

K962827

510(k) Summary of Safety and Effectiveness

2/24/97

Date: June 11th, 1996

Submitter/ Manufacturing Information

The sponsor of this 510(k) Premarket Notification is:

Marquette Electronics, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Establishment registration number is 2124823.

The Pagers and People Finder Series are manufactured by:

Motorola Inc.
Paging Terminal Products Division
1500 NW 22nd Avenue
Boynton Beach, CA 33426-8292 USA

Any questions regarding the contents of this submission may be directed to:

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Marquette Electronics Inc.

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General Information

Trade/ Proprietary Name

Marquette Electronics, Inc. name for this device is the ADU/ Pager-LAN System.

Common/ Usual Name

This device is commonly known as a pager and an alarm display unit.

Device Classification

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 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.

Device Description and Intended Use

The 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 a pager.

Conclusion

Validation test results indicate that the pager meets the requirements of its intended use. This information is secondary to the primary care provided. Primary care remains unchanged by the addition of a pager.

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