

**K232064 Powder-Free Frost Nitrile Examination Gloves (Blue)
(Tested for use with Chemotherapy Drugs and Fentanyl Citrate)**Oct 2, 2023
83 days to decisionK232064 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k232064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 11, 2023
Decision date	Oct 2, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Isikel Manufacturing, LLC
Location	Katy, TX, US
Contact	Chris Betts
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	Yolanda Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232064/>; 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 26, 2026