

K211864 Powder Free Nitrile Patient Examination Gloves, Blue ColorJan 21, 2022
219 days to decisionK211864 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 16, 2021
Decision date	Jan 21, 2022
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siyang Jaysun Medtech Co., Ltd.
Location	Suqian, CN
Contact	Chen Fang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Beijing Easy-Link Company
Contact	Chu Xiaoan

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/k211864/>; 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 27, 2026