

K252075 Program insite® Powder-Free, Disposable Nitrile Exam Gloves

Oct 17, 2025
107 days to decision

K252075 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k252075/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 2, 2025
Decision date	Oct 17, 2025
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Program Insite, LLC
Location	Olney, MD, US
Contact	Emnet Menyahil
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k252075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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