

**K253003 Non-sterile Level 3 Surgical Gown (4025)**Apr 20, 2026  
213 days to decisionK253003 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k253003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 19, 2025
Decision date	Apr 20, 2026
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterile Level 3 Surgical Gown (M4025); Non-sterile Reinforced Level 4 Surgical Gown (G4025); Reinforced Sterile Level 4 Surgical Gown (GM4025)

**APPLICANT**

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Company	<b>Hubei Xinxin Non-Woven Co., Ltd.</b>
Location	Xiantao, CN
Contact	Nicole Jin
510(k) history	4 submissions · 4 cleared · 2022-2026

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