DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 12, 2016

GE Medical Systems Information Technologies, Inc.
Amy Yang
Regulatory Affairs Program Manager
9900 West Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K152993
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: December 10, 2015
Received: December 14, 2015

Dear Amy Yang:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152993

Device Name
MUSE Cardiology Information System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date:	09 October 2015
Submitter:	GE Medical Systems *Information Technologies,* Inc. 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Amy Yang Regulatory Affairs Program Manager GE Medical Systems *Information Technologies,* Inc. Phone: (414)721-3807 Fax: (414) 721-3863
Secondary Contact Person:	Doug Kentz Regulatory Affairs Director GE Medical Systems *Information Technologies,* Inc. Phone: (414)581-8987 Fax: (414)362-2585
Device Trade Name:	MUSE Cardiology Information System
Common/Usual Name:	ECG Analysis Computer
Classification Names:	Programmable Diagnostic Computer (21 CFR 870.1425)
Regulatory Class:	II
Product Code:	DQK
Predicate Device(s):	MUSE Cardiology Information System K130155 12SL ECG Analysis Program K141963 No reference devices were used in this submission

Device Description: The MUSE Cardiology Information System is a network based cardiology information management system that manages adult and pediatric diagnostic cardiology data by providing centralized storage and ready access to a wide range of data types and reports from GE and non-GE data acquisition devices. The MUSE Cardiology Information System 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.
- Translates and transfers patient demographic and administrative data from EMR/HIS systems to clinical acquisition devices and translates and transfers tests results from clinical acquisition devices to EMR/HIS systems.
- Configurable workflow capabilities for managing administrative and clinical tasks in the diagnostic cardiology department, including order/patient demographic management, clinical test review/edit, clinical report distribution, and billing.

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.

Comparison of Technological Characteristics with the predicate device:

At a high level, the subject and predicate devices are based on the following same technological elements:

- Incorporated12SL ECG Analysis Program provides computerized measurements and interpretive diagnostic statements that assist the physician interpreting the ECG.
- 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.
- Translates and transfers patient demographic and administrative data from EMR/HIS systems to clinical acquisition devices and translates and transfers tests results from clinical acquisition devices to EMR/HIS systems.
- Configurable workflow capabilities for managing administrative and clinical tasks in the diagnostic cardiology department, including order/patient demographic management, clinical test review/edit, clinical report distribution, and billing.

The following technological differences exist between the subject and predicate devices:

- The DICOM communication services provide workflow functionality for managing ECG Test orders and results as an alternative to HL7.
- eDOC connection feature provide the ability for the user to create custom test types and import test data using industry standard formats.
- LDAP/AD authentication and authorization provide user the ability to log into the MUSE system using the customer's AD infrastructure.

Technology: The proposed MUSE Cardiology Information System is a software device that runs on IT hardware employing the same functional scientific technology as the predicate device MUSE Cardiovascular Information System (K130155).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MUSE Cardiology Information System complies with voluntary standards:

- IEC 62304:2006 – Medical device software – Software life-cycle processes
- IEC 62366:2007 – Medical devices – Application of usability engineering to medical devices.
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices

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 device.