K083639

FEB 17 2009

GE Healthcare

510(k) Premarket Notification Submission

MUSE Cardiology Information System with VMWare

510(k) Summary

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

Date: December 5, 2008

Submitter: Larry Lepley
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Larry Lepley
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226
T: (414) 721-2593
F: (414) 721-3899

Secondary Contact Person: Patricia Taige
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226
T: (414) 721-3222
F: (414) 721-3899

Device: Trade Name: MUSE Cardiology Information System

Common/Usual Name: ECG Analysis Computer, Programmable Diagnostic Computer

Classification Names: 21 CFR 870.1425

Product Code: DQK

Predicate Device(s): K072502 MUSE Cardiology Information System

Device Description: The MUSE Cardiology Information System is intended to store, access and manage cardiology information on adult and pediatric patients. MUSE Cardiology Information System has been marketed to operate within Microsoft Windows Operating System (OS) directly interacting with the host hardware. GE Healthcare intends to change this interaction by running MUSE Cardiology Information System with an Off the Shelf virtualization software layer. GE feels that this proposed change alters the principal of operation of the Operating System. This proposed change will be marketed as a software only offering, which will utilize an OTS software that virtualizes the host hardware. This will allow multiple OS shells to run on a single hardware server, one of which is the OS hosting the predicate MUSE Cardiology Information System program.

The functional intent of MUSE Cardiology Information System with VMWare will remain the same as the premarket notification reviewed in 2007 (K072502). For conveyance the description for (K072502) is the following:
The MUSE Cardiology Information System is a network PC based system comprised of a client workstation /server configuration that manages adult and pediatric diagnosis cardiology data by providing centralized storage and ready access to a wide range of data/report (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.

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.

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 MUSE Cardiology Information System with VMWare

employs a different functional scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MUSE Cardiology Information System with VMWare and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 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)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

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

Conclusion: GE Healthcare considers the MUSE Cardiology Information System with VMWare to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2009

GE Medical Systems Information Technologies
c/o Mr. Larry Lepley
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K083639
Trade/Device Name: MUSE Cardiology Information System with VMWare
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: December 5, 2008
Received: December 6, 2008

Dear Mr. Lepley:

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): K083639

Device Name: **MUSE Cardiology Information System with VMWare**

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_____
(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 BZuckerman

(Division Sign-Off) 2/17/09
Division of Cardiovascular Devices
510(k) Number K083639