

K921154 O.R./SURGEONS GOWN, ITEM NO. 4962Jul 9, 1993
492 days to decisionK921154 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k921154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 4, 1992
Decision date	Jul 9, 1993
Days to decision	492 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Sewing Source, Inc.
Location	Spring Hope, NC, US
Contact	JANET SLOAD
510(k) history	9 submissions · 9 cleared · 1993-1996

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