SIEMENS

510 (k) SUMMARY

JUN 20 1997

K971055

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:	Kathleen M. Rutherford Manager, Regulatory Submissions (908) 321-4779
• Date of Summary Preparation:	3/21/97

Device Name:

• Trade Name:	Diffusion Weighted- MR Imaging/ MAGNETOM Vision
• 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 the Substantial Equivalence Determination.

Device Description:

Diffusion sensitivity has been added to the basic echo-planar pulse sequence by applying a large magnetic field gradient pulse before the 180 degree refocusing rf pulse and an identical gradient pulse after the 180 degree rf pulse.

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Intended Use

The Siemens Diffusion-Weighted MR Imaging Package has been designed to image the diffusive mobility of water or other proton-containing molecules. One important clinical application is to visualize the apparent loss of mobility by water molecules in brain tissue affected by acute stroke.

Technological Characteristics

The technological characteristics of the system remain the same. New sequences will be added to the imaging platform.

General Safety and Effectiveness Concerns:

The most serious drawback of this diffusion-weighted pulse sequence is a consequence of using the echo-planar technique. Echo-planar imaging is very sensitive to magnetic field inhomogeneities, and images are distorted wherever susceptibility effects cause field inhomogeneities. Additional warnings have been included in the applications guide for the Siemens MAGNETOM.

Substantial Equivalence:

The new Diffusion Weighted MRI Sequences are substantially equivalent to commercially available Echo Planar Sequences.

Kathleen Rutherford
Signature

3/21/97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

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

Re: K971055
Diffusion Weighted Imaging (DWI) for MAGNETOM Vision
Dated: March 21, 1997
Received: March 24, 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

510(k) Number (if known) K971055

Device Name: Diffusion MR Imaging

Indications for Use:

The Siemens Diffusion-Weighted MR Imaging Package has been designed to image the diffusive mobility of water or other proton-containing molecules. One important clinical application is to visualize the apparent loss of mobility by water molecules in brain tissue affected by acute stroke. Areas of decreased diffusion, as is observed in acute cerebral infarcts, appear as areas of higher image intensity.

Diffusion weighted MR pulse sequences are more accurate than conventional MRI pulse sequences in identifying the occurrence of acute stroke during the first 24 hours after onset of symptoms.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use ___

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971055