September 1, 2023

Apnea Sciences Coporation
% James Smith
Regulatory Consultant
Apnea Sciences Corporation
28591 Springfield Drive
Laguna Niguel, California 92677

Re: K223901
Trade/Device Name: ApneaRX Pro
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: August 3, 2023
Received: August 4, 2023

Dear James Smith:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
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)*

K223901

Device Name
ApneaRx Pro

Indications for Use *(Describe)*

The ApneaRx Pro is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea (OSA), and/or snoring.

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."

APNEA SCIENCES®

Advancing the Science of Sleep Medicine

K223901

510(k) SUMMARY

Submitted by:

Owner's Name:	Apnea Sciences Corporation
Address:	27121 Aliso Creek Road, Ste. 140 Aliso Viejo, CA 92656
Contact:	James Fallon, President/CEO
Telephone:	(949) 680-2770
Fax:	(928) 569-5974
E-mail:	jfallon@apneasciences.com

Contact Person:

Name	James Smith, Ph.D.
Address	28591 Springfield Drive Laguna Niguel, CA 92677
Telephone	949-422-1512
E-mail:	jrsmith00@cox.net

Date Prepared: March 13, 2023

Trade Name: ApneaRx Pro

Common Name:	Mandibular repositioning device
Classification Name:	Device, Anti-Snoring
Device Class:	Class II
Product Code:	LRK
Regulation No.	21 CFR 872.5570

Predicate Device:	ApneaRx (Apnea Sciences Corporation) (Primary predicate)
Predicate 510(k) #:	K113569
Reference Device 1	K203000 (KeyPrint KeySplint Hard; Keystone Industries)
Reference Device 2	K170825 (SnoreRx; Apnea Sciences Corporation)

Device Description: The ApneaRx Pro is an intraoral device that repositions the jaw anteriorly in order to increase the patient's pharyngeal space and minimizing air obstruction and turbulence. The device consists of two custom fabricated liners that fit separately over the upper and lower dental arches and engage in the posterior area of the mouth. The lower liner is snap-fitted to a polycarbonate chassis that enables mandibular repositioning in 1 mm increments. The upper liner employs a hinged design to enable vertical movement of the jaws.

APNEA SCIENCES®

Advancing the Science of Sleep Medicine

Intended Use: The ApneaRx Pro is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea (OSA), and/or snoring.

Technology Comparison: Both the ApneaRx Pro and its predicate consist of intraoral mouth pieces that are molded to the patient's teeth and allows slight adjustment of the anterior positioning of the jaw to the patient's comfort. The ApneaRx Pro utilizes custom-fabricated liners and incorporates design changes to slightly increase freedom of movement of the upper liner. The ApneaRx Pro is provided non-sterile and uses a similar packaging system as the predicate device. The table below compares the technological aspects of the new and predicate devices.

Subject Area	New Device	Predicate	Differences
Product Code	- LRK	- LRK	
Product Classification	- Class II	- Class II	
Classification Name	- Anti-Snoring Device	- Anti-Snoring Device	
Proprietary Name	ApneaRx Pro	ApneaRx	
Technological Features	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.	
Intended Use	The ApneaRx Pro is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea (OSA), and/or snoring.	The Apnea Sciences Corporation "ApneaRx" is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea (OSA), and/or snoring.	

Subject Area	New Device	Predicate	Differences
Materials	- Polycarbonate resin - KeyPrint KeySplint Hard	- Copolyester Plastic - Ethylene vinyl acetate copolymer	The polycarbonate resin is the same as used in a 510(k) cleared device of similar design and intended use. The ApneaRx Pro incorporates custom-fabricated liners utilizing an FDA-cleared material indicated for this purpose.
Desirable Characteristics	- Home use - Adjustable jaw advancement position - Custom-fabricated liners - Enhanced jaw mobility	- Home use - Adjustable jaw advancement position - Heat sensitive / moldable liners	The ApneaRx Pro retains the same essential adjustable tray design, but incorporates custom-fabricated liners and enables modest jaw mobility.
Specifications: - Physical: - Mechanical: - Single use:	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 10 mm - Reusable - Upper liner allows vertical jaw movement.	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 10 mm - Reusable	The upper tray design to enhance range of motion does not create new risks and mitigates issues of discomfort and dislodging.
Sterility	Non-sterile	Non-sterile	
Biocompatibility	ISO 10993	ISO 10993	

Nonclinical Testing:

The ApneaRx Pro materials were tested for cytotoxicity, irritation, and sensitization and were determined to be biocompatible in accordance with ISO 10993. The material utilized for the custom-fabricated liners was previously cleared under K203000.

Device materials were tested for various physical properties. The tray material was tested for flexural modulus and strength (ISO 178), stress and strain at break (ISO 527), and water absorption (ISO 62). The liner material was tested for flexure strength (ASTM D790), and shore hardness (ASTM D2240). All materials met device specifications. The device was tested to failure under increasing strain in the medial and lateral directions and the force required to cause integrity failure

exceeds the natural jaw forces expected under anticipated use conditions.

Conclusion of Comparison: ApneaRx Pro and its predicate are technologically equivalent. The ApneaRx is fitted by the 'boil-and-bite' method that is equivalent to that used for multiple OTC devices while the ApneaRx Pro incorporates custom-fabricated liners assembled to a molded polycarbonate chassis. The slight design changes to enable a slightly greater degree of freedom in upper-liner movement does not raise substantial new questions of safety or effectiveness. Therefore, the new device (ApneaRx Pro) is determined to be substantially equivalent to the predicate device.