DEC 0 3 2001

SECTION E - 510(k) SUMMARY

K011144

Submitter's Name and Address:

Medtronic Physio-Control Corp.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, WA 98073

Contact Person:

Sherri L. Pocock
(425) 867-4332

Date Summary Prepared:

November 28, 2001

Device:

Medtronic Physio-Control LIFEPAK® CR PLUS Automated External Defibrillator

Classification:

Low-Energy DC - Defibrillator: Class II (21 CFR 870.5300)

Automatic External Defibrillators have been considered Class III devices by FDA.

Description:

The LIFEPAK CR PLUS automated external defibrillator is a small lightweight device intended for use by minimally trained responders to treat victims of sudden cardiac arrest. It includes a patented shock advisory system that notifies the user if it detects a cardiac rhythm that requires a shock.

Substantial Equivalence:

The features and functions of the LIFEPAK CR PLUS AED are substantially equivalent to those of the Medtronic Physio-Control LIFEPAK 500 AED, 510(k) no. K983393, cleared May 5, 1999.

Indications for Use:

The LIFEPAK CR PLUS Automated External Defibrillation is indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation, for example, no pulse, no coughing, no movement. The LIFEPAK CR PLUS AED is not intended for use on patients less than eight years old.

Summary of Performance Information:

The 510(k) includes documentation related to the compliance of the LIFEPAK CR PLUS AED with the standard, ANSI/AAMI DF39-1993, "Automatic External Defibrillators and Remote Control Defibrillators

The information in this 510(k) demonstrates that the LIFEPAK CR PLUS AED is substantially equivalent to the predicate device 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 0 3 2001

Ms. Sherri L. Pocock
Medtronic Physio-Control Corp.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, WA 98073

Re: K011144
LIFEPAK CR PLUS Automated External Defibrillator
Regulation Number: 870.1025
Regulation Name: Defibrillators, Automatic, External
Regulatory Class: III (three)
Product Code: MKJ
Dated: September 5, 2001
Received: September 6, 2001

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 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 James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D - STATEMENT OF INDICATIONS FOR USE

Ver/ 3 - 4/24/96

Applicant: Medtronic Physio-Control Corp.

510(k) Number (if known): 510(k) Number Not yet assigned K011144

Device Name: LIFEPAK CR PLUS Automated External Defibrillator

Indications For Use:

The LIFEPAK CR PLUS Automated External Defibrillator is indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation, for example, no pulse, no coughing, no movement. The LIFEPAK CR PLUS AED is not intended for use on patients less than eight years old.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011144

Prescription Use ✓
(Per 21 CFR 801.109)