

K250502 SafeSource Direct Blue Powder-Free Nitrile Exam Gloves (AMERI-TUFF Series 4000, AMERI-TOUCH Series 5000)Mar 19, 2025
27 days to decisionK250502 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k250502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 20, 2025
Decision date	Mar 19, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Safesource Direct, LLC
Location	Broussard, LA, US
Contact	Courtney Cormier
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Powers Regulatory Consulting
Contact	Grace Powers

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/k250502/> 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 13, 2026