

K223304 Disposable Isolation Gowns (S,M,L,XL,XXL,XXXL)Feb 8, 2023
104 days to decisionK223304 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k223304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Oct 27, 2022
Decision date	Feb 8, 2023
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiamen Probtain Medical Technology Co., Ltd.
Location	Xiamen, CN
Contact	Jianli Kang
510(k) history	1 submissions · 1 cleared · 2023-2023

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)

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