SECTION E: 510(k) SUMMARY

Submitter's Name and Address:

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

Contact Person:

Michelle Ackermann
(425) 867-4744

Date Summary Prepared:

September 22nd, 2003

Devices:

Medtronic Physio-Control LIFEPAK® 12, 20, 500, and CR Plus Defibrillators

Classification:

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

Substantial Equivalence:

The features and functions of the LIFEPAK 12, LIFEPAK 20, LIFEPAK 500, and LIFEPAK CR Plus are substantially equivalent to the previously cleared version of each device listed in the table below.

Device	510(k) Information
Medtronic Physio-Control LIFEPAK 12 Defibrillator	K991910 (09/03/99) K010918 (08/23/01)
Medtronic Physio-Control LIFEPAK 20 Defibrillator	K012274 (02/05/02)
Medtronic Physio-Control LIFEPAK 500 AED	K983393 (05/05/99) K012428 (09/28/01)
Medtronic Physio-Control LIFEPAK CR Plus AED	K011144 (12/03/01)

Description:

The LIFEPAK 500 and LIFEPAK CR Plus automated external defibrillators are small, portable, battery operated devices intended for treatment of cardiac arrest. Both devices use a patented software algorithm to analyze the patient's electrocardiogram (ECG) to determine if a shockable rhythm is present. The LIFEPAK 500 and the semi-automatic version of the LIFEPAK CR Plus will then inform the operator if it detects a shockable rhythm and the operator can then press the shock button to deliver energy. The energy is delivered via disposable defibrillation electrodes applied to the chest. The LIFEPAK CR Plus is also available in a fully automatic version which does not require operator interaction to charge and discharge.

The LIFEPAK 12 and LIFEPAK 20 devices use the same shock advising software algorithm as the devices described above. Features available in addition to automated external defibrillation include manual external defibrillation, noninvasive pacing, ECG monitoring, pulse oximetry, and synchronized cardioversion. The LIFEPAK 12 also offers noninvasive blood pressure monitor, invasive blood pressure monitor, and end-tidal CO_2 monitor features.

Intended Use:

The LIFEPAK 500, LIFEPAK CR Plus, and the LIFEPAK 12 and LIFEPAK 20 in automated external defibrillation mode are intended for use on patients in cardiac arrest.

Technological characteristics of new and predicate devices:

The features and functions of the LIFEPAK 12, LIFEPAK 20, LIFEPAK 500, and LIFEPAK CR Plus are the same as those of the currently marketed versions of each device.

Summary of Design Controls:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2003

Medtronic Physio-Control Corp.
c/o Ms. Michelle Ackermann
Regulatory Affairs Specialist
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706

Re: K033275
Trade Name: LIFEPAK® 12, 20, 500 and CR Plus Defibrillators
Regulation Number: 21 CFR 870.1025
Regulation Name: Automatic External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: October 9, 2003
Received: October 10, 2003

Dear Ms. Ackermann:

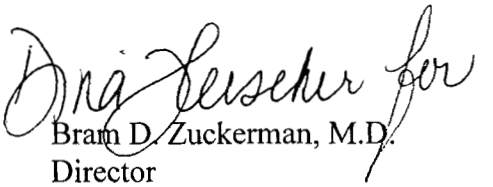
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,



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): Not yet assigned

Device Name: **LIFEPAK 12 and LIFEPAK 20 Defibrillator/Monitor/Pacemakers**

Indications for AED Use:

The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 12 and LIFEPAK 20 defibrillator/monitors are not intended for use on pediatric patients less than 8 years old.

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).

Device Name: **LIFEPAK CR Plus Automated External Defibrillator**

Indications for Use:

The LIFEPAK CR Plus 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, or no movement). With Infant/Child Reduced Energy Defibrillation Electrodes, the LIFEPAK CR Plus defibrillator may be used on children up to 8 years old of 25kg (55 lb).

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

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

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K033275