

K220528 Surgical Isolation Cover GownJun 10, 2022
106 days to decisionK220528 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k220528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Feb 24, 2022
Decision date	Jun 10, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Dymex Healthcare Co., Ltd.
Location	Wuhan, CN
Contact	Lynn Wu
510(k) history	4 submissions · 4 cleared · 2019-2022

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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