

K211586 Nitrile Examination Gloves (Blue, Violet)Nov 1, 2021
161 days to decisionK211586 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211586/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 24, 2021
Decision date	Nov 1, 2021
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lyncmed Medical Technology (Beijing) Co., Ltd.
Location	Beijing, CN
Contact	Jiali Zhou
510(k) history	2 submissions · 2 cleared · 2021-2022

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](https://accessdata.fda.gov)

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