

K230093 Disposable 4 Layers Surgical Face MaskMar 2, 2023
49 days to decisionK230093 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k230093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 12, 2023
Decision date	Mar 2, 2023
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Social Medical Supply, LLC
Location	Dallas, TX, US
Contact	Shahzil Amin
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Guangdong Jianda Medical Technology Co., Ltd.
Contact	Jett Lee

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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