

K261134 Dormiva Anti-Snoring Mouth GuardMay 14, 2026
37 days to decisionK261134 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k261134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Apr 7, 2026
Decision date	May 14, 2026
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Koncept Innovators, Inc.
Location	Myrtle Beach, SC, US
Contact	Maureen Garner
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Newworld Regulatory Solutions, Inc.
Contact	Maureen Garner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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