

K223901 ApneaRX ProSep 1, 2023
247 days to decisionK223901 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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