

K223401 Disposable Surgical Gowns (S,M,L,XL,XXL,XXXL)Mar 7, 2023
118 days to decisionK223401 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k223401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 9, 2022
Decision date	Mar 7, 2023
Days to decision	118 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

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