

K252244 Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, Xylazine, Gastric acid, Fentanyl in Gastric acid and Xylazine in Gastric acidAug 21, 2025
34 days to decisionK252244 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k252244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 18, 2025
Decision date	Aug 21, 2025
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ever Global (Vietnam) Enterprise Corporation
Location	Long Tanh District, VN
Contact	Elizabeth Deng
510(k) history	5 submissions · 5 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252244/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026