FDA 510(k) Premarket Notification

K190058 PureSleep (OTC use)

CLEARED

Apr 11, 2019
90 days to decision

K190058 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k190058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Jan 11, 2019
Decision date	Apr 11, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sleep Science Partners, Inc.**
Location	Larkspur, CA, US
Contact	Noel P. Lindsay
510(k) history	2 submissions · 2 cleared · 2012-2019

REGULATORY CONSULTANT

Consulting firm	**leanRAQA, LLC**
Contact	Valerie Followell

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