



Food and Drug Administration
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December 7, 2015

Respire Medical Holding
c/o Mr. Stephen Inglese
Founder and CEO
Quality Solutions and Support, LLC
PO Box 8271
Holland, Michigan 49422

Re: K152292

Trade/Device Name: Respire Blue Series-EF

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: September 7, 2015

Received: September 8, 2015

Dear Mr. Inglese:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

 Tina Kiang -
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for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Respire Blue Series – EF

Traditional 510(k)

Respire Medical

4.0 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)
K152292

Device Name
Respire Blue Series - EF

Indications for Use (Describe)
The Respire Blue Series - EF is indicated to treat mild to moderate OSA (Obstructive Sleep Apnea)

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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K152292
510(k) Summary

Device Common Name: Device, Anti-Snoring

Device Proprietary Name: Respire Blue Series – EF

Submitter: Respire Medical, LLC
18 Bridge St Ste 4J
Brooklyn, NY 10021
Phone: 718-643-7326

Contact: Stephen Inglese
Consultant
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swi@qss-llc.com

Date Prepared: December 8, 2015

Classification Regulation: 21 CFR §872.5570, Class II – Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

Panel: Dental

Product Code: LRK

Predicate Device: K111207 – Submitter’s own previously cleared device

Indication for Use: The Respire Blue Series – EF is indicated to treat mild to moderate OSA (Obstructive Sleep Apnea)

Device Description:

The Respire Blue Series – EF (Endurance Frameworks) – is available with a hard device fitting surface. The hard surface consists of Acrylic (side plates / trays) and chrome - Wironit material (upper / Palatal and lower / Lingual plates / trays). **Refer to Figure 1 Representative Drawing.** The device is retained with ball and clasps which are used to hold elastic bands which guide the jaw to the desired position. In addition there are expansion screws inside the Acrylic side plates / trays that allows for device expansion based on patient needs.

The upper and lower components are connected by an adjustable hinge, thus the patient can open and close the mouth while wearing the appliances

Figure 1 – Respire Blue Series – EF – Front View



Performance Data:

The subject of this 510(k) is a modification to the material used for the manufacturing of the top and bottom plates / trays of the device. The material “Wironit” is a widely used dental material, demonstrated via biocompatibility and cytotoxicity testing. The following nonclinical tests were performed:

- Biocompatibility testing was accomplished according to the standards of ISO 10993. The results of testing determined that the material didn’t cause skin irritation or allergenic sensitization.
- Minimal Essential Medium (MEM) Elution testing was designed to determine the cytotoxicity of extractable substances. The testing passed with a reactivity of 0 (zero) or none.
- Material Integrity testing demonstrates the strength of the Wironit material as compared to the Acrylic material. The predicate device consisted of only Acrylic. The Wironit / Acrylic and Acrylic only (predicate device) were tested together to determine substantial equivalence as it relates to specimen elongation (stretching) and load bearing force to break. In both tests the points of failure were identified at the same location; yet the amount of energy required to cause failure was less for Wironit /Acrylic. However, the amount of energy shown in the results, still far exceeds the amount of energy required by biting to create such a failure which occurred at an average of 275.6 lbf using five (5) sample devices. Thus, the proposed Wironit/Acrylic parts are sufficient to survive a load exposure exerted by a human oral cavity. In addition the intended use of this device is indicated to treat mild to moderate OSA (Obstruction Sleep Apnea) and not applying the necessary force for biting.

Substantial Equivalence:

The modification of the added material to the originally cleared device is demonstrated in Chart 1. The device function remains the same, the option for the Wironit material for the upper and lower plates / trays provides the patient with a more comfortable fit and durability. Therefore the modified device is substantially equivalent to the previously cleared Respire Blue Series.

Respire Blue Series – EF

Traditional 510(k)

Respire Medical

Chart 1

Substantial Equivalence Topic	Respire Blue Series	Respire Blue Series –EF
510(k)	K111207	K152292
Company Name	Respire Medical	Respire Medical
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)
Device Name	Device, Anti Snoring	Device, Anti Snoring
Product Code	LRK	LRK
Classification	Class II	Class II
Intended Use	The Respire Blue Series is indicated to treat mild to moderate OSA.	The Respire Blue Series - EF is indicated to treat mild to moderate OSA.
Single or Multiple Use	Multiple Use	Multiple Use
Target Population	Adult Patients	Adult Patients
Prescription or OTC Use	Prescription	Prescription
Device Components	Orthodontic Acrylic plates / trays, Telescopic Hardware and Ball Clasp	Orthodontic Acrylic plates / trays, and Wironit plates / trays, Telescopic Hardware and Ball Clasp
Appliance Design	Customized device Rigid plates / trays two pieces Upper/Lower and sides Acrylic.	Customized device Rigid plates and trays / two pieces / Upper and Lower / Acrylic and Wironit and sides Acrylic
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower plates / trays unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep Upper and lower plates / trays unhook for easy removal from mouth Works by mandibular advancement Adjustable using titration keys
Mandibular Advancement Range	6mm	6mm
Raw Material: Side / Upper and Lower Trays	Acrylic (side and upper and lower plates / trays)	Acrylic (side plates / trays) and Wironit (upper and lower / plates / trays)
Raw Material: Metal Components	Stainless Steel	Stainless Steel
Colorants	Blue	Blue

Note: Bold "Substantial Equivalence Topic" – Difference between the cleared device and the modifications in the Subject Device