

K211516 Disposable Vinyl Nitrile Synthetic Gloves Powder FreeAug 24, 2021
99 days to decisionK211516 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k211516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	May 17, 2021
Decision date	Aug 24, 2021
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tangshan Hongyun Plastic Products Co., Ltd.
Location	Huan Zhong, Roa; Beijing, CN
Contact	Suying Le
510(k) history	5 submissions · 5 cleared · 2007-2021

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/k211516/> 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