

**K210445 Nordiwell Surprotect Face Mask**Jun 29, 2021  
133 days to decisionK210445 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k210445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 16, 2021
Decision date	Jun 29, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210445/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026