October 9, 2020

Vyaire Medical, Inc.
Suzanne Moreno
Regulatory Affairs Associate
26125 N. Riverwoods Blvd.
Mettawa, Illinois 60045

Re: K200510
Trade/Device Name: Multi-Link™ X2 ECG Adapter and Leadwires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: September 4, 2020
Received: September 8, 2020

Dear Suzanne Moreno:

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 control's 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 post marketing 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,

for

Jennifer Shih Kozen
Assistant Director
DHT2A: 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

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)*
K200510

Device Name
Multi-Link™ X2 ECG ADAPTERS AND LEAD WIRES

Indications for Use *(Describe)*
The Multi-Link™ X2 ECG Adapters and Leadwires are used to transmit ECG signals from the electrodes to ECG monitors for monitoring purposes. The Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link Direct-Connect Leadwires are single-patient-use, nonsterile and cannot be reprocessed. The Multi-Link X2 ECG Adapters and Direct Connect Leadwire System are used with any patient population requiring ECG monitoring.

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 ADAPTER AND LEADWIRES

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

## 1.0 Submitter Information

Submitter: VYAIRE MEDICAL, INC.
Address: 26125 N. Riverwoods Blvd.
Mettawa, IL 60045
USA
Establishment Registration Number: 3013421741

Contact: Suzanne Moreno
Title: Regulatory Affairs Associate
Telephone: (872) 757-0147
e-mail Suzanne.Moreno@Vyaire.com

Date Summary
Prepared: February 28, 2020

## 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 |
| Proprietary Name: | Multi-Link ™ X2 ECG ADAPTER AND LEADWIRES |
| Common Name: | Cable, Transducer and Electrode, Patient, (Including Connector) |

## 3.0 Predicate and Reference Device Information

| Predicate Device | 510(k) No. | Decision Date |
|---|---|---|
| Multi-Link X2 ECG Cable and Lead Wire System | K162432 | 01/18/2017 |
| **Reference Device** | **510(k) No.** | **Decision Date** |
| Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System | K163316 | 06/22/2017 |

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

The Multi-Link™ X2 ECG Cable, Adapter and Direct Connect Leadwires is an FDA cleared accessory portfolio. The cleared device portfolio consists of adapters & leadwires (reusable adapters and direct connect disposable single patient use leadwires, K163316), and (leadwires reusable, and disposable single patient use, K162432). The cleared portfolio is compatible multiple FDA cleared ECG monitoring platforms, such as Philips, Mindray, Nihon Kohden, GE and Spacelabs. This pre-market notification is to expand the portfolio to be used with additional FDA cleared ECG monitoring platforms.

The Subject device, Multi-Link ™ X2 ECG ADAPTER AND LEADWIRES consists of reusable adapters and direct connect single patient use leadwires that connect to FDA cleared Dräger Infinity (R) monitoring platforms. Design modifications are made to allow for connections with specific additional platforms to allow patients to move throughout the facility without the hassle of disconnecting and reconnecting leadwires.

The system is used to transmit signals from patient ECG electrodes to monitoring equipment, providing patients with continuous ECG (electrocardiogram) monitoring.

This device is common to both industry and medical establishments. The Multi-Link™ X2 ECG ADAPTER AND LEADWIRES is not a stand-alone device but is used with the host monitoring device and functions as conductors on the system to carry the electrical signals.

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

Intended Use

The Multi-Link™ X2 ECG Adapter and Leadwires are intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes.

Indications for Use

The Multi-Link™ X2 ECG Adapters and Leadwires are used to transmit ECG signals from the electrodes to ECG monitors for monitoring purposes. The Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link Direct-Connect Leadwires are single-patient-use, nonsterile and cannot be reprocessed. The Multi-Link X2 ECG Adapters and Direct Connect Leadwire System are used with any patient population requiring ECG monitoring.

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

| Element of comparison | Subject Device Multi-Link™ X2 ECG ADAPTER AND LEADWIRES | Predicate Device Multi-link X2 ECG Cable and Lead Wire System (K162432) | Reference Device Multi-link X2 ECG Adapter and Direct Connect Lead Wire System (K163316) |
|---|---|---|---|
| **Intended Use** | The Multi-Link™ X2 ECG Adapter and Leadwires are intended to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for monitoring purposes. | The Multi-Link Cable and Lead Wire System is intended to transmit signals from patient electrodes to various electrocardiograph recorders /monitors for monitoring purposes. | The Multi-Link™ X2 ECG Adapter and Direct Connect Lead Wire 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 Adapters and Leadwires are used to transmit ECG signals from the electrodes to ECG monitors for monitoring purposes. The Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link Direct-Connect Leadwires are single-patient-use, nonsterile and cannot be reprocessed. The Multi-Link X2 ECG Adapters and Direct Connect Leadwire System are used with any patient population requiring ECG monitoring. | The Multi-Link Cable and Lead Wire 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. The Multi-Link lead wires are available reusable and disposable (single patient use). The Multi-Link Cable and Lead Wire System is compatible with GE Healthcare, Philips, Mindray, Spacelabs and Nihon Kohden electrocardiograph monitors. | The Multi-Link™ X2 ECG Adapter and Direct Connect Lead Wire System are used in telemetry to transmit ECG signals from the electrodes to the transmitters on ambulatory patients within a defined coverage area for monitoring purposes. The Multi-Link Direct-Connect Lead wires are single-patient-use, nonsterile and cannot be reprocessed. The Multi-Link Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System are used with any patient population requiring ambulatory ECG, and are compatible with Philips, Mindray and Nihon Kohden electrocardiograph monitors. |
| **Principal of Operation** | The adapters and leadwires are cable conductors that conduct the ECG signal from patient ECG electrodes to the monitoring equipment. The signal is conducted through insulated signal wires made | The trunk cables and leadwires are cable conductors that conduct the ECG signal from patient ECG electrodes to the monitoring equipment. The signal is conducted from the ECG | The adapters and leadwires are cable conductors that conduct the ECG signal from patient ECG electrodes to the monitoring equipment. The signal is |

| | | | |
|---|---|---|---|
| | of conductive material. The signal wires are protected from environmental noise factors with metal shielding around it, acting as Faraday´s cage. The adapters have an insulating jacket made of thermoplastics providing electrical insulation. | electrode through insulated signal wires made of conductive material. The signal wires are protected from environmental noise factors with metal shielding around it, acting as Faraday´s cage. The trunk cables and lead wires have an insulating jacket made of thermoplastics providing electrical insulation. | conducted through insulated signal wires made of conductive material. The signal wires are protected from environmental noise factors with metal shielding around it, acting as Faraday´s cage. The adapters have an insulating jacket made of thermoplastics providing electrical insulation. |
| **Patient Population** | Limited to indications for use of the connected monitoring equipment | Limited to indications for use of the connected monitoring equipment | Any patient population requiring ambulatory ECG |
| **Anatomical Sites** | Chest and Leg | Chest and Leg | Chest and Leg |
| **Environment of Use** | Hospital Environment | Hospital Environment | Hospital Environment |
| **Compatibility with environment and other devices** | Dräger electrocardiograph monitors | Philips, GE, Mindray, Spacelabs and Nihon Kohden electrocardiograph monitors | Philips, Mindray and Nihon Kohden electrocardiograph monitors |
| **Characteristics** | | | |
| **Number of lead wires** | 3, 5 or 6 lead version | 3, 5, 6 or 12-lead lead version | 3, 5 or 6 lead version |
| **Sterility** | The Multi-Link adapters are reusable, and nonsterile<br>The Multi-Link direct connect leadwires are single patient-use, and nonsterile | The Multi-Link trunk cables are reusable, and nonsterile<br>The Multi-Link leadwires are available as reusable and disposable (single patient use) and are nonsterile | The Multi-Link adapters are reusable, and nonsterile<br>The Multi-Link direct connect leadwires are single patient-use, and nonsterile |
| **Cable coating materials: Adapters** | Thermoplastic polyurethane (TPU), and Polyvinyl chloride (PVC) | TPU, PVC | TPU, PVC |

## 7.0 Performance Data

The MULTI-LINK™ X2 ECG ADAPTER AND LEADWIRES were tested to ensure compliance to the following standards:

### 7.1 Performance Testing

| Standard Number | Performance Characteristic |
|---|---|
| AAMI ANSI ES 60601-1:2005/(R):2012 and A1:2012 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| AAMI ANSI IEC 60601-2-27:2011(R)2016 | Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment |
| AAMI ANSI EC53: 2013 | ECG trunk cables and patient lead wires |
| IEC 60601-1-6 Edition 3.1 2013-10 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |

## 7.2 Biocompatibility

The Multi-Link™ X2 adapters do not have patient contact. Per the requirements outlined in ISO 10993-1 biocompatibility testing is not applicable for the adapters for the subject device.
The direct connect single-patient-use lead wires are considered to have surface contact, intact skin with prolonged exposure greater than 24 hours to 30 days. Based on the contact type and duration the following testing was conducted on the leadwires; Cytotoxicity, Sensitization, and Irritation according to the standards listed below.

| Standard Number | Performance Characteristic |
|---|---|
| ISO 10993-1 Fifth edition 2018-08 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| AAMI ANSI ISO 10993-5:2009/(R) 2014 | Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity |
| AAMI ANSI ISO 10993-10:2010/(R) 2014 | Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization |

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

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

## 7.3 Non-Clinical Performance Test Summary

| Test | Standard | Standard Section | Result |
|---|---|---|---|
| Compatibility Testing with Dräger Infinity (R) System | AAMI ANSI IEC 60601-2-27:2011(R)2016 | 201.12.1, and 101.15 | Pass |
| EC53 section 5.3.5, 5.3.6 and 5.3.7 for Subject Device Multi-Link™ X2 ECG Adapter Yoke and Instrument Connector | AAMI ANSI EC53:2013 | 5.3.5, 5.3.6, and 5.3.7 | Pass |
| Inspection of Air Clearance for Subject Device | AAMI ANSI ES60601-1: 2005/(R):2012 and A1:2012 | 8.5.2.3 | Pass |
| | ANSI IEC 60601-2-27:2011 (R)2016 | 201.8.5.2.3 | |
| Defibrillation Protection and Energy Reduction | AAMI ANSI ES 60601-1: 2005/(R):2012 and A1:2012 | 8.5.5.1, and 8.5.5.2 | Pass |
| Dielectric Withstand Testing according 60601-1 section 8.8.3 and EC53 section 5.3.9 | AAMI ANSI EC53:2013 | 5.3.9 | Pass |
| Storage Conditioning and Drop Test | AAMI ANSI ES 60601-1: 2005/(R):2012 and A1:2012 | 15.3.1, 15.3.6, and 15.3.7 | Pass |
| Material Resistance for Cleaning and Disinfection Stress | AAMI ANSI ES 60601-1: 2005/(R):2012 and A1:2012 | 11.6.6 8.8.3 | Pass |
| | AAMI ANSI EC53:2013 | 5.3.9 | |
| EC53 section 5.3.2 for Cable Noise | AAMI ANSI EC53:2013 | 5.3.2 | Pass |
| EC53 section 5.3.3 for Flex Life | AAMI ANSI EC53:2013 | 5.3.3 | Pass |
| EC53 section 5.3.4 for Tensile Strength | AAMI ANSI EC53:2013 | 5.3.4 | Pass |
| EC53 section 5.3.8 for Leadwire Resistance | AAMI ANSI EC53:2013 | 5.3.8 | Pass |

## 8.0 Conclusions Safety and Effectiveness SW [21 CFR 807.92(b) (3)]

Based on the same intended use, similar indications for use, same technological characteristics and same principle of operation the subject device, Multi-Link™ X2 ECG ADAPTER AND LEADWIRES are substantially equivalent to the predicate identified in this submission and do not present any different issues of safety or effectiveness.