

K180505 Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low-Dermatitis Potential Claim and Tested For Use with Chemotherapy Drugs (White)Jun 14, 2018
108 days to decisionK180505 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k180505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 26, 2018
Decision date	Jun 14, 2018
Days to decision	108 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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