Section 2: 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 Solutions. Inc.
51 Valley Stream Parkway
Malvern. PA 19355

Registration Number

2240869

Manufacturer

Siemens Mindit Magnetic Resonance Ltd.
R1-B1, Hi-Tech Industrial Park, Shennan Ave.
Shenzhen 518057
P.R. China

Registration Number

9063112

Contact Person

Ms. Nealie Hartman
Technical Specialist. Regulatory Submissions
51 Valley Stream Parkway E50
Malvern. PA 19355
Phone: (610) 448-1769
Fax: (610) 448-1787

Device Name

Trade Name:	MAGNETOM C! System
Classification Name:	Magnetic Resonance Diagnostic Device
CFR Code:	21 CFR § 892.1000
Classification:	Class II

Performance Standards

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

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

The MAGNETOM C! is indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM C! 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 C! system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times, which is was described in premarket notification K041111 which received FDA clearance on July 16, 2004. Siemens further market the Body spine XL coil, Wrist Array coil with 4 channels, Cordless Coil, Breast Array coil, Breast biopsy device, MR guided procedure Package, In Room MRC, Foot switch and the software update for the existing MAGNETOM C! MR system.

Substantial Equivalence

Siemens believes that, within the meaning of the Safe Medical Device Act of 1990, the MAGNETOM C!, which is configured with a new Body spine XL Coil, Wrist Array Coil with 4 channels, Cordless Coil, Breast Array Coil, Breast Biopsy Device, MR Guided Procedure Package, In Room MRC, Foot switch and the software update, is substantially equivalent to the following cleared medical devices, which offers the same applications and handling:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM 0.2 T Concerto	K003192	12/21/2000
Siemens MAGNETOM 1.0 T Harmony	K970852	06/05/1997
Siemens MAGNETOM 0.35 T C !	K041111	07/16/2004

General Safety and Effectiveness Concerns

Operation of the MAGNETOM C! System is substantially equivalent to the commercially available MAGNETOM 0.2 T Concerto System and 1.0 T Harmony System. Below are the parameter specified by the FDA guidance document for MR Diagnostic Devices that will be evaluated with the following levels:

Performance Levels
- Signal to Noise
- Image Uniformity

The MAGNETOM C! will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the international IEC standard for safety issues with Magnetic Resonance Imaging Devices. This will assure that the performance of this device can be considered safe and effective with respect to the currently available MAGNETOM Concerto and Harmony systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Ms. Nealie Hartman
Technical Specialist,
Regulatory Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
MALVERN PA 19355

Re: K043030
Trade/Device Name: 0.35 T MAGNETOM C!
MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: October 29, 2004
Received: November 3, 2004

Dear Ms. Hartman:

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/dsma/dsmamain.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

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K043030

Device Name: **MAGNETOM C!**

Indications for Use:

The MAGNETOM C! is indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM C! 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

(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 ____

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043030