

K251638 Mobility Scooter (MS160C)Jul 22, 2025
54 days to decisionK251638 · Product code: **INI** · Physical Medicine
Source: <https://www.510kdatabase.net/k251638/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Vehicle, Motorized 3-wheeled (INI) |
| Date received | May 29, 2025 |
| Decision date | Jul 22, 2025 |
| Days to decision | 54 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](https://accessdata.fda.gov)

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