

**K161961 UniTex Non-Sterile, Powder-Free, Latex Examination Glove**May 11, 2017  
297 days to decisionK161961 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k161961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 18, 2016
Decision date	May 11, 2017
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ug Global Resources Sdn. Bhd.</b>
Location	Costa Mesa, CA, US
Contact	Wong See Keong
510(k) history	5 submissions · 5 cleared · 2012-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161961/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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