

K222456 High Protection Surgical GownMar 12, 2023
209 days to decisionK222456 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k222456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 15, 2022
Decision date	Mar 12, 2023
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3A Medical Products Co., Ltd.
Location	Liu An, CN
Contact	Amy Ma
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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