

K212408 Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs Use and Simulated Gastric Acid)May 18, 2022
288 days to decisionK212408 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 3, 2021
Decision date	May 18, 2022
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pt. Maja Agung Latexindo
Location	Indonesia, ID
Contact	Sivaprakash S
510(k) history	11 submissions · 11 cleared · 1990-2022

REGULATORY CONSULTANT

Consulting firm	Shamrock Marketing Co., Inc.
Contact	Jeni Chuason

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212408/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026