

**K213981 Nitrile Examination Gloves**Nov 12, 2022  
327 days to decisionK213981 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k213981/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 20, 2021
Decision date	Nov 12, 2022
Days to decision	327 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Emerald Glove Manufacturing Sdn Bhd</b>
Location	Taiping, MY
Contact	Amran A. Aziz
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Novo Quality Services Sdn Bhd</b>
Contact	Lim Pooi Yee

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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