

**K220194 Procedure mask/Surgical mask/Face mask**May 17, 2022  
113 days to decisionK220194 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k220194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 24, 2022
Decision date	May 17, 2022
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Winner Medical Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Mingni Liu
510(k) history	18 submissions · 18 cleared · 2019-2025

**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](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220194/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026