OCT 20 1999

K991014

Section 2 Summary and Certification

2.1 510(k) Summary of Safety and Effectiveness

Date: March 25, 1999

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

Contact Person:
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Corporate Regulatory Affairs
GE Marquette Medical Systems
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Device: Trade Name: CASE 8000 exercise testing system

Common/Usual Name: ECG analysis computer

Classification Names:

21 CFR 870.1425 Programmable diagnostic computer	Class II	74DQK
21 CFR 870.2920 Transmitters and Receivers, Electrocardiograph, Telephone	Class II	74DXH
21 CFR 870.2340 Electrocardiograph	Class II	74DPS
21 CFR 870.2340 System, ECG Analysis	Class III	74LOS

Predicate Devices: K951130 CardioSoft/CardioSys
K973403 12SL Analysis System

Device Description:

The CASE 8000 exercise testing system is a PC-based device capable of being operated as a stand-alone system or in conjunction with a centralized electronic/digital storage system such as the MUSE CV Information System - K980495 (MUSE). Major components include a CPU, display, modem, mouse, printer, keyboard, power supply, acquisition module and a cart. It is intended to be used primarily in hospital based exercise testing laboratories. It can also be used in clinics and outreach centers or wherever exercise testing is performed.

The primary application of the device is to acquire, process, record, archive, analyze and output data during a period of physiologic stress or during rest. Ancillary functions include control of an external exercise device, typically a treadmill or ergometer, and communication with a centralized electronic/digital storage system such as the MUSE.

When used in conjunction with MUSE, the CASE 8000 exercise testing system is capable of bringing computerized information management to the exercise laboratory. Demographic and order information can be downloaded to the system to simplify order management and data entry operation. Results from previous tests can be reviewed on the system after network download from the MUSE. New results can be quickly sent to the MUSE for long term storage.

Intended Use:

The intended use of the CASE 8000 exercise testing system is to acquire, process, record, archive, analyze, and output data during a period of physiologic stress or during a resting ECG condition. The CASE 8000 exercise testing system has the ability to calculate prognostic scores. These include DUKE treadmill score and Risk Factor Prediction, which are Coronary Heart Disease Risk Factor and Stroke Risk Factor. A user selectable option can provide printout of prognostic scores on select reports. A vector loops report is also available.

Ancillary functions include control of an external device (typically a treadmill or ergometer) and communications with centralized electronic/digital storage system.

The device records 12 lead ECG data taken in resting and exercise modes, as well as real-time rhythm and median morphology recordings. The device can perform a 12 lead interpretive analysis on the resting ECG, providing the user with statements of morphology, rhythm and conduction. No changes have been made to this algorithm - 12SL Analysis System K973403.

The CASE 8000 exercise testing system is intended to be used by trained operators under the direct supervision of a licensed health care practitioner when exercise or resting ECG records are required.

The CASE 8000 exercise testing system is intended to be used primarily in hospital based exercise testing laboratories, but can be used in clinics, physician offices, outreach centers or wherever exercise testing is performed.

Technology:

CASE 8000 exercise testing system employs the same technology as the predicate devices.

Test Summary:

The CASE 8000 exercise testing system complies with the 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 CASE 8000 exercise testing system:

- Risk analysis
- Requirements specification reviews
- Code inspections
- Software and Hardware Testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measures demonstrate that the CASE 8000 exercise testing system is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 1999

Ms. Laura L. McComis
GE Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K991014
CASE 8000 Exercise Testing System
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: July 21, 1999
Received: July 22, 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.

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"(21 CFR 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,

Joann M Weichhaus

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

Enclosure

K991014

Section 11 Indications for Use Statement

510(k) Number (if known): Unknown - 510(k) filed March 25, 1999

Device Name: CASE 8000 exercise testing system

Indications For Use:

The CASE 8000 exercise testing system is a diagnostic device intended to monitor and record electrocardiographic data from the patient during exercise, as well as perform resting ECG analysis.

The intended use of the CASE 8000 exercise testing system is to acquire, process, record, archive, analyze, and output data during a period of physiologic stress or during a resting ECG condition. The CASE 8000 exercise testing system has the ability to calculate prognostic scores. A user selectable option can provide printout of prognostic scores on select reports. A vector loops report is also available.

Ancillary functions include control of an external device (typically a treadmill or ergometer) and communications with centralized electronic/digital storage system.

This device uses a computerized analysis program, which can be used as a tool in ECG tracing interpretation.

The device records 12 lead ECG data taken in resting and exercise modes, as well as real-time rhythm and median morphology recordings. The device can perform a 12 lead interpretive analysis on the resting ECG, providing the user with statements of morphology, rhythm and conduction.

The CASE 8000 exercise testing system is intended to be used by trained operators under the direct supervision of a licensed health care practitioner when exercise or resting ECG records are required.

The CASE 8000 exercise testing system is intended to be used primarily in hospital based exercise testing laboratories, but can be used in clinics, physician offices, outreach centers or wherever exercise testing is performed. This device is not intended for use with high frequency surgical units.

The CASE 8000 system is not intended to be used as a vital signs physiological monitor.

This equipment will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulator.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991014