

K233520 Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and FentanylJan 12, 2024
72 days to decisionK233520 · Product code: LZA · General Hospital
Source: <https://www.510kdatabase.net/k233520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 1, 2023
Decision date	Jan 12, 2024
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Powerguard Technology Co., Ltd.
Location	Jiujiang, CN
Contact	Nick Dai
510(k) history	3 submissions · 3 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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/k233520/>. 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 14, 2026