May 7, 2024

Stryker Physio-Control
Craig Schultz
Senior Staff Regulatory Affairs Specialist
11811 Willows Road NE
Redmond, Washington 98052

Re: K240377
Trade/Device Name: LIFEPAK® ECG Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: February 7, 2024
Received: February 7, 2024

Dear Craig Schultz:

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,
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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)*

K240377

Device Name

LIFEPAK ECG Cables

Indications for Use *(Describe)*

The LIFEPAK ECG cables are reusable electrode cable systems intended to transmit signals from patient electrodes to the LIFEPAK monitor/defibrillator for monitoring purposes. LIFEPAK ECG cables are intended for use in outdoor and indoor emergency care settings.
LIFEPAK ECG Cables:
- LIFEPAK 3-wire ECG Cable
- LIFEPAK 5-wire ECG Cable
- LIFEPAK 4-wire ECG cable
- LIFEPAK 3-wire extended precordial ECG Cable
- LIFEPAK 6-wire expandable precordial ECG cable

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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510(k) SUMMARY

1.0 Submitter Information [21 CFR 807.92(a) (1)]

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

Contact:

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Date of Preparation: April 29, 2024

2.0 Device Information [21 CFR 807.92 (a) (2)]

Device Trade/Proprietary Name:
LIFEPAK® ECG Cables

Device Common Name:
LIFEPAK ECG Cables

Table 1 Device Classification

Device Classification and CFR Reference	Classification Panel	Product Code
Cable, Transducer and Electrode, Patient, (Including Connector), Class II (870.2900)	Cardiovascular Devices	DSA

3.0 Predicate Device [21 CFR 807.92(a) (3)]

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

Table 2 Predicate Device

Predicate Device	510(k) Number(s) / Clearance Date
Multi-Link™ X2 ECG Cable and Leadwire System	K211294/August 16, 2021

4.0 Purpose and Device Description [21 CFR 807.92(a) (4)]

The LIFEPAK ECG cables are an accessory designed to be used with Physio-Control LIFEPAK 35 monitor/defibrillator. The LIFEPAK ECG cables are intended for use by Advanced Life Support (ALS) and Basic Life Support (BLS) providers to transmit signals from patient electrodes to the LIFEPAK monitor/defibrillator for monitoring purposes.

The LIFEPAK ECG Cables are reusable ECG trunk cables and lead wires that connect to the LIFEPAK 35 monitor/defibrillator for ECG monitoring. There are several types or configurations of ECG cables: 3-wire, 5-wire, a 4-wire cable assembly to be used with the LIFEPAK 6-wire precordial cable and/or the LIFEPAK 3-wire precordial cable to perform a 12 or 15-lead ECG Cable assembly. When the LIFEPAK 4-wire ECG cable is configured with a 6-wire expandable precordial cable, a 12-lead ECG is constructed. Likewise, when the LIFEPAK 4-wire ECG cable is configured with a 6-wire expandable precordial cable and a 3-wire extended precordial ECG cable a 15-lead ECG is constructed.

The 4- wire ECG cable is available in two lengths, 5 feet or 8 feet. Additionally, the 3-, 4-, and 5-wire ECG Cables and the 6-wire precordial ECG cable are available with color coding according to the American Heart Association (AHA) or International Electrotechnical Commission (IEC) standards.

The LIFEPAK ECG cables are a reusable electrode cable system intended to transmit signals from patient electrodes to the LIFEPAK 35 monitor/defibrillator for both diagnostic and monitoring purposes. These accessories consist of conductor wires that are shielded and insulated by a polyurethane jacket material. The lead wires are color coded according to which electrode location they are attached to on the patient.

The LIFEPAK ECG cables are not intended for use with other manufacturers' defibrillators. The LIFEPAK ECG cables are intended only for use with LIFEPAK 35 monitor/defibrillator.

5.0 Intended Use of device and Indications for Use [21 CFR 807.92(a) (5)]

The LIFEPAK ECG cables are reusable electrode cable systems intended to transmit signals from patient electrodes to the LIFEPAK monitor/defibrillator for monitoring purposes. LIFEPAK ECG cables are intended for use in outdoor and indoor emergency care settings.

LIFEPAK ECG Cables:

- LIFEPAK 3-wire ECG Cable
- LIFEPAK 5-wire ECG Cable
- LIFEPAK 4-wire ECG cable
- LIFEPAK 3-wire extended precordial ECG Cable
- LIFEPAK 6-wire expandable precordial ECG cable

6.0 Summary of Substantial Equivalence [21 CFR 807.92 (a)(6)]:

The fundamental scientific technology is the same for the proposed and the predicate devices. The ECG cables transmit signals from patient electrodes to an electrocardiograph monitor for monitoring purposes. The LIFEPAK ECG cables are substantially equivalent to the Multi-Link X2 Cable and Lead Wire System regarding safety, effectiveness, intended use and performance. The proposed LIFEPAK ECG Cables are designed to work with the LIFEPAK 35 monitor/defibrillator.

No new questions regarding the safety and effectiveness of the device have been raised with the proposed LIFEPAK ECG Cables.

Table 3 Comparison of Predicate Device and Subject Device

Characteristic	**Predicate Device** Multi-Link X2 ECG Cable and Leadwire System (**K211294**)	**Subject Device** LIFEPAK ECG Cables
Trade Name	Multi-Link X2 ECG Cable and Leadwire System	LIFEPAK ECG Cables
Manufacturer	Vyaire Medical Inc.	Physio-Control Inc.
FDA Product Code	DSA	DSA
Prescription/Over-the-Counter Use	Prescription	Same
Indications for Use/Intended Use	The Multi-LinkTM X2 ECG Cable and Leadwire System is intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes.	The LIFEPAK ECG cables are reusable electrode cable systems intended to transmit signals from patient electrodes to the LIFEPAK monitor/defibrillator for monitoring purposes.
Contraindications	None known	Same
Intended Environment	Hospital Environment and Pre-Hospital Environment (i.e., scene of emergency, transport, including airborne).	Indoor and outdoor emergency care settings.
Patient Population	Any patient requiring ECG monitoring, according to the monitor's intended use.	Same
Anatomical sites	The anatomical site of the compatible previously cleared ECG Leadwires is Chest	Attached to electrodes placed at standard specified locations on chest or extremities.

Characteristic	**Predicate Device** Multi-Link X2 ECG Cable and Leadwire System (**K211294**)	**Subject Device** LIFEPAK ECG Cables
Usage	Reusable	Same
Sterile	Nonsterile	Same
ECG Monitoring	3 or 5 lead	3, 5, 6, 12 or 15-lead
Cable Materials	TPU	PU, PVC, TPU
Cable Length	Variable	5 ft, 8 ft
Compatibility with Environment and other devices	Philips, Mindray, Nihon Kohden, GE, Spacelabs,	LIFEPAK 35 monitor/defibrillator
Biocompatibility	ISO 10993-1	ISO 10993-1

The subject and predicate devices are based on the following same technological principles:

- Conducting electrical signals passively from ECG lead wires to the monitoring equipment.
- Device contains interfaces to allow the ECG wires and the ECG monitoring to connect.
- Device composed of a plug face, contact pins, pre-mold, over-mold, and cable.
- Cable coating materials are the same.

The following technological differences exist between the subject and predicate devices:

- The predicate device is compatible with Leadwires containing 3-Wire and 5-Wire ECG cables, while the subject device is compatible with 3, 5, 6, 12 and 15-leads.
- The trunk cable monitor interfaces are different as the predicate and subject devices are compatible with different monitors.

7.0 Performance Data [21 CFR 807.92(b)(1)]:

Performance testing has been completed to demonstrate that the proposed LIFEPAK ECG Cables meet the safety and performance requirements established in the design specifications. Comprehensive testing included the following:

- ASCA Test Reports
- Design Verification Testing
- Biocompatibility Assessment

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

Test Performed	Applicable Standard	Result
Connector mating/unmating, Retention force	60601-2-25:2011 60601-2-27:2011 ANSI AAMI EC53:2013/(R)2020	Met
Inspection of Air Clearance	IEC 60601-1:2005/AMD2:2020 60601-2-25:2011 60601-2-27:2011	Met
Cable Noise Testing	ANSI AAMI EC53:2013/(R)2020	Met
Flex/Twist Life Testing	ANSI AAMI EC53:2013/(R)2020	Met
Tensile Strength Testing	ANSI AAMI EC53:2013/(R)2020	Met

Test Performed	Applicable Standard	Result
Defibrillation Protection and Energy Reduction	IEC 60601-1:2005/AMD2:2020 IEC 60601-2-25:2011 IEC 60601-2-27:2011	Met
Dielectric Withstand Testing	IEC 60601-1:2005/AMD2:2020 ANSI AAMI EC53:2013/(R)2020	Met
Leakage Current Testing	IEC 60601-1:2005/AMD2:2020	Met
Storage Conditioning and Drop Test	IEC 60601-1:2005/AMD2:2020 IEC 60601-2-27:2011	Met
Material Resistance for Cleaning and Disinfection Stress	IEC 60601-1:2005/AMD2:2020	Met
Electromagnetic Compatibility	IEC 60601-1-2:2014	Met
Shock, Vibration and IP Classification	IEC 60601-1:2005/AMD2:2020 IEC 60601-2-27:2011 2011 IEC 60529: 2013	Met

8.0 Conclusion [21 CFR 807.92(b)(3)]:

The subject device and the predicate device have the same intended use, similar indications for use, same technological characteristics, and the subject device does not raise any new issues affecting safety or effectiveness of the device. A risk benefit assessment concluded that the benefits associated with the subject device do outweigh any potential risks. The subject device has passed all acceptance criteria for the non-clinical performance testing. Therefore, it was determined that the subject device is substantially equivalent to the predicate devices identified in this submission.