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 9, 2016

Apnea Sciences Corporation
c/o James Smith, Ph.D.
29442 Pointe Royale
Laguna Niguel, California 92677

Re: K153200
Trade/Device Name: SnoreRx®
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: July 27, 2016
Received: July 28, 2016

Dear Dr. 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. 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" (21CFR 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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)*
K153200

Device Name
SnoreRx

Indications for Use *(Describe)*

The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of 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.

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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	29442 Pointe Royale Laguna Niguel, CA 92677
Telephone	949-340-7261
Fax:	949-340-7141
E-mail:	jrsmith00@cox.net

Date Prepared: October 30, 2015

Trade Name: SnoreRx

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

Predicate Device: SnoreRx NS 9.0 (Consumer Health Products, Inc.)
Predicate 510(k) #: K112205

Device Description: The SnoreRx is an intraoral device that repositions the jaw anteriorly in order to increase the patient's pharyngeal space, which improves the ability to exchange air and decreases air turbulence, a causative factor in snoring. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth.

Intended Use: The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Technology Comparison: The devices are nearly identical in design and functionality. Both the SnoreRx and its predicate consist of intraoral mouth pieces that are molded to the patient's teeth using a 'boil and

bite' method, and allows adjustment of the anterior positioning of the jaw to the patient's comfort. The SnoreRx is provided non-sterile and uses the same 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	SnoreRx	SnoreRx NS 9.0	
Technological	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	Minimize air turbulence that causes snoring. Device is intended for prescription use.	Minimize air turbulence that causes snoring. Device is intended for prescription use.	
Materials	- Polycarbonate resin - Ethylene vinyl acetate copolymer	- Polycarbonate resin - Ethylene vinyl acetate copolymer	The new device utilizes a polycarbonate resin with a higher tensile strength, and a copolymer with a slightly different durometer.
Desirable Characteristics	- Home use, heat sensitive / moldable, adjustable jaw advancement position	- Home use, heat sensitive / moldable, adjustable jaw advancement position	
Specifications: - Physical: - Mechanical: - Single use:	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 6 mm - Reusable	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 6 mm - Reusable	The new device utilizes a streamlined manufacturing process and has a frontal airway opening that is larger than the predicate device.
Sterility	Non-sterile	Non-sterile	
Biocompatibility	ISO 10993	ISO 10993	

Nonclinical Testing: The SnoreRx materials were tested for cytotoxicity, irritation, and sensitization and were determined to be biocompatible in accordance with ISO 10993. Biocompatibility test reports have been submitted as part of this filing.

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 melting point (ISO 3146), and density and melt flow rate (ISO 1183). All materials met device specifications.

Conclusion of Comparison: SnoreRx and its predicate are technologically identical. The minor differences in design and materials do not raise any new questions of safety or effectiveness. Therefore, the new device (SnoreRx) is determined to be substantially equivalent to the predicate device.