

**K121591 FLAVORED POWDER FREE AND POLYMER COATED  
EXAMINATION GLOVE (VANLLA, GRAPE AND STRAWBERRY)**Oct 11, 2012  
133 days to decisionK121591 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k121591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 31, 2012
Decision date	Oct 11, 2012
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Tekmedic (M) Sdn Bhd</b>
Location	Kuala Lumpur, MY
Contact	PATRICK LEONG
510(k) history	11 submissions · 11 cleared · 1989-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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