

**K220825 Sapphire Pro Powder-Free Royal Blue Nitrile Exam Gloves**Jul 8, 2022  
109 days to decisionK220825 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k220825/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 21, 2022
Decision date	Jul 8, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Nitrile Operations, LLC</b>
Location	Grove City, OH, US
Contact	Stephen Perrin
510(k) history	1 submissions · 1 cleared · 2022-2022

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220825/> 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 May 27, 2026