

K210821 Medical PVC Examination GlovesJul 9, 2021
112 days to decisionK210821 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k210821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Mar 19, 2021
Decision date	Jul 9, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangxi Hongda Medical Equipment Group , Ltd.
Location	Nanchang, CN
Contact	Yang Qinghua
510(k) history	6 submissions · 6 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray 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/k210821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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