K973799

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.

JAN - 2 1998

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: October 3, 1997

Device Name:

- Trade Name: Cardiac Tagging Techniques/
  MAGNETOM Vision, Impact
- 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:

The Magnetom Cardiac Tagging Techniques consist of software and sequences designed to apply a series of equally spaced saturation bands to generate a grid on a cardiac image, for use in cardiac evaluation.

Intended Use

Siemens Cardiac Tagging pulse sequences for the Magnetom Vision and Impact systems allow for the non-invasive evaluation of cardiac wall motion and blood flow.

Technological Characteristics

The magnet, RF system, and gradient system of the Magnetom Vision and Impact configured with the Cardiac Tagging option are unchanged from that of the standard Magnetom Vision and Impact systems. Introduction of Cardiac Tagging will not affect the technological characteristics of the system, which allows presentation of images and other parameters based upon the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance.

General Safety and Effectiveness Concerns:

Operation of the MAGNETOM Vision and Impact systems with the new Cardiac Tagging feature is substantially equivalent to standard operation of the MAGNETOM Vision and Impact system. The following safety parameter action levels:

- static field strength,
- RF exposure,

and performance levels:

- high contrast spatial resolution,
- slice thickness,
- geometric distortion,
- SNR, and
- image uniformity

specified by the FDA guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

Substantial Equivalence:

Siemens believes that, within the meaning of the Safe Medical Device Act of 1990, MR Cardiac Tagging Techniques are substantially equivalent to Siemens Magnetom Cardiac Cine Techniques which were originally described in premarket notification K900889 which received FDA clearance on 03/23/90.

Kathleen Rutherford
Signature

10/3/97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 1998

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

Re: K973799
Cardiac Tagging Techniques for Magnetom
Vision and Impact (MR accessory)
Dated: October 3, 1997
Received: October 6, 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 Current Good Manufacturing Practice requirement, 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/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) K973799

Device Name: Cardiac Tagging

Indications for Use:

Siemens developed Cardiac Tagging pulse sequences for the Magnetom Vision and Impact Systems to allow for the non-invasive evaluation of cardiac wall motion and blood flow. Absence of tag deformation throughout the cardiac cycle is an indicator of dysfunctional myocardium which accompanies a variety of disease states. In addition, Cardiac Tagging may assist in differentiating between fixed thrombus and slowly flowing blood.

Cardiac Tagging is intended as an add-on to routine MR imaging examinations of the heart and great vessels. Tagging may provide additional diagnostic information, which in the hands of a qualified physician, can be useful in the diagnosis of disease.

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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 K973799