

**K210694 Silent Nite Sleep Appliance with the Glidewell Hinge**Jun 16, 2021  
100 days to decisionK210694 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k210694/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Mar 8, 2021
Decision date	Jun 16, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prismatik Dentalcraft, Inc.</b>
Location	Newport Beach, CA, US
Contact	Herbert Schoenhoefer
510(k) history	57 submissions · 57 cleared · 2010-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qserve Group, Us, Inc.</b>
Contact	Patsy J Trisler

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

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