

K243133 Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid

Jun 17, 2025
260 days to decision

K243133 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243133/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 30, 2024
Decision date	Jun 17, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	KI-Kepong Rubber Products Sdn. Bhd.
Location	Ipoh, Perak, Darul Ridzuan, MY
Contact	Phooi Yann Cheng
510(k) history	3 submissions · 3 cleared · 2003-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k243133/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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