FEB 17 2006

K052057

510(k) SUMMARY

Submitter's Name and Address:

Medtronic Emergency Response Systems
11811 Willows Road Northeast
Redmond, WA 98052

Contact Person:

Sherri Pocock
Regulatory Affairs Manager

Date Summary Prepared:

December 12, 2005

Device:

Medtronic biphasic LIFEPAK® 500 Automated External Defibrillator (AED)

Classification:

Low Energy DC-Defibrillator: Class II
Automatic External Defibrillator: Class III

Substantial Equivalence:

The features and functions of the modified biphasic LIFEPAK 500 AED are substantially equivalent to the previously cleared Medtronic LIFEPAK 500 AED, 510(k) numbers K955854 (11/4/96), K983393 (05/05/99), K012428 (09/28/01), and K033275 (11/06/03); and the Philips Medical Systems Heartstream Heartstart FR2+ AED, 510(k) number K013425 (01/14/2002).

Description:

The LIFEPAK 500 automated external defibrillator is a small, portable, battery operated device intended for treatment of cardiac arrest. The device uses a patented software algorithm to analyze the patient's electrocardiogram (ECG) to determine if a shockable rhythm is present. The LIFEPAK 500 AED will inform the operator if it detects a shockable rhythm and the operator can press the shock button to deliver energy. The energy is delivered via disposable defibrillation electrodes applied to the chest.

Intended Use:

The LIFEPAK 500 AED intended for use on patients in cardiac arrest. It is intended for use in the hospital and in out-of-hospital environments.

The LIFEPAK 500 AED is intended for use by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training
- AED training equivalent to that recommended by the American Heart Association
- Training in the use of the LIFEPAK 500 AED

Indications For Use:

The LIFEPAK 500 AED is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, not breathing normally, and showing no signs of circulation (for example, no pulse, and/or no coughing, no movement) before the device is used to analyze the patient's ECG rhythm. With Infant/Child Reduced Energy Defibrillation Electrodes, the specially configured biphasic LIFEPAK 500 AED may be used on children up to 8 years old or 25kg (55 lb).

Technological characteristics of new and predicate device:

Defibrillation technology and functionality are unchanged from the previously cleared device. The biphasic LIFEPAK 500 AED software has been modified to allow the medical director or physician greater control over CPR settings.

The setup options, collectively known as cprMax technology, are intended to allow medical directors or physicians to more easily implement resuscitation protocol adjustments in their Emergency Medical Services systems or AED programs.

Summary of Design Controls:

This 510(k) includes a summary of design control activities and a declaration of conformity to design controls.

The information in this 510(k) notification demonstrates that the modified LIFEPAK 500 AED is substantially equivalent to the predicate devices.

K052057

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Medtronic Emergency Response Systems
c/o Ms. Sherri Pocock
Regulatory Affairs Manager
11811 Willows Road Northeast
Redmond, WA 98052

Re: K052057
Trade Name: LIFEPAK 500 Automatic External Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: January 9, 2006
Received: January 10, 2006

Dear Ms. Pocock:

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,

Bram D. Zuckerman, MD
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):

Device Name: LIFEPAK 500 Automated External Defibrillator

Indications For Use:

The LIFEPAK 500 AED is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, not breathing normally, and showing no signs of circulation (for example, no pulse, and/or no coughing, no movement) before the device is used to analyze the patient's ECG rhythm. With Infant/Child Reduced Energy Defibrillation Electrodes, the specially configured biphasic LIFEPAK 500 AED may be used on children up to 8 years old or 25kg (55 lb).

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)

[signature]
ion Sign-Off)
ion of Cardiovascular Devices
(k) Number K052057