FDA 510(k) Premarket Notification

K252942 ShaeferH

CLEARED

Apr 10, 2026
207 days to decision

K252942 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k252942/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Sep 15, 2025
Decision date	Apr 10, 2026
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shaeferh, LLC**
Location	Boston, MA, US
Contact	Andy Cheung
510(k) history	1 submissions · 1 cleared · 2026-2026