Vyaire Medical, Inc.
Suzanne Moreno
Regulatory Affairs Associate
26125 N. Riverwoods Blvd.
Mettawa, Illinois 60630

Re: K191273
Trade/Device Name: Multi-Link X2 ECG and SpO2 Adapter
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA, DQA
Dated: August 16, 2019
Received: August 20, 2019

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 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,

Nicole Goodsell
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191273

Device Name

MULTI-LINK X2 ECG AND SpO2 ADAPTER

Indications for Use *(Describe)*

The Multi-Link™ X2 ECG Adapter and Lead Wire System are used in telemetry to transmit ECG and/or SpO2-signals from the electrodes and sensors to the transmitters on ambulatory patients within a defined coverage area for monitoring purposes. The Multi-Link Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link X2 ECG Adapter and Lead Wire System are used with any patient population requiring ambulatory monitoring, and are compatible with the Philips MX40 electrocardiograph monitor.

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 AND SpO_2 ADAPTER

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: August 16, 2019

2.0 Device Information

Device Name:	Multi-Link™ X2 ECG AND SpO_2 ADAPTERS
Trade Name:	Multi-Link™
Primary Product Code:	DSA
Device Classification:	Class II per 21 CFR 870.2900
Regulation Name:	870.2900 Patient transducer and electrode cable (including connector)
Common Name:	Patient transducer and electrode cable (including connector)
Subsequent Product Code:	DQA
Device Classification:	Class II per 21 CFR 870.2700
Regulation Name:	870.2700 Oximeter
Common Name:	Oximeter

3.0 Purpose of Submission

The purpose of this submission is to gain clearance for the new device, The Multi-Link™ X2 ECG AND SpO_2 ADAPTERS.

4.0 Predicate and Reference Device Information

The Multi-Link™ X2 ECG AND SpO_2 ADAPTERS described in this submission is substantially equivalent to the following predicate:

Predicate Device	510(k) No.	Decision Date
Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System	K163316	06/22/2017
Reference Device	**510(k) No.**	**Decision Date**
MX40 Release B.07	K172226	11/09/2017

5.0 Device Description

The Multi-Link™ X2 ECG AND SpO_2 ADAPTERS is a reusable telemetry Adapter that connects the Philips IntelliVue MX40 (cleared under telemetry transmitter K172226), on one end to Vyaire-owned lead wires (cleared under K980582 and K101660) and market available SpO_2 sensors (cleared under K172226 and K111888) on the other end. The Adapter functions to transmit signals from patient ECG electrodes and SpO_2 sensors to ambulatory monitoring equipment, providing ambulatory patients with continuous ECG (electrocardiogram) and SpO_2 (blood oxygen saturation) monitoring.

This device is common to both industry and medical establishments. The Multi-Link X2 ECG and SpO_2 Adapter 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.

5.1 Intended Use

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

5.2 Indications for Use

The Multi-Link™ X2 ECG Adapter and Lead Wire System are used in telemetry to transmit ECG and/or SpO_2-signals from the electrodes and sensors to the transmitters on ambulatory patients within a defined coverage area for monitoring purposes. The Multi-Link Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link X2 ECG Adapter and Lead Wire System are used with any patient population requiring ambulatory monitoring, and are compatible with the Philips MX40 electrocardiograph monitor.

6.0 Summary of Substantial Equivalence

Element of comparison	Subject Device	Primary Predicate Device Multi-Link™ X2 ECG Adapter and Direct Connect Lead Wire System (K163316)	Reference Device K172226
Intended Use	The Multi-Link X2 ECG Adapter 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.	The device is intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.
Indications for Use	The Multi-Link™ X2 ECG Adapter and Lead Wire System are used in telemetry to transmit ECG and/or SpO_2-signals from the electrodes and sensors to the transmitters on ambulatory patients within a defined coverage area for monitoring purposes. The Multi-Link™ Adapters are reusable, nonsterile and can be reprocessed. The Multi-Link™ X2 ECG Adapter and Lead Wire System are used with any patient population requiring ambulatory monitoring and are compatible with the Philips MX40 electrocardiograph monitor.	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.	Indicated for use of healthcare professional s whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals.
Principal of Operation	Adapters are cable conductors to conduct ECG signal from patient ECG electrodes and SpO_2-signal from sensors to monitoring equipment. Signal is conducted through insulated signal wires made of conductive material. Signal wires are protected from	Adapters are cable conductors to conduct ECG signal from patient ECG electrodes to monitoring equipment. Signal is conducted through insulated signal wires made of conductive material. Signal wires are protected from environmental noise factors	Detects and process ECG the signal conducted by sensors and lead wires

	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.	with metal shielding around it, acting as Faraday´s cage. The adapters have an insulating jacket made of thermoplastics providing electrical insulation.	
Patient Population	Any patient population requiring ambulatory monitoring	Any patient population requiring ambulatory ECG	Any patient population requiring monitoring
Anatomical Sites	Adapters do not have patient contact	Adapters do not have patient contact	SpO2-sensors are connected to finger or toe. Monitor does not have patient contact.
Environment of Use	Hospital Environment	Hospital Environment	Hospital Environment
Compatibility with environment and other devices	Philips MX40 electrocardiograph monitors	Philips, Mindray and Nihon Kohden electrocardiograph monitors	N/A
Characteristics			
Number of lead wires	5 or 6 lead version	3, 5 or 6 lead version	3, 5 or 6 lead version
Sterility	Adapters are reusable, nonsterile	Adapters are reusable, nonsterile	SpO2-sensors are non-sterile, disposable, monitor is reusable
Cable coating materials: Adapters	TPU	TPU	N/A

7.0 Performance Data

The Multi-LinkTM X2 ECG AND SpO_2 ADAPTERS was tested to ensure compliance to the following standards:

7.1 Performance Testing

Standard Number	Performance Characteristic
AAMI ANSI ES60601-1:2005/(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

The following standard has been used as a guidance for compatibility testing of adapter with Philips IntelliVue MX40-system and SpO_2-sensors:

Standard Number	Performance Characteristic
ISO 80601-2-61 : 2017-12 (Corrected Version 2018-02)	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

7.2 Non-Clinical Performance Test Summary

Test	Standard	Standard Section	Result
Compatibility Testing with Philips IntelliVue MX40 System, ECG Lead wires and SpO_2-sensors	60601-2-27:2011(R)2016 80601-2-61	201.12.1. 101.15	Pass
Lifecycle and Contact Resistance According to EC53 Section 5.3.5 and 5.3.7 for SpO_2-connector	EC53:2013	5.3.5 and 5.3.7	Pass
EC53 section 5.3.5, 5.3.6 and 5.3.7 for Subject Device Multi-Link™ X2 ECG and SpO_2 Adapter Yoke and Instrument Connector	EC53:2013	5.3.5, 5.3.6 and 5.3.7	Pass
Inspection of Air Clearance for Subject Device Multi-Link™ X2 ECG and SpO_2 Adapter	60601-1:2012 and 60601-2-27:2011	8.5.2.3 and 201.8.5.2.3	Pass
Defibrillation Protection and Energy Reduction	60601-1:2012	8.5.5.1 and 8.5.5.2	Pass
Dielectric Withstand Testing according EC53 section 5.3.9 for Multi-Link™ X2 ECG and SpO_2 Adapter	EC53:2013	5.3.9	Pass
Dielectric Withstand Testing according 60601-1 section 8.8.3 for Multi-Link™ X2 ECG and SpO_2 Adapter	60601-1:2012	8.8.3	Pass
Storage Conditioning and Drop Test	60601-1:2012	15.3.1, 15.3.6 and 15.3.7	Pass
Connector mating/unmating	EC53:2013	5.3.5	Pass
Retention force test	EC53:2013	5.3.6	Pass
Contact Resistance Test	EC53:2013	5.3.7	Pass
Material Resistance for Cleaning and Disinfection Stress	60601-1:2012 EC53:2013	11.6.6 8.8.3 5.3.9	Pass

8.0 Biocompatibility

The Multi-LinkTM X2 ECG and SpO_2 Adapters do not have patient contact. Per the requirements outlined in ISO 10993-1 biocompatibility testing is not applicable for the subject device.

Standard Number	Performance Characteristic
AAMI ANSI ISO 10993-1:2009/ (R) 2013 ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

9.0 Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate, the Multi-Link™ X2 ECG AND SpO_2 ADAPTERS has been shown to be substantially equivalent to the predicate devices identified in this submission and does not present any different issues of safety or effectiveness.