

**K031408 DEROYAL POLY-REINFORCED SURGICAL GOWNS
(STERILE, NON-STERILE)**Oct 15, 2003
163 days to decisionK031408 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k031408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 5, 2003
Decision date	Oct 15, 2003
Days to decision	163 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Deroyal
Location	Knoxville, TN, US
Contact	AUDREY DANIELS
Website	http://www.deroyal.com/
510(k) history	5 submissions · 5 cleared · 2002-2004

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