

K250366 Electric Wheelchair (LW01301A07)Apr 8, 2025
57 days to decision

K250366 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k250366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Feb 10, 2025
Decision date	Apr 8, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Longway Medical Technology Co., Ltd.
Location	Mingguang, CN
Contact	Xie Alan
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Amanda Sun

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

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