K970012

510(k) Summary

JUN 26 1997

ESCORT LINK Central Station Model 20500

1. Submitter:

Medical Data Electronics
12720 Wentworth Street
Arleta, California 91331

Telephone: 818-768-6411
Telefax: 818-768-4197

Contact: David M. Trueblood
Regulatory Affairs Manager

2. Date of Preparation: December 31, 1996

3. Device Name:

Trade Name: ESCORT LINK Central Station Monitor Model 20500

Common Name: Central Station Monitor
Classification Name: Monitor, Electrocardiograph
Detector and Alarm, Arrhythmia

4. Substantial Equivalence:

The ESCORT LINK Central Station Monitor Model 20500 is substantially equivalent to the ESCORT LINK Central Station Monitor Model 3200.

5. Description of the Device:

The ESCORT LINK Central Station Monitor Model 20500 is a Central Station monitor comprised of a standard VGA Display, a standard Personal Computer Base, and an auxiliary base used to mount the Network communications hardware (i.e. Spread Spectrum transponders and UHF telemetry receivers).

The ESCORT LINK Central Station Monitor Model 20500 can provide the centralized display, storage, and recording (or printing) of patient vital sign and waveform data that is being monitored at ESCORT II 100, 300, or 400 bedside monitors or UHF Telemetry Receivers.

Data accumulated at ESCORT II bedsides is sent via a proprietary Spread Spectrum Local Area Network to the Central Station for display and storage. Data accumulated from any of Medical Data Electronics' analog or digital telemetry transmitters is sent directly to the Central Station on standard UHF telemetry frequencies. The Central Station oversees all communications activity, allowing each system component to pass information without interruption to patient monitoring.

The Central Station can provide alarm detecting and reporting for all vital sign parameters that are available to the Central Station. This alarm response is in addition to alarms that are available at the ESCORT 100, 300, or 400 bedsides. Also, arrhythmia monitoring is available for up to 16 patients at the Central Station to provide the configurable ability to detect and report certain cardiac abnormalities.

The Central Station can provide storage of patient data for up to 24 hours. This includes waveform and vital sign information for all available waveforms and parameter values. The waveform and vital sign data that has been stored in a patient file at the Central Station can be retrieved and viewed on the display or printed out on a Thermal Array recorder or a LaserJet® Printer.

6. Intended Use of the Device:

The ESCORT LINK Central Station Monitor Model 20500 is intended to be used to provide centralized surveillance and documentation of patient vital sign data for a variable number of ESCORT Series 100, 300, and 400 bedside monitors and a variable number of UHF telemetry transmitters in the hospital environment.

7. Summary of the Technological Characteristics of the New Device Compared to the Predicate Device:

The MDE ESCORT LINK Central Station Monitor Model 20500 is a new Central Station monitor, however, its intended use and method of operation are substantially equivalent to the MDE ESCORT LINK Central Station Monitor Model 3200.

The primary differences between the two devices are summarized in the following table:

SPECIFICATION	MODEL 20500	MODEL 3200
PC Specifications	Pentium PC, 16MB RAM, 2GB HDD	386 PC, 8MB RAM, 200MB HDD
Operating System	MS Windows	MS DOS
Configuration	External to the PC base	Internal to the PC base
Patient Monitoring Capacity	Up to 16	Up to 32
Viewable Waveforms per Patient	Up to 8 per patient	1 per patient
Viewable Vital Sign Values per Patient	Up to 20 per patient	Up to 6 per patient
Telemetry Communication	902 - 928 Mhz Spread Spectrum communication between the bedside and the Central Station; 450 - 470 Mhz UHF communication between telemetry receivers and the Central Station	450 - 470 Mhz UHF communication between the bedside and the Central Station
Alarm Handling	Alarms are interactively enabled and disabled from either the bedside or the Central Station	Alarms are enabled and disabled from the bedside only
Full Disclosure	Up to 3 waveforms per patient can be reviewed at a time.	1 Waveform per patient can be reviewed at a time.
Arrhythmia Algorithm	Provided by Zymed Inc.	Provided by PCI Inc.

8. Device Testing:

The ESCORT LINK Central Station Monitor Model 20500 is designed to functional standards developed by independent and regulatory agencies.

The criteria for these standards are identified in the following FDA documents:

- Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review; Office of Device Evaluation, August 1991.
- Reviewer Guidance for Premarket Notification Submissions, Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory and Neurological Devices; November 1993.

Tests demonstrating consideration of and mitigation of hazards identified to have potentially arisen as the result of the modifications in the new device were developed. Conformance to product development procedures and plans is assured by application of system tests, reviews, and product verification and validation studies.

9. Test Conclusions:

The MDE ESCORT LINK Central Station Monitor Model 20500 is shown by performance testing, stressing the areas of alarm detecting and reporting, arrhythmia detecting and reporting, and accuracy of patient vital sign and waveform data, to be a safe, effective Central Station Monitor. The MDE ESCORT LINK Central Station Monitor Model 20500 is substantially equivalent to the ESCORT LINK Central Station Monitor Model 3200.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1997

Mr. David M. Trueblood
Medical Data Electronics, Inc.
12720 Wentworth Street
Arleta, California 91331-4329

Re: K970012
ESCORT Link Central Station Monitor Model 20500
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: April 11, 1997
Received: April 14, 1997

Dear Mr. Trueblood:

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

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): K970012 14 APR 97 1106

Device Name: ESCORT-LINK® CENTRAL STATION MONITOR

FDA/CDRH/ODE/DHC

Indications for Use:

MODEL 20500

The ESCORT-LINK™ Central Station Monitor is intended to be used to provide, using a wireless LAN for communication, centralized surveillance and documentation of patient vital sign data and arrhythmia monitoring and alarms for a variable number of ESCORT II bedside monitors and a variable number of UHF telemetry transmitters in the hospital environment. It is intended for use by healthcare practitioners trained in the use of the equipment only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

E. Ocampo

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

510(k) Number _____

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 2.1 CFR 801.109)

(Optional Format 1-2-96)