FDA 510(k) Premarket Notification

CLEARED

K253355 Difiney Advanced Anti Snoring Device 4.0

Oct 29, 2025
29 days to decision

K253355 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k253355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Anti-snoring (LRK)
Date received	Sep 30, 2025
Decision date	Oct 29, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fissiontech, LLC**
Location	New York, NY, US
Contact	Mike Lee
510(k) history	3 submissions · 3 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Shanghai Spica Management Consulting Co., Ltd.**
Contact	Purity Chen

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