

K220550 Disposable Surgical Face Mask (M663BE, M663BT)Jun 14, 2022
109 days to decisionK220550 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k220550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 25, 2022
Decision date	Jun 14, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Makrite Industries, Inc.
Location	Webster, MA, US
Contact	Bob Wen
510(k) history	4 submissions · 4 cleared · 2002-2026

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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