FDA 510(k) Premarket Notification

K203415 Surgical Isolation Gown

CLEARED

May 20, 2021
182 days to decision

K203415 · Product code: **FYC** · General Hospital
Source: https://www.510kdatabase.net/k203415/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Nov 19, 2020
Decision date	May 20, 2021
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Yanbian Pacific Textile Co., Ltd.**
Location	Longjing, CN
Contact	Juan Zhuang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Pacific Fortune Management, Inc.**
Contact	Rafi Wong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k203415/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026