

**K210372 Disposable Surgical Mask**Jun 7, 2021  
119 days to decisionK210372 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k210372/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 8, 2021
Decision date	Jun 7, 2021
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dongguan Shin YI Healthcare Products Factory</b>
Location	Dong Guan, CN
Contact	Zhao Shuge
510(k) history	2 submissions · 2 cleared · 2021-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Joyce Yang

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/k210372/> 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 25, 2026