5 510(k) Summary

NOV - 7 2008

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 AG. Henkestrasse 127 D-91052 Erlangen. Germany
Registration Number	8010024
Contact Person	Elizabeth Lazaro Regulatory Technical Specialist. 51 Valley Stream Parkway Malvern, PA 19355 Phone: (610) 448-3393 Fax: (610) 448-1787

Device Name

Trade name	MAGNETOM Systems with software *syngo* MR B17
Classification Name	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation number:	21 CFR § 892.1000
Device Class:	II
Product Code:	LNH

Summary Device Description

The software update *syngo* MR B17 offers additional and improved applications for MAGNETOM Systems. It includes sequences and image processing functions for oncology, neurology, orthopaedics and cardio-vascular imaging.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

MAGNETOM Systems:

MAGNETOM Avanto
MAGNETOM Espree
MAGNETOM Symphony a Tim System
MAGNETOM Trio a Tim System
MAGNETOM Verio

with software *syngo* MR B17

Intended Use

The MAGNETOM systems described above are 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 systems described above 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

Performance Standards

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

Substantial Equivalence
Siemens believes that the MAGNETOM systems with software *syngo* MR B17 are substantially equivalent to the following cleared medical devices:

Predicate Device Name	*Predicate Software Name*	*FDA Clearance Number*	*FDA Clearance Date*
MAGNETOM Verio	software *syngo* MR B15V	K072237	Oct 10, 2007
MAGNETOM Systems – I and T-class releases	software *syngo* MR B15	K062454	Nov 3, 2006

General Safety and Effectiveness Concerns:
The introduction of the MAGNETOM systems with software *syngo* MR B17 has no significant concerns of safety and efficacy.

Siemens is adding a software upgrade to the currently available MAGNETOM Systems. 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 Risk Analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

The MAGNETOM Systems with software *syngo* MR B17 will conform to the measurement of safety and performance parameters to the international IEC and ISO standards, where applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Elizabeth Lazaro
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19533

NOV - 7 2008

Re: K082427
Trade/Device Name: Magnetom Systems: Magnetom Avanto, Magnetom Espree, Magnetom Symphony a Tim System, Magnetom Trio a Tim System and Magnetom Verio with software *Syngo* MR B17
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 22, 2008
Received: August 22, 2008

Dear Ms. Lazaro:

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 (PMA), 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting 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): K082427

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Prescription Use ✓ (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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082427