

K934171 ULTRA SHIELD PFFeb 1, 1994
159 days to decisionK934171 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k934171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 26, 1993
Decision date	Feb 1, 1994
Days to decision	159 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Resources International, Inc.
Location	Tampa, FL, US
Contact	ISOE IRIZARRY
510(k) history	2 submissions · 2 cleared · 1994-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934171/> 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 July 6, 2026