

**K231435 KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid**Aug 28, 2023  
103 days to decisionK231435 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k231435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 17, 2023
Decision date	Aug 28, 2023
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kimberly Clark Corporation</b>
Location	Neenah, WI, US
Contact	Kimberly Tempas
510(k) history	13 submissions · 12 cleared · 2010-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pathmaker FDA Law, PLLC</b>
Contact	Amy Fowler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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