

**K202719 Disposable Medical Face Masks**Jan 4, 2021  
109 days to decisionK202719 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202719/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 17, 2020
Decision date	Jan 4, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangxi Sanxin Medtec Co., Ltd.</b>
Location	Nanchang, CN
Contact	Shuiqing Sun
510(k) history	3 submissions · 3 cleared · 2015-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202719/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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