

**K220429 Violet Nitrile Powder-Free Patient Examination Glove,  
Non Sterile**May 13, 2022  
87 days to decisionK220429 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k220429/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 15, 2022
Decision date	May 13, 2022
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>One Glove Industrial Sdn Bhd</b>
Location	Taiping, MY
Contact	Marcus Low
510(k) history	4 submissions · 4 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Representative, LLC</b>
Contact	Michael Van Der Woude

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220429/> 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 27, 2026