K014294

JAN 2 5 2002

ATTACHMENT 4

510(k) Summary

Date December 27, 2001

Contact

Greg Alkire
Director, Regulatory Affairs
Medical Data Electronics
12720 Wentworth Street
Arleta, California 91331
Telephone: 818-768-6411
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Device Name ESCORT II+ 400 Series (ESCORT Prism) Monitor

Common Name Patient Monitor, Vital Signs Monitor
May Include Options:

Cardiac Monitor	Carbon Dioxide Analyzer
Breathing Frequency Monitor	Cardiac Output Computer
Invasive Blood Pressure	Recorder
Temperature	RF Physiological Transmitter/Receiver
Noninvasive Blood Pressure	Defibrillator
Pulse Oximetry	External Pacer

Classification The classification names and classifications of the Options available for the ESCORT II+ 400 Series (ESCORT Prism) monitors are as follows:

Option	Classification Number	Class
Cardiac Monitor	870.2300	II
Breathing Frequency Monitor	868.2375	II
Invasive Blood Pressure	870.1110	II
Temperature	880.2910	II
Noninvasive Blood Pressure	870.1130	II
Pulse Oximetry	870.2700	II
Carbon Dioxide Analyzer	868.1400	II
Cardiac Output Computer	870.1435	II
Recorder	870.2810	II
RF Physiological Transmitter/Receiver	870.2910	II
Defibrillator	870.5300	II
External Pacer	870.3600	II

The ESCORT Prism monitor is classified as a Class II Device.

Predicate Device	ESCORT II+ 400 Series (ESCORT Prism) Monitor
Device Description	The modified ESCORT II+ 400 Series (ESCORT Prism) monitor is identical to the to the currently marketed device with the exception of the functionality of the Pulse Oximeter (SpO_2) options available. The predicate device, incorporating Nellcor MP204 technology, does not include special signal processing techniques to compensate for patient motion. The modified device, incorporating Nellcor MP405 technology, incorporates features to compensate for patient motion.
Indications For Use	The Medical Data Electronics ESCORT II+ 400 Series Monitor is a portable patient monitor intended to be used for monitoring vital signs of critically ill adult, pediatric and neonatal patients in the hospital environment.
Technological Characteristics	The modified ESCORT II+ 400 Series (ESCORT Prism) has the same technological characteristics as the predicate device with the exception of the type of signal processing utilized for pulse oxygen saturation and pulse rate information incorporated in the modified device.
Testing	Testing of the modified ESCORT II+ 400 Series (ESCORT Prism) monitors was conducted by MDE to ensure mitigation of hazards. V&V testing and testing of the modified device to safety standards are the same as those conducted on the predicate device.
Conclusions	Medical Data Electronics, in accordance with the FFDCA and 21 CFR Part 807 and data included in this premarket notification, concludes that the modified ESCORT II+ Model 400 Series (ESCORT Prism) Monitor is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Mr. Greg Alkire
Medical Data Electronics, Inc.
12723 Wentworth Street
Arleta, CA 91331

Re: K014294
ESCORT II+ 400 Series (ESCORT Prism) Monitor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: December 26, 2001
Received: December 28, 2001

Dear Mr. Alkire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. In addition, if you wish to change or expand the current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Indications for Use Statement

510(k) Number (if known): _____

Device Name: ESCORT II+ 400 Series (ESCORT Prism) Monitor

Indications for Use:

The Medical Data Electronics ESCORT II+ 400 Series Monitor is a portable patient monitor intended to be used for monitoring vital signs of critically ill adult, pediatric and neonatal 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)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014294

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

(Optional Format 1-2-96)