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K031561  
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510(k) Summary of Safety and Effectiveness

Date:

May 15, 2003

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  
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Device:

Trade Name:

CardioSoft/CASE Cardiac Testing System

Common/Usual Name:

ECG Analysis Computer

Classification Names:

21 CFR 870.1425 Programmable diagnostic computer  
21 CFR 870.2920 Transmitters and Receivers, Electrocardiograph, Telephone  
21 CFR 870.2340 Electrocardiograph  
21 CFR 870.2340 System, ECG Analysis  
21 CFR 870.1025 Detector and Alarm, Arrhythmia

Predicate Devices:

CASE 8000 exercise testing system	K991014
CardioSoft CardioSys	K951130
Twave Alternans	K023380
GE Marquette ECG Analysis Program (12SL)	K002209

Device Description:

The CardioSoft/CASE Cardiac Testing System is designed to be used for resting ECG, stress test ECG, Spirometry, Ambulatory Blood Pressure and for recording ECG in real-time with and without arrhythmia detection.

The CardioSoft will be offered as a software only package including a front end for data acquisition.

The CASE is a turnkey product utilizing the CardioSoft software. The CASE device is designed for the US markets. A version designed for the European market, the CardioSys, will not be offered for sale in the US.

Intended Use:

CardioSoft/CASE Cardiac Testing System is intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CardioSoft/CASE Cardiac Testing System is designed to acquire process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection portion of CardioSoft/CASE Cardiac Testing System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

CardioSoft/CASE Cardiac Testing System provides the control of external device (typically a treadmill or Ergometer) and communicates with centralized electronic/digital storage system via network. CardioSoft/CASE Cardiac Testing System provides a user selectable option for printouts of prognostic scores on select reports. Vector loops are also available.

CardioSoft/CASE Cardiac Testing System can be configured in a network environment for multiple CASE and CardioSoft stations allowing the user to create a central database of patient demographics and collected patient physiological data.

CardioSoft/CASE Cardiac Testing System is intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, Spirometry or ambulatory blood pressure testing is performed.

CardioSoft/CASE Cardiac Testing System offers no diagnostic opinion to the user. Instead it provides interpretive statements of morphology, rhythm, and conduction for which the physician renders his/her own medical opinion.

CardioSoft/CASE Cardiac Testing System is not intended to be used as a transport device or for home use. CardioSoft/CASE Cardiac Testing System is not intended for the use as a vital signs physiological monitor or for intracardiac use.

Technology:

The proposed CardioSoft/CASE Cardiac Testing System employs the same technology as the predicate device.

Test Summary:

The CardioSoft/CASE Cardiac Testing System complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the CardioSoft/CASE Cardiac Testing System is as safe, as effective, and performs as well as the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K031561

Trade Name: CardioSoft/CASE Cardiac Testing Systems  
Regulation Number: 21 CFR §870.1025  
Regulation Name: Patient Physiological Monitor with arrhythmia detection and alarms  
Regulatory Class: Class III (three)  
Product Code: MHX  
Dated: May 15, 2003  
Received: May 19, 2003

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.

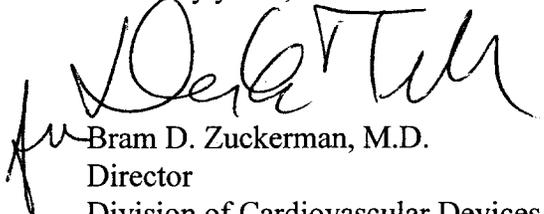
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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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) you may obtain. 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):

Device Name: CardioSoft/CASE Cardiac Testing System

Indications For Use:

CardioSoft/CASE Cardiac Testing System is intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CardioSoft/CASE Cardiac Testing System is designed to acquire process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometry and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection portion of CardioSoft/CASE Cardiac Testing System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K031561