

K214088 Disposable Surgical GownApr 12, 2022
105 days to decisionK214088 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k214088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 28, 2021
Decision date	Apr 12, 2022
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Weihai Hongyu Nonwoven Fabric Products Co., Ltd.
Location	Weihai, KM
Contact	Bin Dong
510(k) history	6 submissions · 6 cleared · 2012-2022

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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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