

**K970625 POLY-MED**Mar 27, 1997  
36 days to decisionK970625 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k970625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Feb 19, 1997
Decision date	Mar 27, 1997
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shinemound Enterprise, Inc.</b>
Location	North Billerica, MA, US
Contact	HUAN-CHUNG LI
510(k) history	8 submissions · 8 cleared · 1997-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970625/> 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 1, 2026