

**K232359 Surgical face mask**Oct 2, 2023  
56 days to decisionK232359 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k232359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 7, 2023
Decision date	Oct 2, 2023
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kingstar Medical (Xianning) Co., Ltd.</b>
Location	Xianning, CN
Contact	Fan Rong
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Ivy Wang

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

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