

K213437 Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs, with Gastric Acid and Fentanyl Permeation Resistance Claims

Apr 11, 2022
171 days to decision

K213437 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213437/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 22, 2021
Decision date	Apr 11, 2022
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Central Medicare Sdn Bhd
Location	Diamond Bar, CA, US
Contact	Fatin Nor Irdina Bt Ahmad Fauzi
510(k) history	15 submissions · 15 cleared · 2010-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k213437/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026