



SECTION E – 510(K) SUMMARY

Submitter:

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

AUG 21 2013

Contact Person:

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Principal Regulatory Affairs Specialist
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Date Summary Prepared:

February 21, 2013

Device Trade Name:

LIFEPAK®20 defibrillator/monitor
LIFEPAK®20e 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 Cardiometer & Rate Alarm) (21CFR870.2300, Product Code DRT)	II
External Cardiac Transcutaneous (Non-Invasive) Pacemaker (21CFR870.5550, Product Code DRO)	II
Electrocardiograph	II
Hydraulic, Pneumatic, or Photoelectric Plethysmographs	II
Oximeter (21CFR870.2700, Product Code DQA)	II
Carbon-Dioxide Gas Analyzer Gaseous-Phase (21CFR868.1400 Product Code CCK)	II



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Predicate Devices:

The features and functions of the proposed LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors are substantially equivalent to the previously cleared LIFEPAK 20 defibrillator/monitor, LIFEPAK 20e defibrillator/monitor and the LIFEPAK 15 monitor/defibrillator. 510(k) clearance numbers for the predicate devices are below:

Predicate Device	510(k) Number(s)
LIFEPAK [®] 20 defibrillator/monitor	K012274, K033275, K063119
LIFEPAK [®] 20e defibrillator/monitor	K073089
LIFEPAK [®] 15 monitor/defibrillator	K082937, K103567

Description:

The LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors were designed especially for hospitals and clinics for use on "crash carts" as well as for portable emergency response throughout a hospital. Features of the LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors include manual and automated external defibrillation, noninvasive pacing, ECG monitoring (3-wire or 5-wire), pulse oximetry, and synchronized cardioversion. The LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors are powered by AC power and a backup internal battery. The LIFEPAK 20 defibrillator/monitor utilizes a nickel-metal hydride internal battery while the LIFEPAK 20e defibrillator/monitor utilizes a lithium-ion internal battery. The LIFEPAK 20e defibrillator/monitor also has a battery status indicator on the device screen.

In addition to the features described above, the proposed LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors have a new CO₂ monitoring feature, CPR metronome feature, wireless data transmission capability and a new optional accessory named the CodeManagement Module™.



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Intended Use:

The LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors are intended for use in the hospital, physician's office, and clinic setting by personnel who are authorized by a physician/medical director. They are intended for use on a "crash cart" as well as for portable emergency response throughout a hospital.

Indications for Use (for both the LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors):

Manual Defibrillation

Indications: Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy 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 idioventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation:

Indications: The 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 20 (and LIFEPAK 20e) 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.



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Pulse Oximetry

Indications: The pulse oximeter is indicated for use in any patient who is at risk of developing hypoxemia.

End-Tidal CO₂ monitoring:

Indications

EtCO₂ monitoring is used to detect the level of expired CO₂. 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.



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Technological characteristics of the proposed and predicate devices:

The main difference between the predicate LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors and the proposed LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors is the new CO₂ monitoring indication and CPR metronome feature. Device characteristics such as defibrillation waveform and the ECG analysis system are unchanged from the predicate LIFEPAK 20 and LIFEPAK 20e devices.

The CO₂ monitoring and CPR metronome features in the proposed LIFEPAK 20 and LIFEPAK 20e defibrillator/monitor are similar to the CO₂ monitoring and CPR metronome features in the predicate LIFEPAK 15 monitor/defibrillator.

Conclusion of Testing

The information in this 510(k) notification demonstrates that the LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors are substantially equivalent to the predicate LIFEPAK 20 defibrillator/monitor, LIFEPAK 20e defibrillator/monitor and the LIFEPAK 15 monitor/defibrillator with respect to safety, effectiveness, and performance.

No clinical studies or non-clinical (i.e. animal) studies were submitted as part of this 510(k) notification. Performance testing of the proposed devices consisted of bench testing.



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

August 21, 2013

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

Re: K130454
Trade/Device Name: LIFEPAK 20/20e defibrillator/monitor
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: July 23, 2013
Received: July 24, 2013

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.

Page 2 – Ms. Michelle Ackermann

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 contact 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>. 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,

Owen P. Faris -S

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

510(k) Number (if known): _____

Device Name: **LIFEPAK[®] 20 defibrillator/monitor and LIFEPAK[®] 20e defibrillator/monitor**

Indications For Use:

Manual Defibrillation

Indications: Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy 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 idioventricular escape rhythms, and in the treatment of asystole.

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Indications: The 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 20 (and LIFEPAK 20e) defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.

Prescription Use AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Physio-Control Inc.
LIFEPAK 20 and LIFEPAK 20e defibrillator/monitors
510(k) Premarket Notification

SECTION D – STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: LIFEPAK[®] 20 defibrillator/monitor and LIFEPAK[®] 20e defibrillator/monitor

Indications For Use:

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.

Pulse Oximetry

Indications: The pulse oximeter is indicated for use in any patient who is at risk of developing hypoxemia.

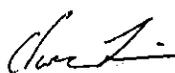
End-Tidal CO₂ monitoring:

Indications: EtCO₂ monitoring is used to detect the level of expired CO₂. 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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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