

K180691 TrueDorsal DevicesFeb 11, 2019
332 days to decisionK180691 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k180691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Mar 16, 2018
Decision date	Feb 11, 2019
Days to decision	332 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	True Function Laboratory, Inc.
Location	La Mesa, CA, US
Contact	Frank Madrigal
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Azar & Associates
Contact	Nicolas Azar

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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