

K220211 Nitrile Powder Free Examination GlovesMay 18, 2022
112 days to decisionK220211 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 26, 2022
Decision date	May 18, 2022
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hebei Kangxida Medical Technology Development Co., Ltd.
Location	Handan, CN
Contact	Xiaomin Liu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Purevisionai, Inc.
Contact	Bryan Wong

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

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