K971667

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

July 23, 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 414-544-3894, April 29, 1997

- Identification of the Product
  Cardiac Phased Array Coil

  Manufacturer Address: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Marketed Device
  The Cardiac Phased Array Coil is substantially equivalent to the currently marketed ScanMed Cardiac/Vascular Coil and the GE Pelvic Phased Array Coil.

- Device Description
  The Cardiac Phased Array Coil is a receive only coil with two separate coils matched with a front and a back (anterior and posterior) section.

- Indications for Use
  It is intended to be used in the heart and mediastinum regions for 2D and 3D imaging.

- Comparison with Predicate

  The Cardiac Phased Array Coil is similar in construction to the both predicate devices. The circuitry on the Cardiac Phased Array Coil is similar to the circuitry of the GE Pelvic Phased Array Coil.

- Summary of Studies

  The Cardiac Phased Array Coil was evaluated to NEMA performance standard MS#6 for Special Purpose Coils as well as the IEC 601-1 International medical equipment safety standard. The Coil is comparable to the predicate devices.

- Conclusions

  It is the opinion of GE that the Cardiac Phased Array Coil is substantially equivalent to the ScanMed Cardiac/Vascular Coil and the GE Pelvic Phased Array Coil. The use of this Coil does not result in any new potential hazards.

37

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1997

Larry A. Kroger, Ph.D.
Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K971667
Cardiac Phased Array Surface Coil
Dated: April 29, 1997
Received: May 6, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Dr. Kroger:

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

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): K971667

Device Name: Cardiac Phased Array Coil

Indications For Use:

It is intended to be used in the heart and mediastinum regions for 2D and 3D Magnetic Resonance imaging

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971667

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)