FDA 510(k) Premarket Notification

K212618 iRelieve Microcurrent Pain Relief System

CLEARED

Sep 14, 2022
392 days to decision

K212618 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k212618/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Aug 18, 2021
Decision date	Sep 14, 2022
Days to decision	392 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fast Track Technologies, Inc.**
Location	Newport Beach, CA, US
Contact	Geoffrey Pfeifer
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Affairs Associates, LLC**
Contact	Stephen Goldner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov