

K213625 Vinyl Examination GlovesFeb 17, 2022
92 days to decisionK213625 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k213625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Nov 17, 2021
Decision date	Feb 17, 2022
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dezhou Hengchang Medical Technology Co., Ltd.
Location	Dezhou City, CN
Contact	Jing Li
510(k) history	3 submissions · 3 cleared · 2022-2022

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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213625/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026