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 21, 2016

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

Re: K151303
Trade/Device Name: AirLife Infant Heated Wire Circuit
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: December 20, 2015
Received: December 23, 2015

Dear Ms. 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.
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Infection Control and Dental Devices
Office of Device Evaluation
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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)*

Device Name
AirLife Infant Heated Wire Circuit

Indications for Use *(Describe)*
The heated breathing circuit is intended to deliver and warm breathing gases before they enter the patient's airway. The heated breathing circuit is used with Fisher and Paykel MR850 humidifier. The AirLife Infant Heated Wire Circuit is used with pediatric population, specifically the neonate (birth to 1 month of age) and infant (greater than 1 month to 2 years of age) pediatric subgroups. 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 Infant Heated Wire Circuit is used for flow rates greater than 4 LPM.

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 Hill, IL 60061

Phone: 847 362-8097
Fax: 312 949-0731

Contact Person: Erika Fernandez

Date Prepared: January 20, 2016

2. Device

Product Name:	AirLife Infant 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 Fisher and Paykel Heated Breathing Circuit K020332 cleared on July 7th, 2003 and AirLife Heated Ventilator and Anesthesia Breathing Circuits, K000697 cleared on March 30, 2000. The predicate devices have 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 humidifiers.

5. **Indication for use**

The heated breathing circuit is intended to deliver and warm breathing gases before they enter the patient's airway. The heated breathing circuit is used with Fisher and Paykel MR850 humidifier. The AirLife Infant Heated Wire Circuit is used with pediatric population, specifically the neonate (birth to 1 month of age) and infant (greater than 1 month to 2 years of age) pediatric subgroups. 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 Infant Heated Wire Circuit is used for flow rates greater than 4 LPM.

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

The fundamental scientific technology is the same for both proposed and predicate devices. 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 differences in the design do not raise any different questions of safety and effectiveness.

Element of comparison	**Predicate Device 1 Fisher and Paykel heated wire breathing circuit RT131 with flow rate >4L/min**	**Predicate Device 2 AirLife Heated and Anesthesia Breathing Circuits with flow rate >3L/min**	**Proposed Device AirLife Infant Heated Wire Circuit with flow rate >4L/min**
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	Resistance wires within the tubing generate heat to maintain temperatures and humidity
Circuit Characteristics			
Infant Inspiratory Limb with Unheated Extension	5 ft	5 ft	5 ft
Dryline Length	2 ft	2 ft	2 ft
Inspiratory Limb Length	4 ft	4 ft	4 ft
Heated wire	Present	Present	Present
Expiratory Limb Length	5ft 6in	4 ft 3 in	4 ft 5in
Water trap	Present	Not Present	Not Present
Heated Wire	Not Present	Present	Present
Patient population	Neonates	Infants, pediatric and Adults	Infants and Neonates
Usage	Disposable	Disposable	Disposable

Element of comparison	Predicate Device 1 Fisher and Paykel heated wire breathing circuit RT131 with flow rate >4L/min	Predicate Device 2 AirLife Heated and Anesthesia Breathing Circuits with flow rate >3L/min	Proposed Device AirLife Infant Heated Wire Circuit with flow rate >4L/min
Design	Dual Limb	Dual Limb	Dual Limb
Tube Specifications			
ID	0.44in-0.45in	0.394in	0.45in-0.46in
Design	Corrugate	Corrugate	Corrugate
Wire Design			
Minimum Resistance at ambient	22 Ω	27 Ω	22 Ω
Wire Total Length	115in	99in	121in
Constant Power	22W	16W	22W
Typical Wattage/foot of wire	2	1.9	2
Typical Watt/ foot of circuit	6	4	6
Conductor	Copper	Copper/Ni alloy	304 Steel
Anchor Position of Wire	19 cm	5-10 cm	19 cm
Compatible Humidifier	Fisher and Paykel MR850	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
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.

Test	Description	Relevant Standard
Electrical safety Patient Leakage Current	To ensure, under normal system operating conditions, that excessive current does not reach the patient	IEC 60601-1:2005, 3rd Edition (Equivalent to AAMI ES60601-1:2005)
Electrical safety Dielectric Strength Means	To check the integrity of the wire insulation under excessive power conditions.	IEC 60601-1:2005, 3rd Edition (Equivalent to AAMI ES60601-1:2005)
Electrical Safety Insulation	To ensure IEC requirements for creepage and clearance were met.	IEC 60601-1:2005, 3rd Edition (Equivalent to AAMI ES60601-1:2005)
Length	To ensure that the actual length of the device is within ±10% of the labeled length	ISO 5367:2000, 4th Edition

Test	Description	Relevant Standard
Resistance to Flow/Rated Flow	To ensure, when tested per the standard, that the pressure increase at the rated flow through the breathing tube does not exceed 0.2 kPa	ISO 5367:2000, 4th Edition
Resistance to Flow @ 2.5 LPM	To ensure, when tested per the standard, that the flow resistance at 2.5 LPM through the breathing tube does not exceed 0.74 cmH2O/l/min	ISO 5367:2014, 5th Edition
Increase in Flow Resistance w/Bending @ Rated Flow (10 LPM)	To ensure, when tested per the standard, that the pressure at the rated flow when the breathing tube is suspended over a metal cylinder does not exceed 150% of the value obtained with the tube straight.	ISO 5367:2000, 4th Edition
Increase in Flow Resistance w/Bending @ 2.5 LPM	To ensure, when tested per the standard, that the pressure at 2.5 LPM when the breathing tube is suspended over a metal cylinder does not exceed 150% of the value obtained with the tube straight.	ISO 5367:2014, 5th Edition
Conical Connectors	To ensure, when tested per the standard, that required ports are correctly sized.	ISO 5367:2000, 4th Edition ISO 5356-1:2004, 3rd Edition ISO 8185:2008, 3rd Edition (Corrected Version)
Security of Attachment	To ensure, when tested per the standard, that the adaptor shall not become detached from the tube at a force greater than 45N.	ISO 5367:2000, 4th Edition
Leakage	To ensure, when tested per the standard, that the system supplied ready to use does not leak at a rate greater than 50 ml/min.	ISO 5367:2000, 4th Edition
Compliance per Meter	To ensure, when tested per the standard, that the compliance per meter at a pressure of 6 kPa does not exceed 10 ml*kPa-1 per meter length of tube.	ISO 5367:2000, 4th Edition ISO 8185:2008, 3rd Edition (Corrected Version)

Test	Description	Relevant Standard
Humidity Output (Invasive Mode)	To ensure, when tested per the standard, that the system delivers at least the minimum humidity of at least 33 mg/L to the patient.	ISO 8185:2008, 3rd Edition (Corrected Version)
Humidity Output (Non-Invasive Mode)	To ensure, when tested per the standard, that the system delivers at least the minimum humidity of at least 10 mg/L to the patient.	ISO 8185:2008, 3rd Edition (Corrected Version)
Corrugate Melt (100% Duty Cycle, Zero Gas Flow)	To ensure that the breathing tubes do not collapse on bending, occlude, or otherwise cause a safety hazard at the maximum output of the humidification system.	ISO 8185:2008, 3rd Edition (Corrected Version)
Security of engagement temperature sensor	To ensure that the temperature probes that accompany the circuit do not become disconnected under the condition of no flow or maximum rated flow.	ISO 8185:2008, 3rd Edition (Corrected Version)
Leakage from sensing port	To ensure, when tested per the standard, that the sensing port does not leak more than 5 ml/min.	ISO 8185:2008, 3rd Edition (Corrected Version)
Specific enthalpy	To ensure under normal and single fault conditions, a thermal overshoot at the patient connection port shall not exceed an energy equivalent to 43C and 100% relative humidity (a specific enthalpy not to exceed 194 kJ/kg dry gas) when averaged over 30 seconds.	ISO 8185:2008, 3rd Edition (Corrected Version)
Surface temperature	To ensure that the accessible temperature within 25 cm of the patient port connection does not exceed 44°C	ISO 8185:2008, 3rd Edition (Corrected Version)
Steady state noise	To ensure, when tested per the standard, that the noise at any point within 1 m of the system does not exceed 50 dB.	ISO 8185:2008, 3rd Edition (Corrected Version)

Test	Description	Relevant Standard
Duration of Use (30 days)	To assess the circuit use over a 30 day time period	N/A
Longitudinal Temperature Profile	To assess the temperature range of the wire once a nominal voltage is induced across it.	N/A
Patient End Temperature Profile	To assess the temperature of the airway gas delivered to the patient when a given humidified circuit is used with a ventilator and the Fisher & Paykel MR850 heater base.	N/A

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.