

K253587 Cala kIQ PlusMar 17, 2026
120 days to decisionK253587 · Product code: **QBC** · Neurology
Source: <https://www.510kdatabase.net/k253587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Upper Limb Tremor Stimulator (QBC)
Date received	Nov 17, 2025
Decision date	Mar 17, 2026
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cala Health, Inc.
Location	Burlingame, CA, US
Contact	Khushboo Surendran
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 - NCT03597100**Prospective Study for Symptomatic Relief of ET With Cala Therapy**

Status	Completed
Enrollment	263 patients (actual)
Study sites	32 sites
Condition studied	Essential Tremor
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 29, 2019
Sponsor	Cala Health, Inc. (Industry)

Primary outcome

TRG (Tremor Research Group) Essential Tremor Rating Assessment Scale (TETRAS) Subset Score

Secondary outcome

Kinematic Measurements, as Collected With the Device During Postural Holds, Change From Pre-stimulation to Post-stimulation Across Sessions

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03597100