

**K150110 Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - White, Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Dawn Blue, Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Dark Blue (DKBU), Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Dark Violet Blue (DVBU)**

Apr 23, 2015  
93 days to decision

K150110 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k150110/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 20, 2015
Decision date	Apr 23, 2015
Days to decision	93 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/k150110/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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