

**K153708 Halyard Black-Orange Powder-Free Nitrile Exam Glove**Mar 31, 2016  
99 days to decisionK153708 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k153708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 23, 2015
Decision date	Mar 31, 2016
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Halyard Health</b>
Location	Minneapolis, MN, US
Contact	Christine L Macauley
510(k) history	7 submissions · 7 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153708/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 23, 2026