K050614

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Section 2 Summary

APR - 5 2005

510(k) Summary of Safety and Effectiveness

Date: March 7, 2005

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

Contact Person: Lisa M. Baumhardt
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
Phone: (262) 293-1699
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Device: Trade Name: MUSE Cardiology Information System
Common/Usual Name: ECG Analysis Computer
Classification Names: 21 CFR 870.1425 Computer, Diagnostic, Programmable
Predicate Device: MUSE Cardiovascular Information System (K992637)

Device Description: The MUSE Cardiology Information System comprises a client workstation/server configuration whose purpose is to manage diagnostic cardiology data. The MUSE Cardiology Information System is a network PC-based system that provides centralized storage and ready access to a wide range of data/reports (e.g. Resting ECG, Stress, Holter, HiRes) from GE and non-GE diagnostic and monitoring equipment.

Intended Use: The MUSE Cardiology Information System is intended to store, access and manage cardiovascular information on adult and pediatric patients. The information consists of measurements, text, and digitized waveforms. The MUSE Cardiology Information System provides the ability to review and edit electrocardiographic procedures on screen, through the use of reviewing, measuring, and editing tools including ECG serial comparison. The MUSE Cardiology Information System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or facility providing patient care. The MUSE Cardiology Information System is not intended for primary monitoring. The MUSE Cardiology Information System is not intended for pediatric serial comparison.

Technology: The proposed MUSE Cardiology Information System employs the same functional scientific technology as the predicate device MUSE Cardiovascular Information System (K992637).

Test Summary: The MUSE Cardiology Information 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 device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration Testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental Testing

Conclusion: The results of these measurements demonstrated that the MUSE Cardiology Information System is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2005

General Electric Medical Systems Information Technologies
c/o Ms. Lisa Baumhardt
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K050614
Trade Name: MUSE Cardiology Information System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: March 22, 2005
Received: March 23, 2005

Dear Ms. Baumhardt:

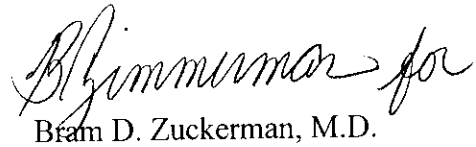
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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): K050614

Device Name: **MUSE Cardiology Information System**

Indications For Use:

The MUSE Cardiology Information System is intended to store, access and manage cardiovascular information on adult and pediatric patients. The information consists of measurements, text, and digitized waveforms. The MUSE Cardiology Information System provides the ability to review and edit electrocardiographic procedures on screen, through the use of reviewing, measuring, and editing tools including ECG serial comparison. The MUSE Cardiology Information System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or facility providing patient care. The MUSE Cardiology Information System is not intended for primary monitoring. The MUSE Cardiology Information System is not intended for pediatric serial comparison.

Prescription Use__X__ AND/OR Over-The-Counter Use____
(Per 21 CFR 801 Subpart D) (Per 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)

B Summerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050614