

**K233405 Blue Powder Free Nitrile Examination Glove with  
Chemotherapy Drugs and Fentanyl Test Claim**Dec 28, 2023  
84 days to decisionK233405 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k233405/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 5, 2023
Decision date	Dec 28, 2023
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eco Medi Glove Sdn. Bhd.</b>
Location	Kamunting Perak, MY
Contact	Suresh Kumar
510(k) history	15 submissions · 15 cleared · 2014-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233405/> 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 13, 2026