

K182706 External upper limb tremor stimulatorOct 25, 2018
28 days to decisionK182706 · Product code: **QBC** · Neurology
Source: <https://www.510kdatabase.net/k182706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	External Upper Limb Tremor Stimulator (QBC)
Date received	Sep 27, 2018
Decision date	Oct 25, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cala Health, Inc.
Location	Burlingame, CA, US
Contact	Scott A. Wilson
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...
