

**K220118 Nitrile Powder Free Examination Gloves,  
Chemotherapy Nitrile Powder Free Examination Gloves**May 12, 2022  
118 days to decisionK220118 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k220118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 14, 2022
Decision date	May 12, 2022
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KI-Kepong Rubber Products Sdn. Bhd.</b>
Location	Ipoh, Perak, Darul Ridzuan, MY
Contact	Cheng Phooi Yann
510(k) history	3 submissions · 3 cleared · 2003-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdi Consultants, Inc.</b>
Contact	Kewin Tham

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/k220118/> 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