

**K213929 Halyard Purple Nitrile, Powder-Free Exam Gloves
Tested for Use with Chemotherapy Drugs, Fentanyl Citrate,
Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid**Aug 1, 2022
228 days to decisionK213929 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213929/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 16, 2021
Decision date	Aug 1, 2022
Days to decision	228 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	Steven Dowdley
510(k) history	23 submissions · 23 cleared · 2019-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213929/> 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 13, 2026