

K212812 Surgical GownNov 16, 2022
439 days to decisionK212812 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k212812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 3, 2021
Decision date	Nov 16, 2022
Days to decision	439 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xianning Marvelas Protective Articles Co., Ltd.
Location	Xianning, CN
Contact	Zhuxiao Kang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Imd Medical & Drug Technology Service Institutions
Contact	Salon Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212812/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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