FDA 510(k) Premarket Notification

K181123 ApnoDent Appliance

CLEARED

Nov 21, 2018
205 days to decision

K181123 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k181123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Apr 30, 2018
Decision date	Nov 21, 2018
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apnomed, Inc.**
Location	Bellevue, WA, US
Contact	Joseph Yousefian
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Dr. Colette Cozean, PHD**
Contact	Colette Cozean

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