5 510(k) Summary

OCT 17 2013

[As required by 21 CFR 807.92]

510(k) Number: K132127 **Date Prepared: October 17, 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 Auto
Common/Usual Name	Non-continuous ventilator
Classification	Ventilator, Non-continuous (Respirator) 21 CFR 868.5905, Class II
Product Code	BZD
Predicate Devices	Somnetics International, Inc., Model 300157 CPAP System (K100121) Respironics REMstar Auto CPAP with C-Flex (K041010)

Device Description

The Transcend Auto is a microprocessor-controlled, blower-based system that generates positive airway pressure to support treatment of obstructive sleep apnea. It utilizes a differential pressure sensor connected to an internal pneumotach positioned in the airstream to determine flow levels. This flow signal, coupled with pressure sensing, is used to monitor breathing and adjust pressure. When interfaced with a mask, the system provides pressure from 4 to 20 cmH_2O above the ambient atmospheric pressure to a patient's oral/nasal airway.

Indications for Use

The Transcend Auto provides positive airway pressure for treatment of obstructive sleep apnea (OSA) in adults weighing over 66 pounds (30 kg). The device is intended for home and hospital/institutional use.

Substantial Equivalence and Summary of Studies

The Transcend Auto complies with the following standards:

Document Number	Title
IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
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 60601-11	Medical Electrical Equipment – Collateral Standard: Requirements for home health care environment
ISO 10993-1	Biological evaluation of medical devices
ISO 14971	Medical devices -- Application of risk management to medical devices
BS EN 17510-1	Sleep apnoea breathing therapy, Part 1: Sleep apnoea breathing therapy equipment

The Transcend Auto is substantial equivalent to the predicate devices based on comparison of indications for use and technological characteristics.

Substantial Equivalence Comparison				
	Transcend Auto	**Model 300157 (Transcend) CPAP System**	**REMstar Auto CPAP System with C-Flex**	**Comparison**
510(k) Number	Under review	K100121	K041010	NA
Product Code	BZD	BZD	BZD	Identical
Regulation Number	868.5905	868.5905	868.5905	Identical
Regulation Name	Ventilator, non-continuous (respirator)	Ventilator, non-continuous (respirator)	Ventilator, non-continuous (respirator)	Identical
Indications for Use	The Transcend Auto provides positive airway pressure for treatment of obstructive sleep apnea (OSA) in adults weighing over 66 pounds (30 kg). The	The Model 300157 CPAP System is a single patient reusable device. The Model 300157 CPAP System provides continuous positive airway pressure (CPAP) to	The REMstar Auto with C-Flex CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult	Identical

Substantial Equivalence Comparison				
	Transcend Auto	**Model 300157 (Transcend) CPAP System**	**REMstar Auto CPAP System with C-Flex**	**Comparison**
	device is intended for home and hospital/institutional use.	support treatment of adults (over 30 kg) with Obstructive Sleep Apnea.	Obstructive Sleep Apnea (OSA) only. The device is for use in the home or hospital/institutional environment.	
Intended Population of Use	Adult	Adult	Adult	Identical
Accessories	For use with Transcend CPAP accessories	For use with Transcend CPAP accessories	For use with REMstar accessories	Identical
Therapy Pressure	4-20 cm H_2O	4-20 cm H_2O	4-20 cm H_2O	Identical
Pressure Regulation	±1 cm H_2O or 10%, whichever is greater	±1 cm H_2O or 10%, whichever is greater	<10.0 cm H_2O (±0.5 cm H_2O) ≥10.0 to 20.0 cm H_2O (±1.0 cm H_2O)	Identical to Transcend CPAP, equivalent to REMstar
Ramp Feature	Yes	Yes	Yes	Identical
Ramp Time	0 – 45 min (5 min increments)	0 – 45 min (5 min increments)	0 – 45 min (5 min increments)	Identical
Auto Adjust	Yes	No	Yes	Equivalent to REMstar
Expiratory Pressure Relief	Yes	No	Yes	Identical to REMstar
Operating Altitude	0 to 8,000 ft	0 to 8,000 ft	0 – 7500 ft	Identical to Transcend CPAP
Operating Temperature	5° C (41° F) to 35° C (95° F)	5° C (41° F) to 35° C (95° F)	5° C (41° F) to 35° C (95° F)	Identical
Operating Humidity	10 - 80% relative humidity, non-	10 - 80% relative humidity, non-	15 - 95% relative humidity, non-	Identical to Transcend

Substantial Equivalence Comparison				
	Transcend Auto	**Model 300157 (Transcend) CPAP System**	**REMstar Auto CPAP System with C-Flex**	**Comparison**
	condensing	condensing	condensing	CPAP
Shipping/Storage Temperature	-20° C (-4° F) to 60° C (140° F)	-20° C (-4° F) to 60° C (140° F)	-20° C (-4° F) to 60° C (140° F)	Identical
Shipping/Storage Humidity	10 - 90% relative humidity, non-condensing`	10 - 90% relative humidity, non-condensing`	15 - 95% relative humidity, non-condensing`	Identical to Transcend CPAP
Shipping/Storage Humidity	10 - 90% relative humidity, non-condensing`	10 - 90% relative humidity, non-condensing`	15 - 95% relative humidity, non-condensing`	Identical to Transcend CPAP
Data Storage Download	PC connection	PC connection	Data card; PC connection	Identical
Power Supply	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Identical
IEC 60601 Classification	Class II, Type BF	Class II, Type BF	Class II, Type BF	Identical
Warranty	2 years	2 years	2 years	Identical

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: shock and vibration, cycling, pressure regulation including pressure adjustment, sound, flow, altitude, battery life, particulate generation, volatile organic compounds, and clinical validation

In addition, a 2 x 2 crossover clinical evaluation was conducted that enrolled 41 adult patients with obstructive sleep apnea to assess the non-inferiority of the Transcend Auto to the REMstar Auto in the treatment of obstructive sleep apnea, as measured by apnea hypopnea index (AHI) during treatment. No unanticipated adverse device effects were reported during the study. One adverse event was reported by a patient who had a low-level headache following treatment with the Transcend Auto. The adverse event resolved without intervention and the investigator reported that the it was possibly related to the device. The study met its primary efficacy endpoint of non-inferiority in AHI ($p<0.0001$) and demonstrated comparable safety data.

Results of non-clinical and clinical tests and assessments did not raise new safety or efficacy questions. Therefore, the conclusion is that the Transcend Auto is as safe and effective as the REMstar.

Conclusion

The Transcend Auto is substantially equivalent to the Transcend CPAP (K100121) and the Respironics REMstar Auto CPAP with C-Flex (K041010). The subject and predicate devices are used for the treatment of obstructive sleep apnea. They are equivalent in terms of technology and intended use. Risk assessments, biocompatibility evaluation, software, electromagnetic compatibility and electrical safety, bench testing, clinical validation, and compliance with recognized standards demonstrate that any differences do not raise new questions of safety or effectiveness. The Transcend Auto is, therefore, substantially equivalent to the predicate devices.

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

October 17, 2013

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

Re: K132127
Trade/Device Name: Transcend Auto
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 20, 2013
Received: September 23, 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,

Mary S. Runner -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): K132127

Device Name: Transcend Auto

Indications for Use:

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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
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