FDA 510(k) Premarket Notification

K250122 SleepRight Snore Aid

CLEARED

May 19, 2025
122 days to decision

K250122 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k250122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Jan 17, 2025
Decision date	May 19, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Splintek, Inc.**
Location	Lenexa, KS, US
Contact	Thomas Brown
510(k) history	5 submissions · 5 cleared · 2017-2025