

K212488 Synthetic Nitrile Examination GlovesNov 26, 2021
109 days to decisionK212488 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k212488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Aug 9, 2021
Decision date	Nov 26, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Hongxin Chemicals Co., Ltd.
Location	Beijing, CN
Contact	Ping Wang
510(k) history	2 submissions · 2 cleared · 2012-2021

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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