

K240286 PRIMED Surgical Masks and PRIMED Procedure MasksAug 26, 2024
207 days to decisionK240286 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k240286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 1, 2024
Decision date	Aug 26, 2024
Days to decision	207 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

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