

MAR 28 2000

K994430

510(k) Summary of Safety and Effectiveness

Date:

December 29, 1999

Submitter:

GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

Karen Webb
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems, Inc.
Phone: (414) 362-3329
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Device: Trade Name:

IMPACT.wf Mobile Waveform Receiving System

Common/Usual Name:

Pager

Classification Names:

System, Network and Communication, Physiological 74 MSX
Monitor

Predicate Devices:

K971868
Marquette IMPACT (Informing Mobile Personnel and Care Tracking)
Pager System

Device Description:

The IMPACT.wf provides a secondary means for displaying and annunciating patient monitoring system alarm conditions at remote locations throughout a defined area of coverage in a hospital. The IMPACT.wf is not intended to replace the primary monitoring via the central station, patient bedside monitor, or telemetry system.

The IMPACT.wf consists of the following basic components: the IMPACT.wf Server (PC platform); Micro Serial Server; Transmitter; and Receiver(s) (Pagers). Optional components include Workstation(s).

The IMPACT.wf Server observes the Unity™ network for alarm packets containing information about patient events that are generated by the patient monitors. When alarm packets are observed, it processes the information, and transmits the information to the caregiver worn receiver(s). Data provided includes name, bed, heart rate, arrhythmia call, an ECG waveform, and enabled monitored parameter numerics (i.e. ECG heart rate, SpO2, ST, arterial BP, NBP and ART disconnect).

The IMPACT.wf Server does not acquire physiological signals from a patient nor does it process the physiological data received from the patient monitors to determine patient status. These functions are reserved for the patient monitoring system.

Intended Use:

The IMPACT.wf Mobile Waveform Receiving System is intended for the secondary annunciation and display of selected alarm conditions at remote locations throughout a defined area of coverage. The device is intended for use within the hospital/facility environment. The intended patient population is the same as the device generating the information used by the IMPACT.wf. The IMPACT.wf is not intended to replace primary monitoring via the central station, telemetry system, or patient bedside monitor.

Technology:

The IMPACT.wf employs the same functional technology as the predicate device.

Test Summary:

The IMPACT.wf complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the IMPACT.wf:

- Requirements specification review
- Software validation and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrate that IMPACT.wf is as safe, as effective, and performs as well as the predicate device.



MAR 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Webb
GE Marquette Medical Systems
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K994430
IMPACT.wf Mobile Waveform Receiving System
Regulatory Class: III (three)
Product Code: 74 MSX
Dated: December 29, 1999
Received: December 30, 1999

Dear Ms. Webb:

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.

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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,



James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(K994430)

510(k) Number (if known): Unknown; 510(k) filed on December 29, 1999

Device Name: IMPACT.wf Mobile Waveform Receiving System

Indications For Use:

The IMPACT.wf Mobile Waveform Receiving System is intended for the secondary annunciation and display of selected alarm conditions at remote locations throughout a defined area of coverage. The device is intended for use within the hospital/facility environment. The intended patient population is the same as the device generating the information used by the IMPACT.wf. The IMPACT.wf is not intended to replace primary monitoring via the central station, telemetry system, or patient bedside monitor.

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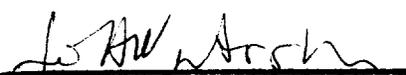
Concurrence of CDRH, Office of Device Evaluation (ODE)

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 _____

K994430