

K210355 Surgical Gown, Model: surgical gown-hp-3Dec 16, 2021
311 days to decisionK210355 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k210355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Feb 8, 2021
Decision date	Dec 16, 2021
Days to decision	311 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Weihai Dishang Medical Technology Co., Ltd.
Location	Weihai, CN
Contact	Ricky Xia
510(k) history	2 submissions · 2 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210355/> 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 26, 2026