

**K944545 BODY FLUIDS BARRIER KIT**Nov 2, 1994  
47 days to decisionK944545 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k944545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 16, 1994
Decision date	Nov 2, 1994
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ani Safety, Inc.</b>
Location	Skokie, IL, US
Contact	KRIKOR TOPOUZIAN
510(k) history	2 submissions · 2 cleared · 1994-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944545/> 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 6, 2026