K970852

SIEMENS

JUN - 5 1997

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: Ms. Kathleen Rutherford
Manager, Regulatory Submissions
(908) 321-4779
(908) 321-4841

Date of Summary Preparation: 3/06/97

Device Name:

- Trade Name: MAGNETOM Project 024
- Classification Name: Magnetic Resonance Diagnostic Device, CFR § 892.1000
- Classification: Class II
- Performance Standards: None established under Section 514 of the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Device Description:

The SIEMENS MAGNETOM Project 024 is a 1.0T whole body magnetic resonance imaging (MRI) system. The MAGNETOM Project 024 is the first member of a family of magnetic resonance imaging (MRI) systems. The Project 024 is being introduced as a new system and as an upgrade to the commercially available MAGNETOM Impact system.

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Intended Use:
Whole body magnetic resonance imaging.

Technological Characteristics:
The MAGNETOM Project 024 system is a high field strength system. The new MAGNETOM system has a new compact design and a redesigned patient table and rf coil system.

General Safety and Effectiveness Concerns:
The safety and performance characteristics for this system are within the scope of parameters cleared for market for the MAGNETOM Vision and MAGNETOM Impact systems. No additional safety concerns have been raised.

The device labeling for the Project 024 system will contain instructions for use, indications for use, precautions, cautions, contraindications, and warnings to the user.

Substantial Equivalence:
The MAGNETOM Project 024 system is substantially equivalent to the SIEMENS MAGNETOM Vision and MAGNETOM Impact magnetic resonance imaging systems.

Kathleen Rutherford for d_ CAP

Kathleen M. Rutherford
Manager, Regulatory Submissions
Imaging Systems Group
Siemens Medical Systems, Inc.

3/6/97

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 1997

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Re: K970852
MAGNETOM Project 024 (Numeris 3.5 Software)
Dated: March 6, 1997
Received: March 7, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. Rutherford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known) _____

Device Name: MAGNETOM Project 024

Indications for Use:

The SIEMENS MAGNETOM Project 024 is a 1Tesla whole body magnetic resonance imaging (MRI) system intended for general diagnostic use. This MRI system will present images which reflect the spatial distribution and/or magnetic resonance spectra which are a function of the frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging.

(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, ENT, and Radiological Devices
510(k) Number K970852

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