

K243604 Halyard Purple Nitrile-XTRA* Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Fentanyl Citrate in Simulated Gastric Acid

Aug 18, 2025
270 days to decision

K243604 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243604/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 21, 2024
Decision date	Aug 18, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Caitlin Senter
510(k) history	23 submissions · 23 cleared · 2019-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k243604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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