

K220092 YADU Surgical GownsOct 7, 2022
268 days to decisionK220092 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k220092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jan 12, 2022
Decision date	Oct 7, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Henan Yadu Industrial Co., Ltd.
Location	Changyuan, CN
Contact	Charles Shen
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Charles Shen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220092/> 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 25, 2026