FDA 510(k) Premarket Notification

K242430 Power-Flex (PFX1214)

CLEARED

Nov 12, 2024
89 days to decision

K242430 · Product code: **ITI** · Physical Medicine
Source: https://www.510kdatabase.net/k242430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Aug 15, 2024
Decision date	Nov 12, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Power-Flex (PFX1517); Power-Flex (PFX1820)

APPLICANT

Company	**Soul Mobility**
Location	Oconomowoc, WI, US
Contact	Troy Tesmer
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Spectramedex, LLC**
Contact	John Ziobro

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