

K252964 PRIMED Surgical and Procedure MasksNov 4, 2025
48 days to decisionK252964 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k252964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 17, 2025
Decision date	Nov 4, 2025
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Primed Medical Products, Inc.
Location	Edmonton, Alberta, CA
Contact	Mitra Fard
510(k) history	8 submissions · 8 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252964/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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