MAY 25 2011

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:	January 12, 2011
Submitter:	GE Medical Systems *Information Technologies* 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Kristin Pabst Regulatory Affairs Manager GE Medical Systems *Information Technologies* Phone: (414) 721-3104 Fax: (414) 721-3863
Secondary Contact Person:	Patricia Taige Regulatory Affairs Leader GE Medical Systems *Information Technologies* Phone (414) 721-3222 FAX: (414) 721-3863
Device: Trade Name:	MUSE Cardiology Information System
Common/Usual Name:	ECG Analysis Computer
Classification Names:	Programmable Diagnostic Computer (21 CFR 870.1425)
Product Code:	DQK
Predicate Device(s):	MUSE Cardiology Information System K#072502 MUSE Cardiology Information System w/ VMWare K#083639
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 and interpretive 12-lead analysis. •Generate formatted management reports, ad-hoc database search reports and clinical patient reports on selected stored data.

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 and interpretive 12-lead analysis. 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 real time 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 devices MUSE Cardiovascular Information System (K072502) and MUSE Cardiovascular Information System w/ VMWare (K083639).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MUSE Cardiology Information System complies with voluntary standards as detailed in Section 9 and 17 of this premarket submission. The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Code Inspection
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, MUSE Cardiology Information System, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the MUSE Cardiology Information System to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems Information Technologies, Inc
c/o Ms. Kristin Pabst
Regulatory Affairs Manager
9900 West Innovation Drive
Wauwatosa, WI 53226

MAY 25 2011

Re: K110132
Trade/Device 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: May 4, 2011
Received: May 6, 2011

Dear Ms. Pabst:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

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GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known):

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 and interpretive 12-lead analysis. 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 real-time patient monitoring. The MUSE Cardiology Information System is not intended for pediatric serial comparison.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110132