DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2017

Respire Medical Holding
Mr. Jonathan Sandler
Quality Assurance Manager
18 Bridge Street, Suite 4j
Brooklyn, New York 11201

Re: K170692
Trade/Device Name: Respire Pink Series With DentiTrac®
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: PLC
Dated: March 7, 2017
Received: March 7, 2017

Dear Jonathan Sandler:

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,

Lori A. Wiggins -S6

for

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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)*
K170692

Device Name
Respire Pink Series with DentiTrac®

Indications for Use *(Describe)*
The Respire Pink Series intraoral appliances are intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older.

Optionally, the DentiTrac® micro-recorder may be incorporated into a Respire Pink Series device. The micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac® system.

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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510(k) Summary

510(k) Submission Number: K170692

Submitter
Respire Medical
18 Bridge Street, Suite 4J
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Phone: 718-643-7326

Official Contact:
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Quality Assurance Manager
Phone: 718-360-9209
Email: Jonathan@respiremedical.com

Date Prepared:
May 16, 2017

Device Identification

Proprietary Name:	Respire Pink Series with DentiTrac®
Common Name:	Device, Anti-Snoring
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Classification:	Class II
Product Code:	PLC
Regulation Number:	21 CFR 872.5570

Predicate Devices

Candidate	Predicate	Manufacturer	510(k) Number
Respire Pink Series with DentiTrac®	SomnoDent® with Micro-Recorder	SomnoMed, Inc.	K150369
	Respire Pink Series-Herbst	Respire Medical, LLC	K131138
	Respire Pink Series-Herbst-EF	Respire Medical, LLC	K150572

The primary predicate device used for substantial equivalence is the SomnoMed SomnoDent® with Micro-Recorder. The reference predicate devices are the Respire Pink Series-Herbst devices which includes both the standard Respire Pink Series-Herbst device and the Respire Pink Series-Herbst-EF.

Device Description
The Respire Pink Series with DentiTrac® refers to two devices: Respire Pink Series-Herbst and the Respire Pink Series-Herbst-EF, herein referred to collectively as Respire Pink Series. These devices function as mandibular advancement splints which hold the jaw in a forward

position. The forward jaw placement moves the tongue and pharyngeal tissue into a position to help maintain an open airway, which allows the passage of more air per breath and helps in the treatment of snoring and mild to moderate Obstructive Sleep Apnea (OSA). Respire Pink Series appliances are customizable devices which are produced according to the individual patient anatomy and prescription.

The Respire Pink Series-Herbst consists of full hard acrylic upper and lower fitting surfaces, and the Respire Pink Series-Herbst-EF consists of hard acrylic fitting side plates and chrome (BEGO Wironit®) upper palatal and lower lingual plates. The Herbst hardware on the side of the device allows for forward and lateral jaw movement while restricting backward jaw movement, and allows the patient to open and close the mouth. The Herbst hardware contains an expansion screw for mandibular position adjustment, and is attached to the appliance using medical grade stainless steel fixing elements and screws.

This submission is to provide clinicians the option to incorporate a Braebon DentiTrac® micro-recorder into a Respire Pink Series device. The micro-recorder is encapsulated in Loctite epoxy and fully encased into the device acrylic, and is not patient contacting. The micro-recorder is utilized to track patient compliance to prescribed oral appliance therapy by collecting data for wear-time through oral temperature, movement tracking, and head position. The data can be uploaded to a cloud-based web application using the DeniTrac® system which allows clinicians to review the patient data. The inclusion of the micro-recorder provides additional treatment information to clinicians without effecting the operating principles of the Respire Pink Series devices.

Respire Pink Series with DentiTrac®

Figure 1

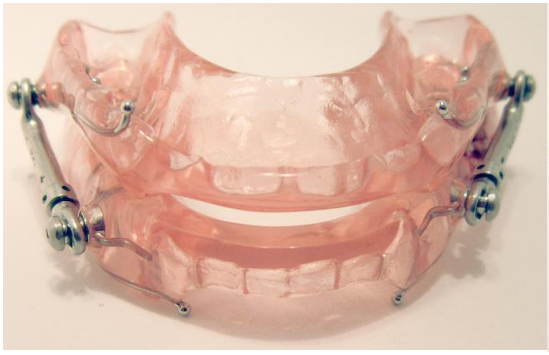
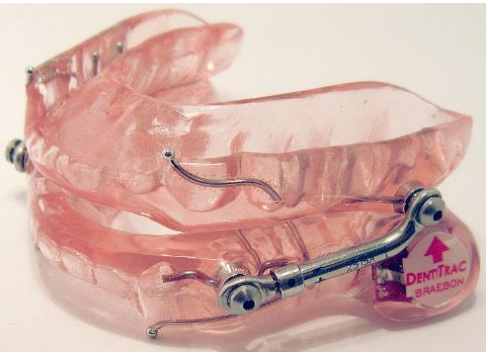


Figure 2



Intended Use

The Respire Pink Series intraoral appliances are intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older.

Optionally, the DentiTrac® micro-recorder may be incorporated into a Respire Pink Series device. The micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac® system.

Comparison to Predicate Devices:

Substantial Equivalence Topic	**Proposed:** Respire Pink Series with DentiTrac®	**Primary Predicate:** SomnoMed SomnoDent® with Micro-Recorder	**Reference Predicate:** Respire Pink Series-Herbst / Pink Series-Herbst-EF
510(k)	N/A	K150369	K131138 / K150572 (EF)
Company Name	Respire Medical	SomnoMed	Respire Medical
Device Name	Device, Anti-Snoring	Device, Anti-Snoring	Device, Anti-Snoring
Indications for Use Statement	The Respire Pink Series intraoral appliances are indented to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older. Optionally, the DentiTrac micro-recorder may be incorporated into a Respire Pink Series device. The micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac system.	The SomnoDent Intraoral devices are intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older Optionally, if the DentiTrac micro-recorder is completely embedded into the SomnoDent device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System.	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.
Intended Use			
Intended as an intraoral device	Yes	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes	Yes
Intended for night time use	Yes	Yes	Yes
Indicated for single patient multiuse	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes
Design			
Separate upper and lower tray pieces	Yes	Yes	Yes
Works by mandibular advancement	Yes	Yes	Yes
Can be adjusted or refit	Yes	Yes	Yes
Lower jaw adjustment using supplied components	Yes	Yes	Yes
Permits patient to breathe through mouth	Yes	Yes	Yes

Upper and lower trays disengage for easy removal	Yes	Yes	Yes
Cleaned and inspected daily by patient	Yes	Yes	Yes
Materials			
Advancement mechanism: surgical grade stainless steel	Yes	Yes	Yes
Acrylic fitting surface	Yes	Yes	Yes
Acrylic/Wironit® fitting surfaces	Yes (EF)	No	Yes (EF)
Micro-Recorder embedded into device	**Yes**	**Yes**	**No**

Performance Testing

Non-clinical performance testing:

The addition of the DentiTrac® micro-recorder does not adversely affect the original design, therefore, not introducing any new issues of concern. A risk assessment shows that risks are mitigated to acceptable levels, and performance testing related to the DentiTrac® micro-recorder confirms that EMC and electrical safety, biocompatibility, and software elements were evaluated. DentiTrac® performance testing is located in the Braebon DentiTrac® Master File MAF 2557. Process validation concerning the incorporation and functionality of the DentiTrac® micro-recorder is certified by Braebon. Respire Medical performs 100% visual and functional inspections throughout the production process to ensure that the device meets manufacturing specifications for the Respire Pink Series device and specifications for the incorporation of the DentiTrac® micro-recorder.

Discussion of Similarities and Differences Between the Subject and Predicate Devices

The Respire Pink Series predicate devices (K131138 and K150572) are identical to the Respire Pink Series with DentiTrac® candidate device apart from the addition of the DentiTrac® micro-recorder. The general characteristics and specifications are unchanged in that each devices utilizes the same materials, manufacturing procedures, principles of operation, and overall design. The DentiTrac® micro-recorder used in the Respire Pink Series with DentiTrac® is identical to that which is used in the SomnoDent® (K150369) predicate device, and the indications for use are similar between the two devices. However, the age population has been added which is not present on K131138 and K150572 predicates.

Conclusion

Based on the similarities in the indications for use, technology, biocompatibility assessment, and non-clinical performance testing, Respire Pink Series with DentiTrac® is substantially equivalent to the SomnoMed SomnoDent® with Micro-Recorder and the Respire Pink Series predicate devices.