

K213019 Vinyl Exam GlovesJan 5, 2022
107 days to decisionK213019 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k213019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Sep 20, 2021
Decision date	Jan 5, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hebei Astro Medical Supply Co., Ltd.
Location	Jinzhou, CN
Contact	Ning Zheng
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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