

**K212349 Powder Free, White, Blue, Pink, Black Nitrile Synthetic Rubber Examination Gloves**Dec 10, 2021  
135 days to decisionK212349 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 28, 2021
Decision date	Dec 10, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medi Legion Sdn.Bhd</b>
Location	Kuala Langat, MY
Contact	N.S. Kumar
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212349/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026