

**K210686 Nitrile Patient Examination Glove**Jul 21, 2021  
135 days to decisionK210686 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k210686/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 8, 2021
Decision date	Jul 21, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Yunnan Huazhiyuan Medical Technology Co., Ltd.</b>
Location	Honghe Hani And Yi Autonomous Prefecture, CN
Contact	Yun Gao
510(k) history	4 submissions · 4 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/k210686/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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