FDA 510(k) Premarket Notification

K230947 C.A.R.E. Appliance (DNA, mRNA, mmRNA)

CLEARED

Nov 28, 2023
238 days to decision

K230947 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k230947/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Apr 4, 2023
Decision date	Nov 28, 2023
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vivos Therapeutics, Inc.**
Location	Murray, KY, US
Contact	Kimberly Griffith
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Eyedeas Company**
Contact	Colette Cozean

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov