

**K233434 Silent Nite® Sleep Appliance with the Glidewell Hinge™
(SNGLHG)**

Nov 14, 2023
32 days to decision

K233434 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k233434/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Oct 13, 2023
Decision date	Nov 14, 2023
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prismatik Dentalcraft, Inc.
Location	Newport Beach, CA, US
Contact	Jiahe Li
510(k) history	57 submissions · 57 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k233434/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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