

# K221165 Non-Sterile, Powder-Free Nitrile Examination Glove Violet Blue Tested for use with Chemotherapy Drugs and Fentanyl and Non-Sterile, Powder-Free Nitrile Examination Glove Blue Tested for use with Chemotherapy Drugs and Fentanyl

Nov 20, 2022  
212 days to decision

K221165 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k221165/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 22, 2022
Decision date	Nov 20, 2022
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

## APPLICANT

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Company	<b>Sri Trang Gloves (Thailand) Public Company Limited</b>
Location	Hatyai, TH
Contact	Jordan Smith
510(k) history	8 submissions · 8 cleared · 2020-2024

## REGULATORY CONSULTANT

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Consulting firm	<b>Sri Trang USA, Inc.</b>
Contact	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)

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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k221165/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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