

**K250564 Surgical Gown (Level 3: S, M, L, XL, XXL, XXXL)**Dec 3, 2025  
280 days to decisionK250564 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k250564/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gown, Surgical (FYA)               |
| Date received         | Feb 26, 2025                       |
| Decision date         | Dec 3, 2025                        |
| Days to decision      | 280 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Yadu Medical (Henan) Co., Ltd.</b> |
| Location       | He Nan, CN                            |
| Contact        | Peilong Shi                           |
| 510(k) history | 2 submissions · 2 cleared · 2025-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250564/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026