

K931145 NON-STERILE ISOLATION GOWNJun 10, 1994
462 days to decisionK931145 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k931145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Mar 5, 1993
Decision date	Jun 10, 1994
Days to decision	462 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Amsco Sterile Recoveries, Inc.
Location	Great Neck, NY, US
Contact	DENISE A SCHOTTLER
510(k) history	12 submissions · 12 cleared · 1992-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k931145/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026