July 2, 2019

Stephen J Harkins, DDS, PC
% Paul Dryden
Consultant
Stephen J Harkins, DDS, PC c/o ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K190687
Trade/Device Name: Twilite 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
Dated: June 5, 2019
Received: June 6, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K190687

Device Name

Twilite Appliance ®

Indications for Use *(Describe)*

The Twilite Appliance ® is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years and 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.

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."

510(k) Summary
1-July-19

Stephen J Harkins, DDS, PC
4781 E. Camp Lowell Dr. #101
Tucson, AZ 85712 Tel - 520-465-7203

Official Contact: Stephen Harkins, DDS

Submission Correspondent: Paul Dryden
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Proprietary or Trade Name: Twilite Appliance ®

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

Primary Predicate: K172859 - Prosomnus [CA] Sleep and Snore Device
Reference Device: K153490 – Dental Direkt – DD Biosplint P

Device Description:
The Twilite Appliance ® is a customized oral device intended to mitigate night-time snoring and mild to moderate obstructive sleep apnea. The function of the Twilite Appliance ® 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.

Indications for Use
The Twilite Appliance ® is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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

Primary Predicate Comparison:
We selected a predicate for the Twilite Appliance ® and present the similarities in **Table 1**.

Table 1 – Primary Predicate Comparison

	Subject Device Twilite Appliance ®	**Primary Predicate Prosomnus [CA] Sleep and Snore Device - K172859**
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
CFR	872.5570	872.5570
Attributes		
Indications for Use	The Twilite Appliance ® is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The Prosomnus [CA] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The DentiTrac® micro-recorder is completely embedded into the Prosomnus [CA] Sleep and Snore appliance. The microrecorder is intended to measure patient compliance to the oral appliance therapy in combination with the DentiTrac® System
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

510(k) Summary
1-July-19

	Subject Device Twilite Appliance ®	**Primary Predicate Prosomnus [CA] Sleep and Snore Device - K172859**
Contraindications	• 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	• 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
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	No limitation	No limitation
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the trays by the use of an elastic bands 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	The Prosomnus [CA] Sleep and Snore device series consists of one or multiple lower device(s) together with one or multiple mated-post upper device(s) that are manufactured to the dentist prescriber's requested advancement positions up to 11mm to provide a selection of gentle adjustments according to patient comfort and need.
Design		
Customized trays	Yes	Yes
Allows lateral and vertical movement	Yes	Yes
User can breathe through their mouth	Yes	Yes
Adjustment method for setting the Amount of protrusion	Posts on the lower tray are adjusted to hold the lower jaw forward at a dentists pre-determined distance	Multiple lower trays can be made where each has greater protrusion up to 11 mm User can substitute different lower trays to advance the jaw
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water and toothbrush	Yes	Yes
Single patient, multi-use	Yes	Yes
Principle of operation / means of mandibular advancement	Fixed posts on the lower tray hold the lower jaw forward.	Fixed posts on the lower tray hold the lower jaw forward.
Adjustment method for setting the amount of protrusion	Fixed posts on the lower tray hold the lower jaw forward. The dentist adjusts the posts for the required amount of protrusion	Fixed posts on the lower tray hold the lower jaw forward. The dentist adjusts the posts for the required amount of protrusion

510(k) Summary
1-July-19

	Subject Device Twilite Appliance ®	**Primary Predicate Prosomnus [CA] Sleep and Snore Device - K172859**
Materials and Biocompatibility	Surface contact Mucosal Prolonged duration per FDA Special Controls for intraoral appliances Material is identical to K153490.	Surface contact Mucosal Prolonged duration per FDA Special Controls for intraoral appliances
Material Properties	Use of standard dental tray materials Material is identical to K153490	Use of standard dental tray materials
Performance Testing	• Flexural strength / Fracture Toughness • Water absorption / solubility • Mechanical / Tensile testing	Compression and Shear Torsion Testing

Discussion of Substantial Equivalence

The Twilite Appliance ® is viewed as substantially equivalent to the predicate device because:

Indications –
Similar to predicate – Prosomnus [CA] Sleep and Snore Device – K172859. 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 – Prosomnus [CA] Sleep and Snore Device – K172859. Both devices use separate customized trays with a means to advance the mandible / lower jaw.
Discussion –
Both devices use separate customized 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 – Prosomnus [CA] Sleep and Snore Device – K172859. 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 – Prosomnus [CA] Sleep and Snore Device – K172859. 18 years and older.
Discussion –
The patient population is identical and therefore they can be found as substantially equivalent.

510(k) Summary
1-July-19

Non-clinical performance testing

Bench Testing
The materials for the trays are made from materials cleared for use as dental trays. In additions to the materials meeting dental standards, we performed testing after manufacture and aging for:

- Flexural strength / Fracture Toughness

Biocompatibility / Materials
The materials in contact with the patient have been cleared for the intended use of dental trays. The materials are dental tray materials cleared under K153490.

Clinical
Based upon Twilite Appliance ® 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 Substantial Equivalence to Reference

Table 2 – Comparison of the Subject Device vs. the Reference K153490

	Subject Device Twilite Appliance ®	**Reference Dental Direkt DD BioSplint P**
Product Classification	LRK – device, anti-snoring Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	EBG, MQC Temporary crown and bridge resin
CFR	872.5570	872.3770
510(k)	K190687	K153490
Attributes		
Indications for Use	The Twilite Appliance ® is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	DD medical polymers are indicated for temporary (:S 12 months) crowns, bridges and bite splints. Applications include both anterior and posterior structures.
Environments of use	Home, Dental and Physician offices, Sleep laboratories	Home, Dental offices
Patient Population	Adult patients 18 years and older	No patient limitations
Contraindications	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age	No noted contraindications
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	No limitation	Less than 12 months
Design		
Customized trays	Yes	Yes
Single patient, multi-use	Yes	Yes
Materials and Biocompatibility	Surface contact Mucosal Prolonged duration per FDA Special Controls for intraoral appliances Identical to K153490	Tested per ISO 10993-1 ISO 10477:2004 – Polymer-based Crown and Bridge Materials ISO 20795-1:2013 Dentistry – Base Polymers - Denture
Material Properties	Use of standard dental tray materials Material is identical to K153490	Crowns, bridges, bile splints
Performance Testing	• Flexural strength / Fracture Toughness • Mechanical / Tensile testing Identical material to K153490	• Flexural strength • Flexural modulus • Residual MMA monomer • Water sorption • Solubility

The Twilite Appliance ® is viewed as substantially equivalent for the applicable performance to the reference device because:

Indications –
The reference is indicated for use for crowns, bridges and bite splints. The subject device is a form of dental tray similar to a bite splint.

The difference in indications for use does not raise new or different concerns that haven't been addressed by the predicate.

Technology / Principle of Operation –
Similar to reference the subject device is a customized tray that can be used by a patient. The material is identical and is provided in a block which is then milled to the patient's specific shape. This is the identical intended method of the reference, K153490.
Discussion – The reference is a tray form that can be used as needed. The difference does not raise new or different concerns that can't be addressed by the predicate.

Patient Population –
Discussion – The patient population is not identified in the reference, but the general population are people who require a dental tray.

Non-clinical performance testing

Bench Testing
The materials for the trays are made from reference tested materials that have been tested and the data provided in K153490. In addition to the materials meeting dental standards, we performed testing after manufacture and aging for:

- Flexural strength / Fracture Toughness

Biocompatibility / Materials
The materials in contact with the patient are identical to the reference K153490.
There are no differences.

Discussion of Differences and Substantial Equivalence Conclusion

There are few differences between the Twilite Appliance ® and the predicate. These are discussed above.

For the reference comparison, the materials are identical, but the reference was only cleared for crowns, bridges and bite splints for use of less than 12 months. However, the clinical experience for the proposed device has shown that it can be used for greater than 12 months based upon the indications for use. All differences have been addressed via performance testing and has demonstrated substantial equivalence to the primary predicate device.

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 Twilite Appliance ® is substantially equivalent the predicate device.