

K210780 Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)May 14, 2021
60 days to decisionK210780 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k210780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Mar 15, 2021
Decision date	May 14, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Shangwei Medical Products Co., Ltd.
Location	Heze, CN
Contact	Li Hua
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Beijing Easy-Link Company
Contact	Chu Xiaoan

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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