

K252301 Henan Yadu Level 4 Surgical Gowns (Reinforced)Feb 4, 2026
195 days to decisionK252301 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k252301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jul 24, 2025
Decision date	Feb 4, 2026
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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