

**K213574 Nitrile Vinyl Blend Powder Free Examination Gloves
(Black)**Jul 12, 2022
244 days to decisionK213574 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 10, 2021
Decision date	Jul 12, 2022
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Grand Work Plastic Products Co., Ltd.
Location	Zanhuang County, CN
Contact	Wu Yuli
510(k) history	19 submissions · 19 cleared · 2004-2023

REGULATORY CONSULTANT

Consulting firm	Hongray USA Medical Products, Inc.
Contact	Kathy Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213574/>; Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026