

K210785 Disposable Surgical GownsNov 13, 2021
242 days to decisionK210785 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k210785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Mar 16, 2021
Decision date	Nov 13, 2021
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chongqing Litai Fashion Group Limited Company
Location	Chongqing, CN
Contact	David Ni
510(k) history	1 submissions · 1 cleared · 2021-2021

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210785/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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