

K250578 Nitrile Examination Gloves Powder Free Tested for Use With Chemotherapy Drugs & Fentanyl Citrate (Blue & Black)Apr 1, 2025
33 days to decisionK250578 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k250578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 27, 2025
Decision date	Apr 1, 2025
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Careglove Global Sdn. Bhd.
Location	Seremban, MY
Contact	Lim Kwee Shyan
510(k) history	8 submissions · 8 cleared · 2017-2025

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