

K223437 Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour)May 17, 2023
184 days to decisionK223437 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 14, 2022
Decision date	May 17, 2023
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	Kuan Mun Leong
510(k) history	28 submissions · 28 cleared · 2014-2025

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