K131388

5 510(k) Summary

SEP 2 6 2013

[As required by 21 CFR 807.92]

510(k) Number: K131388 **Date Prepared: June 3, 2013**

Submitter/Manufacturer	Somnetics International, Inc. 33 5th Ave NW, Suite 500 New Brighton, MN 55112 Establishment Registration # 3008770104
Contact Person	Melinda Swanson Regulatory Consultant Telephone: 651-621-1800 Email: mswanson@somnetics.com
Trade Name	Transcend Heated Humidifier
Common/Usual Name	Respiratory Humidifier
Classification	21 CFR 868.5450, product code BTT Humidifier, Respiratory Gas, (Direct Patient Interface)
Product Code	BTT
Predicate Device	ResMed HumidAire 2i™, K080797

Device Description

The Transcend Heated Humidifier is a humidifier that is designed to humidify the air delivered to the airway during positive airway pressure (PAP) therapy with a compatible Transcend PAP device.

Indications for Use

The Transcend Heated Humidifier is indicated for the humidification of the air delivered from a compatible Transcend positive airway pressure therapy device. The Humidifier is intended for single patient re-use in the home environment and in a hospital/institutional environment. The Humidifier is for use only as recommended by a physician.

Substantial Equivalence and Summary of Studies

The Transcend Heated Humidifier was tested and shown to be compliant with the following standards.

Document Number	Title
IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety, Ed. 3
IEC 60601-1-2	Medical Electrical Equipment – Collateral Standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-11	Medical Electrical Equipment – Collateral Standard: Requirements for home health care environment
ISO 8185:2007	Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems
ISO 10993-1	Biological evaluation of medical devices
ISO 14971	Medical devices -- Application of risk management to medical devices

The Transcend Heated Humidifier is substantially equivalent to the predicate device based on comparisons of indications for use and technological characteristics.

Summary of Predicate Comparisons			
Characteristic	**Transcend Heated Humidifier**	**ResMed Ltd HumidAire 2i™**	**Comparison**
Indications for use:	The Transcend Heated Humidifier is indicated for the humidification of the air delivered from a compatible Transcend positive airway pressure therapy device. The Humidifier is intended for single patient re-use in the home environment and in a hospital/institutional environment. The Humidifier is for use only as recommended by a physician.	The HumidAire 2i is indicated for the humidification of the air delivered from a ResMed compatible CPAP therapy device. The HumidAire 2i is intended for single patient re-use in the home environment and multi-patient re-use in a hospital / institutional environment. The HumidAire 2i is for use only as recommended by a physician.	Similar. The Transcend Heated Humidifier is intended for use only by a single patient.
Intended Population of Use	Adult	Adult	Identical

Summary of Predicate Comparisons			
Characteristic	**Transcend Heated Humidifier**	**ResMed Ltd HumidAire 2i™**	**Comparison**
Compatible Devices	Transcend PAP device and associated accessories	ResMed PAP device and associated accessories	Similar. The humidifiers are made to be used with manufacturers' existing PAP devices.
Dimensions	9 in X 5.5 in X 4.7 in	4.8 in X 7.2 in X 8.6 in	Similar. Overall dimensions do not effect substantial equivalence determination.
Weight	2.2 lbs	2 lb	Similar. Overall weight does not affect substantial equivalence determination.
Disinfection	None	Should be disinfected when used between patients.	The Transcend Heated Humidifier is for single patient re-use only.
Cleaning	Distilled water using a mild detergent.	Warm water using a mild detergent.	Identical
Sterilization	Not sterilized	Not sterilized	Identical
Biocompatible	Yes	Yes	Identical
Pressure Regulation	Determined by compatible PAP device.	Determined by compatible PAP device.	Identical
Working pressure range	4-20 cm H_2O	4-20 cm H_2O	Identical
Humidifier Settings	1-5	1-6	Similar. Both devices deliver a range of humidity based on setting level.
Inspiratory / Expiratory Pressure Drop	0.375 cmH_2O at 50 L/min	Not reported	Subject device meets requirements of ISO 8185.
Gas Leak at Max Operating Pressure	4.85 L/min	Not reported	Subject device meets requirements of ISO 8185.
Sound power level at 10 cm H_2O static pressure	37 dB	Not reported	Subject device meets requirements of ISO 8185.
Maximum Heater Plate Temperature	131 °F	167 °F	Subject device meets requirements of ISO 8185.
Maximum output humidity	>95%	95%	Similar
Maximum gas temperature	77 ° F	Not reported	Subject device meets requirements of ISO 8185.
Water Capacity	325 ml	400 ml	Similar. Devices are intended to have enough water to last a minimum of 8 hours (equivalent to a full night of sleep)
Operating Temperature	+41°F to +95°F	+41°F to +104°F	Similar. Operating temperature is based on compatible PAP device.
Operating Humidity	10 - 80% relative humidity, non-condensing	10–95% relative humidity, non-condensing	Similar. Operating humidity is based on compatible PAP device.

Summary of Predicate Comparisons			
Characteristic	**Transcend Heated Humidifier**	**ResMed Ltd HumidAire 2i™**	**Comparison**
Shipping/Storage Temperature	-4° F to +140° F	-4°F to +140°F	Identical
Gas inlet temperature range	+41°F to +95°F	+41°F to +104°F	Similar. Inlet temperature is based on compatible PAP device.
Shipping/Storage Humidity	10 - 90% relative humidity, non-condensing	15 - 95% relative humidity, non-condensing	Similar
Power Supply	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Identical
IEC 60601-1 Classification	Type BF	Type CF	Subject device is compliant with ISO 8185 Section 6.8.2-14 which states the device should be either BF or CF.
Electromagnetic compatibility	Compliant with IEC 60601-1-2	Compliant with IEC 60601-1-2	Identical
ISO 8185 compliant	Yes	Unknown – not stated in 510k summary or Users Manual	Consensus standards can be used to determine substantial equivalence to a legally marketed device.

The device design was qualified through the following tests and assessments:

- Electrical Safety
- Electromagnetic Compatibility
- Biocompatibility Assessment
- Cleaning Validation
- Software Validation
- Packaging and Shipping
- Performance: physical (cycling), resistance to flow, spillage, flow sensing, sound power level, humidification output, out of water shutdown, temperature, runtime, warm-up duration, and reservoir gas leak

These tests and assessments did not raise new safety or efficacy questions.

Conclusion

The Transcend Heated Humidifier is substantially equivalent to the HumidAire 2i (K080797). The subject and predicate devices are used in conjunction with CPAP devices to humidify air. They are equivalent in terms of technology and intended use. Risk assessments, biocompatibility evaluation, software, electromagnetic compatibility and electrical safety, bench testing, and compliance with recognized standards demonstrate that any differences do not raise new

questions of safety or effectiveness. The Transcend Heated Humidifier is, therefore, substantially equivalent to the predicate HumidAire 2i device.

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 26, 2013

Somnetics International, Incorporated
Ms. Melinda Swanson
Regulatory Consultant
33 5th Avenue NW, Suite 500
NEW BRIGHTON MN 55112

Re: K131388
Trade/Device Name: Transcend Heated Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: August 22, 2013
Received: August 26, 2013

Dear Ms. Swanson:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kwame O. Ulmer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K131388

Device Name: Transcend Heated Humidifier

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2019.09.26 12:07:28 -04'00'

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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