

**K223895 Disposable Medical Nitrile Examination Gloves**Mar 23, 2023  
85 days to decisionK223895 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k223895/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 28, 2022
Decision date	Mar 23, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hebei Titans Hongsen Medical Technology Co., Ltd.</b>
Location	Nangong, CN
Contact	Xiaoqing Shao
510(k) history	7 submissions · 7 cleared · 2018-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Believe Technology Service Co., Ltd.</b>
Contact	Ray 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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