

**K213548 Nitrile Classic Powder Free Nitrile Blue Examination Gloves Tested for Use with Chemotherapy**Feb 21, 2022  
105 days to decisionK213548 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213548/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 8, 2021
Decision date	Feb 21, 2022
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mercator Medical (Thailand), Ltd.</b>
Location	Littleton, CO, US
Contact	Praneet Inthajak
510(k) history	7 submissions · 7 cleared · 2015-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Insight, Inc.</b>
Contact	Kevin Walls

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/k213548/> 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 25, 2026