

**K213843 Nitrile Examination Gloves**Mar 31, 2022  
112 days to decisionK213843 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213843/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 9, 2021
Decision date	Mar 31, 2022
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dong Tai City Huayi Gloves Co., Ltd.</b>
Location	Dongtai, CN
Contact	Huamei Wang
510(k) history	1 submissions · 1 cleared · 2022-2022

**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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