SECTION E – 510(K) SUMMARY

OCT 11 2012

Submitter:

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

Contact Person:

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Date Summary Prepared:

August 24th, 2012

Device Trade Name:

LIFEPAK®1000 defibrillator

Device Common Name:

External defibrillator

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

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Predicate Devices:

The features and functions of the proposed LIFEPAK 1000 defibrillator are substantially equivalent to the previously cleared LIFEPAK 1000 defibrillator. The 510(k) number for the predicate LIFEPAK 1000 defibrillator is K042404 (cleared on 12/22/05).

Description:

The LIFPAK 1000 defibrillator is a semi-automatic defibrillator with optional manual mode and ECG display. It is intended for use by personnel who are authorized by a physician/medical director and are trained in CPR and the use of the LIFEPAK 1000 defibrillator. There are 3 modes of operation for the LIFEPAK 1000 defibrillator: AED mode (automated external defibrillation), manual mode (operator ECG interpretation, operator control of charge and shock functions), and ECG mode (ECG display allows for rhythm and heart rate monitoring). The currently marketed LIFEPAK 1000 defibrillator is powered by a non-rechargeable lithium-manganese battery.

The proposed LIFEPAK 1000 defibrillator has the same features and functions as the predicate LIFEPAK 1000 defibrillator with an additional battery option – a rechargeable lithium-ion battery.

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Intended Use:

The LIFEPAK 1000 defibrillator is intended for use by personnel who are authorized by a physician/medical director and are trained in CPR and the use of the LIFEPAK 1000 defibrillator. The manual and ECG modes of the LIFEPAK 1000 defibrillator are intended for use by health care providers trained in ECG rhythm recognition.

Indications for Use:

Defibrillation

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia.

The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.

The defibrillator may be used with standard defibrillation pads only on adults and children who are 8 years old or more or who weigh more than 25 kg (55lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25kg (55lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

ECG Monitoring

ECG monitoring is for use on conscious and unconscious patients of all ages for the purpose of ECG rhythm recognition and heart rate monitoring

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Technological characteristics of the proposed and predicate device:

The only difference between the predicate LIFEPAK 1000 defibrillator and the proposed LIFEPAK 1000 defibrillator is a new battery option. The defibrillation waveform, ECG analysis system, and monitoring and defibrillation features of the proposed LIFEPAK 1000 defibrillator are unchanged from the previously cleared LIFEPAK 1000 defibrillator.

Conclusion of Testing

The information in this 510(k) notification demonstrates that the LIFEPAK 1000 defibrillator is substantially equivalent to the predicate LIFEPAK 1000 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

MAR 20 2013

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

Re: K122600
Trade/Device Name: LIFEPAK 1000 defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator (Non-Wearable)
Regulatory Class: Class III
Product Code: MKJ
Dated: August 24, 2012
Received: August 27, 2012

Dear Ms. Ackermann:

This letter corrects our substantially equivalent letter of October 11, 2012.

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 (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 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,

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 K122600

Device Name: **LIFEPAK® 1000 defibrillator**

Indications For Use:

Defibrillation

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia.

The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.

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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 K122600