FDA 510(k) Premarket Notification

K210203 mmRNA appliance

CLEARED

Aug 19, 2021
205 days to decision

K210203 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k210203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Anti-snoring (LRK)
Date received	Jan 26, 2021
Decision date	Aug 19, 2021
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vivos Therapeutics, Inc. (Formerly Vivos Biotechnologies, I)**
Location	Highland Ranch, CO, US
Contact	Catheryn Bonar
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Colette Cozean, PHD**
Contact	Colette Cozean

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210203/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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