

K233042 Sterile Nitrile Examination Gloves Powder Free Tested for Use with Chemotherapy Drugs and Fentanyl CitrateDec 6, 2023
72 days to decisionK233042 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k233042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 25, 2023
Decision date	Dec 6, 2023
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Intco Medical Products Co, Ltd.
Location	Qingzhou, CN
Contact	Max Li
510(k) history	4 submissions · 4 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233042/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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