

**K211177 Powder Free Vinyl Patient Examination Gloves**Jul 17, 2021  
88 days to decisionK211177 · Product code: LYZ · General Hospital  
Source: <https://www.510kdatabase.net/k211177/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Apr 20, 2021
Decision date	Jul 17, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shijiazhuang Hongjun Plastic Manufacture Co., Ltd.</b>
Location	Shijiazhuang, CN
Contact	Lv Zhanmin
510(k) history	1 submissions · 1 cleared · 2021-2021

**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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211177/> 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 27, 2026