

K242471 Power Wheelchair (W5538)Nov 18, 2024
90 days to decision

K242471 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k242471/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wheelchair, Powered (ITI) |
| Date received | Aug 20, 2024 |
| Decision date | Nov 18, 2024 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Zhejiang Innuovo Rehabilitation Devices Co.,Ltd |
| Location | Dongyang, CN |
| Contact | Shuangshuang Li |
| 510(k) history | 16 submissions · 16 cleared · 2022-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Shanghai Sungo Management Consulting Company Limited. |
| Contact | Ivy Wang |

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/k242471/> 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 14, 2026