

**K182840 Element Pediatric Wheelchair**Apr 29, 2019  
202 days to decisionK182840 · Product code: **IOR** · Physical Medicine  
Source: <https://www.510kdatabase.net/k182840/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Oct 9, 2018
Decision date	Apr 29, 2019
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Leggero, LLC</b>
Location	Burnet, TX, US
Contact	Gabriela Romero
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Philosopher&amp;apos;S River, LLC</b>
Contact	Mike Johnson

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182840/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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