

**K934608 BARRIER FABRIC 450 SURGICAL GOWN**Apr 11, 1994  
196 days to decisionK934608 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k934608/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 27, 1993
Decision date	Apr 11, 1994
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Johnson &amp; Johnson Medical, Inc.</b>
Location	Arlington, TX, US
Contact	LINDA G HILL
510(k) history	53 submissions · 50 cleared · 1990-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934608/> 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 June 29, 2026