

K220561 Disposable Medical Nitrile Examination GlovesApr 14, 2022
45 days to decisionK220561 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k220561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 28, 2022
Decision date	Apr 14, 2022
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Nanjing Universal Medical Equipment Co., Ltd.
Location	Nanjing, CN
Contact	Jerry Gao
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220561/> 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