October 13, 2023

Telesair, Inc.
℅ Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr. NE
Saint Petersburg, Florida 33704

Re: K223863
Trade/Device Name: BONHAWA Respiratory Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: September 18, 2023
Received: September 19, 2023

Dear Paul Dryden:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ting Song -S

for Ethan Nyberg
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 on last page.

510(k) Number *(if known)*

K223863

Device Name

Bonhawa Respiratory Humidifier

Indications for Use *(Describe)*

The BONHAWA Respiratory Humidifier is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing patients 20 kg and up, child to adults in hospitals. It adds heat and moisture to the flow of gases. The flow may be from 2 to 70 L/min depending on the patient interface.

The BONHAWA Respiratory Humidifier provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients without bypassed upper airways in hospitals.

Type of Use *(Select one or both, as applicable)*

☒ XX 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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510(k) Summary

Date Prepared:	12-Oct-2023
Sponsor:	Telesair Inc 204 Technology Drive, Suite F Irvine, CA 92618
Official Contact:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	Bonhawa Respiratory Humidifier
Common/Usual Name:	Respiratory Gas Humidifier
Classification Name:	Respiratory Gas Humidifier
Regulation Number:	21 CFR 868.5450
Predicate Device:	Airvo 2 Humidifier series (K131895)
Classification Name:	Respiratory Gas Humidifier
Regulation Number:	21 CFR 868.5450
Reference Device:	Airvo 3 High Flow Humidified Oxygen Delivery (K221338)
Classification Name:	High Flow Humidified Oxygen Delivery Device
Regulation Number:	21 CFR 868.5454

Device Description:
The BONHAWA Respiratory Humidifier is a heated humidifier with integrated blower, heater plate and heated breathing circuit that delivers warm and humidified respiratory gas to a patient via nasal cannula. A blower inside the device blends the externally provided oxygen with entrained filtered air and controls the gas flow rate delivered to the patient per the professional user established setting. An internal oxygen sensor monitors and reports the delivered oxygen concentration. The patient interface, heated breathing circuit chamber and chamber adapter are single use.

Principle of Operation:
The Bonhawa Respiratory Humidifier entrains filtered ambient air and mixes it with the user selected Oxygen source to achieve a intended oxygen concentration and flow. The respiratory gas is transported over a heated water bath to attain humidity and is delivered to the patient through heated breathing circuits and nasal interface. O2 concentration, respiratory gas flow, and temperature are controlled and monitored to achieve the intended use of the device. The device is primarily operated by professional users known as Respiratory Therapists.

Indications for Use:
The BONHAWA Respiratory Humidifier is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing patients 20 kg and up, child to adults in hospitals. It adds heat and moisture to the flow of gases. The flow may be from 2 to 70 L/min depending on the patient interface.

The BONHAWA Respiratory Humidifier provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients without bypassed upper airways in hospitals.

Patient Population:
Humidifier is for patients, 20kg and above, in hospitals.

Contraindications:
The Bonhawa Respiratory Humidifier is contraindicated for use with unresolved tension pneumothorax and facial trauma.

Substantial Equivalence:
The following information presents summary technological features in the determination of substantial equivalence comparison of the proposed Bonhawa Respiratory Humidifier to the identified predicate and reference devices.

Attributes	Subject Device Telesair Bonhawa Respiratory Humidifier (K223863)	Predicate Device Fisher & Paykel Airvo 2 Humidifier Series (K131895)	Reference Fisher & Paykel Airvo 3 High Flow (K221338)	Differences
Classification Name	Humidifier, Respiratory Gas, (Direct Patient Interface)	Humidifier, Respiratory Gas, (Direct Patient Interface)	High Flow Humidified Oxygen Delivery Device	Similar to the predicate
Regulation	21 CFR 868.5450	21 CFR 868.5450	21 CFR 868.5454	Similar
Indications for Use	The BONHAWA Respiratory Humidifier is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing patients 20 kg and up, child to adults in hospitals. It adds heat and moisture to the flow of gases. The flow may be from 2 to 70 L/min depending on the patient interface. The BONHAWA Respiratory Humidifier provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients without bypassed upper airways in hospitals.	The AIRVO 2 is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed.	The Airvo 3 is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals and sub-acute facilities. It adds heat and moisture to the flow of air, or blended air/medical oxygen mixture, and assures the user of the air/oxygen mixture using an integrated oxygen analyzer and visual display. The flow may be from 2 to 70 L/min depending on the patient interface. The Airvo 3 provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals and sub-acute facilities. The Airvo 3 provides high flow gases with simultaneous oxygen delivery through nasal cannula interfaces to augment the breathing of spontaneously breathing patients suffering from	Both the predicate, reference and the subject device have the same overall intended use, of delivering high flow breathing gases (air/oxygen mixtures) with humidification for patients Subject is substantially equivalent to both predicate and reference

Attributes	Subject Device Telesair Bonhawa Respiratory Humidifier (K223863)	Predicate Device Fisher & Paykel Airvo 2 Humidifier Series (K131895)	Reference Fisher & Paykel Airvo 3 High Flow (K221338)	Differences
			respiratory distress and/or hypoxemia in the hospital setting. The Airvo 3 is not intended to provide total ventilatory requirements and is not for use during field transport.	
Environment of Use	BONHAWA respiratory humidifier is for hospitals.	The AIRVO 2 is for patients in hospitals and long-term care facilities.	The AIRVO 3 is for patients in hospitals and sub-acute facilities.	Similar but not for long-term facility use
Patient Population	Pediatric patients, 20kg and above, and Adult	Pediatric to Adult	Infant to adults	Similar
Patients	Spontaneously breathing	Spontaneously breathing	Spontaneously breathing	Similar
Performance	Flow rate up to 70 lpm	Flow rate up to 60 lpm	Flow rate up to 70 lpm	Similar
Operating principle	Constant flow of warmed, humidified gas delivery via blower and humidifier	Constant flow of warmed, humidified gas delivery via blower and humidifier	Constant flow of warmed, humidified gas delivery via blower and humidifier	Similar
Oxygen input sources	Low-Pressure Oxygen (LPO) low-pressure connector (from rotameter)	Low-Pressure Oxygen (LPO) low-pressure connector (from rotameter)	High-Pressure Oxygen (HPO) Inlet from wall supply 280-600 kPa (41-87 psi) and Low-Pressure Oxygen (LPO) low-pressure connector (from rotameter)	Similar
Humidity source	Heated humidification chamber.	Heated humidification chamber.	Heated humidification chamber.	Similar
Humidity Performance	At 37°C >= to 33mg/L At 34°C >= to 12mg/L At 31°C >= to 12mg/L	At 37°C >= to 33mg/L At 34°C >= to 12mg/L At 31°C >= to 12mg/L	At 37°C >= to 33mg/L At 34°C >= to 12mg/L At 31°C >= to 12mg/L	Similar
Flow range	Pediatric: 2 – 25 L/min Adults: 10 – 70 L/min The achievable flow range depends on the patient interface selected.	Junior mode: 2 – 25 L/min Default mode: 10 – 60 L/min	Infants: 2 – 25 L/min Children: 2 – 36 L/min Adolescents: 10 – 70 L/min Adults: 20 – 70 L/min The achievable flow range depends on the patient interface selected.	Flow rates up to 60 lpm are available for the predicate. Up to 70 lpm in the reference.
Temperature range	31 – 37 °C	31 – 37 °C	31 – 37 °C	Similar

Attributes	Subject Device Telesair Bonhawa Respiratory Humidifier (K223863)	Predicate Device Fisher & Paykel Airvo 2 Humidifier Series (K131895)	Reference Fisher & Paykel Airvo 3 High Flow (K221338)	Differences
Ambient operating temperature range	18 – 28 °C	18 – 28 °C	18 – 28 °C	Similar
Alarms	Visual and audible alarm system. Mute button.	Visual and audible alarm system. Mute button.	Visual and audible alarm system. Mute button.	Similar
Patient interfaces	Nasal cannula	Nasal cannula And Unsealed tracheostomy connector And Unsealed mask adapter	Nasal cannula And Unsealed tracheostomy connector And Unsealed mask adapter	Similar for the patient without bypassed airway.
Heated Breathing tube	Heated breathing tube: single-lumen, spiral heater wires	Heated breathing tube: single-lumen, spiral heater wires	Heated breathing tube: single-lumen, spiral heater wires	Similar
Duration of Use – Heated Breathing Tube	14 Days single patient use	14 Days single patient use	14 Days single patient use	Similar
Non Clinical Testing	IEC 60601-1:2005+AMD1:2012 IEC 60601-1-2 2014 ANSI/AAMI ES 60601-1:2005 A1:2012 EN 60601-1:2006 + A1:2013 IEC 60601-1-8:2006+AMD1:2012 ISO 80601-2-74;2017 ISO 80601-2-55:2018	IEC 60601-1:2005+AMD1:2012 IEC 60601-1-2 2014 ANSI/AAMI ES 60601-1:2005 A1:2012 EN 60601-1:2006 + A1:2013 IEC 60601-1-8:2006+AMD1:2012 ISO 80601-2-74:2017	IEC 60601-1:2005+AMD1:2012 IEC 60601-1-2 2014 ANSI/AAMI ES 60601-1:2005 A1:2012 IEC 60601-1-6:2010 +AMD1:2013 IEC 60601-1-8:2006+AMD1:2012 ISO 80601-2-61:2017 ISO 80601-2-74:2017	Similar
Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2010 ISO 18562-1	ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017 ISO 10993-18:2020 ISO 18562-1	Similar patient contact and duration of use

Table – Comparison of Technological Characteristics

	Subject	Predicate	Reference	Remarks Substantial equivalence
System Components	Device, power cord, water chamber, water chamber adapter, heated breathing circuit, cannula	Device, power cord, water chamber, water chamber adapter, heated breathing circuit, cannula	Device, power cord, water chamber, water chamber adapter, heated breathing circuit, cannula	Same – Substantially equivalent
Device Weight	5.7 lb (unit)	4.8 lb (unit)	9.8 lb (unit)	Substantially equivalent
Dimension H x W x D	12.5” x 8.7” x 7.2”	11.6” x 6.7” x 6.9”	11.6" x 8.1” x 7.5”	Substantially equivalent
Technological Characteristics	Intake from User chosen flowmeter is mixed by a blower and gas is delivered to the patient after mixing by passing over a heated water chamber to add humidity the respiratory gas. Gas is delivered to the patient via a heated breathing circuit and cannula interface.	Intake from User chosen flowmeter is mixed by a blower and gas is delivered to the patient after mixing by passing over a heated water chamber to add humidity the respiratory gas. Gas is delivered to the patient via a heated breathing circuit and cannula interface.	Intake from User chosen flowmeter or high pressure oxygen source is mixed by a blower and gas is delivered to the patient after mixing by passing over a heated water chamber to add humidity the respiratory gas. Gas is delivered to the patient via a heated breathing circuit and cannula interface.	Similar Differences do not raise questions of safety or effectiveness
Temperature Dew point settings	Adult: 37°C, 34°C, 31°C Pediatric 34°C	Adult: 37°C, 34°C, 31°C Pediatric 34°C	31°C to 37°C Not specified by population	Similar
Oxygen Concentration	Input Oxygen < 80 lpm O2 concentration mixing of 21 to 100%	Input Oxygen < 60 lpm O2 concentration mixing of 21 to 100%	Input Oxygen < 70 lpm O2 concentration mixing of 21 to 100%	Substantially equivalent where the subject allows a greater O2 flow input which allows attainment of intended FiO2 by matching patient inspiratory demand.
Accessories Sponsor	Single Use Water Chamber, Chamber adapter, Heated breathing circuit, nasal cannula, and masks	Single Use Water Chamber, Chamber adapter, Heated breathing circuit, nasal cannula, and masks	Single Use Water Chamber, Chamber adapter, Heated breathing circuit, nasal cannula, and masks	Similar Single Use approach Similar, differences do not raise new concerns of safety or

	Subject	Predicate	Reference	Remarks Substantial equivalence
				effectiveness compared to the predicate.
Accessories User supplied	Oxygen source Oxygen flowmeter Oxygen tubing	Oxygen source Oxygen flowmeter Oxygen tubing	Oxygen source Oxygen flowmeter Oxygen tubing	Identical
Power Input	110-120 V 50-60 Hz 1.2 A (1.4 A max)	110-115 V 50-60 Hz 2.2 A (2.4 A max)	110-115 V 50-60 Hz 2.2 A (2.4 A max)	Substantially equivalent
Heater plate maximum power	150 W	160 W	Not stated	Lower wattage reduces heat and power .
Battery	none	none	Lithium Ion	Similar to predicate
Operating Conditions	Ambient temperature 18-28°C Humidity 10-95% Altitude 0-2000 m (6,000 ft)	Ambient temperature 18-28°C Humidity 10-95% Altitude 0-2000 m (6,000 ft)	Ambient temperature 18-28°C Humidity 10-95% Altitude 0-3000 m (9,000 ft)	Similar to predicate

Performance Testing:

Substantial equivalence to the predicate is based upon performance testing which consists of meeting the product validation and risk mitigation verification testing, which coincide with the pertinent requirements for the product category of BTT including:

- ISO 80601-2-74:2017 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.
- IEC 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 +A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-8 Medical electrical equipment 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
- ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 1: Evaluation and testing within a risk management process

Discussion of the Comparison and Differences

The fundamental scientific principle for use is the same for both the predicate and subject device. The proposed devices have the similar technological characteristics and these characteristics are summarized above. As further evidence of substantial equivalence the proposed device meets the pertinent essential requirements of the FDA recognized consensus standards. Compliance to the pertinent technological characteristics found within the recognized consensus standards for the proposed device.

Key characteristics differing from the predicate are:

- More specific limit to 20 kg weight – to facilitate proper use of nasal interface size.
- Higher set flowrate of 70 liters per minute – to assure attainment of intended use
- Graphical user interface – to better inform users of the device function and attainment of intended use.

These differences in technological characteristics do not alter the safety or effectiveness of the device relative to the predicate nor raise concerns of safety and effectiveness.

Conclusion

The Bonhawa Respiratory Humidifier is substantially equivalent based upon comparative testing when compared to the predicate Airvo 2 cleared under K131895 and the higher flow rate is similar to the reference Airvo 3, K221338, which goes up to 70 lpm. Differences in the subject device do not raise different questions of safety or effectiveness in the subject device.