

K210369 Powder Free Nitrile Examination GloveMay 13, 2021
94 days to decisionK210369 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k210369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 8, 2021
Decision date	May 13, 2021
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pastel Glove Sdn Bhd
Location	Pusing, MY
Contact	Siou Wei Law
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210369/> 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 27, 2026