

NOV 19 1999

K992848

Summary of Safety and Effectiveness:

Data Critical Corporation

510(k) Notification: *AlarmView™ - Physiological Monitor System, Network and Communication*

August 23, 1999

510(k) SUMMARY:

SAFETY AND EFFECTIVENESS SUMMARY

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

Submitter's Name/Address:

Drew D. Weaver	(425) 482-7000
Director of Regulatory Affairs	(425) 482-7010 facsimile
Data Critical Corporation	
19820 North Creek Parkway, #100	
Bothell, WA 98011	

Contact Person:

Same as above

Date Summary Prepared:

August 23, 1999

Device Name:

Common Name: Physiological Monitor System, Network and Communication (Patient information Paging System)

Trade Name: AlarmView™ System

Classification (if known): Physiological Monitor System, Network and Communication (21 CFR 870.2910)

74 MSX
Class II

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Predicate Devices:

AlarmView™ System is substantially equivalent to the following predicate devices:

- 1) StatView™ System by Data Critical Corporation
- 2) TS2000 by Trincore Systems
- 3) Pager-LAN by GE Marquette Medical Systems
- 4) "Paging" by Vitalcom.

Applicant Device Description:

AlarmView™ is a paging system that interfaces with a primary patient clinical device in order to provide a secondary means of annunciating and displaying patient alarm information to mobile health care providers.

AlarmView reads the patient information from the output data port and does not change the primary monitor in any way. It formats the patient information into a message that can be transmitted to a pager carried by mobile health caregivers. AlarmView does not diagnose alarms.

AlarmView consists of the AV Transmitter, AV Pager, and the AC PDA (Personal Digital Assistant) used for administration.

Applicant Device Intended Use:

This device is intended for use in real-time monitoring of routine patient status and alarm events on medical devices. It serves as a parallel, redundant mechanism to inform the clinical staff of patient events. It is intended to be a secondary means of annunciating and displaying patient alarm information to mobile healthcare providers.

AlarmView is limited to use by qualified medical professionals who have been trained on the use of the device. It is intended for use in hospital and hospital type environments and is not for home use.

AlarmView is intended to supplement and not to replace any part of the current device monitoring procedures.

AlarmView is not considered in and of itself to be diagnostic without skilled interpretation and does not replace physician's care.

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Technological Characteristics:

AlarmView is the same in technological characteristics as the cited predicate devices. Most of the predicate devices consist of a paging system. In all cases, the predicates are connected to a medical device that is used to transmit patient data to an appropriate health care provider.

AlarmView has the same safety and efficacy characteristics as the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Drew D. Weaver
Director of Regulatory Affairs
Data Critical Corporation
19820 North Creek Parkway, #100
Bothell, WA 98011

Re: K992848
Alarmview System
Regulatory Class: II (Two)
Product Code: MSX
Dated: August 23, 1999
Received: August 24, 1999

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 legally marketed predicate 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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

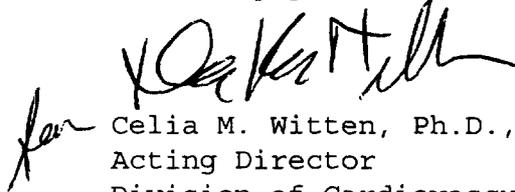
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name. The signature is fluid and cursive.

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992848

INDICATIONS FOR USE STATEMENT

Indications For Use:

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AlarmView is not considered in and of itself to be diagnostic without skilled interpretation and does not replace physician's care.

AlarmView is currently validated for use with the N-x9y and N-3x00 data protocols.

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

Concurrence of [Signature] Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K992848

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)