

K222507 Mobility Scooter (Models: W3431Q, W3431R)Feb 28, 2023
194 days to decisionK222507 · Product code: **INI** · Physical MedicineSource: <https://www.510kdatabase.net/k222507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Aug 18, 2022
Decision date	Feb 28, 2023
Days to decision	194 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	Leo Zheng
510(k) history	16 submissions · 16 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Jarvis Wu

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

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