

**K202331 Medical Face Mask**Feb 2, 2021  
169 days to decisionK202331 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202331/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 17, 2020
Decision date	Feb 2, 2021
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gentier Medical (Shanghai), Inc.</b>
Location	Shanghai, CN
Contact	Li Zhiqing
510(k) history	5 submissions · 5 cleared · 2017-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Medical Business Consulting Co., Ltd.</b>
Contact	Julie Chen

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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