Perma Pure LLC
% Paul Dryden
President - consultant to Perma Pure
Perma Pure LLC c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K193411
Trade/Device Name: O2asis Personal Oxygen Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: October 9, 2020
Received: October 13, 2020

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,

Brandon Blakely, PhD
Assistant Director (Acting)
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193411

Device Name

O_2asis Personal Oxygen Humidifier

Indications for Use *(Describe)*

The O_2asis Personal Oxygen Humidifier is indicated to add moisture and may warm breathing gases for administration to infant, pediatric and adult patients in the home, hospital, and clinical settings. It is used with an external gas source of up to 6 Lpm via nasal cannula.

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: 04-Nov-2020

Sponsor:
Perma Pure LLC
1001 New Hampshire Ave
Lakewood, NJ 08701

Sponsor Contact: Sidra Hankins, RA/QA
T - 732-244-0010

Proprietary or Trade Name: O_2asis Personal Oxygen Humidifier

Common/Usual Name: Humidifier, Respiratory Gas (Direct Patient Interface)

Classification Name: Respiratory gas humidifier
Classification: Class II
Product Code: BTT
Regulation Number: 21CFR 868.5450

Predicate Device: K042245 – Vapotherm TM 2000h and 2000i
Reference Device: K041693 – American Bantex

Device Description: The O_2asis Personal Oxygen Humidifier is a self-contained, palm-sized, mobile device, making it possible for an individual to move the system to a new location without assistance. The O_2asis Personal OxygenHumidifier provides heat and humidified gas when used with a home oxygen concentrator or cylinder supply with flow rates up to 6 lpm. The subject device humidifies and heats the gas (oxygen) and delivers the warmed gas via a nasal cannula. When unplugged, the subject device provides passive humidification but no heat.

Principle of Operation: The O_2asis Personal Oxygen Humidifier is a respiratory humidifier that provides a heat source, temperature control to heat and humidify dry respiratory gases. It uses semi-permeable membrane technology to deliver water vapor to dry gas.

Indications for Use: The O_2asis personal Oxygen Humidifier is indicated to add moisture and may warm breathing gases for administration to infant, pediatric and adult patients in the home, hospital, and clinical settings. It is used with an external gas source of up to 6 Lpm via nasal cannula.

Patient Population: Infant, pediatric and adult patients.

Environments of use: Home, hospital, and clinical environments.

510(k) Summary

Substantial Equivalence Comparison

Table 1 – Comparison – Subject vs. Predicate

Attribute	Proposed O_2asis Personal Oxygen Humidifier	Predicate Vapotherm 2000i	Discussion
K#	K193411	K042245	N/A
Classification	BTT – Humidifier, Respiratory Gas (Direct Patient Interface) CFR 868.5450	BTT – Humidifier, Respiratory Gas (Direct Patient Interface) CFR 868.5450	No
Indications for Use	The O_2asis Personal Oxygen Humidifier is indicated to add moisture and may warm breathing gases for administration to infant, pediatric and adult patients in the home, hospital, and clinical settings. It is used with an external gas source of up to 6 Lpm via nasal cannula.	The Vapotherm ™ 2000h and 2000i are designed to add moisture to and to warm breathing gases for administration to patients, including neonates/infant, pediatrics, and adults. The flow rates may be from I to 40 liters per minute via nasal cannula.	Similar Subject device is within the range of predicate, Vapotherm which has a range of flow rates based upon the disposable cartridge 1 to 8 lpm and up to 40 Lpm. It is intended for high flow while the subject device is not.
Principle of Operation	Humidity transfer via membrane transfer with tubing submerged in distilled water where water molecules then are picked up by the stream of dry gases. Heat is supplied by a heater plate, but the device can also provide humidity in a non-heated mode	Humidity transfer through membrane fibers that are surrounded by warm water. Heat is supplied by circulating heated water around the gas delivery tube.	No. This difference does not raise new concerns as the use of membrane technology is similar to the predicate Vapotherm Model 2000i, K042245.
Patient Population	Infants, Pediatrics, Adults	Neonates / Infants, Pediatrics Adults	Similar. The proposed device has narrower population.
Environments of use	Home, hospital, and clinical setting	Home, Hospital, Sub-acute Institutions	Similar
Connection to other devices	Oxygen concentrator or other gas source	Wall gas source	Similar
Patient interface	Standard nasal cannula	Specific nasal cannula for high flow device	Similar, subject device delivers subset of flow range delivered by the Vapotherm
Prescriptive	Yes	Yes	Similar
Water source	Distilled water	Sterile	Similar. Testing has demonstrated that the proposed device does not transfer any contaminates.

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Attribute	O_2asis Personal Oxygen Humidifier	Predicate Vapotherm 2000i	Discussion
Water reservoir	Water Well Chamber Can be refilled Up to 30 days use	No internal reservoir, water is supplied via a hang-up bag	Similar. Each use water to generate humidity. Vapotherm and the subject device both have a reservoir which supplies water to be transferred across the membrane.
Connections	Inlet from gas source Outlet to patient Port for refilling water well	Inlet from gas source Outlet to patient Water is autofilled from a bag	Similar
Heating source	Heater plate and heated patient tubing	Heater of surrounding water for the heated patient tubing	Similar. Both heat the humidified gas with an externally heated outer tube
Basic components	Heater Water Well Chamber Heated tube Nasal Cannula Pump to fill water well chamber from bottles	Heater Reservoir bag for water Heated tube Nasal Cannula Filled from water bag	Similar
Performance testing	ISO 80601-2-74 (Respiratory Humidifying Equipment)	ISO 8185 (Respiratory Humidifying Equipment)	Similar. ISO 8185 was replaced by ISO 80601-2-74
Flow rate range	0.5 to 6 Lpm based upon clinician judgement	1 to 40 Lpm Pediatric Cartridge – 1 to 8 Lpm	Similar. The subject device is intended for low flow oxygen therapy while the predicate is a high flow system but can deliver the lower flow rates.
Heated Patient Delivery Tube Temperature	Up to 41ºC at exit of nasal cannula Passive temperature – ambient room temperature	Up to 41ºC >95% RH	Similar. The propose device can deliver humidity as a passive device whereas the predicate cannot.
Adjustable heat and Humidity Levels	3 pres-set temperature levels Low – 34ºC, Medium – 36ºC High – 39ºC	Adjustable temperature and flow settings	Similar Vapotherm is adjustable
Humidification Output	Up to 49 mg H_2O/l Depends upon flow rate, ambient temperature and heat setting	40-50 mg H_2O/l Depends upon flow rate and heat setting	Similar Humidification output varies with flow and temperature settings.
?Biocompatibility	**Gas Pathway** Externally Communicating Tissue, Permanent Duration (>30 days) **Cannula** Surface Contact Mucosa, Permanent Duration (>30 days)	**Gas Pathway** Externally Communicating Tissue, Permanent Duration (>30 days) **Cannula** Surface Contact Mucosa, Permanent Duration (>30 days)	Similar
Connectors	Standard oxygen tube fitting Luer fitting for water refill port	Proprietary cartridge and fittings to proprietary cannula	Similar

510(k) Summary

Table 2 – Reference vs. proposed

Attribute	Proposed O_2asis Personal Oxygen Humidifier	Reference American Bantex	Discussion
K#	K193411	K041963	N/A
Classification	BTT – Humidifier, Respiratory Gas (Direct Patient Interface) CFR 868.5450	BTT – Humidifier, Respiratory Gas (Direct Patient Interface) CFR 868.5450	No
Indications for Use	The O_2asis Humidifier is indicated to add moisture and may warm breathing gases for administration to infant, pediatric and adult patients in the home, hospital, and clinical settings. It is used with an external gas source of up to 6 Lpm via nasal cannula.	The American Bantex Humidifier is intended for use with oxygen concentrators or gas sources in a patient's home, physician's office or hospital / institutional environment. The humidifier increases the moisture content of the airstream gases for administration directly to the patient	No, The predicate does not mention flow rate and does not provide warmth
Principle of Operation	Humidity transfer via Nafion tubing submerged in distilled water where water molecules then are picked up by the stream of dry gases. Heat is supplied by a heater plate, but the device can also provide humidity in a non-heated mode	Dry gases are bubbled through a container of distilled water and in the process pick up moisture to humidify the gases being delivered to the patient	No. This difference does not raise new concerns as the use of membrane technology is similar to the predicate Vapotherm Model 2000i, K042245.
Patient Population	Infants, Pediatrics, Adults	Not specified by intended for use with any patient on oxygen or a concentrator	No This predicate did not specify population
Environments of use	Home, hospital, and clinical setting	Patients home, physician's office or hospital / institutional	No.
Connection to other devices	Oxygen concentrator or other gas source	Oxygen concentrator or other gas source	No.
Patient interface	Standard nasal cannula	Standard nasal cannula	No.
Water source	Distilled water	Distilled water	No.
Water reservoir	Water Well Chamber Can be refilled Up to 30 days use	Disposable Bottle No specified limitation as bottle is refillable	No
Connections	Inlet from gas source Outlet to patient Port for refilling water well	Inlet from gas source Outlet to patient Ability to refill by removing lid	No.

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Attribute	Proposed O_2asis personal Oxygen Humidifier	Reference American Bantex	Discussion
Basic components	Heater Water Well Chamber Heated tube Nasal Cannula Pump to fill water well chamber from bottles	 Reservoir for water Nasal Cannula Filled from bottles	No No heating
Biocompatibility Testing	ISO 10993-1 ISO 18562	Not available	Similar
Performance testing	ISO 80601-2-74 (Respiratory Humidifying Equipment)	No data provided	Similar
Recommended flow rates	0.5 to 6 Lpm based upon clinician judgement	Not specified but oxygen concentrators have an upper flow rate limit of 6 Lpm	Similar
Heated Patient Delivery Tube O_2 Temperature	Up to 41°C at exit of nasal cannula Passive temperature – ambient room temperature	No heat provided Passive temperature – ambient room temperature	Similar. Reference does not provide active heat.
Adjustable heat and Humidity Levels	3 Levels of Heat and Humidity	No adjustments other than flow rate into the device.	No. Reference does not provide active heat.

Non-Clinical Testing Summary –

Bench testing –
We performed tests related to the following standards:

- ISO 80601-2-74:2017: Particular requirements for basic safety and essential performance of respirAAMI ANSI ES 60601-1: 2005 +Al: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic disturbances Requirements and Tests
- IEC 60601-1-11: 2015 Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare Environment
- AIM Standard 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers Humidifier Active and Passive Performance
- Cleaning compatibility
- Cross-contamination transfer
- Effects of Age and Durability
- Software Verification and Validation

Discussion – The device meet the applicable performance for the applicable standards

510(k) Summary

Biocompatibility –
We performed and the results were :
ISO 10993-5:2009 – Cytotoxicity
ISO 10993-10:2010 – Sensitization and Irritation
ISO 10993-11:2017 – Acute Systemic Toxicity
ISO 10993-18:2020 – Chemical Characterization
ISO 18562-2:2017 – Particulate Matter
ISO 18562-3:2017 – VOC Compounds
ISO 18562-4:2017 – Leachables in Condensate

The materials were found to meet the applicable endpoints of the specific tests.

Human Factors / Usability
A Human Factors / usability study was performed with the user population following FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices:2016.

Discussion of Differences –
There are no significant differences between the proposed device and the predicate and reference devices.

Conclusion
The performance testing has demonstrated that the subject devise met the applicable standard performance requirements.

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