

**K211434 Nitrile Patient Examination Gloves**Aug 5, 2021  
87 days to decisionK211434 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k211434/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 10, 2021
Decision date	Aug 5, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhangjiagang Huayuan Protective Equipment Co., Ltd.</b>
Location	Zhangjiagang, CN
Contact	Huamei Wang
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](https://accessdata.fda.gov)

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