

**K202211 Disposable Medical Surgical Face Masks**Dec 22, 2020  
138 days to decisionK202211 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202211/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 6, 2020
Decision date	Dec 22, 2020
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangdong Kaidi Garments Co.,Ltd</b>
Location	Shantou, CN
Contact	MR./MRS. Vicky
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</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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