

K213893 Comfort Gown, Safewear GownDec 21, 2022
372 days to decisionK213893 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k213893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 14, 2021
Decision date	Dec 21, 2022
Days to decision	372 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xuchang Zhengde Environstar Medical Products Co., Ltd.
Location	Xuchang, CN
Contact	Vincent Yu
510(k) history	2 submissions · 2 cleared · 2020-2022

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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