K971868

NOV 13 1997

510(k) Summary of Safety and Effectiveness

1. Submitter

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

Establishment Registration Number
2124823

Contact Name / Telephone Number
Dianne Schmitz
Corporate Regulatory Affairs
Marquette Medical Systems

Phone: (414) 362-3230

Date: 8 May 97

2. General Information

Trade/Proprietary Name

Marquette's name for this device is IMPACT (Informing Mobile Personnel and Care Tracking) Pager System.

Common/Usual Name

This device is commonly known as a pager.

Device Classification

This device is unclassified according to a review performed of the CDRH Manual - FDA 91-4246 *Classification Names for Medical Devices and In Vitro Diagnostic Products*, as well as the Diogenes - *The 510(k) Register* and database.

Performance Standards

Performance standards (Section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

3. Legally Marketed Predicate Device(s)

The legally marketed predicate product is the ADU/ Pager-LAN System, K962827.

4. Device Description and Intended Use

The IMPACT pager is intended for the annunciation of events to provide zone information that is secondary to the primary care provided. It provides specific information within a zone and alerts or draws an identified individual's attention to a defined patient condition in a timely manner. Primary care via the central station, telemetry system, or patient bedside monitor remains unchanged by the addition of the IMPACT pager.

6. Test Summary & Conclusion

The CardioPager Server, Micro Serial Server, and the Pager Transmitter are not used in the patient environment. These devices are purchased from the manufacturer with appropriate U.L. listing or classification on the device and/or the external power modules. The devices' U.L. Listing or Classification was reviewed by Marquette's Technical Coordinator and found to be appropriate. Marquette's reliability group also performed additional electrical and mechanical performance and safety tests which were specified and included in the submission.

While the CardioPager system functions as a secondary enunciator of alarms, the bedside monitor and central station make up the patient monitoring system. Patient waveform acquisition, determination of alarm conditions, and alarm notifications are primary functions of the patient monitoring system, which has been previously verified for accuracy. Because the CardioPager replicates arrhythmia type, heart rate, and waveform information obtained from the monitoring system via Ethernet, this Information was compared for correctness during the functional performance testing.

Functional performance testing of the CardioPager system was accomplished and provided in the submission. This test plan fully exercised the administrator application running on the server as well as the operation of the Unity™ alarm monitoring services of the CardioPager server. Additionally, the information at the pager was checked for correctness, as mentioned above.

Validation test results indicated that the IMPACT Pager System met the requirements of its intended use. Again, this information is secondary to the primary care provided. Primary care remains unchanged by the addition of the IMPACT pager.

Marquette Medical Systems has demonstrated that use of the IMPACT Pager System is as safe and effective, and performs substantially equivalent to use of the ADU/ Pager-LAN System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

Ms. Dianne Schmitz
Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K971868
IMPACT (Informing Mobile Personnel and Care Tracking)
Pager System
Regulatory Class: III (three)
Product Code: 74 MSX
Dated: September 5, 1997
Received: September 8, 1997

Dear Ms. Schmitz:

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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown; 510(k) filed on May 16, 1997

Device Name: IMPACT (Informing Mobile Personnel and Care Tracking) Pager System

Indications For Use:

The IMPACT Pager System is intended to be used for the annunciation of events within a zone coverage area that is secondary to the primary care that is provided. Primary care via the central station, patient bedside monitor, or telemetry system remains unchanged.

This device is intended to be used within the hospital/facility environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman for AAC

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

~~Over-The-Counter~~ Use____

(Optional Format 1-2-96)