

K251784 Hushd Pro Z-Link

Oct 24, 2025
135 days to decision

K251784 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k251784/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Jun 11, 2025
Decision date	Oct 24, 2025
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Good Sleep CO Pte , Ltd.
Location	Singapore, SG
Contact	Alwin Ngai
510(k) history	3 submissions · 3 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Aztech Regulatory & Quality, LLC
Contact	Joseph Azary

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