

**K943552 POWDER-FREE GLOVES**Dec 8, 1994  
140 days to decisionK943552 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k943552/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 21, 1994
Decision date	Dec 8, 1994
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Healthcare Gloves Sdn Bhd</b>
Location	Batu Caves Selangor, MY
Contact	TAN S CHUAN
510(k) history	2 submissions · 2 cleared · 1989-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943552/> 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