

**K212916 Black Nitrile Powder Free Patient Examination Glove,
Non Sterile**Mar 24, 2022
192 days to decisionK212916 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 13, 2021
Decision date	Mar 24, 2022
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rimba Glove Sdn Bhd
Location	Ipoh, MY
Contact	Zahari Bin Darus
510(k) history	1 submissions · 1 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)

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