

K191618 SleepTight Mouthpiece STZDec 11, 2019
176 days to decisionK191618 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k191618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Jun 18, 2019
Decision date	Dec 11, 2019
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Michael D Williams Dds PA
Location	Davie, FL, US
Contact	Michael Williams
510(k) history	2 submissions · 2 cleared · 2014-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191618/> 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