

**K221173 Surgical Mask (Model: 0868F, 0866F)**Jul 6, 2022  
72 days to decisionK221173 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k221173/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 25, 2022
Decision date	Jul 6, 2022
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangxi Sanhao Medical Instruments Co.,Ltd</b>
Location	Ji&apos;An, CN
Contact	Jiali Chen
510(k) history	2 submissions · 2 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Share Info (Guangzhou) Medical Consultant , Ltd.</b>
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221173/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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