

K212148 Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy DrugsMar 10, 2022
244 days to decisionK212148 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 9, 2021
Decision date	Mar 10, 2022
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ansell Healthcare Products, LLC
Location	Dothan, AL, US
Contact	Donald Cronk
510(k) history	26 submissions · 26 cleared · 2005-2023

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