

K211581 Disposable Nitrile Examination Gloves (Powder free, Blue)Oct 28, 2021
160 days to decisionK211581 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 21, 2021
Decision date	Oct 28, 2021
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Leping Shengde Medical Technology Company Limited
Location	Jingdezhen, CN
Contact	Sheng Jianchao
510(k) history	1 submissions · 1 cleared · 2021-2021

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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