

SEP 20 1999

K990378



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) 885-3500
Director of Regulatory Affairs (425) 885-3377 facsimile
Data Critical Corporation
2733 152nd Avenue NE
Redmond, WA 98052

Contact Person:

Same as above

Date Summary Prepared:

February 5, 1999

Device Name:

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

Trade Name: StatView™ System

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

74 MSX
Class III

0039

Predicate Devices:

StatView™ System is substantially equivalent to the following predicate devices: StatView™ System (previously cleared) by Data Critical Corporation, Pager-LAN by GE Marquette Medical Systems, and Palm Vue (M1490A) by Hewlett Packard, and "Paging" by Vitalcom.

Applicant Device Description:

StatView™ System is a paging system that interfaces with primary patient monitoring systems (PPMS) in order to provide a secondary means of annunciating and displaying patient alarm information to mobile health care providers.

StatView interfaces with the PPMS and reads the same alarm information that the PPMS uses, then formats that information into a message that can be transmitted to the receivers carried by mobile health caregivers. Although StatView reads the same alarm information that the PPMS LAN sends, it does not change it or modify it in any way. StatView does not diagnose alarms but transmits what the PPMS determines to be an alarm.

StatView consists of the StatView Server (WT Server), StatView Transmitter, and StatView Receiver.

In addition to the capabilities of the previous version of StatView (predicate device), users of the StatView system can send pre-programmed text messages that can be easily selected when initiating a text page as well as scheduling text messages. Semi-automatic mode is used for facilities that with their monitoring technicians to continue to filter the alarm traffic sent to the mobile caregivers.

Applicant Device Intended Use:

This device is intended for use in real-time monitoring of routine patient status and alarm events. StatView is limited to use by qualified medical professionals who have been trained on the use of the device. StatView is not intended for home use.

StatView™ is a paging system that interfaces with primary patient monitoring systems (PPMS) to serve as a parallel, redundant mechanism to inform the clinical staff of patient events. It intended to be a secondary means of annunciating and displaying patient alarm information to mobile healthcare providers.

Technological Characteristics:

StatView is the same in technological characteristics as the cited predicate devices. All the predicate devices consist of a paging system connected to primary patient monitoring equipment that is used to transmit patient data to an appropriate health care provider.

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 1999

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

Re: K990378
StatView™ System
Regulatory Class: III (three)
Product Code: MSX
Dated: July 16, 1999
Received: July 19, 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 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.

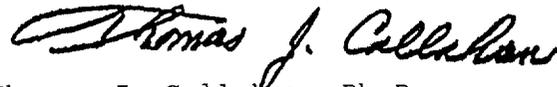
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Drew 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Indications For Use:

This device is indicated for use in real-time monitoring of routine patient status and alarm events. StatView is limited to use by qualified medical professionals who have been trained on the use of the device. StatView is not intended for home use.

StatView™ is a paging system that interfaces with primary patient monitoring systems (PPMS) to serve 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.

StatView™ has been validated for use with the following networks: Hewlett-Packard CareNet, GE Marquette Medical Unity, and Siemens Medical Systems Infinity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990378

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)