

K243818 Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Jan 8, 2025
27 days to decision

K243818 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243818/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 12, 2024
Decision date	Jan 8, 2025
Days to decision	27 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k243818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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