

K240008 Mobility Scooter (W3331)Jun 5, 2024
155 days to decisionK240008 · Product code: **INI** · Physical Medicine
Source: <https://www.510kdatabase.net/k240008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Jan 2, 2024
Decision date	Jun 5, 2024
Days to decision	155 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)

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