FDA 510(k) Premarket Notification

K223624 Emerald Herbst

CLEARED

May 10, 2023
156 days to decision

K223624 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k223624/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Dec 5, 2022
Decision date	May 10, 2023
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Island Dental Lab, Inc Dba Emerald Dental**
Location	Valley Stream, NY, US
Contact	Israel Wettenstein
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**The Eyedeas Company**
Contact	Colette Cozean, PHD

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