

**K232252 Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black), Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Orange)**Nov 28, 2023  
123 days to decisionK232252 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k232252/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 28, 2023
Decision date	Nov 28, 2023
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dehai (Shandong) Medical Gloves, Co., Ltd.</b>
Location	Chino, CA, US
Contact	Max Li
510(k) history	2 submissions · 2 cleared · 2013-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Intco Medical Industries, Inc.</b>
Contact	Deze Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232252/> 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 26, 2026