

K250158 Electric Wheelchair (ZH-W001,ZH-W002 ,ZH-W003)Apr 28, 2025
97 days to decision

K250158 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k250158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Jan 21, 2025
Decision date	Apr 28, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhe Jiang Cleisman Industry and Trade Co.,Ltd
Location	Lishui, CN
Contact	Chongjie Zheng
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ariel Xiang

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

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