

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. Durkhani Roshan
Technical Specialist, Regulatory Submissions
Telephone: (732) 321-4625
FAX: (732) 321-4841

Date of Summary Preparation: 9/18/98

Device Name:

- Trade Name: Active ECG Electrodes / MAGNETOM VISION
- Systems 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 Active ECG Electrodes (AECGE) is an ECG acquisition option for the Magnetom Vision

• Intended Use

The Active ECG Electrodes (AECGE) are designed to allow for an optimized ECG acquisition during MR examinations. The small dimensions and the method of placing the AECGE directly above the patient's heart are means of minimizing the interference with the MR system.

• Technological Characteristics

The magnet, RF system, and gradient system, of the MAGNETOM Vision configured with the Active ECG Electrodes (AECGE) is substantially equivalent to the standard MAGNETOM Vision system.

• General Safety and Effectiveness Concerns:

Operation of the MAGNETOM Vision with the Active ECG Electrodes (AECGE) is substantially equivalent to standard operation of the MAGNETOM Vision system. The following MR safety and performance parameters are unaffected by the modification:

[Safety]

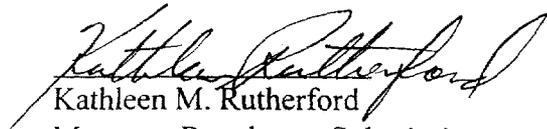
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels
- Specification Volume

[Performance]

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

• Substantial Equivalence:

Siemens believes that, within the meaning of the Safe Medical Device Act of 1990, the Magnetom Vision with the Active ECG Electrodes is substantially equivalent to the Siemens Magnetom Impact, 42 SP and 63 SP with the Disposable ECG Electrodes which were originally described in premarket notification K915112 which received FDA clearance on 12/27/91.


Kathleen M. Rutherford
Manager, Regulatory Submissions

9/21/98
Date



OCT - 9 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Woods Avenue South
Iselin, NJ 08830Re: K983327
Active ECG Electrodes MAGNETOM VISION Systems
Dated: September 18, 1998
Received: September 22, 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 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,

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) K983327

Device Name: Active ECG Electrodes

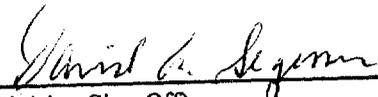
Indications for Use:

The Active ECG Electrodes (AECGE) are designed to allow for an optimized ECG acquisition during MR examinations. The small dimensions and the method of placing the AECGE directly above the patient's heart are means of minimizing the interference with the MR system.

(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 K983327