

**K945506 ACRYLIC DIPPED LATEX EXAMINATION GLOVES**Oct 12, 1995  
337 days to decisionK945506 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k945506/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 9, 1994
Decision date	Oct 12, 1995
Days to decision	337 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ganz Industries Sdn. Bhd.</b>
Location	Nilai 71800, Negeri Sembilan, MY
510(k) history	4 submissions · 4 cleared · 1995-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945506/>; 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 6, 2026