

K202536 Non-sterile, Powder Free Nitrile Examination Aloe Vera Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, And Non-Sterile, Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs and Fentanyl Citrate

Aug 11, 2021
344 days to decision

K202536 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k202536/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 1, 2020
Decision date	Aug 11, 2021
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Yty Industry (Manjung) Sdn Bhd
Location	Selangor, Malaysia, MY
Contact	Punitha Samy
510(k) history	27 submissions · 27 cleared · 1989-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202536/> 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 14, 2026