

**K213371 Disposable Medical Nitrile Examination Gloves  
(Model:XYS-001)**Dec 9, 2021  
58 days to decisionK213371 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 12, 2021
Decision date	Dec 9, 2021
Days to decision	58 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anhui Xinyisheng Medical Technology Co.,Ltd</b>
Location	Suzhou, CN
Contact	Shyla Tang
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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