

K243441 Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid (Light blue, Dark blue)Jan 31, 2025
86 days to decisionK243441 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 6, 2024
Decision date	Jan 31, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Basic Medical Technology, Inc.
Location	Ontario, CA, US
Contact	Zhao John
510(k) history	8 submissions · 8 cleared · 2025-2026

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