

K203181 Nerivio, FGD000075-4.7Jan 22, 2021
88 days to decisionK203181 · Product code: **QGT** · Neurology
Source: <https://www.510kdatabase.net/k203181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Distal Transcutaneous Electrical Stimulator For Treatment Of Acute Migraine (QGT)
Date received	Oct 26, 2020
Decision date	Jan 22, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Theranica Bioelectronics , Ltd.
Location	Netanya, IL
Contact	Alon Ironi
510(k) history	4 submissions · 3 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

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

CLINICAL EVIDENCE - NCT04089761**Safety and Efficacy of Nerivio™ for the Acute Treatment of Migraine in Adolescents**

Status	Terminated
Enrollment	60 patients (actual)
Study sites	12 sites
Condition studied	Acute Migraine
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 24, 2020
Sponsor	Theranica (Industry)

Primary outcome**Safety of Nerivio Device****Secondary outcome****Pain Relief at 2 Hours Post Treatment**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04089761