

K960272

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510(k) Summary of Safety and Effectiveness

1. **Manufacturer/ Submitter**  
Marquette Electronics, Inc.  
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Milwaukee, WI 53223 U.S.A.

**Establishment Registration Number: 2124823**

**Contact Name/ Telephone Number:**  
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**Date: October 1, 1996**

2. **General Information**

Common/ Usual Name

This device is commonly known as a patient monitoring system.

Trade/ Proprietary Name

Marquette Electronics, Inc's trade/ proprietary name for this device is the Eagle 3000 Patient Monitor.

Classification Name(s)

The Marquette Eagle 3000 Patient Monitor's classification names, classification panels, and regulation citations include:

- \* 21 CFR 870.1110 Monitor, Blood Pressure, Indwelling 74CAA
- \* 21 CFR 870.1130 Monitor, Blood Pressure, Non-Indwelling 74BXD
- \* 21 CFR 870.1400 Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase 73CCK
- \* 21 CFR 880.2910 Monitor, Temperature (with probe) 80BWX
- \* 21 CFR 870.2300 Monitor, Cardiac (Incl. cardiometer & rate alarm) 74DRT
- \* 21 CFR 870.2700 Oximeter, Pulse 74BWS

Device Classification

Devices monitoring similar parameters have been determined to be Class II or III devices according to the Cardiovascular and Anesthesiology Device Classification Panels. FDA has determined this to be 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 Marquette Eagle 3000 Patient Monitor is substantially equivalent, with similar indications for use to the following devices which are currently legally marketed and in commercial distribution:

Marquette Eagle Monitor	K920790
Eagle 3000 Patient Monitor	K952474
Carbon Dioxide Module	K904789

**4. Device Description**

The Marquette Eagle 3000 Patient Monitor is a patient monitoring system that is designed to be used to monitor a patient's basic physiological parameters including: electrocardiography (ECG), invasive blood pressure, non-invasive blood pressure, oxygen saturation, temperature, and end tidal carbon dioxide (EtCO<sub>2</sub>). PA Wedge is also available.

The Eagle 3000 Patient Monitor is a factory configured or fixed-parameter patient monitoring device.

Options which allow for the monitoring of invasive blood pressure and the printing of information by a paper recorder may be added to the basic monitor configuration at the factory prior to shipment to the customer.

The Eagle 3000 Patient Monitor has **NOT** been designed as a modular patient monitoring device which allows the addition and deletion of monitoring parameters at the point-of-use.

The Eagle 3000 Patient Monitor has **NOT** been designed as a transport monitor. Therefore, no battery power feature or option has been included with this device.

**5. Intended Use**

The Marquette Eagle 3000 Patient Monitor is designed to monitor and display patient data. Its design allows the operator to adjust parameter alarm settings that would audibly and visually notify the operator when a violation occurs.

The option is provided for the printing of information by a paper recorder.

Use of the Marquette Eagle 3000 Patient Monitor is

intended for patient populations including: adult, pediatric, and/ or neonatal.

Use of the Marquette Eagle 3000 Patient Monitor is not recommended for use in patient's home or residence, during patient transport, or when it has not been ordered by a physician or other qualified medical personnel.

Use of the Marquette Eagle 3000 Patient Monitor is intended for operating room (OR), post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care. These departments are typically located in hospitals or may be located in outpatient clinics or free standing surgical centers. It is intended for use by physicians, physician assistants, registered nurses, certified registered nurse anesthetists, or other hospital personnel trained in the use of the equipment.

#### **6. Conclusion**

Comparative testing was done on the Eagle 3000 Patient Monitor and its predicate devices. Precision and accuracy testing was also performed. Test results indicate that the Eagle 3000 Patient Monitor provides an equivalent level or better in performance, when compared to the legally marketed predicate devices when tested to the accuracy requirements as specified in the contents of the premarket notification submission.

Marquette Electronics, Inc. has demonstrated that the Eagle 3000 Patient Monitor is as safe and effective, and performs substantially equivalent to the predicate devices.