

**K213048 Nitrile Patient Examination Gloves (Tested for Use with Chemotherapy Drugs)**Dec 18, 2021  
87 days to decisionK213048 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 22, 2021
Decision date	Dec 18, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Huayuan Medical Technology(Shangqiu) Co., Ltd.</b>
Location	Shangqiu, CN
Contact	Huamei Wang
510(k) history	3 submissions · 3 cleared · 2021-2021

**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/k213048/> 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