K132951

NOV 15 2013

Section 5 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR § 807.92. The 510(k) Summary is provided on the next page and is suitable for publication on the FDA website.

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	January 31, 2013
Registration Number	2240869
Manufacturers	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany Registration Number 3002808157 Siemens Shenzhen Magnetic Resonance Ltd. Siemens MRI Center Gaoxin C. Ave., 2nd Hi-Tech Industrial Park, Shenzhen 518057, P.R. China Registration Number 3004754211
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 D02 Malvern, PA 19355, USA Phone: (610) 448-4918 Fax: (610) 448-1787
Device Name	Trade Names: MAGNETOM Aera Classification Name: Magnetic Resonance Diagnostic Device CFR Code: 21 CFR § 892.1000 Product Code: LNH Classification: Class II

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The intended use for the MAGNETOM Aera with *syngo* MR D13E is the same as MAGNETOM Aera with *syngo* MR D13A that is described in K121434 and cleared on November 05, 2012.

The MAGNETOM Aera with *syngo* MR D13E 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 atrained physician yield information that may assist in diagnosis.

The MAGNETOM Aera 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

The MAGNETOM Aera is a 1.5T, utilizing a superconducting magnet design. The open bore, whole body scanner is designed for increased patient comfort The MAGNETOM Aera is being modified to include another configuration to the MAGNETOM portfolio to be available for Ex-factory (new) systems. The full modifications for the new MAGNETOM Aera configuration include 24 receive channels, modified Measurement and Reconstruction System (MaRS) and *Syngo* Acquisition Workplace (MRAWP)/*Syngo* MR Workplace(MRWP), an update to the software *syngo* MR D13E and the addition of three new coils to the existing MAGNETOM Aera Magnetic Resonance System.

Substantial Equivalence

Siemens feels that the new system is substantially equivalent to the following predicate devices:

Predicate Device Name-System	*FDA Clearance Number*	*Product Code*	*FDA Clearance Date*
Siemens MAGNETOM Aera(1.5T) with *syngo* MR D13A	K121434	LNH	November 5, 2012

General Safety and Effectiveness Concerns:

The MAGNETOM Aera with software *syngo* MR D13E 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.

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.

Siemens adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

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 15, 2013

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

Re: K132951
Trade/Device Name: MAGNETOM Aera
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 23, 2013
Received: October 24, 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,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K132951

Device Names: **MAGNETOM Aera**

Indications for Use:

The MAGNETOM Aera with *syngo* MR D13E 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 Aera 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

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