

K211045 Synthetic Vinyl Examination GlovesJun 23, 2021
76 days to decisionK211045 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k211045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Apr 8, 2021
Decision date	Jun 23, 2021
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Huayuan Medical Technology Co., Ltd.
Location	Dongtai, CN
Contact	Yun Gao
510(k) history	2 submissions · 2 cleared · 2021-2022

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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