

**K202548 Surgical Face Mask**Mar 10, 2021  
189 days to decisionK202548 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202548/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 2, 2020
Decision date	Mar 10, 2021
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wanxinda (Guangzhou) Technology Product Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Zeng Xueping
510(k) history	2 submissions · 2 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Joyce No Last Name Provided

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202548/> 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 27, 2026