

K210145 Nitrile Glove Powder Free BlueApr 21, 2021
90 days to decisionK210145 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 21, 2021
Decision date	Apr 21, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Universal Medical Equipment Co., Ltd.
Location	Xinbei District, CN
Contact	Xiaohai Wan
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	R. Dubois Consulting, LLC
Contact	Roxanne Dubois

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210145/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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