

**K212925 Disposable Surgical Gown**Dec 13, 2021  
90 days to decisionK212925 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k212925/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 14, 2021
Decision date	Dec 13, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Henan Robestain Medical Products Co., Ltd.</b>
Location	Changyuan, CN
Contact	Yonghong Liu
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
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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