



October 14, 2025

Physio-Control, Inc.
Elisha McGaff
Senior Staff Regulatory Affairs Specialist
11811 Willows Road NE
Redmond, Washington 98052

Re: K253099

Trade/Device Name: LIFEPAK 15 AC Power Adapter (41577-000333)

Regulation Number: 21 CFR 870.5300

Regulation Name: DC-Defibrillator (Including Paddles)

Regulatory Class: Class II

Product Code: MPD

Dated: September 19, 2025

Received: September 24, 2025

Dear Elisha McGaff:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253099

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Please provide the device trade name(s).

?

LIFEPAK 15 AC Power Adapter (41577-000333)

Please provide your Indications for Use below.

?

The LIFEPAK 15 AC power adapter is an optional accessory intended to connect to the LIFEPAK 15 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 15 AC Power Adapter is intended for the in-hospital environment and ground transport vehicles.

Please select the types of uses (select one or both, as applicable).

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

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510(K) SUMMARY

Submitter:

Physio-Control, Inc.
11811 Willows Road Northeast
Redmond, Washington 98052
Registration Number: 3015876, 3006703820

Contact:

Elisha McGaff
Senior Staff Regulatory Affairs Specialist
425-867-4619 (office)
Elisha.McGaff@stryker.com

Date of Preparation: September 19, 2025

Device Trade/Proprietary Name: LIFEPAK® 15 AC Power Adapter (41577-000333)

Device Common Name: AC Power Adapter (ACPA)

Device Classification:

Device Classification and CFR Reference	Classification Panel	Product Code
Auxiliary power supply (AC or DC) for low-energy DC-Defibrillator (21 CFR 870.5300)	Cardiovascular Devices	MPD

Predicate Device(s):

The features and functions of the proposed LIFEPAK 15 AC Power Adapter accessory is equivalent to the following previously cleared device:

Predicate Device	510(k) Number(s) / Clearance Date
LIFEPAK 35 AC Power Adapter	K240162 / Cleared on 04/19/2024

Device Description:

The LIFEPAK 15 AC Power Adapter is an optional accessory meant to be used with only the LIFEPAK 15 monitor/defibrillator. The LIFEPAK 15 AC Power Adapter provides power to operate the monitor/defibrillator with or without batteries installed. Additionally, the LIFEPAK 15 AC Power Adapter provides power to the internal battery charger (installed in the LIFEPAK 15 monitor/defibrillator) to charge the LIFEPAK 15 device's batteries, if they are installed. To help manage and maintain a battery charge, the power adapter should be kept plugged into the monitor/defibrillator whenever possible.

Indications for Use:

The LIFEPAK 15 AC power adapter is an optional accessory intended to connect to the LIFEPAK 15 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 15 AC Power Adapter is intended for the in-hospital environment and ground transport vehicles.

Summary of Technological Characteristics:

The intended use, features, and functional characteristics of the proposed LIFEPAK 15 AC Power Adapter are equivalent to the predicate device.

The proposed modifications have not raised any new issues of safety and effectiveness when compared to the existing predicate device.

Characteristic	Predicate Device: LIFEPAK 35 AC Power Adapter	Modified Device: LIFEPAK 15 AC Power Adapter
Manufacturer	Physio-Control Inc.	Same
Trade Name	LIFEPAK 35 AC Power Adapter	LIFEPAK 15 AC Power Adapter
510(k) Number	K240162	K253099
Device Classification	2	2
Product Code	MPD	Same
Regulation Number	21 CFR 870.5300	Same
Prescription/ Over-the-Counter Use	Prescription	Same

Characteristic	Predicate Device: LIFEPAK 35 AC Power Adapter	Modified Device: LIFEPAK 15 AC Power Adapter
Indications for Use/ Intended 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.	The LIFEPAK 15 AC power adapter is an optional accessory intended to connect to the LIFEPAK 15 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 15 AC Power Adapter is intended for the in-hospital environment and ground transport vehicles.
Usage	Reusable	Same
Sterile	Non-sterile	Same
Input Voltage Rating/Frequency	100-240 VAC 50/60/400 Hz 1.8 A	Same
Output Voltage/Amperage	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	11.0 to 14.0 Volts 7 A DC from 0° to 40°C; at least 6.5 A DC from >40° to 45°C
Nominal Cable Length	35.43 inches	9.331 inches
Mating Connector Type for Device Compatibility	Plug in connector compatible with the LIFEPAK 35 monitor/defibrillator	Plug in connector compatible with the LIFEPAK 15 monitor/defibrillator
Operating Temperature	0° to 45°C (32° to 113°F)	Same
Non-Operating Temperature	-40° to 70°C (-40° to 158°F)	Same
Operating Relative Humidity	5 to 95%, non-condensing	Same

Characteristic	Predicate Device: LIFEPAK 35 AC Power Adapter	Modified Device: LIFEPAK 15 AC Power Adapter
Operating Altitude	795 to 429 mmHG (-1,253 to 15,000 ft)	Same
Non-Operating Altitude	-382 to 5,486 m (-1253 to 18,000 ft)	Same
Dust and Water Resistance	IP32	Same
Safety Class	Class II with a functional earth (FE). No patient-applied parts.	Same
Electrical Safety and Performance	IEC60601-1 IEC60601-1-2 IEC60601-1-12 IEC60601-2-4	Same

Performance Data:

Performance testing has been completed to demonstrate that the proposed LIFEPAK 15 AC Power Adapter meets the safety and performance requirements established in the design specifications. Comprehensive testing included the following:

- Electrical Safety and Electromagnetic Compatibility Testing
- Design Verification Testing

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

In summary, the design verification testing was successfully completed, and the predetermined acceptance criteria were satisfied.

Conclusion:

The information in this 510(k) notification demonstrates that the Physio-Control LIFEPAK 15 AC Power Adapter is substantially equivalent to the predicate LIFEPAK 35 AC Power Adapter with respect to safety, effectiveness, and performance.