

K181294 Honda Walking Assist DeviceDec 14, 2018
212 days to decisionK181294 · Product code: **PHL** · Neurology
Source: <https://www.510kdatabase.net/k181294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	May 16, 2018
Decision date	Dec 14, 2018
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Honda Motor Company, Ltd.
Location	Wako-Shi, JP
Contact	Kazushi Hamaya
Website	http://www.honda.it/
510(k) history	1 submissions · 1 cleared · 2018-2018

Honda Motor Company, Ltd. is a global manufacturer with a manufacturing facility in Wako-Shi, Japan. The company is primarily known for automotive, motorcycle, and power equipment production. Honda has received FDA 510(k) clearance from total submission. The company's FDA regulatory activity focused on Neurology devices, with clearance granted in 2018. This represents a historical regulatory record; Honda has not pursued additional FDA 510(k) submissions in recent years. The cleared device was a walking assistance product designed to support mobility and neurological func...

REGULATORY CONSULTANT

Consulting firm	American Honda Motor Company, Inc.
Contact	Mark DiPietro

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

CLINICAL EVIDENCE - NCT01994395**Development of Walk Assist Device to Improve Community Ambulation**

Status	Completed
Enrollment	53 patients (actual)
Study sites	1 site
Condition studied	Stroke
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Feb 1, 2020
Sponsor	Shirley Ryan AbilityLab (Other)

Primary outcome

Change in 10 Meter Walk Test From Baseline in Gait Speed

Secondary outcome

Activities-Specific Balance Confidence Scale (ABC)

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181294/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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