September 16, 2024

Vivos Therapeutics
℅ Coletter Cozean
Regulatory Consultant
The EyeDeas Company
21581 Midcrest Dr
Lake Forest, California 92630

Re: K234089
Trade/Device Name: DNA 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, LQZ
Dated: December 20, 2023
Received: December 22, 2023

Dear Coletter Cozean:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023.
See PRA Statement below.

510(k) Number *(if known)*

K234089

Device Name

DNA Appliance

Indications for Use *(Describe)*

The DNA Appliance is intended to reduce nighttime snoring and to treat moderate and severe obstructive sleep apnea in children, 6- 17 years of age who are diagnosed with snoring and/or moderate or severe obstructive sleep apnea and need orthodontic treatment.

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.

5. 510(k) Summary - K234089

Applicant:	Vivos Therapeutics 300 S. 5th Street Murray, KY, 42017, USA (270)-226-9237
Contact Person:	Colette Cozean, PhD 21581 Midcrest Drive Lake Forest, CA 92630 (949) 855-2885 colettecozean@gmail.com
Date Prepared	September 13, 2024
Proprietary Name	DNA Appliance
Common Name	Dental Device – Anti Snoring /Obstructive Sleep Apnea Device
Classification Name	Anti Snoring/ Obstructive Sleep Apnea Device
Proposed Product Code	LRK, LQZ
Primary Predicate Device	DNA (K230947)
Reference Predicate Devices	DNA (K222072)

Device Description

The DNA appliance is an intraoral device that consists of either an upper tray, lower tray, or both, and is designed to open the airway during sleep. The device is customized to each patient, and features an adjustment mechanism to allow it to be further customized to each patient.

Scientific Principles

During sleep, the muscles in the tongue and back of the throat relax, which can cause them to sag and

narrow the airway. Airflow through a narrow airway is the cause of snoring. When this narrowing of the airway is severe, it results in Obstructive Sleep Apnea (OSA), where the airway closes. This can happen up to hundreds of times during the night, lasting for a minute or longer.

With these closures, the brain detects the lack of oxygen and disturbs sleep to draw breath. In many cases, the individual isn't completely aware of the stoppages, which don't fully awaken the sleeper. Sleep apnea has been linked to major medical conditions, including hypertension, headaches, heart disease, diabetes, depression, and more.

Device Function

The DNA appliance is a customized oral device featuring a lower tray, upper tray, or both, depending on patient need. These trays put gentle pressure on the tissue at the back of the throat to prevent the airway from collapsing during sleep.

Studies have shown that customized oral devices that function by increasing the patency of the airway show comparable efficacy to continuous positive airway pressure (CPAP) devices, considered the gold standard of treatment for OSA. On the basis of these studies, use of oral devices has been recommended by the American Academy of Sleep Medicine for patients with mild or moderate OSA, or for those with severe OSA who are unable to tolerate the CPAP device. The FDA has now also cleared the DNA for treatment of severe OSA in adults, 18 years of age and older along with positive airway pressure (PAP) devices and/or myofunctional therapy, as needed.

The DNA Appliance aims to expand the nasal airway through jaw expansion and mid-facial redevelopment. In doing so, an oral device may be able to permanently improve the oropharyngeal airway. Studies have shown that the DNA appliance can increase nasal cavity volume and reduce the incidence of apnea-hypopnea episodes.

The DNA appliance is customized on models of the patient's teeth, using standard orthodontic acrylics and standard orthodontic wires for clasps and retention. The DNA appliance allows for six degrees of freedom in customization, including antero-posterior (AP) adjustment, transverse (TV) adjustment, as well as permitting adjustments of the vertical dimension of occlusion (VDO).

The addition of an optional extender on the back of the device further prevents the patient's airway from collapsing during sleep.

Intended Use

The DNA appliance is intended to reduce nighttime snoring and to treat moderate and severe obstructive sleep apnea in children, 6- 17 years of age who are diagnosed with snoring and/or moderate or severe obstructive sleep apnea and need orthodontic treatment.

In the predicate device submission, the indication for use is the same except for 18 years of age and older and can be used with other modalities.

Target Population: Patients 6-17 years of age diagnosed with nighttime snoring, and/or moderate and severe obstructive sleep apnea associated with dentofacial abnormalities.

Environment of Use: Fitting of the DNA appliance in the dental office for patient use at home.

Comparison to Predicate Devices: The DNA appliance with the same as the predicate DNA appliance for

adults. The device allows the airway to remain open during sleep. The device is made of the same materials (standard dental acrylic, stainless steel orthodontic wires, and orthodontic adjustment screws) using the same manufacturing procedure.

The cleaning instructions, indications for use, and labeling are nearly identical to those currently used for the already-marketed predicate device. The precautions, warnings, risk analysis and other critical statements have not been substantially changed.

Shelf Life: The device is provided non-sterile. Shelf life will be identical to the predicate device. No shelf life is required as the device is custom-manufactured and immediately fitted to the patient by the dentist.

Non-clinical Testing: A risk analysis was performed, which considered soreness, obstruction of breathing, tooth movement, and breakage. The product was compared to predicate devices in each area to show the risks were equivalent to the predicate devices. No biocompatibility testing was done as all the components are the same as the predicate device.

Clinical Testing: A prospective, clinical trial of 48 patients ages 6-15 was conducted at 5 sites (4 U.S. and 1 Canadian) under the auspices of WCG-IRB. Patients were diagnosed with obstructive sleep apnea by a medical physician reading a HSAT, a pediatric questionnaire, and needed orthodontic treatment for dentofacial abnormalities. Prior to treatment and following 6-24 months of oral appliance treatment, they underwent a clinical exam, dental x-rays or images and impressions, a sleep study, a CBCT exam and took the Pediatric Sleep Questionnaire and SDRB subsection.

With the DNA appliance, 94% of the patients had their AHI improve or stay the same. Sixty-one (61%) improved by 50% or more, 57% improved by 1 classification and 18% of patients had their OSA resolved. AHI scores improved by 46%. All these results are measured during sleep studies without the appliance in the mouth. In clinical trials with the predicate device for adults with severe OSA and moderate OSA respectively, 97% and 91% had their AHI improve or stay the same, 78% and 80% had their AHI improve by 1 classification and 14% and 20% of patients had their OSA resolved. These were very similar results, except fewer children improved by one classification.

PSQ scores improved by 50% and 92% of patients improved or had their PSQ score stay the same. SRBD scores improved by 58% and 92% of patients improved or had their SRBD score stay the same.

Airway volume increased by 40% and all patients showed an increase in intramolar width by an average of 13.6%. All adult patients showed transpalatal width improvement. There were no safety issues in children while there were no persistent safety issues in adults.

Upon analysis of the data and understanding the $\pm$ 2.6 margin of error in HSAT and PSG sleep studies, it was decided that in children, treatment should be used for patients with moderate and severe sleep apnea (AHI $\geq$ 5). The improvement in moderate and severe AHI was 62.7%. Ninety-six percent (96%) of patients improved or stayed the same while 92% improved by > 50% or 1 classification in the moderate and severe categories (100% of the severe patients achieved this milestone).

Conclusion

In conclusions, the subject device is substantially equivalent based on a comparison of intended use, and technological characteristics and the device is considered to be safe and effective for its intended use.