

**K212290 Examination gloves -Type C (Nitrile gloves)**Oct 28, 2021  
99 days to decisionK212290 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212290/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 21, 2021
Decision date	Oct 28, 2021
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangxi Kemei Medical Apparatus &amp; Instruments Group Co., Ltd.</b>
Location	Nanchang, CN
Contact	Jenny Huang
510(k) history	3 submissions · 3 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Mind-Link Consulting Co., Ltd.</b>
Contact	Evan Hu

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/k212290/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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