

**K220431 Blue Nitrile Powder-Free Patient Examination Glove,
Non-Sterile**Jun 17, 2022
122 days to decisionK220431 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 15, 2022
Decision date	Jun 17, 2022
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	One Glove Industrial Sdn Bhd
Location	Taiping, MY
Contact	Marcus Low
510(k) history	4 submissions · 4 cleared · 2022-2022

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/k220431/> 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