

**K210578 Medical Nitrile Examination Gloves (Power free, Blue)**Jul 10, 2021  
134 days to decisionK210578 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k210578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 26, 2021
Decision date	Jul 10, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangxi Hongda Medical Equipment Group , Ltd.</b>
Location	Nanchang, CN
Contact	Yang Qinghua
510(k) history	6 submissions · 6 cleared · 2017-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Believe-Med 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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