

K201531 Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)Aug 5, 2020
58 days to decisionK201531 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k201531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 8, 2020
Decision date	Aug 5, 2020
Days to decision	58 days
Third-party review	No
Combination product	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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