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

August 27, 2015

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

Re: K150572
Trade/Device Name: Respire Pink Series-Herbst-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: July 27, 2015
Received: July 30, 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,

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

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.

510(k) Number *(if known)*
NA K150572

Device Name
Respire Pink Series - Herbst - EF

Indications for Use *(Describe)*
The Respire Pink Series - Herbst - EF is indicated to treat mild to moderate OSA.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Respire Pink Series - Herbst - EF

Traditional 510(k)

March 1, 2015

Submitter: Respire Medical LLC
18 Bridge St Ste. 4J
Brooklyn, 11201 NY
Phone: 718-643-7326

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

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Respire Pink Series – Herbst – EF is provided below:

Device Common Name: Device, Anti-Snoring

Device Proprietary Name: Respire Pink Series – Herbst - 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: .March 1st 2015

Classification Regulation: 21 CFR §872.5570, Class II – Device Anti-Snoring

Panel: Dental

Product Code: LRK

Predicate Device: K131138 – Submitter's own previously cleared device

Indication for Use: The Respire Pink Series – Herbst - EF is indicated to treat mild to moderate OSA (Obstruction Sleep Apnea)

Device Description:
The Respire Pink Series – Herbst - EF (Endurance Frameworks) – is available with a hard device fitting surface. The hard surface consists of Acrylic (side plates) and chrome - Wironit material (upper / Palatal and lower / Lingual plates). **Refer to Figure 1 Representative Drawing**. The device is retained with ball and clasps which allows the device to be tightened if it becomes loose. The device is a mandibular advancement splint that holds the jaw in a forward position to help keep the tongue and supporting tissues in a

position to help maintain an open airway, which helps in the treatment of snoring and mild to moderate obstructive sleep apnea

The Herbst hardware on the side of the device allows the patient to move forward and left and right, but not backwards. These movements give the patient some freedom to move which is important for their comfort and overall success of the device. The upper and lower components are connected by an adjustable hinge, thus patient can open and close while wearing the appliances.

Figure 1 – Respire Pink Series – Herbst – 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 trays of the device. The material "Wironit" is a widely used dental material and demonstrated via biocompatibility and cytotoxicity testing

Material integrity testing was also accomplished. The following is a summary of the testing:
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 where identified at the same location yet the amount of energy to cause failure was less for the Wironit /Acrylic. The amount energy shown in the results, still far exceeds the amount of energy required by an oral cavity to create such a failure which occurred at an average of 275.6 lbf using five (5) sample devices. 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.

The determination from the tests demonstrated that the Respire Pink Series – Herbst – EF doesn't raise new issues of effectiveness, therefore the Respire Pink Series – Herbst – EF is substantially equivalent to the predicate Respire Pink Series – Herbst.

Based on the completed risk analysis which determined the added material showed the risks were mitigated to acceptable levels in addition to the testing accomplished, the device performance is similar to that of the originally cleared predicate device.

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 tray provides the patient with a more comfortable fit and durability. Therefore the modified device is substantially equivalent to the previously cleared Respire Pink Series – Herbst.

Chart 1

Substantial Equivalence Topic	**Respire Pink Series – Herbst**	**Respire Pink Series – Herbst - EF**
510(k)	K131138	NA
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 Pink Series - Herbst is indicated to treat mild to moderate OSA.	The Respire Pink Series - Herbst – 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	Prescription	Prescription

Substantial Equivalence Topic	Respire Pink Series – Herbst	Respire Pink Series – Herbst - EF
Use		
Device Components	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp
Appliance Design	Customized device Rigid tray two pieces Upper/Lower acrylic.	Customized device Rigid tray / two pieces / Upper and Lower / Acrylic and Wironit
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray 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 tray 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 trays)	Acrylic (side) and Wironit (upper and lower trays)
Raw Material: Metal Components	Stainless Steel	Stainless Steel
Colorants	Pink	Pink

Note: Bold “Substantial Equivalence Topic” – Difference between the cleared device and the modifications called out in this submission

11.0 Substantial Equivalence Discussion

Technological Comparison

The Respire Pink Series – Herbst – EF device that is the subject of this 510(k) is substantially equivalent to the previously cleared version of Respire Pink Series – Herbst in K131138. The only modification to the device is the material the patent now has the option to use. The upper and lower trays which can be made of Acrylic (cleared under K131138) can now be made of Wironit. **Chart 2** demonstrates the comparison between the previously cleared device and the modification for the device identified in this submission.

Design Material Substantial Equivalence

Figure 3 demonstrates the originally cleared device of full Acrylic material that is both the sides and upper and lower trays are made of Acrylic. This figure shows the Herbst hardware, ball, and clasp on the sides.

Figure 3

Figure 4 demonstrates the modified device. The sides remain Acrylic as in the orginal cleared submission but the upper and lower trays are replaced with Wironit. This figure demonstrates the Herbst hardware and ball and clasp on the sides.

Figure 4

Substantial Equivalence Conclusion

The modification of the Respire Pink Series – Herbst to Respire Pink Series – Herbst – EF as demonstrated in the above chart is to only provide the patent with an option to have the upper and lower trays utilize the Wironit material instead of Acrylic. The modified device even though with the added material, the device through performance testing is substantially equivalent to the previously cleared Respire Pink Series – Herbst device. The device still remains as effective as originally cleared.