K971650

SECTION 2
510(k) SUMMARY

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

DEC - 4 1997

Submitter's Name: Data Critical Corporation
100 North Broadway, Suite 2200
Oklahoma City, OK 73102
Telephone: (405) 236-4441
Contact Person: David E. Albert, MD, Chief Scientist

Date of Summary: May 5, 1997

Device Name: Rhythm*Stat XL* System

Device Classification: Telephone electrocardiograph transmitter and receiver (74 DXH); 21 CFR § 870.2920

Legally Marketed Devices To Which Equivalence Is Claimed: The legally marketed predicate devices are the Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) (K945277); the Instromedix® LifeSigns™ Receiving Center (a preAmendment device); and the Micromedical Industries BIOLOG (K915624).

Device Description: The Rhythm*Stat XL* System is a telephone electrocardiograph (ECG) receiving system used for recording and reporting of ECG data from a cardiac event recorder. The System has three main components:

- A ***commercially available cardiac event recorder such as the Micromedical Industries BIOLOG or the Instromedix® Heart Card™***, that conditions and transmits ECG data in the form of a frequency-modulated acoustic waveform to the PSION Series 3 palmtop computer;
- ***Two proprietary software programs***, contained in the commercially available PSION Series 3 palmtop computer, that 1) recondition the received signal into its original format and display the signal to the physician on the computer screen, then 2) transmit the ECG data, along with the physician's comments, from the PSION palmtop computer to the Reporting Server via modem; and
- The Data Critical ***Reporting Server*** that accepts the ECG data and commentary and generates a printed report that is automatically transmitted to the physician's office via fax.

Intended Use: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Devices: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored. The waveforms and accompanying information are then transmitted via modem to the Data Critical Reporting Server for generation of a printed report, which is then faxed to the physician's office. In addition, the PSION palmtop computer with Rhythm*Stat XL* software has the capability of relaying the most recently acquired ECG data as an acoustic signal to another PSION with Rhythm*Stat XL* software or to a conventional transtelephonic ECG receiving system such as the Instromedix LifeSigns Receiving Center.

The Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) is intended to provide remote access to data from an HP patient monitoring system by transmitting data from a patient monitor through a PalmVue dispatch station and paging service provider to a portable hand-held Medical Palmtop personal computer. The HP system requires the use of a Hewlett Packard monitoring system and dispatch station, PalmVue transmission software, an interface card, modem, and a paging service to support the system functions.

The Instromedix® LifeSigns™ Receiving Center is intended to receive, by telephone, ECG data from patients using ambulatory cardiac event monitors or pacer data transmitters. This tabletop device is line-powered and provides a printed record of ECG data; with an optional interface, it allows data to be communicated to a computer.

The Micromedical Industries BIOLOG is intended to acquire, record and store single-lead or 12-lead ECG waveforms via direct patient contact or through a patient cable with electrodes. This portable, hand-held device has an LCD screen, is battery-powered, and is capable of transtelephonic data transmission or receipt. It interfaces directly with the Micromedical Printer to provide a printed record of ECG data.

Performance Data: Testing was conducted by Data Critical Corporation on the Rhythm*Stat XL* System to compare its performance to that of two legally marketed predicate devices, the Micromedical Industries BIOLOG recorder and the Instromedix LifeSigns Receiving Center. Subjects were tested using the PSION palmtop computer with Rhythm*Stat XL* software and the BIOLOG recorder; additional testing was then conducted with three devices: the PSION with Rhythm*Stat XL* software, the BIOLOG recorder, and the Instromedix LifeSigns Receiving Center. ECG recordings were obtained with the BIOLOG, then played back to and recorded by the PSION/Rhythm*Stat XL* and printed by the Rhythm*Stat XL* Reporting Server. The same recording was then printed out by the predicate devices, the BIOLOG and the LifeSigns Receiving Center. For each ECG printout the amplitude and duration of the first ten QRS segments were analyzed and measured, along with the total duration of all QRS segments. The Rhythm*Stat XL* System demonstrated acceptable performance, producing ECG waveforms which were measurably comparable and of equivalent quality to the waveforms of the Micromedical and Instromedix products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 1997

Ms. Lisa S. Jones
Data Critical Corporation
c/o Devices For The Future, LLC
9223 Ilona Lane
Houston, Texas 77025-4218

Re: K971650
RhythmStat XL System
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: September 29, 1997
Received: October 1, 1997

Dear Ms. Jones:

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

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100 North Broadway, Suite 2200
Oklahoma City, OK 73102
Telephone: (405) 236-4441
Contact Person: David E. Albert, MD, Chief Scientist

Date of Summary: May 5, 1997

Device Name: Rhythm*Stat XL* System

Device Classification: Telephone electrocardiograph transmitter and receiver (74 DXH); 21 CFR § 870.2920

Legally Marketed Devices To Which Equivalence Is Claimed: The legally marketed predicate devices are the Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) (K945277); the Instromedix® LifeSigns™ Receiving Center (a preAmendment device); and the Micromedical Industries BIOLOG (K915624).

Device Description: The Rhythm*Stat XL* System is a telephone electrocardiograph (ECG) receiving system used for recording and reporting of ECG data from a cardiac event recorder. The System has three main components:

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- The Data Critical ***Reporting Server*** that accepts the ECG data and commentary and generates a printed report that is automatically transmitted to the physician's office via fax.

Intended Use: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored.

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Sincerely yours,

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

Enclosure

May 5,1997

510(k) Number:

Device Name: Rhythm*Stat XL* System

Indications for Use: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971650

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)