

**K190687 Twilite Appliance**Jul 2, 2019  
106 days to decisionK190687 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k190687/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190687/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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