

**K203288 Cala Trio**Oct 5, 2021  
330 days to decisionK203288 · Product code: **QBC** · Neurology  
Source: <https://www.510kdatabase.net/k203288/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Upper Limb Tremor Stimulator (QBC)
Date received	Nov 9, 2020
Decision date	Oct 5, 2021
Days to decision	330 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cala Health, Inc.</b>
Location	Burlingame, CA, US
Contact	Amanda Johnston
Website	<a href="https://www.calahealth.com">https://www.calahealth.com</a>
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...