

**K222335 Surgical Mask**Oct 11, 2022  
69 days to decisionK222335 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k222335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 3, 2022
Decision date	Oct 11, 2022
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Luoyang Sunmed Devices Co., Ltd.</b>
Location	Luoyang, CN
Contact	Tian Qian
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Grace Liu

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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