

K9M3984

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

JAN 16 1998

**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: 10 October 97

**2. General Information**

Trade/Proprietary Name  
Marquette's name for this device is the RAC 2A.

Common/Usual Name  
This device is commonly known as a module housing.

Device Classification  
This device is viewed as a component of a system. The RAC 2A adds modularity to Marquette's Eagle configured product line. It is used to house the module [SAM (Smart Anesthesia Multi-gas) module] and provides an interface to the Eagle display. Therefore, the submitted device may take on the same classification level as the predicate Eagle patient monitor and module.

FDA determined the predicate devices to be: Eagle patient monitors have been determined to be Class III devices; the SAM modules have been determined to be Class II devices.

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)**

This submission is being filed as a modification to an existing device. It is being filed in support of the position that the proposed modified device, the RAC 2A, which interfaces a module to a Marquette Eagle monitor, is substantially equivalent to devices already in legal commercial distribution: Eagle patient

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monitors: K960272, K960418, K961139; Tram-rac: K900598; Tram-rac / SAM module: K943977, K950581.

#### **4. Device Description and Intended Use**

This device is viewed as a component of a system. The RAC 2A adds modularity to Marquette's Eagle configured product line. It is used to house the module [SAM (Smart Anesthesia Multi-gas) module] and provides an interface to the Eagle display. The RAC 2A is intended to allow the module's patient information to be displayed on the Eagle monitor display.

#### **5. Test Summary & Conclusion**

Various reliability and software testing was performed on the product, and the results indicated that the RAC 2A met the requirements of its intended use. Marquette Medical Systems has demonstrated that use of the RAC 2A is as safe and effective, and performs substantially equivalent its predicate devices.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 16 1998

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

Re: K973984  
RAC 2A  
Regulatory Class: II (two)  
Product Code: 73 CCK  
Dated: October 17, 1997  
Received: October 20, 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 (if known): Unknown; 510(k) filed on October 17, 1997

Device Name: RAC 2A

Indications For Use:

The RAC 2A adds modularity to the Marquette Eagle configured product line. It is used to house the module [SAM (Smart Anesthesia Multi-gas) module] and provides an interface to the Eagle display. The module's patient information may be displayed on the Marquette Eagle monitor.

This device is intended to be used by personnel trained in the use of the equipment. It 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)

*Mr. Payne*

(Division Sign-Off)  
Division of Cardiovascular, ~~Respiratory,~~  
and Neurological Devices  
510(k) Number K973984

Prescription Use ✓  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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