

**K212330 Yadu Medical Face Mask (Level 1)**Mar 14, 2022  
230 days to decisionK212330 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k212330/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 27, 2021
Decision date	Mar 14, 2022
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Henan Yadu Industrial Co., Ltd.</b>
Location	Changyuan, CN
Contact	Charles Shen
510(k) history	2 submissions · 2 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manton Business and Technology Services</b>
Contact	Charles Shen

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/k212330/> 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