

**K162818 Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (Blue)**Jan 9, 2017  
95 days to decisionK162818 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k162818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 6, 2016
Decision date	Jan 9, 2017
Days to decision	95 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/k162818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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