FDA 510(k) Premarket Notification

CLEARED

K223446 eXciteOSA without remote control (3000)

Jan 18, 2023
64 days to decision

K223446 · Product code: **QNO** · Dental
Source: https://www.510kdatabase.net/k223446/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neuromuscular Tongue Muscle Stimulator For The Reduction Of Snoring And Obstructive Sleep Apnea (QNO)
Date received	Nov 15, 2022
Decision date	Jan 18, 2023
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	eXciteOSA with remote control (6000)

APPLICANT

Company	**Signifier Medical Technologies, Ltd.**
Location	London, GB
Contact	Yasser Zayni
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Regchoice, LLC**
Contact	Darren Scheer

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