K060833

AUG 0 1 2006

Section 2 Summary

510(k) Summary of Safety and Effectiveness

Date: March 17, 2006

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Lisa M. Baumhardt
Regulatory Affairs Program Manager
GE Medical Systems *Information Technologies*
Phone: 414-362-3242
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Device: Trade Name: 12SL ECG Analysis Program with Right Ventricular Analysis
Common/Usual Name: ECG Analysis Program

Classification Names:
21 CFR 870.1025 Monitor, Physiological Patient (with Arrhythmia Detection or Alarms) 74MHX

Predicate Device: K042177 MAC 5000 ECG Analysis System

K002209 12SL ECG Analysis Program

Device Description: The 12SL ECG Analysis Program with Right Ventricular Analysis is a software algorithm only.

Intended Use: The 12SL ECG Analysis Program assists the physician in interpreting resting 12-lead ECGs for rhythms and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patient's homes.

Technology: The 12SL ECG Analysis System with Right Ventricular Analysis employs the same functional technology as the predicate devices.

Test Summary: The 12SL ECG Analysis System with Right Ventricular Analysis 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:

- Risk Analysis
- Requirement Specification Reviews
- Code Inspections
- Software Verification and Validation Testing

Conclusion: The results of these measurements demonstrated that the 12SL ECG Analysis System with Right Ventricular Analysis is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

GE Medical Information Technologies
c/o Ms. Lisa M. Baumhardt, M.T.
Regulatory Affairs Manager
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K060833
Trade Name: 12SL ECG Analysis System with Right Ventricular Analysis
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm).
Regulatory Class: Class II (two)
Product Code: MHX
Dated: July 27, 2006
Received: July 28, 2006

Dear Ms. Baumhardt:

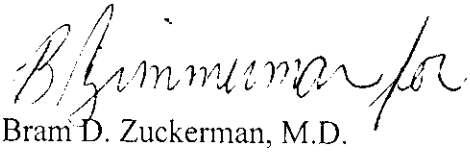
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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: 12SL ECG Analysis System with Right Ventricular Analysis

Indications For Use:

The 12SL ECG Analysis System with Right Ventricular Analysis assists the physician in interpreting resting 12-lead ECGs for rhythms and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patient's homes.

Prescription Use_X_ OR Over-The-Counter Use____
(Per 21 CFR 801.109 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062833