

K212751 Powder Free Nitrile Examination GloveSep 24, 2022
390 days to decisionK212751 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 30, 2021
Decision date	Sep 24, 2022
Days to decision	390 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dainam Glove Joint Stock Company
Location	Thu Dau Mot, VN
Contact	Damon Nguyen
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Bayneto, LLC
Contact	Jenny Nguyen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212751/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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