

K212357 Surgical isolation gownJan 20, 2022
175 days to decisionK212357 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k212357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Jul 29, 2021
Decision date	Jan 20, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Zonsen Medical Products Co., Ltd.
Location	Wuhan, CN
Contact	Cynthia Ye
510(k) history	6 submissions · 6 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212357/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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