

**K220249 Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)**May 26, 2022  
115 days to decisionK220249 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k220249/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 31, 2022
Decision date	May 26, 2022
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Grand Work Plastic Products Co., Ltd.</b>
Location	Zanhuang County, CN
Contact	Wu Yuli
510(k) history	19 submissions · 19 cleared · 2004-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hongray USA Medical Products, Inc.</b>
Contact	Kathy Liu

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/k220249/> 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