ApnoMed, Inc.
% Colette Cozean
Regulatory Consultant
Dr. Colette Cozean, PhD
21581 Midcrest Drive
Lake Forest, California 92630

November 24, 2018

Re: K181123
Trade/Device Name: ApnoDent Appliance
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: October 18, 2018
Received: October 19, 2018

Dear Colette Cozean:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.21 11:29:46 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181123

Device Name
ApnoDent

Indications for Use *(Describe)*
The ApnoDent® appliance is intended to reduce nighttime snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult 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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5. 510(k) Summary

Applicant:	ApnoMed, Inc. 1515 116th Ave NE. Suite 105C Bellevue WA, 98004 (425) 443-4020
Contact Person:	Colette Cozean, PhD 21581 Midcrest Drive Lake Forest, CA 92630 (949) 855-2885 colettecozean@gmail.com
Date Prepared	August 31, 2018
Proprietary Name	ApnoDent® Appliance
Common Name	Device, Snoring and Mild to Moderate Sleep Apnea
Classification Name	Intraoral devices for snoring; intraoral devices for snoring and obstructive sleep apnea (Class II, 21 CFR872.5570, Product Code LRK, LQZ)
Primary Predicate Device	mRNA (K130067)
Reference Predicate Devices	DynaFlex (K103076), OASYS-Oral Airway (K030440), Apinator-Oral Airway (K160123)

Description: The ApnoDent® appliance is a customized oral device featuring both lower and upper trays and interlocking system. The product is non-sterile, biocompatible, and provided in a sealed box with instructions for use.

The ApnoDent® appliance reduces snoring and mild to moderate sleep apnea by guiding the mandible forward during sleep, preventing the tongue and soft tissues of the throat from collapsing into the airway. Designed as a patient-specific device, the ApnoDent® series are manufactured to the dentist prescriber's requested advancement positions to provide a selection of gentle adjustments according to patient comfort and need. As such, prescribed advancements can be achieved by simply turning the advancing screws on both sides which are in contact with the inside of the lower teeth and guide the lower jaw forward.

The ApnoDent® design yields a small and a comfortable patient-specific mandibular advancement device. The design of the device maximizes tongue space and mandibular movement resulting in the ability to open and close during wear for patient comfort.

Indications for Use: The ApnoDent® appliance is intended to reduce nighttime snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older.

Technological Characteristics: The ApnoDent® appliance consists of upper and lower interlocking, customized trays. The ApnoDent® appliance is customized on models of the patient's teeth, using standard orthodontic acrylics and standard orthodontic wires for clasps and retention. The ApnoDent® appliance allows for inter1ocking of the upper and lower trays to adjust the mandibular position of the user. The technical characteristics are identical to the predicate devices.

All predicate devices (mRNA, DynaFlex, OASYS, Apinator-Oral Airway) also function as mandibular advancement devices to increase the patient's pharyngeal space and improve the ability to exchange air during

sleep. They each have customized upper and lower trays that interlock to advance the mandible. In all technological characteristics the subject device is substantially equivalent to the predicate devices.

Technological Characteristics

	Subject Device	***Primary Predicate***	***Reference Predicate #1***	***Reference Predicate #2***	***Reference Predicate #3***
	ApnoDent®	*mRNA Appliance*	*DynaFlex Anti-Snoring and Sleep Apnea Devices*	*Apinator-Oral Airway System*	*OASYS-Oral Airway System*
510(k) Number	*K181123*	*K130067*	*Kl03076*	*K160123*	*K030440*
Indication for Use	*Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.*	*Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.*	*Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.*	*Intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea*	*Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.*
Classification Name	*Device, Anti-Snoring and Obstructive Sleep Apnea*	*Device, Anti-Snoring and Obstructive Sleep Apnea*	*Device, Anti-Snoring and Obstructive Sleep Apnea*	*Device, Anti-Snoring and Obstructive Sleep Apnea*	*Device, Anti-Snoring and Obstructive Sleep Apnea*
Class	*II*	*II*	*II*	*II*	*II*
Product Code	*LRK, LQZ*	*LRK, LQZ*	*LRK, LQZ*	*LRK, LQZ*	*LRK, LQZ*
May be used in CPAP Intolerance	*yes*	*yes*	*yes*	*yes*	*yes*
Area of Use	*mouth*	*mouth*	*mouth*	*mouth*	*mouth*

Construction	*Industry-standard dental acrylic, stainless steel orthodontic wires, orthodontic adjustment screws*	*Industry-standard dental acrylic, stainless steel orthodontic wires, orthodontic adjustment screws*	*Industry-standard dental acrylic, stainless steel orthodontic wires, orthodontic adjustment screws*	*Industry-standard dental acrylic, stainless steel orthodontic wires, orthodontic adjustment screws*	*Industry-standard dental acrylic, stainless steel orthodontic wires, orthodontic adjustment screws*
Fabrication	*Customized*	*Customized*	*Customized*	*Customized*	*Customized*
Mechanism of Action	*Advancing the mandible*	*Advancing the mandible*	*Advancing the mandible*	*Advancing the mandible*	*Advancing the mandible*
Method of positioning of the mandible	*Screw adjustment*	*Screw adjustment*	*Screw adjustment*	*Screw adjustment*	*Screw adjustment*
Amount of mandible protrusion	*6-8 mm*	*6-8 mm*	*6-8 mm*	*6-8 mm*	*6-8 mm*
Prescription only	*yes*	*yes*	*yes*	*yes*	*yes*

Clinical and Non-Clinical Data: A biocompatibility and physical properties assessment was completed based on the material composition of the primary predicate, which concluded that the subject device was substantially equivalent to the primary predicate device. A risk assessment has also been conducted with the subject device, which concluded there are no additional risks as compared to the predicate device(s).

Summary: Based on the intended use, technical characteristics, and other data provided in this submission, the ApnoDent® appliance demonstrates substantial equivalence to the predicate devices in both safety and