JUN 1 3 2002

K020991

11 Appendix: 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.

Establishment:

- Address: Siemens Medical Solutions, Inc.
  186 Wood Avenue South
  Iselin, N.J. 08830

Registration Number: 2240869

Contact Person: Mr. Jamie Yieh
Technical Specialist, Regulatory Affairs
Email: jamie.yieh@siemens.com
Phone: (732) 321-4625
Fax: (732) 321-4841

Date of Summary Preparation: March 26, 2002

Device Name:

- Trade Name: *syngo* MR 2002B

- Classification Name:
  Magnetic Resonance Diagnostic Device, 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.

• Device Description:

•Intended Use

The MAGNETOM Systems with the *syngo* MR 2002B are indicated for use as magnetic resonance diagnostic devices (MRDD's) 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.

• Technological Characteristics

The *syngo* MR 2002B (Numaris 4 VA21A) software upgrade will be available for the following MAGNETOM Family systems:

- The MAGNETOM 1.0 Tesla **Harmony** system was described in premarket notification K970852 which received FDA clearance on June 5, 1997.
- The MAGNETOM 1.5 Tesla **Symphony** system was described in premarket notification K971684 which received FDA clearance on August 4, 1997.
- The MAGNETOM 1.5 Tesla **Sonata** system was described in premarket notification K993731 that received FDA clearance on December 23, 1999.
- The MAGNETOM 0.2 Tesla **Concerto** system was described in premarket notification K003192 which received FDA clearance on December 21, 2000.
- The MAGNETOM 3.0 Tesla **Allegra** system was described in premarket notification K002179 which received FDA clearance on October 11, 2000.
- The MAGNETOM 3.0 Tesla **Trio** system was described in premarket notification K013586 which received FDA clearance on December 28, 2001.

This includes Siemens upgrades of currently used MAGNETOM Impact/Expert, Vision, and Open (Viva) systems to systems described above.

• General Safety and Effectiveness Concerns:

The introduction of the new *syngo* MR 2002B has no significant effect on the following MR safety and performance parameters:

[Safety]

- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance]

- Specification Volume
- Signal to Noise

- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

Siemens Medical Solutions is adding an upgrade in software and hardware to the currently available MAGNETOM Systems. The MRI systems are exactly the same as what was described and cleared in the predicate premarket notifications. Variable safety and performance testing was completed; however the values are not significantly changed and, in the case of safety parameters remain below the level of concern.

- **Substantial Equivalence:**

Laboratory testing were performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2002

Mr. Jamie Yieh
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K020991
Trade/Device Name: MAGNETOM Systems with Syngo MR 2002B
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH and LNI
Dated: March 26, 2002
Received: March 27, 2002

Dear Mr. Yieh:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

3 Appendix: Indications for Use Statement

In accordance with FDA requirements (as of 1/1/96), the indications for use statement is attached on a separate page.

510(k) Number (if known) K02 0 991

Device Name: MAGNETOM systems with *syngo* MR 2002B

Indications for Use:

The MAGNETOM Systems with the *syngo* MR 2002B are indicated for use as magnetic resonance diagnostic devices (MRDD's) 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.

(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 G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020991