

K210908 Surgical MaskSep 26, 2021
181 days to decisionK210908 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 29, 2021
Decision date	Sep 26, 2021
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sichuan Prius Biotechnology Co., Ltd.
Location	Yibin, CN
Contact	Yan Liu
510(k) history	9 submissions · 9 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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