

K212551 Nitrile Examination GlovesNov 5, 2021
84 days to decisionK212551 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 13, 2021
Decision date	Nov 5, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Fine Glove Medical Technology Co., Ltd.
Location	Chuzhou, CN
Contact	Guanghao Liu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Cnmed Consultant
Contact	Johnson Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212551/> 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