K050476

MAR 25 2005

Section 1: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. General Information

Device Name	Trade Name:	Cordless coil
	Classification Name:	Magnetic Resonance Diagnostic Device
	CFR Section:	CFR § 892.1000
	Classification:	Class II
	Product Code:	LNH

Manufacturer

Rapid Biomedical GmbH
Technologiepark Wuerzburg-Rimpar
Kettelerstrasse 3-11
D-97222 Rimpar, Bayern
Germany

Initial Importer/ Distributor

Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number 2240869

Contact Person

Ms. Ana Ladino
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions
51 Valley Stream Parkway E-50
Malvern, PA 19355
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Performance Standards None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Supporting Substantial Equivalence

Intended Use
The Cordless coil is a receive type surface coil.

When used in the MAGNETOM Concerto and C! MR systems, it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of internal structures of the brain and body surface.

The images produced reflect the spatial distribution of protons exhibiting magnetic resonance. Spectra allow the molecules containing the nucleus under investigation to be distinguished. The NMR properties that determine the image and spectra appearance are spin density, spin-lattice relaxation time (T1), and spin-spin echo time (T2) of the corresponding nucleus.

When interpreted by a trained physician, these images and spectra provide information that can be useful in making diagnoses.

Device Description
The Cordless Coil is a surface receive coil. It is a set consisting of two coils. The coupling loop is connected with a cable and one receive coil is inductively coupled to the other.

Substantial Equivalence
Rapid and Siemens believe that, within the meaning of the Safe Medical Devices Act of 1990, the cordless coil for MAGNETOM Concerto and MAGNETOM C! is substantially equivalent to :

Coil Name	Premarket Notification	Clearance Date
Coils used with Siemens Medical Solutions MAGNETOM Concerto	K003192	12/21/2000
Coils used with Siemens Medical Solutions MAGNETOM C!	K043030	12/09/2004

The Cordless Coil for MAGNETOM Concerto and C! described in this Premarket Notification has the same intended use and similar technical characteristics as the devices listed above. In summary, Rapid Biomedical and Siemens are of the opinion that the Cordless coil does not introduce any new safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

General Safety and Effectiveness Concerns
The cordless coil for MAGNETOM Concerto and MAGNETOM C! will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standard for safety issues with Magnetic Resonance Imaging Devices, IEC 60601-2-33: 2002. This will assure that the performance of this device can be considered safe and effective with respect to the currently available MAGNETOM Concerto and C! systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Ms. Ana Ladino
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E50
MALVERN PA 19355

Re: K050476
Trade/Device Name: Cordless Coil for MAGNETOM Concerto and MAGNETOM C! MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: February 18, 2005
Received: February 24, 2005

Dear Ms. Ladino:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K050476

Device Name: Cordless Coil for MAGNETOM Concerto and MAGNETOM C! MR Systems.

Indications for Use:

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(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use ____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050476