

**K160361 PRIMAGARD Isolation Gown (AAMI PB70 Level 3)**Nov 4, 2016  
269 days to decisionK160361 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k160361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Feb 9, 2016
Decision date	Nov 4, 2016
Days to decision	269 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	RICHARD R ROY
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/k160361/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026