FDA 510(k) Premarket Notification

K190687 Twilite Appliance

CLEARED

Jul 2, 2019
106 days to decision

K190687 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k190687/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Mar 18, 2019
Decision date	Jul 2, 2019
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stephen J Harkins, Dds, PC**
Location	Tucson, AZ, US
Contact	Stephen Harkins
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Stephen J Harkins, Dds, PC C/O Promedic, LLC**
Contact	Paul Dryden

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