

K190699 Rowheels Revolution 1.0May 9, 2019
52 days to decisionK190699 · Product code: **IOR** · Physical Medicine
Source: <https://www.510kdatabase.net/k190699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Mar 18, 2019
Decision date	May 9, 2019
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Rowheels, Inc.
Location	Middleton, WI, US
Contact	Matthew Doeppers
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	FDA Compliance Group
Contact	Kevin Walls

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

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