FDA 510(k) Premarket Notification

K202651 NOA Sleep Apnea and Snoring Device

CLEARED

Feb 12, 2021
151 days to decision

K202651 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k202651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Sep 14, 2020
Decision date	Feb 12, 2021
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthoapnea S.L.**
Location	Malaga, ES
Contact	Jose Repolles Llecha
510(k) history	2 submissions · 2 cleared · 2021-2021