

**K151997 Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs-Violet Blue (VBLU)**Mar 31, 2016  
255 days to decisionK151997 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k151997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 20, 2015
Decision date	Mar 31, 2016
Days to decision	255 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hartalega NGC Sdn. Bhd.</b>
Location	Bandar Sri Damansara, MY
Contact	Kuan Mun Leong
510(k) history	28 submissions · 28 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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