

# K221889 ProSomnus EVO [PH] Sleep and Snore Device, ProSomnus EVO [PH] Sleep and Snore Device with Patient Monitoring

Oct 6, 2022  
99 days to decision

K221889 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k221889/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Anti-snoring (LRK)
Date received	Jun 29, 2022
Decision date	Oct 6, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Prosomnus Sleep Technologies</b>
Location	Pleasanton, CA, US
Contact	Divya Mavalli
Website	<a href="https://prosomnus.com">https://prosomnus.com</a>
510(k) history	2 submissions · 2 cleared · 2022-2026

Prosomnus Sleep Technologies develops intraoral medical devices for the treatment of obstructive sleep apnea and snoring. The company is based in Pleasanton, California, and serves hundreds of thousands of patients worldwide with non-CPAP therapy solutions. The company has received FDA 510(k) clearances from total submissions. Dental devices represent 100% of the company's regulatory submissions. The first clearance was granted in 2022, with the latest clearance in 2026, demonstrating continued active development and market presence. Prosomnus devices are engineered with ...