

K221717 Disposable Surgical Gown UM-148Sep 20, 2022
99 days to decisionK221717 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k221717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 13, 2022
Decision date	Sep 20, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Unimax Medical Products Co., Ltd.
Location	Xiantao, CN
Contact	Haibo Ning
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Jarvis Wu

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/k221717/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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