

**K970814 NON-STERILE ISOLATION GOWN**May 27, 1997  
82 days to decisionK970814 · Product code: **FYC** · General HospitalSource: <https://www.510kdatabase.net/k970814/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Mar 6, 1997
Decision date	May 27, 1997
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>American Seal Co.</b>
Location	Hayward, CA, US
Contact	JOSEPH TUNG
510(k) history	6 submissions · 6 cleared · 1989-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970814/> 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 4, 2026