

K201484 Somnos Anti-Snoring Mouth GuardNov 23, 2020
172 days to decisionK201484 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k201484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Jun 4, 2020
Decision date	Nov 23, 2020
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Koncept Innovators, LLC
Location	Myrtle Beach, SC, US
Contact	Sylvan Newby
510(k) history	2 submissions · 2 cleared · 2019-2020

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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