

**K181416 Sapphire Dorsal Comfort Fit**Sep 17, 2019  
474 days to decisionK181416 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k181416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	May 31, 2018
Decision date	Sep 17, 2019
Days to decision	474 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Crane Dental Laboratory, Inc.</b>
Location	Rochester, NY, US
Contact	Sharlene Schultz
510(k) history	2 submissions · 2 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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