

**K921158 O.R./SURGEONS GOWN, ITEM NO. 4950**Jul 9, 1993  
492 days to decisionK921158 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k921158/>**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	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921158/> 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