K970545

510(k) Summary of Safety and Effectiveness

MAY 8 1997

Date: February 7, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter: Marquette Medical Systems
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Corporate Regulatory Affairs
Marquette Medical Systems
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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 domestically within the United States is the DASH 1000 Patient Monitor. Marquette Hellige's trade/ proprietary name internationally is the Eagle 1000 Patient Monitor.

Classification Name(s)
The Marquette Eagle 1000 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 880.2910	Monitor, Temperature (with probe)	80BWX
* 21 CFR 870.2300	Monitor, Cardiac (Incl. cardiotachometer & rate alarm)	74DRT
* 21 CFR 870.2700	Oximeter, Pulse	74BWS
* 21 CFR 870.1025	Detector and Alarm, Arrhythmia	74DSI

Device Classification
Devices monitoring similar parameters have been determined to be Class II devices according to the Cardiovascular Device Classification Panel. Therefore, it is believed that the system will be considered a Class II device.

However, due to ongoing discussions between the Agency and Industry on the definition of 21 CFR 870.1025, Arrhythmia detector and alarm, which is a Class III parameter, Marquette Medical Systems has included the additional information that would be required for a Class III device within the premarket notification submission. This is being provided should the Agency determine the Eagle 1000 Patient Monitor is a Class III device.

Klaus Rudolf /des Jan. 97

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.

Predicate Device: Marquette Eagle 3000 Patient Monitor

Device Description: The Marquette Eagle 1000 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, and temperature.

Intended Use: The Marquette Eagle 1000 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 1000 Patient Monitor is intended for patient populations including: adult, pediatric, and/ or neonatal.

Use of the Marquette Eagle 1000 Patient Monitor is not recommended for use in patient's home or residence, during patient transport outside the hospital, or when it has not been ordered by a physician or other qualified medical personnel.

Use of the Marquette Eagle 1000 Patient Monitor is intended for operating room (OR), post anesthesia recovery, critical care and 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.

Conclusions: The Eagle 1000 Patient Monitor is a microprocessor-based, software-driven device. The signal-acquisition and -processing technologies and the basic parts of the device software were re-used from former devices.

Testing was performed on the Eagle 1000 Patient Monitor and its predicate devices. Precision, accuracy, as well as safety testing was performed. Test results indicate that the Eagle 1000 Patient Monitor provides an equivalent level or better in performance, when compared to the legally marketed predicate device(s) when tested to the accuracy requirements as specified in the contents of the premarket notification submission.

The Eagle 1000 Patient Monitor passed the EC type-examination, and thus bears the CE mark.

Marquette Medical Systems has demonstrated that the Eagle 1000 (DASH 1000) Patient Monitor is as safe and effective, and performs substantially equivalent to the predicate device.

Klaus Rudolf /des Jan. 97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY - 8 1997

Re: K970545
Eagle 1000 (DASH 1000) Series Patient Monitor with Model numbers: Eagle Model 1001 (Software Version 1.0); Eagle Model 1002 (Software Version 1.0); Eagle Model 1003 (Software Version 1.0); Eagle Model 1004 (Software Version 1.0); Eagle Model 1005 (Software Version 1.0); Eagle Model 1006 (Software Version 1.0); Eagle Model 1007 (Software Version 1.0); Eagle Model 1008 (Software Version 1.0); Eagle Model 1009 (Software Version 1.0); Eagle Model 1010 (Software Version 2.0); Eagle Model 1011 (Software Version 2.0); Eagle Model 1014 (Software Version 2.0); and Eagle Model 1015 (Software Version 2.0)
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: February 11, 1997
Received: February 12, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 2 -

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) 594-4646. 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 February 11, 1997

Device Name: Eagle 1000 (DASH 1000) Patient Monitor

Indications For Use: MAY - 8 1997

The Marquette Eagle 1000 (DASH 1000) Patient Monitor is a patient monitor 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, and temperature.

Optionally, the printing of information by a paper recorder may be added to the basic monitor configuration.

Use of this device is intended for patient populations including: adult, pediatric, and/or neonatal.

EAGLE 1002 (101 123 02)	Battery	ECG					
EAGLE 1003 (101 124 02)	Battery	ECG	Recorder				
EAGLE 1004 (101 123 03)	Battery	ECG	SpO_2				
EAGLE 1005 (101 124 03)	Battery	ECG	SpO_2	Recorder			
EAGLE 1006 (101 123 04)	Battery	ECG		NBP			
EAGLE 1007 (101 124 04)	Battery	ECG		NBP	Recorder		
EAGLE 1008 (101 123 05)	Battery	ECG	SpO_2	NBP			
EAGLE 1009 (101 124 05)	Battery	ECG	SpO_2	NBP	Recorder		
EAGLE 1010 (101 123 06)	Battery	ECG	SpO_2	NBP	TEMP		
EAGLE 1011 (101 124 06)	Battery	ECG	SpO_2	NBP	TEMP	Recorder	
EAGLE 1014 (101 123 07)	Battery	ECG	SpO_2	NBP	TEMP	2 x IBP	
EAGLE 1015 (101 124 07)	Battery	ECG	SpO_2	NBP	TEMP	2 x IBP	Recorder

(EAGLE-Variants / NBP = Non-invasive Blood Pressure/ IBP = Invasive Blood Pressure)

Software Version 1.0 for Eagle Models 1002, 1003, 1004, 1005, 1006, 1007, 1008, + 1009
Software Version 2.0 for Eagle Models 1010, 1014, 1011, + 1015.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K970545

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)