November 28, 2023

Vivos Therapeutics, Inc
% Colette Cozean
Regulatory Consultant
Eyedeas Company
21581 Midcrest Dr
Lake Forest, California 92630

Re: K230947
Trade/Device Name: C.A.R.E. Appliance (DNA, mRNA, mmRNA)
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: November 26, 2023
Received: November 27, 2023

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 (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.

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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K230947

Device Name
C.A.R.E. Appliances (DNA, mRNA, mmRNA)

Indications for Use *(Describe)*
The C.A.R.E. Appliances are intended to reduce nighttime snoring and to treat mild and moderate obstructive sleep apnea in adults, 18 years of age and older. The C.A.R.E. Appliances are also intended to treat moderate and severe obstructive sleep apnea (OSA) in adults, 18 years of age and older along with positive airway pressure (PAP) devices and/or myofunctional therapy, as needed.

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 - K230947

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	November 18, 2023
Proprietary Name	C.A.R.E. Appliances (DNA, mRNA, mmRNA)
Common Name	Dental Device – Anti Snoring /Obstructive Sleep Apnea Device
Classification Name	Anti Snoring/ Obstructive Sleep Apnea Device
Product Code	LRK, LQZ
Primary Predicate	DNA (K222872)
Reference Device	mRNA (K130067)
Reference Devices	mmRNA (K210203)

Device Description

The C.A.R.E. appliances are intended to reduce nighttime snoring and to treat mild and moderate obstructive sleep apnea in adults, 18 years of age and older. The C.A.R.E. appliances are also intended to treat moderate and severe obstructive sleep apnea (OSA) in adults, 18 years of age and older along with positive airway pressure (PAP) devices and/or myofunctional therapy, as needed. They consist of an upper tray and a lower tray 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 DNA appliance does not connect the upper and lower trays, while the mRNA and mmRNA appliances connect the trays with a flange and hinge respectively.

The devices are identical to the already-marketed predicates of the same name.

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 C.A.R.E. appliances are customized oral devices featuring a lower tray and an upper tray. 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 C.A.R.E. Appliances aim 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 C.A.R.E. appliances can increase nasal cavity volume and reduce the incidence of apnea-hypopnea episodes. The mRNA and mmRNA also increase air cavity volume by mandibular advancement.

The C.A.R.E. appliances are customized on models of the patient's teeth, using standard orthodontic acrylics and standard orthodontic wires for clasps and retention. The C.A.R.E. appliances allow 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 C.A.R.E. appliances are intended to reduce nighttime snoring and to treat mild and moderate obstructive sleep apnea in adults, 18 years of age and older. The C.A.R.E. appliances are also intended to treat moderate and severe obstructive sleep apnea (OSA) in adults, 18 years of age and older along with positive airway pressure (PAP) devices and/or myofunctional therapy, as needed.

Target Population: Patients 18 years of age and older with obstructive sleep apnea.

Environment of Use: Fitting of the C.A.R.E. appliances in the dental office for patient use at home.

Comparison to Predicate Devices: Each of the C.A.R.E. appliances (DNA, mRNA and mmRNA) are identical to the previously cleared predicate devices of the same name. This is a request for an expanded Indication of Use only.

The cleaning instructions, instructions for use, and labeling are those currently used for the already-marketed predicate device. The have been reworded, but the indications for use, contraindications, warnings and cautions are the same. The precautions, warnings, risk analysis and other critical statements have been changed only slightly to allow for simultaneous treatment with other modalities as was done with the DNA appliance in K222872) according to the Vivos Method.

Shelf Life: The devices are provided non-sterile. Shelf life will be identical to the predicate devices. 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 C.A.R.E. Appliances can treat mild and moderate obstructive sleep apnea in adults, 18 years of age and older and treat moderate and severe obstructive sleep apnea (OSA) in adults, 18 years of age and older along with positive airway pressure (PAP) devices and/or myofunctional therapy, as needed. The C.A.R.E. appliances raise no new questions of safety and efficacy as compared to the predicate device.

A peer-reviewed, blinded, controlled, randomized study evaluated the reduction in AHI in 15 consecutive patients randomly assigned to a DNA or a mRNA treatment group. The sleep studies were conducted pre- and post-treatment (the average treatment period was 9.7 months) without an appliance in the mouth. AHI reduction in DNA patients was 70.2%, mRNA patients was 50.6% and C.A.R.E. appliances combined was 64.0%.

Real Word Clinical Data obtained from a research database over a period of 5 years (2018-2023) was filtered to include i) patients 18 years of age and older, ii) treated with a C.A.R.E. appliance, iii) pre-and post-sleep studies at least six months apart and iv) diagnosed with moderate ($15 \leq AHI < 30$) or severe ($AHI \geq 30$) Obstructive Sleep Apnea (OSA). Results were as follows:

	CARE severe	**CARE severe**	**CARE moderate**	**CARE moderate**
	Count	**%**	**Count**	**%**
Number of patients	73	100%	35	100%
No of Transpalatal Width Same or Improved	72	99%	35	100%
Number of AHI Same or Improved	71	97%	32	91%

Improved by at least 1 Classification	57	78%	28	80%
Improved by 45% or 1 Classification	58	80%	28	80%
Resolved	10	14%	7	20%

AHI Changes

	AHI Pre-Treatment (CARE appliances)	AHI Post-Treatment (CARE Appliances)	AHI Change (CARE appliances)	Percent Decrease
Severe CARE	46.1 $\pm$ 15.1	21.7 $\pm$ 14.8	-24.3 $\pm$ 18.1	50.8%
Moderate	21.6 $\pm$ 4.5	12.0 $\pm$ 10.5	-9.5 $\pm$ 10.8	44.4%

Eighty percent (80%) of patients with severe OSA improved by at least 45% or 1 classification (also by 50% or 1 classification). Eighty percent (80%) of patients with moderate OSA improved by at least 45% or 1 classification. Twenty percent (20%) of moderate patients and fourteen percent (14%) of severe patients completely resolved their OSA.

Thirty-seven (37 patients) were treated with the C.A.R.E. appliance alone resulting in an AHI improvement of 52.8%. Thirty-six (36) patients were treated with C.A.R.E. appliances and positive airway pressure and/or myofunctional therapy as prescribed by their dentist for all or a portion of their treatment.

While there were no persistent safety issues, 10% of patients had inadvertent tooth movement and/or changes in bite that were treated with braces or aligners.

Conclusion: The clinical data supports the finding that the C.A.R.E. appliances raise no new questions of safety and efficacy as compared to the predicate devices for the treatment of mild and moderate obstructive sleep apnea in adults, 18 years of age and older and the treatment of moderate and severe obstructive sleep apnea (OSA) in adults, 18 years of age and older along with positive airway pressure (PAP) devices and/or myofunctional therapy, as needed.