

**K233990 Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl (D5000)**Apr 1, 2024  
105 days to decisionK233990 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k233990/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 18, 2023
Decision date	Apr 1, 2024
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shandong Xingyu Gloves Co., Ltd.</b>
Location	Gaomi, CN
Contact	Carrie Lee
510(k) history	4 submissions · 4 cleared · 2017-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Ivy 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/k233990/> 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 13, 2026