FDA 510(k) Premarket Notification

K221696 ReWalk P6.0

CLEARED

Mar 2, 2023
265 days to decision

K221696 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k221696/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Jun 10, 2022
Decision date	Mar 2, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Re Walk Robotics , Ltd.**
Location	Yokneam, IL
Contact	Miri Pariente
510(k) history	3 submissions · 3 cleared · 2019-2023