

K242982 Mobility Scooter (MS160A)Jan 31, 2025
127 days to decisionK242982 · Product code: **INI** · Physical Medicine
Source: <https://www.510kdatabase.net/k242982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Sep 26, 2024
Decision date	Jan 31, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Master Machinery Manufacturing Co.,Ltd
Location	Kunshan, CN
Contact	Siqi Shangguan
510(k) history	6 submissions · 6 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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