K102972

SECTION E – 510(K) SUMMARY

Submitter:

DEC 2 2 2010

Physio-Control, Inc.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, Washington 98073-9706

Contact Person:

Michelle Ackermann
Principal Regulatory Affairs Specialist
Phone: 425-867-4744, Fax: (425) 867-4154

Date Summary Prepared:

October 1, 2010

Device Trade Name:

LIFEPAK®12 defibrillator/monitor

Device Common Name:

External defibrillator/monitor

Device Classification:

Classification Name	Class
Low Energy DC-Defibrillator (Including Paddles), (21CFR 870.5300, Product Code LDD)	II
Automatic External Defibrillators (Non-Wearable) (21CFR 870.5310, Product Code MKJ)	III
Cardiac Monitor (Including Cardiotachometer & Rate Alarm) (21CFR870.2300, Product Code DRT)	II
External Cardiac Transcutaneous (Non-Invasive) Pacemaker (21CFR870.5550, Product Code DRO)	II
Oximeter (21CFR870.2700, Product Code DQA)	II
Noninvasive Blood Pressure Measurement System (21CFR870.1130, Product Code DXN)	II
Carbon-Dioxide Gas Analyzer Gaseous-Phase (21CFR868.1400 Product Code CCK)	II
Blood Pressure Computer (21CFR870.1110, Product Code DSK)	II

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Predicate Devices:

The features and functions of the proposed LIFEPAK 12 defibrillator/monitor are substantially equivalent to the previously cleared LIFEPAK 12 defibrillator/monitor. 510(k) numbers for the predicate LIFEPAK 12 defibrillator/monitor are listed below.

510(k) Number	Clearance Date
K063510	01/26/07
K041459	07/01/04
K040775	04/23/04
K033275	11/06/03
K010918	03/26/01
K002445	01/31/01
K990338	09/01/99
K991910	06/03/99
K973486	01/09/98

Description:

The LIFEPAK 12 defibrillator/monitor was designed for use in a variety of hospital and pre-hospital settings including emergency departments, critical care areas, and air and ground ambulances. The LIFEPAK 12 defibrillator/monitor is powered by either AC power or battery power. LIFEPAK 12 defibrillator/monitor features include manual and automated external defibrillation, noninvasive pacing, ECG monitoring (3-lead, 7-lead and interpretive 12-Lead), pulse oximetry, synchronized cardioversion, noninvasive blood pressure monitoring, end-tidal CO2 monitoring, and invasive pressure monitoring.

The proposed LIFEPAK 12 defibrillator/monitor has the same features and functions as the predicate LIFEPAK 12 defibrillator/monitor and includes an additional battery option; a rechargeable lithium-ion battery. Use of the proposed lithium-ion battery in the LIFEPAK 12 defibrillator/monitor provides an increase in the available operating time and an increase in the number of 360-Joule discharges available while on battery power as compared to using the existing batteries.

SECTION E – 510(K) SUMMARY

Intended Use:

Intended users of the LIFEPAK 12 defibrillator/monitor are Advanced Life Support and Basic Life Support providers in a variety of hospital and pre-hospital settings. The device is used in various areas of the hospital such as critical areas (emergency departments, critical care, operating room, etc.) and general duty floors (e.g. medical/surgical). The device is also used for in and out of hospital transport (air and ground ambulance, in hospital transport, etc.)

Indications for Use:

Manual Defibrillation:

Indications
Defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Energy delivered in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Contraindications
Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as indioventricular or ventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation:

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

Noninvasive Pacing

Indications
Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications: Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

SECTION E – 510(K) SUMMARY

Indications for Use, cont)

12-lead Electrocardiography:

Indications
The 12-lead electrocardiogram 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

Indications
Pulse Oximetry is indicated for use in any patient who is at risk of developing hypoxemia.

Noninvasive Blood Pressure Monitoring:

Indications
Noninvasive blood pressure monitoring is indicated for detection in trends of hypertension or hypotension. These include patient conditions indicated by abnormalities in various physiologic parameters such as shock, evaluation of perfusion during dysrhythmias, major fluid shifts, evaluation of response to fluid therapy, and titration of vasoactive and cardiotonic drugs. Noninvasive blood pressure monitoring may be useful during ECG monitoring or for post-defibrillation recovery analysis.

End-Tidal CO2 monitoring:

Indications
$EtCO_2$ monitoring is indicated for detection of trends in the level of expired CO_2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully. It is intended for use on adult and pediatric patients.

Invasive Pressure Monitoring:

Indications
The LIFEPAK 12 invasive pressure monitor is indicated for use in measuring arterial, venous, intracranial and other physiological pressures using and invasive catheter system with a compatible transducer. It may be used on the adult or pediatric patient.

SECTION E – 510(K) SUMMARY

Technological characteristics of the proposed and predicate device:

The only difference between the predicate LIFEPAK 12 defibrillator/monitor and the proposed LIFEPAK 12 defibrillator/monitor is an additional rechargeable battery option. Use of the lithium-ion rechargeable battery in the LIFEPAK 12 defibrillator/monitor provides an increase in the available operating time and an increase in the number of 360-Joule discharges available while on battery power as compared to using existing LIFEPAK 12 batteries. The defibrillation waveform, ECG analysis system, and monitoring and defibrillation features of the proposed LIFEPAK 12 defibrillator/monitor are unchanged from the previously cleared LIFEPAK 12 defibrillator/monitor.

Conclusion of Testing

The information in this 510(k) notification demonstrates that the LIFEPAK 12 defibrillator/monitor is substantially equivalent to the predicate LIFEPAK 12 device with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Physio-Control, Inc.
c/o Ms. Michelle Ackermann
Principal Regulatory Affairs Specialist
11811 Willows Road Northeast
P.O. BOX 97006
Redmond, WA 98073-9706

DEC 2 2 2010

Re: K102972
Trade/Device Name: LIFEPAK 12 defibrillator/monitor Lithium-ion battery
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: November 29, 2010
Received: November 30, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

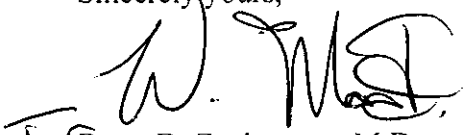
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102972

SECTION D – STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): not yet assigned

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number _____

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