

K220055 Disposable, vinyl examination gloves, YellowAug 25, 2022
231 days to decisionK220055 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k220055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Jan 6, 2022
Decision date	Aug 25, 2022
Days to decision	231 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220055/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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