

K212718 Surgical gownsJan 12, 2022
138 days to decisionK212718 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k212718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 27, 2021
Decision date	Jan 12, 2022
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiantao Dingcheng Non-Woven Product Co., Ltd.
Location	Xiantao, CN
Contact	Cheng Qin
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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/k212718/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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