FDA 510(k) Premarket Notification

K241822 ReWalk® 7 Personal Exoskeleton (50-20-0005)

CLEARED

Mar 12, 2025
261 days to decision

K241822 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k241822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Jun 24, 2024
Decision date	Mar 12, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rewalk Robotics Ltd. Dba Lifeward**
Location	Yokneam Ilit, IL
Contact	Pariente Miri
510(k) history	1 submissions · 1 cleared · 2025-2025