

K211236 Disposable Vinyl Examination GlovesSep 27, 2021
154 days to decisionK211236 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k211236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Apr 26, 2021
Decision date	Sep 27, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Tangshan Hongyun Healthcare Products Co., Ltd.
Location	Tangshan, CN
Contact	Suying Le
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

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