FDA 510(k) Premarket Notification

K221322 CUSTMBITE Snoring System

CLEARED

Oct 27, 2022
174 days to decision

K221322 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k221322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	May 6, 2022
Decision date	Oct 27, 2022
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dental Choice Holdings, LLC**
Location	Louisville, KY, US
Contact	Danielle M Jackson
510(k) history	2 submissions · 2 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	**Smith Associates**
Contact	Yolanda Smith

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