

K250630 Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl CitrateMay 22, 2025
80 days to decisionK250630 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k250630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 3, 2025
Decision date	May 22, 2025
Days to decision	80 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250630/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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