

**K940069 DRESSING CHANGE KIT**Mar 18, 1994  
71 days to decisionK940069 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k940069/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jan 6, 1994
Decision date	Mar 18, 1994
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mason-Keller Corp.</b>
Location	Roseland, NJ, US
Contact	ALFRED R CAGGIA
510(k) history	4 submissions · 0 cleared · 1994-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940069/> 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