

K210777 Powder Free Nitrile Patient Examination Gloves, Blue ColorNov 2, 2021
232 days to decisionK210777 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 15, 2021
Decision date	Nov 2, 2021
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Jieshi Medical Products Co., Ltd.
Location	Heze, CN
Contact	Li Biao
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Beijing Easy-Link Company
Contact	Chu Xiaolan

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/k210777/>. 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 26, 2026