

K240012 Mobility Scooter (W3431)May 2, 2024
121 days to decisionK240012 · Product code: **INI** · Physical Medicine
Source: <https://www.510kdatabase.net/k240012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Jan 2, 2024
Decision date	May 2, 2024
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd
Location	Dongyang, CN
Contact	Grace Li
510(k) history	16 submissions · 16 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Jarvis Wu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240012/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026