K091594
p1/2

JUL 29 2009

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	May 29, 2009
Submitter:	GE Healthcare, GE Medical Systems Information Technologies GmbH Munzinger Str. 3 79111 Freiburg, Germany
Primary Contact Person:	Patricia Taige Regulatory Affairs – Diagnostic Cardiology GE Healthcare, GE Medical Systems Information Technologies 9900 Innovation Drive Wauwatosa, WI 53226 Phone: (414) 721-3222 Fax: (414) 721-3863
Secondary Contact Person:	David Wahlig RA Director - Patient Monitoring GE Healthcare, GE Medical Systems Information Technologies 8200 West Tower Avenue Milwaukee, WI 53223 Phone: (262) 510-9997 Fax: (414) 918-8112
Device: Trade Name:	HEART-Exercise
Common/Usual Name:	ECG Analysis Computer, Programmable Diagnostic Computer
Classification Names: Product Code:	21 CFR 870.1425 DQK
Predicate Device(s):	CardioSoft/CASE Cardiac Testing System (K031561)
Device Description:	HEART-Exercise is an algorithm library for exercise testing systems. It is able to process up to 15 lead ECGs with a high noise and artifact level and provides real-time and retrospective computerized analysis of stress test ECGs for evaluation by the user.
Intended Use:	The HEART-Exercise is to be used in a hospital, doctor's office, or clinical environment by competent healthcare professionals for assessing exercise test results. The results of HEART-Exercise are intended to be used by

qualified personnel in evaluating the patient in conjunction with the patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment.

HEART-Exercise provides measurements, prognostic scores, and interpretive statements of the exercise test for which the physician renders his/her own opinion. HEART-Exercise does not offer a diagnostic opinion to the user.

The Exercise Test Interpretation (XTI) is restricted to adults (age ≥ 18 years). The measurements apply to adults and children able to accomplish an exercise test

Technology: The proposed HEART-Exercise algorithm library employs the same fundamental scientific technology as the HEART-Exercise algorithm library currently cleared as part of the predicate device CardioSoft/CASE Cardiac Testing System (K031561)

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The HEART-Exercise algorithm library and its applications comply with voluntary standards as detailed in Section 9 and 16 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, HEART-Exercise, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the HEART-Exercise algorithm library to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2009

GE Healthcare, GE Medical Systems Information Technologies GmbH
c/o Ms. Patricia Taige
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K091594
HEART - Exercise
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhytmia detector and alarm (including ST- segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX, (DQK, DXH, DPS)
Dated: May 29, 2009
Received: June 02, 2009

Dear Ms. Taige:

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 (240) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K091594

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name: HEART-Exercise

Indications for Use:

The HEART-Exercise is to be used in a hospital, doctor's office, or clinical environment by competent healthcare professionals for assessing exercise test results.

The results of HEART-Exercise are intended to be used by qualified personnel in evaluating the patient in conjunction with the patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgment.

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Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 7/29/09
Division of Cardiovascular Devices
510(k) Number K091594