

**K220428 Black Nitrile Powder-Free Patient Examination Glove,
Non-Sterile**May 10, 2022
84 days to decisionK220428 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 15, 2022
Decision date	May 10, 2022
Days to decision	84 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

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