Airway Management, Inc.
Paul Dryden
Consultant
3418 Midcourt Road
Carrollton, Texas 75006

August 31, 2018

Re: K181482
Trade/Device Name: myTAP2
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: June 3, 2018
Received: June 5, 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 -S

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)*
K181482

Device Name

myTAP2

Indications for Use *(Describe)*

The myTAP2 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) [X] 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.

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Official Contact: Eric Jarrett - Director of Quality and Regulatory
Airway Management
3418 Midcourt Road, #114
Carrollton, TX 75006
866.264.7667 x 354

Proprietary or Trade Name: myTAP2

Common/Usual Name: Intra-oral appliance

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

Predicate Devices: K170825 – Apnea Sciences – SnoreRx

Device Description
The myTAP2 is an oral appliance design concept based upon the use of a standard set of upper and lower trays filled with an impression material. A screw is used to advance the lower tray. The myTAP2 is of a design often referred to as a "Boil and Bite" and the concept of advancement is commonly referred to as a Mandibular Repositioning Device (MRD).

The principle of advancing a lower or upper tray so that it advances the mandible to aid in reducing snoring is well known and there are a number of predicate devices.

Indications for Use
The myTAP2 is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Environment of Use
Home and clinical settings

Contraindications
Oral Device-OA
The device is contraindicated for patients who:

- Has central sleep apnea
- Is under the age of 18
- Has a history of TMD, temporomandibular disorder
- Has received dental implants, crowns, caps, unless approved by your dentist
- Has other dental appliances, dentures or is undergoing orthodontic treatment
- Has loose teeth, abscesses, or severe gum disease
- Have a history of chronic asthma, emphysema, or any respiratory disorder, unless approved by their physician

Comparison of myTAP2 to Predicate

We present in **Table 1** a comparison of the subject device, myTAP2 compared to the predicate Apnea Sciences – SnoreRx – K170825.

Table 5.1 – Comparison to Predicate

	Proposed Device myTAP2	**Predicate Device SnoreRx K170825**
Attributes		
Indications for Use	The myTAP2 is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	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	• Has central sleep apnea • Is under the age of 18 • Has a history of TMD, temporomandibular disorder • Has received dental implants, crowns, caps, unless approved by your dentist • Has other dental appliances , dentures or is undergoing orthodontic treatment • Has loose teeth, abscesses, or severe gum disease • Have a history of chronic asthma, emphysema, or any respiratory disorder, unless approved by their physician	• Has central sleep apnea • Is under the age of 18 • Has a history of TMD, temporomandibular disorder • Has received dental implants within the past year • Has dentures or is undergoing orthodontic treatment • Has loose teeth, abscesses, or severe gum disease • Have a history of chronic asthma, emphysema, or any respiratory disorder, unless approved by their physician
Warnings	• Tooth movement or changes in dental occlusion • Dental sensitiveness after removing the myTAP2 • Gingival (gum) or dental soreness • Pain or soreness of the jaw • Obstruction of oral breathing • Excessive salivation	• Tooth movement or changes in dental occlusion • Gingival or dental soreness • Pain or soreness to the temporomandibular joint • Obstruction of oral breathing • Excessive salivation
OTC	Yes	Yes
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.	Adjustment of the relative position of the trays using fixed advancement on the side of the trays.
Design		
Tray Design	Pre-formed and fixed	Pre-formed and fixed
Allows lateral and vertical movement	Allows for lateral and vertical movement	Does **not** allow for lateral and vertical movement
Maximum adjustment by the user	Up to 5 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

	Proposed Device myTAP2	**Predicate Device SnoreRx K170825**
Performance Testing		
Biocompatibility and Patient contact	Cytotoxicity Sensitization Irritation Surface Contacting, Mucosal membrane, with duration of use prolonged > 24 hours ≤ 30 days	Cytotoxicity Sensitization Irritation Surface Contacting, Mucosal membrane, with duration of use prolonged > 24 hours ≤ 30 days
Durability testing	1 year	N/A
Performance testing	• Functional testing for durability after multiple cleanings equivalent to 365 days use • Flexural strength • Mechanical / Tensile testing • Drop test	Testing not available

Discussion of Substantial Equivalence for myTAP2

The myTAP2 is viewed as substantially equivalent to the predicate device because:

Indications –
Similar to predicate – SnoreRx – K170825 **–** indicated as an aid for the reduction of snoring.
Discussion – The indications for use between the subject device and predicate are similar.

Technology / Principle of Operation –
Similar to predicate – SnoreRx – K170825. 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 that is similar. Both devices use pre-formed trays filled with an impression material to mold to the individual's teeth and to keep the trays in place. The means of setting the advancement is done with a screw on the subject device while the predicate has latches on the side which are locked to keep the trays in the advanced position. The difference in advancement means does not raise different concerns of safety or effectiveness from the predicate.

Environment of Use –
Similar to predicate – SnoreRx – K170825. They are used in Home settings.
Discussion – Both devices have similar environments of use.

Population –
Similar to predicate – SnoreRx – K170825 - 18 years and older
Discussion – The patient population is similar.

Labeling –
We made several changes which we believe are applicable and appropriate and have incorporated them in the proposed labeling.

Contraindications –
The contraindications are similar for both devices.

STOP Bang Survey –
There is the inclusion of the Stop Bang survey in both device labels. We propose a slight difference in wording from the subject device to the available predicate wording. The wording changes we believe that the intent and description is clear for the potential user.

The Instructions for Use have been designed to be nearly identical to the predicate labeling to reflect appropriate content for the user.

OTC Designation –
Both devices are designated for OTC. The predicate SnoreRx – K170825 was originally cleared as Rx Only and then recently was cleared for OTC designation under K170825.
Discussion – Both are OTC designation and thus similar.

Non-clinical performance testing
The myTAP2 underwent the following testing:

- Functional testing for durability after multiple cleanings equivalent to 365 days use
- Flexural strength
- Mechanical / Tensile testing

Biocompatibility of Materials
All the materials are considered per ISO 10993-1 as Surface Contacting, Mucosal membrane, with duration of use prolonged > 24 hours ≤ 30 days, 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

Based upon the *Guidance* the ISO 10993-1 testing would be:

- Cytotoxicity
- Sensitization
- Irritation

In addition to the aforementioned biocompatibility tests, Airway Management also performed Acute Systemic Toxicity.

Discussion of Differences
The differences between the myTAP2 and predicate – SnoreRx – K170825 are:

- The mechanism for advancing the trays is an adjustment screw for the myTAP2 and a manual clip mechanism for the predicate.
- Labeling
    - Slight wording changes to the Stop Bang survey

These differences do not raise difference concerns of safety or effectiveness.

Substantial Equivalence Conclusion
Based upon the performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance demonstrates that myTAP2 is substantially equivalent to the predicate SnoreRx– K170825.