January 28, 2020

Advanced Facialdontics LLC
Scott Simonetti
President
325 Lake Ave. Unit 759
St James, New York 11780

Re: K192581
Trade/Device Name: The NightBlocks 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: LQZ, LRK
Dated: December 17, 2019
Received: December 19, 2019

Dear Scott Simonetti:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K192581

Device Name
The NightBlocks™ Appliance

Indications for Use *(Describe)*
The NightBlocks™ Appliance is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The NightBlocks™ Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.

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.

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510(k) Summary

1. Owner Information

Owner's Name:	Advanced Facialdontics LLC
Owner's Address:	325 Lake Ave Unit 759 St James, NY 11780
FDA Registration #:	3015733038
Telephone:	(631) 379-3902
Fax:	(631) 234-7985
Contact Person:	Dr Scott Simonetti
Email:	ssimonettidds@yahoo.com
Date Prepared:	1/10/2020

2. Device Name

Trade Name:	The NightBlocks™ Appliance
510K Number:	K192581
Common Name:	Device, Jaw Repositioning
Classification:	Class II
Product Code:	LQZ, LRK
Review Panel:	Dental
Regulation:	CFR 872.5570

3. Predicate Devices

Primary Predicate:	ATG/SM-OSA Appliances (K130130)
Reference Devices:	SML-OSA2 Appliances (K162816) Lamberg Sleep Well-Smartrusion, LSW-S (K101709)

4. Device Description

The NightBlocks™ appliance consist of two removable, custom fabricated acrylic trays that fit separately over the upper and lower dental arches and engage each other in order to reposition the mandible in a slightly anterior position. They contain stainless-steel ball clasps for extra retention and stainless-steel orthodontic expansion screws on

the buccal portion of the upper tray that engage with the dorsal wings of the lower tray. The trays occlude on the left or right molar and premolar region. Every device is custom prescribed and fabricated for each patient from dental models and is adjustable at the time of delivery and anytime thereafter as it is intended to be used in the home setting.

The principal of operation is jaw repositioning. Worn during sleep, the NightBlocks™ function as a mandibular advancement device which acts to increase the patient's pharyngeal airway space, improving their ability to exchange air during sleep. The anterior repositioning of the mandible prevents the tongue from sliding backward or downward for a prone sleeping individual. Therefore, the airway will be larger, contributing to the reduction in snoring and mild to moderate sleep apnea.

Materials: Polymethylmethacrylate Polymer and Monomer (Lang Orthodontic Acrylic K141439), medical grade stainless steel wire (AJ Wilcock), and orthodontic stainless-steel expansion screws (Leone).

5. ***Indications for Use***:

The NightBlocks™ Appliance is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The NightBlocks™ Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.

6. Technological Characteristics Comparison to Predicate Device:

Intended Use*:* The intended use and the *Indications of Use* for the proposed device and predicate are identical.

Technological Characteristics: The predicate and the subject device have the exact same following technological characteristics:

Principle of operation, *Indications of Use*, Prescription device custom fabricated, intraoral jaw repositioning device for sleep apnea, environment of use: home, removable by patient and reusable, location of advancement mechanism, provided non-sterile, and identical raw materials, manufacturing, finishing and cleaning process.

The only minor design differences between the proposed device and predicate is the location of the occluding surface of the upper and lower trays, and the inclusion of additional braided stainless-steel supporting wire within the dorsal wings.

Table 1: Comparison of Intraoral Jaw Repositioning Devices

Device	**Subject Device** **NightBlocks™ Appliance**	**Predicate Device** **ATG/SM-OSA, Adjustable Dorsal Appliance K130130**	**Reference Device** **SML-OSA2 Appliances K162816**	**Reference Device** **Lamberg Sleep Well Smartrusion K101709**
Product Codes	LQZ, LRK	LQZ, LRK	LQZ, LRK	LQZ, LRK
Indications for Use	The NightBlocks™ Appliance is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The NightBlocks™ Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.	The ATG/SM-OSA Appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The ATG/SM-OSA appliances are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.	The SML-OSA2 Appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The SML-OSA2 appliances are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.	For the reduction of nighttime snoring and mild to moderate obstructive sleep apnea in adults 18 years of age or older. Prescription use only.
Target Population	Adults who snore or have obstructive sleep apnea.	Same	Same	Same
Design Features	Prescription device custom fit	Same	Same	Same

	Intraoral device fitted over upper and lower dentition	Same	Same	Same
Sterility	Provided Non-sterile	Same	Same	Same
Human Factors	Removable by patient and reusable	Same	Same	Same
Environment of Use	Home	Same	Same	Same
Principle of Operation	Mandibular Repositioning with custom fitted acrylic upper and lower components. This advances the mandible anteriorly to enlarge the airway.	Same	Same	Same
	Expansion mechanism placed on buccal portions for unobstructed airway passage.	Same	Same	Expansion mechanism located in anterior portion of mouth.
	Mandible can be advanced with two buccal expansion screws up to 6mm.	Same	Varying advancement mechanisms.	Advancement by dentist adding acrylic material to the anterior protrusive element
Materials	Methyl methacrylate, medical grade stainless steel, Orthodontic Expansion screws	Same, and additional colorant	Same	Methyl methacrylate, Stainless steel, and copolyester.
Biocompatibility	Uses all FDA cleared Class I materials that are commonly used in dentistry.	Same	Same	Same
Compatibility with the environment and other devices	Does not release any compounds harmful to the environment and pother devices.	Same	Same	Same

Electrical, radiation, chemical, and thermal safety	The device does not use electricity, radiation, heat or chemicals to function.	Same	Same	Same

7. Non-Clinical Tests Performed

The materials used in the predicate device are identical to those in the subject device, but without the colorant. The three raw materials are obtained from the same manufacturers (Lang Dental Orthodontic Acrylic K141439, medical grade stainless steel orthodontic wire from AJ Wilcock, and stainless-steel orthodontic expansion screws from Leone). Both the predicate device and the subject device are manufactured in the same manufacturing facility (Space Maintainers Laboratory). The manufacturing process and sterilization and cleaning process of the predicate device and the subject device are identical. Biocompatibility and physical properties have been leveraged from the predicate.

A risk analysis was performed as per ISO 14971 which considered intraoral soreness, obstruction of oral breathing, tooth movement or loosening, TMD concerns, excessive saliva and breakage. The subject device was compared to the predicate in each area to show the risks were equivalent or less to the predicate device.

8. Clinical Tests Performed

Clinical testing has not been performed.

9. Conclusion

The subject device has the identical Indications of Use, intended use, materials of construction, sterilization and processing, principle of operation and technological characteristics as the predicate device. The devices are both manufactured, finished and shipped from the same FDA registered facility. Based upon the comparative analysis of features, materials and design, the minor design difference between the subject device and the predicate device does not affect the substantial equivalence of the subject device since: it does not change the Indication of Use of the subject device, it does not change the principle of operation, it does not change the manufacturing or sterilization process, and it does not elevate the risk. It is concluded that the proposed NightBlocks™ Appliance is substantially equivalent to the previously cleared device.

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