FDA 510(k) Premarket Notification

K180691 TrueDorsal Devices

CLEARED

Feb 11, 2019
332 days to decision

K180691 · 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