May 31, 2022

Respire Medical, LLC
David Walton
CEO
18 Bridge St.
Brooklyn, New York 11201

Re: K214096
Trade/Device Name: Respire Clear
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, LQZ
Dated: February 8, 2022
Received: February 11, 2022

Dear David Walton:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214096

Device Name
Respire Clear

Indications for Use *(Describe)*
The Respire Clear is 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k): Respire Clear

K214096

510(k) Summary

Form 21 CFR Part 807.92:

(a) (1) – (3)

Device Common Name:	Device, Anti-Snoring
Device Proprietary Name:	The Respire Clear
Submitter:	Respire Medical, LLC 18 Bridge St. Suite 3J, Brooklyn, NY 11201
Contact:	Walton David
Date Prepared:	May 28, 2022
Classification Regulation:	21 CFR 872.5570, Class II – Device Anti-Snoring
Panel:	Dental
Product Code:	LRK
Predicate Device:	K192127 - Respire Pink AT (Hard, Hard/Soft, 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.
Reference Device:	K191320- Slow Wave DS8
Indication for Use:	Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults.

(4) The Respire Clear 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 Clear is made out of

dental industry standard 3D printed resins & metals, and is custom designed to fit each patients' unique oral anatomy.

(5) The intended use of the Respire Clear 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 Clear 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 Clear have always been ordered by medical professionals for adult patients only.

(6) The subject of this Traditional 510(k) submission is a change to the Respire Pink AT (Hard, Hard/Soft, EF) (hereinafter referred to as Pink AT) to make the Respire Clear. This change will remove the materials, the standard acrylic resin (Product Code: KMY) and use the 3D Printed resin (Product Code: KMY), as an alternative material to produce trays. Accordingly, the design process will change from hand-fabrication only to the use of additive manufacturing and hand-fabrication processes. After the trays are produced using the additive manufacturing process, the trays are adjusted by hand fabrication and stainless-steel parts are added to the trays. The dimensions have not changed as a result of the modifications.

Table1.

	Respire Clear	**Respire Pink AT (Hard, Hard/Soft, EF)**	**Slow Wave DS8**	
Relationship	Current submission	Predicate device	Reference Device	-
510(k) #	K214096	K192127	K191320	-
Device Propriety / Trade name	Respire Clear	Respire Pink AT (Hard, Hard/Soft, EF)	Slow Wave DS8	-
Company name	Respire Medical, LLC	Respire Medical, LLC	Slow Wave Inc.	IDENTICAL to the predicate
Product Code	LRK	LRK	LQZ, LRK	IDENTICAL to the predicate
Classification	Class II	Class II	Class II	IDENTICAL
Indication for Use	Our devices are indicated to	Our devices are indicated to	Intended to reduce or alleviate snoring, mild to moderate	IDENTICAL to the predicate

	Respire Clear	Respire Pink AT (Hard, Hard/Soft, EF)	Slow Wave DS8	
Relationship	Current submission	Predicate device	Reference Device	-
510(k) #	K214096	K192127	K191320	-
	treat mild to moderate Obstructive Sleep Apnea (OSA) in patients, 18 years of age or older.	treat mild to moderate Obstructive Sleep Apnea (OSA) in patients, 18 years of age or older.	Obstructive Sleep Apnea (OSA) while sleeping in adults.	
Single or Multiple Use	Multiple Use	Multiple Use	Multiple Use	IDENTICAL
Target Population	18 years of age or older	18 years of age or older	Adult Patients	Identical to the predicate
Material of Tray	3D printed resin	Acrylic resin	3D printed resin	IDENTICAL to the reference
Tray's material Biocompatibility	• ISO 7405 • ISO 10993-5 • ISO 10993-10 • ISO 10993-12	• ISO 7405 • ISO 10993-5 • ISO 10993-10 • ISO 10993-12	ISO 7405 and ISO 10993 compliant biocompatibility assessment on 3D printed material based on the risk assessment	IDENTICAL to the predicate
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	-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	DS8 consists of two trays worn on the maxilla and mandible. The device is manufactured at Slow Wave facilities using additive manufacturing, specifically, on a Formlabs 3D Printer utilizing stereolithography (SLA) using biocompatible	IDENTICAL to the predicate

	Respire Clear	Respire Pink AT (Hard, Hard/Soft, EF)	Slow Wave DS8	
Relationship	Current submission	Predicate device	Reference Device	-
510(k) #	K214096	K192127	K191320	-
	for easy removal from mouth -Works by mandibular advancement. -Adjustable using titration keys.	for easy removal from mouth -Works by mandibular advancement. -Adjustable using titration keys.	material. The trays are designed to be an exact custom fit by a trained dental technician, using a 3Shape intraoral scanning device, or comparable intraoral scanner such as the iTero, or Cerec, registering one's full impressions of the upper teeth, lower teeth. A bite scan registration with a gap (typically 8 mm), which is a crucial design feature. The gap results from the design of the lower and upper trays. The upper and lower trays, the molars, premolars, and canines, are covered by the device. However, the lateral or central incisors are not	

	Respire Clear	Respire Pink AT (Hard, Hard/Soft, EF)	Slow Wave DS8	
Relationship	Current submission	Predicate device	Reference Device	-
510(k) #	K214096	K192127	K191320	-
			covered, which effectively leaves eight teeth (four maxillary incisors and four mandibular incisors) uncovered. The trays are shaped like arch because the covered portion of the device is connected to each other by two palatal bands one connecting the upper left and upper tray, and the other connecting the lower tray. Additionally, the trays are built with ramps that guide the mandible forward and downward, thus maintaining advancement, enlarging the airway, allowing more room for the tongue to migrate forward naturally. The vertical opening of the jaw is	

	Respire Clear	Respire Pink AT (Hard, Hard/Soft, EF)	Slow Wave DS8	
Relationship	Current submission	Predicate device	Reference Device	-
510(k) #	K214096	K192127	K191320	-
			not fixed in a single position. DS8 is a tractionbased mandibular repositioning device that allows nasal and/or oral breathing.	
Maximum Mandibular Advancement range	7 mm	7 mm	15 mm	IDENTICAL to the predicate

(b) (1) In order to demonstrate the substantial equivalence of the Respire Clear, 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 Clear 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)"

o (the design for the Respire Clear is similar to the design for the Respire Pink-AT)

• "uses new technology, i.e., technology different from that used in legally marketed intraoral devices for snoring and/or obstructive sleep apnea"

o (the technology used for the Respire Clear is still mandibular adjustment via titration and this technology is almost same as Slow Wave DS8)

• "makes changes in the indication for use."

o (the indication for use has not changed)

(3) The conclusions drawn from the nonclinical tests demonstrate that the Respire Clear is as safe, as effective, and performs as well as the legally marketed predicate device and reference device. The mechanical safety, performance validation, and biocompatibility tests criteria were all evaluated thoroughly, and passed successfully.