

**K231029 Nitrile Exam Glove, Tested For Use With  
Chemotherapy Drugs And Fentanyl**Oct 30, 2023  
202 days to decisionK231029 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k231029/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 11, 2023
Decision date	Oct 30, 2023
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhonghong Pulin Medical Products Co., Ltd.</b>
Location	Tangshan, CN
Contact	Li Yunjiao
510(k) history	5 submissions · 5 cleared · 2016-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle Wang

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/k231029/> 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