

**K971076 PRIMED SHOE COVERS, PRIMED HEAD COVERS**Jan 13, 1998  
295 days to decisionK971076 · Product code: **FXP** · General HospitalSource: <https://www.510kdatabase.net/k971076/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Mar 24, 1997
Decision date	Jan 13, 1998
Days to decision	295 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971076/> 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