

**K190337 ReWalk Restore**Jun 3, 2019  
109 days to decisionK190337 · 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	<b>Re Walk Robotics , Ltd.</b>
Location	Yokneam, IL
Contact	Ofir Koren
510(k) history	3 submissions · 3 cleared · 2019-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190337/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026