

K223169 NerivioFeb 6, 2023
118 days to decisionK223169 · Product code: **QGT** · Neurology
Source: <https://www.510kdatabase.net/k223169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Distal Transcutaneous Electrical Stimulator For Treatment Of Acute Migraine (QGT)
Date received	Oct 11, 2022
Decision date	Feb 6, 2023
Days to decision	118 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223169/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026