

**K221322 CUSTMBITE Snoring System**Oct 27, 2022  
174 days to decisionK221322 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k221322/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	May 6, 2022
Decision date	Oct 27, 2022
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dental Choice Holdings, LLC</b>
Location	Louisville, KY, US
Contact	Danielle M Jackson
510(k) history	2 submissions · 2 cleared · 2019-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Smith Associates</b>
Contact	Yolanda Smith

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/k221322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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