August 19, 2021

Vivos Therapeutics, Inc. (formerly Vivos Biotechnologies, I)
% Colette Cozean
Regulatory Consultant
Colette Cozean, PhD
21581 Midcrest Dr.
Lake Forest, California 92630

Re: K210203
Trade/Device Name: mmRNA 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: January 20, 2021
Received: January 26, 2021

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,

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

Indications for Use

510(k) Number: K201203

Device Name: mmRNA appliance™

Indications for Use: To reduce nighttime snoring and mild to moderate sleep apnea in adults.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ___X____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Applicant

510(k) Summary

mmRNA appliance™
VIVOS THERAPEUTICS, INC.
9137 S. RIDGELINE BLVD. SUITE 135
HIGHLANDS RANCH, CO 80129

Date Prepared :	August 13, 2021
Official Contact:	Colette Cozean, PhD (949) 855-2885; colettecozean@gmail.com
Proprietary/Trade Name:	mmRNA appliance™
510(k) Number	K210203
Common/Usual 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:	Vivos Therapeutics mRNA Device, K130067
Reference Device:	SomnoMed® SomnoDent Herbst, K130558

Device Description

The mmRNA appliance is an intraoral device used for treating snoring and mild to moderate sleep apnea. 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 (expansion screw) 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 interlock using the Herbst telescoping hinge instead of the mRNA flange. It is used in the predicate SomnoMed® device as well as many other devices in the market, e.g. Oasys Sleep (K181571) reference and Oasys Oral/Nasal Airway system (K030440). The mechanism of action is mandibular advancement, the same mechanism of action is used in the primary predicate device.

Technical Features:

	Subject Device mmRNA	Primary Predicate mRNA device
Upper and lower trays	Customized, acrylic	Customized, acrylic
Degrees of Freedom	6	6
Expansion mechanism	Expansion screw	Expansion screw
Mandibular advancement mechanism	Herbst hinge	Flange
Optional extender	Yes	Yes

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.

Device Function

The mmRNA appliance is a customized oral device featuring a lower tray and 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 mmRNA appliance is customized on models of the patient's teeth, using standard orthodontic acrylics and standard orthodontic wires for clasps and retention. The mmRNA 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

To reduce nighttime snoring and mild to moderate sleep apnea in adults. These are the same indications as the primary predicate device (mRNA).

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

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

Comparison to Predicate Devices: The mmRNA appliance with the extender is identical in both mechanism of action and design to the predicate mRNA device, except that it advances the mandible via a telescoping hinge instead of a flange. 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 the already-marketed predicate device.

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: No additional biocompatibility testing is necessary, as the materials are use are identical to those of the predicate device. 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.

Mechanical Testing: The Somnodent predicate device, K130558, provided mechanical testing on the hinge. All other components are the same as the predicate mRNA.

Labeling: The labeling has been changed to reflect the hinge.

Conclusion: The subject device, mmRNA, is substantially equivalent to the primary predicate device, mRNA in its design, mechanism of action, intended use, target population, materials, testing, and labeling. The only difference between the two devices is the mmRNA advances the mandible via a telescoping hinge instead of the flange used in the mRNA.