

K213325 Disposable Medical Nitrile Examination Gloves- Tested for Use With Chemotherapy DrugsJan 28, 2022
115 days to decisionK213325 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k213325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Oct 5, 2021
Decision date	Jan 28, 2022
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Anhui Xinyisheng Medical Technology Co.,Ltd
Location	Suzhou, CN
Contact	Wei Wei Tang
510(k) history	2 submissions · 2 cleared · 2021-2022

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/k213325/> 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