

K242139 Mobility Scooter (YL-09B, YL-07)Jan 6, 2025
168 days to decisionK242139 · Product code: **INI** · Neurology
Source: <https://www.510kdatabase.net/k242139/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Vehicle, Motorized 3-wheeled (INI) |
| Date received | Jul 22, 2024 |
| Decision date | Jan 6, 2025 |
| Days to decision | 168 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|----------------------------------------|
| Company | Yongkang Yile Vehicle Co., Ltd. |
| Location | Yongkang, CN |
| Contact | David Shi |
| 510(k) history | 2 submissions · 2 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)

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