

K210225 Surgical Face MaskMar 4, 2021
35 days to decisionK210225 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 28, 2021
Decision date	Mar 4, 2021
Days to decision	35 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Feng Chun Yuan Medical Equipment (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Qiyuan Ning
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
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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