

K220597 Disposable Surgical Face Mask (FM-34EE,FM-44EE)May 26, 2022
86 days to decisionK220597 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k220597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 1, 2022
Decision date	May 26, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qingdao Bestex Rubber & Plastic Products Co., Ltd.
Location	Sunnyvale, CA, US
Contact	Lucy Wang
510(k) history	6 submissions · 6 cleared · 2000-2022

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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