

**K212826 Disposable Medical Mask**Jan 19, 2022  
138 days to decisionK212826 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k212826/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 3, 2021
Decision date	Jan 19, 2022
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Nanfang Medical Co., Ltd.</b>
Location	Changzhou, CN
Contact	Li Xia
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Irc</b>
Contact	Charles Mack

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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