

SEP 3 1999

K991910

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: Mike Willingham, Tel. (425) 867-4329

Date Summary Prepared: August 5, 1999

Device:

Physio-Control Corporation Biphasic LIFEPAK® 12 defibrillator / monitor /  
pacemaker system

Classification:

Low-Energy DC - Defibrillators (including Paddles): Class II (21 CFR  
870.5300)

Cardiac Monitors (including cardiometers and Rate Alarms): Class II  
(21 CFR 870.2300)

External Transcutaneous Cardiac Pacemakers (noninvasive): Class III  
(870.5550)

Oximeter: Class II (21 CFR 870.2700)

Automated External Defibrillator and Interpretive 12 lead ECG: Class III

Substantial Equivalence:

The intended use and function of the Biphasic LIFEPAK 12 system are  
substantially equivalent to those of the:

Physio-Control LIFEPAK 12 defibrillator/pacemaker, 510(k) no.  
K973486.

Physio-Control LIFEPAK 500 automated external defibrillator,  
510(k) no. K983393

Heartstream Forerunner defibrillator, 510(k) no. K955628.

Mine Safety defibrillator, Preamendment.

**Description:**

The LIFEPAK 12 defibrillator/monitor series is a complete acute cardiac response system - battery or auxiliary powered defibrillator (manual and AED), monitor, pacemaker, 3 lead ECG, interpretive 12 lead ECG and pulse oximeter. Data can be transmitted by landline or cell phone to computer, fax, printer, or ECG storage system

The users will be Advanced Life Support and Basic Life Support providers in a variety of hospital and prehospital settings. Emergency Medical Services users will include Paramedics and Emergency Medical Technicians trained and authorized to respond to medical emergencies. This device will be used in the prehospital setting and in the hospital, in critical areas (emergency departments, critical care, operating rooms, etc.) and on general duty floors (e.g. medical/surgical.) It will also be used for in and out of hospital transport (air and ground ambulance, in hospital transport, etc.)

**Indications for Use:**

Defibrillation is a means of terminating ventricular fibrillation and ventricular tachycardia. The biphasic waveform used in this device has only been clinically tested on adults; it has not been tested on pediatric patients. The AED mode is for use on patients in cardiopulmonary arrest. Pacing is used to treat symptomatic bradycardia and asystole. ECG monitoring is used for identifying and diagnosing cardiac rhythms and dysrhythmias and calculating heart rate. Pulse oximetry is used to check the saturation of in the arterial blood of patients who are at risk of developing hypoxemia.

**Technological characteristics of new and predicate devices:**

The new Biphasic LIFEPAK 12 defibrillator uses a Biphasic Truncated Exponential (BTE) waveform. The predicate LIFEPAK 12 defibrillator uses a monophasic damped sine waveform; the predicate LIFEPAK 500 and Heartstream Forerunner defibrillators use a BTE waveform; the Mine Safety defibrillator uses a biphasic exponential waveform. The pacing, 12 lead monitor, 3 lead monitor, and Pulse Oximetry features are the same as those in the original LIFEPAK 12 defibrillator.

**Summary of Performance Information:**

The efficacy of the Physio-Control BTE waveform was demonstrated in a multi site clinical study. The results of that study are reported in the 510(k).

Information is also provided in the 510(k) regarding compliance to applicable sections of the following voluntary industry standards:

- ANSI/AAMI DF2 - 1989, Cardiac Defibrillator Devices Standard
- ANSI/AAMI DF39 - 1993, Automatic External Defibrillator Standard

This information demonstrates that the LIFEPAK 12 is substantially equivalent to the predicate devices with respect to safety, effectiveness, and performance.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 3 1999

Mr. Michael D. Willingham  
Vice President, Quality and Regulatory Affairs  
Medtronic Physio-Control Corp.  
11811 Willows Road Northeast  
Post Office Box 97006  
Redmond, WA 98073-9706

Re: K991910  
LIFEPAK® 12 Biphasic Defibrillator/Monitor System  
Regulatory Class: III (three)  
Product Code: 74 MKJ, DRO, LOS, LDD, and DQA  
Dated: June 3, 1999  
Received: June 7, 1999

Dear Mr. Willingham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for

Page 2 - Mr. Michael D. Willingham

devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

### LIFEPAK 12 biphasic defibrillator/monitor series - Indications for Use

#### Defibrillator

Defibrillation therapy is used as a means of terminating ventricular fibrillation and ventricular tachycardia. The biphasic waveform used in this device has only been clinically tested on adults; it has not been tested on pediatric patients. *The device has not been evaluated for AF or for direct cardiac defibrillation.*

#### Automated External Defibrillator feature

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. The AED mode is not intended for use on children less than eight years of age, per AHA guidelines.

#### Noninvasive Pacemaker

Noninvasive pacing is used as a means of treating symptomatic bradycardia and asystole.

#### Electrocardiograph

##### 3-Lead (3 wire) and 6-Lead (4 wire) ECG Monitoring:

The 3 and 4 wire ECG allows for identification or interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate.

##### 12-lead electrocardiogram (ECG)

The 12-lead electrocardiogram (ECG) is used to identify, diagnose, and treat patients with cardiac disorders and is useful in the early detection and prompt treatment of patients with acute myocardial infarction.

#### Pulse Oximetry

A pulse oximeter is a noninvasive device that checks the saturation of oxygen in arterial blood (SpO<sub>2</sub>). It is used for monitoring patients who are at risk of developing hypoxemia.

✓ *C. Dwyer*  
*8/26/99*  
Prescription Use

*[Signature]*  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K.991910