

**K922442 ISOLATION GOWNS**Oct 12, 1993  
508 days to decisionK922442 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k922442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	May 22, 1992
Decision date	Oct 12, 1993
Days to decision	508 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pfb Inter-Apparel Corp.</b>
Location	Medley, FL, US
Contact	WILHELM E LEMKE
510(k) history	2 submissions · 2 cleared · 1993-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922442/> 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 7, 2026