

K221026 Power WheelchairJul 1, 2022
86 days to decision

K221026 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k221026/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wheelchair, Powered (ITI) |
| Date received | Apr 6, 2022 |
| Decision date | Jul 1, 2022 |
| Days to decision | 86 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 | Leo Zheng |
| 510(k) history | 16 submissions · 16 cleared · 2022-2026 |

REGULATORY CONSULTANT

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|-----------------|--|
| 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221026/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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