

K262014 PUREZERO* MARIN* Nitrile Powder-Free Exam Gloves

Jul 21, 2026
36 days to decision

K262014 · Product code: LZA · General Hospital
Source: <https://www.510kdatabase.net/k262014/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 15, 2026
Decision date	Jul 21, 2026
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary
Other names	PUREZERO* MARIN-XTRA* Nitrile Powder-Free Exam Gloves

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Sahrudin Shah
510(k) history	26 submissions · 26 cleared · 2019-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k262014/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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