October 30, 2026

CB Innovations, LLC
Oxana Pantchenko
Director, R&D and Regulatory
5835 Avenida Encinas, Suite 118
Carlsbad, California 92008

Re: K262816
Trade/Device Name: EXG PulseLinQ Cables (EXGPL)
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: October 11, 2026
Received: October 13, 2026

Dear Oxana Pantchenko:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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
OHT2: 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.	K262816

Please provide the device trade name(s).

EXG PulseLinQ Cables (EXGPL)

Please provide your Indications for Use below.

The EXG PulseLinQ Cables are a reusable electrode cable system intended to transmit signals from EXG electrodes to compatible ECG monitors/defibrillators for diagnostic and monitoring purposes. The system is intended for use in outdoor and indoor emergency care settings.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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510(k) Summary

Date prepared: October 11, 2026

Manufacturer and 510(k) Premarket Notification Owner

CB Innovations, LLC
5835 Avenida Encinas STE 118
Carlsbad, CA 92008
Official Contact:
Oxana Pantchenko, Ph.D.
Director of R&D and Regulatory
(650)269-4915

Device Information

Name: EXG PulseLinQ Cable System
Regulation Number: 21 CFR 870.2900 – Patient transducer and electrode cable (including connector)
Class: II
Product Code: DSA - Cable, Transducer and Electrode, Patient, (including connector)
Medical Specialty: Cardiovascular

Predicate/Device Identification

K240377 LIFEPAK® ECG Cables by Stryker Physio-Control

Device Description

The following cables are available:
•EXGPLZ: Compatible with ZOLL X Series & Propaq MD/M
•EXGPL15: Compatible with STRYKER LIFEPAK 15
•EXGPL12L: Connects EXGPL15 or EXGPLZ to EXG electrodes
•EXG3L: Connects EXGPL15 or EXGPLZ with the EXGPL12L

Indications for Use

The EXG PulseLinQ Cables are a reusable electrode cable system intended to transmit signals from EXG electrodes to compatible ECG monitors/defibrillators for diagnostic and monitoring purposes. The system is intended for use in outdoor and indoor emergency care settings.

Comparison of Technological Characteristics

The proposed and predicate devices share the same fundamental technological characteristics. Both ECG cable systems transmit physiological signals from patient electrodes to an ECG monitor/defibrillator for patient monitoring. The EXG PulseLinQ Cables are substantially equivalent to the LIFEPAK ECG Cables with respect to intended use, safety, effectiveness, and performance.

Please see the device comparison table for additional details.

	Subject Device	**Predicate**
Device Name	EXG PulseLinQ Cables	LIFEPAK ECG Cables
510(k) clearance	K262816	K240377
Regulation Number	21 CFR 870.2900	21 CFR 870.2900
Product Class	II	II
Product Code	DSA	DSA
Prescription Use	Rx	Rx
Indications for Use / Intended Use	The EXG PulseLinQ Cables are a reusable electrode cable system intended to transmit signals from EXG electrodes to compatible ECG monitors/defibrillators for diagnostic	The LIFEPAK ECG cables are reusable electrode cable systems intended to transmit signals from patient

	and monitoring purposes. The system is intended for use in outdoor and indoor emergency care settings.	electrodes to the LIFEPAK monitor/defibrillator for monitoring purposes.
Intended Environment	Indoor and outdoor emergency care settings.	Indoor and outdoor emergency care settings.
Patient Population	Any patient requiring ECG monitoring, according to the monitor's intended use.	Any patient requiring ECG monitoring, according to the monitor's intended use.
Anatomical Sites	Attaches to EXG electrodes placed at standard specified locations on chest or extremities.	Attached to electrodes placed at standard specified locations on chest or extremities.
Usage	Reusable	Reusable
Sterile	Not sterile	Not sterile
ECG Monitoring	1, 3, 5, 6 and 12-lead	3, 5, 6, 12 or 15-lead
Cable Materials	TPU, TPE, PBT	PU, PVC, TPU
Cable Length	9 ft	5 ft, 8 ft
Compatibility with monitors/defibrillators	STRYKER LIFEPAK 15, ZOLL X Series & Propaq MD/M	LIFEPAK 35 monitor/defibrillator

The subject and predicate devices are based on the same fundamental technological principles and share comparable designs. Specifically:

1. Both devices passively conduct electrical signals from ECG electrodes to compatible ECG monitoring equipment.
2. Both devices incorporate interfaces and connectors that facilitate secure connections between ECG electrodes and ECG monitoring devices.
3. Both devices are constructed from similar core components, including connector plug-ins, contact pins, pre-molded and over-molded components, and insulated cable assemblies.
4. Both devices utilize similar cable insulation and jacket materials designed to provide flexibility, durability, and electrical isolation during use.

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

1. The subject device is designed for use exclusively with EXG disposable electrodes, whereas the predicate device is compatible with traditional ECG electrodes.
2. The predicate device supports multiple ECG lead configurations, including 3, 4, 6, 12, and 15-lead cable systems, while the subject device is limited to 1, 3, 5, 6 and 12-lead configuration.
3. The subject device incorporates a 9-foot cable assembly, whereas the predicate device is available with cable lengths of 5 feet and 8 feet.
4. The ECG monitor/defibrillator interface connectors differ between the subject and predicate devices, reflecting their compatibility with different ECG monitoring and defibrillation platforms.

While minor differences exist between the two devices, these differences do not alter the intended use of the subject device. Both devices share the same fundamental technological characteristics. Furthermore, the identified differences, together with the results of successfully completed testing, do not affect the safety and effectiveness of the subject device. Nor do they raise any new or novel questions of safety and effectiveness compared to those associated with the predicate device.

Summary of Non-Clinical Testing

The following testing has been successfully completed to demonstrate that the proposed EXG PulseLinQ Cable System meets the safety and performance requirements. Comprehensive testing included the following:

1) ANSI/AAMI EC53:2013/(R) 2020
2) IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
3) IEC60601-1-2:2014/A1:2020

Summary of Clinical Testing

Clinical testing was determined not applicable for the EXG PulseLinQ Cable System.

C-BOOTH INNOVATIONS

Conclusion

Based on the testing performed, it can be concluded that the EXG PulseLinQ Cable System does not raise new questions of safety or effectiveness when compared to the predicate device. The similar indications for use/intended use, technological characteristics, and performance characteristics for the proposed EXG PulseLinQ Cable System are assessed to be substantially equivalent to the predicate device.