

K220512 Disposable Surgical Face Mask (M01, M02)Apr 25, 2022
62 days to decisionK220512 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k220512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 22, 2022
Decision date	Apr 25, 2022
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fomed Industries, Inc.
Location	Qianjiang, CN
Contact	He Xing
510(k) history	2 submissions · 2 cleared · 2022-2025

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

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