

K242558 Halyard Black Nitrile Powder-Free Exam Gloves with Textured Grip Technology, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

Dec 17, 2024
111 days to decision

K242558 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k242558/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 28, 2024
Decision date	Dec 17, 2024
Days to decision	111 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/k242558/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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