

K212735 Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs)Jan 11, 2022
134 days to decisionK212735 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 30, 2021
Decision date	Jan 11, 2022
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xingyu Medical Tech Co., Ltd.
Location	Weifang, CN
Contact	Cathrine Luan
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Eva Li

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/k212735/> 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