

**K212299 Medical Surgical Mask**Jan 4, 2022  
166 days to decisionK212299 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k212299/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 22, 2021
Decision date	Jan 4, 2022
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wepon Medical Technology Co., Ltd.</b>
Location	Wenling, CN
Contact	Yongxian Sun
510(k) history	5 submissions · 5 cleared · 2022-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212299/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026