K132119

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SIEMENS

Section 5 510(k) Summary

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.

I. General Information

Establishment	Siemens Medical Solutions USA. Inc. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA
Registration Number	2240869
Date Prepared	July 8, 2013
Manufacturer	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany
Registration Number	3002808157
Contact Person	Ms. Nadia Sookdeo Regulatory Affairs Technical Specialist Siemens Healthcare Siemens Medical Solutions USA, Inc. Customer Solutions Group 51 Valley Stream Parkway Mail Code G01 Malvern, PA 19355, USA Phone: (610) 448-4918 Fax: (610) 448-1787
Device Name	Trade Names: MAGNETOM Prisma MAGNETOM Prisma^{fit}
Classification Name: **CFR Code:** **Classification:**	Magnetic Resonance Diagnostic Device 21 CFR § 892.1000 Class II
Performance Standards	None established under Section 514, Subpart J of the Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use
The MAGNETOM Prisma and the MAGNETOM Prisma^{fit} systems are 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.

The MAGNETOM Prisma and the MAGNETOM Prisma^{fit} MR systems 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.

Device Description
MAGNETOM Prisma (3 T) and MAGNETOM Prisma^{fit} (3 T) are similar to the previously cleared MAGNETOM Skyra (3 T) and MAGNETOM Trio a Tim System (TaTS) (3 T) systems utilizing a superconducting magnet design. The open bore, whole body scanners are designed for increased patient comfort. They focus on ergonomics and usability to reduce complexity of the MR workflow.

The MAGNETOM Prisma will be offered as ex-factory (new production) and the MAGNETOM Prisma^{fit} will be offered as an upgrade to the currently installed MAGNETOM Trio a Tim System (TaTS) systems.

Substantial Equivalence
It is Siemens opinion that the MAGNETOM Prisma systems and the upgraded MAGNETOM Prisma^{fit} systems with *syngo*® MR VD13D software i are substantially equivalent to the following predicate devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM Skyra (3 T) MR system with *syngo*® MR D13D	K123510	May 17, 2013
Siemens MAGNETOM Trio a Tim System (TaTS) (3 T) MR System with *syngo*® MR B19	K123938	February 12, 2013

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 beginning early in the design cycle and continuing throughout the development of the product.. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards, such as the IEC 60601-1 series.

Operation of the MAGNETOM Prisma (3T) and the MAGNETOM Prisma^{fit} (3T) systems with *syngo*® MR VD13D software is substantially equivalent to the commercially available MAGNETOM Skyra (3T) Systems with syngo® MR VD13C SW (K123510) and MAGNETOM Trio a Tim System (TaTS) (3T) with syngo® MR B19 SW (K123938)

Additionally, as specified in the FDA guidance document "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Devices" (released Nov. 1998) the following measurements of performance and safety data have been performed following NEMA or equivalent IEC and ISO standards:

Safety:
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels

Performance:
- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile. Thickness and Gap
- High Contrast Spatial Resolution

The MAGNETOM Prisma and MAGNETOM Prisma^{fit} *syngo*® MR VD13D software will conform to the measurements of safety parameters to the international IEC, ISO and NEMA standards for safety issues with Magnetic Resonance Imaging Diagnostic Devices.

Furthermore performance testing has been completed to show that the performance of the MAGNETOM Prisma and MAGNETOM Prisma^{fit} with *syngo*® MR VD 13D Software is equivalent with respect to the predicate devices.

This assures that the performance of these devices can be considered as safe and effective with respect to the currently available MAGNETOM Skyra and MAGNETOM Trio a Tim System (TaTS) MR systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Siemens Medical Solutions USA, Inc.
% Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway, D02
MALVERN PA 19355

Re: K132119
Trade/Device Name: MAGNETOM Prisma, MAGNETOM Prisma^{fit}
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 5, 2013
Received: November 8, 2013

Dear Ms. Sookdeo:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Michael D. O'Hara for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132119

Device Name
MAGNETOM Prisma and MAGNETOM Prisma fit

Indications for Use *(Describe)*

The MAGNETOM Prisma and MAGNETOM Prismafit systems are 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.

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The MAGNETOM Prisma and MAGNETOM Prismafit systems 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara