

**K212401 Disposable Nitrile Examination Glove**Oct 25, 2021  
84 days to decisionK212401 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 2, 2021
Decision date	Oct 25, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inner Mongolia Cureguard Medical Technology Co., Ltd.</b>
Location	Baotou, CN
Contact	Guo Hua
510(k) history	3 submissions · 3 cleared · 2021-2022

**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/k212401/> 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