August 16, 2021

Vyaire Medical, Inc.
Joshua Davis
Regulatory Affairs Advisor
26125 North Riverwoods Blvd.
Mettawa, Illinois 60045

Re: K211294
Trade/Device Name: Multi-Link X2 ECG Cable and Leadwire System
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: July 11, 2021
Received: July 15, 2021

Dear Joshua Davis:

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Shih
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211294

Device Name
Multi-Link X2 ECG Cable and Leadwire System

Indications for Use *(Describe)*
The Multi-Link X2 ECG Cable and Leadwire System is intended to transmit ECG signals from patient electrodes to patient monitors for monitoring purposes. The Multi-Link Cable and Lead Wire System is limited to indications for use of the connected monitoring equipment. The Multi-Link trunk cables (care cables) are reusable, nonsterile and can be reprocessed.

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
Multi-Link™ X2 ECG Cable and Leadwire System

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

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

Submitter: Vyaire Medical, Inc.
Address: 26125 N. Riverwoods Blvd.
Mettawa, IL 60045
USA
Establishment Registration Number: 3013421741

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Date Summary Prepared: April 27, 2021

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

Device Classification:	Class II
Product Code:	DSA
Regulation:	21 CFR 870.2900
Regulation Name:	Patient transducer and electrode cable (including connector)
Classification Panel:	74-Cardiovascular
Device Name:	Multi-Link™ X2 ECG Cable and Leadwire System
Proprietary Name:	Multi-Link™
Common Name:	Cable, Transducer and Electrode, Patient, (Including Connector)

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

The Multi-Link™ X2 ECG Cable and Leadwire System described in this submission is substantially equivalent to the following predicate:

Predicate Device	510(k) No.	510(k) Owner	Decision Date
Multi-Link™ X2 ECG Cable and Leadwire System	K162432	Vyaire Medical, Inc.	18-Jan-2017

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

The purpose of this subject pre-market notification is to introduce a modified set of Reusable Trunk Cables within the Multi-Link™ X2 ECG Cable and Leadwire System in order to expand the system compatibility with additional FDA-cleared ECG (electrocardiogram) monitoring platforms. There are no changes to the other components within the system, such as Leadwires, and therefore they are not part of this submission.

The Multi-Link™ X2 ECG Cable and Leadwire System is a product portfolio that is intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes. The system consists of Reusable Trunk Cables (K980582, K101660, K162432), Reusable Leadwires (K980582) and Disposable Single Patient Use Leadwires (K101660, K162432). The existing portfolio is compatible with the following ECG monitoring platforms: Philips, Mindray, Nihon Kohden, GE, and Spacelabs.

The subject device of this pre-market notification consists of a modified set of Reusable Trunk Cables that are designed to be compatible with the following cardiac defibrillation systems: Physio Control Lifepak, Zoll R, and Zoll X monitoring platforms. The subject device is used to transmit signals from patient electrodes and sensors to support continuous ECG monitoring only. The subject device does not interpret or deliver the shock applied when the defibrillators are in use. The subject device was evaluated in accordance with ANSI AAMI ES60601-1 and determined to be defibrillation-proof.

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

Intended Use

The Multi-Link™ X2 ECG Cable and Leadwire System is intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes.

Indications for Use

The Multi-Link™ X2 ECG Cable and Leadwire System is intended to transmit ECG signals from patient electrodes to patient monitors for monitoring purposes. The

Multi-Link™ ECG Cable and Leadwire System is limited to indications for use of the connected monitoring equipment. The Multi-Link trunk cables (care cables) are reusable, nonsterile and can be reprocessed.

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

The rationale for substantial equivalence is based on consideration of the following characteristics:

- Intended use: Same as the predicate
- Indications for use: Similar to the predicate
- Materials: Similar to the predicate
- Technology: Same as the predicate
- Design Features: Same as the predicate
- Performance: Same as the predicate

Element of comparison	Subject Device Multi-Link X2 ECG Cable and Leadwire System	Predicate Device Multi-Link X2 ECG Cable and Leadwire System (K162432)
Intended Use	The Multi-Link X2 ECG Cable and Leadwire System is intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes.	The Multi-Link Cable and Leadwire System is intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes.
Indications for Use	The Multi-Link X2 ECG Cable and Leadwire System is intended to transmit ECG signals from patient electrodes to patient monitors for monitoring purposes. The Multi-Link ECG Cable and Leadwire System is limited to indications for use of the connected monitoring equipment. The Multi-Link trunk cables (care cables) are reusable, nonsterile and can be reprocessed.	The Multi-Link Cable and Leadwire System is intended to transmit ECG signals from patient electrodes to patient monitors for monitoring purposes. The Multi-Link Cable and Leadwire System is limited to indications for use of the connected monitoring equipment. The Multi-Link trunk cables (care cables) are reusable, nonsterile and can be reprocessed. The Multi-Link Cable and Leadwire System is compatible with GE Healthcare, Philips, Mindray, Spacelabs and Nihon Kohden electrocardiograph monitors.

Principal of Operation	Trunk Cables and Leadwires are cable conductors to conduct ECG signal from patient ECG electrodes to monitoring equipment. Signal is conducted from ECG electrode through insulated signal wires made of conductive material. Signal wires are protected from environmental noise factors with metal shielding around it, acting as a Faraday´s cage. The trunk cables have an insulating jacket made of thermoplastics providing electrical insulation.	Trunk cables and leadwires are cable conductors to conduct ECG signal from patient ECG electrodes to monitoring equipment. Signal is conducted from ECG electrode through insulated signal wires made of conductive material. Signal wires are protected from environmental noise factors with metal shielding around it, acting as a Faraday´s cage. The trunk cables and leadwires have an insulating jacket made of thermoplastics providing electrical insulation.
Patient Population	Any patient requiring ECG monitoring, according to the monitor's intended patient population.	Any patient population requiring ECG monitoring, according to the monitor's intended patient population.
Anatomical Sites	Proposed device does not have anatomical sites itself. The anatomical site of the compatible previously-cleared ECG Leadwires is Chest.	Predicate device cable does not have anatomical sites itself. The anatomical site of the compatible previously-cleared ECG Leadwires is Chest.
Environment of Use	Hospital Environment and Pre-Hospital Environment (i.e., scene of emergency, transport including airborne transport).	Hospital Environment.
Compatibility with environment and other devices	Physio Control Lifepak, Zoll R and Zoll X electrocardiograph monitors.	Philips, GE, Mindray, Spacelabs and Nihon Kohden electrocardiograph monitors.
Characteristics		
Number of lead wires	3 or 5 lead	3, 5, 6 or 12 lead version
Sterility	Multi-Link cables are reusable, nonsterile	Multi-Link cables are reusable, nonsterile
Cable coating materials:	TPU C78A Grey (Munsell N7)	TPU C78A Grey (Munsell N7)

Transmitting signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes is the technological principle for both the subject and predicate devices.

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

- Conducting electrical signals passively from ECG lead wires to the ECG monitoring equipment
- Device contains interfaces to allow connection to ECG lead wires and ECG monitoring equipment
- Device composed of a plug face, contact pins, pre-mold, over-mold, and cable
- Cable coating materials are the same
- Signal wires are protected from environmental noise factors with metal shielding around it, acting as Faraday´s cage
- The cables have an insulating jacket made of thermoplastics providing electrical insulation

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

- The predicate device is compatible with leadwires containing 3, 5, 6 or 12 leads whereas the subject device is only compatible with leadwires containing 3 or 5 leads
- The trunk cable monitor interfaces are different, as the subject and predicate devices are compatible for connection with different monitors

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

The subject device was tested and analyzed to demonstrate substantial equivalence to the predicate device. The test reports are listed below:

7.1 Non-Clinical Performance Testing

Test Performed	Applicable Standard	Result
Compatibility Testing with Zoll R, Zoll X and Physio Control Systems	ANSI AAMI IEC 60601-2-27:2011(R)2016	Pass
Connector mating/unmating, Retention force and Contact Resistance for Instrument Connectors	ANSI AAMI EC53:2013	Pass

Test Performed	Applicable Standard	Result
Connector mating/unmating, Retention force and Contact Resistance for Multilink Cable Yokes	ANSI AAMI EC53:2013	Pass
Inspection of Air Clearance	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) ANSI AAMI IEC 60601-2-27:2011(R)2016	Pass
Cable Noise Testing	ANSI AAMI EC53:2013	Pass
Flex Life Testing	ANSI AAMI EC53:2013	Pass
Tensile Strength Testing	ANSI AAMI EC53:2013	Pass
Defibrillation Protection and Energy Reduction	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) ANSI AAMI IEC 60601-2-27:2011(R)2016	Pass
Dielectric Withstand Testing	ANSI AAMI EC53:2013 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Pass
Leakage Current Testing	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Pass
Storage Conditioning and Drop Test	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Pass
Material Resistance for Cleaning and Disinfection Stress	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and	Pass

Test Performed	Applicable Standard	Result
	A2:2010/(R)2012 (Consolidated Text) ANSI AAMI EC53:2013	
Resistance from electrosurgery interference	ANSI AAMI IEC 60601-2-27:2011(R)2016	Pass
Shock, Vibration and IP Classification	IEC 60601-1-12:2014+AMD1:2020 IEC 60529:1989+A1:1999+A2:2013 IEC 60068-2-27:2008 IEC 60068-2-64:2008+AMD1:2019	Pass

7.2 Biocompatibility

The Multi-Link™ X2 ECG Cables do not have any direct or indirect patient contact. The cables have transitory contact with intact skin of the clinician. Per the requirements outlined in ISO 10993-1, biocompatibility testing is not applicable for the subject device.

Analysis Performed	Applicable Standard
Biocompatibility Evaluation Plan	ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

7.3 Clinical Data [21 CFR 807.92(b)(2)]

Based on the similarities in the safety and effectiveness profiles of the subject and predicate devices, no clinical studies were deemed necessary to support this submission.

8.0 Conclusions [21 CFR 807.92(b)(3)]

The subject device and predicate device have the same intended use, similar indications for use, same technological characteristics, and the same principle of

operation. A benefit-risk assessment has concluded that the benefits associated with the subject device outweigh the potential risks. The subject device has successfully passed all acceptance criteria for non-clinical performance testing, demonstrating that the subject device is as safe, as effective, and performs as well as or better than the predicate device for its intended use. Therefore, it can be concluded that the subject device has been shown to be substantially equivalent to the predicate device identified in this submission.