

**K222495 Mobility Scooter, Model: W3331F**Oct 17, 2022  
60 days to decisionK222495 · Product code: **INI** · Physical MedicineSource: <https://www.510kdatabase.net/k222495/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Vehicle, Motorized 3-wheeled (INI) |
| Date received         | Aug 18, 2022                       |
| Decision date         | Oct 17, 2022                       |
| Days to decision      | 60 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Zhejiang Innuovo Rehabilitation Devices Co.,Ltd</b> |
| Location       | Dongyang, CN   |
| Contact        | Leo Zheng  |
| 510(k) history | 16 submissions · 16 cleared · 2022-2026                |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Shanghai Sungo Management Consulting Company Limited.</b> |
| 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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