

K250027 Powered Mobility ScooterFeb 21, 2025
46 days to decisionK250027 · Product code: **INI** · Physical MedicineSource: <https://www.510kdatabase.net/k250027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Jan 6, 2025
Decision date	Feb 21, 2025
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Intradin (Shanghai) Machinery Co., Ltd.
Location	Shanghai, CN
Contact	Mark Li
510(k) history	4 submissions · 4 cleared · 2024-2025

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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250027/> 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