

**K023117 PRIMAGARD SURGICAL GOWNS**Nov 8, 2002  
58 days to decisionK023117 · Product code: **KKX** · General Hospital  
Source: <https://www.510kdatabase.net/k023117/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Sep 11, 2002
Decision date	Nov 8, 2002
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Primeline Medical Products, Inc.</b>
Location	Edmonton, Alberta, CA
Contact	BRANDA LEE
510(k) history	9 submissions · 9 cleared · 1997-2002

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k023117/> 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 July 2, 2026