February 5, 2020

Respire Medical Holdings
Madubuike Okafor
Quality Assurance Manager
18 Bridge St. Suite 3J
Brooklyn, New York 11201

Re: K192127
Trade/Device Name: Respire Pink AT (Hard, Hard/Soft, EF)
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: LRK
Dated: January 8, 2020
Received: January 9, 2020

Dear Madubuike Okafor:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192127

Device Name
Respire Pink AT (Hard, Hard/Soft, EF)

Indications for Use *(Describe)*
Our devices are indicated to treat mild to moderate Obstructive Sleep Apnea (OSA) in patients, 18 years of age or older.

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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Special 510(k): Respire Pink AT (Hard, Hard/Soft, EF)

K192127

510(k) Summary

From 21 CFR Part 807.92:

(a) (1) – (3)

Device Common Name:	Device, Anti-Snoring
Device Proprietary Name:	The Respire Pink AT (Hard, Hard/Soft, EF)
Submitter:	Respire Medical Holdings, LLC 18 Bridge St. Suite #3J Brooklyn, NY 11201 Phone: 718-360-9209
Contact:	Madubuike Okafor
Date Prepared:	Januray 8, 2020
Classification Regulation:	21 CFR 872.5570, Class II – Device Anti-Snoring
Panel:	Dental
Product Code:	LRK
Predicate Device:	K150572 - Respire Pink Series-Herbst-EF
Indication for Use:	Our devices are indicated to treat mild to moderate Obstructive Sleep Apnea (OSA) in patients, 18 years of age or older.

(4), The Respire Pink AT (Hard, Hard/Soft, EF) is an oral appliance used in the treatment of mild to moderate obstructive sleep apnea. This device helps move a patient's jaw forward, thus opening their airways, and allowing them to breathe more easily throughout the night. The Respire Pink AT (Hard, Hard/Soft, EF) is made out of dental industry standard acrylic resins & metals, and is custom designed to comfortably fit each patients' unique oral anatomy.

(5) The intended use of the Respire Pink AT (Hard, Hard/Soft, EF) is "Our devices are indicated to treat mild to moderate Obstructive Sleep Apnea (OSA) in patients, 18 years of age or older.". Obstructive sleep apnea (or OSA) is a sleep disorder that occurs when a patient's throat muscles intermittently relax and block their airway during sleep. The intended used for the Respire Pink AT (Hard, Hard/Soft, EF) has the phrase "in adult patients" replaced and clarified with the phrase "18 years of age or older". This is not a new indication, rather just a clarification since both of the devices shown in the below comparison chart. Are for adult patients. This addition is not critical to the intended therapeutic use of the device, and does not affect the safety and effectiveness of the device when used as labeled because both the predicate devices, and Respire Pink AT (Hard, Hard/Soft, EF) have always been ordered by medical professionals for adult patients only.

(6) Respire Medical has developed its own custom telescopic arm, and this arm is the technological difference between the Respire Pink AT (Hard, Hard/Soft, EF), and its legally marketed predicate device; the Respire Pink (Hard, Hard/Soft, EF). This new arm was developed in order to create a hinge with more self-contained features, allow for more ease of titration, and more accurate titration/mandibular advancement readings. The below comparison chart summarizes features of the Respire Pink AT (Hard, Hard/Soft, EF), and its predicate; the Respire Pink (Hard, Hard/Soft, EF). The chart also further demonstrates the substantially equivalence of the Respire Pink AT (Hard, Hard/Soft, EF) to the Respire Pink (Hard, Hard/Soft, EF). The 1mm increase of the "Maximum mandibular Advancement range" identified in Figure 1. is meant to allow for slightly more titration. The extra millimeter (7mm) maximum advancement of the MIM Hinge allows allows adjustment consistent with other cleared devices.

Substantial Equivalence Topic	**Respire Pink EF**	**Respire Pink AT (Hard, Hard/Soft, EF)**
Relationship	Predicate device	Current submission
510(k) #	K150572	K192127
Device Propriety/Trade name	Respire Pink Series-Herbst-EF	Respire Pink AT (Hard, Hard/Soft, EF)
Company Name	Respire Medical	Respire Medical
Product Code	LRK	LRK
Classification	Class II	Class II

Substantial Equivalence Topic	**Respire Pink EF**	**Respire Pink AT (Hard, Hard/Soft, EF)**
Relationship	Predicate device	Current submission
510(k) #	K150572	K192127
Indications For Use	The Respire Pink Series – Herbst – EF is indicated to treat mild to moderate OSA.	Our devices are indicated to treat mild to moderate Obstructive Sleep Apnea (OSA) in patients, 18 years of age or older.
Single or Multiple Use	Multiple Use	Multiple Use
Target Population	Adult Patients	Adult Patients
Prescription or OTC Use	Prescription	Prescription
Design considerations: • Risk Management • Verification and Validation • Labeling Considerations • Use of Consensus Standards	 • Design Failure Mode and Effect Analysis • Inspection of devices according to Design Outputs • Labeling shall contain adequate doctor and patient directions • ISO 7405 • ISO 10993-5 • ISO 10993-10 • ISO 10993-12	 • Design Failure Mode and Effect Analysis • Inspection of devices according to Design Outputs, and Third-Party Lab testing of devices according to Design Inputs • Labeling shall contain adequate doctor and patient directions • ISO 7405 • ISO 10993-5 • ISO 10993-10 • ISO 10993-12
Description of the design and operational principles of the device	-Customized oral appliance -Allows for an increase in the pharyngeal opening, and improves the ability for the patient to inhale and exhale during sleep -Upper and lower tray unhook for easy removal from mouth	-Customized oral appliance -Allows for an increase in the pharyngeal opening, and improves the ability for the patient to inhale and exhale during sleep -Upper and lower tray unhook for easy removal from mouth

Substantial Equivalence Topic	Respire Pink EF	Respire Pink AT (Hard, Hard/Soft, EF)
Relationship	Predicate device	Current submission
510(k) #	K150572	K192127
	-Works by mandibular advancement. -Adjustable using titration keys.	-Works by mandibular advancement. -Adjustable using titration keys.
Maximum mandibular Advancement range	6mm	7mm

Figure 1.

(b) (1) In order to demonstrate the substantial equivalence of the Respire Pink AT (Hard, Hard/Soft, EF), bench testing was conducted on the device in order to ensure that it safely & effectively performs as intended. This testing included mechanical safety & performance validation, biocompatibility tests, and shipping validation tests. The results indicated that the Respire Pink AT (Hard, Hard/Soft, EF) performs as well as the predicate device.

(2) N/A (Clinical Testing is not required per *"Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Guidance for Industry and FDA".* This is due to the fact that none of the below criteria requiring clinical testing apply:

- "uses designs dissimilar from designs previously cleared under a 510(k)"
  - (the design for the Respire Pink AT (Hard, Hard/Soft, EF) is similar to the design for the Respire Pink (Hard, Hard/Soft, EF)
- "uses new technology, i.e., technology different from that used in legally marketed intraoral devices for snoring and/or obstructive sleep apnea"
  - (the technology used for the Respire Pink AT (Hard, Hard/Soft, EF) is still mandibular adjustment via titration)
- "makes changes in the indication for use."
  - (the intended use has not changed)

(3) The conclusions drawn from the nonclinical tests demonstrate that the Respire Pink AT (Hard, Hard/Soft, EF) is as safe, as effective, and performs as well as the legally marketed predicate device. The mechanical safety & performance validation, biocompatibility tests, and shipping validation tests criteria were all evaluated thoroughly, and passed successfully.