FDA 510(k) Premarket Notification

K203419 Relivion

CLEARED

Feb 16, 2021
89 days to decision

K203419 · Product code: **PCC** · Neurology
Source: https://www.510kdatabase.net/k203419/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Nov 19, 2020
Decision date	Feb 16, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurolief , Ltd.**
Location	Netanya, IL
Contact	Michal Kedar-Datel
510(k) history	2 submissions · 2 cleared · 2021-2021

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 - NCT02438553

Short-term Effectiveness of Transcutaneous Nerve Stimulation in Reducing Migraine Related Pain

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	40 patients (actual)
Study sites	1 site
Condition studied	Headache, Migraine
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Oct 1, 2015
Sponsor	Neurolief Ltd. (Industry)

Primary outcome

Pain visual analogue scale (VAS)

Secondary outcome

"Responder" rate at 20-60 minutes of treatment.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02438553