

K202615 Nordiwell Medical Face MaskDec 31, 2020
113 days to decisionK202615 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 9, 2020
Decision date	Dec 31, 2020
Days to decision	113 days
Third-party review	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

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