

K251141 Powder Free Nitrile Patient Examination Glove, Blue colored, Non-sterile Tested for Use with Chemotherapy Drugs and Fentanyl CitrateNov 17, 2025
217 days to decisionK251141 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k251141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 14, 2025
Decision date	Nov 17, 2025
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Powder Free Nitrile Patient Examination Glove, Black colored, Non-sterile Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

APPLICANT

Company	Mercator Medical (Thailand), Ltd.
Location	Littleton, CO, US
Contact	Praneet Inthajak
510(k) history	7 submissions · 7 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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