

**K220215 Powder Free Nitrile Examination Glove, Non-sterile,
Tested for Use with Chemotherapy Drugs, and the Opioid
Fentanyl citrate, simulated Gastric Acid, and Fentanyl in Gastric
Acid (Blue)**Mar 26, 2022
59 days to decisionK220215 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 26, 2022
Decision date	Mar 26, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Ksg Medicare Sdn. Bhd.
Location	Tangkak, MY
Contact	Jennifer Yeo
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Truscott Medsci Associates, LLC
Contact	Wava Truscott

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220215/> 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