

**K250819 Electric Wheelchair (Rollz Motion Electric 2M)**Nov 7, 2025  
234 days to decision

K250819 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k250819/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Mar 18, 2025
Decision date	Nov 7, 2025
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Rollz International BV</b>
Location	Delft, NL
Contact	Martijn Schaaper
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250819/> 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 13, 2026