

K971683

510(k) Summary of Safety and Effectiveness

OCT 22 1997

1. **Manufacturer / 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: 21 April 97

2. **General Information**

Trade/Proprietary Name

There is no trade/ proprietary name that will be associated with this technology change. Marquette will refer to it as wireless LAN (Local Area Network) - wireless Ethernet.

Common/Usual Name

This device is commonly known as wireless networking.

Device Classification

The wireless LAN technology change may be used with devices which are Class III, therefore, it will remain in Class III. The modified device that is the subject of this 510(k) submission is a Class III device.

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 device chosen to be used to demonstrate SE for the wireless LAN capability was the Eagle 4000 Patient Monitor. Support testing compared the Eagle 4000 using wired LAN to the Eagle 4000 using wireless LAN. Its 510(k) equivalency references include the following:

- K912799 Eagle System
- K920790 Eagle Monitor
- K964750 Eagle 4000 Patient Monitor

4. Device Description

The Marquette Eagle 4000 Patient Monitor is a multi-parameter patient monitoring system that is cleared to market as part of Marquette's wired Unity network. The Marquette Eagle 4000 Patient Monitor is now indicated for use on Marquette's wireless LAN.

Wireless LAN is a method of communicating to the Marquette Unity Network using a wireless connection. This capability:

- ~provides identical networking function to standard Ethernet;
- ~permits integration to the network without physical connection to the Ethernet wall plate.

5. Intended Use

This device is viewed as a technology change and can be used with various other Marquette devices. Marquette has clearances for various patient monitors and its central station which are part of its wired Unity network. The intended patient population is limited to the same population as the device that the technology is being used with.

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

6. Brief Description of Testing & Conclusion

The Wireless LAN device when used in conjunction with the patient monitor meets the safety requirements of IEC 601-1-1. It also meets the requirements of IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz (IEEE C95.1-1991) and has the appropriate FCC certification. Electromagnetic compatibility testing demonstrates that the device meets the requirements of CISPR 11 Class A for both radiated and conducted emissions. Immunity testing demonstrates that the device meets the requirements of the IEC 1000-4 series and MIL-STD 462D.

Verification and validation testing was done on the wireless LAN in use with the Eagle 4000 Patient Monitor. Test results indicate that the Eagle 4000 Patient Monitor with wireless LAN provides an equivalent level in performance, when compared to the Eagle 4000 Patient Monitor with wired LAN, when tested to the accuracy requirements as specified in the contents of the premarket notification submission.

Marquette Medical Systems has demonstrated that use of the wireless LAN capability in its devices is as safe and effective, and performs substantially equivalent to use of the wired LAN in its devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1997

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

Re: K971683
Marquette Wireless LAN (Local Area Network) Wireless Ethernet
Regulatory Class: III (three)
Product Code: 74 MSX
Dated: August 26, 1997
Received: August 27, 1997

Dear Ms. Schmitz:

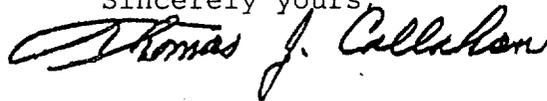
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K971683

Device Name: Marquette Wireless LAN (Local Area Network) Wireless Ethernet

Indications For Use:

The Marquette Eagle 4000 Patient Monitor is a multi-parameter patient monitoring system that is cleared to market as part of Marquette's wired Unity network. The Marquette Eagle 4000 Patient Monitor is now indicated for use on Marquette's wireless LAN.

Wireless LAN is a method of communicating to the Marquette Unity Network using a wireless connection. This capability:

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This device is viewed as a technology change and can be used with various other Marquette devices. Marquette has clearances for various patient monitors and its central station which are part of its wired Unity network. The intended patient population is limited to the same population as the device that the technology is being used with.

This device should be used by people who are trained in the use of the equipment.

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)

Arthur A. Ciarkowski
 (Division Sign-Off)
 Division of Cardiovascular, Respiratory,
 and Neurological Devices

CV Prescription Use
 (Per 21 CFR 801.109)

OR 510(k) Number _____ Over-The-Counter Use _____