

**K964168 PROCEDURE SPECIFIC KITS**Mar 3, 1997  
137 days to decisionK964168 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k964168/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 17, 1996
Decision date	Mar 3, 1997
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sage Products, Inc.</b>
Location	Mchenry, IL, US
Contact	KAREN PINTO
510(k) history	31 submissions · 30 cleared · 1978-1998

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