August 10, 2023

Vyaire Medical, Inc.
Megan Walsh
Manager, Regulatory Affairs
26125 N. Riverwoods Blvd.
Mettawa, Illinois 60045

Re: K231380
Trade/Device Name: AirLife DuoTherm™ Humidification System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT, BZE
Dated: May 12, 2023
Received: May 12, 2023

Dear Megan Walsh:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231380

Device Name
AirLife DuoTherm™ Humidification System

Indications for Use *(Describe)*
The AirLife DuoTherm™ Heated Humidifier is intended to add moisture to, and warm, the breathing gases for administration to a patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed. This product is non-sterile, reusable, and intended to be used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The AirLife DuoTherm™ Humidification Chamber is intended to hold water required to humidify breathing gases delivered to patients ranging from neonates to adults using a heated humidifier. The product is a single use device, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The AirLife DuoTherm™ Neonate Heated-Wire Circuits are intended to deliver and warm breathing gases before they enter the patient's airway. The Neonate Heated-Wire Circuits are used with a pediatric population, specifically the neonate (birth to 28 days) and infant (29 days to 2 years) pediatric subgroups with an ideal body weight of 0.5 to 8kg that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Neonate Heated-Wire Circuits are used for flow rates greater than 1 LPM. The product is single patient use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The AirLife DuoTherm™ Pediatric Heated-Wire Circuits are intended to deliver and warm breathing gases before they enter the patient's airway. The Pediatric Heated-Wire Circuits are used with the pediatric patient population, specifically infant (29 days to 2 years) and children (2 years to 12 years) with an ideal body weight of 6 to 42kg that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Pediatric Heated-Wire Circuits are used for flow rates greater than 2 LPM. The product is single use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The AirLife DuoTherm™ Adult Heated-Wire Circuits are intended to deliver and warm breathing gases before they enter the patient's airway. The Adult Heated-Wire Circuits are used with the adult population and pediatric population, specifically those with an ideal body weight of 30kg or above, that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Adult Heated-Wire Circuits are used for flow rates greater than 3 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The AirLife DuoTherm™ Adult Heated-Wire NIV Circuit is intended to deliver and warm breathing gases before they enter the patient's airway. The Adult Heated-Wire NIV Circuit is used with the spontaneously breathing adult population (>21 years), specifically those with an ideal body weight of 30kg or above, that benefit from high flow therapy. The Adult Heated-Wire NIV Circuits are used for flow rates greater than 5 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

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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K231380

510(k) Summary
AirLife DuoTherm™ Humidification System

Date Prepared: August 8, 2023

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter (21 CFR §807.92(a)(1))

Vyaire Medical, Inc.
26125 N. Riverwoods Blvd.
Mettawa, IL 60045
USA

Applicant:	Aaron Lynch
Title:	Senior Regulatory Affairs Specialist
Email:	aaron.lynch@vyaire.com
Official Correspondent:	Megan Walsh
Title:	Manager, Regulatory Affairs
Email:	megan.walsh@vyaire.com

II. Device Information (21 CFR §807.92(a)(2))

Device Name:	AirLife DuoTherm™ Humidification System
Proprietary Name:	AirLife DuoTherm™
Device Classification:	Class II
Primary Product Code:	BTT
Regulation:	21 CFR §868.5450
Regulation Name:	Respiratory gas humidifier
Review Panel:	73 – Anesthesiology
Common Name:	Humidifier
Secondary Product Code:	BZE
Common Name:	Heated Breathing Circuits

III. Primary Predicate Device and Reference Device Information (21 CFR §807.92(a)(3))

Primary Predicate Device		
Device Name	**510(k) Number**	**Decision Date**
MR850 Respiratory Humidifier, Model MR850JHU	K033710	April 13, 2004
Reference Devices		
Device Name	**510(k) Number**	**Decision Date**
MODELS MR700/MR720/MR730 DUAL SERVO RESP HUMID ACC	K913368	January 13, 1992
AirLife™ Autofill Humidification Chamber	K160764	August 25, 2016
AirLife™ Adult Heated Wire Circuit	K153234	July 7, 2016
AirLife™ Adult Heated Wire BiPAP/NIV Circuit	K170378	September 14, 2017
AirLife™ Infant Heated Wire Circuit	K151303	January 21, 2016

IV. Device Description (21 CFR §807.92(a)(4))

The **AirLife DuoTherm™ Humidification System** is used to deliver heated, humidified breathing gases to a patient's airway when he/she is mechanically ventilated, receiving continuous non-invasive (NIV) positive airway pressure or high-flow oxygen therapy. The system is intended for use in a standard hospital or professional health care environment.

The AirLife DuoTherm™ Humidification System consists of:

- A **heated humidifier**, which includes reusable temperature probes, heated wire adapters, and a power cord,
- A **humidification chamber**, and
- **Heated wire circuits**, which include neonate, pediatric, and adult single and dual limb circuits, as well as an adult heated wire NIV circuit.

V. Intended Use (21 CFR §807.92(a)(5))

The AirLife DuoTherm™ Humidification System is intended to add moisture and warmth to breathing gases administered to patients that require assistance breathing or mucosal humidification. Gases that are available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract.

Indications for Use:

The **AirLife DuoTherm™ Heated Humidifier** is intended to add moisture to, and to warm, the breathing gases for administration to a patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of

patients whose supraglottic airways have been bypassed. This product is non-sterile, reusable, and intended to be used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The **AirLife DuoTherm™ Humidification Chamber** is intended to hold water required to humidify breathing gases delivered to patients ranging from neonates to adults using a heated humidifier. The product is a single-use device, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The **AirLife DuoTherm™ Neonate Heated-Wire Circuits** are intended to deliver and warm breathing gases before they enter the patient's airway. The Neonate Heated-Wire Circuits are used with a pediatric population, specifically the neonate (birth to 28 days) and infant (29 days to 2 years) pediatric subgroups with an ideal body weight of 0.5 to 8kg that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Neonate Heated-Wire Circuits are used for flow rates greater than 1 LPM. The product is single patient use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The **AirLife DuoTherm™ Pediatric Heated-Wire Circuits** are intended to deliver and warm breathing gases before they enter the patient's airway. The Pediatric Heated-Wire Circuits are used with the pediatric patient population, specifically infant (29 days to 2 years) and children (2 years to 12 years) with an ideal body weight of 6 to 42kg that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Pediatric Heated-Wire Circuits are used for flow rates greater than 2 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The **AirLife DuoTherm™ Adult Heated-Wire Circuits** are intended to deliver and warm breathing gases before they enter the patient's airway. The Adult Heated-Wire Circuits are used with the adult population and pediatric population, specifically those with an ideal body weight of 30kg or above, that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Adult Heated-Wire Circuits are used for flow rates greater than 3 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The **AirLife DuoTherm™ Adult Heated-Wire NIV Circuit** is intended to deliver and warm breathing gases before they enter the patient's airway. The Adult Heated-Wire NIV Circuit is used with the spontaneously breathing adult population (>21 years), specifically those with an ideal body weight of 30kg or above, that benefit from high flow therapy. The Adult Heated-Wire NIV Circuits are used for flow rates greater than 5 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

VI. Summary of Substantial Equivalence (21 CFR §807.92(a)(6))

See below for a device comparison table for the AirLife DuoTherm™ Humidification System, which compares the system (subject device) to its primary predicate device (MR850 Heated Humidifier, K033710) and reference device (MR730 Heated Humidifier, K913368) with respect to intended use, technological characteristics, and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Device Comparison Table – AirLife DuoTherm™ Humidification System

	Subject Device AirLife DuoTherm™ Humidification System **Manufacturer:** Vyaire Medical, Inc.	**Primary Predicate Device** MR850 Heated Humidifier **Manufacturer:** Fisher & Paykel Healthcare, Ltd. **(K033710)**	**Reference Device** MR730 Heated Humidifier **Manufacturer:** Fisher & Paykel Electronics, Ltd. **(K913368)**	**Comparison**
AirLife DuoTherm™ Humidification System				
Intended Use	The AirLife DuoTherm™ Humidification System is intended to add moisture and warmth to breathing gases administered to patients that require assistance breathing or mucosal humidification. Gases that are available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract.	The MR850 humidifier is intended to add moisture to, and to warm, the breathing gases for administration to a patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed.	Not published on the FDA website	The subject device is similar to the primary predicate device cleared under K033710. Both are intended to add moisture and warmth to breathing gases administered to patients. Verbiage differences between the intended use of the subject device and the primary predicate device are only cosmetic in nature. These differences have no impact to

	Subject Device AirLife DuoTherm™ Humidification System **Manufacturer:** Vyaire Medical, Inc.	**Primary Predicate Device** MR850 Heated Humidifier **Manufacturer:** Fisher & Paykel Healthcare, Ltd. **(K033710)**	**Reference Device** MR730 Heated Humidifier **Manufacturer:** Fisher & Paykel Electronics, Ltd. **(K913368)**	**Comparison**
AirLife DuoTherm™ Humidification System				
				safety and effectiveness.
Principle of Operation	The AirLife DuoTherm™ Heated Humidifier heats and humidifies respiratory gases that are delivered to patients via mechanical ventilation, the trachea with assisted, positive air pressure, or a nose and/or face mask. The AirLife DuoTherm™ Humidification Chamber fits to the heated humidifier and holds the water required to humidify the breathing gases that are delivered to patients. Resistance wires within the tubing generate heat to	Heat is used to provide evaporated water content to dry breathing gases. Heated or unheated breathing tubes can be used to deliver the humidified gas to the patient. Heated breathing tubes increase operating efficiency and reduce excessive water and heat loss. The chamber slides onto the heater plate and contains the water supply for adding humidity to breathing gases. Resistance wires within the tubing generate heat to maintain	Not available	The subject device is similar to the primary predicate device cleared under K033710. Both heat and humidify respiratory gases that are delivered to patients. Verbiage differences between principle of operation of the subject device and the primary predicate device are only cosmetic in nature. These differences have no impact to safety and effectiveness.

	Subject Device AirLife DuoTherm™ Humidification System **Manufacturer:** Vyaire Medical, Inc.	**Primary Predicate Device** MR850 Heated Humidifier **Manufacturer:** Fisher & Paykel Healthcare, Ltd. **(K033710)**	**Reference Device** MR730 Heated Humidifier **Manufacturer:** Fisher & Paykel Electronics, Ltd. **(K913368)**	**Comparison**
AirLife DuoTherm™ Humidification System				
	maintain temperature and humidity.	temperature and humidity.		
Patient Population	IDENTICAL TO K033710	Neonates to Adults	Not available	The subject device is identical to the primary predicate device cleared under K033710.
Use Environment	Hospital, subacute care facilities and intra-hospital transfer by trained personnel	Hospital intensive care units by trained personnel	Hospital use by trained personnel	The subject device is similar to the primary predicate device and reference device cleared under K033710 and K913368, respectively. All are intended to be used in a professional healthcare facility. Verbiage differences in use environment between the subject device and the primary predicate and reference devices have no impact to safety and effectiveness.

	Subject Device AirLife DuoTherm™ Humidification System **Manufacturer:** Vyaire Medical, Inc.	**Primary Predicate Device** MR850 Heated Humidifier **Manufacturer:** Fisher & Paykel Healthcare, Ltd. **(K033710)**	**Reference Device** MR730 Heated Humidifier **Manufacturer:** Fisher & Paykel Electronics, Ltd. **(K913368)**	**Comparison**
AirLife DuoTherm™ Humidification System				
System Components (Comparison on Subsequent Pages)	IDENTICAL to K033710 & K913368	Heated humidifier (electrical adapters and temperature/flow probes), humidification chamber, and breathing circuits (multiple configurations)	Heated humidifier (electrical adapters and temperature/flow probes), humidification chamber, and breathing circuits (multiple configurations)	The subject device is identical to the primary predicate device and the reference device cleared under K033710 and K913368, respectively.

VII. Performance Testing (21 CFR §807.92(b)(1))

The subject device was designed and tested in accordance with the consensus standards listed below:

- **Non-clinical Performance Testing**

Standard	Description
ISO 80601-2-74:2017	Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
IEC 60601-1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC TR 60601-4-2	Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: Performance of medical electrical equipment and medical electrical systems
IEC 60601-1-6:2013-10	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-8:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General

	requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2015	Medical device software – Software life cycle processes
ISO 5356-1:2015	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
ISO 5367:2014	Anaesthetic and respiratory equipment – Breathing sets and connectors

- **Biocompatibility**

Standard	Description
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-17:2022 (draft)	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances (draft)
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation

ISO 21726:2019	Biological evaluation of medical devices – Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

- **Clinical Performance Data (21 CFR §807.92(b)(2)):** There was no clinical testing required to support the AirLife DuoTherm™ Humidification System, as the intended use and indications for use are equivalent to the primary predicate and reference devices. These types of devices, including the primary predicate device, have been on the market with a proven safety and efficacy record for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the AirLife DuoTherm™ Humidification System, and its safety and effectiveness.

VIII. Substantial Equivalence Conclusion (21 CFR §807.92(b)(2))

The AirLife DuoTherm™ Humidification System is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution: MR850 Heated Humidifier (K033710). The AirLife DuoTherm™ Humidification System met all specified criteria and did not raise new safety and/or effectiveness questions. The substantial equivalence of the subject device is based on similar indications for use, fundamental technology, including design, and operational principles. Based on the similarities to the primary predicate device, reference devices, and performance data, the AirLife DuoTherm™ Humidification System is substantially equivalent to its primary predicate device (K033710) and reference devices.