

K223411 Disposable Isolation Gowns (S,M,L,XL,XXL,XXXL)Jan 4, 2023
56 days to decisionK223411 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k223411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Nov 9, 2022
Decision date	Jan 4, 2023
Days to decision	56 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	4 submissions · 4 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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