

K213088 ZQuiet AdvanceJun 15, 2022
264 days to decisionK213088 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k213088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Sep 24, 2021
Decision date	Jun 15, 2022
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sleeping Well, LLC
Location	Crofton, MD, US
Contact	Daniel Webster
510(k) history	6 submissions · 6 cleared · 2009-2022

REGULATORY CONSULTANT

Consulting firm	Keystone Regulatory Services, LLC
Contact	William McLain

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213088/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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