

K221164 Powder Free Nitrile Examination Glove - Blue, Non-Sterile, Tested for use with Chemotherapy Drugs and FentanylAug 30, 2022
130 days to decisionK221164 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 22, 2022
Decision date	Aug 30, 2022
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hong Seng Gloves Sdn Bhd
Location	Sungai Petani, MY
Contact	Zahari Bin Darus
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/k221164/>; 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