December 21, 2022

Vincent Healthcare Products Limited
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K222351
Trade/Device Name: inspired™ VHB20 Heated Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: August 3, 2022
Received: August 4, 2022

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 (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

for James Lee, Ph.D.
Division 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)*
K222351

Device Name
inspired™ VHB20 Heated Humidifier

Indications for Use *(Describe)*
The inspired™ VHB20 Heated Humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases.

The inspired™ VHB20 Heated Humidifier is indicated for use by trained personnel only within a hospital/institutional environment. It is compatible with the Fisher and Paykel MR290 Humidification Chamber (Single Use), RT380 Dual Heated Breathing Circuit and RT265 Dual Heated Infant Breathing Circuit.

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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510(k) Summary

Date Prepared: 19-Dec-22

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Hung Hom, Kowloon Hong Kong

Official Contact: Patrick Dennis, QA/RA Supervisor

Submission Correspondent: Paul Dryden
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, FL 33704

Proprietary or Trade Name: inspired™ VHB20 Heated Humidifier
Common/Usual Name: Respiratory gas humidifier
Classification Name: 21CFR 868.5450
Product Code: BTT

Predicate Device: K073706 – Fisher & Paykel MR850 Respiratory Humidifier
Common/Usual Name: Respiratory gas humidifier
Classification Name: 21CFR 868.5450
Product Code: BTT

Device Description:
The subject device, inspired™ VHB20 Heated Humidifier, is indicated to add humidity and heat to the breathing gasses delivered to patients requiring mechanical ventilation or positive pressure breathing assistance.

It consists of an electrically powered heat controller, which is controlled with a microprocessor to provide software control of the heating element that transfers heat to the water in a chamber.

Breathing tubes enable the humidified gas to be transported to the patient which may also be electrically heated (if connected), by means of a heater-wire placed internally to the tubes, to minimize the loss of humidity. A passive electrical adaptor provides electrical energy from the humidifier to the heater-wire in the breathing circuit. Over-current protection is provided by the SMPS inside the inspired™ VHB20 Heated Humidifier, which incorporates an over-current protection that will be triggered (cut-out) if output power of the SMPS reaches 110% to 150% of the rating (100W). The SMPS will recover automatically after fault condition is removed, while the humidifier will restart. This safety feature protects the humidifier from short-circuits in the DC part of the circuit, and prevents voltage and current transients on the heater-wire.

The inspired™ VHB20 Heated Humidifier provides heated and humidified gas with flow rates of 5 to 60 lpm (invasive) and 5 to 120 lpm (non-invasive).

The inspired™ VHB20 Heated Humidifier is a mains powered device that complies with ES60601-1, IEC 60601-1-2, ISO 80601-2-74 and AIM 7351731.

Principle of Operation:
The inspired™ VHB20 Heated Humidifier is a respiratory humidifier that provides a heat source and temperature control to warm a water container, referred as a water chamber, to heat and humidify dry respiratory gases.

Indications for Use:
The inspired™ VHB20 Heated Humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases.

The inspired™ VHB20 Heated Humidifier is indicated for use by trained personnel only within a hospital/institutional environment. It is compatible with the Fisher and Paykel MR290 Humidification Chamber (Single Use), RT380 Dual Heated Breathing Circuit and RT265 Dual Heated Infant Breathing Circuit.

Patient Population:
Infant to adult patients.

Environments of use:
Hospital/institutional environment

We present the proposed device vs. the predicate in **Table 1.**

As part of the comparison we will present and discuss the:

- Indications for Use
- Technology and Principle of Operation
- Performance and Specifications

510(k) Summary

Table 1 – Comparison – Subject vs. Predicate

510(k) Number	Subject Device	K073706 Predicate	Comment
Device Name	Vincent Medical inspired™ VHB20 Heated Humidifier	Fisher & Paykel MR850 Respiratory Humidifier	
Classification No. & Product code	868.5450 / BTT	868.5450 / BTT	Similar
Indications for Use	The inspired™ VHB20 Heated Humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases. The inspired™ VHB20 Heated Humidifier is indicated for use by trained personnel only within a hospital/institutional environment. It is compatible with the Fisher and Paykel MR290 Humidification Chamber (Single Use), RT380 Dual Heated Breathing Circuit and RT265 Dual Heated Infant Breathing Circuit.	The Fisher & Paykel Healthcare MR850 humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases.	Similar
Principle of operation	The device has two heating control units and two temperature sensors respectively. Water within a humidification chamber is heated by the device's heating plate and this temperature is controlled by the device with the use of temperature probes. Dry medical gases passing through the chamber gain increased humidity and heat. The heater wire adaptor supplies current to heater wires within breathing tubes that maintain gas temperature travelling to patient. Temperature probes measurement temperature and device controls chamber temperature to achieve desired gas warmth and humidify for patient.	The device has two heating control units and two temperature sensors respectively. Water within a humidification chamber is heated by the device's heating plate and this temperature is controlled by the device with the use of temperature probes. Dry medical gases passing through the chamber gain increased humidity and heat. The heater wire adaptor supplies current to heater wires within breathing tubes that maintain gas temperature travelling to patient. Temperature probes measurement temperature and device controls chamber temperature to achieve desired gas warmth and humidify for patient.	Similar
Components	The device consists of VHB20 Heated Humidifier, Heater wire adaptor and Temperature-humidity data/sensor cable.	The device consists of MR850 Respiratory Humidifier, Heater wire adaptor and Temperature probe.	Similar
Electrical Protection Classification	Class I	Class I	Similar
Applied part	Type BF	Type BF	Similar
Drip proof	IPX1	IPX1	Similar
Target population	Infant to adult	Any patient requiring active humidification	Similar
Heating Method	Pass over	Pass over	Similar
Dimensions (H x D x W)	159mm x 204mm x 150mm	140mm × 173mm × 135mm	Similar
Weight (without humidification chamber)	1.9kg	2.8kg	Similar
Supply voltage	110 - 127V	115V	Similar

510(k) Number	Subject Device	K073706 Predicate	Comment
Device Name	Vincent Medical inspired™ VHB20 Heated Humidifier	Fisher & Paykel MR850 Respiratory Humidifier	
Supply frequency	50/60 Hz	50/60 Hz	Similar
Supply current	3.0A max at 110V	2.0 A max at 115V	Similar
Heater plate power	150W	150 W	Similar
Heater plate over temperature cutout (hardware)	118 ± 7°C	118 ± 6°C	Similar
Safety cutoff temperature (software control)	105°C	110°C	Similar
Heater Wires power supply	24VDC, 80VA	22V~, 2.73A max, 60W, 50/60Hz	Similar
Temperature control settings			
Airway			
Invasive	Default: 39°C Range: 35-40°C	Default: 40°C Range: 35-40°C, (Versions 7.22)	Similar
Non-invasive	Default: 34°C Range: 30-37°C	Default: 34°C Range:28-34°C, (Versions 7.22)	Similar
Chamber outlet			
Invasive	Default: 36°C Range: 35-43°C	Default: Range: 35.5-42°C, (Versions 7.22)	Similar
Non-Invasive	Default: 31°C Range: 30-32°C	Default: Range: 31-36°C, (Versions 7.22)	Similar
Display	2.8-inch - LCD display	3 digit 14 mm - 7 segment LED	Similar
Display Range	10 - 70°C	10 - 70°C	Similar
Accuracy	± 2°C	± 0.3°C (in 25 to 45°C temperature range)	Similar
Alarms			
High temperature alarm	Invasive mode: Patient-side temperature exceeds 41°C Non-invasive mode: Patient-side temperature exceeds 38°C	Invasive and Non-invasive mode: Displayed temperature exceeds 41°C or Airway temperature exceeds 43°C	Similar
Low temperature alarm -	Invasive mode: Patient-side temperature <34°C for 22 minutes Non-invasive mode: Patient-side temperature <29°C for 22 minutes	Invasive mode only: After 10 minutes @ 29.5°C or After 60 minutes @ 34.5°C	Similar
Sound Pressure Level	Alarms exceed 50 dBA @ 1m	Alarms exceed 50 dBA @ 1m	Similar

510(k) Summary

510(k) Number	Subject Device	K073706 Predicate	Comment
Device Name	Vincent Medical inspired™ VHB20 Heated Humidifier	Fisher & Paykel MR850 Respiratory Humidifier	
Performance			
Recommended ambient Temperature range	18 - 28°C	18 - 26°C	Similar
Recommended flow range	Invasive – 5 to 60 Lpm Non-invasive – 5 to 120 Lpm	Invasive – Up to 60 Lpm Non-invasive – Up to 120 Lpm	Similar
Humidity Performance	Invasive - ≥ 33mg/L Non-Invasive - ≥12 mg/L	Invasive - > 33mg/L Non-Invasive - > 10 mg/L	Similar
Warm-up time	≤25 minutes	Less than 30 minutes	Similar
Standards	ANSI AAMI ES60601-1 IEC 60601-1-2 ISO 80601-2-74 AIM 7351731	IEC 60601-1 EN 60601-1 IEC 60601-1-2 EN 60601-1-2 EN ISO 8185:2009	Similar
Biocompatibility	Externally Communicating, Tissue, permanent Duration	Externally Communicating, Tissue, permanent Duration	Similar
Accessories			
Heater Wire Adapter			
Type/configuration	Utilizes F&P accessories - Dual limb	Dual limb	Similar
Circuit connector	Inspiratory limb / Expiratory Limb	Inspiratory limb / Expiratory Limb	Similar
	2 pin clover-type / 2 pin S-type	2 pin clover-type / 2 pin S-type	Similar
Temperature Probe Lead			
Number of probes	2	2	Similar
Probe location	Chamber outlet Patient end	Chamber outlet Patient end	Similar
Function	Airway temperature measurement Chamber outlet temperature measurement	Airway temperature measurement Chamber outlet temperature measurement	
Compatible Consumables			
Humidification Chamber			
Type/configuration	Autofeed	Autofeed	
Model	Fisher & Paykel MR290	Fisher & Paykel MR290	
Breathing Circuits			
Type/configuration	Dual heated	Dual heated	
Model	Fisher & Paykel RT265 Fisher & Paykel RT380	Fisher & Paykel RT265 Fisher & Paykel RT380	

Substantial Equivalence Discussion

Table 1 above compares the key features of the proposed with the identified predicate – Fisher & Paykel MR850, K073706. The comparison demonstrates that the proposed device can be found to be substantially equivalent.

Indications for Use
The indications for use are similar for the proposed device when compared to the predicate device.
Discussion – Both devices are indicated for use for humidification of gasses and heating of the gas going to the patient. The subject device have equivalent flow, humidification and heating ranges. Minor difference do not raise different concerns of risk than the predicate.

Technology and construction
The technology is identical heated plate, humidification chamber.
Discussion – There are no differences that raise new concerns of safety or effectiveness.

Environment of Use
The environments of use are similar to predicate which are clinical settings.
Discussion – The environments of use are the same.

Patient Population
The patient population of the subject device is infant to adult, which is more restrictive than the predicate which is neonate to adult
Discussion – The subject device is more restrictive than the predicate.

Non-Clinical Testing Summary

Bench testing
We performed tests related to demonstrate:

- Temperature and humidification performance at various flow and temperature settings
- Electrical safety and EMC
- Software verification and Validation

Discussion – The test results met the applicable standards and are similar to the reported performance of the predicate device.

Biocompatibility
Both devices are considered externally communicating, tissue with permanent duration of use (> 30 days). We performed the applicable ISO 10993 and ISO 18562.
Discussion – The subject materials were found to meet the applicable requirements for biocompatibility safety for the intended population.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device predicate and reference have been found to substantially equivalent.