

**K213937 Halyard Lavender Nitrile, Low Dermatitis Potential,  
Powder-Free Exam Gloves Tested for Use with Chemotherapy  
Drugs, Fentanyl Citrate and Simulated Gastric Acid  
Fluid/Fentanyl Citrate Injection Mix 50/50 Solution**Aug 16, 2022  
243 days to decisionK213937 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213937/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 16, 2021
Decision date	Aug 16, 2022
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>O&amp;M Halyard, Inc.</b>
Location	Alpharetta, GA, US
Contact	Steven Dowdley
510(k) history	23 submissions · 23 cleared · 2019-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213937/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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