

K243694 Nitrile Powder Free Examination Glove with Tremella Fuciformis Extract, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate - BlueJun 6, 2025
189 days to decisionK243694 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k243694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 29, 2024
Decision date	Jun 6, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mah Sing Healthcare Sdn. Bhd.
Location	Kuala Lumpur, MY
Contact	Ivan Tan Chee Wei
510(k) history	5 submissions · 5 cleared · 2021-2025

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