DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 18, 2017

CareFusion 2200 Inc.
Erika Fernandez
Regulatory Affairs Manager
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K162432
Trade/Device Name: Multi-link X2 ECG Cable and 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: December 9, 2016
Received: December 12, 2016

Dear Erika Fernandez:

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.

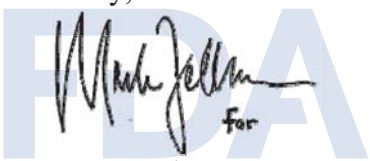
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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)*
K162432

Device Name

Multi-Link X2 ECG Cable and Lead Wire System

Indications for Use *(Describe)*

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.

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.

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Summary of Safety and Effectiveness

510k summary complying with 21 CFR 807.92.

1. SUBMITTER

CareFusion 2200, Inc.
75 N Fairway Drive, Vernon Hills, IL 60061
Phone: 847-362-8097
Fax: 312 949-0731

Contact Person: Erika Fernandez
Date Prepared: December 9th, 2016

2. Device

Product Name:	Multi-Link X2 ECG Cable and Lead Wire System
Device Name:	Cable and Lead Wire System
Common Name:	Cable, Transducer and Electrode, Patient, (Including Connector)
Classification Name:	Patient transducer and electrode cable(including connector) (21 CFR 870.2900)
Regulatory Class:	II
Product Code:	DSA

3. Predicate Device

This submission demonstrates substantial equivalence to the Multi-Link Cable and Lead Wire System, K980582 was cleared on March 16, 1998. The secondary predicate device, ECG Single Patient Use Lead Wire Set, K101660 was cleared on August 11, 2010. This predicate device has not been subject to a design-related recall.

4. Device Description

The Multi-Link X2 ECG Cable and Lead Wire Systems are a combination of reusable ECG trunk cables and single-patient use lead wires (SPUL) used to transmit signals from patient electrodes to various electrocardiograph monitors for monitoring purposes. This type of device is common to both the industry and to most medical establishments. The Multi-Link X2 ECG Cable and Lead Wire Systems are not stand alone devices but are accessories to the host monitoring devices.

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5. Indication for use

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.

6. Comparison of technological characteristics with the predicate device

The fundamental scientific technology is the same for both proposed and predicate device. The trunk cables and lead wires transmit signals from patient electrodes to various electrocardiograph recorders/ monitors for monitoring purposes. The Multi-Link X2 Cable and Lead Wire System is substantially equivalent to the predicate devices Multi-Link Cable and Lead Wire Systems and ECG Single Patient Use Lead Wire Set regarding safety, effectiveness, intended use and performance. The proposed Multi-Link X2 Cable and Lead Wire System is designed to work with GE Healthcare, Philips, Mindray, Spacelabs and Nihon Kohden electrocardiograph monitors. Successful verification test results ensured that the proposed device does not raise any different question of safety and effectiveness.

Element of comparison	Proposed Device	Primary Predicate Device K980582 Multi-Link Cable and Lead Wire System	Secondary Predicate Device K101660: ECG Single Patient Use Lead Wire Set
Indications for Use	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.	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

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Element of comparison	Proposed Device	Primary Predicate Device K980582 Multi-Link Cable and Lead Wire System	Secondary Predicate Device K101660: ECG Single Patient Use Lead Wire Set
Principal of Operation	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.	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	Limited to indications for use of the connected monitoring equipment	Limited to indications for use of the connected monitoring equipment	Limited to indications for use of the connected monitoring equipment
Anatomical Sites	Chest and Leg	Chest and Leg	Chest and Leg
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	GE Healthcare, Philips, Mindray, Spacelabs and Nihon Kohden electrocardiograph monitors	GE Healthcare electrocardiograph monitors	GE Healthcare electrocardiograph monitors
Characteristics			
Number of lead wires	3, 5, 6 or 12 lead version	3,5 or 12	3,5 or 12
Sterility	Multi-Link trunk cables are reusable, nonsterile Multi-Link leadwire is single-patient-use, nonsterile	Multi-Link trunk cables are reusable, nonsterile Multi-Link leadwire is reusable, nonsterile	Multi-Link trunk cables are reusable, nonsterile Multi-Link leadwire is single-patient-use, nonsterile
Lead wire colors	According 60601-2-27	According 60601-2-27	According 60601-2-27

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Element of comparison	Proposed Device	Primary Predicate Device K980582 Multi-Link Cable and Lead Wire System	Secondary Predicate Device K101660: ECG Single Patient Use Lead Wire Set
Cable coating materials: trunk cables	TPU 75-80A Grey (Munsell N7)	POLYURETHANE,ELASTOLIAN1185A10 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
Cable coating materials: Single Patient Use lead wires	POM BASF N2320 003 UNC Grey (Munsell N7) POM BASF N2320 003 UNC White (Pantone Bright White) POM BASF N2320 003 UNC Brown (Pantone 161C) Medical PVC Green (RAL6019) TPU C78A Grey (Munsell N7) TPU C78A Brown (Pantone 161C) TPU C78A White (Pantone Bright White)	SANTOPRENE 271-87 PP Hival 2420NA(Body)+SANTOPRENE 271-73(color band TPU4675 N7 Gray DOW TPU 2102-75A	POM BASF N2320 003 UNC Grey (Munsell N7) POM BASF N2320 003 UNC White (Pantone Bright White) POM BASF N2320 003 UNC Brown (Pantone 161C) Medical PVC Green (RAL6019) TPU C78A Grey (Munsell N7) TPU C78A Brown (Pantone 161C) TPU C78A White (Pantone Bright White)
Cable coating materials: Reusable lead wires	SANTOPRENE 271-87 PP Hival 2420NA(Body)+SANTOPRENE 271-73(color band TPU4675 N7 Gray DOW TPU 2102-75A	SANTOPRENE 271-87 PP Hival 2420NA(Body)+SANTOPRENE 271-73(color band TPU4675 N7 Gray DOW TPU 2102-75A	POM BASF N2320 003 UNC Grey (Munsell N7) POM BASF N2320 003 UNC White (Pantone Bright White) POM BASF N2320 003 UNC Brown (Pantone 161C) Medical PVC Green (RAL6019) TPU C78A Grey (Munsell N7) TPU C78A Brown (Pantone 161C) TPU C78A White (Pantone Bright White)

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7. Performance Data

The proposed device was tested to ensure compliance to the following standards:

Biocompatibility

The lead wire is considered to be a skin contact, with a prolonged duration (greater than 24 hours to 30 days): Cytotoxicity, Sensitization, and Irritation. The trunk cable has no patient contact.

Standards

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)

Performance

The following tests were performed for the proposed device to support the substantial equivalence decision.

Test	Relevant Standard
Compatibility Testing with Bedside Monitors	60601-2-27:2011
Lifecycle and Contact Resistance According to EC53 Section 5.3.5 and 5.3.7 for Instrument Connectors of X2-Cables and Grabber and Snap Lifecycle According EC53 Section 5.3.5 and 5.3.7 for Long SPUL and Direct Connect Lead wires	EC53:2013
EC53 Section 5.3.5, 5.3.6 and 5.3.7 for Multi-Link Yoke and Long Lead wires	EC53:2013
Inspection of Air Clearance for Multi-Link X2	60601-1:2012 and 60601-2-27:2011
Defibrillation Protection and Energy Reduction	60601-1
Leakage Current Test for Multi-Link X2 Cables, Long SPUL´s and Predicates	60601-1:2012