

**K150103 Nitrile Powder Free Examination Gloves (Orange)
Tested For Use With Chemotherapy Drugs**Apr 23, 2015
93 days to decisionK150103 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k150103/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150103/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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