

K973527



Cardio-Pager™ System 510(k) -- K973527
Supplemental Information
Confidential- Data Critical Corp.
Redmond, WA

Data Critical Corp.

MAR 31 1998

Summary of Safety and Effectiveness

This summary of safety and effectiveness is submitted for public release in accordance with the requirements of SMDA 1990 and 21 CFR 820.92.

Submitter's Name: Data Critical Corp.
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(425) 885-3500

Contact Person
Drew D. Weaver,
Director, Regulatory Affairs
Data Critical Corp.
(206) 885-3500

Date of Summary: February 3, 1998

Device Name: Cardio-Pager™ System

Classification Name: (74DRG) 21 CFR 870.2910
Radiofrequency physiological signal transmitter and receiver

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- 1) MMS Pager-LAN Paging System
Marquette Medical Systems
Milwaukee, WI
K962827
- 2) Palmvue
Hewlett Packard
K945277
- 3) Marquette Impact.wf
Marquette Medical Systems
Milwaukee, WI
K971868



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Device Description:

The Cardio-Pager™ System (also referred to as StatView) is a secondary alarm notification system that transmits text and waveform data from patient monitoring devices to a graphical pager worn by a trained professional in a hospital environment. The system monitors the patient monitoring devices for alarm conditions, and responds by transmitting a page that includes text and waveform information from the patient. This system is not intended to be a primary alarm enunciator. The Cardio-Pager™ System alerts and informs the clinician about critical patient alarms without requiring them to be at or near the bedside or central monitors. The system can also provide periodic updates of heart rate and waveform data at intervals established by the caregivers.

The primary components in the Cardio-Pager™ System are the Critical-Server (also referred to as the WT Server) and the Transmission Subsystem. The server is a standard IBM-compatible PC that connects directly to the patient-monitoring network. The Transmission Subsystem consists of the paging transmitter, a standard serial-to-Ethernet converter, and the Cardio-Pager™ receiver units.

Software modules in the Critical-Server acquire patient information from the patient monitoring network, manage the initiation of paging messages, convert the data to proper format for transmission to the paging transmitter, and send the message to the paging transmitter via a LAN. The paging transmitter then sends the page, using standard POCSAG paging protocol. One or more of the Cardio-Pager™ receiver units may receive the page.

Addition of the Cardio-Pager™ System to the patient monitoring computer network does not in any way affect, modify, or interrupt the normal operation of the hospital patient monitoring system.

Intended Use:

The Cardio-Pager™ System described in this submission is a paging system that interfaces with Primary Patient Monitoring Systems in order to provide a secondary means of annunciating and displaying patient alarm information to mobile health care providers. This pager is intended to serve as a parallel, redundant mechanism to inform the clinical staff of patient events.

This device is indicated for use in real-time monitoring of routine patient status and alarm events. The Cardio-Pager™ is limited to use by qualified medical professionals who have been trained on the use of the device. It is intended for use only in a hospital



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environment. The device has been validated for use with the Marquette Unity Network and the Hewlett-Packard Systems CareNet System.

Descriptive Summary of Technological Characteristics and Those of Predicate

The Cardio-Pager™ System has the same basic intended use as the predicate devices, namely to extend access to information from patient monitoring systems to mobile caregivers. Cardio-Pager™ is the same device as the Marquette Impact.wf. The Cardio-Pager™ System has identical technological characteristics and is intended for use in the same application as the Marquette Impact.wf device. Both the Marquette Impact.wf and the Cardio-Pager serve as a secondary means of annunciating patient events and relaying information from the primary monitoring station through the use of a graphical interface paging system. The Cardio-Pager™ combines the alarm annunciation features of Marquette's Pager-LAN with the waveform paging capabilities of the Hewlett-Packard PalmVue. The underlying wireless communication technology, standard alpha-numeric paging based on the POCSAG protocol, is identical in all three devices. The information provided to the caregiver in Cardio-Pager™ is a combination of the textual alarm information provided by Pager-LAN and the waveform information provided by PalmVue. Essentially, the Cardio-Pager™ System enhances the functionality of the Pager-LAN by adding the important patient waveform to the information set available to the mobile caregiver.

Performance Data

Following software validation and verification activities, two types of performance testing were conducted for the Cardio-Pager™ System. First, the software was tested using a Data Acquisition (DA) module simulator to test the software in simulated conditions using no specific manufacturer's patient monitoring equipment (PME). The second type of testing consisted of finished device or "systems level" testing. Systems level testing was performed for two specific Cardio-Pager™ configurations: One with the DA module customized to facilitate interface with the Marquette Unity Network and the other with the DA module customized to facilitate interface with the Hewlett-Packard CareNet System. Both performance tests challenged all functional requirements for the Cardio-Pager™ System including: the receipt and transmission of patient alarms, the request, receipt and transmission of scheduled updates, the transmission of text messages, and the Cardio-Pager™ receipt of transmitted alarms, scheduled updates, and text messages. In addition, all communication requirements between the Cardio-Pager System™ and Marquette or Hewlett-Packard patient monitoring equipment (PME) were challenged by testing with a variety of Marquette and Hewlett-Packard patient monitoring devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1998

Mr. Drew D. Weaver
Data Critical Corporation
2733 152nd Avenue, NE
Redmond, WA 98052

Re: K973527
Cardio-Pager™ System
Regulatory Class: III (three)
Product Code: 74 MSX
Dated: February 18, 1998
Received: February 19, 1998

Dear Mr. Weaver:

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.

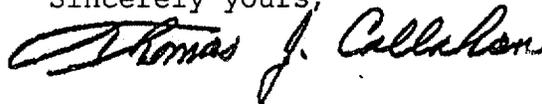
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Drew D. Weaver

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



Cardio-Pager™ System 510(k)
Supplemental Information
Confidential- Data Critical Corp.
Redmond, WA

510(k) Number (if known): K973527

Device Name: Cardio-Pager™ System

Indications for Use:

The Cardio-Pager™ System described in this submission is a paging system that interfaces with primary patient monitoring systems in order to provide a secondary means of annunciating and displaying patient alarm information to mobile health care providers. The Cardio-Pager™ System has been validated for use with the Marquette Unity Network and the Hewlett-Packard System CareNet. This pager is intended to serve as a parallel, redundant mechanism to inform the clinical staff of patient events.

This device is indicated for use in real-time monitoring of routine patient status and alarm events. The Cardio-Pager™ is limited to use by qualified medical professionals who have been trained on the use of the device. It is intended for use only in a hospital environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use
Per 21 CFR 801.109

3/25/98 C. Casey
for W. [unclear]
Division Sign-Off
Division of Cardiovascular, Respiratory,
and Neurological Devices