

**K213739 Nitrile Examination Gloves**Jun 22, 2022  
205 days to decisionK213739 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213739/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 29, 2021
Decision date	Jun 22, 2022
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Runheng Medical Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Yaya Lu
510(k) history	2 submissions · 2 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213739/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026