FDA 510(k) Premarket Notification

# K232152 NerivioInfinity

**CLEARED**

Nov 8, 2023
112 days to decision

K232152 · Product code: **QGT** · Neurology
Source: https://www.510kdatabase.net/k232152/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Distal Transcutaneous Electrical Stimulator For Treatment Of Acute Migraine (QGT) |
| Date received | Jul 19, 2023 |
| Decision date | Nov 8, 2023 |
| Days to decision | 112 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