

**K940720 BUSSE ISOLATION AND PROCEDURAL MASKS**Nov 2, 1994  
257 days to decisionK940720 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k940720/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 18, 1994
Decision date	Nov 2, 1994
Days to decision	257 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Busse Hospital Disposables, Inc.</b>
Location	Mchenry, IL, US
Contact	EILEEN RAMA
510(k) history	31 submissions · 29 cleared · 1983-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940720/> 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 May 14, 2026