

**K892166 NON-STERILE PATIENT EXAM GLOVES (LATEX)**Jul 14, 1989  
100 days to decision

K892166 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k892166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 5, 1989
Decision date	Jul 14, 1989
Days to decision	100 days
Third-party review	No

**APPLICANT**

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Company	<b>Ergo Intl., Ent., Inc.</b>
Location	North Miami Beach, FL, US
Contact	BERTHA ERTEL
510(k) history	5 submissions · 5 cleared · 1988-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892166/>; 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 8, 2026