FDA 510(k) Premarket Notification

K223901 ApneaRX Pro

CLEARED

Sep 1, 2023
247 days to decision

K223901 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k223901/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Dec 28, 2022
Decision date	Sep 1, 2023
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apnea Sciences Coporation**
Location	Aliso Viejo, CA, US
Contact	James Fallon
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Apnea Sciences Corporation**
Contact	James Smith

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