

K904750

**510(k) Summary of  
Safety and Effectiveness**

FEB 21 1997

**1. Manufacturer/ Submitter**  
Marquette Medical Systems  
8200 West Tower Avenue  
Milwaukee, WI 53223 U.S.A.

**Establishment Registration Number:** 2124823

**Contact Name/ Telephone Number:**

Dianne Schmitz  
Corporate Regulatory Affairs  
Marquette Medical Systems

**Phone:** (414) 362-3230

**Date:** November 15, 1996

**2. General Information**

Common Usual Name

This device is commonly known as a patient monitoring system.

Trade Proprietary Name

Marquette's trade/ proprietary name for this device is the Eagle 4000 Patient Monitor.

Classification Name(s)

The Marquette Eagle 4000 Patient Monitor's classification names, classification panels, and regulation citations include:

- \* 21 CFR 870.1025 Detector and Alarm, 74DSI  
Arrhythmia
- \* 21 CFR 868.2375 Monitor, Breathing 73BZQ  
Frequency
- \* 21 CFR 868.2375 Monitor, (Apnea Detector) 73FLS  
Ventilatory Effort
- \* 21 CFR 870.1110 Monitor, Blood Pressure, 74CAA  
Indwelling
- \* 21 CFR 870.1130 Monitor, Blood Pressure, 74BXD  
Non-Indwelling
- \* 21 CFR 880.2910 Monitor, Temperature 80BWX  
(with probe)
- \* 21 CFR 870.1435 Monitor, Cardiac Output, 74KFN  
Thermal (Balloon Type Catheter)
- \* 21 CFR 870.2300 Monitor, Cardiac (Incl. 74DRT

cardiotachometer & rate alarm)  
\* 21 CFR 870.2700 Oximeter, Pulse 74DQA

**Device Classification**

Both of the main predicate devices included parameters which are Class III parameters, and both devices were cleared to market via the 510(k) notification route. The modified device that is the subject of this 510(k) submission remains in Class III.

**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 4000 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
Marquette SL Series Tram Module	K921669

**4. Device Description**

The Marquette Eagle 4000 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, respiration, apnea detection, pulse rate, cardiac output, and full arrhythmia analysis. The device now includes Marquette's 12 lead ECG Analysis program (commonly referred to as 12 SL).

**5. Intended Use**

The Marquette Eagle 4000 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 printing of information by a paper recorder.

Use of the Marquette Eagle 4000 Patient Monitor is intended for patient populations including: adult, pediatric, and/ or neonatal.

Use of the Marquette Eagle 4000 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 4000 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**

Verification and validation testing was done on the Eagle 4000 Patient Monitor and its predicate devices. Test results indicate that the Eagle 4000 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 Medical Systems has demonstrated that the Eagle 4000 Patient Monitor is as safe and effective, and performs substantially equivalent to the predicate devices.