

K181123 ApnoDent ApplianceNov 21, 2018
205 days to decisionK181123 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181123/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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