

**K092012 PRIMAGARD DELTA FIT 80,120, 160 SURGICAL FACE MASK (SMALL, MEDIUM, LARGE) MODEL PG4-7061,-7071,-7081, PG4-7062, 7072-70**

Sep 25, 2009  
81 days to decision

K092012 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k092012/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mask, Surgical (FXX)
Date received	Jul 6, 2009
Decision date	Sep 25, 2009
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k092012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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