

K221747 Nitrile Patient Examination Gloves Tested For Use With Chemotherapy Drugs

Dec 1, 2022
168 days to decisionK221747 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 16, 2022
Decision date	Dec 1, 2022
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fitone Latex Products Co., Ltd. Guangdong
Location	Zhanjiang, CN
Contact	Christine Ou
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Stuart Situ

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/k221747/>; 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 25, 2026