

K232614 Non-sterile, Powder-Free Nitrile Examination Glove Tested for use with Chemotherapy Drugs and Fentanyl (White, Black, and Violet Blue)

May 13, 2024
259 days to decision

K232614 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k232614/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 28, 2023
Decision date	May 13, 2024
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Sri Trang Gloves (Thailand) Public Company Limited
Location	Hatyai, TH
Contact	Jarinya Jirojkul
510(k) history	8 submissions · 8 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Sri Trang USA, Inc.
Contact	M. Jordan 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.net

Device record: <https://www.510kdatabase.net/k232614/>; 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