

**K963568 MASK SURGICAL**Feb 25, 1997  
173 days to decisionK963568 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k963568/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 5, 1996
Decision date	Feb 25, 1997
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The Innovative Approach, Corp.</b>
Location	Hato Rey, PR, US
Contact	ELISA N PEREZ
510(k) history	1 submissions · 1 cleared · 1997-1997

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