

**K042654 PROTECTION PLUS EARLOOP PROCEDURE MASK**Dec 17, 2004  
80 days to decisionK042654 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k042654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 28, 2004
Decision date	Dec 17, 2004
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Safety-Med Products, Inc.</b>
Location	Burlington, WI, US
Contact	CHRIS WAGNER
510(k) history	1 submissions · 1 cleared · 2004-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042654/> 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