

**K011789 PROCEDURE MASKS: PM4-301 AND PM4-304**Jun 22, 2001  
14 days to decisionK011789 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k011789/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mask, Surgical (FXX)
Date received	Jun 8, 2001
Decision date	Jun 22, 2001
Days to decision	14 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	KATHERINE CO
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/k011789/> 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