

K252650 Disposable Medical Face MaskJan 5, 2026
136 days to decisionK252650 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k252650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 22, 2025
Decision date	Jan 5, 2026
Days to decision	136 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 Co., Ltd.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252650/> 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 14, 2026