K981190

JUN 30 1998

GE Medical Systems

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

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, March 25, 1998

- Identification of the Product
  High Impedance Cardiac Gating Cables

  Manufactured by: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Marketed Devices

  The High Impedance Cardiac Gating Cable is substantially equivalent to the currently marketed Invivo Cables #9240A and the GE Flat Film Leads #E8811JA.

- Device Description

  The high impedance cardiac gating cable is a four lead ECG patient cable used for gating the MR scanner. The cable has a high distributed impedance to limit any RF currents induced into the cable by the MR scanner.

- Indications for Use

  The GE high impedance cardiac gating cable is designed for MR applications where cardiac gating is required to reduce motion and flow artifacts. The cable may be used in the presence of surface coils.

- Comparison with Predicate

  The GE high impedance cardiac gating cable is comparable to the Invivo cable in mechanical flexibility and with the GE Thin Film cable in regard to impedance.

- Summary of Studies

  In-house as well as volunteer testing was completed. There was no significant heating of the cables and the cables gated the MR System properly.

- Conclusions

  It is the opinion of GE that the High Impedance Cardiac Cables are substantially equivalent to the presently marketed cables. These cables do not include any new indications for use, nor does use of this cable result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Larry A. Kroger, Ph.D.
Senior Regulatory Affairs Programs Manager
General Electric Systems
P.O. Box 414, W-827
Milwaukee, Wisconsin 53201

Re: K981190
High Impedance Cardiac Gating Cable
Dated: March 25, 1998
Received: April 2, 1998
Regulator Class: II
21 CFR 892.1000/Procode: 90 LNH

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 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):_____

Device Name: High Impedance Cardiac Gating Cable

Indications For Use:

The GE High Impedance Cardiac Gating Cable is designed for MR applications where cardiac gating is desired to reduce motion and flow artifacts. The cable may be used in the presence of surface coils.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981190

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)