

**K232025 Hushd Pro Avera**May 9, 2024  
307 days to decisionK232025 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k232025/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Jul 7, 2023
Decision date	May 9, 2024
Days to decision	307 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Good Sleep CO Pte , Ltd.</b>
Location	Singapore, SG
Contact	Joel Simoson
510(k) history	3 submissions · 3 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Evo820, LLC</b>
Contact	Na Zhang

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/k232025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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