

K223713 Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl CitrateAug 7, 2023
238 days to decisionK223713 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 12, 2022
Decision date	Aug 7, 2023
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Better Care Plastic Technology Co., Ltd.
Location	Chino, CA, US
Contact	Zhu Chunyan
510(k) history	11 submissions · 11 cleared · 2014-2025

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/k223713/> 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