

**K221350 Non-Sterile Powder Free Nitrile Examination Gloves
(Tested for Use with Chemotherapy Drugs)**Aug 5, 2022
87 days to decisionK221350 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 10, 2022
Decision date	Aug 5, 2022
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rubberex Alliance Products Sdn Bhd
Location	Ipoh, MY
Contact	Sabri Bin Abdul Hamid
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Kewin Tham

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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