

**K202409 Surgical Mask**Mar 9, 2021  
200 days to decisionK202409 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202409/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 21, 2020
Decision date	Mar 9, 2021
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Allmed Medical Products Co., Ltd.</b>
Location	Zhijiang, CN
Contact	Vince Tian
510(k) history	4 submissions · 4 cleared · 2021-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202409/> 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