FDA 510(k) Premarket Notification

K241756 Nerivio

CLEARED

Oct 8, 2024
112 days to decision

K241756 · Product code: **QGT** · Neurology
Source: https://www.510kdatabase.net/k241756/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Distal Transcutaneous Electrical Stimulator For Treatment Of Acute Migraine (QGT)
Date received	Jun 18, 2024
Decision date	Oct 8, 2024
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NerivioInfinity

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