

**K181396 Oral Device OA, Oral Device S**Nov 16, 2018  
171 days to decisionK181396 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k181396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	May 29, 2018
Decision date	Nov 16, 2018
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Passion For Life Healthcare (Uk) Limited</b>
Location	Ellesmere Port, GB
Contact	Paul Earps
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181396/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026