

K220609 Powder-Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl (White, Blue, Black, Orange and Green Color)

May 27, 2022
86 days to decision

K220609 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220609/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 2, 2022
Decision date	May 27, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Encompass Industries Sdn. Bhd.
Location	Kemaman, MY
Contact	Nur Atikah binti Muhammad Muhyiddin
510(k) history	3 submissions · 3 cleared · 2019-2025
