FDA 510(k) Premarket Notification

K250405 Nerivio

CLEARED

May 14, 2025
90 days to decision

K250405 · Product code: **QGT** · Neurology
Source: https://www.510kdatabase.net/k250405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Distal Transcutaneous Electrical Stimulator For Treatment Of Acute Migraine (QGT)
Date received	Feb 13, 2025
Decision date	May 14, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Nerivio Infinity

APPLICANT

Company	**Theranica Bio-Electronics, Ltd.**
Location	Netanya, IL
Contact	Alon Ironi
510(k) history	3 submissions · 3 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT05464069

Safety of Nerivio in Pregnant Women With Migraine

Status	Completed
Enrollment	145 patients (actual)
Study sites	2 sites
Condition studied	Migraine; Pregnancy Related
Study type	Observational
Completion date	Dec 7, 2022
Sponsor	Theranica (Industry)

Primary outcome

Gestational Age at Delivery

Secondary outcome

Birth Weight

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05464069