DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 7, 2017

Fuselier Enterprises, LLC
Paul Dryden
Consultant
2051 Mohican Trail
Maitland, Florida 32751

Re: K161980
Trade/Device Name: Fuselier Intraoral Nighttime Device (find)
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: January 4, 2017
Received: January 6, 2017

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. 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" (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 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.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

510(k) Number *(if known)*

K161980

Device Name

Fuselier Intraoral Nighttime Device

Indications for Use *(Describe)*

A patient specific mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.

Type of Use *(Select one or both, as applicable)*

XX 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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Fuselier Enterprises, LLC
2051 Mohican Trail
Maitland, FL 32751

Official Contact:	Brian Fuselier, Owner
Proprietary or Trade Name:	Fuselier Intraoral Nighttime Device
Common/Usual Name:	Device, Anti-Snoring
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 Device:	K972061 – Keith Thornton, DDS – Thornton Oral Appliance (TOA)
Reference Devices:	K090436 – Orthoplant Dental - Airwayease MAS K896130 – Ivoclar Vivadent - SR Ivocap Polymer

Device Description:
The Fuselier Intraoral Nighttime Device (FIND) is a patient specific oral device intended to mitigate night-time snoring and mild to moderate obstructive sleep apnea. The function of the FIND is to continuously hold the mandible in an advanced position to prevent the tongue from compressing against the oropharyngeal wall keeping the airway open during sleep.

The principle of advancing a lower tray is to advance the mandible for the treatment of night-time snoring and / or mild to moderate obstructive sleep apnea.

Indications for Use
A patient specific mandibular repositioning oral appliance intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.

Contraindications
The following contraindications are noted in the labeling. These are typical of oral appliances for the proposed indications for use and suggested by FDA's guidance document.

The device is contraindicated for patients who:
- have central sleep apnea
- have severe respiratory disorders
- have loose teeth or advanced periodontal disease
- have loose dental work
- oral conditions which would be adversely affected by wearing dental appliances
- full denture user
- are under 18 years of age

Warnings
Use of this device may cause:
- tooth movement
- changes in dental occlusion
- gingival soreness

- tooth soreness
- pain or soreness to the temporomandibular joint
- obstruction of oral breathing
- excessive salivation
- excessive dry mouth
- loosening of dental restorations
- loosening of teeth

Environment of Use
Home, Dental offices, and Sleep laboratories

Predicate Device Comparison:
We selected a predicate for the Fuselier Intraoral Nighttime Device and present the similarities in **Table 1**.

Table 1 – Predicate Device Comparison

	Subject Device **Fuselier Intraoral Nighttime Device**	**Predicate** **Thornton Oral Appliance (TOA)** **K972061**
Product Classification	LRK – device, anti-snoring Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	LRK – device, anti-snoring Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Attributes		
Indications for Use	A patient specific mandibular repositioning oral appliance intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.	The TOA is intended to reduce or alleviate nighttime snoring and obstructive sleep apnea, OSA.
Environments of use	Home, dental and Physician offices, Sleep laboratories	Home, dental and Physician offices, Sleep laboratories
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the trays by the use of an adjustable post that holds the mandible forward and maintains mandibular advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position	Adjustment of the relative position of the trays by the use of hook which pulls the mandible forward and maintains mandibular advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position

	Subject Device **Fuselier Intraoral Nighttime Device**	**Predicate** **Thornton Oral Appliance (TOA)** **K972061**
Design		
Patient specific trays	Yes	Yes
Allows lateral and vertical movement	Yes	Yes
User can breathe through their mouth	Yes	Yes
Maximum adjustment by the user	8 mm	8 mm
Adjustment method for setting the amount of protrusion	Adjustable screw/post holds the lower tray forward	Hook pulls the lower tray forward
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water and toothbrush	Yes	Yes
Materials and Biocompatibility	Surface contact Mucosal Prolonged duration per FDA Guidance for intraoral appliances	Surface contact Mucosal Prolonged duration per FDA Guidance for intraoral appliances
Performance Testing		
Material Properties	Performance testing related to torque and tensile strength was performed and compared to the predicate	Use of standard dental tray materials
Flexural Strength **Breakage Strength**	Angle of deflection – 0.85 degrees 77 lbs. to damage	Angle of deflection – 1.25 degrees 70 lbs. to damage
Cleaning and Effects of Aging	Private clinical practice of 1 year with 150 patients has demonstrated that the FIND does not degrade with time, cleaning or age	Data not available

Discussion of Substantial Equivalence to the Predicate

The Fuselier Intraoral Nighttime Device is viewed as substantially equivalent to the predicate device because:

Indications – Similar to predicate – Thornton Oral Appliance - K972061. Indicated for treating night-time 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 – Thornton Oral Appliance - K972061. Both devices use separate patient specific trays with a means to advance the mandible / lower jaw.
Discussion – Both devices use separate patient specific trays with a means to advance the mandible / lower jaw are similar and therefore they can be found as substantially equivalent.

Environment of Use – Similar to predicate – Thornton Oral Appliance - K972061. They are used in Home, Dental and Physician offices, Sleep laboratories.
Discussion – Both devices have the same environments of use and therefore they can be found as substantially equivalent.

Patient Population – Identical to predicate – Thornton Oral Appliance - K972061. 18 years and older

Discussion – The patient population is identical and therefore they can be found as substantially equivalent.

Non-clinical performance testing

Real-time Aging
The FIND has been used in a private dental practice for more than 1 year without device failures. The results of this experience support the substantial equivalence of the FIND for its proposed intended use to that of the predicate device.

The observations support:

- Cleaning via rinsing with water and use of a toothbrush
- Mechanical and durability after 1 year real-time use
- Effects of aging do not alter the performance of the device

Mechanical Performance
We performed flexural and breakage strength testing on the subject device and the predicate and the construction and design performance were tested and found to be substantially equivalent.
Discussion – We evaluated the strength of the tray materials and design based upon its intended use and flexural and breakage strength were the key factors to evaluate. Flexural strength saw the FIND to be slightly strong, less angular deflection under torque and the breakage strength – FIND had a slightly high force need before damage was observed. The comparative testing to the predicate demonstrated equivalence in performance.

Biocompatibility / Materials
The materials in contact with the patient have been cleared for the intended use of dental trays. The materials for the trays are identical to K896103 – IVOCap materials for the intended purpose of dental trays. In addition, the reference device, Orthoplant Dental Lab Airwayease MAS, K090436, utilizes the identical material for their oral appliance.

Clinical
Based upon Fuselier Intraoral Nighttime Device design concept, it was determined that no clinical testing would be required as we are identical in this principle of operation and technology as well as performance specification, namely maximum advancement distance. Also, the specifications of the ability to advance the lower tray are the same and the maximum advancement is similar to the predicate.

Discussion of Differences

The primary difference between the Fuselier Intraoral Nighttime Device and the predicate is the coupling system that holds the movable lower jaw in a forward position. This difference does not raise new concerns of substantial equivalence to the predicate device.

As presented in the above table, the proposed Fuselier Intraoral Nighttime Device is substantially equivalent to the identified predicate. The Fuselier Intraoral Nighttime Device and predicate are patient specific upper and lower trays, with a means of advancing the mandible to treat mild to moderate obstructive sleep apnea and snoring.

As indicated and discussed above, the fundamental features, indications for use, environment of use are identical to the predicates and thus the proposed Fuselier Intraoral Nighttime Device oral

appliance can be found to be substantially equivalent to the listed predicate - Thornton Oral Appliance – K972061.

We have also included reference devices and **Table 2** presents the comparison to the subject device.

Table 2 – Comparison of Reference Devices to Subject Device

	K896130 **Ivoclar Vivadent** **SR Ivocap Polymer**	**K090436** **Orthoplant Dental** **Airwayease MAS**	**FIND** **Proposed Device**
Intended Use	For the making of dental trays	The Airwayease MIAS is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea.	A patient specific mandibular repositioning oral appliance intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.
Population	No restrictions on population as this is dental tray material only	Adult patients 18 years or older who have a problem with snoring or obstructive sleep apnea.	Adult patients 18 years and older.
Environment of Use	Dental applications	The device is initially fitted under the supervision of a licensed practitioner (dentist or physician) and is subsequently used in either a home environment or in a sleep laboratory.	Home, dental and Physician offices, Sleep laboratories
Materials	Material specifications sent directly to FDA	The material composition of the Airwayease MAS is identical to the Ivocap Elastomer cleared in K896130. No colorants or additives have been added to the originally cleared Ivocap Elastomer.	The material composition of the FIND is identical to the Ivocap Elastomer cleared in K090436. No colorants or additives have been added to the originally cleared Ivocap Elastomer.
Technological features	This is material to make dental trays so there are technological features that relate to the subject device except that the material is intended for dental applications such as the subject device	2 trays which are adjustable to act as a mandibular repositioner	2 trays which are adjustable to act as a mandibular repositioner

Discussion of Reference Devices

We have selected reference devices which support the use of the intended materials for the intended use. K896130 is the Dental Tray material that has been used for many types of dental trays. K090436 specifically is an intra-oral appliance with the same intended use, patient population, and environment of use that utilizes the identical materials.

There are no differences between the reference devices and the subject device that would raise concerns of substantial equivalence.

Substantial Equivalence Conclusion –

Based upon the performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance we have demonstrated that the FIND is substantially equivalent to the predicate device.