NOV 19 2007

Attachment B

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

Submitter: GE Medical Systems Information Technologies
9900 Innovation Drive
Wauwatosa, WI 53226

Contact Person: Patricia Taige
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GE Medical Systems Information Technologies
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Date Prepared: September 4, 2007

Device Names:
- Proprietary Name: MUSE Cardiology Information System
- Common/Usual Name: ECG Analysis Computer
- Classification Name: Programmable Diagnostic Computer (21 CFR 870.1425 – Product Code DQK)

Predicate Device: MUSE Cardiovascular Information System (K050614)

Device Description: The MUSE Cardiology Information System is a network PC-based system comprised of a client workstation/server configuration that manages adult and pediatric diagnostic cardiology data by providing 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.

The device provides the ability

- To review and edit stored data consisting of measurements, text, and digitized waveforms on screen, through the use of reviewing, measuring, and editing tools including ECG serial comparison.
- To generate formatted management reports, ad-hoc database search reports and clinical patient reports on selected stored data.

This modification will provide the capability to generate median waveforms and ECG measurements from 12-lead ECG data received in a GE specified XML format. Other added functionality includes an additional QTc calculation method, a refined tool (Interval Editor) to manually measure, review, and document ECG waveform parameters, and workflow enhancements.

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.

Technology: The proposed MUSE Cardiology Information System employs the same functional scientific technology as the predicate device MUSE Cardiovascular Information System (K050614).

Test Summary: Non-clinical Tests: The MUSE Cardiology Information System complies with the voluntary standards as detailed in Section 3.2 of this submission. The following quality assurance measures were applied to the development of the device modification subject to this submission:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Integration Testing (System verification)
- Final acceptance testing (Validation)
- Performance testing

Clinical Tests: None required

Conclusion: Based on the results of the performed testing it is concluded that the MUSE Cardiology Information System with the modifications subject to this submission is substantially equivalent to and is as safe, as effective, and performs as well as the currently marketed predicate device cleared in K050614.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

GE Medical Systems Information Technologies
c/o Patricia Taige
Sr. Regulatory Affairs Specialist
9900 Innovation Dr.
Wauwatosa, WI 53226

Re: K072502
Trade/Device Name: Muse Cardiology Information System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 16, 2007
Received: October 17, 2007

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,

M. A. Hillebrenner

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

Enclosure

Attachment E

Indications for Use

510(k) Number (if known): K072502

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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072502