

K202577 Medical Surgical Mask-Model MP002-5, MP002-6Jan 11, 2021
125 days to decisionK202577 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 8, 2020
Decision date	Jan 11, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangmen Sure&Me Medical Product Co., Ltd.
Location	Jiangmen, CN
Contact	Liang Meixia
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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