DEC 0 3 2002

K023380
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510(k) Summary of Safety and Effectiveness

Date:	October 4, 2002
Submitter:	GE Medical Systems *Information Technologies* 8200 West Tower Avenue Milwaukee, WI 53223 USA
Contact Person:	David Wahlig Sr. Regulatory Affairs Specialist GE Medical Systems *Information Technologies* Phone: (262) 293-1705 Fax: (414) 918-8112
Device: Trade Name:	T-Wave Alternans (TWA) Algorithm Option
Common/Usual Name:	ECG Analysis Algorithm
Classification Names:	Classification Name: 21 CFR 870.1425 Programmable diagnostic computer Classification Number: 74 DQK
Predicate Devices:	K991014 CASE 8000 Exercise Testing System
Device Description:	T-Wave Alternans (TWA) Algorithm Option is a software algorithm that runs on GE Medical Systems *Information Technologies*' electrocardiographs.
Intended Use:	The T-Wave Alternans (TWA) Algorithm Option is to be used in a hospital, doctor's office, or clinic environment by competent health care professionals for recording ST-T wave morphology fluctuations for patients who are undergoing Cardiovascular disease testing. The T-Wave alternans analysis is intended to provide only the measurements of the fluctuations of the ST-T-waves. The T-Wave alternans measurements produced by the T-Wave Alternans analysis are intended to be used by qualified personnel in evaluating the patient in conjunction with the patients clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment. No interpretation is generated.
Technology:	The T-Wave Alternans (TWA) Algorithm Option employs the same functional technology as the predicate device.
Test Summary:	The T-Wave Alternans (TWA) Algorithm Option and its host electrocardiograph comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of T-Wave Alternans (TWA) Algorithm Option: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Code inspections ▪ Verification and Validation
Conclusion:	The results of these measures demonstrate T-Wave Alternans (TWA) Algorithm Option is as safe, as effective, and performs as well as the predicate software option offered with device, CASE 8000 Exercise Testing System.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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GE Medical Systems Information Technologies
c/o Mr. David Wahlig
Sr. Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K023380
Trade Name: T-Wave Alternans (TWA) Algorithm Option
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: October 4, 2002
Received: October 8, 2002

Dear Mr. Wahlig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): 510(k) filed on October 4, 2002

Device Name: T-Wave Alternans (TWA) Algorithm Option

Indications For Use:

The T-Wave Alternans (TWA) Algorithm Option is to be used in a hospital, doctor's office, or clinic environment by competent health care professionals for recording ST-T wave morphology fluctuations for patients who are undergoing Cardiovascular disease testing.

The T-Wave alternans analysis is intended to provide only the measurements of the fluctuations of the ST-T-waves. The T-Wave alternans measurements produced by the T-Wave Alternans analysis are intended to be used by qualified personnel in evaluating the patient in conjunction with the patients clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment. No interpretation is generated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)