

K211103 Powder Free Vinyl Examination GlovesNov 4, 2021
205 days to decisionK211103 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k211103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Apr 13, 2021
Decision date	Nov 4, 2021
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shanghai Shengda Medical Applications Co., Ltd.
Location	Shanghai, CN
Contact	Ying Su
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Charles Shen

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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