K013586

DEC 2 8 2001

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 Systems, Inc.
  186 Wood Avenue South
  Iselin, N.J. 08830

Registration Number: 2240869

Contact Person:

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

Date of Summary Preparation: 10/29/01

Device Name:

- Trade Name: MAGNETOM Trio System

- 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 Trio system is a whole body scanner designed to support higher resolution imaging and shorter scan times. The Trio system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head and whole body. The images produced by the Trio system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin echo time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

• Technological Characteristics

The MAGNETOM Trio System is substantially equivalent to both the MAGNETOM 3.0 T Allegra Dedicated Head only System and GE's Body Imaging Coil for 3.0T Signa VH/I system.

• General Safety and Effectiveness Concerns:

Operation of the MAGNETOM Trio System is substantially equivalent to the commercially available MAGNETOM 1.5 T Sonata System and 3.0 T Dedicated Head Only Allegra System. The following are the safety parameter with action levels:

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

and performance levels

- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

specified by the FDA guidance document for MR Diagnostic Devices were evaluated within this notification. The increase in static magnetic field of the system will affect the maximum static field and acoustic noise level, as well as certain performance levels with the system. However, the new levels 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

DEC 2 8 2001

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

Re: K013586
Trade/Device Name: Magnetom Trio System
Magnetic resonance imaging system
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: October 29, 2001
Received: October 30, 2001

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

510(k) Number (if known) K013586

Device Name: MAGNETOM Trio System

Indications for Use:

The MAGNETOM Trio system is a whole body scanner designed to support higher resolution imaging and shorter scan times. The Trio system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head and whole body. The images produced by the Trio system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin echo time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining 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____

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013586