

**K211239 Vinyl Patient Examination Gloves**Jul 17, 2021  
82 days to decisionK211239 · Product code: **LYZ** · General Hospital  
Source: <https://www.510kdatabase.net/k211239/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Apr 26, 2021
Decision date	Jul 17, 2021
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangxi Shengda Medical Technology Co., Ltd.</b>
Location	Shangrao, CN
Contact	Yun Gao
510(k) history	1 submissions · 1 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211239/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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