

K202529 ProSomnus EVO Sleep and Snore Device, ProSomnus EVO Sleep and Snore Device with Patient MonitoringNov 20, 2020
80 days to decisionK202529 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k202529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Sep 1, 2020
Decision date	Nov 20, 2020
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prosomnus Sleep Technologies, Inc.
Location	Pleasanton, CA, US
Contact	Divya Mavalli
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026