April 30, 2024

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

Re: K240156
Trade/Device Name: LIFEPAK® Invasive Pressure Adapter Cable (Interfaces with ICU Medical Transpack IV Invasive Pressure Transducers (or equivalent)) (11230-000021); LIFEPAK® Invasive Pressure Adapter Cable (interfaces with Edwards Lifesciences TruWave Invasive Pressure Transducers (or equivalent)) (11230-000024)
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: January 19, 2024
Received: January 19, 2024

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.

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 Shih 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)*

K240156

Device Name

LIFEPAK® Invasive Pressure Adapter Cable (Interfaces with ICU Medical Transpack IV Invasive Pressure Transducers (or equivalent)) (11230-000021);
LIFEPAK® Invasive Pressure Adapter Cable (interfaces with Edwards Lifesciences TruWave Invasive Pressure Transducers (or equivalent)) (11230-000024)

Indications for Use *(Describe)*

The LIFEPAK Invasive Pressure Adapter Cable is intended to connect invasive pressure transducers from the patient to the LIFEPAK monitor/defibrillator for invasive pressure monitoring purposes and/or aid in diagnostic evaluation by a health care professional. The LIFEPAK Invasive Pressure Adapter Cable is intended for use in outdoor and indoor emergency care settings.

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 98073-9706
Registration Number: 3015876, 3006703820

Contact:

Elisha McGaff
Senior Staff Regulatory Affairs Specialist
425-605-3483 (office)
Elisha.McGaff@stryker.com

Date of Preparation: January 19, 2024

Device Trade/Proprietary Name: LIFEPAK® Invasive Pressure Adapter Cable

Device Common Name: Invasive Pressure (IP) Cable

Device Classification:

Device Classification and CFR Reference	Classification Panel	Product Code
Patient transducer and electrode cable (21 CFR 870.2900)	Cardiovascular Devices	DSA

Predicate Device(s):

The features and functions of the proposed LIFEPAK Invasive Pressure Adapter Cable accessory are equivalent to the following previously cleared device(s):

Predicate Device	510(k) Number(s) / Clearance Date
JKH USA, LLC Patient Monitoring Cables	K203635 / Cleared on 02/05/2021

Device Description:

The LIFEPAK Invasive Pressure Adapter Cable is a reusable, insulated, shielded, electrical cord (trunk cable) with a proximal connector (to connect with the LIFEPAK 35 device) and a main yoke that houses three distal leans with connectors (to connect with invasive pressure transducers). The LIFEPAK Invasive Pressure Adapter Cable is designed to transmit an electrical signal (data) between devices (i.e., to connect invasive pressure transducers from the patient to the LIFEPAK 35 monitor/defibrillator). The invasive pressure cable is designed to connect up to three pressure transducers to the front panel of the LIFEPAK 35 monitor/defibrillator for invasive pressure monitoring. Three channels are available for invasive pressure (IP) monitoring, with labels P1, P2, and P3. Each channel also has a user-selectable label for the line type through the LIFEPAK 35 monitor/defibrillator.

Invasive Pressure monitoring involves the conversion of fluid pressure into an electrical signal. The conversion is accomplished with a pressure transducer (i.e., IP Probe). The invasive pressure cable passes the electrical signal from the transducers to the LIFEPAK 35 monitor/defibrillator.

The LIFEPAK Invasive Pressure Adapter Cable is available in two different models that are compatible with either ICU Medical Transpac® IV Disposable Pressure Transducers or Edwards Lifesciences TruWave® Disposable Pressure Transducers. These pressure transducers provide industry standard sensitivity and defibrillation protection of at least 360 joules.

The LIFEPAK Invasive Pressure Adapter Cable is not intended for use with other manufacturers' defibrillators and/or monitors. The LIFEPAK Invasive Pressure Adapter Cable is intended only for use with LIFEPAK 35 monitor/defibrillator.

Indications for Use:

The LIFEPAK Invasive Pressure Adapter Cable is intended to connect invasive pressure transducers from the patient to the LIFEPAK monitor/defibrillator for invasive pressure monitoring purposes and/or to aid in diagnostic evaluation by a health care professional. The LIFEPAK Invasive Pressure Adapter Cable is intended for use in outdoor and indoor emergency care settings.

Summary of Technological Characteristics:

The intended use, features, and functional characteristics of the proposed LIFEPAK Invasive Pressure Adapter Cable are equivalent to the predicate device. A minor difference related to limiting the connection to one type (i.e., patient IP transducers to the monitoring device) was noted. Overall, this difference does not alter the effect or raise new issues for the safety and effectiveness of the invasive pressure adapter cable as compared to the predicate.

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

Characteristic	Predicate Device: Patient Monitoring Cables K203635	Subject Device: LIFEPAK Invasive Pressure Adapter Cable
Manufacturer	JKH USA, LLC	Physio-Control Inc.
Trade Name	Patient Monitoring Cables	LIFEPAK Invasive Pressure Adapter Cable
510(k) Number	K203635	K240156
Device Classification	II	II
Product Code	DSA	DSA
Regulation Number	21 CFR 870.2900	21 CFR 870.2900
Prescription/ Over-the-Counter Use	Prescription	Prescription
Indications for Use/ Intended Use	The Patient Monitoring Cables are intended to be used with ECG, EKG, SpO2 and BP monitoring devices. The Patient Monitoring Cables are used to connect electrodes, catheters, and/or sensors placed at appropriate site on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by health care professional.	The LIFEPAK Invasive Pressure Adapter Cable is intended to connect invasive pressure transducers from the patient to the LIFEPAK monitor/defibrillator for invasive pressure monitoring purposes and/or to aid in diagnostic evaluation by a health care professional. The LIFEPAK Invasive Pressure Adapter Cable is intended for use in outdoor and indoor emergency care settings.
Contraindications	None known	Same
Usage	Reusable	Same
Sterile	Non-sterile	Same
Design / Appearance	Connectors on each cable end and a shielded bulk cable	Same

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Characteristic	Predicate Device: Patient Monitoring Cables K203635	Subject Device: LIFEPAK Invasive Pressure Adapter Cable
Material	Shielded and unshielded Copper with PVC or TPU jacket	Same
Cable Length	Various specified standard lengths	96 inches (2.44 meters)
Patient Connection	Electrodes, catheters, and/or sensors placed at appropriate site on the patient.	Invasive Pressure transducers placed at appropriate site on the patient.
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-1
Electrical Safety and Performance	IEC 60601-1 AAMI/ANSI EC53	IEC 60601-1 IEC 60601-2 IEC 60601-2-34

Performance Data:

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

- Biocompatibility Evaluation
- Design Verification Testing

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

Conclusion:

The information in this 510(k) notification demonstrates that the Physio-Control LIFEPAK Invasive Pressure Adapter Cable is substantially equivalent to the predicate JKH USA, LLC Patient Monitoring Cables with respect to safety, effectiveness, and performance.

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