

K210460 NitriTec Vinyl Glove Powder Free BlueMay 17, 2021
90 days to decisionK210460 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k210460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Feb 16, 2021
Decision date	May 17, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zhonghong Pulin Medical Products Co., Ltd.
Location	Tangshan, CN
Contact	Jia Yongmin
510(k) history	5 submissions · 5 cleared · 2016-2023

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)

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