

K221977 Disposable Surgical Gown (G4003)Oct 20, 2022
107 days to decisionK221977 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k221977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jul 5, 2022
Decision date	Oct 20, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiantao Topmed Nonwoven Protective Products Co., Ltd.
Location	Xiantao, CN
Contact	Vivian Zhu
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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