FDA 510(k) Premarket Notification

K213088 ZQuiet Advance

CLEARED

Jun 15, 2022
264 days to decision

K213088 · 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