K970763

JUL 14 1997

MEDICAL DATA ELECTRONICS

ESCORT® II

MODULAR TELEMETRY SYSTEM

510(k) SUBMISSION

510(K) SUMMARY

K970763

510(k) Summary

MTS Option for the ESCORT® II Monitor

1. Submitter:

Medical Data Electronics
12720 Wentworth Street
Arleta, California 91331

Telephone: 818.768.6411
Telefacsimile: 818.768.4197

2. Date of Preparation: February 28, 1997

3. Device Name:

Trade Name: MTS Option for the ESCORT® II Monitor
Common Name: Portable Patient Monitor
Classification Name: Portable Patient Monitor, consisting of:

- Cardiac Monitor
- Pulse Oximetry
- Radiofrequency Physiological Signal Transmitter & Receiver

4. Substantial Equivalence:

The MTS Patient Monitor is substantially equivalent to the MDE ESCORT® II+ 400 Series Monitor and to the MDE ESCORT® II Series 300 Monitor.

5. Description of the Device:

The MTS Option for the ESCORT® II Monitor is a modular patient monitor capable of monitoring two parameters simultaneously, including dual-vector ECG and SpO_2. The MTS Module is equipped with an alphanumeric LCD display that is capable of displaying vital signs providing the detail needed to aid clinical decisions.

The MTS Patient Monitor can monitor adult and pediatric patients. The appropriate monitoring mode for each patient, ADULT or PED, is selectable. Changing from one mode to another automatically changes all appropriate algorithms, alarm limits and any applicable parameter defaults.

The MTS Module functions through fixed function keys labeled on the front panel.

Factory defaults have been established and installed for all system and physiological monitoring issues (i.e., default ECG lead, initial inflation pressure, etc.). These values may be configured for specific needs.

6. Indications for use of the Device:

The MTS Option for the ESCORT® II Monitor is a portable patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment.

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

The MTS Option for the ESCORT® II Monitor is substantially equivalent to the MDE ESCORT® II Series 300 Monitor and the ESCORT® II+ 400 Series Monitor. The main difference between the ESCORT® with MTS Option Monitor and the current ESCORT® Series Monitors is the addition of a new multiparameter module (MPM) that can be communicate via hardwired or wireless connection. The wireless option will be configured to monitor ECG and oxygen saturation via pulse oximetry.

8. Device Testing:

The MTS Monitor is designed to meet established standards as follows:

- Reviewer Guidance for Premarket Notification Submissions, Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory and Neurological Devices; November, 1993;
- Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review; Office of Device Evaluation, August, 1991.
- ANSI/AAMI EC-13: 1992, Cardiac monitors, heart rate meters, and alarms, 2nd edition
- ASTM F 1415 - 92, Standard Specification for Pulse Oximeters

Tests demonstrating consideration of and mitigation of hazards identified as having potentially arisen as the result of the modifications described were developed. Conformance to product development procedures and plans is assured by application of comprehensive bench testing and product verification and validation studies.

9. Test Conclusions:

The MTS Option for the ESCORT® II Monitor is shown by performance testing to be a safe, effective portable patient monitor. The MTS Monitor is substantially equivalent to the MDE ESCORT® II 300 Series and the MDE ESCORT® II+ 400 Series Monitors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 14 1997

Re: K970763
Modular Telemetry System (MTS) Option for the MDE ESCORT® II Monitor
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: June 2, 1997
Received: June 3, 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): K970763

Device Name: MTS Option for the ESCORT II Monitor

Indications for Use: The MTS Option for the ESCORT II Monitor is a portable monitor intended to be used for monitoring vital signs (ECG & SpO_2) of critically ill adult and pediatric patients in the hospital environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard N. Phillips

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K970763

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

(Optional Format 1-2-96)