FDA 510(k) Premarket Notification

K212106 Relivion

CLEARED

Aug 2, 2021
27 days to decision

K212106 · Product code: **PCC** · Neurology
Source: https://www.510kdatabase.net/k212106/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Jul 6, 2021
Decision date	Aug 2, 2021
Days to decision	27 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