SIEMENS Healthcare

AUG 27 2010

Attachment B - 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 SolutionsUSA, 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

Kim Rendon
Manager, Regulatory/Clinical Affairs
51 Valley Stream Parkway, MS G01
Malvern, PA 19355
Phone: (610) 717-8085
Fax: (610) 448-1787
E-mail address: kimberly.rendon@siemens.com

Device Name

Trade Name:	14-Channel Extremity Coil for 1.5T MAGNETOM ESSENZA
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.

SIEMENS Healthcare

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use
The new 14-Channel Extremity Coil is indicated for use in conjunction with the 1.5T MAGNETOM ESSENZA, in the MR examination of the human knee, foot, ankle, hand and wrist.

Used in the MAGNETOM ESSENZA, the 14-Channel Extremity Coil is indicated for use as a magnetic resonance diagnostic device (MRDD) to produce transverse, sagittal, coronal and oblique cross sectional images that display the internal structure and/or function of the knee, foot, ankle, hand and wrist.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

The intended use of the MAGNETOM ESSENZA is not affected in any way by the use of the new 14-Channel Extremity Coil.

Device Description
The new 14-Channel Extremity Coil is indicated for use in conjunction with the 1.5T MAGNETOM ESSENZA, in the MR examination of the human knee, foot, ankle, hand and wrist.

Used in the MAGNETOM ESSENZA, the 14-Channel Extremity Coil is indicated for use as a magnetic resonance diagnostic device (MRDD) to produce transverse, sagittal, coronal and oblique cross sectional images that display the internal structure and/or function of the knee, foot, ankle, hand and wrist.

Substantial Equivalence
Siemens believes that, within the meaning of the Safe Medical Device Act of 1990, the 14-Channel Extremity Coil is substantially equivalent to the QED TxRx 15Ch Knee Coil 1.5T.

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
TxRx 15Ch Knee Coil 1.5T (QED)	K082636	Sep. 25, 2008

General Safety and Effectiveness Concerns:

The following are the safety and performance parameters:

SIEMENS Healthcare

Safety
-Maximum Static Field
-Rate of Change of Magnetic Field
-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 14-Channel Extremity Coil:

Safety
-RF Power Deposition
-Biocompatibility

Performance
-Signal to Noise Ratio
-Image Uniformity

No new materials were used for the new 14-Channel Extremity Coil compared to the predicate device. Therefore no new biocompatibility tests were performed. Signal to Noise Ratio (SNR), image uniformity and SAR tests were performed for the new 14-Channel Extremity Coil 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. Judith Campbell
Regulatory Technical Specialist
Siemens Medical Solution USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

AUG 2 7 2010

Re: K100141
Trade/Device Name: 14-Channel Extremity Coil for MAGNETOM ESSENZA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 6, 2010
Received: August 9, 2010

Dear Ms. Campbell:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K100141

SIEMENS

Attachment A - Indications for Use

510(k) Number (if known): **K100141**

Device Name: **14-Channel Extremity Coil for MAGNETOM ESSENZA**

Indications for Use:

The intended use of the new 14-Channel Extremity Coil is, in conjunction with THE 1.5T MAGNETOM ESSENZA Magnetic Resonance Scanner, the MR examination of the human knee, foot, ankle, hand and wrist.

Used in the MAGNETOM ESSENZA, the 14-Channel Extremity Coil is indicated for use as a magnetic resonance diagnostic device (MRDD) to produce transverse, sagittal, coronal and oblique cross sectional images that display the internal structure and/or function of the knee, foot, ankle, hand and wrist. The images produced by the MAGNETOM ESSENZA with the 14-Channel Extremity Coil reflects the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

The intended use of the MAGNETOM ESSENZA is not affected in any way by the use of the new 14-Channel Extremity Coil.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D)

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100141