April 19, 2024

Stryker Physio-Control
Roshonda Knight
Staff Regulatory Affairs Specialist
11811 Willows Road NE
Redmond, Washington 98052

Re: K240162
Trade/Device Name: LIFEPAK® 35 AC Power Adapter (41335-000001)
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator (Including Paddles)
Regulatory Class: Class II
Product Code: MPD
Dated: January 18, 2024
Received: January 22, 2024

Dear Roshonda Knight:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

LIFEPAK® 35 AC Power Adapter (41335-000001)

Indications for Use *(Describe)*

The LIFEPAK 35 AC power adapter is an optional accessory intended to connect to the LIFEPAK 35 monitor/defibrillator to provide auxiliary power. The bracket and screws provided are intended to attach the power adapter to a wall or shelf.

The LIFEPAK 35 AC power adapter is intended for indoor environments and for fixed installation in ground transportation vehicles.

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.

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510(K) SUMMARY

Submitter:

Physio-Control, Inc.
11811 Willows Road Northeast
Redmond, Washington 98052-2003
Registration Number: 3015876

Contact:

Roshonda Knight
Staff Regulatory Affairs Specialist
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roshonda.knight@stryker.com

Date of Preparation: January 19, 2024

Device Trade/Proprietary Name:

LIFEPAK 35 AC Power Adapter

Device Common Name:

LIFEPAK 35 AC Power Adapter

Device Classification:

Device Classification and CFR Reference	Classification Panel	Product Code
Auxiliary Power Supply (AC or DC) for Low-Energy Defibrillators, Class II (870.5300)	Cardiovascular	MPD

Predicate Device(s):

The features and functions of the proposed subject accessory are equivalent to the following previously cleared device(s):

Predicate Device	510(k) Number(s) / Clearance Date
LIFEPAK 15 AC Power Adapter, accessory to the LIFEPAK 15 Monitor/Defibrillator	K142430 / cleared on 12/19/2014

Device Description:

The LIFEPAK 35 AC Power Adapter is an optional accessory for use with only the LIFEPAK 35 monitor/defibrillator. This accessory contains: AC power adapter with output cable, mounting bracket, bracket screws, region-specific AC power cord (packed separately). The power adapter:

- Provides operating power to the monitor/defibrillator with or without batteries installed.
- Provides power to charge batteries installed in the monitor/ defibrillator.

The LIFEPAK 35 AC Power Adapter operates on 100 to 240 VAC line power. Installed batteries are charged whenever the power adapter is connected to the LIFEPAK 35 monitor/defibrillator. To help manage and maintain battery charge, the power adapter should be kept plugged into the defibrillator whenever possible. For more information about maintaining the batteries, see the LIFEPAK 35 device Operating Instructions.

Indications for Use:

The LIFEPAK 35 AC power adapter is an optional accessory intended to connect to the LIFEPAK 35 monitor/defibrillator to provide auxiliary power. The bracket and screws provided are intended to attach the power adapter to a wall or shelf.

The LIFEPAK 35 AC power adapter is intended for indoor environments and for fixed installation in ground transportation vehicles.

Summary of Technological Characteristics:

The LIFEPAK 35 AC Power Adapter is both non-active and external (non-invasive) and is limited to the transfer of electricity from a power source, such as a wall outlet, to the LIFEPAK 35 device. The LIFEPAK 35 device displays AC input whenever the device is powered on and is connected to the device via the LIFEPAK 35 AC Power Adapter.

Table of Comparison

Device	**Predicate Device** LIFEPAK 15 AC Power Adapter accessory for the LIFEPAK 15 monitor/defibrillator (K142430)	**Subject Device** LIFEPAK 35 AC Power Adapter (K240162)
FDA Product Code	MKJ, LDD, DRT, DRO, DQA, DSK, CCK, FLL	MPD
Intended Use/ Intended Purpose	The AC Power Adapter is intended for use with the LIFEPAK 15 monitor/defibrillator. Use the power adapter only in a controlled indoor or mobile environment.	The LIFEPAK 35 AC power adapter is an optional accessory intended to connect to the LIFEPAK 35 monitor/defibrillator to provide auxiliary power. The bracket and screws provided are intended to attach the power adapter to a wall or shelf. The LIFEPAK 35 AC power adapter is intended for indoor environments and for fixed installation in ground transportation vehicles.
Usage	Reusable	Reusable
Input Voltage/Frequency	100-240 Vac, 50/60 Hz, 1.4-0.6 A	100-240 VAC 50/60/400 Hz 1.8 A

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Device	Predicate Device LIFEPAK 15 AC Power Adapter accessory for the LIFEPAK 15 monitor/defibrillator (K142430)	Subject Device LIFEPAK 35 AC Power Adapter (K240162)
Output Voltage/Amperage	12 Vdc, 7 A	14.8 to 16.0 Volts 8.6 A DC from 0 to 40°C; at least 6.5 A DC from > 40 to 45°C
Operating Temperature	0° to 45°C (32° to 113°F)	0° to 45°C (32° to 113°F)
Non-Operating Temperature	-40° to 70°C (-40° to 158°F)	-40° to 70°C (-40° to 158°F)
Relative Humidity, Operating	5 to 95%, non-condensing	5 to 95%, non-condensing
Altitude, Operating	795 to 429 mmHg -382 to 4572 m (-1253 to 15,000 ft)	-382 to 4572 m (-1253 to 15,000 ft)
Altitude, Non-Operating	Not listed	-382 to 5486 m (-1253 to 18,000 ft)
Protection Against Electric Shock	Class II No patient applied parts	Class II with a functional earth (FE). No patient-applied parts.
Protection Against Solid Object and Liquid Ingress	IP44	IP32
Mode of Operation	Continuous	Continuous

Performance Data:

Performance testing has been completed to demonstrate that the subject device, LIFEPAK 35 AC Power Adapter, is substantially equivalent to the predicate device, LIFEPAK 15 AC Power Adapter, by meeting the safety and performance requirements established in the design specifications. Comprehensive testing included the following:

- Biocompatibility Evaluation
- Electrical Safety and Electromagnetic Compatibility Testing
- Design Verification Testing
- Design Validation Testing

No animal nor human clinical studies were submitted as part of this 510(k) Premarket Notification.

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Conclusion:

The proposed LIFEPAK 35 AC Power Adapter accessory has the same indications, intended use, intended users, intended environment, features, and functional characteristics as the predicate accessories selected for this submission.

No new safety and effectiveness questions as compared to the predicate device have been presented with the new design changes. The proposed LIFEPAK 35 AC Power Adapter accessory is substantially equivalent to the predicate Physio-Control LIFEPAK 15 AC Power Adapter.

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