

K221454 Disposable Medical Nitrile Examination Gloves - Non SterileJul 12, 2022
54 days to decisionK221454 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 19, 2022
Decision date	Jul 12, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Guangzhou Kangling Biotechnology Co., Ltd.
Location	Guangzhou, CN
Contact	Yan Wang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Cnmed Consulting
Contact	Johnson Liu

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/k221454/>; 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