SECTION E - 510(k) SUMMARY

K022732

Submitter's Name and Address:

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

DEC 13 2002

Contact Person:

Sherri L. Pocock
(425) 867-4332

Date Summary Prepared:

August 12, 2002

Device:

Medtronic Physio-Control Infant / Child Reduced Energy Electrodes

Classification:

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

Description:

The attenuating electrode is designed to allow minimally trained responders to safely and effectively defibrillate infants and children under 8 using the LIFEPAK® CR Plus or biphasic LIFEPAK 500 AEDs manufactured after a certain date. (Compatible biphasic LIFEPAK 500 AEDs can be identified by the pink connector on the AED.)

The Infant / Child Reduced Energy Electrode assembly consists of currently marketed Pediatric QUIK-COMBO electrode pads, wires, a connector, and an attenuator. The attenuator is comprised of multiple resistors and a surge protector mounted on a PCB and installed in a flat plastic case.

The attenuator reduces the standard "adult" AED energy at a ratio of about 4 to 1. When used with the Infant / Child Reduced Energy electrodes, an AED set to deliver 200J first shock, 300J second shock,

and 360J third shock for adult patients, will instead deliver about 50, 75, and 86J.

Packaging and labeling have been designed to make it (1) readily apparent if Infant/Child electrodes are available, (2) intuitive that these electrodes are for infants and children only, (3) easy for the user to determine when to select the pediatric electrode, and (4) easy for the user to quickly deliver defibrillation therapy regardless of patient's age.

Substantial Equivalence:

The features and functions of the Infant / Child Reduced Energy Electrodes are substantially equivalent to those of the Medtronic Physio-Control Pediatric QUIK-COMBO electrodes, 510(k) no. K979301, (cleared March 6, 1997) and the Heartstream Attenuated Defibrillation Pads, 510(k) no. K003819 (cleared May 2, 2001.)

Indications for Use:

Use the Infant/Child defibrillation electrodes on an infant or child up to 8 years old or up to 25kg (55lbs). Do not delay therapy to determine child's exact age or weight.

These electrodes are to be used only with LIFEPAK CR PLUS defibrillators and biphasic LIFEPAK 500 AEDs configured with a pink cable connector.

The LIFEPAK CR PLUS and LIFEPAK 500 biphasic defibrillators are indicated for use 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.

The LIFEPAK CR PLUS and LIFEPAK 500 biphasic defibrillators are intended to be used by personnel who have been trained on the device operation and in basic life support or other physician authorized emergency medical response system.

Summary of Performance Information:

The 510(k) includes:

Clinical testing of algorithm accuracy on pediatric rhythms;

Non-Clinical testing of energy dosing;

Bench testing to verify electrodes meet their specifications; and

Labeling Usability Validation.

The information in this 510(k) demonstrates that the Infant / Child Reduced Energy Electrodes are 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 13 2002

Medtronic Physio-Control Corporation
c/o Ms. Sherri Pocock
Regulatory Advisor
11811 Willows Road NE
Redmond, WA 98073-9706

Re: K022732
Trade Name: Infant/Child Reduced Energy Electrodes
Regulation Number: 21 CFR 870.1025
Regulation Name: Automated External Defibrillator Electrode
Regulatory Class: Class III (three)
Product Code: 74 MKJ, MLN
Dated: November 25, 2002
Received: November 26, 2002

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 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

Ver/ 3 - 4/24/96

Applicant: Medtronic Physio-Control Corp.

510(k) Number (if known): 510(k) Number Not yet assigned K022732

Device Name: Infant / Child Reduced Energy Electrodes

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The LIFEPAK CR PLUS and LIFEPAK 500 biphasic defibrillators are intended to be used by personnel who have been trained on the device operation and in basic life support or other physician authorized emergency medical response system.

(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)

Prescription Use X
(Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Cardiovascular and Respiratory Devices

510(k) Number K022732