

K212861 Surgical Gown, Reinforced Surgical GownDec 15, 2021
98 days to decisionK212861 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k212861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 8, 2021
Decision date	Dec 15, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Zonsen Medical Products Co., Ltd.
Location	Wuhan, CN
Contact	Cynthia Ye
510(k) history	6 submissions · 6 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy 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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