

K230707 Skypro, Surgical Gown 6021Oct 12, 2023
212 days to decisionK230707 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k230707/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 14, 2023
Decision date	Oct 12, 2023
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skypro Medical Supplies Company
Location	Hong Kong, CN
Contact	Cyrus Wong
510(k) history	3 submissions · 3 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230707/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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