

**K081633 PRIMAGARD 80, 120, 160 FLUID RESISTANT
PROCEDURE/SURGICAL FACE MASKS**Aug 11, 2008
61 days to decisionK081633 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k081633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mask, Surgical (FXX)
Date received	Jun 11, 2008
Decision date	Aug 11, 2008
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081633/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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