

K213832 AAMI3 Isolation GownMay 16, 2022
158 days to decisionK213832 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k213832/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Dec 9, 2021
Decision date	May 16, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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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