

K212698 Plus Medical Isolation Gown Level 3Mar 2, 2022
189 days to decisionK212698 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k212698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Aug 25, 2021
Decision date	Mar 2, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Foshan Nanhai Plus Medical Co, Ltd.
Location	Dover, DE, US
Contact	Eric Li
510(k) history	8 submissions · 8 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
Contact	Olivia Meng

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212698/> 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 25, 2026