

K231320 Zhenjiang Assure Mechanical Wheelchair,model:K1Jun 5, 2023
28 days to decisionK231320 · Product code: **IOR** · Physical MedicineSource: <https://www.510kdatabase.net/k231320/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Wheelchair, Mechanical (IOR) |
| Date received | May 8, 2023 |
| Decision date | Jun 5, 2023 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Zhenjiang Assure Medical Equipment Co., Ltd. |
| Location | Hsin Chu City, TW |
| Contact | Eric Shi |
| 510(k) history | 6 submissions · 6 cleared · 2012-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231320/> 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 26, 2026