

**K203591 Single-use Medical Face Mask**Jul 2, 2021  
206 days to decisionK203591 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k203591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 8, 2020
Decision date	Jul 2, 2021
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Conod Medical Co., Limited</b>
Location	Changshu, CN
Contact	Carrie Wu
510(k) history	2 submissions · 2 cleared · 2018-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou Osmunda Medical Device Technical Service Co., Ltd.</b>
Contact	Olivia Meng

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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