

**K161390 Vinyl Exam Gloves, Powder Free, Clear**Dec 19, 2016  
214 days to decisionK161390 · Product code: **LYZ** · General Hospital  
Source: <https://www.510kdatabase.net/k161390/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	May 19, 2016
Decision date	Dec 19, 2016
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zibo Hongchin Plastic and Rubber Co., Ltd.</b>
Location	Zibo, CN
Contact	James Ren
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161390/> 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 June 2, 2026