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SECTION E: 510(k) Summary

JAN 2 0 2006

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Medtronic Emergency Response Systems, Inc. 11811 Willow Road Northeast P.O. Box 97006 Redmond, Washington 98073-9706 Registration Number: 3015876
Contact Person	Teresa Davidson Telephone: (425) 867-4733 Fax: (425) 867-4154
Date Prepared	October 5, 2005
Name	LIFENET® Exchange System
Common Name	System, Network and Communication, Physiological Monitors
Device Classification	Classification: Class II Product Code: MSX Classification Panel: Cardiovascular Device Regulation Number: 870.2300
Substantial Equivalence	The features and functions of the LIFENET Exchange System, an optional data transmission system is substantially equivalent to the existing data transmission functionality previously cleared for the LIFEPAK® 12 device and the Phillips 12-Lead Transfer Station.
Intended Use	The LIFENET Exchange System is an optional data transmission system that provides the capability to transmit 12-Lead ECG reports and other physiological data to a receiving device at a remote location. Data is received from the field and can be used for diagnosis, disposition, and therapy decisions by qualified medical personnel.

The users of the LIFENET Exchange System are Advanced Life Support providers (e.g. Emergency Medical Technicians) and Basic Life Support providers (e.g. paramedics) in a variety of hospital and pre-hospital settings.

The system is used in various areas of the hospital such as critical areas (emergency departments, critical care, operating room, etc.) and general duty floors (e.g. medical/surgical, clinics, physician offices, cardiac catherization labs). The system is also used for hospital transport (air and ground ambulance, in- hospital transport, etc).

Technological Characteristics

The LIFENET® Exchange System performs and functions in the same manner as the currently marketed predicate data transmission systems. Both predicate systems and the subject system use similar data transmission and communication technologies.

Performance Information

This 510(k) includes documentation related to the verification and validation of the individual system components and the overall V&V of the LIFENET Exchange System, including the LIFEPAK 12 to ensure device compatibility.

Conclusion

The information in this 510(k) demonstrates that the LIFENET® Exchange System, an optional data transmission system is substantially equivalent to the predicate data transmission systems with respect to safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 0 2006

Medtronic Emergency Response Systems
c/o Ms. Teresa M. Davidson
Principal Regulatory Affairs Specialist
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073

Re: K052854
Trade Name: LIFENET®Exchange System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: December 20, 2005
Received: December 21, 2005

Dear Ms. Davidson:

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.

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), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

B Zimmerman for

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

Enclosure

SECTION D: "Indications for Use" Sheet

Indications for Use Statement

510(k) Number (if known): Not yet assigned

Device Name: LIFENET® Exchange System

Indications for Use:

The LIFENET Exchange System is an optional data transmission system that provides the capability to transmit real time 12-Lead ECG reports and other physiological data to a receiving destination at a remote location.

Data received from the field can be used for diagnosis, disposition, and therapy decisions by qualified medical personnel.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052854