

**K180644 Nitrile Powder Free Examination Gloves with Colloidal Oatmeal - Lemon Green**Aug 10, 2018  
151 days to decisionK180644 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k180644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 12, 2018
Decision date	Aug 10, 2018
Days to decision	151 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hartalega Sdn Bhd</b>
Location	Kuala Lumpur, MY
Contact	Mr. Kuan Kam Hon
510(k) history	61 submissions · 61 cleared · 1989-2020

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