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K052423

Section 1 - 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 Medicl Solutions Henkestrasse 127 D91052 Erlangen, Germany
Registration Number	8010024
Contact Person	Ms. Judy Campbell Technical Specialist, Regulatory Submissions 51 Valley Stream Parkway Malvern. PA 19355 Phone: (610)448-4918 Fax: (610) 448-1787
Device Name	Trade Name: MAGNETOM Systems with *syngo* Expert—i option
Classification Name: CFR Section: Classification:	Magnetic Resonance Diagnostic Device 21 CFR § 892.1000 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 following MAGNETOM systems:

MAGNETOM 1.5 T Avanto
MAGNETOM 1.5 T Espree
MAGNETOM 1.5 T Symphony a Tim System
MAGNETOM 3.0 T Trio a Tim System

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MAGNETOM 1.0 T Harmony
MAGNETOM 1.5 T Symphony
MAGNETOM 1.5 T Sonata
MAGNETOM 0.2 T Concerto
MAGNETOM 3.0 T Trio

with *syngo* Expert—i option described in this premarket notification are 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.

They may also be used for imaging during interventional procedures performed with MR compatible devices such as, in room display and MR safe biopsy needles.

Siemens Medical Solutions, Inc., intends to offer a software option called *syngo* Expert—i. The indications for use will stay exactly the same, with respect to the previous software versions mentioned in the comparison matrix.

Substantial Equivalence
Within the definition of the Safe Medical Devices Act of 1990, the

MAGNETOM 1.5 T Avanto
MAGNETOM 1.5 T Espree
MAGNETOM 1.5 T Symphony a Tim System
MAGNETOM 3.0 T Trio a Tim System
MAGNETOM 1.0 T Harmony
MAGNETOM 1.5 T Symphony
MAGNETOM 1.5 T Sonata
MAGNETOM 0.2 T Concerto
MAGNETOM 3.0 T Trio

with *syngo* Expert—i Option are substantially equivalent to the following cleared medical devices:

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
MAGNETOM 1.5 T Avanto	K032428	October 16, 2003
MAGNETOM 1.5 T Espree	K041112	July 21, 2004
MAGNETOM 1.5 T Symphony a Tim System	K050199	February 18, 2005
MAGNETOM 3.0 T Trio a Tim System	K050200	February 28, 2005
MAGNETOM 1.0 T Harmony	K970852	June 5, 1997
MAGNETOM 1.5 T Symphony	K971684	August 5, 1997
MAGNETOM 1.5 T Sonata	K993731	December 23, 1999
MAGNETOM 0.2 T Concerto	K003192	December 21, 2000
MAGNETOM 3.0 T Trio	K013586	December 28, 2001.

General Safety and Effectiveness Concerns:
The introduction of the *syngo* Expert—i Option has effect on the MR safety. Therefore a risk analysis has been performed including new safety measures to reduce the residual risks to an acceptable level.

The MRI systems are exactly the same as what was described and cleared in the predicate premarket notifications. Safety testing will be completed before commercial introduction to the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

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

Re: K052423
Trade/Device Name: MAGNETOM Systems with *syngo* Expert—i option
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 22, 2005
Received: December 30, 2005

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 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

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Section 3 - Indications for Use

Device Name	FDA Clearance Number
MAGNETOM 1.5 T Avanto	K032428
MAGNETOM 1.5 T Espree	K041112
MAGNETOM 1.5 T Symphony a Tim System	K050199
MAGNETOM 3.0 T Trio a Tim System	K050200
MAGNETOM 1.0 T Harmony	K970852
MAGNETOM 1.5 T Symphony	K971684
MAGNETOM 1.5 T Sonata	K993731
MAGNETOM 0.2 T Concerto	K003192
MAGNETOM 3.0 T Trio	K013586

The above listed MAGNETOM systems 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. These images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

They may also be used for imaging during interventional procedures performed with MR compatible devices such as, in room display and MR safe biopsy needles.

The *syngo* Expert—i feature allows the local user of the MRI (e.g. tech) to get help and assistance from other personnel of the radiology department (e.g. other tech or physician) to perform scans faster and with better quality. For this purpose, a remote user within the local network of the MRI (i.e. the network of the radiology) can log onto the MR main or satellite console.

(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. Seyforth

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K052423

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