FDA 510(k) Premarket Notification

K212342 ZIIP+ Device

CLEARED

Sep 23, 2021
57 days to decision

K212342 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k212342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Jul 28, 2021
Decision date	Sep 23, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ziip, Inc.**
Location	Oakland, CA, US
Contact	David Mason
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Hill Regulatory Consulting, LLC**
Contact	Heather Tanner

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k212342/ 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