

K222237 Cala kIQNov 22, 2022
119 days to decisionK222237 · Product code: **QBC** · Neurology
Source: <https://www.510kdatabase.net/k222237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Upper Limb Tremor Stimulator (QBC)
Date received	Jul 26, 2022
Decision date	Nov 22, 2022
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cala Health, Inc.
Location	Burlingame, CA, US
Contact	Danielle McDonnell Boyd
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...

CLINICAL EVIDENCE - NCT05012579**Transcutaneous Afferent Patterned Stimulation (TAPS) for Reduction of Parkinson's Disease (PD) Related Action Tremor**

Status	Completed
Enrollment	40 patients (actual)
Study sites	1 site
Condition studied	Parkinson Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 12, 2021
Sponsor	Cala Health, Inc. (Industry)

Primary outcome

Tremor Power

Secondary outcome

Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05012579