

K223859 Rhino Non-sterile Powder-Free Nitrile Exam Glove – Periwinkle Color Tested for Use with Chemotherapy Drugs and Fentanyl

Feb 13, 2023
52 days to decision

K223859 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223859/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 23, 2022
Decision date	Feb 13, 2023
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rhino Health, Inc.
Location	Church Rock, NM, US
Contact	Mark Lee
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Capote Law Firm
Contact	Lisa Capote

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

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Device record: <https://www.510kdatabase.net/k223859/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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