K042404

DEC 2 2 2005

SECTION E: 510(k) SUMMARY

Submitter's Name and Address:

Medtronic Emergency Response Systems
(formerly known as Medtronic Physio-Control)
11811 Willows Road Northeast
Redmond, WA 98052

Mailing address:
PO Box 97006
Redmond, WA 98073-9706

Contact Person:

Michelle Ackermann
(425) 867-4744

Date Summary Prepared:

November 22nd, 2005

Device:

Medtronic LIFEPAK® 1000 Defibrillator

Classification:

Low Energy DC-Defibrillator: Class II
Automatic External Defibrillator (AED): Class III

Substantial Equivalence:

The features and functions of the LIFEPAK 1000 defibrillator are substantially equivalent to the:

- Medtronic LIFEPAK 500 AED, 510(k) K983393 (05/05/99) and K033275 (11/06/03), and
- Philips HeartStart FR2+ Defibrillator with ECG Assessment Module, 510(k) K013425 (01/14/02) and K014157 (01/17/02).

Description:

The LIFEPAK 1000 defibrillator is a semi-automatic defibrillator with manual mode and ECG mode available as options. The manual mode allows a caregiver skilled in rhythm recognition to switch to manual mode and treat the patient without relying on the automated analysis feature and without connecting a separate defibrillator.

Features and options of the LIFEPAK 1000 defibrillator include: ECG rhythm and heart rate monitoring using defibrillation electrodes or using an ECG cable with monitoring electrodes, data transmission via serial infrared link, power via non-rechargeable lithium manganese battery, and configurable voice prompts.

Intended Use:

The LIFEPAK 1000 defibrillator is intended for indoor or outdoor use in a wide variety of hospital and pre-hospital settings including ground and air ambulances, physician's offices, aircraft, stadiums and specialty medical clinics. It is intended for use by personnel who are authorized by a physician/medical director and are trained in CPR and the use of the LIFEPAK 1000 defibrillator. The manual and ECG modes of the LIFEPAK 1000 defibrillator are intended for use by health care providers trained in ECG rhythm recognition.

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. The LIFEPAK 1000 defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.

The defibrillator may be used with standard defibrillation pads only on adults and children who are 8 years old or more or who weigh more than 25 kg (55lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

ECG monitoring is intended for use on conscious and unconscious patients of all ages for the purpose of ECG rhythm recognition and heart rate monitoring.

Performance Information

The 510(k) includes documentation related to the conformance of the LIFEPAK 1000 defibrillator to IEC electrical safety, electromagnetic compatibility, and defibrillator standards.

The information in this 510(k) demonstrates that the LIFEPAK 1000 defibrillator is substantially equivalent to the predicate devices 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

DEC 2 2 2005

Medtronic Emergency Response Systems
c/o Ms. Michelle Ackermann
Sr. Regulatory Affairs Specialist
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073

Re: K042404
LIFEPAK® 1000 Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: III
Product Code: MKJ
Dated: November 22, 2005
Received: November 23, 2005

Dear Ms. Ackermann:

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) 276-0120. 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 Zuckerman for

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

Enclosure

SECTION D: STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K042404

Device Name: LIFEPAK 1000 Defibrillator

Indications For Use:

Defibrillation:

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia.

The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.

The defibrillator may be used with standard defibrillation pads only on adults and children who are 8 years old or more or who weigh more than 25 kg (55lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

ECG Monitoring:

ECG monitoring is for use on conscious and unconscious patients of all ages for the purpose of ECG rhythm recognition and heart rate monitoring.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042404