

K213058 O'Star Nitrile Examination Gloves Powder FreeFeb 8, 2022
139 days to decisionK213058 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 22, 2021
Decision date	Feb 8, 2022
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Star Investment and Trade Joint Stock Company
Location	Bac Ninh, VN
Contact	Do Van Binh
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group Limited
Contact	Manoj Zacharias

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

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