

K183152 PhoenixApr 17, 2019
154 days to decisionK183152 · Product code: **PHL** · Physical Medicine
Source: <https://www.510kdatabase.net/k183152/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Nov 14, 2018
Decision date	Apr 17, 2019
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Us Bionics, Inc. (Db a Suitx)
Location	Emeryville, CA, US
Contact	Kelly Mettler
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison C. Komiyama

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

CLINICAL EVIDENCE - NCT03175055**Phoenix Exoskeleton for SCI Users**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	40 patients (actual)
Study sites	4 sites
Condition studied	SCI - Spinal Cord Injury
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 31, 2018
Sponsor	US Bionics (Industry)

Primary outcome

Timed Up and Go (TUG)

Secondary outcome

Surface Walk Test

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03175055