

**K221273 Medical Face Mask (M001)**Jun 28, 2022  
57 days to decisionK221273 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k221273/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 2, 2022
Decision date	Jun 28, 2022
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xingyu Medical Tech Co., Ltd.</b>
Location	Weifang, CN
Contact	Carrie Li
510(k) history	4 submissions · 4 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Jarvis Wu

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/k221273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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