

K240258 Disposable Medical Face Mask (M643BE)Apr 18, 2024
78 days to decisionK240258 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k240258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 31, 2024
Decision date	Apr 18, 2024
Days to decision	78 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240258/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026