

K212869 Disposable Surgical Gown, Disposable Reinforced Surgical GownDec 13, 2021
95 days to decisionK212869 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k212869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 9, 2021
Decision date	Dec 13, 2021
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fugou County Shenxiang Manufacturing Co., Ltd.
Location	Zhoukou, CN
Contact	Carina Si
510(k) history	1 submissions · 1 cleared · 2021-2021

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212869/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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