

K202411 Surgical MaskMar 10, 2021
201 days to decisionK202411 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 21, 2020
Decision date	Mar 10, 2021
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Allmed Medical Products Co., Ltd.
Location	Zhijiang, CN
Contact	Vince Tian
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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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