

K211077 Surgical GownOct 7, 2021
178 days to decisionK211077 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k211077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Apr 12, 2021
Decision date	Oct 7, 2021
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wujiang Tutaik Textiles & Finishing Co., Ltd.
Location	Suzhou, CN
Contact	Zhang Yanwen
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Microkn Business Consulting (Shanghai) Co., Ltd.
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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