

K243172 Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Pairs

Jun 18, 2025
261 days to decision

K243172 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243172/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 30, 2024
Decision date	Jun 18, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Halyard Purple Nitrile* Powder-Free Exam Gloves, Sterile Singles

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/k243172/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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