

**K200453 NON-STERILE, POWDER FREE NITRILE  
EXAMINATION GLOVES, LOW DERMATITIS POTENTIAL, AND  
TESTED FOR USE WITH CHEMOTHERAPY DRUGS BLUE-AC**May 1, 2020  
67 days to decisionK200453 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k200453/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 24, 2020
Decision date	May 1, 2020
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Yty Industry (Manjung) Sdn Bhd</b>
Location	Selangor, Malaysia, MY
Contact	Punitha Samy
510(k) history	27 submissions · 27 cleared · 1989-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200453/> 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 June 6, 2026