

**K223467 Disposable Isolation Gown**Feb 10, 2023  
85 days to decisionK223467 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k223467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Nov 17, 2022
Decision date	Feb 10, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanning Tecbod Biological Technology Co., Ltd.</b>
Location	Nanning, CN
Contact	Bing Yao Chen
510(k) history	2 submissions · 2 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company , Ltd.</b>
Contact	Eva Li

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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