

**K202513 Disposable Medical Face Mask-Model FM-04**Apr 9, 2021  
221 days to decisionK202513 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 31, 2020
Decision date	Apr 9, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Jinko Industrial Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Wang Yinghui
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Joyce Yang

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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