

K180645 Powder Free Examination Gloves with Colloidal Oatmeal USP and Tested for Use with Chemotherapy Drugs - (Lemon Green)Nov 16, 2018
249 days to decisionK180645 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k180645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 12, 2018
Decision date	Nov 16, 2018
Days to decision	249 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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