

**K212613 Powder Free Nitrile Examination Gloves, Non-sterile, Tested For Use with Chemotherapy Drugs and Opioid Fentanyl Citrate (Blue)**Dec 21, 2021  
125 days to decisionK212613 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 18, 2021
Decision date	Dec 21, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Koon Seng Sdn Bhd</b>
Location	81707 Pasir Gudang, Johor, MY
Contact	Jennifer Yeo
510(k) history	7 submissions · 7 cleared · 1989-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Truscott Medsci Associates, LLC</b>
Contact	Wava Truscott

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212613/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026