

K221269 Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Jul 27, 2022
86 days to decision

K221269 · Product code: LZA · General Hospital
Source: <https://www.510kdatabase.net/k221269/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 2, 2022
Decision date	Jul 27, 2022
Days to decision	86 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)

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Device record: <https://www.510kdatabase.net/k221269/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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