FDA 510(k) Premarket Notification

K190337 ReWalk Restore

CLEARED

Jun 3, 2019
109 days to decision

K190337 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k190337/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Feb 14, 2019
Decision date	Jun 3, 2019
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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