

K211509 Surgical GownOct 24, 2021
163 days to decisionK211509 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k211509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 14, 2021
Decision date	Oct 24, 2021
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hubei Wanli Protective Products Co., Ltd.
Location	Xiantao, CN
Contact	Andy Wen
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
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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