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

September 14, 2017

Vyaire Medical
Colleen Watson (O'Keeffe)
Acting Director, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K170378
Trade/Device Name: AirLife Adult Heated Wire BiPAP/NIV Circuit
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing system heater
Regulatory Class: Class II
Product Code: BZE
Dated: August 11, 2017
Received: August 14, 2017

Dear Colleen Watson (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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
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)*
K170378

Device Name
AirLife Adult Heated Wire BiPAP/NIV Circuit

Indications for Use *(Describe)*
AirLife Adult Heated Wire BiPAP/NIV Circuit is intended for use with adult population that requires mechanical ventilation. The AirLife Adult Heated Wire BiPAP/NIV Circuit is used with spontaneously breathing individuals that benefit from high flow therapy.
The product is single use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinicians. The AirLife Adult Heated Wire BiPAP/NIV Circuit is designed to work with noninvasive ventilators and 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.

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
PRAStaff@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."

75 N. Fairway Dr.
Vernon Hills, IL 60061
Phone: 847 362-8107
Vyaire Medical.com

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: September 11, 2017

2. **Device**

Product Name:	AirLife Adult Heated Wire BiPAP/NIV Circuit
Trade or proprietary name:	AirLife™
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**

RT 219 BiLevel /CPAP Circuit was cleared under 510(k) K983112 MR850 Respiratory Humidifier from Fisher and Paykel. The RT219 is an accessory of F&P 850 System. This predicate device has not been subject to a design-related recall.

4. **Device Description**

The AirLife Adult Heated Wire BiPAP/NIV Circuit is intended to deliver and warm breathing gases before they enter the patient's airway. The heated wire circuit is intended for use for adult population that requires non-invasive (NIV) mechanical ventilation. It is intended for spontaneously breathing individuals who require mechanical ventilation. The duration of use is up to 7 days in a hospital environment. The aim is to maintain adequate ventilation and minimize the effort of breathing.

5. **Principle of Operation**

75 N. Fairway Dr.
Vernon Hills, IL 60061
Phone: 847 362-8107
Vyaire Medical.com

The AirLife Adult Heated Wire BiPAP/NIV Circuit is a corrugated plastic tube with a spiral resistance wires within the tubing that generate heat to maintain temperatures and humidity. It is intended to warm gases before they enter a patient's airway. The device delivers humidity to patients requiring active non-invasive humidification, acting as a conduit transporting gases between ventilators, humidifiers and the patient. The AirLife Adult Heated Wire BiPAP/NIV Circuit is designed to operate at a minimum flow rate of 3 LPM and a maximum flow rate of 60 LPM.

6. Indication for use

The AirLife Adult Heated Wire BiPAP/NIV Circuit is intended for use with adult only population that requires mechanical ventilation. The AirLife Adult Heated Wire BiPAP/NIV Circuit is used with spontaneously breathing individuals that benefit from high flow therapy.

The product is single use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinicians. The AirLife Adult Heated Wire BiPAP/NIV Circuit is designed to work with noninvasive ventilators and compatible with the Fisher & Paykel MR850 humidifier.

7. 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. The AirLife Adult Heated Wire BiPAP/NIV Circuit is substantially equivalent to the predicate device RT 219 BiLevel /CPAP Circuit regarding safety, effectiveness, design (technology), materials and intended use. The proposed AirLife Adult Heated Wire BiPAP/NIV Circuit is designed to operate at the same minimum flow rate of 3 LPM and maximum 60 LPM. Successful test results (specific enthalpy, humidity output and surface temperature) ensured that the flow rate of the proposed device does not raise any concerns regarding safety and effectiveness. The similarities and differences between the proposed device and the predicate device are outlined below:

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
Principle 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
Limb Length (Inspiratory)	5 ft	5 ft
Dryline Length	1.7 ft	1.7 ft

75 N. Fairway Dr.
Vernon Hills, IL 60061
Phone: 847 362-8107
Vyaire Medical.com

Element of comparison	Proposed Device	Predicate Device
Unheated Extension Length	1 ft	1 ft
Intended Patient Use	Adult	Adult
Usage	Disposable	Disposable
Design	Single Limb	Single Limb
Flow rate	Max 60 LPM	Max 70 LPM
Nominal Inside Diameter	30 mm	30 mm
Design	Corrugated Breathing Tube with 22mm Adapters	Corrugated Breathing Tube with 22mm Adapters
Circuit Design	Single	Single
Maximum Power of Heater Base	60W	60W
Maximum Power of Circuit	36W	60W
Min circuit resistance per Limb	20.5 Ω	12.0 Ω
Maximum Power/foot of Limb	7.2W/ft	12W/ft
Conductor	Copper/Ni alloy	Copper alloy
Disposable Exhalation Port (DEP)	Present	Present
Compatible Humidifiers	Fisher and Paykel MR850	Fisher and Paykel MR850

8. Performance Data

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

8.1 Performance Testing

Performance Characteristic	Standard
Anaesthetic and respiratory equipment – Breathing sets and connectors	ISO 5367, 5th Ed: 2014-10-15
Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification system	ISO 8185, 3rd Ed: 2008-06-15
Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets	ISO 5356-1: 3rd Ed; 2004-05-15
Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (iec 60601-1:2005, mod)	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,

75 N. Fairway Dr.
Vernon Hills, IL 60061
Phone: 847 362-8107
Vyaire Medical.com

Performance Characteristic	Standard
	C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text)
Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests	AAMI / ANSI / IEC 60601-1-2:2014

Performance Characteristic	Results
Inspiratory Limb	Pass
Extension Line	Pass
Dry Line	Pass
System Leak Test	Pass
Resistance to Flow	Pass
% Increase in Flow Resistance with Bending	Pass
Compliance of Breathing Tubes	Pass
Security of Attachment	Pass
Conical Connector	Pass
Resistance to Melt	Pass
Temperature Sensor Leakage	Pass
Temperature Sensor Compatibility	Pass
Breathing Tube Surface Temperature	Pass
Specific Enthalpy	Pass
Humidity Output	Pass
ANSI/AAMI IEC 60601-1:2005	Pass
IEC 60601-1-2, Ed. 4.0, 2014-02	Pass

8.2 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

Performance Characteristic	Standard
Biological Evaluation of Medical Devices–Part 1: Evaluation and Testing	AAMI/ANSI/ISO 10993-1:2009
Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	AAMI/ANSI/ISO 10993-3:2009 (R2014)
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 6: Tests for local effects after implantation	AAMI/ANSI/ISO 10993-6:2009 (R2014)

75 N. Fairway Dr.
Vernon Hills, IL 60061
Phone: 847 362-8107
Vyaire Medical.com

Performance Characteristic	Standard
Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	AAMI/ANSI/ISO 10993-10:2010 (R2014)
Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	AAMI/ANSI/ISO 10993-11:2006 (R2010)
Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	AAMI/ANSI/ISO 10993-12: 2012
Biological Evaluation of Medical Devices Part 17: Establishment of allowable limits for leachable substances	AAMI/ANSI/ISO 10993-17:2002
Biological Evaluation of Medical Devices Part 18: Chemical characterization of materials	AAMI/ANSI/ISO 10993-18:2005

9. Conclusion

The non-clinical data demonstrates that the AirLife Adult Heated Wire BiPAP/NIV Circuit is as safe and as effective as the predicate and therefore substantially equivalent to the predicate device.