

**K931288 ISOLAIR 2 FULL FACE SPLASH GUARD**Jan 21, 1994  
315 days to decisionK931288 · Product code: **LYU** · General Hospital  
Source: <https://www.510kdatabase.net/k931288/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Surgical Apparel (LYU)
Date received	Mar 12, 1993
Decision date	Jan 21, 1994
Days to decision	315 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Louis M. Gerson Co., Inc.</b>
Location	MA, US
Contact	KATHLEEN WESLEY
510(k) history	8 submissions · 8 cleared · 1980-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931288/> 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 June 29, 2026