Physio-Control, Inc.
Chelsea Cullen
Sr. Regulatory Affairs Specialist
11811 Willow Road NE
Redmond, Washington 98052

Re: K182503
Trade/Device Name: Sterilizable Internal Defibrillation Paddles for use with LIFEPAK defibrillators/monitors
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator (Including Paddles)
Regulatory Class: Class II
Product Code: LDD
Dated: April 30, 2019
Received: May 1, 2019

Dear Chelsea Cullen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Matthew Hillebrenner
Deputy Director
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182503

Device Name
Sterilizable Internal Defibrillation Paddles

Indications for Use *(Describe)*
The Sterilizable Internal Defibrillation Paddles are intended for use with LIFEPAK defibrillators to internally detect ECG rhythm and provide defibrillation or synchronized cardioversion directly to the surgically exposed heart within a sterile use environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 5: 510(k) SUMMARY

Submitter:
Physio-Control, Inc.
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Registration Number: 3015876, 3006703820

Contact:
Chelsea Cullen
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Date of Preparation: April 23, 2019

Device Trade/Proprietary Name:
Sterilizable Internal Defibrillation Paddles for use with LIFEPAK® defibrillators/monitors

Device Common Name:
Internal Defibrillation Paddles

Device Classification:

Device Classification and CFR Reference	Classification Panel	Product Code
Low Energy DC-Defibrillator (Including Paddles), Class II (21CFR 870.5300)	Cardiovascular Devices	LDD

Predicate Devices:

The features and functions of the proposed Sterilizable Internal Defibrillation Paddles accessory are equivalent to the following previously cleared Internal Paddles:

Predicate Device	510(k) Number(s)/ Clearance Date
Internal Paddles and Paddle Handles with Discharge Control	K895379 / cleared in 1990

Device Description:

The Sterilizable Internal Defibrillation Paddles is an accessory designed to be used with biphasic LIFEPAK defibrillator/monitors during open heart cardiac surgery. The Sterilizable Internal Defibrillation Paddles are intended for use by highly-trained medical professionals to internally detect electrocardiogram (ECG) rhythm and deliver internal defibrillation and synchronized cardioversion therapy directly to the surgically exposed heart. This accessory consists of metal paddle electrodes, and molded plastic handles with discharge control (located on the right handle) which connects directly to the defibrillator.

The Sterilizable Internal Defibrillation Paddles accessory requires sterilization before initial use and after each use, per the Sterilizable Internal Defibrillation Paddles Instructions for Use.

Indications for Use:

The Sterilizable Internal Defibrillation Paddles are intended for use with LIFEPAK defibrillators to internally detect ECG rhythm and provide defibrillation or synchronized cardioversion directly to the surgically exposed heart within a sterile use environment.

Intended Use:
Defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia.

Synchronized cardioversion is indicated for the treatment of atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, supraventricular tachycardia, and in relatively stable patients, ventricular tachycardia.

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

Synchronized cardioversion is contraindicated in the treatment of Pulseless Electrical Activity (PEA) such as idioventricular or ventricular escape rhythms, asystole, and ventricular fibrillation.

Summary of Technological Characteristics:

The intended use, features, and functional characteristics of the proposed Sterilizable Internal Defibrillation Paddles are equivalent to the predicate device. The main differences between the previously cleared predicate Internal paddles and paddle handles with discharge control and the proposed Sterilizable Internal Defibrillation Paddles are 1) an integrated handle-electrode assembly which is available in two (2) connector configurations, and 2) material change to the device to increase durability and resistance of the paddles to better withstand the harshness of cleaning and repeated sterilization methods.

The proposed changes have not raised any new issues when compared to the existing predicate devices.

Performance Data:

Performance testing has been completed to demonstrate that the proposed Sterilizable Internal Defibrillation Paddles meet the safety and performance requirements established in the design specifications. Comprehensive testing included the following:

- Design Verification Testing
- Biocompatibility Testing
- Electrical Safety and Electromagnetic Compatibility Testing
- Design Validation Testing
    - Animal Testing, and Simulated Use Testing

No human clinical studies were submitted as part of this 510(k) Premarket Notification.

Conclusion:

The information in this 510(k) notification demonstrates that the Sterilizable Internal Defibrillation Paddles are substantially equivalent to the predicate Internal Defibrillation Handles and Electrodes with respect to performance.