

K240545 GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (XS/S/M/L/XL)

Aug 28, 2024
183 days to decision

K240545 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k240545/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 27, 2024
Decision date	Aug 28, 2024
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genabio Diagnostics, Inc.
Location	Bedford, MA, US
Contact	Vincent Cai
Website	https://genabiodiagnostics.com
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k240545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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