

K240328 eXciteOSA without remote control (3000)May 16, 2024
101 days to decisionK240328 · Product code: **QNO** · Dental
Source: <https://www.510kdatabase.net/k240328/>**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	Feb 5, 2024
Decision date	May 16, 2024
Days to decision	101 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**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026