

**K001951 PRIMED PLEATED TIE-BACK, PROCEDURE MASK
PM4-305, PRIMED PLEATED EAR-LOOP, PROCEDURE MASK
PM4-306**Sep 8, 2000
73 days to decisionK001951 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k001951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 27, 2000
Decision date	Sep 8, 2000
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Primeline Medical Products, Inc.
Location	Edmonton, Alberta, CA
Contact	KATHERINE CO
510(k) history	9 submissions · 9 cleared · 1997-2002

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