

K210522 Disposable Vinyl Examination GlovesJun 10, 2021
107 days to decisionK210522 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k210522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Feb 23, 2021
Decision date	Jun 10, 2021
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Shengshixincheng Medical Science & Technology Co.,
Location	Binzhou, CN
Contact	Ping Wang
510(k) history	2 submissions · 2 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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