

**K230779 Powder Free Nitrile Examination Gloves (Black),
Tested for Use with Chemotherapy Drugs and Fentanyl Citrate**Jun 9, 2023
80 days to decisionK230779 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k230779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 21, 2023
Decision date	Jun 9, 2023
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanxi Hongjin Plastic Technology Co., Ltd.
Location	Linfen City, CN
Contact	Wu Zhigang
510(k) history	7 submissions · 7 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Hongray(Usa) Medical Products, Inc.
Contact	Liu Kathy

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

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