

K221027 Isolation Gown (S, M, L, XL, XXL (Yellow, Blue))Aug 12, 2022
128 days to decisionK221027 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k221027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Apr 6, 2022
Decision date	Aug 12, 2022
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Allmed Medical (Hubei) Protective Products Co., Ltd.
Location	Zhijiang, CN
Contact	Vince Tian
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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221027/> 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