DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 22, 2017

Carefusion/Vyaire Medical, Inc.
Colleen O'Keeffe
Acting Director, Regulatory Affairs
26125 Riverwoods Blvd
Mettawa, Illinois 60045

Re: K163316
Trade/Device Name: Multi-link X2 ECG Adapter and Direct Connect Lead Wire System
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: May 23, 2017
Received: May 24, 2017

Dear Colleen O'Keeffe:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163316

Device Name
Multi-Link™ X2 ECG Adapter and Direct Connect Lead Wire System

Indications for Use *(Describe)*
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, non-sterile and cannot be reprocessed. The Multi-Link Adapters are reusable, non-sterile 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.

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

1. SUBMITTER

Carefusion/Vyaire Medical, Inc.
26125 Riverwoods Blvd Mettawa, IL 60045
Phone: (224) 706-6818

Contact Person: Colleen O'Keeffe
Acting Director, Regulatory Affairs

Date Prepared: May 22, 2017

2. Device

Product Name:	Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System
Trade or proprietary name	Multi-Link™
Device Name:	Patient transducer and electrode cable (including connector)
Common Name:	Patient transducer and electrode cable (including connector)
Classification Name:	Patient transducer and electrode cable (including connector) 21 CFR 870.2900
Regulatory Class:	II
Product Code:	DSA

3. Predicate Device

Multi-Link Cable and Lead Wire Systems cleared under K980582 on March 16, 1998, and secondary predicate device, ECG Single Patient Use Lead Wire Set, cleared under K101660 on August 11, 2010. These predicate devices have not been subject to a design-related recall.

4. Device Description

The Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System is a combination of reusable adapters, already cleared lead wires (reusable K980582 and disposable single patient use K101660) and direct connect disposable single patient use lead wires, used to transmit signals from patient electrodes to the transmitters on ambulatory patients within a defined coverage area for monitoring purposes. This type of device is common to both the industry and to most medical establishments. The Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System are not stand alone devices, but are accessories to the host monitoring devices. The adapters and lead wires are conductors carrying the signal

from the patient to the monitor.

5. Principle of Operation

Adapters and lead wires 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 Faraday´s cage. The adapters and lead wires have an insulating jacket made of thermoplastics providing electrical insulation.

6. Indication for use

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, non-sterile and cannot be reprocessed. The Multi-Link Adapters are reusable, non-sterile 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.

7. Comparison of technological characteristics with the predicate device

Element of comparison	Proposed Device	Primary Predicate Device Multi-Link Cable and Lead Wire Systems K980582	Secondary Predicate Device ECG Single Patient Use Lead Wire Set K101660
Indications for Use	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 Leadwires 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	Multi-Link Cable and Lead Wire Systems are reusable electrode cable system used to transmit signals from patient electrodes to various electrocardiograph recorders/monitors from both diagnostic and monitoring purposes. Multi-Link Cable and Lead Wire Systems are limited to indications for use of the connected monitoring or diagnostic equipment. Such equipment is commonly located in hospitals, doctor's offices, and emergency vehicles, as well as in home use	The Single Patient Use ECG Lead Wire is an electrode cable systems used to transmit signals from patient electrodes to various electrocardiograph recorders / monitors for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. The Single Patient Use ECG Lead Wire set is intended to be used by trained operators in a medical professional's environment

Element of comparison	Proposed Device	Primary Predicate Device Multi-Link Cable and Lead Wire Systems K980582	Secondary Predicate Device ECG Single Patient Use Lead Wire Set K101660
	monitors.		
Principle of Operation	Adapters and lead wires 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 Faraday´s cage. The adapters and lead wires have an insulating jacket made of thermoplastics providing electrical insulation.	Trunk cables and lead wires 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 Faraday´s cage. The trunk cables and lead wires have an insulating jacket made of thermoplastics providing electrical insulation.	Trunk cables and lead wires 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 Faraday´s cage. The trunk cables and lead wires have an insulating jacket made of thermoplastics providing electrical insulation.
Patient Population	Any patient population requiring ECG monitoring	Any patient population requiring ECG monitoring	Any patient population requiring ECG monitoring
Anatomical Sites	Chest	Chest	Chest
Environment of Use	Hospital Environment	Hospitals, doctor's offices, and emergency vehicles, as well as in home use	Medical professional's environment
Compatibility with environment and other devices	Philips, Mindray and Nihon Kohden electrocardiograph monitors	GE Healthcare electrocardiograph monitors	GE Healthcare electrocardiograph monitors
Characteristics			
Number of lead wires	3, 5 or 6 lead version	3,5 or 12 lead version	3,5 or 12 lead version
Sterility	Multi-Link adapters are reusable, nonsterile Multi-Link direct connect lead wire is single-patient-use, nonsterile	Multi-Link trunk cables are reusable, nonsterile Multi-Link lead wire is reusable, nonsterile	Trunk cables are reusable, nonsterile Lead wire is single-patient-use, nonsterile

Element of comparison	Proposed Device	Primary Predicate Device Multi-Link Cable and Lead Wire Systems K980582	Secondary Predicate Device ECG Single Patient Use Lead Wire Set K101660
Lead wire colors	According 60601-2-27	According 60601-2-27	According 60601-2-27
Cable coating materials: Adapters	TPU C78A Grey (Munsell N7)	Polyurethane, Elastolia N1185A10 Durometer 85A Color-Munsell N7 (GREY) Colorant: TSE RV73442435 Load at 3% TPU 1185A10 Polyurethane: Resin PUR Natural 75D Durometer Color Munsell N7 Grey	N/A

8. Performance Data

The Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System was tested to ensure compliance to the following standards:

8.1 Performance Testing

Performance Characteristic	Standard
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	AAMI ANSI ES60601-1:2005/(R):2012 and A1:20012
Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	AAMI ANSI IEC 60601-2-27:2011
ECG trunk cables and patient leadwires	AAMI ANSI EC53: 2013
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	IEC 60601-1-6 Edition 3.1 2013-10

Non-clinical Performance Test Summary:

Test	Relevant Standard	Standard Section	Result
Compatibility Testing with	60601-2-27:2011	201.12.1.101.15	Pass

Test	Relevant Standard	Standard Section	Result
Telemetry Systems			
Lifecycle and Contact Resistance According to EC53 Section 5.3.5 and 5.3.7 for host Connectors of Multi-Link X2 Adapters and Direct Connect Leadwires and Grabber and Snap Lifecycle According EC53 Section 5.3.5 and 5.3.7 for Direct Connect Lead wires	EC53:2013	5.3.5 and 5.3.7	Pass
EC53 Section 5.3.5, 5.3.6 and 5.3.7 for Multi-Link Yoke of adapter and Lead wires	EC53:2013	5.3.5, 5.3.6 and 5.3.7	Pass
Inspection of Air Clearance for Multi-Link X2 Telemetry Adapters and Direct Connect´s	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 for Direct Connect´s and Telemetry Adapters	60601-1:2012 EC53:2013	8.8.3 5.3.9	Pass
Storage Conditioning and Drop Test (Results in tables 19.2 B C F and I)	60601-1:2012	15.3.1, 15.3.6 and 15.3.7	Pass
Cable and Lead wire Noise for Multi-Link X2	EC53:2013	5.3.2	Pass
Flex Life Test	EC53:2013	5.3.3	Pass
Tensile Strength	EC53:2013	5.3.4	Pass
Connector mating/unmating (Results in tables 19.2 B and 19.2C)	EC53:2013	5.3.5	Pass
Retention force test (Results in table 19.2.C) Clinician validation test	EC53:2013	5.3.6	Pass
Contact Resistance Test (Results in tables 19.2.B and 19.2.C)	EC53:2013	5.3.7	Pass
Lead wire Resistance According EC53 section 5.3.8 for Long SPUL and Direct Connect Lead wires	EC53:2013	5.3.8	Pass
Material Resistance for Cleaning and Disinfection Stress for Multi-Link X2	60601-1:2012 EC53:2013	11.6.6 8.8.3 5.3.9	Pass

Test	Relevant Standard	Standard Section	Result
Wiping Durability Test for Long SPUL, Direct Connect Lead wires and Predicate SPUL	60601-1:2012 EC53:2013	11.6.6 8.8.3 5.3.9	Pass

8.2 Biocompatibility

Test for skin contact, with a prolonged duration (greater than 24 hours but less than 30 days): Cytotoxicity, Sensitization and Irritation.

Performance Characteristic	Standard
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	AAMI ANSI ISO 10993-1:2009/ (R) 2013
Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity	AAMI ANSI ISO 10993-5:2009/ (R2014)
Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	AAMI ANSI ISO 10993-10:2010/ (R2014)

9. Conclusion

The non-clinical data demonstrates that the Multi-Link X2 ECG Adapter and Direct Connect Lead Wire System is as safe and as effective as the predicate and therefore substantially equivalent to the predicate device.