

**K945885 PATIENT EXAMINATION GLOVES**Mar 23, 1995  
112 days to decisionK945885 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k945885/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 1, 1994
Decision date	Mar 23, 1995
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hartalega Sdn Bhd</b>
Location	Kuala Lumpur, MY
Contact	KUAN K HON
510(k) history	61 submissions · 61 cleared · 1989-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945885/> 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 June 18, 2026