K991786

NOV 18 1999

Section 2 Summary and Certification

2.1 510(k) Summary of Safety and Effectiveness

Date:	May 24, 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:	MARS Unity Workstation with Heart Rate Variability (HRV) Option
Common/Usual Name:	Holter Analysis System
Classification Names:	Classification Name: Computer, Diagnostic, Programmable Classification Number: 74DQK
Predicate Devices:	K922171 CENTRA II Analysis System K950779 Spacelabs Heart Rate Variability Software Option
Device Description:	The Multi-Parameter Analysis and Review System (MARS) unity workstation is an off-the-shelf computer hardware platform that supports a number of software applications including Holter analysis and editing system software and full disclosure clinical review software. 1) The Holter analysis software performs acquisition, analysis, editing, review, reporting and storage of ambulatory ECG and multiparameter data acquired from solid-state electronic ECG recorders, tape recorders and the monitoring real-time network. 2) The clinical review software (CRS) is a full disclosure system that acquires ECG and mixed parameter waveform data from Marquette's Unity monitoring network for display and reporting. Heart Rate Variability (HRV) Option is a software option for Marquette Holter analysis systems which measures the variation from one cardiac cycle to the next, utilizing specific morphology. Heart rate variability can be analyzed using either the Time Domain mode, which quantifies variations using simple statistics, or the Spectral mode, which characterizes interval variations as a power spectrum.

Intended Use:	The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric. The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data. Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis. The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement. The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.
Technology:	MARS Unity Workstation with Heart Rate Variability (HRV) Option employs the same technology as the predicate devices.
Test Summary:	The MARS Unity Workstation with Heart Rate Variability (HRV) Option 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 MARS Unity Workstation with Heart Rate Variability (HRV) Option: • Risk analysis • Requirements specification reviews • Code inspections • Software and Hardware Testing • Safety testing • Environmental testing • Final validation
Conclusion:	The results of these measures demonstrate MARS Unity Workstation with Heart Rate Variability (HRV) Option is as safe, as effective, and performs as well as the predicate devices, CENTRA II Analysis System and Spacelabs Heart Rate Variability Software Option.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

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

Re: K991786
MARS Unity Workstation with Heart Rate Variability
Regulatory Class: II (two)
Product Code: DPS
Dated: September 17, 1999
Received: September 20, 1999

Dear Ms. McCornis:

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.

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,

Nancy C. Brogdon for

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 Indications for Use Statement

510(k) Number (if known): Unknown - 510(k) filed: May 24, 1999

Device Name: MARS Unity Workstation with Heart Rate Variability (HRV) Option

Indications For Use:

The MARS Unity Workstation is intended to acquire, analyze, edit, review, report and store ambulatory and monitoring network ECG and multiparameter data. The MARS Unity Workstation is intended to be used by trained operators under the direct supervision of a licensed health care practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric.

The Heart Rate Variability (HRV) Option is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability heart rate data.

Heart Rate Variability (HRV) Option is intended to provide only HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The HRV measurements produced by Heart Rate Variability (HRV) Option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.

The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991786