

K212436 NBR Synthetic Nitrile Examination GlovesDec 23, 2021
141 days to decisionK212436 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k212436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Aug 4, 2021
Decision date	Dec 23, 2021
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Langtai International Trade Co., Ltd.
Location	Binzhou, CN
Contact	Ping Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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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