FDA 510(k) Premarket Notification

K242259 Cala kIQ

CLEARED

Nov 22, 2024
114 days to decision

K242259 · Product code: **QBC** · Neurology
Source: https://www.510kdatabase.net/k242259/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Upper Limb Tremor Stimulator (QBC)
Date received	Jul 31, 2024
Decision date	Nov 22, 2024
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cala Health, Inc.**
Location	Burlingame, CA, US
Contact	Alexander Kent
Website	https://www.calahealth.com
510(k) history	7 submissions · 6 cleared · 2018-2026

Cala Health, Inc. develops wearable neuromodulation devices for tremor management. The company operates with a manufacturing facility in Burlingame, California. Cala's flagship technology delivers transcutaneous afferent patterned stimulation (TAPS) therapy to reduce hand tremor in patients with essential tremor and Parkinson's disease. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2018. All submissions focus on Neurology devices. The most recent clearance was in 2026, confirming active regulatory engagement and ongoing...

REGULATORY CONSULTANT

Consulting firm	**Gardner Law Pllc**
Contact	Amanda Johnston

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