5 510(k) Summary

JAN 1 1 2011

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 Malvern, PA 19355
Registration Number	2240869
Manufacturer	Siemens Mindit Magnetic Resonance Ltd. Siemens MRI Center, Gaoxin C. Ave. 2nd Hi-Tech Industrial Park, ShenZhen 518057, PR. China
Registration Number	3004754211
Contact	Alicia Bustos-Juergensen Technical Specialist, Regulatory Submissions 51 Valley Stream Parkway Malvern, PA 19355 Phone: (610) 448-4056 Fax: (610) 448-1787 E-mail address: alicia.bustos-juergensen@siemens.com

Device Name	Trade Name:	Specialty Coils for MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T MR Systems
	Classification Name:	Coil, Magnetic Resonance Specialty
	Device Class:	Class II 21 CFR § 892.1000
	Product Code:	MOS
	Classification Panel:	Radiology

Performance Standards

None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

The specialty coils are indicated for use in conjunction with the MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T MR Systems, Magnetic Resonance Diagnostic Devices (MRDD), that produce transverse, sagittal, coronal and oblique cross sectional images, and display the internal structure and/or function of the body. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Device Description

The specialty coils are intended to be used in conjunction with the MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T MR Systems, Magnetic Resonance Diagnostic Devices. These coils will be used to present images which reflect the spatial distribution and the other physical parameters derived from the images may also be produced.

The specialty coils will include: Shoulder Large 16, Shoulder Small 16, Hand/Wrist 16 and Foot/ Ankle 16 for the existing MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T MR Systems.

Substantial Equivalence

Siemens believes that, within the meaning of the Safe Medical Device Act of 1990, the MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T Systems with specialty coils are substantially equivalent to the following cleared medical devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM ESSENZA 1.5 T (Focus Shoulder Array Coil)	K071925	Aug 14, 2007
Siemens MAGNETOM ESSENZA 1.5 T (Focus Shoulder Array Coil, Small, 8-Channel Wrist Coil, 8-Channel Foot-Ankle Coil)	K083166	Jan 13, 2009
Siemens MAGNETOM Verio 3T (Large 4-Channel Shoulder Array Coil, Small 4-Channel Shoulder Array Coil, 8- Channel Wrist Coil, 8-Channel Foot -Ankle Coil)	K072237	Oct 10, 2007

General Safety and Effectiveness Concerns:

The following safety and performance parameters:

[Safety]
-Maximum Static Field
-Rate of Change of Magnetic Field
-RF Power Deposition
-Acoustic Noise Level

[Performance]
-Geometric Distortion
-Slice Profile, Thickness and Gap
-High Contrast Spatial Resolution

Specified by the FDA Guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

The following parameters were considered for the new Specialty Coils:

[Safety]
-Biocompatibility

[Performance]
-Signal to Noise Ratio
-Image Uniformity

No new materials were used for the new specialty coils compared to their predicate devices. Therefore no new biocompatibility tests were performed. Signal to Noise Ratio (SNR) and image uniformity tests were performed for the new specialty coils and the results presented in this submission show that they are equivalent with the predicate devices.

Conclusion as to Substantial Equivalence

Laboratory testing was performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Ms. Alicia Bustos-Jeurgensen
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

JAN 11 2011

Re: K103275
Trade/Device Name: Specialty Coils for MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 4, 2010
Received: November 5, 2010

Dear Ms. Bustos-Jeurgensen:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known) K103275 JAN 11 2011

Device Name: **Specialty Coils for** MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T MR Systems

Indications for Use:

The specialty coils are indicated for use in conjunction with the MAGNETOM Aera 1.5T & MAGNETOM Skyra 3T Systems, magnetic resonance diagnostic devices (MRDD), which produce transverse, sagittal, coronal and oblique cross sectional images, and display the internal structure and/or function of the body.

These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

The intended use of the Aera and Skyra Systems is not affected by the use of the new specialty coils.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103275