FDA 510(k) Premarket Notification

K233926 accufit

CLEARED

Mar 21, 2024
99 days to decision

K233926 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k233926/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Dec 13, 2023
Decision date	Mar 21, 2024
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mettler Electronics Corporation**
Location	Anaheim, CA, US
Contact	An Le
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Lutronic Corporation**
Contact	Kevin O'Connell

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