

**K203190 Surgical Face Mask**Jun 2, 2021  
218 days to decisionK203190 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k203190/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 27, 2020
Decision date	Jun 2, 2021
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rfx+Care Manufacturing Co., Ltd.</b>
Location	Shao Xing, CN
Contact	Zhou Xiufeng
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	James Tsai

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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