

K210143 Standard Surgical Gown (AAMI Level 3), Reinforced Surgical Gown (AAMI Level 3)Jul 22, 2021
184 days to decisionK210143 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k210143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jan 19, 2021
Decision date	Jul 22, 2021
Days to decision	184 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

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