



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

January 20, 2016

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

Re: k151959

Trade/Device Name: AirLife Infant Single Limb Heated Wire Circuit  
Regulation Number: 21 CFR 868.5270  
Regulation Name: Breathing System Heater  
Regulatory Class: Class II  
Product Code: BZE  
Dated: December 18, 2015  
Received: December 23, 2015

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  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

Device Name

AirLife Infant Single Limb 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 heated humidifier MR850. The AirLife Infant Single Limb Heated Wire Circuit is intended for use 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.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 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 19<sup>th</sup>, 2016

### 2. Device

Product Name:	AirLife Infant Single Limb 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 MR850.

## 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 heated humidifier MR850. The AirLife Infant Single Limb Heated Wire Circuit is intended for use 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.

## 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).

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
<b>Single limb High Flow</b>	<b>Proposed Device</b>	<b>Predicate Device</b>
<b>Circuit Characteristics</b>		
Infant Inspiratory Limb with Unheated Extension	5 ft	2 - 6 ft
Dryline Length	2 ft	2 ft
Inspiratory Limb Length Heated Wire	4 ft Present	4 ft Present
Intended Patient Use	Infant	Infant
Usage	Disposable	Disposable
Design	Single Limb	Single Limb
<b>Tube Specifications</b>		
Nominal ID	11-12 mm (0.45in-0.46in)	10-22mm
Design	Corrugate and smooth bore	Corrugate and smooth bore
<b>Wire Design Criteria</b>		
Maximum Power	60W	60W
Min circuit resistance	7.5 Ω	7.5 Ω
Typical Wattage/foot of wire	2	1.8-2.5

Element of comparison	Proposed Device	Predicate Device
Maximum Power/ft of wire	3.2 W/ft	3.2 W/ft
Slack in wire (length in relation to tubing length)	6-9 in	2-4in
Conductor	304 Steel	Copper/Ni alloy
Compatible Humidifier	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.

Performance Characteristic	Relevant Standard
Length	ISO 5367:2000
Resistance to flow/ Rated Flow	ISO 5367: 2000
Resistance to Flow @ 2.5 lpm	ISO 5367:2014
Increase in Flow Resistance with Bending	ISO 5367:2000
	ISO 5367:2014
Conical Connectors	ISO 5367:2000
	ISO 5356-1:2004
	ISO 8185:2008
Security of Attachment	ISO 5367:2000
Leakage	ISO 5367:2000
Compliance	ISO 5367:2000
	ISO 8185:2008
Humidity Output	ISO 8185:2008
Security of Engagement Temperature Sensor	ISO 8185:2008
Leakage from Sensing Port	ISO 8185:2008
Specific Enthalpy	ISO 8185:2008
Surface Temperature	ISO 8185:2008
Steady State Noise	ISO 8185:2008
Electrical safety Patient Leakage Current	IEC 60601-1:2005, 3rd Edition (Equivalent to AAMI ES60601-1:2005)
Electrical safety Dielectric Strength Means	IEC 60601-1:2005, 3rd Edition (Equivalent to AAMI ES60601-1:2005)

## **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.