

K231510 Surgical Gown (S,M,L,XL,XXL,XXXL)Aug 22, 2023
89 days to decisionK231510 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k231510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 25, 2023
Decision date	Aug 22, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Reinforced Surgical Gown (S,M,L,XL,XXL,XXXL)

APPLICANT

Company	Xiantao Zhibo Non-Woven Products Co., Ltd.
Location	Xiantao, CN
Contact	Fen Peng
510(k) history	2 submissions · 2 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Jarvis Wu

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/k231510/> 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