

K250096 Felix NeuroAI SystemJul 1, 2025
168 days to decisionK250096 · Product code: **QBC** · Neurology
Source: <https://www.510kdatabase.net/k250096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Upper Limb Tremor Stimulator (QBC)
Date received	Jan 14, 2025
Decision date	Jul 1, 2025
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fasikl Incorporated
Location	Bloomington, MN, US
Contact	Zhen Zhang
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT06235190**Assessment of the Safety and Efficacy of the Felix NeuroAI Wristband in Essential Tremor**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	126 patients (actual)
Study sites	12 sites
Condition studied	Essential Tremor
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Nov 1, 2025
Sponsor	Fasikl Inc. (Industry)

Primary outcome

Change in Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) modified Activities of Daily Living (mADL) score from baseline pre-stimulation to Day 90

Secondary outcome

Change in Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) modified Activities of Daily Living (mADL) score from baseline pre-stimulation to 14 days, 30 days, 60 days, 180 days, and 1 year

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06235190