

K212801 Powder free nitrile examination glove- black, non sterileJan 9, 2022
129 days to decisionK212801 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 2, 2021
Decision date	Jan 9, 2022
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hong Seng Gloves Sdn Bhd
Location	Sungai Petani, MY
Contact	Ho Chia Yao
510(k) history	4 submissions · 4 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Emergo Global Representative, LLC
Contact	Michael Van Der Woude

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212801/>; 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 26, 2026