Passion for Life Healthcare (UK) Limited
Paul Dryden
Consultant
Pioneer House, Pioneer Business Park North Road
Ellesmere Port, CH65 1AD GB

November 16, 2018

Re: K181396
Trade/Device Name: Oral Device OA, Oral Device S
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: October 16, 2018
Received: October 17, 2018

Dear Paul Dryden:

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: 2018.11.16 08:47:03 -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)*
K181396

Device Name
Oral Device-OA

Indications for Use *(Describe)*

The Oral Device-OA is intended to reduce night-time snoring and / or mild to moderate obstructive sleep apnea (OSA) for adults 18 and 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."

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)*
K181396

Device Name
Oral Device-S

Indications for Use *(Describe)*

The Oral Device-S is intended to reduce night time snoring for adults 18 and 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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510(k) Summary
9-Nov-18

Official Contact: Passion for Life Healthcare (UK) Limited
Pioneer House, Pioneer Business Park North Road
Ellesmere Port, CH65 1AD, United Kingdom

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Tel - +44 151 550 4708
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Submission Correspondent: Paul Dryden
Tel – (239) 307-6061
E-mail – paul.dryden@promedic.cc

Proprietary or Trade Name: Oral Device-OA and Oral Device-S

Common/Usual Name: Intra-oral appliance

Product Code: LRK
Product Classification Name: Device, anti-snoring, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
CFR Number: 21 CFR 872.5570
Class: 2

Predicate Devices: Oral Device-OA - K113569 – ApneaRx
Oral Device-S - K170825 – SnoreRx

Device Description
Passion for Life Healthcare UK Limited is offering two devices: 1) the Oral Device-S is an OTC device intended as an aid for the reduction of snoring; and 2) the Oral Device-OA is a Rx device intended as an aid for the reduction of mild to moderate obstructive sleep apnea, and/or snoring.

Both the Oral Device-S and Oral Device-OA are an oral appliance design concept based upon the use of a standard set of upper and lower trays of one size.

The Oral Device-OA is fitted by a dentist to act as a Mandibular Repositioning Device (MRD).

Whereas the Oral Device-S, an OTC device, is fitted by the user at home and any adjustments can be made without clinician interaction.

Indications for Use
Oral Device-OA
The Oral Device-OA is intended to reduce night-time snoring and / or mild to moderate obstructive sleep apnea (OSA) for adults 18 and older.

Oral Device-S
The Oral Device-S is intended to reduce night time snoring for adults 18 and older.

Environment of Use
Oral Device-OA
Home and clinical settings

510(k) Summary
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Oral Device-S
Home

Cautions, Warning, and Contraindications
Oral Device-OA

Warnings
Use of this device may cause:

- Tooth movement or changes in dental occlusion
- Dental sensitiveness after removing the Oral Device
- Gingival (gum) or dental soreness
- Pain or soreness of the jaw
- Obstruction of oral breathing
- Excessive salivation

Contraindications
The device is contraindicated for patients who:

- Suffer with central sleep apnea
- Have a severe respiratory disorder, such as asthma or emphysema
- Are under 18 years old
- Have been diagnosed with a joint disorder related to the jaw
- Have severe jaw pain, loose teeth or periodontal disease
- Have full dentures that are removed at night
- Wear fixed braces or a retainer at night
- Have had an implant less than 1 year ago

Cautions, Warning, and Contraindications
Oral Device-S
Warnings
Use of this device may cause:

- Tooth movement or changes in dental occlusion
- Dental sensitiveness after removing the Oral Device
- Gingival (gum) or dental soreness
- Pain or soreness of the jaw
- Obstruction of oral breathing
- Excessive salivation

Contraindications
The device is contraindicated for patients who:

- You suffer with central sleep apnea
- You have a severe respiratory disorder, such as asthma or emphysema
- You are under 18 years old
- You have been diagnosed with a joint disorder related to the jaw
- You have severe jaw pain, loose teeth or periodontal disease
- You have full dentures that are removed at night
- You wear fixed braces or a retainer at night
- You had a dental implant less than 1 year ago

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Comparison of Oral Device-OA to Predicate

We present in **Table 1** a comparison of the subject device, Oral Device-OA compared to the predicate ApneaRx – K113569.

Table 1 – Oral Device-OA vs. K113569 - ApneaRx

	Proposed Device Oral Device-OA	**Predicate Device ApneaRx K113569**
Attributes		
Indications for Use	The Oral Device-OA is intended to reduce night-time snoring and / or mild to moderate obstructive sleep apnea (OSA) for adults 18 and older.	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.
Environments of use	Home and clinical settings	Home and clinical settings
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• Suffer with central sleep apnea • Have a severe respiratory disorder, such as asthma or emphysema • Are under 18 years old • Have been diagnosed with a joint disorder related to the jaw • Have severe jaw pain, loose teeth or periodontal disease • Have full dentures that are removed at night • Wear fixed braces or a retainer at night • Have had an implant less than 1 year ago	• Suffer with central sleep apnea • Have a severe respiratory disorder, such as asthma or emphysema • Are under 18 years old • Have been diagnosed with a joint disorder related to the jaw • Have severe jaw pain, loose teeth or periodontal disease • Have full dentures that are removed at night • Wear fixed braces or a retainer at night • Have had an implant less than 1 year ago
Prescription	Prescription use	Prescription use
Duration of Use	Single patient, multi-use	Single patient, multi-use
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the trays by the use of screw adjustment to obtain a fixed advancement.	Adjustment of the relative position of the trays by the use of a latch adjustment to obtain a fixed advancement.
Design		
Tray Design	Pre-formed and fixed	Customized trays
Method to advance the mandible	Adjustable upper / lower tray for mandible repositioning	Adjustable upper / lower tray for mandible repositioning
Allows lateral and vertical movement	Allows for lateral and vertical movement	Allows for lateral and vertical movement
Maximum adjustment by the user	Up to 10 mm	Up to 10 mm
How it opens airway	Holds mandible / lower jaw forward	Holds mandible / lower jaw forward
Method of cleaning	Cleaned by simple rinsing with water and toothbrush	Cleaned by simple rinsing with water and toothbrush

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	Proposed Device Oral Device-OA	**Predicate Device ApneaRx K113569**
Performance Testing		
Biocompatibility and Patient contact	ISO 10993 Cytotoxicity Sensitization Irritation	ISO 10993 Cytotoxicity Sensitization Irritation
Durability testing	180 days	Not available
Performance testing	• Functional testing for durability after multiple cleanings equivalent to 180 days use • Flexural strength / Fracture Toughness • Water absorption / solubility • Mechanical / Tensile testing • Drop testing	Testing not available

Discussion of Substantial Equivalence for Oral Device-OA

The Oral Device-OA is viewed as substantially equivalent to the predicate device because:

Indications – Similar to predicate – ApneaRx – K113569; indicated for treating snoring and mild to moderate obstructive sleep apnea (OSA).
Discussion – The indications for use between the subject device and predicate are similar and therefore they can be found as substantially equivalent.

Technology / Principle of Operation – Similar to predicate – ApneaRx – K113569. Both devices use upper and lower trays with a means to advance the mandible / lower jaw.
Discussion – Both devices use separate upper and lower trays with a means to advance the mandible / lower jaw are similar. The predicate uses customized trays while the proposed device uses pre-formed trays. Both utilize an impression material to mold to the individual's teeth and to keep the trays in place. There is a difference in the trays is only related to sizing and the mechanism of advancing the trays with the proposed device using screws and the predicate a latch and lock mechanism.

Environment of Use – Similar to predicate – ApneaRx – K113569. They are used in Home and clinical settings.
Discussion – Both devices have similar environments of use and therefore they can be found as substantially equivalent.

Patient Population – Similar to predicate – ApneaRx – K113569. 18 years and older
Discussion – The patient population is similar and therefore they can be found as substantially equivalent.

Non-clinical performance testing
The Oral Device underwent the following testing:

- Functional testing for durability after multiple cleanings equivalent to 180 days use
- Flexural strength / Fracture Toughness

- Water absorption / solubility
- Mechanical / Tensile testing
- Drop testing

Biocompatibility of Materials
All the materials are considered per ISO 10993-1 per *FDA Guidance Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA* dated 11/12/2002

- Cytotoxicity
- Sensitization
- Irritation

Comparison of Oral Device-S to Predicate

Table 2 – Oral Device-S vs. K170825 – SnoreRx OTC

	Proposed Device Oral Device-S	**Predicate Device SnoreRx OTC K170825**
Attributes		
Indications for Use	The Oral Device-S is intended to reduce night time snoring for adults 18 and older.	The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.
Environments of use	Home	Home
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• You suffer with central sleep apnea • You have a severe respiratory disorder, such as • asthma or emphysema • You are under 18 years old • You have been diagnosed with a joint disorder • related to the jaw • You have severe jaw pain, loose teeth or periodontal disease • You have full dentures that are removed at night • You wear fixed braces or a retainer at night • You had a dental implant less than 1 year ago	• You suffer with central sleep apnea • You have a severe respiratory disorder, such as • asthma or emphysema • You are under 18 years old • You have been diagnosed with a joint disorder • related to the jaw • You have severe jaw pain, loose teeth or periodontal disease • You have full dentures that are removed at night • You wear fixed braces or a retainer at night • You had a dental implant less than 1 year ago

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	Proposed Device Oral Device-S	**Predicate Device SnoreRx OTC K170825**
OTC	OTC	OTC
Duration of Use	Single patient, multi-use	Single patient, multi-use
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the trays by the use of screw adjustment to obtain a fixed advancement.	Adjustment of the relative position of the trays by the use of latch adjustment to obtain a fixed advancement.
Design		
Tray Design	Pre-formed and fixed	Pre-formed and fixed
Method to advance the mandible	Adjustable upper / lower tray for mandible repositioning	Adjustable upper / lower tray for mandible repositioning
Allows lateral and vertical movement	Allows for lateral and vertical movement	Allows for lateral and vertical movement
Maximum adjustment by the user	Up to 6 mm	Up to 6 mm
How it opens airway	Holds mandible / lower jaw forward	Holds mandible / lower jaw forward
Method of cleaning	Cleaned by simple rinsing with water and toothbrush	Cleaned by simple rinsing with water and toothbrush
Performance Testing		
Biocompatibility and Patient contact	ISO 10993 Cytotoxicity Sensitization Irritation	ISO 10993 Cytotoxicity Sensitization Irritation
Durability testing	180 days	Not available
Performance testing	• Functional testing for durability after multiple cleanings equivalent to 180 days use • Flexural strength / Fracture Toughness • Water absorption / solubility • Mechanical / Tensile testing • Drop testing	Testing not available

Discussion of Substantial Equivalence for Oral Device-S

The Oral Device-S is viewed as substantially equivalent to the predicate device because:

Indications – Similar to predicate – SnoreRx OTC – K170825; indicated for reducing night-time snoring.
Discussion – The indications for use between the subject device and predicate are similar and therefore they can be found as substantially equivalent.

Technology / Principle of Operation – Similar to predicate – SnoreRx OTC – K170825. Both devices use upper and lower trays with a means to advance the mandible / lower jaw.
Discussion – Both devices use separate pre-formed trays with a means to advance the mandible / lower jaw that are similar. Both utilize an impression material to mold to the individual's teeth and to keep the trays in place. They use a screw or a latch and lock mechanism to advance and hold the trays in their advanced position.

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Environment of Use – Similar to predicate – SnoreRx OTC – K170825. They are used in Home settings.
Discussion – Both devices have similar environments of use and therefore they can be found as substantially equivalent.

Patient Population – Similar to predicate – SnoreRx OTC – K170825. 18 years and older
Discussion – The patient population is similar and therefore they can be found as substantially equivalent.

Non-clinical performance testing
The Oral Device underwent the following testing:

- Functional testing for durability after multiple cleanings
- Flexural strength / Fracture Toughness
- Water absorption / solubility
- Mechanical / Tensile testing
- Drop testing

Biocompatibility of Materials
All the materials are considered per ISO 10993-1 per *FDA Guidance Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA* dated 11/12/2002

- Cytotoxicity
- Sensitization
- Irritation

Discussion of Differences
The differences between the Oral Device –OA predicate – ApneaRx – K113569 and the Oral Device-S and the predicate SnoreRx – K170825 are:

- For the Oral Device-OA the predicate trays are customized but the principle of a boil and bite tray with impression material is similar.
- The mechanism for advancing the trays is a set of screws for the Oral Device while the predicate uses clips on the side to latch and hold the trays in the advanced position.

Substantial Equivalence Conclusion
Based upon the performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance we believe we have demonstrated that the Oral Device-OA is substantially equivalent to the predicate ApneaRx – K113569 and the Oral Device-S is substantially equivalent to the predicate SnoreRx OTC – K170825.