

**K980318 POWDER-FREE LATEX EXAMINATION GLOVES  
(BLUE)**

Mar 11, 1998  
43 days to decision

K980318 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k980318/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 27, 1998
Decision date	Mar 11, 1998
Days to decision	43 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 KAM 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/k980318/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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