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MEDICAL REGISTRATION

AUG 2 3 2011

SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K 111207

1	Submission Owner	Respire Medical® LLC 18 Bridge St., Ste. 4J Brooklyn, 11201 NY Phone 718-643-7326 Fax 718-643-7322		
2	Official Correspondent Contact Person	Sterling Inc. Daniela Levy - Regulatory Consultant 607 South Hill st., suite#506 Los Angeles, 90014 CA Phone 213-447-5297 Fax 213-627-0340 Web www.sterlingmedicalregistration.com		
3	Submission Date	April 2011		
4	Device Trade Name	Respire Blue Series		
5	Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)		
6	Classification	Device Name	:	Device, Anti-Snoring
		Product Code	:	LRK
		Regulation No	:	872.5570
		Class	:	II
		Panel	:	Dental
7	Reason for the Premarket Notification Submission		:	New Device

8 Identification of Legally Marketed Predicate Devices :

- Respire Blue Series is substantially equivalent to TAP II K060388 ; Somnomed MAS K050592; Somnomed MAS Flex SK073004 ; OASYS K030440 in terms of intended use, indication for use, technological characteristics, performance and user interface. The predicate devices are Class II medical devices.

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9 Device Description :

Respire Blue Series is a patented, custom made device for each patient which consists of two dental plates, upper and lower, made of Acrylic.

The attachment is at a 65 degree angle to enable movement of the appliances, thus patient can open and close while wearing the appliances. The appliance is open in the front to add comfort by allowing the patient to inhale and exhale more air per breath.

Respire Blue Series are offered in two options: (1) Hard/Soft which has a dual laminate layer that provides a soft layer on the tooth surface (2) Hard devices which are all acrylic and retained with ball clasps, this allows the device to be tightened if it becomes loose.

10 Intended use :

- The Respire Blue Series is indicated to treat mild to moderate OSA.

11 Performance Standards or Special Controls :

- Recognized Consensus Standard: ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

12 Substantial Equivalence :

Substantial Equivalent Table	**Respire Blue Series (Hard/Soft Surface)**	**Respire Blue Series (Hard Surface)**	**Somnomed MAS**	**OASYS**	**TAP II**	**Somnomed MAS Flex S**
			K050592	**K030440**	**K060388**	**K073004**
Intended Use						
Intended as an intraoral device	YES	YES	YES	YES	YES	YES
Intended to reduce snoring or help alleviate snoring	YES	YES	YES	YES	YES	YES
Treatment of mild to moderate obstructive sleep apnea	YES	YES	YES	YES	YES	YES
Indicated for single patient multi - use	YES	YES	YES	YES	YES	YES
Indicated for use at home or sleep labratories	YES	YES	YES	YES	YES	YES

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Substantial Equivalent Table	Respire Blue Series (Hard/Soft Surface)	Respire Blue Series (Hard Surface)	Somnomed MAS	OASYS	TAP II	Somnomed MAS Flex S
			K050592	K030440	K060388	K073004
Target population - Adults patients	YES	YES	YES	YES	YES	YES
Prescription Device	YES	YES	YES	YES	YES	YES
Design						
Rigid tray pieces	YES	YES	YES	YES	YES	YES
Separate tray pieces	YES	YES	YES	YES	YES	YES
Custom fit for each patient	YES	YES	YES	YES	YES	YES
Works by mandibular advancement	YES	YES	YES	YES	YES	YES
Can be adjusted or refit	YES	YES	YES	YES	YES	YES
Placed in patient mouth each evening	YES	YES	YES	YES	YES	YES
Cleaned daily	YES	YES	YES	YES	YES	YES
Easily removed from mouth	YES	YES	YES	YES	YES	YES
Lower jaw adjustment using a supplied adjustment key	YES	YES	YES	YES	YES	YES
Upper and lower tray unhook for easy removal from mouth	YES	YES	YES	YES	YES	YES
Permits patients to breat through mouth	YES	YES	YES	YES	YES	YES
Material						
Trays constructed from molded hard acrylic and ball clasps	YES	YES	YES	NO	NO	NO
Trays constructed from a soft lining material adhered to a hard surface acrylic	YES	NO	NO	NO	NO	YES
Trays constructed from a heat sensitive impermissible material for fitting to teeth	NO	NO	NO	YES	YES	NO
Non Sterile	YES	YES	YES	YES	YES	YES

Summary of Equivalence: The Respire Blue Series is considered to be substantially equivalent to TAP II, Somnomed MAS, Somnomed MAS Flex and OASYS devices. As similar to its predicate device Respire Blue Series is a custom made device, consists of two parts, upper and lower trays, made of acrylic. The design differences is that the TAP design holds the jaw in a more fixed position and does not allow for the patient to open and close their mouth, while the Respire Blue Series allow jaw movement and is more comfortable. Respire Blue Series is similar to Somnomed both devices contain expansion screw which enable the device to be titratable and allows simple adjustment and positioning of the device.

Respire Blue Series enables an anterior opening in the front of the device to allow for patient comfort. The design differences emphasis the advantages of Respire Blue Series technology and thus, raise no new safety and/or effectiveness issues. Respire Blue Series shares the same technological characteristics as its predicate devices and raise no new issues of safety or effectiveness, thus, the Respire Blue Series is substantially equivalent to its predicate devices.

Risk Assessment performance has demonstrated no new safety and/or effectiveness issues.

Bench testing results have demonstrated that all test method acceptance criteria were met and demonstrated equivalent results to the predicated devices. Thus, Respire Blue Series shares similarity with its predicate devices and raise no new safety and/or effectiveness issues.

Clinical evaluation and observation results have demonstrated the success rate of reduction of snoring and the success rate of reduction of apneic events measured by polysomnograms. Thus, Respire Blue Series shares similarity in the indication of use and raise no new safety and/or effectiveness issues.

Conclusion:

As verified by clinical and non clinical data, bench testing and substantial equivalence table, Respire Blue Series shares similarity with its predicated device by term of intended use, raw material and technical design. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, thus Respire Blue Series is as safe and effective for its intended use and performs as well the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Respire Medical
C/O Ms. Daniela Levy
Regulatory Consultant
Sterling Incorporated (Sterling Medical Registration)
607 South Hill Street, Suite 506
Los Angeles, California 90014

AUG 23 2011

Re: K111207
Trade/Device Name: Respire Blue Series
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: August 2, 2011
Received: August 3, 2011

Dear Ms. Levy:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 - Indication for Use Statement

Indications for Use

Indications for Use

510(k) Number (if known): K111207

Device Name:

Respire Blue Series

Indications for Use:

The Respire Blue Series is indicated to treat mild to moderate OSA.

Prescription Use _✓__ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (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)

Susan Runner

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

510(k) Number: K111207