

**K230610 Disposable Surgical Gown (Level 3, MF2103 Series),
Disposable Surgical Gown (Level 3, MF2104 Series), Disposable
Surgical Gown (Level 4, MF2105 Series)**Aug 23, 2023
170 days to decisionK230610 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k230610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 6, 2023
Decision date	Aug 23, 2023
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Dongguan Shin Yi Healthcare Products Factory
Location	Dong Guan, CN
Contact	Shuge Zhao
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Melody Huang

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

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