

**K232198 Reclining wheelchair (YJ-011S 16"D, YJ-011S 16"DF, YJ-011S 18"D, YJ-011S 18"DF, YJ-011S 20"D, YJ-011S 20"DF)**Sep 15, 2023  
52 days to decisionK232198 · Product code: IOR · Physical Medicine  
Source: <https://www.510kdatabase.net/k232198/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wheelchair, Mechanical (IOR)       |
| Date received         | Jul 25, 2023                       |
| Decision date         | Sep 15, 2023                       |
| Days to decision      | 52 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Zhenjiang Assure Medical Equipment Co., Ltd.</b> |
| Location       | Hsin Chu City, TW                                   |
| Contact        | Ying Mei  |
| 510(k) history | 6 submissions · 6 cleared · 2012-2025               |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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