

K223221 Non-Sterile Powder Free Nitrile Examination GlovesJan 13, 2023
88 days to decisionK223221 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k223221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 17, 2022
Decision date	Jan 13, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Dynacare Sdn Bhd
Location	Sitiawan, MY
Contact	Chow Choong Keong
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Novo Quality Services Sdn Bhd
Contact	Nancy Nga

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/k223221/> 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 28, 2026