

K223235 Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)Oct 26, 2022
13 days to decisionK223235 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 13, 2022
Decision date	Oct 26, 2022
Days to decision	13 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pt. Sintong Unigolden Glove
Location	Kota Kisaran, ID
Contact	MP Vivekanandan
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group , Ltd.
Contact	Manoj Zacharias

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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