

**K954221 POLYMER COATED CHLORINATED POWDER-FREE  
LATEX EXAMINATION GLOVES**May 3, 1996  
235 days to decisionK954221 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k954221/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 11, 1995
Decision date	May 3, 1996
Days to decision	235 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hartalega Sdn Bhd</b>
Location	Kuala Lumpur, MY
Contact	EU JIN KUAN
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/k954221/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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