

**K210990 Non-sterile Powder Free Nitrile Examination Gloves**Nov 22, 2021  
234 days to decisionK210990 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k210990/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 2, 2021
Decision date	Nov 22, 2021
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rubberex Alliance Sdn Bhd</b>
Location	Ipoh, MY
Contact	Sabri Abd Hamid
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdi Consultants, Inc.</b>
Contact	Aristotle Nafpliotis

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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