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

July 7, 2016

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

Re: K153234
Trade/Device Name: AirLife Adult Heated Wire Circuit
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: May 27, 2016
Received: May 31, 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
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Infection Control and Dental 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)*

K153234

Device Name
AirLife Adult Heated Wire Circuit

Indications for Use *(Describe)*

The AirLife Adult Heated Wire Circuit is intended to warm breathing gases before they enter a patient's airway. The AirLife Adult Heated Wire Circuit is used with the adult patient population that requires mechanical ventilation, positive pressure breathing or general medical gases. The product is single use device, non-sterile and used in professional healthcare environments and intra-hospital transport environments under a doctor's supervision and by skilled clinicians. The AirLife Adult Heated Wire Circuit is compatible to the Fisher & Paykel MR850 humidifier.

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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CareFusion
has joined BD

Summary of Safety and Effectiveness

510k summary complying with 21 CFR 807.92.

1. SUBMITTER

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

Contact Person: Erika Fernandez

Date Prepared: July 6, 2016

2. Device

Product Name:	AirLife Adult Heated Wire Circuit
Device Name:	Heated Breathing Circuit
Common Name:	Heater, breathing system w/wo controller (not humidifier or nebulizer)
Classification Name:	Breathing system heater (21 CFR 868.5270)
Regulatory Class:	II
Product Code:	BZE

3. Predicate Device

This submission demonstrates substantial equivalence to the AirLife Heated Ventilator and Anesthesia Breathing Circuits, K000697 was cleared on March 30, 2000. This predicate device has not been subject to a design-related recall.

4. Device Description

The heated breathing circuit is intended to deliver and warm breathing gases before they enter the patient's airway. It is provided non sterile for single patient use. The heated breathing circuit is used with Fisher and Paykel heated humidifier.

5. **Indication for use**

The AirLife Adult Heated Wire Circuit is intended to warm breathing gases before they enter a patient's airway. The AirLife Adult Heated Wire Circuit is used with the adult patient population that requires mechanical ventilation, positive pressure breathing or general medical gases. The product is single use device, non-sterile and used in professional healthcare environments and intra-hospital transport environments under a doctor's supervision and by skilled clinicians. The AirLife Adult Heated Wire Circuit is compatible to the Fisher & Paykel MR850 humidifier.

6. **Comparison of technological characteristics with the predicate device**

The fundamental scientific technology is the same for both proposed and predicate device. It is based on acting as an airway conduit between a breathing machine and the patient (typically attached to an endotracheal or tracheal tube previously insert into the patient's airway). The AirLife Adult Heated Wire Circuit is substantially equivalent to the predicate device AirLife Heated Wire Breathing Circuits regarding safety, effectiveness, design (technology), materials and intended use. The proposed AirLife Adult Heated Wire Circuit is designed to operate at the same minimum flow rate of 3 LPM as the predicate device. Successful test results (specific enthalpy, humidity output and surface temperature) ensured that the flow rate of the proposed device does not raise any different question of safety and effectiveness

Element of comparison	Proposed Device	Predicate Device
Intended Use	Intended to warm breathing gases before they enter a patient's airway	Intended to warm breathing gases before they enter a patient's airway
Principal of Operation	Resistance wires within the tubing generate heat to maintain temperatures and humidity	Resistance wires within the tubing generate heat to maintain temperatures and humidity
Circuit Characteristics		
Limb Length (Inspiratory and Expiratory)	5 ft	5 ft
Dryline Length	1.7 ft	1.7 ft
Intended Patient Use	Adult	Adult
Usage	Disposable	Disposable
Design	Dual and Single Limb	Dual and Single Limb
Tube Specifications		
Nominal Inside Diameter	21 mm	21 mm
Design	Corrugated Breathing Tube with 22mm Adapters	Corrugated Breathing Tube with 22mm Adapters

Element of comparison	Proposed Device	Predicate Device
Circuit Specifications		
Circuit Design	Dual or Single	Dual or Single
Maximum Power	60W	60W
Min circuit resistance per Limb	16.15 Ω	16.24 – 17.75 Ω
Maximum Power/foot of Limb	6.0	6.0
Conductor	Copper/Ni alloy	Copper/Ni alloy
Compatible Humidifiers	Fisher and Paykel MR850	Fisher and Paykel MR850

7. Performance Data

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

Biocompatibility

Tests for an externally communicating, tissue by way of gas path and direct mucosal contact with prolonged contact (greater than 24 hours but less than 30 days): Cytotoxicity, Sensitization, Irritation, Muscle Implantation, Genotoxicity and Extractables/Leachables

Standards

Performance Characteristic	Standard
Biological Evaluation of Medical Devices Part 1: Evaluation and Testing FDA Guidance: Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"	ISO 10993-1:2009
Biological Evaluation of Medical Devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3:2014
Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
Biological Evaluation of Medical Devices Part 6: Tests for local effects after implantation	ISO 10993-6:2007
Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization	ISO 10993-10:2010
Biological Evaluation of Medical Devices Part 17: Establishment of allowable limits for leachable substances	ISO 10993-17:2002

Performance Characteristic	Standard
Biological Evaluation of Medical Devices Part 18: Chemical characterization of materials	ISO 10993-18:2005

Performance

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

Performance Characteristic	Standard
Length	BS EN ISO 5367: 2014
Resistance to Flow	BS EN ISO 5367: 2014
Resistance to Flow with Bending	BS EN ISO 5367: 2014
Conical Connectors	BS EN ISO 5367: 2014
	BS EN ISO 8185: 2009
	ISO 5356-1
Security of Attachment	BS EN ISO 5367: 2014
Leakage	BS EN ISO 5367: 2014
Compliance	BS EN ISO 5367: 2014
Resistance to Melt	BS EN ISO 8185: 2009
Security of Engagement Temperature Sensor	BS EN ISO 8185: 2009
Leakage from Sensing Port	BS EN ISO 8185: 2009
Specific Enthalpy	BS EN ISO 8185: 2009
Surface Temperature	BS EN ISO 8185: 2009

Performance Characteristic	Standard
Humidity Output Invasive	BS EN ISO 8185: 2009
Humidity Output Non-Invasive	BS EN ISO 8185: 2009
Electrical Safety	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Electromagnetic Compatibility	60601-1-2 Edition 3: 2007-03

8. Conclusion

The test results demonstrate that the device is as safe and effective as the predicate and therefore substantially equivalent to the predicate device.