

**K213601 Surgical Mask**Dec 16, 2022  
396 days to decisionK213601 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k213601/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 15, 2021
Decision date	Dec 16, 2022
Days to decision	396 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wuhan Zonsen Medical Products Co., Ltd.</b>
Location	Wuhan, CN
Contact	Cynthia Ye
510(k) history	6 submissions · 6 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213601/> 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 24, 2026