

K241745 Powder Free Nitrile Examination Glove, Non-sterile, Tested for Use with 46 Chemotherapy Drugs, the Opioid Fentanyl citrate, simulated Gastric Acid, Fentanyl in Gastric Acid, the tranquilizer Xylazine, and Xylazine in Fentanyl citrate (Blue)

Sep 11, 2024
85 days to decision

K241745 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k241745/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 18, 2024
Decision date	Sep 11, 2024
Days to decision	85 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 Yow
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](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k241745/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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