

**K182851 SkyBreeze Zero Nitrile Powder-Free Exam Glove  
Tested for Use with Chemotherapy Drugs**Jun 26, 2019  
259 days to decisionK182851 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k182851/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 10, 2018
Decision date	Jun 26, 2019
Days to decision	259 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	Angela L. Bunn
510(k) history	24 submissions · 24 cleared · 2019-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182851/>. 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 28, 2026