

**K964358 AMSEAL SURGICAL FACE MASK**Feb 14, 1997  
105 days to decisionK964358 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k964358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 1, 1996
Decision date	Feb 14, 1997
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>American Seal Co.</b>
Location	Hayward, CA, US
Contact	LISA CHEN
510(k) history	6 submissions · 6 cleared · 1989-1997

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