

K210401 Microflex Nitrile Patient Examination Gloves Blue Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex Nitrile Patient Examination Gloves Green Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, Microflex Nitrile Patient Examination Gloves Black Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Jun 13, 2021
123 days to decision

K210401 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210401/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 10, 2021
Decision date	Jun 13, 2021
Days to decision	123 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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Device record: <https://www.510kdatabase.net/k210401/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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