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
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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.