

**K220228 Powder Free Nitrile Examination Gloves, Blue and Violet Blue, Test For Use With Chemotherapy Drugs**Mar 18, 2022  
50 days to decisionK220228 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k220228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 27, 2022
Decision date	Mar 18, 2022
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shandong Blue Sail Health Technology Co., Ltd.</b>
Location	Weifang, CN
Contact	Shi Haifeng
510(k) history	1 submissions · 1 cleared · 2022-2022

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220228/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026