

**K030364 DEROYAL GOWNS, STERILE, NON-STERILE**Apr 28, 2003  
83 days to decisionK030364 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k030364/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Feb 4, 2003
Decision date	Apr 28, 2003
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Deroyal Industries, Inc.</b>
Location	Mchenry, IL, US
Contact	AUDREY DANIELS
510(k) history	91 submissions · 88 cleared · 1984-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030364/> 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 17, 2026