

K260867 Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Jun 17, 2026
92 days to decision

K260867 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k260867/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 17, 2026
Decision date	Jun 17, 2026
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary
Other names	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black)

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	Kuan Mun Leong
510(k) history	29 submissions · 29 cleared · 2014-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k260867/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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