

**K211515 Nitrile Examination Gloves**Aug 24, 2021  
99 days to decisionK211515 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k211515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 17, 2021
Decision date	Aug 24, 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>Beijing Reagent Latex Products Co., Ltd.</b>
Location	Crofton, MD, US
Contact	HaiTao Liu
510(k) history	4 submissions · 4 cleared · 2001-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bayside Life Science Consultants, LLC</b>
Contact	Stephen Beier

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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