MAY 17 2013 K123510

SIEMENS

510(k) Summary: TimTX TrueShape and *syngo* MR D13C for MAGNETOM Skyra

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.

Date of Summary Preparation: November 9, 2012

I. General Information

Importer/Distributor Siemens Medical Solutions USA, Inc.
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Device Name and Classification

Data	Details
Trade name / Device Proprietary Name:	MAGNETOM Skyra option TimTX TrueShape with *syngo MR* D13C
Classification Name:	Regulation Description: - Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Device Classification:	Class II devices
Regulation number:	21 CFR § 892.1000
Product Code:	LNH

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The MAGNETOM Skyra 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.

The MAGNETOM Skyra 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.

Device Description

TimTX TrueShape, an option for the MR system MAGNETOM Skyra, allows parallel transmission of RF pulses, shaping the RF excitation field locally and thus enabling selective excitation.

syngo ZOOMit (introduced with the software version *syngo* MR D13C) is the application that utilizes TimTX TrueShape. It allows "zooming into" a part of the human body by selective excitation.

The option TimTX TrueShape and *syngo* ZOOMit include two independent RF transmit paths fully integrated with the system, a modified whole-body RF coil, new options for

B1 shimming, as well as new inline RF pulse generation. Pulse sequences allowing for different kinds of excitation, or zooming are derived from EPI and SPACE sequences. Protocol optimization for neurological, musculoskeletal, angiographic and oncological imaging is also inherent to the TimTX TrueShape option.

General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Product Risk Management is accomplished through a process in compliance with ISO 14971:2009 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 Skyra with option TimTX TrueShape and software *syngo* MR D13C 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.

Substantial Equivalence

MAGNETOM Skyra with TimTX TrueShape and software *syngo* MR D13C is a magnetic resonance diagnostic device that includes all of the features of MAGNETOM Skyra with *syngo* MR D13A. Therefore, the MAGNETOM Skyra with the option TimTX TrueShape and software *syngo* MR D13C is substantially equivalent to the following current legally marketed device (please refer to **Table 1**):

Table 1: Predicate device for MAGNETOM Skyra with TimTX TrueShape and software *syngo* MR D13C

Predicate Device Name	**FDA Clearance Number**	**FDA Clearance Date**
MAGNETOM Skyra with *syngo* MR D13A	K121434	November 05, 2012

Conclusion as to Substantial Equivalence

MAGNETOM Skyra with option TimTX TrueShape and software *syngo* MR D13C has the same intended use and the same basic technical characteristics as the predecessor device MAGNETOM Skyra with *syngo* MR D13A, with respect to the magnetic resonance features and functionalities. MAGNETOM Skyra with option TimTX TrueShape and software *syngo* MR D13C will be used for acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic

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images and/or spectra). The predicate device, MAGNETOM Skyra with software *syngo* MR D13A, is also capable of acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra). The differences between the subject device and the predicate device, which include the aforementioned new / modified technology and software version, give the subject device greater capabilities than the predicate device, but have the enhanced technological characteristics as the predicate device. MAGNETOM Skyra with option TimTX TrueShape and software *syngo* MR D13C is similar to the functionalities of the predicate device, and does not introduce any new issues of safety or effectiveness.

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

May 17, 2013

Siemens Medical Solutions, USA. INC
% Ms Nadia Sookdeo
Technical Specialist, Regulatory Affairs
51 Valley Stream Parkway, D 02
MALVERN PA 19355

Re: K123510
Trade/Device Name: MAGNETOM Skyra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: May 13, 2013
Received: May 15, 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

Indications for Use

510(k) Number (if known): K123510

Device Name: MAGNETOM Skyra

Indications for Use:

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The MAGNETOM Skyra 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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