

K251319 Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Jul 30, 2025
92 days to decision

K251319 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k251319/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 29, 2025
Decision date	Jul 30, 2025
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff

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/k251319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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