee Coil 7T Clinic for head and knee imaging.

Device Modifications

The subject device, MAGNETOM Terra, has the same fundamental technological characteristics as the predicate device, MAGNETOM Trio A Tim System with *syngo* MR B19A, (K123938 cleared February 12, 2013). Components such as: magnet, gradient coil, RF Subsystem, software and local Tx/Rx coils have been modified for 7T. Specific details are listed in the Predicate and Reference Device Information table (# 5) above.

The modifications that are new to the subject device are not cleared on other systems and are discussed in detail within the submission. The list below describes the new features and components followed by the modified components.

Hardware

- New Magnet: The new magnet, OR 107, is based on the already cleared magnet design OR 65 of the reference device MAGNETOM Prisma. The magnet electronics developed for the MAGNETOM Prisma were modified for the subject device magnet. Unlike OR 65, the OR 107 magnet does not support the mounting of the RF components on the magnet. The subject device has a separate RF cabinet instead. OR 107 has two cold heads due to the higher volume of helium in the magnet.
- New Gradient Coil: The mechanical dimensions and design of the gradient coil (GC) of the reference device, MAGNETOM Prisma were modified to create the subject device GC to accommodate the wider magnet bore diameter and the additional 3rd order shims. The subject device Gradient system 80/200 (80mT/m @ slewrate 200T/ms – simultaneous) has a new Gradient Coil and the Gradient Power Amplifier used in the reference device, MAGNETOM Verio has been modified.
- New Coils: Two new Tx/Rx local coils for head and knee examinations designed for 7T
 - -1Tx32Rx Head Coil 7T Clinic from Nova Medical, Inc.
 - -1Tx28Rx Knee Coil 7T Clinic from Quality Electrodynamics LLC
- The subject device does not have an integrated body resonator. Only local transmit (Tx) and receive (Rx) coils are used for RF excitation.
- Modified RF Subsystem 1ch Tx: The RF transmit/receive system of the subject device is based on Siemens' Tim technology of the predicate device MAGNETOM Trio A Tim System. The RF Subsystem of the subject device was

modified to accommodate the 7T System frequency of 297.18 MHz. The RF amplifier, receive electronics and the new MaRS computer are located in separate cabinets.

- Modified patient table: The patient table of the reference device, MAGNETOM Prisma was modified. The horizontal movement speed of the 7T subject device patient table is limited to 35 mm/s compared to 200 mm/s of the 3T reference device to maintain the maximum dB/dt value of 3 T/s defined in IEC 60601-2-33 Ed3, 2010. The subject device patient table has no vertical movement. Coil plugs and patient infrastructure (vacuum, headphone, squeeze ball) are moved to a separate Coil Interface Box. The subject device includes enhancements to the software that controls Specific Absorption Rate (SAR) based on simulations for adult humans only. Therefore the subject device patient table fits the needs for patients from 30 kg up to 200 kg.

Software

The subject device software, *syngo* MR E11K, was developed based on the commercially available MAGNETOM software line E11, latest cleared with *syngo* MR E11C for the reference device MAGNETOM Prisma (K153343, cleared April 15, 2016).

- There are no new applications available with *syngo* MR E11K in comparison to *syngo* MR E11C.
- Pulse sequence types were adapted according to the different conditions caused by the 7T system frequency of 297.18 MHz. No new 7T specific clinical pulse sequence types were developed.
- One new non-clinical pulse sequence type for B0 field mapping has been added. This sequence is not used for clinical imaging.
- The subject device includes enhancements to the software that controls Specific Absorption Rate (SAR) based on simulations for adult humans only. Therefore the MAGNETOM Terra is intended for patients > 30 kg/66 lbs. This weight limitation is not there for the 3T predicate device.

The subject device, MAGNETOM Terra is substantially equivalent to the predicate device, MAGNETOM Trio A Tim System with *syngo* MR B19A.

7. Technological Characteristics

The subject device, MAGNETOM Terra, has the same fundamental technological characteristics as the predicate device, MAGNETOM Trio A Tim System with *syngo* MR B19A, (K123938 cleared February 12, 2013).

7T specific components such as: magnet, gradient coil, RF Subsystem, software and local Tx/Rx coils have been modified as described in Device Description (#6) above. The subject device includes enhancements to the software that controls Specific Absorption Rate (SAR) based on simulations for adult humans only. Therefore the MAGNETOM Terra is intended for patients > 30 kg/66 lbs. This weight limitation is not there for the 3T predicate device.

The subject device is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance. MAGNETOM Terra conforms to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

8. Nonclinical Tests

The following performance testing was conducted on the subject device

- Sample clinical images were acquired for all available clinical pulse sequences and local coils,
- Image quality assessments of all clinical pulse sequences types, were completed during system test,
- Acoustic noise measurements according to NEMA standard were performed,
- Performance Tests according to IEC 62464-1 as well as surface heating test for the 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.

9. Clinical Tests

A clinical study of 35 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 animal testing has been performed on this device.

In addition to providing clinical sample images for all clinical sequences and coils of the subject device, reports from two U.S. board-certified radiologists have been provided after the radiologists reviewed image pairs comparing the subject and the predicate device. Their comments on any observed artifacts and concerns have also been included.

10. 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 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 |

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

The local transmit coils available with the MAGNETOM Terra are supervised as local transmit coils. The estimation of local (10g average) SAR is based on results of computational modeling on finite-difference time domain (FDTD) algorithm, using eight Human models of the Virtual Population (Christ et al, PhysMedBiol 2010, Gosselin et al, PhysMedBiol 2014) and the MIDA Model (Iacono et al, Plos One 2015). The models include male and female models, ages ranging from 6 years to 84 years, weights ranging from 18.6 kg to 119 kg. The FDTD modeling used a mesh size of 2 mm, which has been determined to accurately evaluate the local SAR in the different structures of the human head and reproduce the constructive/destructive interference between anatomical structures.

This local SAR limit effectively also limits whole body SAR, partial body SAR and head SAR to a value that is lower than required by IEC 60601-2-33 for volume coils.

11. Substantial Equivalence

The subject device, MAGNETOM Terra, has the same fundamental technological characteristics as the predicate device, MAGNETOM Trio A Tim System with *syngo* MR B19A, (K123938 cleared February 12, 2013). 7T specific components such as: magnet, gradient coil, RF Subsystem, software and local Tx/Rx coils have been modified as described in Device Description (#6) above. The subject device is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

The subject device software, *syngo* MR E11K, was developed based on the commercially available MAGNETOM software line E11, latest cleared with *syngo* MR E11C for the reference device MAGNETOM Prisma (K153343, cleared April 15, 2016).

- There are no new applications available with *syngo* MR E11K in comparison to *syngo* MR E11C.
- Pulse sequence types were adapted according to the different conditions caused by the 7T system frequency of 297.18 MHz. No new 7T specific clinical pulse sequence types were developed.
- One new non-clinical pulse sequence type for B0 field mapping has been added. This sequence is not used for clinical imaging.
- The subject device includes enhancements to the software that controls Specific Absorption Rate (SAR) based on simulations for adult humans only. Therefore the MAGNETOM Terra is intended for patients > 30 kg/66 lbs. This weight limitation is not there for the 3T predicate device.

12. Conclusion as to Substantial Equivalence

The MAGNETOM Terra has the same fundamental technological characteristics as the predicate device MAGNETOM Trio A Tim System with *syngo* MR B19A (K123938).

7T specific components such as: magnet, gradient coil RF Subsystem, software and local Tx/Rx coils have been modified and this gives the subject device greater capabilities in terms of image quality in the available body regions. All of the modifications do not introduce any new issues of safety or effectiveness. The modifications to the MAGNETOM Terra do not change the fundamental scientific technology of the Magnetic Resonance Diagnostic device and the indications for use of the subject device fall within the intended use of the predicate device.

The subject device includes enhancements to the software that controls Specific Absorption Rate (SAR) based on simulations for adult humans only. Therefore the MAGNETOM Terra is intended for patients > 30 kg/66 lbs. This weight limitation is not there for the 3T predicate device.

Siemens believes that the subject device, MAGNETOM Terra is substantially equivalent to the predicate device, MAGNETOM Trio A Tim System with *syngo* MR B19A.