

**K974853 LATEX (POWDER FREE) LOW PROTEIN**Feb 9, 1998  
42 days to decisionK974853 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k974853/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 29, 1997
Decision date	Feb 9, 1998
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>P.T. Healthcare Glovindo</b>
Location	Jakarta, ID
Contact	ELLEN HUTAPEA
510(k) history	7 submissions · 7 cleared · 1993-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974853/> 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 2, 2026