

K253707 Electric wheelchair (W1,W3)Feb 24, 2026
92 days to decision

K253707 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k253707/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Nov 24, 2025
Decision date	Feb 24, 2026
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
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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