

**K253643 Mobility Scooter (S3)**Feb 18, 2026  
91 days to decisionK253643 · Product code: **INI** · Physical Medicine  
Source: <https://www.510kdatabase.net/k253643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Nov 19, 2025
Decision date	Feb 18, 2026
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shenzhen Zhimahuaerkai Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Xianwei Zhang
510(k) history	2 submissions · 2 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Kiwi Xu

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/k253643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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