K984224

SIEMENS

FEB 2 1999

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:

Ms. Kathleen Rutherford
Manager, Regulatory Submissions
Telephone: (732) 321-4779
FAX: (732) 321-4841

Date of Summary Preparation: 10/29/98

Device Name:

- Trade Name: Perfusion Package for Magnetom Vision and Symphony MR systems.
- Systems Classification Name: Magnetic Resonance Diagnostic Device, 21 CFR § 892.1000
- Classification : Class II
- Performance Standards : None established under Section 514 of the Food, Drug, and Cosmetic Act.

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II. Safety and Effectiveness Information Supporting Substantial Equivalence.

• Device Description:
The Perfusion Package is a post processing option for the MAGNETOM VISION and SYMPHONY MR system.

• Intended Use
The Perfusion Package for MAGNETOM VISION and SYMPHONY MR Systems is a software package which allows the display of temporal variations in dynamic MR Datasets, showing changes in contrast over time. Its purpose is to provide either time intensity curves or the creation of parametric images for parameters like time to peak that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis. One clinical application where this could be useful is the diagnosis of lesions by temporal analysis of tumor enhancement.

• Technological Characteristics
The magnet, RF system, and gradient system, of the MAGNETOM VISION and SYMPHONY configured with the Perfusion Package is substantially equivalent to the standard MAGNETOM Vision and Symphony system.

• General Safety and Effectiveness Concerns:
Operation of the MAGNETOM VISION and SYMPHONY system, with the Perfusion Package is substantially equivalent to standard operation of the MAGNETOM VISION and SYMPHONY system. The following MR safety and performance parameters are unaffected by the modification:

[Safety]
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels
- Specification Volume

[Performance]
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

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• **Substantial Equivalence:**
Laboratory and clinical 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.

Kathleen M. Rutherford
Manager, Regulatory Submissions

1/19/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

Kathleen Rutherford
Manager, Regulatory Submission
Siemens Medical Systems, Inc.
Sales and Service
186 Wood Avenue South
Iselin, NJ 08830

Re: K984224
Magnetic Resonance (MR) Diagnostic Device Accessory
Dated: November 24, 1998
Received: November 25, 1998
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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting 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) _K984224_____

Device Name: Perfusion Package for MAGNETOM Vision and Symphony Systems

Indications for Use:

The Perfusion Package for MAGNETOM Vision and Symphony MR Systems is a software package which allows the display of temporal variations in dynamic MR Datasets, showing changes in contrast over time. Its purpose is to provide either time intensity curves or the creation of parametric images for parameters like time to peak that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis. One clinical application where this could be useful is the diagnosis of lesions by temporal analysis of tumor enhancement.

(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 K984224