

**K151684 Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim(Blue)**

Sep 18, 2015  
88 days to decision

K151684 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k151684/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 22, 2015
Decision date	Sep 18, 2015
Days to decision	88 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/k151684/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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