

**K202708 Surgical Face Masks**Mar 30, 2021  
195 days to decisionK202708 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 16, 2020
Decision date	Mar 30, 2021
Days to decision	195 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intco Medical(Hk) Co., Ltd.</b>
Location	Hong Kong, CN
Contact	Max Li
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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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