NOV 25 1998

510(k) SUMMARY K982104

ESCORT-LINK® CENTRAL STATION MONITOR MODEL 20500 WITH ST OPTION

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: June 12, 1998

3. Device Name:

Trade Name: ESCORT-LINK® Central Station Monitor Model 20500 with ST Option

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

4. Substantial Equivalence:

The ESCORT-LINK® Central Station Monitor Model 20500 with ST Option is substantially equivalent to the ESCORT-LINK® Central Station Monitor Model 20500.

5. Description of the Modified Device:

The modified 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.

The modified ESCORT-LINK® Central Station Monitor Model 20500 can provide centralized display, storage and recording (or printing) of patient vital sign and waveform data that are being monitored at ESCORT® II, 100, 300 or 400 Series Bedside Monitors or UHF Telemetry Receivers.

Data accumulated at ESCORT® II Bedside Monitors is sent via a proprietary Spread Spectrum Local Area Network to the modified ESCORT-LINK® Central Station Model 20500 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. Telemetry transmitter communication may include patient data similar to that described for the ESCORT® II Bedside Monitors. The modified ESCORT-LINK® Central Station Monitor Model 20500 oversees all communications activity, allowing each system component to pass information without interrupting patient monitoring.

The modified ESCORT-LINK® Central Station Monitor Model 20500 can provide alarm detection and reporting for all vital sign parameters available to the central station. This alarm response is in addition to alarms available at the ESCORT® II 100, 300 or 400 Series Bedside Monitors. Also, arrhythmia monitoring, with ST reporting, is available for up to 16 patients at the Central Station to provide the configurable ability to detect and report certain cardiac abnormalities, including ST abnormalities. Parameter alarms, arrhythmia alarms and ST alarms are independently configurable to accommodate the wide range of patients encountered in the hospital environment.

The Central Station provides storage of patient data. Stored patient data includes waveform and vital sign information. Stored waveform and vital sign data can be retrieved for viewing or printing.

6. Intended Use of the Device:

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, including ST analysis, 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.

7. Summary of the Technological Characteristics of the Modified Device Compared to the Unmodified Device:

The modification which is the subject of this premarket notification regarding the ESCORT-LINK® Central Station Monitor Model 20500 consists of adding an ST analysis with alarms option. The primary differences between the modified and the unmodified devices are summarized in the following table.

SPECIFICATION	UNMODIFIED MODEL 20500	MODIFIED MODEL 20500
ST Measurement	None	Automatic
ST Alarms	None	ST Deviation
Annotation	Time, date, parameter values, ID source, speed, abnormal events with arrhythmia option	Time, date, parameter values, ID source, speed, abnormal events with arrhythmia option, ST deviation with ST option

8. Device Testing

The modified ESCORT-LINK® Central Station Monitor Model 20500 is designed and tested to functional standards developed by independent and regulatory agencies. 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, 1991.

The algorithm comprising the modification was validated against the European ST-T (ESC) database. Validation of system, including the modification, performance was demonstrated by testing against the MDE Software Validation System Test Report, predicated on the performance of the unmodified device.

Tests demonstrating consideration of and mitigation of hazards identified to have potentially arisen as the result of the modifications to the ESCORT-LINK® Central Station Monitor Model 20500 were developed. Conformance to design control procedures were assured by application of design reviews, system tests and device verification and validation studies.

9. Test Conclusions:

The MDE ESCORT-LINK® Central Station Model 20500, modified by the addition of an ST analysis and alarm option, is shown by performance testing, stressing the areas of alarms detection and reporting, arrhythmia detecting and alarms, ST event detecting and alarms, and accuracy of patient vital sign and waveform data, to be a safe, effective Central Station Monitor. The modified ESCORT-LINK® Central Station Monitor Model 20500 is substantially equivalent to the unmodified ESCORT-LINK® Central Station Monitor Model 20500.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

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

Re: K982104
ESCORT-LINK® Central Station Monitor Model 20500
Regulatory Class: III (three)
Product Code: 74 MLD
Dated: October 30, 1998
Received: November 2, 1998

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 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.

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/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

510(k) Number (if known): K 982104

Device Name: ESCORT-LINK® CENTRAL STATION MONITOR

Indications for Use:

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/ST monitoring 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.

The ST algorithm has been tested for accuracy of the ST segment measurement data. The significance of the ST segment changes must be determined by a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(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)