

K210181 Nordiwell Surgical Face MaskMar 9, 2021
46 days to decisionK210181 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mask, Surgical (FXX)
Date received	Jan 22, 2021
Decision date	Mar 9, 2021
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Combat Protective Equipment Co., Ltd.
Location	Changzhou, CN
Contact	Yanmei Song
510(k) history	3 submissions · 3 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210181/> 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 27, 2026