

NOV - 3 1999

K992637  
P/2

## Section 2 Summary and Certification

### 2.1 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date: July 30, 1999

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

Contact Person: Laura L. McComis  
Corporate Regulatory Affairs  
GE Marquette Medical Systems  
Phone: (414) 362-2688  
Fax: (414) 355-3790

Device:      Trade Name: MUSE Cardiovascular Information System

Common/Usual Name: Computer, diagnostic, programmable  
Detector and Alarm, Arrhythmia

Classification Names: Classification Name: Computer, Diagnostic, Programmable  
Classification Number: 74DQK

Predicate Devices: K980495 MUSE Cardiovascular Information System  
K912829 CardioTrace Cardiac Evaluation System

Device Description: MUSE CV is a large capacity client server based computer system that accesses, stores, and manages cardiovascular information. The information can consist of measurements, text, digitized waveforms and angiographic images.

Intended Use:

MUSE CV is intended to be used in a hospital environment by trained operators.

MUSE CV is designed for network compatibility to facilitate retrieval and distribution of cardiovascular information.

MUSE CV is designed to interface with other hospital information systems through various communication protocols to support information continuity and results reporting.

MUSE CV can provide serial comparison of cardiovascular information to facilitate review of current and previous records.

MUSE CV can provide serial trending of cardiovascular information to facilitate review of current and previous records.

Through integration with Accusketch (CardioTrace), MUSE aids the physician or trained technologist in providing and documenting an objective quantification of coronary artery stenosis and measurement and quantification of left ventricular function. Also provided is the ability to digitize and store video images and the ability to interactively annotate and report current and post procedural patient cardiac status.

Use of MUSE CV is intended for accessing, storage and management of both adult and pediatric cardiovascular information.

The intended use of MUSE CV is identical to the intended use of the predicate devices

Technology:

MUSE CV employs the same functional technology as the predicate devices. The only difference being the technological improvements made by manufacturers with respect to speed, performance and reliability.

Test Summary:

The MUSE CV complies with voluntary standards as detailed in *Section 9 Specific Standards and Guidances* of this submission. The following quality assurance measures were applied to the development of MUSE CV:

- Requirements specification review
- Risk analysis
- Design, software and test plan reviews
- Code inspections
- Testing on unit level
- Software and hardware testing
- System Integration testing
- Final acceptance testing
- Environmental Testing
- Safety testing

Conclusion:

The results of these measures demonstrate MUSE CV is as safe, as effective, and performs as well as the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 3 1999

Laura L. McComis  
Regulatory Affairs Specialist  
GE Marquette Medical Systems  
8200 W. Tower Avenue  
Milwaukee, WI 53223

Re: K992637  
Muse Cardiovascular Information System  
Regulatory Class: III (three)  
Product Code: DSI  
Dated: August 5, 1999  
Received: August 6, 1999

Dear Ms. McComis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

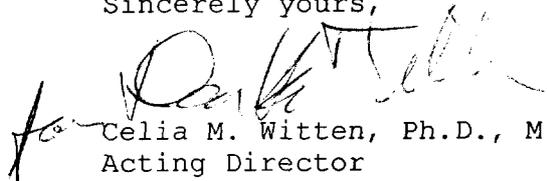
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Laura L. McComis

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 11 Intended Use Statement**

510(k) Number (if known): K992637 ~~Unknown~~ 510(k) filed: July 30, 1999

Device Name: MUSE CV Cardiovascular Information System

Indications For Use:

MUSE CV is a large capacity client server based computer system that accesses, stores, and manages cardiovascular information. The information can consist of measurements, text, digitized waveforms and angiographic images.

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MUSE CV is designed for network compatibility to facilitate retrieval and distribution of cardiovascular information.

MUSE CV is designed to interface with other hospital information systems through various communication protocols to support information continuity and results reporting.

MUSE CV can provide serial comparison of cardiovascular information to facilitate review of current and previous records.

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Use of MUSE CV is intended for accessing, storage and management of both adult and pediatric cardiovascular information.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

[Handwritten Signature]  
\_\_\_\_\_  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K992637