December 30, 2022

Vivos Therapeutics, Inc.
℅ Colette Cozean
Regulatory Consultant
Colette Cozean, PhD
21581 Midcrest Dr.
Lake Forest, California 92630

Re: K222872
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: September 15, 2022
Received: September 22, 2022

Dear Colette 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 (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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222872

Device Name

DNA Appliance

Indications for Use *(Describe)*
The DNA Appliance is intended to reduce snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older.

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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5. 510(k) Summary- K222872

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 15, 2022
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	mRNA (K130067)
Reference Predicate Devices	mmRNA (K210203)

Device Description

The DNA appliance is an intraoral device to reduce snoring, and/or mild to moderate sleep apnea in adults 18 years of age and older. It 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.

The device is identical to the already-marketed mRNA appliance except the top and bottom trays do not interlock to advance the jaw.

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 (*Oral appliance therapy in Obstructive Sleep Apnea-Hypopnea syndrome - A clinical study on therapeutic outcomes* Hoekema A PhD thesis, University Medical Centre Groningen Department of Oral and Maxillofacial Surgery. pp 110, 2007). 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 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

No change is requested in the indication for use as compared to the predicate "indication" device (mRNA), which remains: "To reduce snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older." In the predicate device submission, the indication for use just states adults, but then specifies the target population as 18 years of age and older as stated below.

Target Population: Patients 18 years of age and older with snoring, and /or mild to moderate obstructive sleep apnea.

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 extender is similar in both mechanism of action and design to the predicate mRNA device, except that it does not advance the mandible. 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).

The cleaning instructions, instructions for use, and labeling are identical to those currently used for the

already-marketed predicate device. These have been revised slightly since the original application for the predicate device, mRNA about 10 years ago. 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: This submittal relies on peer-reviewed literature and clinical data (RWD) demonstrating that DNA can reduce the incidence of snoring and/or mild to moderate sleep apnea, and raises no new questions of safety and efficacy as compared to mRNA, the primary predicate device.